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ABSTRACT

Leah Menees Gardner

BREAST CANCER REHABILITATION: IMPACT ON PHYSICAL ACTIVITY AND QUALITY OF LIFE

Thesis under the direction of Shannon L. Mihalko, Ph.D., Department of Health and Exercise Science

Breast cancer is the most common form of cancer that affects women in the United States. For 2010, it was estimated that there were 207,090 new cases of invasive breast cancer diagnoses in women (ACS, 2010). Treatments for breast cancer have many side effects, including decreased physical activity and quality of life. Although physical activity has a positive impact on quality of life, breast cancer survivors often decrease physical activity participation during the treatment time period. The purpose of this study was to examine the impact of comprehensive rehabilitation on physical activity and quality of life in breast cancer survivors immediately following treatment. Participants were recruited from Wake Forest Baptist Health and Moses Cone Cancer Centers. Upon consenting to the study, the participants were required to attend three exercise sessions that included aerobic, resistance and flexibility training. Along with the exercise component, the program included baseline patient assessment, nutrition counseling, physical activity counseling, and social support. Physical activity was assessed by the Godin Physical Activity Questionnaire (PAQ) and accelerometers. Quality of life was assessed by the Satisfaction with Life Scale (SWLS), FACT-G and FACT-B. A
Repeated Measures ANOVA showed a significant (p < .0001) increase over the six months in PAQ minutes per week of moderate physical activity and a significant (p < .05) increase from baseline to three months in physical activity energy expenditure, calories expended per day doing physical activity, and minutes of moderate to vigorous exercise per day. There was also a significant (p < .05) increase in the FACT-B, FACT-G overall, and its functional subscale. There was no overall significant change in SWLS; however, there was a trend for an increase from baseline to six months (p = 0.056). At baseline, a Spearman Correlation demonstrated a significant moderate correlation between minutes of moderate-vigorous exercise and the FACT-G (r = 0.51), functional subscale (r = 0.59), and a trend with SWLS (r = 0.46). There was also a significant moderate correlation between PAEE and the functional subscale (r = 0.48) at baseline. Future research and the continuation of this study should assist in developing exercise prescription guidelines for this population. Efforts aimed at recruiting a larger sample and implementing a comprehensive rehabilitation program on a larger scale are warranted.
INTRODUCTION

It is estimated that in 2010 there were 261,100 new cases of breast cancer. In fact, almost 1 in 8 women (12%) develop invasive breast cancer in their lifetime. There are many methods of detection including: mammograms, MRI scans, breast ultrasounds, ductograms, and biopsies (ACS, 2011). The most common diagnoses are ductal carcinoma and lobular carcinoma. Stages are assigned after diagnosis ranging from I-IV, the higher the number representing further spread of cancer (CDC, 2011). After diagnosis participants can undergo surgery, radiation, chemotherapy, hormone therapy or a combination of treatments. These treatments have many long term or late effects such as fatigue, depression, pain, weight gain, and reduced quality of life (James et al., 2011).

Physical activity is an effective method for increasing quality of life in cancer survivors. Studies of this relationship have varied in both time related to treatment and exercise prescription, but have focused on the benefits of exercise for breast cancer survivors. At the roundtable on Exercise Guidelines for Cancer Survivors a discussion was held on the benefits of exercise following cancer treatment (Schmitz et al., 2010) and the number two objective listed for all cancer survivors was to improve body image and quality of life.

Quality of life (QOL) has been heavily researched and cited in hundreds of papers, with multiple definitions and yet no standard measure. This has made it difficult to compare findings across research studies, as well as forming any conclusions or implications. Defining and measuring quality of life can be a difficult task as it is a
multidimensional concept. Quality of Life (QOL) has been defined as “a conscious
cognitive judgment of satisfaction with one’s life” (Diener, 1997). More recently, QOL
has been used as an umbrella term to describe numerous outcomes that are important in
one’s life. To focus on some of these important components, health-related quality of life
(HRQL) was developed. This term was developed to narrow quality of life to the effects
of health, illness, and its treatment on quality of life (Ferrans, Zerwic, Wilbur, & Larson,
2005). Despite there being a lack of a clear definition, exercise programs have been
aimed to enhance patient’s quality of life.

Standard guidelines have been established for increasing physical activity in
cancer survivors, yet there is no formal rehabilitation program in place for this
population. Comprehensive rehabilitation is a multicomponent program that has been
successfully implemented in the cardiac population, and research has shown that this
model has effectively enhanced quality of life in young and old cardiac patients.
Comprehensive rehabilitation programs are composed of five components: patient
assessment, exercise, nutrition counseling, risk factor management, and social support.
Although there is evidence of its effectiveness in other populations, few studies have
sought to examine the impact of comprehensive rehabilitation on breast cancer survivors.
The purpose of the present study was to examine the effects of a comprehensive
rehabilitation intervention on physical activity and quality of life in breast cancer
survivors directly after their treatment. This pilot may potentially provide preliminary
support for the beneficial impacts of breast cancer rehabilitation as well as offer rationale
for a larger scale study to implement a multi component program.

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REVIEW OF THE LITERATURE

Epidemiology of Breast Cancer

Of the 207,090 new cases of breast cancer in 2010 less than 1% of all cases were in men. White women are more likely to develop breast cancer; however, African American women are much more likely to die from breast cancer. Asian, Hispanic and Native American women have a lower risk for developing breast cancer than both white and African American women (“U.S. Breast Cancer Statistics”).

There are many non-modifiable risk factors: age, having changes in the breast cancer-related genes BRCA1 or BRCA2, being younger at menarche, later menopause, personal history of breast cancer or some non-cancerous breast diseases, family history of breast cancer, or treatment with radiation therapy to the breast/chest. There are also modifiable risk factors: being overweight, long-term use of hormone replacement therapy, age at first child birth, never giving birth, not breastfeeding, using birth control pills, drinking alcohol (more than one per day), and physical inactivity (CDC, 2011).

Being a woman and growing older are the most important risk factors for breast cancer. The younger a woman is, the lower their absolute risk. Women aged 30-39 have an absolute risk of 1 in 233, 0.43%; women aged 40-49 have a risk of 1 in 69, 1.4%; women aged 50-59 have a risk of 1 in 38, 2.6%; women aged 60-69 have a risk of 1 in 27, 3.7%. Therefore, women have a 1 in 8 chance of developing breast cancer in an 80-year lifespan (“U.S. Breast Cancer Statistics”). An estimated 39,840 women in the U.S.
were expected to die from breast cancer in 2010. Death rates have been decreasing since 1990 due to increased awareness, earlier detection, and treatment advances leading to an increase in the number of breast cancer survivors. In fact, in 2010 there were more than 2.5 million breast cancer survivors in the United States (CDC, 2011).

**Pathology**

Breast cancer is caused by abnormal cell growth, specifically by cells of the breast. The most common breast cancer diagnoses are ductal carcinoma and lobular carcinoma. Ductal carcinoma, cancer in the cells lining the milk ducts to the breast, can be either ductal carcinoma in situ (DCIS) or invasive ductal carcinoma. Lobular carcinoma, cancer in the lobules (milk producing glands) of the breast, can be either lobular carcinoma in situ (LCIS) or invasive lobular carcinoma. A tumor can be either benign or malignant; a benign tumor is harmless while a malignant tumor can invade surrounding tissues or even metastasize to other areas of the body (CDC, 2011). A malignant tumor will require the patient to have treatment to eradicate the cancer cells.

**Treatment**

Breast cancer can be treated with an array of therapies such as surgery, radiation, chemotherapy, or a combination of these therapies. Individuals may decide to have a combination of these therapies, which can be in varying order dependent upon the diagnosis.
There are many options for surgery dependent upon many factors including size and location of the tumor. A partial mastectomy is a breast-conserving surgery which includes a lumpectomy or a quadrantectomy. A lumpectomy is removal of the tumor and only the surrounding margin of normal tissue whereas a quadrantectomy removes one-quarter of the breast. Usually radiation and chemotherapy will be used in conjunction with these two surgeries. On the other hand a total mastectomy is another option; this surgery removes the entire breast. An individual can undergo a single or double mastectomy, depending upon their diagnosis and preference. Generally reconstructive surgery follows a total mastectomy. Breast reconstruction is done to restore the appearance of the breast after the surgery (ACS, 2011).

Usually following surgery, individuals have radiation therapy. Radiation therapy uses high-energy rays to destroy cancer cells, specifically after surgery to destroy any remaining cancer cells. There is both external and internal radiation. External beam radiation is the most common form using a machine outside the body to direct these rays on the affected area. Brachytherapy, internal radiation, places radioactive seeds or pellets into the breast tissue next to the cancer and can be used on its own or with external radiation depending upon the tumor factors (ACS, 2011).

Chemotherapy is the use of cancer-killing drugs, taken intravenously or by mouth. This treatment usually takes a few months as it must be given in cycles of treatment and recovery. There are two types of chemotherapy: neoadjuvant chemotherapy and adjuvant chemotherapy. Neoadjuvant chemotherapy is administered before surgery allowing the possibility of shrinking the tumor before surgery or seeing how the tumor responds to the
chemo drugs. Adjuvant chemotherapy is administered after surgery to kill any remaining
cancer cells that cannot be seen (ACS, 2011).

Hormonal therapy is also used in many breast cancer treatments. It is typically
used as an adjuvant therapy for preventing recurrence; it can also be used as neoadjuvant
treatment when appropriate. Hormonal therapy blocks estrogen in an attempt to lower
the body’s levels of estrogen as it promotes the growth of 2 out of 3 breast cancers. This
effectively helps reduce the risk of recurrence and hopefully limits the progression of
cancer cell growth, but does not help with both ER and PR-negative tumors (ACS, 2011).

**Side Effects of Treatment**

There are many side effects of treatment, whether they are long-term or late
effects. Long-term effects are defined as complications arising during or very shortly
after treatment that persist and must be compensated for. Late effects occur months or
years after treatment is finished (Schmitz et al., 2010). There are many common side
effects including: weight gain and fatigue, as well as decreased physical activity, physical
fitness, and quality of life.

**Weight gain**

Weight gain has been found in many women following breast cancer treatment.
Goodwin et al. (1999) conducted a study following 535 women with newly diagnosed
breast cancer who received adjuvant therapy. Anthropometric measurements were taken
at baseline and 1 year. Of the 445 women who participated in the 1-year follow up, 374
(84.1%) gained weight with an average weight gain of 1.6 kg (p < .05). In this study the main predictors of weight gain were identified as adjuvant chemotherapy and onset of menopause.

Attempting to define the mechanism behind weight gain in this population, researchers have identified a few possibilities. First, hyperphagia or overeating due to an increased appetite after treatment. Second, a decrease in physical activity after treatment accompanied by 96% of patients experiencing fatigue. Third, basal metabolic rate seems to be altered after treatment. This is due to overall cell death from chemotherapy leading to fewer cells and therefore less need for energy, or chemotherapy induced menopause which leads to changes in hormones as well as an increase in body fat. Finally, changes in thermogenesis, energy expenditure above basal metabolic rate not due to physical activity, is also an explored mechanism. Although there have been many studies examining these mechanisms none have been proven to be the main source of weight gain in breast cancer survivors (Demark-Wahnefried, Winer, & Rimer, 1993).

**Fatigue**

Fatigue has been cited in multiple research studies as one of the most occurring side effects of breast cancer treatment affecting approximately 70% of cancer patients who receive radiation therapy and/or chemotherapy. In fact, almost 99% report experiencing some level of fatigue during radiation and/or chemotherapy and over 60% rate their fatigue as moderate to severe. The most recent evidence suggests that this fatigue can be experienced months or even years after completion of breast cancer
treatment, especially with patients undergoing adjuvant chemotherapy (Bower et al., 2000).

Breast cancer participants have higher levels of fatigue (p < .05), more weakness (p = .002), as well as less vitality (p < .05) compared to age-matched controls (Andrykowsky et al., 1997). Overall, fatigue is present in the majority of breast cancer participants and can last for months to years after completion of treatment. Because many cancer patients experience a period of inactivity and bed rest during and after cancer treatment, they may experience a decreased cardiorespiratory fitness, which may lead to the inability to perform daily activities and exacerbate fatigue (Biolo et al., 2005; Dimeo, 2001).

Physical Activity

It has been documented that there is a significant decline in physical activity following breast cancer treatment. Irwin et al. (2003) found that physical activity decreased by 2 hours per week, 4-12 months post-diagnosis while Littman et al. (2010) found a 50% decrease in leisure-time activities 1-12 months post-surgery. These results were later replicated with 10% reductions in total physical activity and 60% reductions in recreational physical activity (Devoogdt et al., 2010). Research has identified many different patient, disease, and treatment related factors associated with decreased physical activity in this population. A larger decrease in physical activity is associated with a shorter time from diagnosis, high pre-diagnosis activity level, younger age, high or low pre-diagnosis BMI and adjuvant treatment with either radiation or chemotherapy (Irwin et al., 2003; Littman, Tang, & Rossing, 2010).
The results from these studies were significant, but not without limitations. Physical activity is commonly measured by self-report instruments, which are subjective and open to human error. In physical activity interventions accelerometers are commonly used to supplement self-report questionnaires to have an objective measure of physical activity. However, studies to date have not used accelerometers to examine physical activity habits in the breast cancer population. Decreased physical activity ultimately leads to decreased physical fitness in breast cancer patients.

