EFFECTIVNESS OF A CANCER CENTER BASED PHYSICAL ACTIVITY COUNSELING INTERVENTION IN BREAST CANCER SURVIVORS

by

Meagan Nicole Piland

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Director of Thesis: Kristina Karvinen, PhD

Major Department: Exercise and Sport Science

The purpose of this study was to examine the effectiveness of a cancer center-based physical activity counseling program compared to an attention control condition for (a) improving quality of life and (b) increasing physical activity levels in a rural population of breast cancer survivors. Twenty post-treatment breast cancer survivors were recruited through primarily post-treatment follow-up clinics as well as through a fitness center or university listserv, and were randomized to a cancer center based physical activity counseling program (CCB) condition or an attention control (AC) condition. Participants randomized to the CCB condition received a 20-30 minutes face-to-face physical activity counseling session using Motivational Interviewing with a trained fitness consultant at the site of recruitment. The intervention lasted four weeks and included weekly telephone calls aimed at providing motivation and exploring topics such as goal

setting and overcoming barriers to physical activity. AC condition participants were also telephoned weekly to match the attention that the participants of the CCB group received. Participants in both conditions received a pedometer, weekly step logs, and a package of print materials tailored for breast cancer survivors outlining many physical activity topics (e.g., benefits and barriers of exercise, setting goals, support from others, and planning an exercise program). Participants in both conditions were instructed to record their steps every day for four weeks, and again during the eighth week after the start of the intervention during the follow-up phase. Physical activity was assessed by pedometer steps and the International Physical Activity Questionnaire (IPAQ). Quality of life was assessed using the Functional Assessment of Cancer Therapy-Breast (FACT-B). Both the IPAQ and FACT-B questionnaires were administered at the time of recruitment, immediately at the end of the four week intervention, and after the follow-up phase. Significant improvements in self-reported moderate and moderate-to-vigorous physical activity were noted in both conditions across the course of the intervention, while no significant improvements were seen in quality of life scores. Participants in the CCB condition had significant improvements in change scores in pedometer steps from pre-intervention to follow-up as compared with the AC condition. Based on these findings, the CCB condition was successful in increasing objectively measured physical activity in post-treatment breast cancer survivors compared to the AC condition, however it did not improve quality of life. Future efforts should include a larger sample size that better represents the general population of breast cancer survivors and a longer intervention to better determine the effectiveness of this particular intervention.

EFFECTIVENESS OF A CANCER CENTER BASED PHYSICAL ACTIVITY COUNSELING INTERVENTION IN BREAST CANCER SURVIVORS

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Meagan Nicole Piland

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EFFECTIVNESS OF A CANCER CENTER BASED PHYSICAL ACTIVITY

COUNSELING INTERVENTION IN BREAST CANCER SURVIVORS

by

Meagan Nicole Piland

APPROVED BY:

DIRECTOR OF THESIS: _____
Kristina Karvinen, PhD

COMMITTEE MEMBER: _____
Thomas Raedeke, PhD

COMMITTEE MEMBER: _____
Katrina DuBose, PhD

COMMITTEE MEMBER: _____
David Loy, PhD

CHAIR OF THE DEPARTMENT OF
EXERCISE AND SPORT SCIENCE: _____
Stacey Altman, J.D.

DEAN OF THE GRADUATE SCHOOL: _____
Paul J. Gemperline, PhD

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CHAPTER 1: INTRODUCTION

The prevalence of breast cancer is increasing and is among the most widespread cancer type in women (Centers for Disease Control and Prevention, 2010). Following breast cancer diagnosis, patients commonly have complications and symptoms, such as fatigue, weight gain, mood disturbances, and physical declines, which may negatively affect their quality of life. As the population of breast cancer survivors continues to grow, the issues associated with decreased quality of life must be addressed and treated because they can often hinder the recovery process and also contribute to co-morbidities with the patient's function to carry out their daily life (Knobf, 2007).

One intervention strategy that has been associated with improved quality of life is physical activity (Alfano et al., 2007; McNeely et al., 2006). Physical activity is safe and feasible for this population and has not only been shown to improve quality of life, but may also improve cardiorespiratory fitness, physical function, and decrease fatigue (McNeely et al., 2006). What is troubling about the breast cancer survivor population is that 70.4% do not meet the minimal recommendations for physical activity as established by the American Cancer Society (Bellizzi, 2005). The recommendations include thirty to sixty minutes of moderate-to-vigorous physical activity at least five times per week (Bellizzi, Rowland, Jeffery, & McNeel, 2005; Coups & Ostroff, 2005; Doyle et al., 2006; Schmitz, Courneya, & Matthews, 2010). Despite this fact, breast cancer survivors are interested in receiving one-on-one counseling for physical activity with an exercise professional (Stevinson & Fox, 2005). It is crucial to find enjoyable physical activity interventions that increase both physical activity levels and quality of life that is accessible to all breast cancer survivors.

Indicators of socioeconomic status, such as income and education level, as well as ethnicity have been associated with quality of life and physical activity levels in breast cancer survivors and the general population. Higher education and income levels have been shown to be associated with higher quality of life (Ashing-Giwa, Ganz, & Petersen, 1999; Carver, Smith, Petronis, & Antoni, 2006; Ganz et al., 2002; Mols, Vingerhoets, Coebergh, & van de Poll-Franse, 2005; Powe et al., 2007). Higher education is also associated with higher levels of reported physical activity (Emery, Yang, Frierson, Peterson, & Suh, 2009; Hong et al., 2007). Minority ethnicities, such as African Americans, typically report both lower quality of life and physical activity levels compared to their Caucasian counterparts (Powe et al., 2007). Despite differences in quality of life and physical activity levels based on indicators of socioeconomic status and physical activity, almost all physical activity interventions with cancer survivors have utilized an almost homogeneous sample of well-educated, high income, Caucasian participants. The result is limited generalizability of these findings to all cancer survivors.

