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The Impact of Exercise During Radiation Therapy for Breast Cancer Patients

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Abstract

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by

Diane Yu

MA, San Diego State University, 2010

BS, University of CA-Riverside, 2001

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health—Epidemiology

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Abstract

Breast cancer is one of the leading causes of death among women. In 2017, breast, lung and bronchus, prostate, and colorectal cancers accounted for almost 50% of all new cancer cases in the United States. Breast conservation therapy with lumpectomy (i.e., surgery) and adjuvant radiation therapy is commonly used as treatment for early stage breast cancer. However, side effects such as pain and poor sleep quality can affect quality of life for breast cancer patients undergoing radiation treatment. The main purpose of this quantitative study, using the health belief model (HBM) theoretical framework, was to investigate the correlations between the independent variable of exercise and the dependent variables of pain and sleep quality during radiation treatment. To examine these possible relationships, secondary data from another study were used, *Self-Reported Exercise Behavior and Short-Term Patients Outcomes in Women Undergoing Radiation Treatment for Operable Breast Cancer* by principal investigator Janet K. Horton of the Duke University Health System. The secondary data were analyzed using logistic regression and multiple linear regression statistical models. The findings from this study indicate that mild exercise is positively associated with reduced pain level and improved sleep quality and that vigorous exercise does not have a positive association with improved sleep quality. This study provides health practitioners with resources to encourage physical activity in breast cancer patients while undergoing and after radiation treatment. In this way, the study may serve to promote positive social change not only for breast cancer patients, but also for patients with other types of cancer to reduce side effects from radiation treatment.

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Dedication

This PhD is for my strong and independent mother, who saw me start this doctoral journey but unfortunately was not able to see me finish my journey. Mom, you were my biggest supporter in life, especially when it came to my education. You made me believe I can do anything I put my mind to, and for that I thank you and will be forever grateful. Even though you have passed for about a year now, I still feel your presence with me, supporting me. Life has not been easy, but the one thing I know I had to do is finish my PhD because that would have made you so proud, and also, you expect no less from me. I love you so much, Mom, and this one is for you!

Acknowledgments

I want to take this time to thank my father, who has diligently cooked for me to ensure that I receive nourishment during this doctoral journey; love you, Dad! I want to thank my grizzly bear, who has always told me to forge forward. Anytime I felt discouraged (e.g., when I couldn't find my data sets to analyze) and ready to pull my hair out, you were there to set me straight and told me to get back on that horse and finish what I started! I also want to thank my friends and coworkers who have been understanding of my time throughout this whole process; you ladies always understood what I had to do for this process and were all so supportive. Your encouragement gave me strength.

Last but not least, I want to thank my beautiful 8-year-old daughter, who has been very patient with Mom throughout this whole process. You have kept yourself busy at times when I needed to do some school work and never threw a fit or tantrum. I am truly grateful for that. You are truly the best daughter I could ever ask for, I love you always and forever.

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Chapter 1: Introduction to the Study

Historical Perspective on Cancer Risks

Cancer amongst human beings and other animals have been evident throughout history through fossilized bone tumors, mummified humans in Egypt, and ancient scriptures (American Cancer Society, 2017). Osteosarcoma witnessed in mummies suggest bone cancer, which is a type of cancer that starts in the bones specifically in the bone matrix. Bony skull deterioration seen in the head and neck indicates presence of cancer (American Cancer Society, 2017). Per American Cancer Society, the oldest report of cancer was discovered back in the Egyptian era to about 3000 BC. "It's called the Edwin Smith Papyrus and is a copy of part of an ancient Egyptian textbook on trauma surgery. It describes 8 cases of tumors or ulcers of the breast that were removed by cauterization with a tool called the fire drill" (American Cancer Society, 2017, para. 4).

Katsusaburo Yamagiwa and Koichi Ichikawa introduced cancer for the first time in lab animals by coating coal tar on rabbit skin at Tokyo University in 1915 (American Cancer Society, 2017). Then over 150 years later, clinician John Hill of London recognized tobacco as a *carcinogen* (a substance known or believed to cause cancer in humans; American Cancer Society, 2017). Years later, tobacco was revived as the most destructive source of chemical carcinogens known to man (American Cancer Society, 2017). Today, it is highly recommended to avoid many specific substances that cause cancer such as coal tars and their derivatives (like benzene), hydrocarbons, aniline (a substance used to make dyes), asbestos, and many others. Ionizing radiation from the sun,

is also known to cause cancer (American Cancer Society, 2017). American Cancer Society state that "to ensure the public's safety, the government has set safety standards for many substances, including benzene, asbestos, hydrocarbons in the air, arsenic in drinking water, and radiation" (2017, Development of modern knowledge about cancer causes, para. 2).

DNA (deoxyribonucleic acid) was determined to be the basis of the genetic code that gives orders to all cells. After interpretation of this code, scientists were able to understand how genes worked and how they could be damaged by mutations (changes or mistakes in genes; American Cancer Society, 2017). Modern techniques of chemistry and biology answered many complicated questions about cancer. Scientists learned that sometimes faulty genes are inherited, and sometimes these faulty genes are defective at the locations where certain chemicals also tend to cause damage (American Cancer Society, 2017). According to American Cancer Society, "most of the things that caused cancer (carcinogens) caused genetic damage (mutations) that looked a lot like the mutations that could be inherited and could result in the same types of cancer if more mutations were introduced" (2017, Development of modern knowledge about cancer causes, para. 9). In 2014, the World Health Organization's International Agency for Research on Cancer (IARC) revealed more than 100 chemical, physical, and biological carcinogens. A lot of these associations were recognized long before scientists understood much about how cancer develops (American Cancer Society, 2017). Modern technology and research are uncovering new carcinogens, clarifying how they cause cancer, and providing ways to prevent cancer.

Epidemiology of Cancer

Advanced aging is the most pertinent risk factor for many different types of cancer overall (National Cancer Institute [NCI], 2015). According to the most recent statistical data from NCI Surveillance Epidemiology and End Results program (SEER), "the median age of a cancer diagnosis is 66 years of age. This means that half of cancer cases occur in people below this age and half in people above this age. One-quarter of new cancer cases are diagnosed in people aged 65 to 74" (2015, para. 1-2). The same pattern is commonly seen for many types of cancer. For instance, "the median age at diagnosis is 61 years for breast cancer, 68 years for colorectal cancer, 70 years for lung cancer, and 66 years for prostate cancer" (NCI, 2015, para. 1-2).

Cancer can develop at any age. Per NCI, bone cancer and leukemias are commonly diagnosed in people under age 20. "Some types of cancer, such as neuroblastoma, are more common in children or adolescents than in adults" (NCI, 2015, para. 3). The cancer with the highest incidence in women is breast cancer; in men, it is prostate cancer (NCI, 2015).

Cancer Diagnosis and Treatment Resources

Cancer can begin at any place in the body; it starts with cells growing out of control and overcrowding the normal cells (American Cancer Society, 2016). There are many ways to treat cancer; surgery, chemotherapy, and radiation are common types of treatment (American Cancer Society, 2016). Surgery entails physical removal of the cancer (e.g., lumpectomy, mastectomy), chemotherapy helps kill cancer cells or slow

their proliferation and is usually given by intravenous methods (into a vein through a needle), and radiation treatment or "radiotherapy" is used to kill cancer cells or slow their growth by treating the cancer area with radiation (American Cancer Society, 2016).

Problem Statement

Breast cancer is still the most common threat amongst women. According to Champ et al. (2017), "breast conservation therapy with lumpectomy (i.e., surgery) and adjuvant radiation treatment is commonly used as treatment for early stage breast cancer" (p. 1). Per Champ et al., side effects from radiation treatment are marginal, with fatigue being the most common complaint. Under the general assumption that physical activity levels decrease during breast cancer treatment, this is troublesome because increased physical activity levels after breast cancer treatment are important to improvement in survival and quality of life (QoL). Exercise programs performed in conjunction with radiation treatment have been shown to reduce fatigue, which is the most common side effect, but do not address pain level or sleep quality (Champ et al., 2017). In a prospective study conducted by Sternfeld et al. (2009), the addition of physical activity following diagnosis and treatment was examined to determine the risk for breast cancer recurrence and mortality in women with early-stage breast cancer. The findings supported the fact that physical activity is beneficial for breast cancer survivors in terms of mortality but not necessarily prevention of recurrence. Maintaining a healthy lifestyle has the potential to reduce both cancer- and non-cancer-related morbidity. Physical activity also improves QoL among cancer patients and survivors (Sternfeld et al., 2009). More studies are exploring the potential of physical activity, including aerobic, strength, and

flexibility training to improve cancer survival rates (NCI, 2018b). This research fills a gap in the literature by determining if mild, moderate, and/or vigorous exercise can help restore or improve QoL (i.e., pain, sleep quality) for breast cancer patients undergoing radiotherapy.

Purpose of the Study

The purpose of this research was to determine whether mild, moderate, and/or vigorous exercise can help to restore or enhance QoL for breast cancer patients undergoing radiotherapy. Studies have suggested that exercise can help to alleviate side effects from breast cancer treatments, but unlike prior studies, this study was conducted to establish some facts around these insinuations. According to Champ et al. (2017), "as little as 3 to 5 hours of walking per week as a preventive measure can decrease a woman's risk of dying from breast cancer" (p. 1). In addition, 14 studies have shown that exercise substantially improves quality of life in breast cancer patients, as well as alleviating fatigue (Champ et al., 2017). Women who perform aerobic exercises as well as resistance training with weight training after completion of breast cancer treatment experience health-related improvements and experience these improvements quicker than women who wait to start exercising after the entire treatment is completed (Champ et al., 2017). Wilson (2017) discussed how mobilization stretches and exercises postsurgery can decrease shoulder impairments, chest tightness, and pain. Nurses who provide care for breast cancer patients need to teach and encourage exercise postoperation to eliminate or minimize side effects of surgery. Adherence to an exercise regime may be difficult during treatment; however, research has indicated that exercise and physical activity after

treatment completion have resulted in less pain, decreased fatigue, improved flexibility, and less emotional distress (Wilson, 2017).