Physical Fitness

Physical fitness is comprised of many components the most often measured is cardiorespiratory endurance, by maximal oxygen consumption (VO$_{2\text{max}}$). Cardiorespiratory endurance is defined as “activities in which the body’s large muscles move in a rhythmic manner for a sustained period of time” (CDC, 2011). The U.S. recommendations for health benefits are 150 minutes of moderate or 75 minutes of vigorous exercise. Strength training should be done 2-3 days per week, and flexibility exercises should be done most days of the week. Looking at PAEE, or calories expended per day doing physical activity, people should expend at least 1000 calories per week but aim for 1500-2000 (“Physical Activity Guidelines for Americans”). Finally, guidelines suggest that people should aim to walk 10,000 steps per day (Tudor-Locke & Bassett, 2004).

Women who require a period of inactivity or bed rest after treatment may see a decrease in cardiorespiratory fitness (Biolio et al., 2005; Dimeo, 2001). Many studies have looked at maximal or peak oxygen consumption in breast cancer survivors to
determine their physical fitness. The values found in these studies tended to be lower than healthy adults of the same age (Courneya et al., 2003; McNeely et al., 2006).

**Reduced Quality of Life**

Another side-effect of breast cancer treatment is reduced quality of life. An estimated one third of patients undergoing systemic chemotherapy have declines in cognitive function which tends to interfere with their quality of life. Aside from cognitive changes, women also tend to experience body image concerns, premature menopause, and changes in sexual functioning. Younger women tend to experience greater psychological disturbances than older women (Allen et al., 2002).

Luoma & Hakamies-Blomqvist (2004) conducted a multicenter clinical trial of 25 women with breast cancer. Women were asked to discuss the impact of their diagnosis and treatment on their physical, emotional, social, cognitive and role functioning. The most distressing physical changes was their limited physical functioning which they reported led to an inability to participate in their usual activities, a change in social role from care giver to care receiver, and increased dependency on others. Social isolation was felt as a result of changes in appearance and decreased stamina while emotional well-being was impacted by their ability to maintain and enjoy an active life. In this study no changes in cognitive function were observed, however, many reported feelings of anxiety.

Other studies have attempted to compare QOL ratings of women receiving varying treatments. Bottomley et al. (2005) observed 224 patients with locally advanced breast cancer receiving either short intensified treatment or standard treatment. HRQL
was assessed with the EORTC instrument and measured at baseline, months 1-3, followed by every three months after that until month 26, and every six months stopping after 54 months. The dose-intensive group exhibited much lower HRQL scores than the standard treatment group, significant from baseline to nine months. After nine months HRQL tended to increase in both groups, and return to baseline values within one year. Another study showed similar results in 52 breast cancer patients receiving high-dose chemotherapy. Health related quality of life was significantly reduced following administration of high-dose chemotherapy, and returned to baseline within 8 weeks after treatment was completed. Although HRQL returned close to baseline, women reported difficulty sleeping, headaches, and decreased sexual interest as common long-term symptoms (Conner-Spady, Cumming, Nabholtz, Jacobs, & Stewart, 2005).

To understand the changes in QOL found by these observational studies, we must understand how QOL is measured. All three studies examined here have inconsistent definitions, which is a common trend in QOL research making this term difficult to measure. Although these studies had different definitions and measures of QOL, all of them found significant decreases following diagnosis and treatment, which is important. Therefore an in-depth look at the various QOL measures to better understand this concept is provided.

**Measurement of Quality of Life**

The construct Quality of Life has historically been measured by the Satisfaction With Life Scale (SWLS); however, more recently QOL has been used as an umbrella
term to describe numerous outcomes that are important in one’s life. Stewart and King (1991) categorized these main outcomes under functioning and well-being. Functioning includes constructs such as physical abilities, dexterity, cognition, and the ability to perform activities of daily life. Well-being includes symptoms, bodily states, emotional well-being, self-concept, and global perceptions related to health and overall life satisfaction.

Since QOL has been identified as a global term, HRQL or health status was developed to narrow the focus of quality of life. HRQL was developed to focus on both functional effects of an illness as well as its consequent therapy (Rejeski & Mihalko, 2001). HRQL, health status, and quality of life have similar but different definitions. HRQL involves multiple core dimensions which include, but are not limited to: physical functioning, emotional well-being, social functioning, role activities, health perceptions and global assessment of life satisfaction (Shumaker et al., 1990).

Both HRQL and quality of life define function of the individual at either a generic or a disease-specific level. The most commonly used measure for health status or HRQL is the SF-36 which includes both physical health and mental health scores each comprised of four individual scales. Overall, this measure has shown a strong relationship with global measures of life satisfaction ($r = .68$) (Rejeski & Mihalko, 2001). There are several disease-specific measures of HRQL; specific to cancer is the Functional Assessment of Cancer Therapy (FACT) measure, and specific to breast cancer is the FACT-B scale which will later be discussed in detail. Although there are problems with coming to a single definition of QOL, the majority of studies have shown a decrease in...
QOL following diagnosis and treatment. As a result, researchers are working on interventions to improve QOL after breast cancer diagnosis and treatment.

**Interventions and Quality of Life**

Researchers have implemented varying interventions in an attempt to find the best way to improve the reduced QOL in breast cancer survivors. Studies are done in this population to increase our knowledge of effective methods for improving numerous outcomes. Therefore, researchers have conducted psychological, educational, and physical interventions to determine the most effective method of enhancing QOL.

Andersen (1992) conducted a meta-analysis of psychological interventions for cancer patients to improve quality of life. There were three main interventions discussed. Houts, Whitney, Mortel, & Bartholomew (1986) used a peer counseling intervention involving encouragement to maintain interpersonal relationships, making positive plans for the future, query to the medical staff regarding treatments, side effects, and sexual outcomes, and to maintain normal routines. Sexual functioning had the greatest improvement while the other categories had limited gains. Edgar, Roserberger & Nowlis (1992) used a coping skills intervention, at the four month assessment patients had decreases in anxiety, depression and distress along with increased perceived control. Fawzy et al. (1990) used a group support intervention, six months post intervention patients had lower depression, confusion, and fatigue accompanied by higher vigor leading to a lower overall mood disturbance.
Looking at studies examining women with breast cancer only, the three main interventions used were: Cognitive Behavioral Therapy (CBT), Problem Solving, and Support Groups. In a study of metastatic breast cancer, women in the intervention had group meetings, a cognitive behavioral course, and coping skills training (Edmonds et al., 2006). Quality of life was assessed with The Functional Living Index for Cancer (FLIC). Analyses showed no significant improvements in the intervention group in the long term which the researcher’s said could be due to the women’s diagnosis. Women with metastatic breast cancer have been shown to exhibit lower quality of life and higher stress levels (Edmonds et al., 2006); however, younger women have also been shown to exhibit greater emotional distress throughout breast cancer diagnosis and treatment (Allen et al., 2002).

Allen et al. (2002) looked at women under the age of 50 with breast cancer and implemented a problem solving training to help enhance quality of life. Women were assessed at four and eight months after the intervention using the Cancer Rehabilitation Evaluation System (CARES). Analyses showed improvements in the physical, medical, psychosocial, marital and sexual subscales leading to an overall improvement in the global score of quality of life.

Helgeson, Cohen, Schulz, and Yasko (1999) conducted a trial of support groups that randomized patients to one of the following: education, peer discussion, education plus peer discussion, and no-treatment control. Analyses found better psychological adjustment in the education condition compared to the other three conditions. Overall, the various psychological interventions have proven effective in enhancing some aspect of quality of life. It is important to note, however that studies to improve QOL in breast
cancer survivors have not been limited to only psychological and educational interventions.

**Physical Activity and Quality of Life**

Physical activity interventions have been commonly employed to enhance quality of life in women with breast cancer both during and after treatment. Physical activity interventions range in type of exercise and duration, as well as timing of intervention. A few of the physical activity interventions have been examined during breast cancer treatment to increase QOL.

Physical activity interventions during treatment lasted approximately 12 weeks and included aerobic activities, resistance and flexibility exercises with the exception of two studies that only used physical activity assessments to estimate levels of activity. Both studies that used only physical activity assessments found that women with higher rates of physical activity had higher levels of QOL, and investigators hypothesized that physical activity interventions would help enhance QOL (Faul et al., 2011 & Haas, 2011). Of all the physical activity interventions, only one found no change in QOL from baseline throughout the intervention (Cadmus et al., 2009). Cadmus et al. (2009) had no significant findings, but there were trends in the exercise group, while the rest of the studies found significant improvements in QOL (Adamsen et al., 2005; Campbell, Mutrie, White, McGuire, & Kearney, 2005; Courneya et al., 2007; Faul et al., 2011; Haas, 2011; Hayes et al., 2011; Mutrie et al., 2007; Noble et al., 2011).
Mutrie et al. (2007) studied 203 women with stage 0-III breast cancer during treatment. They employed a usual care group and a supervised exercise group. The intervention lasted 12 weeks, and consisted of 5-10 minutes of warm up, 20 minutes of exercise and a cool down for the supervised exercise group. The primary outcome of this study was quality of life measured by the FACT-G and FACT-B questionnaires. As hypothesized, there was an increase in quality of life, especially at the 6 month follow up. At the end of the 12 weeks there was a trend for an increase in FACT-G in the exercise group compared to the control group \((p = .60)\) while at the 6 month follow up there was a significant increase in the exercise group compared to the control group \((p = .053)\). For the FACT-B subscale, specific to breast cancer, there was a significant improvement in the exercise group compared to the control at both 12 weeks \((p = .0007)\) and 6 months \((p = .039)\).

Another study looking at women during early breast cancer treatment had an exercise group that completed 12 weeks of an exercise program incorporating aerobic and strength exercises 2 times a week. Using the FACT-G, FACT-B and SWLS measures to evaluate quality of life the researchers found significant increases at 12 weeks in FACT-G \((p = .046)\) and a trend in FACT-B measures \((p = .094)\) (Campbell et al., 2005). Therefore, it seems that a physical activity intervention incorporating both aerobic and resistance exercises during breast cancer treatment leads to an increase in quality of life.

The majority of physical activity interventions have been conducted after breast cancer treatment to increase QOL. These interventions all lasted from 4-12 weeks; with the exception of one lasting 26 weeks which is longer than most of these interventions (Segal et al., 2001). The majority of studies include aerobic activities, resistance, and
flexibility exercises. Although these studies were conducted at various points within two years of completion of treatment, all showed significant improvements in QOL (Cheema et al., 2006; Courneya et al., 2003; Daley et al., 2007; Jones et al., 2010; Kim et al., 2011; Kolden et al., 2002; Noble et al., 2011; Turner et al., 2004).

Kolden et al. (2002) in one of the earlier studies recruited a group of 40 surgically treated women for Stage I-III breast cancer within 12 months of their diagnosis. Their only group was a supervised exercise group, that did 16 weeks of aerobic, strength and flexibility exercises. The primary outcome of this study was quality of life, measured using the FACT questionnaires, Global Assessment Scale and Cancer Rehabilitation Evaluation System. As hypothesized, there was a significant increase in quality of life post-intervention compared to pre-intervention. FACT-G broken down into its subscales had the following significant increases at week 8 and week 16 of the intervention, global score (p < .05), physical well-being (p < .01), and functional well-being (p < .05). While this study implemented a comprehensive exercise protocol including aerobic, resistance and flexibility components, other studies have focused on one mode of exercise.

Courneya et al. (2003) studied 53 postmenopausal breast cancer survivors who had completed treatment in the past 14 months. Women were randomized into either a control group or the exercise group. The exercise group completed a 15 week exercise program on cycle ergometers. The exercise group trained three times a week on either a recumbent or upright cycle ergometer at 70-75% maximal oxygen uptake. HRQL, measured by the FACT-G, significantly improved after the 15 weeks in the exercise group compared to the control group (p = .001).
Daley et al. (2007) recruited a total of 108 women after completion of treatment that were randomized into one of three groups: exercise therapy, exercise placebo, or usual care. The exercise therapy and exercise placebo group both met three times a week for a total of eight weeks. The exercise therapy group did 50 minutes of aerobic exercise at 65-85% of their age adjusted HR, or RPE of 12-13. The exercise placebo group had the same time requirement, but only did light conditioning and stretching. Quality of life significantly increased in the exercise therapy group compared to usual care for FACT-G (p = .004) and FACT-B (p = .002), while the exercise-placebo group reported no significant improvements in QOL compared to usual care. Overall, while these studies have had significant improvements in QOL and important findings, they failed to use an objective measure of physical activity and relied on self-report measures only.

Objective measures of physical activity incorporate the use of accelerometers; to the best of our knowledge accelerometers have not been used in many studies attempting to enhance QOL in breast cancer survivors. Schwartz (1999) conducted a study to explore the relationship of exercise to fatigue and quality of life. Twenty-seven women who were about to start chemotherapy completed this home-based exercise intervention. Women were instructed to exercise at home 3-4 times a week for 15-30 minutes. Caltrac accelerometers were distributed to the women and they were instructed to wear them during exercise sessions to keep a record of calories expended to determine exercise intensity. The Quality of Life Index was used to measure QOL at baseline and after the 8-week intervention. Results showed a decrease in QOL for nearly all subjects, but subjects who had increased their functional ability from the exercise intervention had less overall decline (p = 0.04). Researchers did not look at the direct relationship between
physical activity and QOL in this study. However, with nearly all subjects experiencing decreases in QOL it does not seem physical activity and QOL were related. There was however an increase in physical activity. This study used accelerometers to provide an objective measurement of the home-based exercise, which is important to validate the self-report logs that were completed to document their exercise sessions.

Although these physical activity interventions have varied in timing and type of exercise, the majority of interventions both during and after breast cancer treatment have been effective in increasing quality of life in these women. After taking an in depth look at the relationship between physical activity and quality of life in breast cancer patients there is an established positive association. Unfortunately, although physical activity has been shown to be beneficial for this population, breast cancer survivors have been found to significantly decrease their physical activity following diagnosis and treatment.

Physical Activity Participation

Physical activity significantly declines in breast cancer patients following treatment. Researchers have examined this in many studies, and found that with certain diagnoses and treatments up to 68% of women decrease their physical activity up to 60% (Devoogdt et al., 2010; Irwin et al., 2003; Littman et al., 2010). The HEAL study examined physical activity levels before and after diagnosis by administering the Modifiable Activity Questionnaire to 812 women that were within a twelve month timeframe after diagnosis. Women had a significant decrease in physical activity from before to after diagnosis. There was also a significant difference in levels of physical
activity dependent upon treatment type with the following decreases, respectively: surgery, 8.5%; surgery and radiation, 7.0%, surgery and chemotherapy, 18.3%, and surgery, radiation and chemotherapy, 18.5% (Irwin et al., 2003).

Another study attempting to examine the difference between pre-surgical physical activity levels and 12 months post-surgery administered the Flemish Physical Activity Computerized Questionnaire (FPACQ) to 267 breast cancer patients. This self-report measure was used to obtain information about various physical activity habits before, three, six and twelve months post-surgery. Results found that total activity levels were significantly lower at each follow-up visit compared to before surgery (P < 0.01). Similar trends were found for occupational, sport, and household activity levels (Devoogdt et al., 2010).

Another study examining 315 women diagnosed with invasive breast cancer were assessed over a 2-year period for recreational physical activity. Women were given the Modifiable Activity Questionnaire before diagnosis and at three intervals after diagnosis (1-12, 13-18, and 19-30 months). Results found a mean 50% decrease in physical activity level in the year following diagnosis compared to before diagnosis (Littman et al., 2009). All studies which have examined this change in physical activity have found significant decreases following diagnosis and treatment. It is important to note that these studies used self-report measures only versus an objective measure of physical activity participation, which is a major limitation in previous research in this population.

The physical activity guidelines for the breast cancer population are not that different from those for healthy adults. The American Cancer Society recommends 30-60 minutes of moderate to vigorous aerobic physical activity at least five days of the
week for cancer survivors (ACS, 2011). This population should also incorporate at least
two days per week of muscular strengthening and two to seven days a week of flexibility
exercises (ACSM, 2010). Benefits include, but are not limited to: lower risk of coronary
heart disease, stroke, high blood pressure, and type II diabetes, prevention of weight gain,
weight loss, improved cardiopulmonary fitness and muscular strength and reduced
depression (CDC, 2011). Getting individuals physically active after debilitating
treatment is difficult, which is why rehabilitation was created and implemented in certain
populations. To date there is no rehabilitation in place for breast cancer survivors.

Rehabilitation

Rehabilitation is defined as the period following initial treatment, which occurs
during the survivorship phase on the cancer continuum. Rehabilitation is used “to restore
or bring the person back to a condition of good health” (Courneya & Friedenreich, 2001).
Rehabilitation incorporates an exercise component to help patients recover from the side
effects of treatment. Two of the main outcomes of interest in cancer rehabilitation are
physical fitness and quality of life. Aside from these outcomes of interest, cancer
rehabilitation aims to expedite recovery rather than prevent decline (Courneya &
Friedenreich, 2001). Rehabilitation occurs for cancer patients during the survivorship
time period as proposed in the framework titled Physical Exercise Across the Cancer
Experience (PEACE).

PEACE is composed of six time periods: prescreening, screening, pretreatment,
treatment, post-treatment, and resumption. The survivorship period follows initial
treatment and ends with recurrence or death, and is broken down into a rehabilitation period and disease prevention/health promotion period. The rehabilitation period is suggested to last 3-6 months (Courneya & Friedenreich, 2001). Although no current cancer rehabilitation exists, there are multiple reasons why physical activity interventions should be offered during this time period.

First, cancer survivors tend to be deconditioned, possess many acute side effects, and tend to decrease their participation in physical activity following completion of treatment. Cancer survivors would therefore exhibit positive benefits from physical activity interventions as in this population they have been shown to improve physical functioning, quality of life, as well as immune function (Spence, Heech, & Brown, 2010). Second, breast cancer diagnosis and treatment is a life changing event which could serve as a motivator for lifestyle improvements, such as increasing physical activity participation. A recent pilot study of colorectal cancer survivors showed that cancer diagnosis was in fact a motivator for initiating lifestyle changes which were promoted in the intervention. Another important finding of this study was the patients preferred timing to start a rehabilitation program was 3-5 months following the completion of treatment. In another study, the majority of the cancer survivors expressed a preference for beginning rehabilitation immediately or soon after treatment rather than during their treatment (Spence, Heesch, & Brown, 2010).

Finally, at the end of medical treatment breast cancer patients tend to have a significant decrease in both medical and social support, often reporting feeling unanticipated fear and emptiness. A rehabilitation program would offer continuing support for these women, which could help them transition from the intense levels of
support they previously had during treatment. A group-based cancer rehabilitation program would significantly benefit this population following treatment (Spence, Heesh, & Brown, 2010). Though rehabilitation is not available to this population, comprehensive rehabilitation is offered to the cardiac population and has been effectively implemented.

The U.S. Department of Health and Human Services, Agency for Healthcare Policy and Research (AHCPR) and the National Heart, Lung and Blood Institute has described comprehensive rehabilitation as a multicomponent program incorporating a medical evaluation, exercise prescription, cardiac risk factor modification, education, counseling, and behavioral interventions. The American Heart Association and the American Association of Cardiovascular and Pulmonary Rehabilitation lay out core components of rehabilitation which include patient assessment, nutritional counseling, weight, blood pressure, lipid, diabetes management, psychosocial management, physical activity counseling, and exercise training (Wenger, 2008). This multicomponent approach has proven effective in the cardiac population (Belardinelli, Georgiou, Cianci, & Purcaro, 1999; Belardinelli et al., 2001; Dugmore et al., 1999; Specchia et al., 1996; Vermeulen, Lie, & Durrer, 1983); however, this has never been employed in a breast cancer population.

There have been numerous breast cancer interventions following treatment that have implemented physical activity alone while no studies have used this multicomponent approach using patient evaluation, medical screening, risk factor management, nutritional counseling, physical activity counseling, and an exercise component. Similar to established cardiac rehabilitation, implementing a
multicomponent rehabilitation program for breast cancer survivors will allow them to move from treatment to the survivorship stage, while still receiving support and guidance from clinical professionals.

**Limitations in the literature**

There are many limitations in the research on interventions to enhance quality of life in breast cancer survivors. Although there have been many research studies examining physical activity interventions in this population, previous research has varied in time of intervention relative to treatment, duration of the intervention, and no studies to date have included an objective physical activity measure or comprehensive rehabilitation model to guide the intervention.

Research studies have examined physical activity interventions both during and after treatment for breast cancer. Although studies during treatment have been relatively similar in timing, interventions after treatment have started between three to twelve months after completion of treatment. To the best of our knowledge, none of these studies started their intervention directly after completion of treatment.

The majority of studies have involved relatively short physical activity interventions lasting approximately four to twelve weeks. The longest study to date was 6 months, which satisfies the recommendation for longer rehabilitation programs. Courneya and Friedenreich (2001) proposed that rehabilitation programs following treatment should last 3-6 months. Therefore, the majority of physical activity
interventions only lasted barely three months, and more studies should be done examining an extended time period of six months.

Finally, all studies have examined just a physical activity intervention. A limitation of the literature is the lack of objective measures of physical activity. A strength of previous literature is the use of all aspects of physical fitness including aerobic endurance activities, resistance and flexibility exercises, yet none of these studies have sought to incorporate the other aspects of a comprehensive rehabilitation program.

**Objectives**

The objective of this study was to investigate the impact that comprehensive rehabilitation has on cancer outcomes in the breast cancer population following completion of treatment. Specifically, this study examined the impact of a comprehensive rehabilitation program on physical activity participation and quality of life. Change in physical activity was assessed using both self-report and accelerometer data to document whether the women actually became more physically active. Secondly, the relationship between change in physical activity and quality of life at baseline was examined to determine whether physical activity was related to quality of life. Altogether, this study included a rehabilitation program that started directly after completion of treatment, lasted 6 months, and included all aspects of a comprehensive rehabilitation model.
METHODS

Study Design and Participants

The Breast Cancer Rehabilitation Pilot was a prospective study involving women that had recently completed treatment for breast cancer. Participants were recruited from the Comprehensive Cancer Center at Wake Forest Baptist Medical Center or the Regional Cancer Center at Moses Cone. Eligibility criteria included: 1) ≥18 years of age, 2) first occurrence of breast cancer, or a second primary of the opposite breast, 3) BMI ≥20, 4) recently completed treatment (surgery/chemotherapy/radiation or reconstruction) for breast cancer (≤3 months), but can be receiving adjuvant hormonal therapy, and 5) able to participate in a moderate exercise program. Ineligibility criteria included: 1) unstable angina, 2) cardiac conduction disturbances, 3) documented or suspected dementia, 4) advanced arterial disease causing ischemia of any limb, 5) physical immobility or wheelchair dependent, and 6) reoccurrence of breast cancer, unless it is a second primary of the opposite breast.

Eligible women were recruited for the study by a member of the oncology team which included physicians, physician assistants, research nurses, and study staff. Either during treatment or at a follow-up visit, patients were informed about the study and if they expressed interest in participating in the study their information was given to a member of the study staff. Upon request to be informed about the study, patients were contacted by telephone to discuss study outcomes and the intervention, to schedule a
baseline assessment visit, and have any additional questions answered. Eligibility was confirmed prior to the baseline assessment where the registration form was completed and the informed consent was signed (Appendix A).

Measures

The Breast Cancer Rehabilitation Pilot study implemented multiple measures assessing both physical and psychosocial constructs; however, only the measures examined in this thesis will be described. The measures that will be described are: demographics, physical activity, and quality of life.

Demographics

To adequately describe our sample, patient demographics were collected and analyzed. Demographics are important for determining generalizability of the sample to the population, as well as evaluating the potential influence of demographic variables on other outcome variables. Participant baseline visits involved a demographic questionnaire including race, employment status, education, and income (Appendix B). Breast cancer diagnosis, method of diagnosis, date of diagnosis, type of treatment and other medical information was gathered from medical records from Wake Forest University Baptist Hospital or Moses Cone.
Physical Activity

The Godin Physical Activity Questionnaire (PAQ) was used to assess physical activity. Participants were asked to report their current average weekly physical activity. This questionnaire is composed of one item, “how many times per week on average did you do the following kinds of exercise over the past month?” Participants reported on average how many times per week they participate in strenuous, moderate and mild exercise and the average duration of each exercise bout. This measure was scored by computing weekly frequencies of strenuous, moderate, and mild activities. These weekly frequencies are then summed to give a measurement of total weekly physical activity (Appendix C).

Participants were also required to wear an accelerometer for 10 days at their baseline, 3 month and 6 month assessments. Lifecorder-EX accelerometers were worn continuously for the ten day period, except when bathing or sleeping. The accelerometer was worn on the left hip attached to either the participant’s waistband or a belt. All data was stored in the Lifecorder-EX, once the ten day period was over the data was uploaded onto Lifecorder PAAS software. Physical activity levels recorded included steps/day, PAEE (calories expended per day doing physical activity) minutes of light-intensity physical activity (LPA), and moderate to vigorous intensity physical activity (MVPA). Time of LPA and MVPA was determined by the Lifecorder-EX device through a propriety-processing algorithm (Kumahara, Schutz, Ayabe et al., 2004).

Reports were saved and printed from these files to determine a weekly frequency of total physical activity. Inclusion criteria for the accelerometer data included: at least 5 days of the accelerometer being worn for at least 10 hours per day and for 80% of that
time. Once this criterion was reached, average values for steps/day, PAEE, minutes of light exercise, and minutes of moderate to vigorous exercise were calculated for each participant at each time point. At the three month assessment, accelerometer days were also divided into physical activity levels at the intervention and non-intervention days. Descriptive statistics were examined for steps/day, PAEE, LPA and MVPA.

Quality of Life

A few measures were used to capture the different dimensions of quality of life. This thesis included broad measures of quality of life and health status as well as disease-specific measures of health status. The following measurements were included in all three assessments: Satisfaction with Life Scale (SWLS), and Functional Assessment of Cancer Therapy (FACT-G & FACT-B).

The Satisfaction with Life Scale is a short questionnaire aiming to measure an individual’s satisfaction with life as a whole. Composed of 5 items this questionnaire allows the participant to integrate and weigh these domains in whichever way they choose so they can determine what domains in life are the most important. For example “in most ways my life is close to ideal.” Participants are asked to rate the degree to which they agree or disagree with each of the items on a likert scale (1=strongly disagree to 7=strongly agree). Total scores range from 5-35 and higher scores indicate better quality of life (Appendix D).