Research Questions and Hypotheses

RQ1: Is there an association between engaging in mild, moderate, and/or vigorous exercise with reduced pain levels in breast cancer patients undergoing radiotherapy?

- Ho1: There is no association between engaging in mild, moderate, and/or vigorous exercise and reduced pain levels in breast cancer patients undergoing radiotherapy.

- Ha1: There is an association between engaging in mild, moderate, and/or vigorous exercise and reduced pain levels in breast cancer patients undergoing radiotherapy.

RQ2: Is there an association between engaging in mild, moderate, and/or vigorous exercise and improved sleep quality in breast cancer patients undergoing radiotherapy?

- Ho2: There is no association between engaging in mild, moderate, and/or vigorous exercise and improved sleep quality in breast cancer patients undergoing radiotherapy.

- Ha2: There is an association between engaging in mild, moderate, and/or vigorous exercise and improved sleep quality in breast cancer patients undergoing radiotherapy.

Theoretical Framework

The theoretical framework upon which this research was based was the health belief model (HBM). The HBM is defined by six constructs (Walden University, 2014, pp. 18-19):

- Susceptibility: One's perception of chances of getting a condition.

- Severity: One's perception of how serious a condition is.

- Benefits: One's perception of the efficacy of the advised action to reduce risk or impact.

- Barriers: One's perception of the tangible and psychological costs of the advised action.

- Cues to action: Strategies to activate "readiness."

- Self-efficacy: One's confidence level to take action.

Within the HBM, the susceptibility aspect would be breast cancer patients' perceptions of the likelihood of developing pain and sleep issues. Severity would involve the breast cancer patients' perception of how serious pain and sleep issues would be. The benefit would involve how breast cancer patients perceive the efficacy of the advised action (i.e., to participate in an exercise program). The barrier would be the breast cancer patients' perception of tangible and psychological costs associated with the advised action (e.g., lack of motivation, no family support). Cues to action would be joining organized exercise programs (e.g., physical activity meetups, group yoga), and self-efficacy would entail counseling and guidance for breast cancer patients undergoing

radiation treatment to build their confidence that different exercise approaches/intensities will help improve their QoL.

Definition of Terms

All definitions were transcribed from the original study: Self-Reported Exercise Behavior and Short-Term Patient Outcomes in Women Undergoing Radiation Treatment for Operable Breast Cancer, 2014, Identification No. NCT02050620.

Exercise behavior: Patient-reported mean total minutes (frequency x duration) of mild, moderate, and vigorous-intensity physical exercise per week.

Vigorous exercise: Strenuous physical activity in which the heart beats rapidly and sweating occurs (e.g., running, aerobics classes, vigorous swimming, or bicycling).

Moderate exercise: Physical activity that is not exhausting, causing only light perspiration (e.g., fast walking, tennis, easy bicycling, easy swimming).

Mild exercise: Physical activity that requires minimal effort, with no perspiration (e.g., easy walking, yoga, golf).

Baseline characteristics: Demographic data (age, education, employment) as well as body mass index (BMI), waist-to-hip ratio, and health comorbidities at baseline.

Patient-reported outcomes: Include QoL, fatigue, depression, pain, and sleep.

Nature of Study

This study used a quantitative method with data from a secondary source. Quantitative research entails testing theories in an effort to answer questions or evaluate hypotheses. In research, it is important to understand the variables that are used. A variable is a characteristic or attribute of an individual or organization that can be

measured or observed that varies among the people or organizations being studied (Creswell, 2009, pp. 49-50). The study type used during primary data collection was of the prospective observational model. Data (exercise behavior in terms of frequency x duration of mild, moderate, and vigorous-intensity physical exercise per week) were collected prior to the start of radiation therapy at baseline (BL) and again during the last week of therapy (LWRT) that requested that they estimate their physical activity in the 7 days prior.

Assumptions

The original study on which my study was based, *Self-Reported Exercise Behavior and Short-Term Patient Outcomes in Women Undergoing Radiation Treatment for Operable Breast Cancer* (NCT02050620) was conducted by principal investigator Janet K. Horton, MD. It was assumed that the study was conducted under ethical standards, given that Institutional Review Board (IRB) approval was obtained prior to the collection of informed consent from the study subjects. It was assumed that the data used had minimal bias and that the results from each group were comprehensive and comparable.

Limitations and Strengths

A strength of this study was the accessibility of the patients, as radiation therapy occurred at the same place where the study was conducted. This also helped participants adhere to the study and complete follow-up questionnaires; it decreased the chance of patients dropping out of the study.

Limitations of this study included the small sample size (n = 45), exclusion of housework and occupation-related activities as physical activity, and stipulation of ≥ 20 minutes duration for an exercise session. A small sample size decreases confidence levels and decreases statistical power. Exclusion of housework and occupation-related activities may have skewed the data by not including activities that could be categorized as mild, moderate, or vigorous exercise. The stipulation of ≥ 20 minutes duration for an exercise session may have limited data points and prevented accurate reporting of exercise sessions, in that the participants may not have been able to perform 20 minutes or more of physical activity. Another limitation of this study was my inability to control confounding variables that might have impacted side effects of radiotherapy. Such variables included adherence of an individual to an exercise regimen, weight of an individual, exposure to carcinogens, lifestyle behaviors, and hereditary gene composition. Additionally, because this study used secondary data, I had no ability to contact the subjects in the original study with questions about any of the provided data or any missing data. Due to these limitations, more research should be conducted on this topic by future researchers.

Significance of the Study

The significance of this study resides in its potential to help patients understand the possible benefits of exercising as well as what exercise intensity level (i.e., mild, moderate, and/or vigorous) is most effective in alleviating side effects such pain and poor sleep quality after breast surgery and during radiation therapy. If outcomes reveal favorable results from exercising during radiation therapy, this may help make breast

cancer patients aware of the benefits of adhering to a specific exercise regimen during and after radiation treatment and may motivate them to increase their physical activity levels to restore or improve their QoL sooner rather than later. In addition, this research may encourage oncologists and nurses to recommend certain types of physical activity (i.e., stretches, mild to moderate aerobic exercise) during and after radiation treatment to help breast cancer patients restore their QoL more quickly. Finally, if outcomes reveal favorable results from exercising during radiation therapy, promoting exercise may help to reduce patients' reliance on prescribed medication (i.e., insomnia medication) and frequent doctor visits as ways to remedy side effects from radiation treatment.

According to Frakt and Carroll (2018), American personal health spending grew between 1996 and 2013 from $1.2 trillion to $2.1 trillion. The bulk of this spending was on doctor visits and prescription drugs. Doctor visits and the prices of services and procedures were mainly responsible for increases in health care costs from 1996 to 2013. With that being said, the healthier the individual, the less costly health insurance will be.

In summary, promoting exercise (mild, moderate, and/or vigorous) during and after radiation therapy, if outcomes reveal favorable results from exercising during and after radiation therapy, could help to restore breast cancer patients' QoL, reduce health care costs by remediating side effects via the nonpharmacological route, and minimize doctor visits, thereby allowing other patients to be seen who are in dire need of a doctor.

Ethical Concerns

There do not appear to be any ethical concerns with the study, in that I used secondary data from a study in which all participants signed informed consent. The

possibility that the patients' privacy and rights will be violated is very small because no personally identifying information was collected during extraction of the data. Walden IRB approval (approval number 09-12-18-0381548) was obtained before accessing the data, and all policies and regulations of the institutions from which the data were acquired were strictly followed.

Summary and Transition

As stated in this chapter, there are side effects from breast cancer treatments such as radiotherapy. Research needs to be conducted regarding the association between mitigating side effects from radiotherapy and physical activity level in order to determine whether exercising can help to reduce pain and/or insomnia from radiotherapy. By analyzing such associations within the United States, health practitioners on all levels—local, state, and federal—may be given valuable information to help them determine whether exercise plans need to be incorporated in cancer treatments to alleviate side effects from treatment. The literature review in the next chapter highlights research that has been conducted on this topic over the last decade and exposes gaps in the literature that I sought to fill through this research.

Chapter 2: Literature Review

Radiation Therapy for Breast Cancer Patients

In this study, I searched for clinical trials using the key terms *breast cancer* and *QoL* on clinicaltrials.gov. I found over 50 trials dealing with breast cancer patients and their QoL after breast cancer treatments (e.g., surgery, radiotherapy, chemotherapy, adjuvant cancer treatment). I filtered for exercise/physical activity and narrowed down the search results to over 30 trials.

Radiation therapy or *radiotherapy* has an important role in treating stage 0 to stage III breast cancer due to its effectiveness and relative safety (NCI, 2018a). Radiotherapy may be appropriate for patients who have undergone lumpectomy (surgery where the tumor and some surrounding tissue are removed) or mastectomy (surgery to remove a breast). Radiotherapy is recommended to most patients who have undergone lumpectomy to destroy any cancer cells that may have been left after the tumor was removed and is also recommended after mastectomy to eliminate any breast cancer cells that may have remained at the mastectomy site (NCI, 2018a). Radiotherapy is also considered for women who have cancer in four or more lymph nodes and/or cancer that has spread to tissue around the lymph nodes (NCI, 2018a). Radiotherapy appears to be a less invasive treatment plan than chemotherapy and/or adjuvant cancer therapy due to the fact that it is a localized treatment (NCI, 2018a). However, in order for radiotherapy to be effective, early detection and screening are key, given that the greatest use of radiotherapy is for treating cancer that has not spread to other parts of the body. Regular breast cancer screening (e.g., mammograms) is important, and further tests may need to

be performed to confirm breast cancer, such as breast ultrasounds, breast MRI scans, and experimental breast imaging or 3D mammography tests (American Cancer Society, 2018).

Organization, Strategies and Justification

Organization of the Review

My aim in this chapter is to present a thorough literature analysis regarding the association between exercise and reducing side effects (e.g., pain, poor sleep quality) from breast cancer treatment, particularly radiotherapy. In the first section, I discuss published literature in regard to the impact of exercise in preventing chronic diseases (e.g., cancer, diabetes). The second section addresses how exercise might help to mitigate side effects (e.g., pain and poor sleep quality) from radiotherapy. In the third section, I conclude the chapter with a summary of important findings and a transition to the next chapter.

Searching for Literature

The literature review was performed using online databases provided by Walden University. These databases included Medline, Science Direct, PubMed, and Google Scholar. The databases were explored using key terms such as *health-related quality of life for breast cancer patients, side effects of radiation treatment, exercise and breast cancer treatment,* and *physical activity and cancer prevention.* These key terms were searched as individual terms and in various combinations to identify appropriate articles and studies for summary.

Justification for the Study

It is already known that exercise in general can help to preserve or improve QoL in breast cancer patients undergoing radiation treatment. However, there are gaps in the research in terms of the types of exercise (i.e., mild, moderate, vigorous) used in parallel to radiotherapy to preserve or improve QoL for breast cancer patients. Side effects such as pain and poor sleep quality can potentially be remediated with certain types of exercise (i.e., mild, moderate, vigorous) used during radiation therapy, which was what I sought to determine through this research study. There has been little research exploring the effects of different intensity levels of exercise on QoL in breast cancer patients undergoing radiotherapy. I conducted this study in an effort to promote positive social change by raising awareness of the variables (e.g., physical activity level prior to and during radiotherapy, exercise intensity levels) that contribute to increased QoL, as well as understanding of the economic burden of prescribed medication and doctor visits.

Exercise and Breast Cancer Prevention

There are many benefits of exercising. Exercise (e.g., mild, moderate, and/or vigorous) is a highly recommended and cost-effective approach to reducing risks for chronic diseases (e.g., cancer, diabetes). With that being said, what role does exercise play in reducing risks for chronic illnesses? Exercise increases blood flow throughout the body via the circulatory system which consists of the heart, blood vessels, and blood (PubMed Health, 2015). Exercising causes the body to demand more oxygen and forces the body to make short-term and long-term changes. Blood transports oxygen from the lungs to the cells of the body, where it is needed for metabolism (PubMed Health, 2015).

Regular exercise strengthens the lungs, heart, and blood vessels, which enables them to deliver oxygen to muscle cells quicker and more efficiently (Harvard Medical School, 2014). Regular exercise causes the circulatory system to adapt by boosting cardiorespiratory endurance. In turn, the body creates more plasma, the saltwater fluid that carries glucose and other nutrients to cells and transports away waste (Harvard Medical School, 2014). Over a long period, the heart muscle increases in size, which strengthens the heart. In parallel, the capillaries that serve the working muscles, including the heart, increase in number as well. The additional blood vessels serve two very important functions: They feed the muscles more oxygen-rich blood and provide an abundant amount of energy supply so that the heart is able to pump blood with greater ease, allowing more work to be done with less effort (Harvard Medical School, 2014).

Blood contains three different types of cells: white blood cells that fight infection, platelets that aid in clotting, and red blood cells that transport oxygen. Blood has three principal functions:

- Transporting oxygen from the lungs to the cells, where it is needed for metabolism; providing nutrients to cells; transporting hormones; and removing waste products.

- Regulating body temperature by expanding and constricting blood vessels and regulating pH values, which are both critical for bodily functions.

- Protecting the body: Blood clots quickly to make sure that scrapes stop bleeding, while white blood cells play an important role in the immune system (PubMed Health, 2015).

The importance of circulating blood throughout the body with the help of physical

activity and/or exercising is crucial.

According Bassuk & Manson (2014), to improve health and reduce risk for

certain chronic diseases, medical authorities, including the US Surgeon General, the

American Heart Association, and the American College of Sports Medicine "have long

recommended that adults perform at least 30 minutes of moderate-intensity physical

activity on most days of the week or, alternatively, vigorous-intensity physical activity

for at least 20 minutes on 3 days of the week" (p. 467). A large proportion of United

States women do not get sufficient exercise. In a recent national survey reported by

Morbidity Mortality Weekly Report (Harris et al., 2013), approximately half of United

States women do not meet the basic federally recommended standard for aerobic activity,

and 75% do not meet the strength-training federally recommended standard for physical

activity; only 18% of women meet both recommended standards (Bassuk & Manson,

2014). According to American Cancer Society (2018), "the latest recommendations for

adults call for at least 150 minutes of moderate intensity or 75 minutes of vigorous

intensity activity each week, or an equivalent combination, preferably spread throughout

the week" (Be more active, para. 3).

The World Cancer Research Fund and the American Institute for Cancer Research

also recommend moderate exercise for at least 30 minutes every day as fitness advances,

the objective should be for an hour or more of moderate, or for 30 minutes or more of

vigorous exercise every day (The World Cancer Research Fund and The American

Institute for Cancer Research, 2007). Bassuk and Manson report that results from

observational studies and randomized trials have indicated that exercise not only help in cancer prevention by reducing the risk for obesity, but exercise can positively affect the "circulating levels of sex hormones, insulin, and inflammatory cytokines, as well as immune function and apoptosis. Other potential protective mechanisms include decreases in insulin-like growth factors, favorable changes in prostaglandin profile, strengthened DNA (deoxyribonucleic acid) repair systems, increased gut motility and shortened intestinal transit time for potential carcinogens (colon cancer), and improved pulmonary function and reduced exposure time between lung tissue and carcinogens" (lung cancer; 2014, pp. 149-150). Regular exercise, especially recreational physical activity, has been shown to reduce the risk for breast cancer by at least 20% in women classified as highly active ($\geq$ 5 days of the week; Zoeller, 2009).

It has been assessed that the lack of exercise is behind 10% of breast cancer cases worldwide (Lope et al., 2017). According to Lope et al. (2017), "women who report devotion to international exercise recommendations show a significant decrease in risk for all pathologic breast cancer subtypes" (p. 578). Evidence from observational studies suggests a sedentary behavior is positively correlated with breast cancer risk. Per Zhou et al. (2015), "excessive sedentary behaviors may have potential detrimental effects on the development of breast cancer" (p. 695). Exercise may also represent an alternative therapy in patients for whom pharmacological treatment is unobtainable. Per Senchina & Kohut (2007), "the effects of exercise impact multiple aspects of immune response including T cell phenotype and proliferation, antibody response to vaccination, and cytokine production" (p. 3). For breast cancer patients who are undergoing or who just

underwent radiotherapy, T cells are critical in defending the body from infections and foreign matter.

Exercise Used to Mitigate Radiotherapy-Related Side Effects

Evidence suggests that exercise plays a critical role for women diagnosed with breast cancer, in prevention, during treatment, and for survival. According to Sundaresan et al. (2015), "fatigue and insomnia were among the physical symptoms rated worst at baseline, as reported by others…fatigue is a frequent and sustained complaint in breast cancer patients regardless of the treatment received (p. 13). With that being said, per Wilhelmsson et al. (2017), "physical activity such as aerobic exercise during adjuvant treatment has been shown to have a positive effect on fatigue" (p. 18). There is also substantial benefit from partaking in supervised exercise during active cancer treatment. The experiences of women who exercise were associated with feelings of psychological wellbeing, a reduction in treatment symptoms, increased fitness and faster recovery between the treatment cycles. Many women reported that they had more energy because they were exercising (Wilhelmsson et al., 2017). In a study conducted by Fisher et al. (2017), the associations between change in physical activity and changes in fatigue-related daily interference (FRDI) during the course of treatment (lumpectomy, mastectomy, or bilateral mastectomy) was analyzed. Per Fisher et al. (2017), "despite undergoing treatment, women increased moderate and vigorous intensity physical activity, with nearly 60% of women meeting the American College of Sports Medicine (ACSM) recommendation for moderate physical activity post-intervention" (p. 41). The study concluded that increased physical activity was associated with reductions in

depressive symptoms, improved QoL, and a reduction in FRDI during breast cancer treatment (Fisher et al., 2017).

There has been more research in the past decade that indicate exercise improves sleep quality. LaMotte (2017) reports that "exercise improves both self-reported and objective measures of sleep quality, such as what's measured in a clinical sleep lab. Exercise is not quite as effective as sleeping pills" (para. 3-4). However, downsides of sleeping pills are also avoided (e.g., infections, dementia in the elderly, and loss of effectiveness after a few weeks; LaMotte 2017). Exercise has also been shown to aid with restless-leg symptoms, a disorder of the nervous system that occurs when the legs or other parts of the body itch, burn, or move involuntarily usually during the night, amongst all age groups (LaMotte 2017).

In a study performed by LaMotte (2017), a recommendation of about 2.5 hours a week of moderate-intensity exercise and strength training that involves every muscle group two days a week can help reduce restless leg syndrome and therefore improve sleep quality. Exercises such as brisk walking, light biking, and elliptical machine are all types of exercise that increase the heart rate, while still allowing people to converse during exercise while catching a breath between a few sentences (LaMotte, 2017).

A few researches have shown that exercise is also helpful in reducing pain severity; however, the type of exercise intensity has not been specified to help reduce pain severity. A systematic review of randomized controlled trials (RCT) was conducted in the Cochrane Database of Systematic Reviews (CDSR) and 21 reviews were included to examine exercise versus no exercise/minimal intervention in adults with chronic pain

(Geneen et al., 2017). Several reviews noted favorable results from exercise in regard to pain severity being reduced, physical function being significantly improved as a result of the exercise intervention, and psychological function and QoL having favorable results from exercising (Geneen et al., 2017). The evidence suggested that physical activity and exercise is an intervention with few adverse events that improved pain severity and physical function, and ultimately quality of life; however, further research is still required with increasing participant numbers and lengthening of both the intervention itself and the follow-up period (Geneen et al., 2017).

In a study conducted by Scruggs et al. (2017), participants (60 women) were randomized to a 6-month lifestyle physical activity program (Active for Life after Cancer) or standard care using a minimization randomization procedure. There were 35 participants in the intervention group and 25 participants in the standard care group, where a total of 28 in the intervention group and 23 in the standard care group completed all assessments and were included in analyses as data were available. The intervention was a weekly regime for 24 weeks that focused on group-based program to increase self-efficacy, use cognitive and behavioral skills, and positively change decisional balance. Scruggs et al. describes the details of the study in which participants met weekly for the first 16 weeks, then met every other week for the last 8 weeks. "Group sessions focused on cognitive and behavioral strategies for adopting physical activity and lasted 90 minutes each, which included 50 minutes of lifestyle physical activity curriculum, a 10-minute break for moderate to vigorous physical activity (MVPA), and 30 minutes of lectures and discussions related to breast cancer survivorship" (Scruggs et al., 2017, pp.