FACT-G is a 27-item self-report questionnaire that measures quality of life in cancer patients, comprised of four subscales measuring physical well-being, social/family well-being, emotional well-being and functional well-being. Physical well-being
includes questions such as, “I was bothered by side effects of treatment.” Social/family well-being includes questions such as, “I got emotional support from my family.” Emotional well-being includes questions such as, “I was losing hope in the fight against my illness.” Functional well-being includes questions such as, “I was sleeping well.” This questionnaire is a measure of quality of life used for all types of cancer patients. The FACT-B subscale is a breast cancer-specific subscale which gives a more specific quality of life measure for breast cancer patients. The FACT-B subscale includes questions such as, “My arms were swollen or tender.” Both of these measures have established reliability and validity. The FACT scales have the ability to discriminate patients based on their stage of disease, performance status and hospitalization status and are widely used in cancer research. They also demonstrate sensitivity to change over time, meet all the requirements for use in oncology clinical trials which include, ease of administration, brevity, reliability, validity as well as response to clinical change, and they were therefore chosen for this study (Appendix F).

**Procedures**

Following a telephone screening, participants came in for a baseline assessment. Baseline assessments included questionnaires assessing current health history, medications, subjective physical function and activity, self-efficacy, satisfaction with life, social support, fatigue and quality of life. The final part of the visit included physical assessments of height and weight, body mass index, waist circumference, muscular
strength, flexibility, and aerobic endurance. Women were given an accelerometer and asked to wear it for ten days before starting their exercise sessions.

Participants were required to attend exercise sessions three times a week for six months at the Wake Forest University Clinical Research Center, which will later be discussed in more detail. Follow-up testing occurred at three and six months after the start of the intervention using the baseline physical and psychosocial testing battery. All three assessment visits occurred at the Wake Forest University Reynolds Gymnasium.

**Comprehensive Rehabilitation**

The framework for the comprehensive rehabilitation model used for this intervention was based on the comprehensive rehabilitation model that is commonly used in cardiac rehabilitation. This model has been linked with positive cardiac related outcomes and has become the standard of care for patients following cardiac related events. This comprehensive model includes five components: patient assessment, exercise, nutrition counseling, risk factor management, and social support.

**Patient Assessment**

During the baseline assessment, patients performed multiple physical and medical assessments to determine their current level of fitness and health status. Aerobic endurance, muscular strength, and flexibility were all tested. Also included in the assessments were health history, current medications, current risk factors and arm swelling.
Physical Activity Component

Participants came to the Wake Forest University Clinical Research Center three times a week for six months to participate in tailored exercise sessions. Participants could attend either the morning or evening sessions, each lasting approximately one hour. Upon arrival vital signs (blood pressure, heart rate) and change in medical status and symptoms were evaluated. Participants started with a ten minute warm-up of aerobic type exercise and light stretching, followed by endurance aerobic exercise (cycle, walking) in the prescribed rate of perceived exertion of 14 to 16 (moderate to somewhat hard). Walking took place at the 1/13th mile indoor track of the facility where participants recorded their number of laps, minutes walked, and RPE at the end of each exercise session. Participants were instructed to start at a low level and to progress over the 6 months, participants were instructed to complete 30 minutes of walking or cycling. If any of the participants were unable to complete this, an intermittent training approach was used.

Not only did participants complete endurance aerobic exercise, they also engaged in 20 minutes of resistance training utilizing Nautilus strength training machines. The protocol for resistance training was tailored to an individual’s limitations and resistance exercises included: leg press, leg extension, leg curl, overhead press, compound row, incline press, low back extension, abdominal curl, tricep extension, and bicep curl. The initial weight was determined by 50% of their one-repetition max. Once the established weight could be lifted 12 times in proper form on two consecutive sessions, the participant was moved to the next weight level.
Strength training breathing techniques were taught to each participant at the start of the exercise program and reviewed as needed. Participants recorded weight lifted and the number of repetitions completed at each exercise session. Participants were instructed to report any adverse events, symptoms, or problems during the six month intervention. Any inappropriate exercise response and/or symptoms resulted in a termination of the exercise program and were reported to their physician. Exercise could only be recommenced upon clearance from their physician. Any exercise completed at home was recorded with a self-report form including duration, modality, and intensity of exercise.

**Nutritional Component**

During the six month intervention the participants received nutritional counseling and education from the study registered dietitian. The participant completed questionnaires and met with the dietitian twice over the six month period. A nutritional summary was provided for each patient. During the consultation, the dietician discussed caloric needs, vitamin and mineral consumption, as well as administered feedback based on the participant’s current diet and methods to improve it.

**Risk Factor Management Component**

Participants were screened at their baseline assessment for health history, current medications, and breast cancer related health information relating to type of surgery, treatment, and any current complications. Study staff members monitored participants according to their current medications, any diagnosed medical conditions or being at risk
for medical conditions. To effectively monitor health risk factors, study staff members assessed blood pressure at the start of each exercise session, heart rate and rhythm at both rest and exercise, and if needed, glucose. Participants with swelling due to their treatment were required to wear a compression sleeve, obtained from their oncologist, and to report any changes in their symptoms.

Social Support

The exercise sessions during the six month intervention allowed the participants to exercise together giving an opportunity to socialize and rehabilitate with women having undergone a similar experience. Exercise was offered a few hours in the morning and evening, which led to the majority of the participants exercising at the same time. This allowed an exercise environment where the women could share stories and experiences, while giving them the opportunity to support each other. All sessions were overseen by study staff that socialized and supported the women as they exercised and progressed over the course of the six month intervention offering additional social support.

Analytic Plan

The data was first checked for normality. Some variables were skewed therefore log, square root, or rank transformations were used in the analysis. Least squares estimates are based on models performed on the original scales and p-values are based on the transformed data. Descriptive statistics were employed to adequately describe the
population as well as the variables of interest. Repeated measures analysis of variance was used to assess changes over time in physical activity and health related quality of life. A toeplitz covariance structure was used to model the within patient correlations and the outcome measures over time. Spearman correlations were used to quantify the strength of the linear and monotonic associations between quality of life and physical activity.
RESULTS

Participant Characteristics

The final sample of study participants consisted of 21 females (M=52.6 years; SD=7.4) ranging from 33 to 67 years of age. Currently, 21 women have completed the baseline assessment, 14 women have completed the three month assessment, and 11 have completed the six month assessment. Seventy-one percent of the sample was White. Forty-three percent had acquired at least a college degree, and 66% had a household income of over $50,000. The majority of the sample was obese, as categorized by the body mass index scale. The mean BMI was 30.5 (SD=6.7) with 52% of the women having a BMI greater than 30 (obese), 19% had a BMI greater than 25 and less than 30 (overweight), and 29% had a BMI less than 25 (normal weight). Most of the participants worked (62%) with 38% of the participants having full-time jobs and 24% of the participants having part-time jobs. See Table I for participant characteristics.

Cardiovascular Risk Factors

In this sample of women who had been diagnosed and treated for breast cancer, the majority of the participants (90.5%) also had one or more cardiovascular risk factors. Forty-eight percent of the women were diagnosed and being treated for hypertension, and 38% had been diagnosed and treated for hyperlipidemia. This sample also included women with diabetes and a family history of heart disease. Fifty-seven percent of the
sample reported being sedentary at baseline. Table I includes these cardiovascular risk factor characteristics.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
</tr>
<tr>
<td>&lt;50</td>
<td>13 (62%)</td>
</tr>
<tr>
<td>50 to &lt;65</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>65 to &lt;75</td>
<td>7 (33%)</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>15 (71%)</td>
</tr>
<tr>
<td>African American</td>
<td>4 (19%)</td>
</tr>
<tr>
<td>Asian</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>High School Diploma</td>
<td>3 (14%)</td>
</tr>
<tr>
<td>Some College</td>
<td>5 (24%)</td>
</tr>
<tr>
<td>College Graduate</td>
<td>9 (43%)</td>
</tr>
<tr>
<td>Advanced Degree</td>
<td>4 (19%)</td>
</tr>
<tr>
<td>BMI</td>
<td></td>
</tr>
<tr>
<td>Normal (&lt;25)</td>
<td>6 (29%)</td>
</tr>
<tr>
<td>Overweight (25-29.9)</td>
<td>4 (19%)</td>
</tr>
<tr>
<td>Obese (&gt;30)</td>
<td>11 (52%)</td>
</tr>
<tr>
<td>Employment Status</td>
<td></td>
</tr>
<tr>
<td>Full-Time</td>
<td>8 (38%)</td>
</tr>
<tr>
<td>Part-Time</td>
<td>5 (24%)</td>
</tr>
<tr>
<td>Unemployed/Retired</td>
<td>3 (14%)</td>
</tr>
<tr>
<td>Homemaker</td>
<td>3 (14%)</td>
</tr>
<tr>
<td>Disabled/Unable to work</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>Cardiovascular Risk Factors</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>10 (48%)</td>
</tr>
<tr>
<td>High Cholesterol</td>
<td>8 (38%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>3 (14%)</td>
</tr>
<tr>
<td>Family History</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Women &gt;55 and postmenopausal</td>
<td>12 (57%)</td>
</tr>
<tr>
<td>Sedentary</td>
<td>11 (52%)</td>
</tr>
</tbody>
</table>
Disease Characteristics

The sample was made up of women who had been diagnosed and treated for breast cancer. The majority of the participants had been diagnosed with either stage I or II disease, with 38% having stage I and 44% having stage II. The majority (67%) of the women underwent a lumpectomy for their surgical treatment, while 33% had a mastectomy. Thirty-eight percent of the women were given a combination of chemotherapy and radiation following surgery, while 10% were given neoadjuvant chemotherapy, 19% were given adjuvant chemotherapy alone and 29% were given adjuvant radiation alone. Eighty-one percent of the participants were currently taking hormonal therapy (i.e. Tamoxifen) during the intervention. See Table II for disease characteristics at baseline.
Table II: Disease Characteristics (N=21)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stage of Disease</strong></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>8 (38%)</td>
</tr>
<tr>
<td>II</td>
<td>9 (43%)</td>
</tr>
<tr>
<td>III</td>
<td>3 (14%)</td>
</tr>
<tr>
<td>IV</td>
<td>1 (5%)</td>
</tr>
<tr>
<td><strong>Type of Surgery</strong></td>
<td></td>
</tr>
<tr>
<td>Lumpectomy</td>
<td>14 (67%)</td>
</tr>
<tr>
<td>Mastectomy</td>
<td>7 (33%)</td>
</tr>
<tr>
<td><strong>Neoadjuvant Therapy</strong></td>
<td></td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>2 (10%)</td>
</tr>
<tr>
<td><strong>Adjuvant Therapy</strong></td>
<td></td>
</tr>
<tr>
<td>Chemotherapy Alone</td>
<td>4 (19%)</td>
</tr>
<tr>
<td>Radiation Alone</td>
<td>6 (29%)</td>
</tr>
<tr>
<td>Chemotherapy + Radiation</td>
<td>8 (38%)</td>
</tr>
<tr>
<td>Hormone Therapy</td>
<td>17 (81%)</td>
</tr>
</tbody>
</table>

Adherence

On average, women attended 72.6% of the exercise sessions. Thus far, 11 women have completed the intervention which resulted in 599 out of 825 sessions being attended. The most common reason for missing an exercise session was being on vacation or out of town (32%). See Figures 1 & 2 for percentages of missed exercise sessions and individual participant attendance.
Figure 1. Reasons for Missed Exercise Sessions

Figure 2. Individual Participant Session Attendance
Physical Activity

In order to examine physical activity levels in these participants at baseline, 3 and 6 months, each participant was asked to complete the Godin Physical Activity Questionnaire (PAQ) and wore a Lifecorder accelerometer for ten days at each time period. At baseline women were fairly inactive as they did not meet the general guidelines for 150 minutes of moderate physical activity per week, with a mean of 38.7 (SD=82.3) minutes of moderate physical activity per week according to the PAQ measure. In contrast, data from the accelerometers shows that participants were meeting the minimum weekly recommendations with an average of 23.91 (SD=11.62) minutes of moderate to vigorous physical activity per day (167 minutes per week). Although minutes of moderate exercise was higher than anticipated, women were not meeting the suggested 10,000 steps per day with an average of 6362.8 (SD=2444.3) steps per day at baseline. See Table III for physical activity values at the three time points.

We examined the overall change in physical activity across the 6 month intervention as measured by the PAQ and the accelerometer. Repeated Measures ANOVA models were used to assess the change from baseline to six months in each of these measures. PAQ is divided into minutes per week spent doing mild, moderate, and strenuous exercise. Few women reported doing strenuous exercise and so there were no analyses with strenuous physical activity only. Results showed no significant change (p = 0.44) in the minutes of mild exercise per week over the course of the program. Results showed there was a significant change in moderate exercise (p <0.0001) over the six month period, specifically an increase from baseline to three months (p <0.0001) and
baseline to six months (p <0.0001). There was not however a significant change from three to six months (p = 0.28). See Figure 3 for changes in physical activity per week.

A Repeated Measures ANOVA was used for the accelerometer data which was divided into: calories expended during physical activity (PAEE), steps per day, minutes of light exercise (LPA) and minutes of moderate to vigorous intensity exercise (MVPA). Similar to moderate exercise from the PAQ, there was an overall significant increase in PAEE (p = 0.0097), specifically from baseline to three months (p = 0.046). There was also an overall significant increase in MVPA per day (p = 0.021) with a significant increase from baseline to three months of approximately ten minutes per day (p = 0.016). Results showed a borderline significant change in LPA per day (p = 0.061). Results found no overall change in steps per day (p = 0.16) throughout the six month intervention. See Figures 4 & 5 for changes in PAEE, LPA, MVPA, and Steps/day.