136-141). Both standard care arm and intervention group received the same materials but the standard arm care did not attend group sessions or obtain information about MVPA. "Breast cancer survivors enrolled in the *Active for Life After Cancer* lifestyle physical activity intervention experienced greater increases in self-efficacy, perceived fewer cons to physical activity, and reported more use of processes of change than survivors receiving standard care…" (Scruggs et al., 2017, pp. 136-141).

In another study conducted by Harder et al. (2015), women diagnosed with early-stage breast cancer were randomized to standard care (SC) with either having a yoga DVD or not for 10 weeks. "Patient-reported outcomes were collected at baseline, 10 weeks, and 6 months… SC comprised of post-operative exercise materials distributed by the hospital prior to surgery...written instructions for arm and shoulder mobilization or an exercise leaflet, poster or DVD" (Harder et al., 2015, pp. 202-203). The study indicated that practicing post-treatment exercises (e.g., yoga) did improve arm and shoulder mobility. The addition of a self-practice yoga DVD was well received and appeared to improve the QoL of patients at 6 months and 74% of women definitely recommended following the yoga DVD after surgery (Harder et al., 2015).

Exercise is also an appealing adjunct therapy for cancer patients and survivors because of its potentially positive influence on the immune system. One particular component of the immune system, the natural killer (NK) cell, is especially important because of its ability to target and kill virally infected cells and cells that have undergone malicious transformation (Evans et al., 2015). Per Evans et al. (2015), NK cells are extremely responsive to vigorous aerobic exercise in both healthy athletic and nonathletic

people. "They follow a profile that typically shows marked elevations in both cell number and activity immediately post exercise while displaying decreases during the recovery period for up to several hours. It is also thought that exercise-related enhancements in NK cell function may confer a protective effect against pathogen invasion..." (Evans et al., 2015, pp. 436-437).

In a study conducted by Evans et al. (2015), absolute NK cell counts were constantly lower in the breast cancer survivor group compared with the group of physically similar participants who did not have a history of cancer- a finding that was statistically meaningful immediately post exercise amongst breast cancer survivor group. Breast cancer survivors seemed to experience similar NK cell number recruitment as the participants without a history of cancer during and after 30 minutes of intermittent moderate-intensity aerobic exercise (Evans et al., 2015). Immune changes related to cancer treatments may be associated with the lower absolute NK cell counts observed in the breast cancer survivor group (Evans et al., 2015).

Theoretical Framework

The HBM is defined by six constructs (Walden University, 2014, p. 18-19):

- Susceptibility- One's perception of chances of getting a condition;

- Severity- One's perception of how serious a condition is;

- Benefits- One's perception of the efficacy of the advised action to reduce risk or impact;

- Barriers- One's perception of the tangible and psychological costs of the advised action;

- Cues to action- Strategies to activate "readiness"; and

- Self-efficacy- One's confidence level to take action.

Incorporating the HBM, researchers can help determine what the breast cancer patients' perceptions of how severe their side effects will be from radiation therapy and what the efficacy of physical activity during radiation treatment can be to help persuade breast cancer patients to exercise during their radiation treatment. Researchers can determine what the barriers are to the advised action (e.g., lack of knowledge of what type of exercises to perform, lack of motivation) to help break down the barrier to one's confidence to take action. The HBM achieves optimal behavior change if it successfully targets perceived barriers, benefits, self-efficacy, and threat (Jones et al., 2014). According to Jones et al. (2014), there are three potential basic models that are relevant to the HBM. First, in parallel mediation, the variables (mild, moderate, and/or vigorous exercise) could have substantial influence on outcomes (pain and sleep quality). Second, HBM can functions as a causal chain, which is referred to as serial mediation (Jones et al., 2014). In this model, some of the variables of the HBM connect in a serial fashion. For instance, knowledge of benefits from performing physical activity during radiation therapy can increase self-efficacy, which can then influence perceived barriers, and perceived barriers can predict behavior. Finally, the moderated mediation model assumes that one of the HBM constructs serves as a moderator for the influence of the others, particularly that increased severity is required before susceptibility is able to significantly predict behavior (Jones et al., 2014). For example, if breast cancer patients perceive that radiation therapy can cause excruciating pain preventing them from performing daily

functions and/or from sleeping at night, then breast cancer patients are more susceptible to change their behavior and attitude towards exercising during radiation therapy.

Summary and Transition

The articles reviewed in this chapter offered insight into the impact of exercise on cancer risk as well as its impact on remediating side effects during radiotherapy for breast cancer patients. Most of the articles analyzed in this literature review used primary data collected during RCTs. This reinforced the reliability and validity of the data collected and thus provided a strong groundwork for this dissertation.

The information and statistics presented from previous studies certainly suggest that exercise and physical activity can help prevent breast cancer as well as alleviate side effects such as fatigue and pain. Although the findings from these studies are not particularly surprising, they also uncovered gaps in the current research, which indicates a real need for this dissertation to address. Since reducing fatigue by performing certain exercises has been extensively studied through prior research, fatigue alleviation will not be discussed in this study. The measure of sleep quality is not associated with fatigue in this study, these are separate entities from each other. The gaps that were identified were the lack of more studies conducted specifying which exercise intensity levels (i.e., mild, moderate, vigorous) may be effective as a treatment plan along with radiotherapy to alleviate pain and improve sleep quality. Exercise has never really been considered a treatment option or preventative measure for breast cancer, but it should be considered and utilized due to its bountiful benefits in reducing cancer risks and potentially side effects of treatment, as well as its the cost-effective nature. Moving forward, health

initiatives need to provide incentives (e.g., financial cost reduction in health plans, free

gym membership) for people to stay healthy under the health care plans. In Chapter 3, the

study's research design, rationale and methodology will be discussed based on the

findings and gaps highlighted in this chapter.

Chapter 3: Research Method

Overview

The purpose of this study was to explore the impact of exercise in alleviating side effects (e.g., pain and poor sleep quality) for breast cancer patients undergoing radiotherapy. My focus in this chapter is highlighting the method that was used to collect and analyze the data. In the first section, I describe how the research was designed and what approach and justification were used. The next section provides details in regard to the methodology of the study, compartmentalized into population, sampling and procedures, information on obtaining the archived data, instrumentation, the data analysis plan, and ethical concerns. The chapter concludes with a summary of the information presented.

Research Design and Rationale

This quantitative study had a nonexperimental design and used coded, tabulated secondary archived data that were collected and maintained by principal investigator Janet K. Horton, MD. Horton's study, *Self-Reported Exercise Behavior and Short-Term Patient Outcomes in Women Undergoing Radiation Treatment for Operable Breast Cancer,* was conducted from January 2014 to December 2015 (NCT02050620). Its primary goal was to measure the association between self-reported exercise behavior and patient-reported outcomes of QoL. QoL outcomes were measured by patients' self-reported levels of pain and sleep quality. Exercise behavior was defined as patient-reported mean total minutes (frequency x duration) of mild, moderate, and vigorous-intensity physical exercise per week over the month prior to baseline (prior to enrollment

in the study). Additionally, data were collected on patient-reported mean total minutes per week of mild, moderate, and vigorous-intensity physical exercise during the last week of radiation therapy to determine physical activity 7 days prior. Baseline characteristics included demographic data such as age, education, and employment, as well as BMI, waist-to-hip ratio, and health statuses (e.g., smoking status, cardiovascular disease, and diabetes).

Secondary data were appropriate for use in this study, in that it was not possible for me to collect primary data on this topic. According to Frankfort-Nachmias and Nachmias (2008), the advantages of using secondary data include the ability of the researcher to gain a better understanding of the historical context of the subject and to analyze data collected at different times and in different locations. Additionally, the use of secondary data enables the researcher to analyze patterns or trends of change and affords the opportunity to describe possible reasons for these changes (Frankfort-Nachmias & Nachmias, 2008). Using secondary data allowed me to have access to data that were generated in an experimental setting. Because the data had already been collected, coded, and tabulated, the reliability and validity of the data was very high and bias was minimal.

Methodology

Setting and Participants

I researched the principal investigators and their affiliations (e.g., academic institutions, clinics, etc.) in order to introduce myself and ask if I could use the data they had already collected. I explained my intentions for the data and what I wanted to

accomplish with the data they had collected. After making 20 phone calls and leaving messages, I received a return call from Dr. Janet Horton from Duke University, who agreed to let me use her data to help answer my research questions and substantiate or reject my hypotheses.

Sampling and Sampling Procedures

As stated before, this quantitative, nonclinical prospective cohort study used coded, archived, secondary data from the study *Self-Reported Exercise Behavior and Short-Term Patient Outcomes in Women Undergoing Radiation Treatment for Operable Breast Cancer,* which was conducted from January 2014 to December 2015 (NCT02050620). The original study population included 45 ($N = 45$) subjects. In the original study, all participants were numerically coded, and all of the survey questions were asked of the same study population at baseline (BL) and in the last week of radiation therapy (LWRT); the same population size of 45 was applicable for all research questions.

Procedures for Data Collection

Following contact with and agreement from Dr. Horton, the data were transferred in Microsoft Excel tables, and the survey questionnaires were sent as PDF files. Data from these tables were extracted for the purpose of analysis. I extracted data that pertained to the different exercise intensity levels, pain level, and sleep quality at baseline (BL) and last week of radiation therapy (LWRT) to analyze.

Instrumentation and Materials

Prior to data collection in the original study, all data were collected per the study

procedure for the independent variable being analyzed in this study, which was exercise level (e.g., mild, moderate, vigorous). All the data that were collected were nonidentifiable and organized by variable.