Finally, descriptive statistics were used to examine physical activity levels on intervention days versus non-intervention days at the three month assessment. Women had lower levels of physical activity on non-intervention days according to each measure collected from the accelerometer. Most importantly, women did on average 55.23 minutes per day of MVPA on intervention days compared to 23.19 minutes per day on non-intervention days. See Table IV for PA values on intervention vs. non-intervention days at three months.
Table III. Physical Activity Levels at Baseline, Three and Six Months

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Accelerometer (N = 16)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td><strong>Mean</strong></td>
<td><strong>Median</strong></td>
<td><strong>Min</strong></td>
</tr>
<tr>
<td><strong>Baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAQ (N = 21)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAQ Mild (min/week)</td>
<td></td>
<td>57.25 ± 96.79</td>
<td>90</td>
<td>0</td>
</tr>
<tr>
<td>PAQ Moderate (min/week)</td>
<td></td>
<td>38.75 ± 82.3</td>
<td>200</td>
<td>0</td>
</tr>
<tr>
<td>PAQ Strenuous (min/week)</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Steps/day</td>
<td></td>
<td>6362.8 ± 2444.3</td>
<td>6805.6</td>
<td>2163</td>
</tr>
<tr>
<td>PAEE (kcal)</td>
<td></td>
<td>206.9 ± 77.3</td>
<td>216.55</td>
<td>77.2</td>
</tr>
<tr>
<td>LPA (min/day)</td>
<td></td>
<td>44.37 ± 15.24</td>
<td>45.79</td>
<td>18.58</td>
</tr>
<tr>
<td>MVPA (min/day)</td>
<td></td>
<td>23.91 ± 11.62</td>
<td>23.96</td>
<td>2.98</td>
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</table>

<table>
<thead>
<tr>
<th></th>
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<th>Accelerometer (N = 9)</th>
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<tr>
<td></td>
<td></td>
<td><strong>Mean</strong></td>
<td><strong>Median</strong></td>
<td><strong>Min</strong></td>
</tr>
<tr>
<td><strong>3 Months</strong></td>
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<td></td>
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</tr>
<tr>
<td>PAQ (N = 15)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAQ Mild (min/week)</td>
<td></td>
<td>107.33 ± 117.27</td>
<td>90</td>
<td>0</td>
</tr>
<tr>
<td>PAQ Moderate (min/week)</td>
<td></td>
<td>222.33 ± 59.36</td>
<td>200</td>
<td>135</td>
</tr>
<tr>
<td>PAQ Strenuous (min/week)</td>
<td></td>
<td>4 ± 15.49</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Steps/day</td>
<td></td>
<td>7334.2 ± 2218.3</td>
<td>7003</td>
<td>4360.1</td>
</tr>
<tr>
<td>PAEE (kcal)</td>
<td></td>
<td>265 ± 90.38</td>
<td>233</td>
<td>155.5</td>
</tr>
<tr>
<td>LPA (min/day)</td>
<td></td>
<td>41.76 ± 11.34</td>
<td>41.24</td>
<td>24.28</td>
</tr>
<tr>
<td>MVPA (min/day)</td>
<td></td>
<td>34.08 ± 11.85</td>
<td>32.4</td>
<td>14.94</td>
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<td><strong>Median</strong></td>
<td><strong>Min</strong></td>
</tr>
<tr>
<td><strong>6 Months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAQ (N = 11)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAQ Mild (min/week)</td>
<td></td>
<td>108.75 ± 194.65</td>
<td>35</td>
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<tr>
<td>PAQ Moderate (min/week)</td>
<td></td>
<td>174.16 ± 112.12</td>
<td>165</td>
<td>0</td>
</tr>
<tr>
<td>PAQ Strenuous (min/week)</td>
<td></td>
<td>5 ± 17.32</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Steps/day</td>
<td></td>
<td>6475.7 ± 1635.8</td>
<td>6284</td>
<td>4734</td>
</tr>
<tr>
<td>PAEE (kcal)</td>
<td></td>
<td>220.07 ± 39.43</td>
<td>220.7</td>
<td>168.2</td>
</tr>
<tr>
<td>LPA (min/day)</td>
<td></td>
<td>40.97 ± 12.69</td>
<td>35.86</td>
<td>29.34</td>
</tr>
<tr>
<td>MVPA (min/day)</td>
<td></td>
<td>27.88 ± 6.38</td>
<td>26.89</td>
<td>16.65</td>
</tr>
</tbody>
</table>
Figure 3. Minutes of Physical Activity Per Week

Figure 4. PAEE (kcal), LPA, and MVPA Per Day
Table IV. Average PA at Three Months on Intervention Days vs Non-Intervention Days

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th></th>
<th>Non-intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>St. Dev</td>
<td>Min, Max</td>
</tr>
<tr>
<td>PAEE</td>
<td>386.59</td>
<td>163.57</td>
<td>100, 770</td>
</tr>
<tr>
<td>Steps/day</td>
<td>10152.69</td>
<td>4161.3</td>
<td>2590, 19622</td>
</tr>
<tr>
<td>LPA</td>
<td>44.19</td>
<td>16.31</td>
<td>17, 75</td>
</tr>
<tr>
<td>MVPA</td>
<td>55.23</td>
<td>28.26</td>
<td>1, 112</td>
</tr>
</tbody>
</table>

Quality of Life

Quality of Life was examined at baseline, 3 and 6 months by administering the following measures: Satisfaction With Life Scale (SWLS) and the Functional Assessment of Cancer Therapy (FACT-G & FACT-B). Looking at baseline values for the three QOL measures varied relative to standard scores. First, FACT-G was higher than usual in
breast cancer survivors (79.57, SD=17.07) compared to previously reported values of
(70.6, SD=16.59) (Velikova et al., 2004). FACT-B was standard for breast cancer
survivors with a mean score of 101.95 (SD=23.1) compared to previously reported values
of 104.9 (SD=19.9) (Danhauer et al., 2009). Finally, SWLS was significantly lower than
normal values with a mean score of 16.52 (SD=7.72) which classifies this sample as
slightly dissatisfied, with normal values usually ranging from 23-28 (Pavot & Diener,
1993). See Table V for baseline, three and six month QOL values.

We examined the overall change in quality of life for the SWLS, FACT-G and
FACT-B. Repeated Measures ANOVA models were used to assess the change from
baseline to six months in each of these measures. Results showed no overall significant
increase in SWLS (p = 0.14), however, there was a borderline significant increase from
baseline to six months (p = 0.056). In addition there was a significant increase in both
FACT-G (p = 0.032) and FACT-B (p = 0.031). The largest increase in both of the
measures occurred from baseline to three months (FACT-G, p = 0.012; FACT-B, p =
0.011). Based on the results from these two measures QOL increased at three months
and remained stable through the six month assessment. Finally, by examining each
individual subscale from the FACT-G, it is important to note that results revealed a
significant increase in only the functional subscale (p = 0.021), and not the social (p =
0.33), emotional (p = 0.31), or physical (p = 0.12) subscales. See Figure 6 for changes in
QOL measures.
Table V. Baseline, Three and Six Month QOL Values

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N = 21)</td>
<td>Mean</td>
<td>Median</td>
<td>Min</td>
<td>Max</td>
</tr>
<tr>
<td>SWLS</td>
<td></td>
<td>16.52 ± 7.72</td>
<td>14</td>
<td>5</td>
<td>30</td>
</tr>
<tr>
<td>FACT-G</td>
<td></td>
<td>79.57 ± 17.07</td>
<td>82</td>
<td>41</td>
<td>108</td>
</tr>
<tr>
<td>FACT-B</td>
<td></td>
<td>101.95 ± 23.1</td>
<td>108</td>
<td>49</td>
<td>135</td>
</tr>
<tr>
<td>Physical</td>
<td></td>
<td>21.57 ± 5.29</td>
<td>23</td>
<td>6</td>
<td>28</td>
</tr>
<tr>
<td>Social</td>
<td></td>
<td>20.95 ± 5.29</td>
<td>22.17</td>
<td>8</td>
<td>28</td>
</tr>
<tr>
<td>Emotional</td>
<td></td>
<td>18.9 ± 4.71</td>
<td>20</td>
<td>8</td>
<td>24</td>
</tr>
<tr>
<td>Functional</td>
<td></td>
<td>18.14 ± 12.55</td>
<td>19</td>
<td>8</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>3 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(N = 15)</td>
<td>Mean</td>
<td>Median</td>
<td>Min</td>
<td>Max</td>
</tr>
<tr>
<td>SWLS</td>
<td></td>
<td>17.5 ± 8.62</td>
<td>21</td>
<td>5</td>
<td>28</td>
</tr>
<tr>
<td>FACT-G</td>
<td></td>
<td>82.64 ± 15.02</td>
<td>86.5</td>
<td>46</td>
<td>102</td>
</tr>
<tr>
<td>FACT-B</td>
<td></td>
<td>106.49 ± 21.8</td>
<td>113</td>
<td>53</td>
<td>134.58</td>
</tr>
<tr>
<td>Physical</td>
<td></td>
<td>22.87 ± 3.14</td>
<td>23</td>
<td>15</td>
<td>26</td>
</tr>
<tr>
<td>Social</td>
<td></td>
<td>21.04 ± 6.42</td>
<td>22.17</td>
<td>5</td>
<td>27</td>
</tr>
<tr>
<td>Emotional</td>
<td></td>
<td>19.13 ± 4.32</td>
<td>21</td>
<td>9</td>
<td>23</td>
</tr>
<tr>
<td>Functional</td>
<td></td>
<td>19.6 ± 4.56</td>
<td>20</td>
<td>11</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>6 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(N = 11)</td>
<td>Mean</td>
<td>Median</td>
<td>Min</td>
<td>Max</td>
</tr>
<tr>
<td>SWLS</td>
<td></td>
<td>18.73 ± 7.62</td>
<td>20</td>
<td>5</td>
<td>29</td>
</tr>
<tr>
<td>FACT-G</td>
<td></td>
<td>80.94 ± 16.59</td>
<td>84</td>
<td>49.83</td>
<td>108</td>
</tr>
<tr>
<td>FACT-B</td>
<td></td>
<td>105.01 ± 22.8</td>
<td>111.75</td>
<td>60.83</td>
<td>143</td>
</tr>
<tr>
<td>Physical</td>
<td></td>
<td>22.91 ± 4.44</td>
<td>24</td>
<td>15</td>
<td>28</td>
</tr>
<tr>
<td>Social</td>
<td></td>
<td>19.21 ± 7.12</td>
<td>21</td>
<td>5.58</td>
<td>28</td>
</tr>
<tr>
<td>Emotional</td>
<td></td>
<td>20.09 ± 3.3</td>
<td>21</td>
<td>14</td>
<td>24</td>
</tr>
<tr>
<td>Functional</td>
<td></td>
<td>18.73 ± 5.35</td>
<td>18</td>
<td>8</td>
<td>28</td>
</tr>
</tbody>
</table>
Figure 6. Changes in Quality of Life Measures

In order to examine the relationship between physical activity and quality of life we used the PAQ, Lifecorder accelerometer, FACT-G, FACT-B, and SWLS measures. With so few participants completing the 6 month assessment and only data from the accelerometers for 6 participants, only baseline data was used for this analysis. Due to the skewed numbers for the PAQ data, log and square root transformations were used. Therefore, a Spearman Correlation was used to establish the correlation between these variables at baseline. Results showed a significant (p = 0.042) moderate correlation between accelerometer derived MVPA and the FACT-G (r = 0.51). There was also a significant (p = 0.01) moderate correlation between accelerometer derived MVPA and the
functional subscale \((r = 0.59)\). There was a borderline significant \((p = 0.067)\) correlation between accelerometer derived MVPA and SWLS \((r = 0.46)\). Finally, there was a significant moderate correlation \((p = 0.054)\) between accelerometer derived PAEE and the functional subscale \((r = 0.48)\). See Table VI for PA & QOL correlations at baseline.

Finally, to examine the relationship between our two physical activity correlations we also used a Spearman Correlation to examine the relationship between PAQ mild, PAQ moderate, PAEE, steps/day, LPA, and MVPA. There was a significant \((p = 0.035)\) moderate correlation between PAQ mild and MVPA \((r = 0.52)\) and a borderline significant \((p = 0.10)\) moderate correlation between PAQ mild and steps/day \((r = 0.41)\).

Table VI. PA & QOL Correlations at Baseline

<table>
<thead>
<tr>
<th></th>
<th>SWLS</th>
<th>FACT-G</th>
<th>FACT-B</th>
<th>Functional subscale</th>
<th>PAQ Mild</th>
<th>PAQ Moderate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PAQ Mild</strong></td>
<td>0.09</td>
<td>0.11</td>
<td>0.13</td>
<td>0.17</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>PAQ Moderate</strong></td>
<td>-0.27</td>
<td>0.12</td>
<td>0.19</td>
<td>0.16</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>LPA</strong></td>
<td>0.34</td>
<td>0.08</td>
<td>-0.14</td>
<td>0.15</td>
<td>0.16</td>
<td>-0.19</td>
</tr>
<tr>
<td><strong>MVPA</strong></td>
<td>0.46**</td>
<td>0.51*</td>
<td>0.17</td>
<td><strong>0.59</strong></td>
<td><strong>0.52</strong></td>
<td>-0.035</td>
</tr>
<tr>
<td><strong>PAEE (kcal)</strong></td>
<td>0.36</td>
<td>0.31</td>
<td>-0.08</td>
<td><strong>0.48</strong></td>
<td>0.31</td>
<td>-0.02</td>
</tr>
<tr>
<td><strong>Steps/day</strong></td>
<td><strong>0.42</strong></td>
<td>0.31</td>
<td>0</td>
<td>0.41</td>
<td><strong>0.41</strong></td>
<td>-0.12</td>
</tr>
</tbody>
</table>

* \(p < 0.05\)
** \(p < 0.10\)

Safety

None of the participants have experienced adverse events that were linked to program participation. This shows that physical activity interventions are safe in the breast cancer population. It is important to note that women had their vitals (blood pressure and heart rate) taken when they arrived at each exercise session. It was observed
that many of the women had very high resting heart rates (100-130 BPM) which should be kept in mind and further examined. Although these women had high resting heart rates, high blood pressure was only observed in women who were hypertensive.
DISCUSSION

According to the American Cancer Society it is estimated that in 2010 nearly 1 in 8 women were diagnosed with breast cancer. Due to earlier detection as well as more advanced technology, death rates have been on the decline and this has resulted in approximately 2.6 million survivors in the United States. Following diagnosis and treatment, survivors have reported a significant decline in their quality of life (James et al., 2011). Due to this common side-effect, multiple interventions have been tested to examine ways to increase quality of life among this population.

Research has shown that an effective way to enhance quality of life in breast cancer survivors is with physical activity (Adamsen et al., 2005; Cadmus et al., 2009; Campbell et al., 2005; Courneya et al., 2003; Courneya, Segal, et al., 2007; Cheema et al., 2006; Faul et al., 2011; Haas, 2011; Hayes et al., 2011; Jones et al., 2010; Kim et al., 2011; Kolden et al., 2002; Mutrie et al., 2007; Noble et al., 2011; Turner et al., 2004). The majority of these studies found significant improvements in quality of life, however, these studies ranged in length of intervention, exercise type, measurement of quality of life and timing following treatment (Adamsen et al., 2005; Cheema et al., 2006; Jones et al., 2010; Kim et al., 2011; Kolden et al., 2002; Noble et al., 2011; Turner et al., 2004). Although data reflects that exercise positively affects quality of life in breast cancer survivors, research has also shown a significant decline in physical activity following diagnosis and treatment (Devoogdt et al., 2010; Irwin et al., 2003; Littman, Tang, & Rossing, 2010). To date there have been no studies using a comprehensive rehabilitation program to enhance physical activity and quality of life.
This study investigated the impact of a six month comprehensive rehabilitation program on physical activity and quality of life immediately following breast cancer treatment. This multi-component program included: exercise, nutrition counseling, patient assessments, risk factor management, and social support. The results gathered from this program will reveal if this study has added to the body of literature supporting evidence that a comprehensive rehabilitation program helps enhance quality of life in breast cancer survivors.

**Physical Activity**

Session adherence was similar to previously reported values in physical activity intervention feasibility studies conducted in this population at 72.6% (Campbell et al., 2005 & Kolden et al., 2002). Individual participation ranged from 50-95% session attendance, which could have impacted physical activity participation. It is important to note that women completed higher levels of physical activity on intervention days than non-intervention days. Therefore, women who did not attend the majority of the sessions could have negatively skewed our findings of physical activity levels at three months.

It was hypothesized that this six-month comprehensive rehabilitation program would increase physical activity in breast cancer survivors who had completed chemotherapy, radiation and/or surgery within three months prior to the start of the intervention. Results showed a significant increase in moderate exercise over six months, as well as in MVPA in the first three months of the program.
As reflected by the PAQ and the accelerometer data this intervention did in fact enhance physical activity. The observed increase is similar to results found in previous studies where women increased their levels of physical activity during an exercise intervention. Schwartz (2000) recruited 31 women who had recently been diagnosed with breast cancer to participate in an 8-week home based exercise study, by the end of the program women exercised on average 35 minutes, 4 days/week. Pinto et al. (2005) recruited 86 sedentary women for a 12 week physical activity counseling study. Women in the physical activity group were more likely to participate in moderate-intensity PA for at least 5 days of the week compared to the control (p = 0.001).

It is important to note that the self-report measure used in this study, PAQ, had different baseline measures but similar changes to the objective measure, accelerometers. It is interesting that at baseline women self-reported lower levels of physical activity than they actually were doing according to the accelerometer data. It is important to discuss each of these measures to understand the different findings. The PAQ asks women to think about an average week and report how often they do mild, moderate, and strenuous exercise and the duration of these sessions. Leisure time physical activity is all that can be reported, no occupational physical activity. The Lifecorder-EX records light, moderate, and vigorous exercise that is done while the accelerometer is worn, as well as steps/day and PAEE based on the individuals height and weight which is entered before the device is worn. The accelerometer must be worn for at least 10 hours (for 80% of the time) to give an accurate measure of physical activity, and for at least 5 days. The PAQ measure only takes into account leisure time physical activity, while the accelerometer records both leisure time and occupational physical activity. The correlations between
these two measures were also examined. While PAQ mild was somewhat correlated with steps/day and MVPA, these two measures are not capturing the same information. Therefore, self-report and objective measures are both important to get a complete view of physical activity habits.

**Quality of Life**

It was hypothesized that this program would enhance quality of life in breast cancer survivors. Results showed a borderline significant increase from baseline to six months in SWLS ($p = 0.056$). This could be due to numerous factors. Looking at baseline numbers alone, there was wide variability (age, stage of disease, etc) among the 21 participants. This study had a small sample size and fewer participants had completed all three assessments which impacts statistical significance. Notwithstanding, results showed that there were significant improvements in the FACT-G ($p = 0.01$) and FACT-B ($p = 0.01$) measures, which indicates a significant increase in both the cancer specific and breast cancer specific quality of life assessments. Both measures had an increase from baseline to three months that was maintained from three to six months. This has been observed in other studies that implemented exercise interventions following breast cancer treatment (Adamsen et al., 2005; Cheema et al., 2006; Jones et al., 2010; Kim et al., 2011; Kolden et al., 2002; Noble et al., 2011; Turner et al., 2004).

Campbell et al. (2005) had similar findings in their 12 week aerobic pilot study, with a small increase in SWLS in the intervention group ($p = 0.31$) and a significant increase in the FACT-G measure ($p = 0.046$). Kolden et al. (2002) had similar results in
their 16 week exercise program comprised of aerobic, strength and flexibility exercises. Results showed a significant increase in FACT-G (p < 0.05) and functional well-being (p < 0.05) similar to the current findings. Courneya et al. (2003) also observed significant improvements in the FACT-G measure (p = 0.001) following a 15 week cycling program. Therefore, this study had similar findings to the previous body of literature on exercise interventions to enhance disease specific QOL in breast cancer survivors.

It is possible that women experienced the greatest increase in QOL within the first three months as they started the intervention so soon after completion of treatment. Having a bigger increase in the disease specific measures of QOL is not surprising, as these are more sensitive to this population as they have many health related QOL disturbances due to their diagnosis and treatment. Women were in the study immediately following treatment and participated over the course of 6 months. This longer program may have more greatly impacted the disease specific measures as they got farther into their survivorship phase. Although other studies have not identified a significant increase in SWLS, this study identified a borderline significant increase over the 6 month period. It is possible that there was more of a change in SWLS because of the length of the program and the comprehensive rehabilitation model used. Previous studies have used exercise only, while this study also incorporated patient assessment, nutrition counseling, risk factor management and social support. This approach helps modify not only physical activity habits, but also reinforces healthy lifestyle choices and support from study staff. It is possible that a 6 month comprehensive rehabilitation approach has more of a beneficial impact on overall QOL than exercise alone as an intervention.
Relationship between Physical Activity and Quality of Life

It was hypothesized that there would be a relationship between physical activity and quality of life. Results showed there was a significant moderate correlation between moderate-vigorous intensity physical activity and both the FACT-G ($r = 0.51$) and functional subscale ($r = 0.59$) at baseline. PAQ data at baseline showed that the women were inactive, not meeting the general physical activity requirements, while the accelerometer data at baseline showed the women were just meeting the weekly requirements. Both the FACT-G and FACT-B measures in this study were similar to other breast cancer samples in previous literature, but SWLS was lower than usual as “slightly dissatisfied.” Physical activity and quality of life was moderately correlated at baseline in this study, women that had higher levels of moderate-vigorous intensity physical activity also reported higher QOL scores. There was not enough data to examine the correlation at later time points. To the best of our knowledge no previous studies have examined the correlations between physical activity and QOL, so these are new findings and should be explored in the future. Future studies also need to examine the relationship between the change in physical activity and change in QOL over time.

Limitations and Future Directions

Physical activity increased significantly over the first three months, then remained stable. Quality of Life followed the same trend with an increase in the first three months, then no further change at six months. The sample was comprised of women ranging in
age from their early 30’s to late 60’s, being predominantly White but differing in levels of education completed, and having been diagnosed with stage I through stage IV breast cancer. Taking into account that there were only 21 women in the study at the time of this thesis, other than race, the sample is fairly diverse which will make these results more generalizable. However, there are multiple limitations to this study that should be noted and recommendations for future rehabilitation studies.

Clearly the main limitation to this study was the small sample size. The reason for the limited number of participants can be attributed to a multitude of different factors. Because this is a pilot study, recruitment only took place at one cancer treatment center (WFUBMC) which resulted in having a limited number of patients diagnosed and treated for breast cancer at this location and a limited number of patients that lived within driving distance of the intervention site. Because of these factors, the recruitment rate was slow, and future research may need to focus on recruitment from multiple cancer centers. At the time of this thesis, 21 women had been enrolled in the study; however, only 14 women had completed the three month assessment and only 11 had completed the six month assessment. With so few women having completed the study at this time, statistical significance for examining change over time was limited.

Recruitment for this pilot study may also have been limited due to the fact that there was no study staff member specifically assigned to accomplish the recruitment. The participants were initially recruited by oncologists, physician’s assistants, and a research nurse who were given information regarding the study’s objectives and requirements. It is possible that this recruiting team failed to recruit some of the women
that were eligible and receiving treatment. Future research should consider having an actual study staff member in charge of all participant recruitment.

Another limitation of the study was the exercise session availability. Participants were required to exercise at the Wake Forest University Clinical Research Center (CRC) three times per week for the entire six month intervention. The exercise session availability times were very limited, causing many women who were initially interested in the study to decline due to work or family obligations that interfered with these exercise times. Future research should provide more hours for women to attend the exercise sessions to further enhance recruitment.

Finally, the measures included in this pilot study have some limitations. As previously mentioned the Godin Physical Activity Questionnaire, a measure of physical activity, is subjective. Although the PAQ provides valuable information about PA habits, it is important to have an objective measure of physical activity. Using this complimentary approach, women were also required to wear an accelerometer for 10 days at all three time points. It is important to note that accelerometer data could only be used if the women had at least five days that met the inclusion criteria. Unfortunately, there were many missing values as three participants failed to meet the criteria for five days. In fact, data for only 16 participants was available at baseline which could also impact statistical significance. This study highlights the importance of using both subjective and objective measures of physical activity to gather a complete picture of the participant’s physical activity habits.
In light of these limitations, there were no serious adverse events observed in this study which is notable given the condition of the women and levels of physical activity. None of the women had to be stopped in the 20 months of the study; however, some of the women had very high heart rates (100-130 BPM) at rest, which needs to be considered and further examined.

Similar to other pilot studies, this pilot study employed a non-randomized, single group design. Without having a comparison group, it is impossible to imply that any statistically significant results are caused by the intervention. In order to enhance the breast cancer comprehensive rehabilitation literature, future randomized control trials are needed, as well as a complete analysis of all 25 women once they have been recruited and have completed the study.

**Implications**

With an increasing number of breast cancer survivors in the United States each year, it has become evident that this chronic disease will require more survivorship research. The treatments for breast cancer cause extremely debilitating side-effects that affect physical function and QOL. Without research on how to reduce these negative side effects, adequate survivorship programs will not exist. To our knowledge, this pilot study is the first to implement a comprehensive rehabilitation model in the breast cancer population immediately following treatment for breast cancer. Hopefully, this study will provide evidence of the beneficial impacts of breast cancer rehabilitation, as well as guidelines for future studies.
Although limited, this data should be used to fuel the research in cancer rehabilitation. There is a growing number of cancer survivors in the United States, and research is needed to provide support for the implementation of these programs. Future research needs to focus on the most common and severe side-effects of breast cancer treatments, including decreased physical activity and quality of life. Although physical activity research has been found to help decrease side-effects in this population, physical activity rates in breast cancer survivors are disappointingly low.