Data Collection

The secondary data that were analyzed in this study were obtained from the clinical trial *Self-Reported Exercise Behavior and Short-Term Patient Outcomes in Women Undergoing Radiation Treatment for Operable Breast Cancer,* conducted by principal investigator Janet K. Horton, MD. All subjects in the original study were screened for eligibility to participate in the study via medical record review of breast cancer patients scheduled for radiation therapy at Duke Radiation Oncology Clinic. The inclusion criteria applied to women who had a biopsy-proven diagnosis of ductal carcinoma or invasive breast carcinoma, had received definite radiation treatment for the chest and/or regional nodes, were 18 years of age or older, and signed study-specific informed consent. Participants agreed to complete study questionnaires prior to the start of radiation therapy at baseline (BL) and again during the last week of therapy (LWRT) that requested that they estimate their physical activity in the 7 days prior. Data were collected from January 2014 to December 2015, and the entire study population was 45 individuals ($N = 45$). All of the survey questions were asked of the same study population, and the same population size was applicable for all research questions. For the purpose of this dissertation, only pain level and sleep quality were selected for analysis.

The focus of this dissertation was studying a specific independent variable (mild, moderate, and/or vigorous exercise) and determining if any of the types of exercise, either alone or in combination, had an impact on the dependent variables of pain level and sleep quality.

Data Entry

The secondary data were entered into SPSS 24.0 on a password-protected computer and saved in a designated secure location. When entering values for the variable pain level in SPSS, 0 was used to designate *no*, and 1 was used to designate *yes* in response to the survey question *Have you taken pain medication in the last 7 days?* When entering the values for the variable sleep quality in SPSS, 0 was used to designate *not during the past month,* 1 was used to designate *once a week,* 2 was used to designate *once or twice a week*, and 3 was used to designate *three or more times a week* in response to the survey item *Wake up in the middle of the night or early morning.* As for the weekly physical activity survey questions for mild, moderate, and vigorous exercise, the participants were asked to recall on average in a week (7 days) at BL and 7 days prior at LWRT how many times they had performed the different intensity levels of physical activity with the following considerations in mind: exercise sessions that lasted 20 minutes or longer and exercise done during free time (i.e., not occupation or housework related), as well as to note the difference between the three exercise intensity levels (mild, moderate, vigorous).

Data Analysis

Per the approved research proposal, the secondary data were entered into SPSS

and were analyzed using logistic regression and multiple linear regression models. In the analysis, pain level (no pain vs. pain) and sleep quality (how many times the patient woke up during various time intervals (*not during the past month* [0], *once a week* [1], *once or twice a week* [2], and *three or more times a week* [3]) were listed as the dependent variables and with the study variable exercise level with three categories (mild, moderate, and vigorous exercise) as the independent variable. In the following sections, the results of the analysis of each independent variable in relation to the dependent variable as well as the relationship between all of the independent variables and the associated statistical analysis and tables are described.

Data Analysis Plan

In this dissertation, I used the Statistical Package for Social Sciences (SPSS, version 24.0) to analyze the data gathered for the study. In order to thoroughly analyze the characteristics of the cohort under evaluation, I used descriptive statistics and logistic and linear regression models (statistical analytical tables and figures) to analyze the independent variable (mild, moderate, or vigorous exercise) both individually and collectively with respect to dependent variables of pain and sleep quality levels. Logistic and multiple linear regression models were created to analyze the associated variables and produce inferential statistics to test the null and alternative hypotheses. Logistic regression is used to predict the odds of an outcome based on the values of the independent variables; the outcome is measured as a dichotomous variable (Field, 2013). Multiple linear regression is an extension of simple linear regression; it is used in an attempt to model the relationship between two or more explanatory variables and the

dependent variable by fitting a linear equation to the observed data. The value of the independent variable x is correlated with the value of the dependent variable y (Field, 2013). The physical activity values were entered in SPSS as recorded to be able to differentiate between each exercise intensity level and determine how the number of exercise sessions of each type of exercise intensity level may have had an effect on pain level and sleep quality.

The logistic regression analysis used odds ratios, 95% confidence intervals, chi-square, and significance; the significance column was the probability of obtaining the chi-square statistic given that the null hypothesis was not rejected (Field, 2013). The Cox and Snell R square acted as pseudo R-squares that indicated the strength of correlation between the independent variables and the dependent variable (Field, 2013). The Cox and Snell R-square value and Nagelkerke R-square value can range from 0, which indicates that the predictors are useless in predicting the outcome variable, to 1, which indicates that the model predicts the outcome variable perfectly (Field, 2013). As part of the logistic regression analysis that was computed on the independent variable exercise (mild, moderate, and/or vigorous) in relation to the dependent variable (pain level), case processing summary, model summary, tests of model coefficients, variables in the equation, and bar charts at BL and LWRT were computed to test the compatibility of the model with either the null or alternative hypothesis. As part of the multiple linear regression analysis that was performed on each independent variable (mild, moderate, and vigorous exercise) in relation to the dependent variable (sleep quality), correlations, model summaries, ANOVAs, coefficients, and bar charts at BL and LWRT were

computed in an effort to test the compatibility of the model with either the null or alternative hypothesis.

In the following sections, the results of the analysis of the independent variable (mild, moderate, or vigorous exercise) both individually and collectively with respect to dependent variables of pain and sleep quality levels are described. Because the outcomes are dichotomous values (*no* or *yes*), the logistic regression model was the best choice for studying the effect of the independent variables on the dependent variable of pain level. The linear regression analysis was run on the independent variables with a 95.0% confidence interval and a residual Durbin-Watson (Field, 2013) inquiry to ensure that the statistical model was a good fit for the study variables. Because the results of the Durbin-Watson analysis in the sleep quality analysis were all between 0 and 4, the results were considered normal and indicated that the analysis used, multiple linear regression, was the best choice for studying the effect of the independent variables on the dependent variable as well as testing the null and alternative hypotheses for sleep quality (Field, 2013).

As previously stated, the research questions that were analyzed for this quantitative study were the following:

RQ1:   Is there an association between engaging in mild, moderate, and/or vigorous exercise and reduced pain levels in breast cancer patients undergoing radiotherapy?

Ho1: There is no association between engaging in mild, moderate, and/or vigorous exercise and reduced pain levels in breast cancer patients undergoing radiotherapy.

Ha1: There is an association between engaging in mild, moderate, and/or vigorous exercise and reduced pain levels in breast cancer patients undergoing radiotherapy.

The hypothesis for RQ1 was tested using logistic regression models in order to analyze the relationship between engaging in mild, moderate, and/or vigorous exercise and reduced pain levels in breast cancer patients undergoing radiotherapy.

RQ2: Is there an association between engaging in mild, moderate, and/or vigorous exercise and improved sleep quality in breast cancer patients undergoing radiotherapy?

Ho2: There is no association between engaging in mild, moderate, and/or vigorous exercise and improved sleep quality in breast cancer patients undergoing radiotherapy.

Ha2: There is an association between engaging in mild, moderate, and/or vigorous exercise and improved sleep quality in breast cancer patients undergoing radiotherapy.

The hypothesis for RQ2 was tested using multiple linear regression models in order to analyze the relationship between engaging in mild, moderate, and/or vigorous exercise and improved sleep quality in breast cancer patients undergoing radiotherapy.

Threats to Internal and External Validity

There should be very few threats to internal and external validity. However, one threat to internal and external validity would be the possibility that the secondary data used in the study were not properly collected and/or categorized. However, as previously stated, all secondary data that were used in this study were obtained from a reputable clinic, the Duke University Radiation Oncology Clinic. Therefore, validity concerns should be minimal.

<div align="center">

Ethical Procedures

</div>

I submitted an application to the Walden University IRB for approval before analyzing my data. No data were analyzed for the purposes of this research study until IRB approval was granted. Walden IRB granted approval to proceed to the final study stages on September 12, 2018. The Walden IRB approval number for this study is 09-12-18-0381548.

Protection of Human Participants

Potential risks to human participants as a result of this study were minimal. As no personally identifying information was included in the secondary data obtained for the study, there is no possible way for the data to be connected back to individual participants who were numerically categorized for the purpose of this study. Moreover, it is not possible for individual consent to be rescinded because the study was already performed and concluded. Prior to the start of the study conducted by Dr. Horton, all participants signed a study-specific informed consent form. As previously stated, prior to analyzing the data, I received IRB approval from Walden University. The data were securely sent

via email and were stored in a secured, password-protected computer located in my home

and work. All information will be permanently deleted from my computer's hard drive

after a minimum of 5 years following the completion of my analysis.

Summary and Transition

This quantitative study used numerically coded, archived data from the secondary

source previously described. As stated, these data were analyzed using SPSS 24 and

logistic regression and multiple linear regression tests were run to test the null and

alternative hypotheses. The procedures used to collect the specified secondary data were

strict and followed all established and required guidelines to ensure that the data were

protected and not compromised in any way. These included obtaining informed consent,

ensuring confidentiality, ensuring data security, and avoiding identification of

participants. The data results and interpretation may help breast cancer patients

understand how to alleviate the side effects (pain, poor sleep quality) of radiotherapy and

the severity of these side effects. With the HBM in mind, if the results reveal favorable

outcomes from engaging in mild, moderate, and/or vigorous exercise, patients may see

how exercise can help, hinder, or have no effect in alleviating their side effects from

radiotherapy. From there, patients may be persuaded to exercise if results prove to be

positive for alleviating side effects from radiotherapy with mild, moderate, and/or

vigorous exercise.

The results of the data analysis that I conducted using the original data collected

by Dr. Horton are presented in Chapter 4. The final chapter of the dissertation, Chapter 5,

includes a discussion of the results, conclusions, recommendations for further scholarly

research, and the study's social-change impact.

Chapter 4: Results

Overview

As previously stated, the purpose of this dissertation was to determine the

relationship between participating in mild, moderate, and/or vigorous exercise and pain

level and sleep quality in breast cancer patients who underwent radiotherapy. My

objective in this chapter is to present the results of my analyses of the secondary data

originally collected by principal investigator Janet K. Horton, MD, from the Duke

University Health System to determine if significant correlations exist between any of the

independent and dependent variables, with the independent variable of different exercise

levels being considered both individually and in combination to support either the null or

alternative hypotheses for each of the following research questions:

RQ1: Is there an association between engaging in mild, moderate, and/or

vigorous exercise and reduced pain levels in breast cancer patients

undergoing radiotherapy?

Ho1: There is no association between engaging in mild, moderate,

and/or vigorous exercise and reduced pain levels in breast cancer

patients undergoing radiotherapy.

Ha1: There is an association between engaging in mild, moderate,

and/or vigorous exercise and reduced pain levels in breast cancer

patients undergoing radiotherapy.

RQ2: Is there an association between engaging in mild, moderate, and/or vigorous exercise and improved sleep quality in breast cancer patients undergoing radiotherapy?

Ho2: There is no association between engaging in mild, moderate, and/or vigorous exercise and improved sleep quality in breast cancer patients undergoing radiotherapy.

Ha2: There is an association between engaging in mild, moderate, and/or vigorous exercise and improved sleep quality in breast cancer patients undergoing radiotherapy.

This chapter is organized into specific sections that detail how data were analyzed and the analysis of the correlations between the independent variables and the dependent variable. This chapter also includes supporting data tables and graphs.

Results of Data Analysis

Pain and Exercise Level (Mild, Moderate, Vigorous)

The first research question for this study focused on analyzing the effect of mild, moderate, and vigorous exercise in reducing pain level during radiation therapy. To test the null hypothesis, the values for pain level at BL and at LWRT were analyzed. As seen in Tables 1 and 2, out of the study population of 45, 40 participants answered the survey question *Have you taken pain medication in the last 7 days?* at BL, and 36 participants answered the same survey question at LWRT. Unfortunately, missing data can produce inaccurate results.

Table 1

Case Processing Summary of Dependent Variable Pain at BL

Selected cases	*N*	Percent
Included in Analysis	40	88.9
Missing cases	5	11.1
Total	45	100.0

Table 2

Case Processing Summary of Dependent Variable Pain at LWRT

Selected cases	*N*	Percent
Included in analysis	36	80.0
Missing cases	9	20.0
Total	45	100.0

There was a strong correlation, as exhibited by the Cox and Snell *R*-square value (Field, 2013) of 4.6% and Nagelkerke *R*-square value of 6.1% at BL, between the independent variable of exercise incorporating all exercise intensity levels (mild, moderate, and vigorous) in combination and pain level. However, there was a stronger correlation at LWRT, as indicated in Table 4, which shows the Cox and Snell *R*-square value of 25.8% and Nagelkerke *R*-square value of 34.4%. This indicates a stronger correlation between pain level and exercise at LWRT versus BL.

Table 3

Pain at BL Model Summary

-2 log likelihood	Cox & Snell R square	Nagelkerke R square
53.570	.046	.061

Table 4

Pain at LWRT Model Summary

-2 log likelihood	Cox & Snell R square	Nagelkerke R square
39.061	.258	.344

The chi-square test was not significant ($p > 0.05$) between the independent variable of exercise incorporating all exercise intensity levels (mild, moderate, and vigorous) and pain level in Table 5 (BL), which indicates that the null hypothesis should be rejected. Table 6 (LWRT) shows a significance ($p < 0.05$) in the chi-square test, which favors rejection of the null hypothesis in favor of the alternative hypothesis.

Table 5

Test of Model Coefficients of Pain at BL

	Chi-square	*df*	Sig.
Step	1.882	3	.597
Block	1.882	3	.597
Model	1.882	3	.597

Table 6

Test of Model Coefficients of Pain at LWRT

	Chi-square	df	Sig.
Step	10.735	3	.013
Block	10.735	3	.013
Model	10.735	3	.013

Although the Exp(B) values in Table 7 are all under 1, which indicates that as each of the predictors (mild, moderate, and vigorous exercise) increases, the odds of the outcome (reduced pain) occurring decreases, the results were not statistically significant. However, Table 8 (LWRT) indicates a significance value of $p = .016$ and an Exp(B) value greater than 1 for mild exercise, which indicates that as mild exercise increases, the odds of the outcome (reduced pain) occurring significantly increase (Field, 2013). This supports rejecting the null hypothesis in favor of the alternative hypothesis.

Table 7

Variables in the Equation Containing the Dependent Variable Pain and the Independent Variables (Mild, Moderate, Vigorous) at BL

	B	S.E.	Wald	df	Sig.	Exp(B)
Vigorous	-.045	.326	.019	1	.891	.956
Moderate	-.092	.176	.271	1	.602	.912
Mild	-.113	.099	1.291	1	.256	.893

Table 8

Variables in the Equation Containing the Dependent Variable Pain and the Independent Variables (Mild, Moderate, Vigorous) at LWRT

	B	S.E.	Wald	*df*	Sig.	Exp(*B*)
Vigorous	-.479	.538	.793	1	.373	.619
Moderate	-.292	.207	1.990	1	.158	.747
Mild	.543	.226	5.783	1	.016	1.721

The bar charts in Figure 1 (BL) and Figure 2 (LWRT) show a distribution of pain (1) vs. no pain (0) at BL and LWRT. Figure 2 indicate a decrease in pain level.
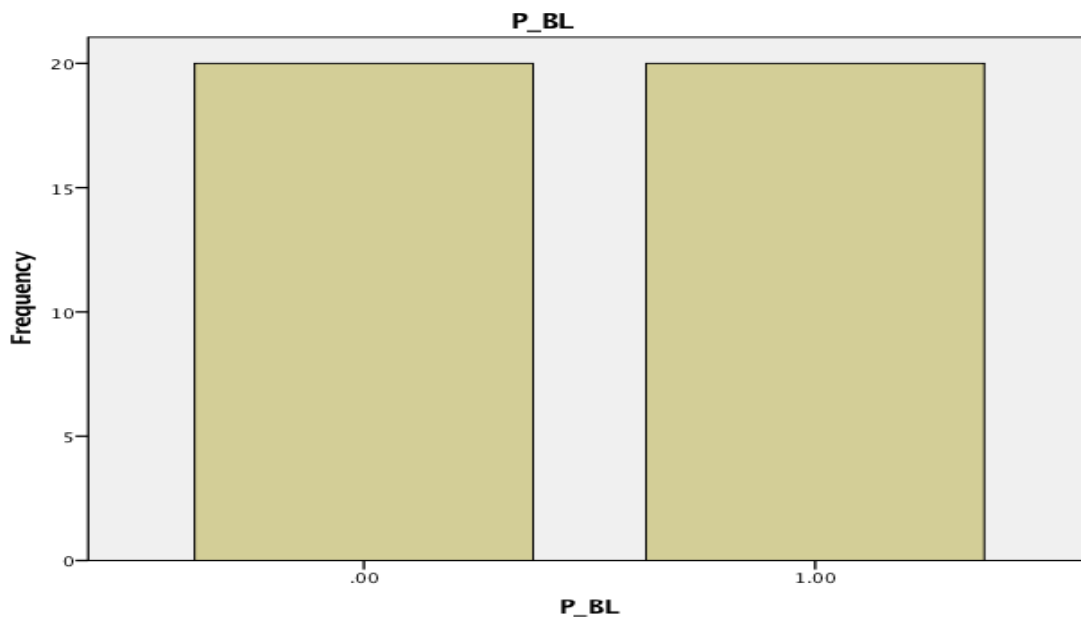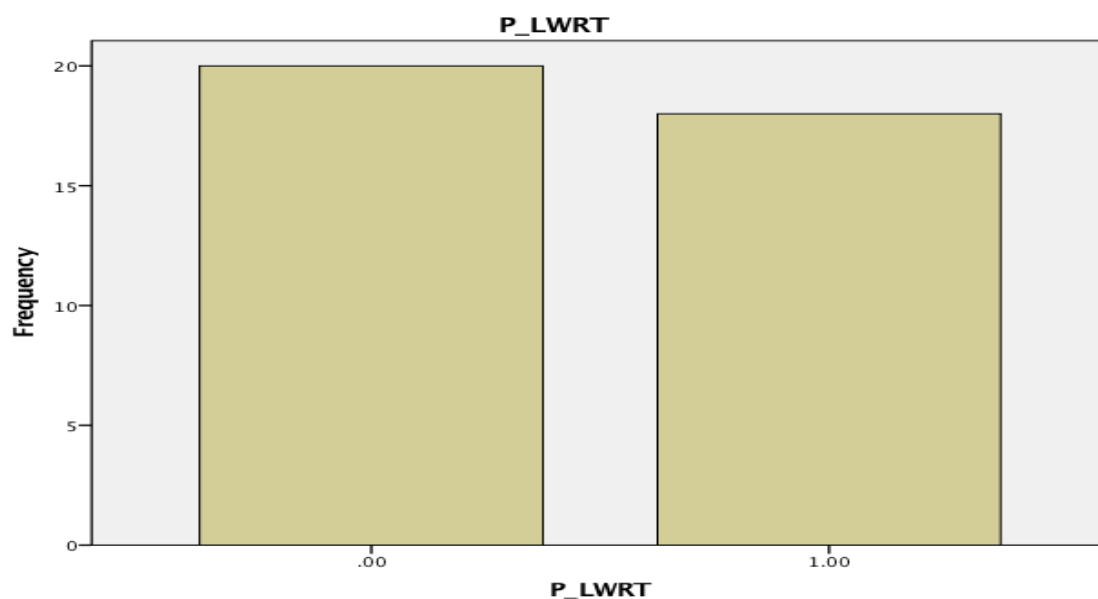

Figure 1. Pain at BL bar chart.

Figure 2. Pain at LWRT bar chart.

Sleep Quality and Exercise Level (Mild, Moderate, Vigorous)

The second research question of this study focused on the effect of mild,

moderate, and vigorous exercise in improving sleep quality during radiation therapy. To

test the hypotheses, the values for sleep quality at BL and at LWRT were analyzed. The

survey question asked whether the patient *Woke up in the middle of the night or early*

morning. The significance levels are all $p > 0.05$ in Table 9 (BL), indicating that each of

the independent categories of the variable (mild, moderate, and vigorous) exercise levels

do not significantly predict or impact the dependent variable sleep quality. However,

Table 10 (LWRT) indicates that mild exercise does significantly predict or impact the

dependent variable of sleep quality due to the fact that the significance is less than $p <$

0.05. In Table 10, vigorous exercise also significantly predicts or impacts the dependent

variable, but it appears there is not a positive correlation with the Pearson correlation of

-.331. This supports rejection of the null hypothesis in favor of the alternative hypothesis that there is an association between engaging in mild, moderate, and/or vigorous exercise and sleep quality in breast cancer patients undergoing radiotherapy. In this case, sleep quality is positively correlated with mild exercise but is not positively correlated with vigorous exercise at LWRT.