The most beneficial exercise prescription for breast cancer survivors is still unclear. Future research studies should focus on finding the most effective physical activity recommendations for breast cancer survivors. Not only are physical activity recommendations important relative to exercise prescription, but the best timing and necessary components of these programs are as well. More research should focus on exercise programs immediately following treatment that employ a comprehensive rehabilitation approach to help enhance physical activity and quality of life and to ultimately “restore or bring the person back to a condition of good health” (Courneya & Friedenreich, 2001).
APPENDIX A
Informed Consent

A PILOT STUDY TO EVALUATE THE FEASIBILITY OF A BREAST CANCER REHABILITATION PROGRAM IN SURVIVORS OF BREAST CANCER

Informed Consent Form to Participate in Research
Mara Z. Vitolins, DrPH, MPH, RD, Principal Investigator

INTRODUCTION
You are invited to be in a research study. You are being asked to take part in this study because you have just completed chemotherapy and/or radiation therapy for breast cancer. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?
The purpose of this research study is to see how easy it is for women like you who have completed breast cancer therapy to participate in a breast cancer rehabilitation program (BCRP). We also hope to see how useful the different parts of this program will be. We will use the results of this study to help us plan a bigger study in the future.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
There will be 25 women taking part in this study which will take place at WFUBMC and Forsyth Medical Center (FMC). Approximately 15 participants will be enrolled at WFUBMC and 10 participants at FMC.

WHAT IS INVOLVED IN THE STUDY?
If you take part in this study you will need to come to three (3) 1-hour rehab/exercise sessions each week for 6 months. Each session will include up to 30 minutes of endurance type exercise (cycle, walking) and approximately 20 minutes of resistance training exercise. Your exercise program will be tailored to meet your individual needs and abilities.

In addition to your participation in these BCRP sessions, we will also collect some data about your health and quality of life at various times throughout the study. Specifically, we will collect your weight, height, waist circumference and blood pressure, as well as other health
information such as your medical history, medications you take, your physical function, etc. We will also have you complete some questionnaires about your symptoms, your recovery and how you are feeling. We will collect all these data when you begin the study, and again after 3 months and at the end of the study at 6 months.

We would also like to find out if participating in the rehabilitation program can improve the function of your heart. To examine your heart, we will use a medical test called Magnetic Resonance Imaging (MRI). An MRI is a procedure in which a magnet linked to a computer is used to create detailed pictures of areas inside the body. This test does not expose you to ionizing radiation (X-rays), and it will not hurt. This test will take about 15 minutes to complete. You will lay down on your back and the machine will take the images of your heart as you lie on your back. As the scanner takes pictures of your heart, it makes “knocking” sounds and this is normal. During the study, you will be asked to hold your breath for periods of 10 seconds. A technologist will speak to you throughout the test and answer any questions you might have. MRI scanning is not associated with any known side effects.

**HOW LONG WILL I BE IN THE STUDY?**
You will be in the study for about 6 months. You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

**WHAT ARE THE RISKS OF THE STUDY?**
Being in this study involves some risk to you that come with becoming more physically active. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the BCRP:

As with any physical activity, there is a risk of shortness of breath, dizziness, increased heart rate and complications that may arise as a result of these symptoms. A slow, gradual warm-up will be completed to minimize these risks. You will be instructed to stop testing should they experience any symptoms. An emergency plan of action has been established to deal with such complications. There is also a risk of muscle soreness, strain, sprain, or bodily injury as a result of completing an activity if you are not accustomed to or as a result of tripping and falling while walking. To minimize the risk of falling, the floor will be free of debris and distractions will be minimized. The warm-up and stretching period prior to the test will be completed to reduce the risk of muscle soreness and strain.

As with traditional CR programs, this intervention will involve an extremely slow and safe progression from the baseline ability level of each individual to the level necessary for safe return to normal daily activity. Each exercise plan will be individualized to allow participants to progress at their own pace, depending on level of function. Strength and range of motion will be a major focus, in addition to walking, due to the physical issues surrounding breast cancer treatment. If you had an axillary node dissection you will be assessed for lymphedema and your program will be modified accordingly and all upper body strength or range of motion activity will be slow and controlled and at no point will maximum effort be encouraged or supported. The exercise prescriptions and activities will be specifically tailored to women with breast cancer and aimed toward injury prevention.
There is risk, although minimal, involved in obtaining study measurements. It is possible that a participant may pull a muscle while extending a limb or reaching, or the subject may experience a joint injury if these movements are performed improperly. However, in past studies, the flexibility and range of motion tests were taken at three different time points in women of this age group previously diagnosed with breast cancer (2-26 months post-surgery), and no adverse events occurred in the 100+ tests that were conducted.

There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

MRI scans are not associated with any known side effects. Some subjects experience discomfort associated with enclosed spaces during MRI scanning. You should discuss the risk of being in this study with the study staff. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

**Are There Benefits to Taking Part in the Study?**

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The physical activity you do as part of the BCRP has the potential to improve your health and your body strength. Through consultations with a Registered Dietitian, you will receive information and recommendations regarding your daily dietary intake and nutritional status. You will obtain information regarding your daily activity level as well as information regarding your body composition (height, weight, and waist circumference). We also hope that your participation in the BCRP will help you recover and feel better after your breast cancer treatment.

**WHAT OTHER CHOICES ARE THERE?**

This is not a treatment study. Your alternative is to not participate in this study.

**WHAT ABOUT THE USE, DISCLOSURE AND CONFIDENTIALITY OF HEALTH INFORMATION?**

By taking part in this research study, your personal health information, as well as information that directly identifies you, may be used and disclosed. Information that identifies you includes, but is not limited to, such things as your name, address, telephone number, and date of birth. Your personal health information includes all information about you which is collected or created during the study for research purposes. It also includes your personal health information that is related to this study and that is maintained in your medical records at this institution and at other places such as other hospitals and clinics where you may have received medical care. Examples of your personal health information include your health history, your family health history, how you respond to study activities or procedures, laboratory
and other test results, medical images, photographs/videotapes/audiotapes and information from study visits, phone calls, surveys, and physical examinations.

Your personal health information and information that identifies you (“your health information”) may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; Forsyth Medical Center; Forsyth Medical Center Institutional Review Board; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If this research study involves the treatment or diagnosis of a medical condition, then information collected or created as part of the study may be placed in your medical record and discussed with individuals caring for you who are not part of the study. This will help in providing you with appropriate medical care. In addition, all or part of your research related health information may be used or disclosed for treatment, payment, or healthcare operations purposes related to providing you with medical care.

When you sign this consent and authorization form you authorize or give permission for the use of your health information as described in the consent form. You can revoke or take away your authorization to use and disclose your health information at any time. You do this by sending a written notice to the investigator in charge of the study at the following address:

Mara Z. Vitolins, DrPH, MPH, RD Forsyth Medical Center
Public Health Sciences Institutional Review Board
Wake Forest University School of Medicine Forsyth Medical Center
Winston Salem, NC 27157 Institutional Review Board
3333 Silas Creek Parkway, Box 48 Winston- Salem, NC 27103

If you withdraw your authorization you will not be able to be in this study. If you withdraw your authorization, no new health information that identifies you will be gathered after that date. Your health information that has already been gathered may still be used and disclosed to others. This would be done if it were necessary for the research to be reliable. You will not have access to your health information that is included in the research study records until the end of the study.
This authorization is valid for six years or five years after the completion of the study, whichever is longer.

**WHAT ARE THE COSTS?**
There are no costs to you for taking part in this study. All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

**WILL YOU BE PAID FOR PARTICIPATING?**
You will receive no payment or other compensation for taking part in this study.

**WHO IS SPONSORING THIS STUDY?**
The study is being sponsored by Wake Forest University Health Sciences.

**WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?**
Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because you get too sick or your doctor feels it is inappropriate for you to continue in the BCRP, or because the entire study has been stopped. You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

**Whom Do I Call if I Have Questions or Problems?**
For questions about the study or in the event of a research-related injury, contact the study investigator, Mara Vitolins at 336-716-2886.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the WFUHS IRB at (336) 716-4542 or the FMC IRB at (336) 718-5964.

You will be given a signed copy of this consent form.

**SIGNATURES**

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I
am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

____________________________
Subject Name (Printed)

____________________________  ______________________
Subject Signature              Date

____________________________  ______________________
Person Obtaining Consent       Date
APPENDIX A

CCCWFU # 99309 PROTOCOL REGISTRATION FORM

A Pilot Study to Evaluate the Feasibility of a Breast Cancer Rehabilitation Program in Survivors of Breast Cancer PI – Mara Vitolins; Shannon Mihalko

DEMOGRAPHICS

NAME (last, first): ____________________, ____________________

PID #: ______________________________

UNIT #: ______________________________

ZIPCODE: _____________________________

SEX: _____MALE _____FEMALE

ETHNICITY (chose one) _____HISPANIC _____NON-HISPANIC

RACE (chose all that apply) _____WHITE _____BLACK _____ASIAN

_____PACIFIC ISLANDER _____NATIVE AMERICAN

BIRTH DATE: _____ / _____ / _____

PRE-PROTOCOL PARAMETERS (*verify eligibility)

HEIGHT: _____ . _____ inches  WEIGHT: _____ . _____ . _____ lbs (actual)

SURFACE AREA: _____ . _____ m²
PRIMARY DIAGNOSIS ______________________

METHOD OF DIAGNOSIS*______________         DATE OF DIAGNOSIS_________________

Inclusion Criteria
*Yes ____ No ____ Women ≥ 18 years of age
*Yes ____ No ____ First occurrence of breast cancer
*Yes ____ No ____ BMI ≥ 20 Value
*Yes ____ No ____ Recently completed treatment(chemotherapy/radiation) for breast cancer (< 3 months), but can be receiving adjuvant hormonal therapy
*Yes ____ No ____ Willing to comply with study visits, as outlined in the protocol
*Yes ____ No ____ Ability to participate in a moderate exercise program, such as freedom from any orthopedic abnormalities that would prevent participation.
*Yes ____ No ____ Ability to understand and the willingness to sign a written informed consent document.

Exclusion Criteria
Yes ____ *No ____ Unstable angina
Yes ____ *No ____ Cardiac conduction disturbances
Yes ____ *No ____ Plans to move from the study area
Yes ____ *No ____ Dementia that is medically documented or suspected
Yes ____ *No ____ Advanced arterial disease causing ischemia of any limb
Yes ____ *No ____ Physical immobility
Yes ____ *No ____ Homebound for medical reasons
Yes ____ *No ____ Dependent on wheelchair for mobility
Yes ____ *No ____ Chronic disease which significantly reduces 4-year survival
Yes ____ *No ____ Recurrent breast cancer

PROTOCOL INFORMATION

DATE OF REGISTRATION:  ___ ___/___ ___/___ ___

MD NAME (last):  _________________________  MD#:  ___ ___ ___

REFERRING MD (last):  ____________________  MD#:  ___ ___ ___

DATE PROTOCOL ASSESSMENTS STARTED:  ___ ___/___ ___/___ ___

INFORMED WRITTEN CONSENT:  ____YES  ___NO  (Consent must be signed prior to Registration)

DATE:  ___ ___/___ ___/___ ___
APPENDIX B
Home-Based Physical Activity Record

Instructions for Your Daily Physical Activity Record

Thank you for participating in this research study. These instructions should help you complete your daily physical activity record. Activities you perform outside of your exercise at the HELPS Center should be included. You may use one page (record) for each day. If you did not perform any physical activity during one of the days, fill out the information you can, and indicate that no physical activity was performed.

Date and Day of the Week
• Please record the date and circle the day of the week.

Activity Column
• Record the specific type of physical activity you performed.
• Activities, such as walking, jogging, vacuuming, aerobics, yoga, hiking, swimming, sports, golf, house cleaning, walking the dog, playing tennis, riding a bike, among others can be included. If you are not sure whether a specific activity counts as physical activity, include it in this record to be on the safe side and follow-up with a research assistant.

Example:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Duration/Time (minutes or hours)</th>
<th>Intensity Level (circle one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Duration/Time Column
• Record the amount of time you spent doing the activity in minutes or hours.

Example:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Duration/Time (minutes or hours)</th>
<th>Intensity Level (circle one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking</td>
<td>30 minutes</td>
<td></td>
</tr>
</tbody>
</table>

Intensity Level Column
The level of effort required by a person to do an activity is known as the intensity of an activity.

Circle the intensity level (low, moderate, vigorous) of the specific activity you recorded, according to the descriptions in the fourth column.

Example:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Duration/Time (minutes or hours)</th>
<th>Intensity Level (circle one)</th>
<th>Intensity Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking</td>
<td>30 minutes</td>
<td>Low, Moderate, Vigorous</td>
<td>The intensity level of physical activity is also known as the level of effort required by a person to do an activity, or how hard you are working.</td>
</tr>
</tbody>
</table>

**Moderate**: If you are doing moderate-intensity physical activity, you can talk, but not sing, during the activity. Examples of moderate-intensity physical activity include: walking briskly, water aerobics, bicycling (slower than 10 mi/hr), tennis (doubles), gardening.

**Vigorous**: If you are doing

**Other Activities**: Please record the approximate amount of time, in hours and minutes, that was spent watching TV, reading for pleasure, using the computer for work-related activities, and using the computer for leisure-time activities. If no time was spent, please write a zero on the corresponding line.

Watching TV: ___1 hr ___30 min
Reading: _____hr ___45 min
Using the Computer (work-related): ___4 hr ___30 min
Using the Computer (leisure-time): 1 hr 0 min

DAILY ACTIVITY RECORD
(for use when you exercise at another location or at home)

Date: _____/_____/_____  Day of the Week: M T W TH F S Sn

(Circle one)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Duration/Time</th>
<th>Intensity Level</th>
<th>Intensity Level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(minutes or hours)</td>
<td>(circle one)</td>
<td>The intensity level of physical activity is also known as the level of effort required by a person to do an activity, or – how hard you are working.</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>Vigorous</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>Vigorous</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>Vigorous</td>
<td></td>
</tr>
</tbody>
</table>

Please record the amount of time, in hours and minutes, that was spent today on the following activities. Write a zero on the line if no time was spent.