Table 9

Correlations Between the Dependent Variable Sleep Quality and the Independent Variables of Exercise Level (Mild, Moderate, Vigorous) at BL

	Pearson Correlation	Significance (1-tailed)	N
Mild	.240	.073	38
Moderate	-.025	.440	38
Vigorous	.054	.374	38

Table 10

Correlations Between the Dependent Variable Sleep Quality and the Independent Variables of Exercise Level (Mild, Moderate, Vigorous) at LWRT

	Pearson correlation	Significance (1-tailed)	N
Mild	.392	.009	36
Moderate	-.050	.386	36
Vigorous	-.331	.024	36

There was not a strong correlation between the independent variable, with all exercise intensity levels combined (mild, moderate, and vigorous exercise) and sleep quality, as exhibited by the *R*-value of 26.1% and an adjusted *r*-square of -1.4% at BL (Table 11). However, there was a strong correlation between the independent variable,

with all exercise intensity levels combined, and the dependent variable sleep quality at LWRT, as indicated in Table 12, which shows an *R*-value of 50.9% and an adjusted *R*-square of 18.9% at LWRT.

Table 11

Sleep Quality at BL Model Summary

Study variable	*R*	*R* square	Adjusted *R* square	Std. error of estimate	Sig. *F* change	Durbin_Watson
Sleep quality BL	.261	.068	-.014	1.23436	.489	2.077

Table 12

Sleep Quality at LWRT Model Summary

Study variable	*R*	*R*square	Adjusted *R* square	Std. error of estimate	Sig. *F* change	Durbin_Watson
Sleep quality LWRT	.509	.259	.189	1.05044	.021	1.659

The ANOVA in Table 13 (BL) had an *F*-value that was not above 1.0, which indicates a weak correlation between the independent variable of exercise with all exercise intensity levels combined and the dependent variable of sleep quality at baseline. The ANOVA in Table 14 had an *F*-value that was well above 1.0, which indicates a strong correlation between the independent variable of exercise with all exercise intensity levels combined and the dependent variable of sleep quality at LWRT.

Table 13

Sleep Quality at BL ANOVA

Sleep quality at BL	Sum of squares	*df*	Mean square	*f*-value	Significance
Regression	3.775	3	1.258	.826	.489
Residual	51.804	34	1.524		
Total	55.579	37			

Table 14

Sleep Quality at LWRT ANOVA

Sleep quality at LWRT	Sum of squares	*df*	Mean square	*f*-value	Significance
Regression	12.330	3	4.110	3.725	.021
Residual	35.309	32	1.103		
Total	47.639	35			

The significance levels in Table 15 (BL) were all $p > 0.05$. As such, the data indicate that each of the independent variable categories of exercise intensity levels (mild, moderate, and vigorous exercise) do not predict or impact the dependent variable of sleep quality. However, Table 16 (LWRT) indicates a correlation between mild exercise and sleep quality, as evident in the significance value of $p = .017$. In Table 16, vigorous exercise also significantly impacts the dependent variable, but it appears that there is a negative correlation with the Beta coefficient of -.334. This supports the rejection of the null hypothesis in favor of the alternative hypothesis that there is an association between engaging in mild, moderate, and/or vigorous exercise and improved

sleep quality in breast cancer patients undergoing radiotherapy. In this case, sleep quality

is positively correlated with mild exercise but is not positively correlated with vigorous

exercise at LWRT.

Table 15

Coefficients Between the Dependent Variable Sleep Quality and the Independent Variables (Mild, Moderate, Vigorous) at BL

Sleep quality at BL	Unstandardized coefficients	Standardized coefficients (beta)	t value	Significance
Mild	.086	.254	1.521	.138
Moderate	-.043	-.070	-.405	.688
Vigorous	.111	.095	.552	.584

Table 16

Coefficients Between the Dependent Variable Sleep Quality and the Independent Variables (Mild, Moderate, Vigorous) at LWRT

Sleep quality at LWRT	Unstandardized coefficients	Standardized coefficients (beta)	t value	Significance
Mild	.137	.386	2.525	.017
Moderate	.034	.073	.463	.646
Vigorous	-.453	-.334	-2.126	.041

The bar charts in Figure 3 (BL) and Figure 4 (LWRT) show a distribution of the

sleep quality as indicated by how many times the patient woke up during various time

intervals (0 was used to designate *not during the past month (0),* 1 was used to designate

once a week (1), 2 was used to designate *one or twice a week (2)*, and 3 was used to

designate *three or more times a week (3)* at BL and LWRT. It appears there was a

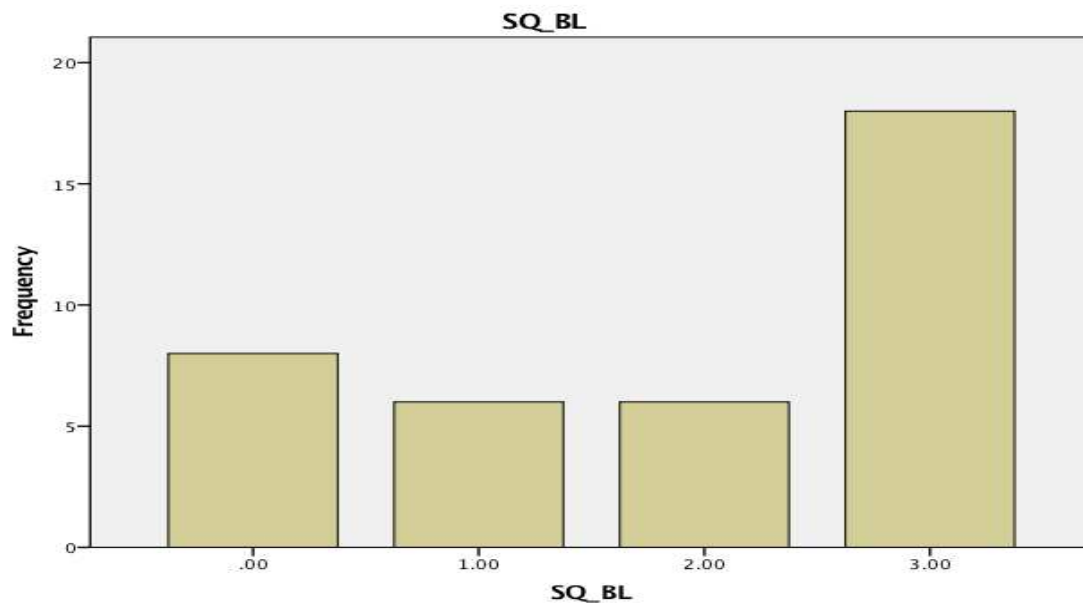decrease in category number 3 at LWRT and an increase in category 2.
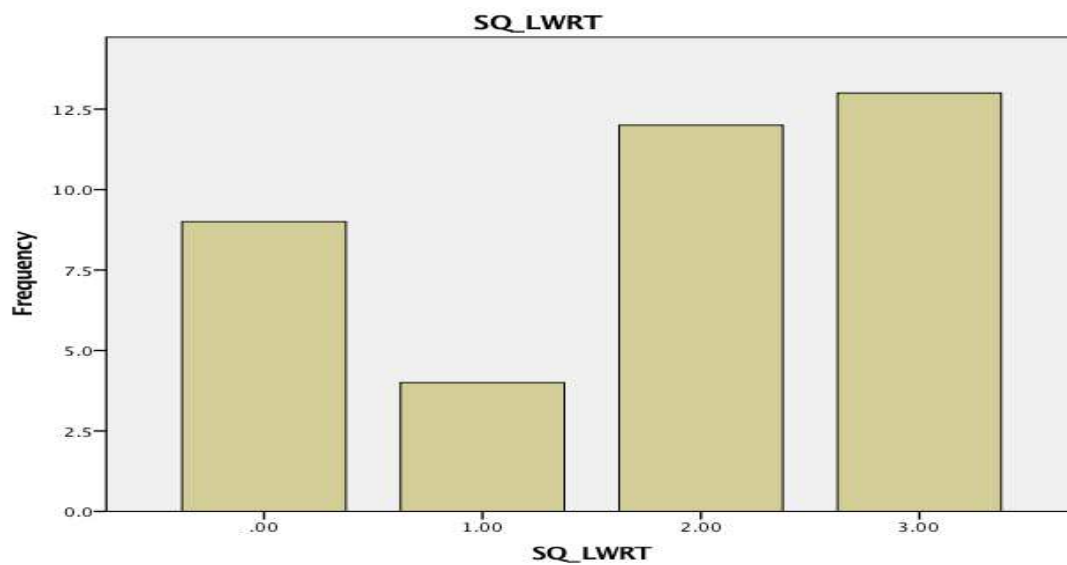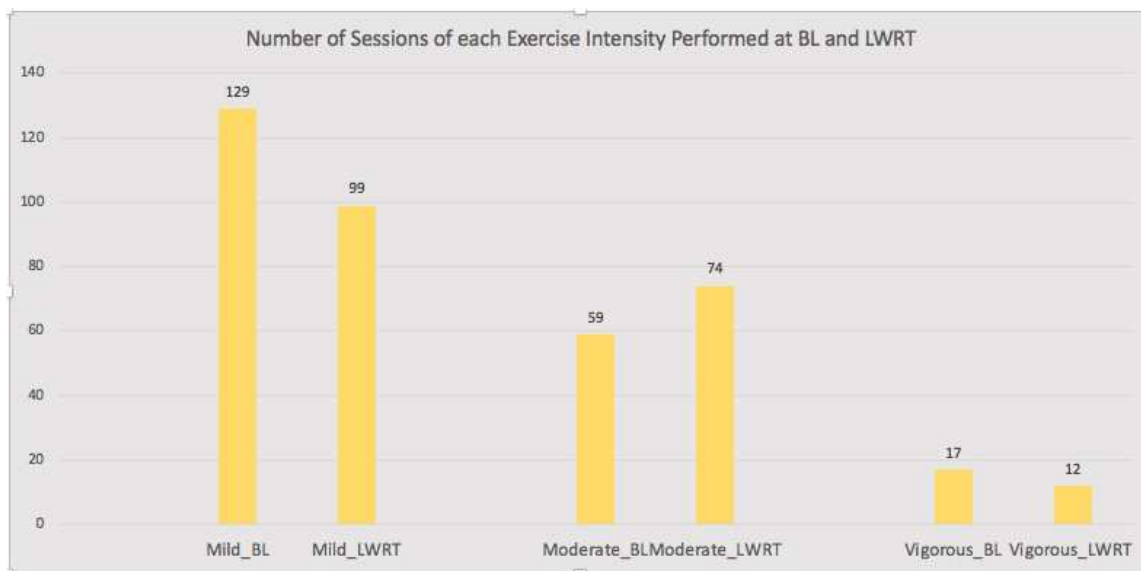

Figure 3. Sleep quality at BL bar chart.