Watching TV: _____ hr _____ min  Reading: _____ hr _____ min

69
Using the Computer (work-related): _____hr _____min

Using the Computer (leisure-time): _____hr _____min
APPENDIX C
Demographics/Health/Medication/AHA (DHMA)
The following questions are about your background. This information will help us describe, in general terms, the women who are participating in the study. Please fill in the appropriate bubble for each question.

1. Which category below best describes the highest level of formal education completed? (Choose the one best answer).

- No formal education
- Grade School (1st through 8th grade)
- Some High School (9th through 11th grade)
- High School diploma or G.E.D
- Business/Vocational training school after high school graduation
- Some College (no degree obtained)
- Associate Degree (A.D. or A.A.)
- College Graduate
- Some college or professional school after college graduation
- Master’s Degree
- Doctoral Degree

2. What was your total family income (before taxes) from all sources last year? (This information is important for describing the women in the study as a group and is kept strictly confidential).

- Less than $10,000
- $10,000 to $19,999
- $20,000 to $34,999
- $35,000 to $49,999
- $50,000 to $74,999
- $75,000 to $100,000
- More than $100,000

3. What is your current employment status?

- Unemployed/Looking for work
- Retired
- Full-time Homemaker
- Employed – full-time
- Employed – part-time
- Disabled, unable to work
Student

Other (Please list: ____________________________)

4. If you are employed, which category best describes your occupation?

Professional, Technical & Related Occupations (such as teachers/professors, nurses, lawyers, physicians, & engineers)

Managers, Administrators, or Proprietors (such as sales managers, real estate agents, or postmasters)

Clerical & Related Occupations (such as secretaries, clerks, or mail carriers)

Sales Occupations (such as salespersons, demonstrators, agents, and brokers)

Service Occupations (such as police, cooks, or hairdressers)

Skilled Crafts, Service Repair Persons, & Related Occupations (such as carpenters, appliance repair, or telephone line workers)

Equipment or Vehicle Operators & Related Occupations (such as drivers, railroad brakemen, or sewer workers)

Laborers (such as helpers, longshoremen, or warehouse workers)

Farmers (owners, managers, operators, or tenants)

Members of the military

Other (please describe) ________________________________

5. Including yourself, what is the total number of persons who are currently living in your household? _______ persons
6. What is your religious preference?

- Catholic
- Jewish
- Hindu
- Greek Orthodox
- Muslim
- Protestant (Indicate which denomination: Baptist, Church of Christ, Episcopalian, Methodist, Moravian, Mormon, Presbyterian, Unitarian, etc., or Inter-Denominational, Non-Denominational)
  ___________________________________________________
- Russian Orthodox
- Buddhist
- Other (Please specify) __________________________________________
- None
APPENDIX D

Rehabilitation Program Evaluation

In order to make this rehabilitation program an effective, we would like to get your feedback after completing 3 months of the program. Please circle the number below that best describes your feelings about each statement.

<table>
<thead>
<tr>
<th>Circle One</th>
<th>Not At All</th>
<th>A Little Bit</th>
<th>Somewhat</th>
<th>Quite A Bit</th>
<th>Very Much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I have liked the rehabilitation program overall.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. The rehabilitation Program has been helpful to me.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. I plan to continue to practice physical activity at the end of the program.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Part II.

1. What have you liked best about participating in this study and the rehabilitation program?

_________________________________________________________________________________
_________________________________________________________________________________

2. What have you liked least about participating in this study and the rehabilitation program?

_________________________________________________________________________________
_________________________________________________________________________________

3. What have you learned from participating in the rehabilitation program?

_________________________________________________________________________________
_________________________________________________________________________________

4. What other suggestions would you make to improve this program?
6. Please share any other thoughts and comments about your participation in the rehabilitation program. (Feel free to use additional space below or on the back of this page if you would like.)
Now we will ask you a few questions about your physical activities before your cancer diagnosis.

For the next questions, we would like you to recall your average weekly exercise over a typical month during the year before your cancer diagnosis. How many times a week on average did you do the following kinds of exercise during a typical month during the year before your cancer diagnosis?

When answering these questions please:

- Consider your average over the month
- Only count exercise sessions that lasted 10 minutes or longer in duration
- Only count exercise that was done during free time (i.e., do not count occupation [job] or housework activities)
- Note that the main difference between the three categories is the intensity of the exercise
- Please write the average frequency on the first line and the average duration (in minutes) on the second line

<table>
<thead>
<tr>
<th>Times Per Week</th>
<th>Average Duration Each Time You Exercised (in minutes)</th>
</tr>
</thead>
</table>

a. STRENUOUS EXERCISE (HEART BEATS RAPIDLY)
   (i.e., running, jogging, hockey, soccer, squash, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling, vigorous aerobic dance classes, heavy weight training)
   
   ___________________ ___________________

b. MODERATE EXERCISE (NOT EXHAUSTING, LIGHT PERSPIRATION)
   (i.e., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)
   
   ___________________ ___________________

c. MILD EXERCISE (MINIMAL EFFORT, NO PERSPIRATION)
   (i.e., easy walking, yoga, archery, fishing, bowling, shuffleboard, horseshoes, golf, Snowmobiling)
   
   ___________________ ___________________
APPENDIX E
Physical Activities Questions (PAQ Current)

Now we will ask you a few questions about your current physical activities.

For the next questions, we would like you to recall your average weekly exercise over the past month. How many times per week on average did you do the following kinds of exercise over the past month?

When answering these questions please:
- Consider your average over the week
- Only count exercise sessions that lasted 10 minutes or longer in duration
- Only count exercise that was done during free time (i.e., do not count occupation [job] or housework activities)
- Note that the main difference between the three categories is the intensity of the exercise
- Please write the average frequency on the first line and the average duration (in minutes) on the second line

<table>
<thead>
<tr>
<th>Times Per Week</th>
<th>Average Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

|                      |                  |
|                      |                  |

|                      |                  |
|                      |                  |

**d. STRENuous EXERCISE (HEART BEATS RAPIDLY**
(i.e., running, jogging, hockey, soccer, squash, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling, vigorous aerobic dance classes, heavy weight training)

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td></td>
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</tbody>
</table>

**e. MODERATE EXERCISE (NOT EXHAUSTING, LIGHT PERSPIRATION)**
(i.e., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)

<p>| | |</p>
<table>
<thead>
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</table>

**f. MILD EXERCISE (MINIMAL EFFORT, NO PERSPIRATION)**
(i.e., easy walking, yoga, archery, fishing, bowling, shuffleboard, horseshoes, golf, snowmobiling)

<p>| | |</p>
<table>
<thead>
<tr>
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</tbody>
</table>
APPENDIX F
Satisfaction with Life Scale

Using the following scale, circle the answer that best corresponds to the extent to which you agree with each statement below.

1. In most ways my life is close to my ideal.

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Slightly Disagree</th>
<th>Neither agree</th>
<th>Slightly Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disagree</td>
<td>Agree</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. The conditions of my life are excellent.

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Slightly Disagree</th>
<th>Neither agree</th>
<th>Slightly Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disagree</td>
<td>Agree</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. I am satisfied with my life.

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Slightly Disagree</th>
<th>Neither agree</th>
<th>Slightly Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disagree</td>
<td>Agree</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. So far I have gotten the important things I want in life.

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Slightly Disagree</th>
<th>Neither agree</th>
<th>Slightly Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disagree</td>
<td>Agree</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. If I could live my life over, I would change almost nothing.

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Slightly Disagree</th>
<th>Neither agree</th>
<th>Slightly Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disagree</td>
<td>Agree</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX G
SF-12

The following questions ask you about your physical functioning.
INSTRUCTIONS: Please place a mark in the box under the appropriate response to each of the following questions.

1. In general, would you say your health is:

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very Good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.

<table>
<thead>
<tr>
<th>Limited a lot</th>
<th>Limited a little</th>
<th>Not limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

3. Climbing several flights of stairs.

<table>
<thead>
<tr>
<th>Limited a lot</th>
<th>Limited a little</th>
<th>Not limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

4. Accomplished less than you would like.
5. Had difficulty performing the work or other activities, for example, it took extra effort.

During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of emotional problems (such as feeling depressed or anxious)?

No  Yes

6. Accomplished less than you would like.

7. Didn’t do work or other activities as carefully as usual.

8. During the past four weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all  Slightly  Moderately  Quite a bit  Extremely

9. During the past four weeks, how much did pain interfere with your normal activities (including both work outside the home, housework, and family activities)?

Not at all  Slightly  Moderately  Quite a bit  Extremely

These questions are about how you feel and how things have been with you during the past four weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

10. During the past four weeks, have you felt calm and peaceful?

All of  Most of  A good bit  Some of  A little of  None of
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>11. During the past four weeks, did you have a lot of energy?</strong></td>
<td>All of the time</td>
</tr>
<tr>
<td><strong>12. During the past four weeks, have you felt downhearted and blue?</strong></td>
<td>All of the time</td>
</tr>
</tbody>
</table>
APPENDIX H

FACT-B

Below is a list of statements that other people with your illness have said are important. By circling one (1) answer per line, please indicate how true each statement has been for you during the past 7 days.

I. PHYSICAL WELL-BEING

_During the past 7 days:_

1. a. I had a lack of energy
   - Not at all  A little bit  Somewhat  Quite a bit  Very much

2. b. I had nausea
   - Not at all  A little bit  Somewhat  Quite a bit  Very much

3. c. Because of my physical condition, I had trouble meeting the needs of my family
   - Not at all  A little bit  Somewhat  Quite a bit  Very much

4. d. I had pain
   - Not at all  A little bit  Somewhat  Quite a bit  Very much

5. e. I was bothered by side effects of treatment
   - Not at all  A little bit  Somewhat  Quite a bit  Very much

6. f. I felt ill
   - Not at all  A little bit  Somewhat  Quite a bit  Very much

7. g. I was forced to spend time in bed
II. SOCIAL/FAMILY WELL-BEING

*During the past 7 days:*

a. I felt close to my friends

Not at all  A little bit  Somewhat  Quite a bit  Very much

b. I got emotional support from my family

Not at all  A little bit  Somewhat  Quite a bit  Very much

c. I got support from my friends

Not at all  A little bit  Somewhat  Quite a bit  Very much

d. My family has accepted my illness

Not at all  A little bit  Somewhat  Quite a bit  Very much

e. I was satisfied with family communication about my illness

Not at all  A little bit  Somewhat  Quite a bit  Very much

f. I felt close to my partner (or the person who is my main support)

Not at all  A little bit  Somewhat  Quite a bit  Very much

*ff. Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box.*

☐

g. I was satisfied with my sex life
Not at all  A little bit  Somewhat  Quite a bit  Very much

III. EMOTIONAL WELL-BEING

*During the past 7 days:*

a. I felt sad

Not at all  A little bit  Somewhat  Quite a bit  Very much

b. I was satisfied with how I’m coping with my illness

Not at all  A little bit  Somewhat  Quite a bit  Very much

c. I was losing hope in the fight against my illness

Not at all  A little bit  Somewhat  Quite a bit  Very much

d. I felt nervous

Not at all  A little bit  Somewhat  Quite a bit  Very much

e. I worried about dying

Not at all  A little bit  Somewhat  Quite a bit  Very much

f. I worried that my condition would get worse

Not at all  A little bit  Somewhat  Quite a bit  Very much
IV. FUNCTIONAL WELL-BEING
   *During the past 7 days:*

a. I was able to work (include work at home)
   Not at all    A little bit    Somewhat    Quite a bit    Very much

b. My work (include work at home) was fulfilling
   Not at all    A little bit    Somewhat    Quite a bit    Very much

c. I was able to enjoy life
   Not at all    A little bit    Somewhat    Quite a bit    Very much

d. I have accepted my illness
   Not at all    A little bit    Somewhat    Quite a bit    Very much

e. I was sleeping well
   Not at all    A little bit    Somewhat    Quite a bit    Very much

f. I was enjoying things I usually do for fun
   Not at all    A little bit    Somewhat    Quite a bit    Very much

g. I was content with the quality of my life right now
   Not at all    A little bit    Somewhat    Quite a bit    Very much

V. ADDITIONAL CONCERNS
   *During the past 7 days:*

a. I was short of breath
b. I was self-conscious about the way I dressed
   Not at all  A little bit  Somewhat  Quite a bit  Very much

b. I was self-conscious about the way I dressed
   Not at all  A little bit  Somewhat  Quite a bit  Very much

c. My arms were swollen or tender
   Not at all  A little bit  Somewhat  Quite a bit  Very much

d. I felt sexually attractive
   Not at all  A little bit  Somewhat  Quite a bit  Very much

e. I was bothered by hair loss
   Not at all  A little bit  Somewhat  Quite a bit  Very much

f. I was worried that other members of my family might someday get the same illness I have
   Not at all  A little bit  Somewhat  Quite a bit  Very much

g. I worried about the effect of stress on my illness
   Not at all  A little bit  Somewhat  Quite a bit  Very much

h. I was bothered by a change in weight
   Not at all  A little bit  Somewhat  Quite a bit  Very much

i. I felt like a woman
   Not at all  A little bit  Somewhat  Quite a bit  Very much
REFERENCE LIST


American Cancer Society. (2010). What is breast cancer?


LEAH MENEES GARDNER

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