Figure 4. Sleep quality at LWRT bar chart.

The bar chart in Figure 5 shows the frequency of mild, moderate, and vigorous exercise performed at BL and LWRT; it appears there was a decrease in mild and vigorous exercise at LWRT. However, moderate exercise increased at LWRT compared to BL.

Figure 5. Number of exercise sessions for each exercise intensity at BL and LWRT.

Summary and Transition

For the independent variable, exercise intensity level, mild and vigorous exercise had statistically significant values that supported the alternative hypotheses which examined if mild, moderate, and/or vigorous exercise has an effect on reduced pain level and improved sleep quality. The data showed that mild exercise had a significant positive effect on reduced pain level and improved sleep quality, while vigorous exercise did not have a positive effect on sleep quality. Logistic regression and multiple linear regression models were run to determine the correlations and coefficients of the independent variables both individually and comprehensively. The interpretation of findings will be

discussed in more detail in Chapter 5 as well as impact for social change,

recommendations for action and further study.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

Breast cancer is still the most common malignancy among women, and breast cancer patients suffer from side effects from radiation treatment, such as pain and poor sleep quality. Identifying factors that can help to alleviate these side effects can help breast cancer patients improve their QoL while undergoing treatment. Because breast cancer is still the most common malignancy among women, I chose to focus on examining whether mild, moderate, and/or vigorous exercise can reduce pain level and/or improve sleep quality for breast cancer patients undergoing radiation therapy. Two research questions were developed to determine whether correlations existed between the dependent variables (reduced pain level and improved sleep quality) and the independent variable (mild, moderate, and vigorous exercise). In Chapter 4, the results of the statistical analyses using logistic regression and linear regression were presented. In this chapter, these results are discussed more thoroughly as well as in light of related literature. In addition, the limitations of the study and recommendations for action and further study are presented.

Interpretation of the Findings

As seen in Chapter 4, mild exercise was the most likely of the three types of exercise to significantly reduce pain and improve sleep quality, while vigorous exercise did not have a positive effect on sleep quality.

Pain and Exercise Level (Mild, Moderate, Vigorous)

The results of the data analysis showed a statistically significant positive correlation between the independent variable of mild exercise and the dependent variable of reduced pain at LWRT, and this finding supports the results of previous studies (Geneen et al., 2017). Geneen et al. conducted a systematic review of 21 randomized controlled trials (RCTs) to examine exercise versus no exercise/minimal intervention in adults with chronic pain and found favorable results regarding exercise and pain severity, physical functioning, psychological functioning, and QoL.

Improved Sleep Quality and Exercise Level (Mild, Moderate, Vigorous)

As seen in Chapter 4, there was a statistically significant positive correlation between the independent variable of mild exercise and the dependent variable of improved sleep quality at LWRT, and this finding supports the results of a previous study by LaMotte (2017). LaMotte reported that exercise improves both self-reported measures and objective measures (those measured in a sleep lab) of sleep quality. Exercising is not as effective as sleeping pills, but it avoids the negative effects associated with sleeping pills, including infections, dementia in the elderly, and loss of effectiveness after a few weeks. The results of my data analysis showed a showed a nonpositive correlation between the independent variable of vigorous exercise and the dependent variable of improved sleep quality at LWRT, which was not discussed in the results of studies highlighted in Chapter 2 because it was not observed in previous studies.

Interpretations

My results indicate that exercise, specifically mild exercise, can help reduce pain level and improve sleep quality. Vigorous exercise, on the other hand, actually did not have a positive effect on improved sleep quality at LWRT. These findings suggest that breast cancer patients may use mild exercise in parallel with radiotherapy to preserve or improve QoL by reducing pain level and improving sleep quality. More data needs to be collected in regards to vigorous exercise and how it effects sleep quality to determine if there is a correlation between vigorous exercise and sleep quality. Moving forward, QoL measures for breast cancer patients should include reduced pain and improved sleep quality because these are important aspects of helping patients feel better and ultimately achieve improved QoL.

Health practitioners (oncologists and nurses) need to be made aware of the benefits of using mild exercise to help their patients regain QoL sooner. Health practitioners should advise walking or even housework as a form of mild exercise to get patients moving around during and after radiation therapy. The public needs to be made aware of the benefits of mild exercise during and after radiation therapy for breast cancer patients.

Limitations

Limitations of this study included the small sample size ($n = 45$), exclusion of housework and occupation-related activities as physical activity, and stipulation of ≥ 20 minutes duration as an exercise session. A small sample size decreases confidence levels and statistical power. Exclusion of housework and occupation-related activities can skew

data by not including activities that can be categorized as mild, moderate, or vigorous exercise. The stipulation of ≥ 20 minutes duration as an exercise session may have limited data points and prevented accurate reporting of exercise sessions because the participants might not have been able to perform 20 minutes or more of physical activity.

In addition, not all study participants responded to all the questionnaires at BL and at LWRT. There were missing data at BL and LWRT for the two research questions. This may have skewed the data and reduced the accuracy of the data presented. To address this limitation in future studies, an interviewer could ask the questions and record the answer to each question, thereby reducing the risk of incomplete data.

Another limitation in this study was the lack of specification of each exercise intensity level to perform for comparison at BL and LWRT. There were no control groups and intervention groups. This prevented accurate comparisons of the different exercise levels and effects of each level of exercise. A way to address this limitation would be to form groups and assign exercise intensity levels to each group or assign individuals to perform a certain amount of mild, moderate, and vigorous exercise at BL and LWRT. This would ensure that there were enough data to make accurate associations between the different exercise levels and dependent variables under study.

Finally, recall bias is a limitation that could have affected the accuracy of the data analysis. The original study conducted by Horton depended on participants to recall their physical activity level 7 days prior at BL and LWRT. A way to address this limitation would be to have the participants log their physical activity level each day, either on paper or online, to track the data.

Implications for Social Change

The implications for social change from this research extend beyond breast cancer patients; the findings can help patients with different types of cancer alleviate side effects from radiation treatment. The results of this study should encourage oncologists and nurses to recommend certain types of physical activity during radiation treatment (e.g., stretches, mild aerobic exercise) and after radiation treatment to help breast cancer patients restore QoL more quickly. The results of this study also have the potential to provide research knowledge to public health agencies so that they may promote physical activity to reduce health care costs (e.g., decreasing health insurance premiums for individuals who are physically active which in turn may reduce doctor visits and reliance on prescription drugs).

Mild exercise can not only improve QoL for breast cancer patients, but also serve a greater societal good by reducing the hefty burden of health spending on doctor visits and prescription-drug reliance for pain and/or sleep issues.

Recommendations for Action

The findings of my study indicate the importance of examining and understanding how specific exercise intensity levels (mild, moderate, and/or vigorous exercise) impact pain level and sleep quality for breast cancer patients undergoing radiation therapy. The research and data analysis conducted for this dissertation provided a valid and statistically sound review of some of the variables that impact pain level and sleep quality in breast cancer patients undergoing radiation therapy and provide justification for further study

and exploration to determine which types of exercise are most effective in alleviating pain and improving sleep quality during radiation therapy.

Recommendations for Further Study

While this study found statistically significant correlations between the independent variable (mild, moderate, and vigorous exercise) and dependent variables (reduced pain level and improved sleep quality), research is still needed regarding specific exercises (e.g., dog walking, taking a stroll, light hiking) to perform to reduce pain level and improve sleep quality. Some literature reviews have stated that exercise helps to reduce pain and improve sleep quality, but specific exercises have not been mentioned. Future studies should include a larger population size to extrapolate more data in regards to how vigorous exercise effects sleep quality to understand the correlation better as well as the time of day when exercises are performed, specifically vigorous exercise, to help explain the non-positive correlation between vigorous exercise and improved sleep quality. Also, the timeline of when patients receive radiation therapy and when they exercise should be documented to see if radiation therapy influences exercise behavior. If so, perhaps recommendations should be provided as to when to exercise to better adhere to an exercise regime. Future studies should also focus on incorporating housework and occupation-related physical activity into measures of exercise, removing the minimum of 20 minutes as an exercise session, and determining which type of exercise (e.g., mild exercise such as walking and/or stretching) can help alleviate other side effects from radiation therapy in breast cancer patients.

Conclusion

Breast cancer is the most common form of cancer among women. The purpose of this study was to explore the impact of different types of exercise intensity levels (mild, moderate, and vigorous) on the side effects (increased pain level and reduced sleep quality) from radiation therapy in early stages of breast cancer. By gaining an understanding of the impact of these variables on side effects from radiation therapy, this study may provide justification for health care practitioners to encourage their breast cancer patients to perform mild exercise, as opposed to prescribing drugs and/or having patients visit the doctor to alleviate side effects from radiation therapy. My study results may encourage public health officials to implement incentives (e.g., reducing health insurance premiums) to promote physical activity.

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