The purpose of this study was to provide information for the future design and implementation of effective physical activity counseling for breast cancer survivors that is accessible to participants of all socioeconomic types. This study aims to examine the effectiveness of a cancer center-based physical activity counseling program compared to a control condition for (a) improving quality of life and (b) increasing physical activity levels in a rural population of breast cancer survivors. The counseling program was based on the findings of a pilot study that was recently completed on physical activity programming and counseling preferences in a rural population of breast cancer survivors, in which the majority of the participants (87%) were interested in receiving physical activity counseling (Karvinen, 2008). It

is hypothesized that the intervention group will show greater improvements in (a) quality of life and (b) physical activity levels compared to the control group.

This study eliminated the need for high literacy, transportation, or other resources in order to encompass the general population of breast cancer survivors. An intervention was used that reflects the activity preferences of the survivors in order to be enjoyable and had increased chances of improving physical activity and quality of life. Overall, the success of this intervention was an effective method to increase physical activity in all breast cancer survivors regardless of socioeconomic type.

Delimitations

Twenty post-treatment female breast cancer survivors were recruited at the Leo W. Jenkins Cancer Center, 21st Century Oncology, LifeStyles Medical Fitness Center, or East Carolina University. Exclusion factors included: currently not on treatment (radiation or chemotherapy), cognitive impairments, under the age of 18, more than five years into survivorship, or medical contraindications to exercise as indicated by the Physical Activity Readiness Questionnaire (PAR-Q).

Limitations

The number of eligible survivors was expected to be limited because the population base at the locations of recruitment (Leo W. Jenkins Cancer Center, 21st Century Oncology, LifeStyles Medical Fitness Center, and East Carolina University) was relatively small. Therefore, the timeline for the study was lengthened based on past studies with participant recruitment at these sites. Another possible limitation was collecting the post intervention and follow-up materials from the participants, since they mailed the materials to the researchers. In order to

minimize this difficulty, postage-paid envelopes was provided to the participant and reminder telephone calls were made weekly and as necessary to remind the participants to return the items.

Definitions

- *Breast cancer survivors*: all individuals with breast cancer who have sustained life from the point of diagnosis.
- *Contraindications*: a clinical symptom or circumstance indicating that the use of an otherwise advisable intervention would be inappropriate.
- *Moderate physical activity*: movement that takes moderate physical effort and makes one breathe somewhat harder than normal and one is able to talk comfortably (i.e. walking briskly, cycling on flat ground).
- *Physical activity*: bodily movement that increases energy expenditure above resting levels.
- *Quality of life*: a multidimensional concept encompassing behavioral competence and health, perceived quality of existence, psychological well-being, physiology, function, and others such as social activity, cognition, emotion, sleep and rest, energy and vitality, health perception, and general life satisfaction.
- *Vigorous physical activity*: movement that takes hard physical effort and makes one breathe much harder than normal and causes one to sweat. One is not able to talk comfortably during vigorous physical activity (i.e. running, playing basketball).

CHAPTER 2: LITERATURE REVIEW

Quality of Life in Breast Cancer Survivors

Breast cancer is one of the most common cancer types and among the top ten causes of death in women (American Cancer Society, 2010). An estimated 230,480 women will be diagnosed with invasive or in situ (early stage) breast cancer and 2,140 men will be diagnosed with breast cancer in 2011 (American Cancer Society, 2011). Based on the most recent data, the American Cancer Society has concluded that the five-year survival rate for women diagnosed with all stages of breast cancer is 88.7%. Those diagnosed with local, regional, and distance breast cancer have five-year survival rates of 98.1%, 83.8%, and 27.2%, respectively (American Cancer Society, 2010).

As the needs of the breast cancer survivor population continue to grow, so do their needs regarding their quality of life. Quality of life encompasses physical, functional, psychological/emotional, and social well-being (Robb et al., 2007). Breast cancer survivors may face fatigue, weight gain, mood disturbances, physical declines, economic and employment problems, familial and marital relationship challenges, and concerns with body image and sexuality (Knobf, 2007; Robb et al., 2007). The issues that affect quality of life in women with breast cancer are important to address because they can hurt the survivors' recovery and may contribute to co-morbidities and a decrease in the breast cancer survivor's function (Knobf, 2007).

There are many reasons why breast cancer survivors may experience decreases in their quality of life post-treatment. Once survivors have completed treatment, many of the physical side effects may still be present, such as hair loss, fatigue, early menopausal symptoms, lymphedema, and decreased libido. These side effects may or may not be anticipated by the

survivor and become a major source of distress (Costanzo, 2007). Psychological issues may also arise because survivors no longer need to focus on their medical treatment. At this time, an active coping strategy and their primary means of managing cancer may leave the survivor dwelling on fears of cancer recurrence (Costanzo, 2007). A loss of support may be an additional cause of distress in breast cancer survivors. Often times, family and friends do not realize that survivors continue to struggle both physically and psychologically post-treatment. Regular contact with health-care providers is also decreased post-treatment and may contribute to the loss of support (Costanzo, 2007).

Cognitive changes also may occur and have been referred to as "chemo brain". These changes include a blunting of mental acuity, trouble with quantitative thinking, short-term memory and recalling certain words. Changes in cognitive function have been found to last up to ten years after treatment completion and in some cases may never improve (Schnipper, 2003). Acute menopause due to chemotherapy results in hot flashes, mood swings, and sexual changes, such as a decreased libido. Many survivors may also become infertile, which is a significant source of distress especially in younger individuals (Schnipper, 2003).

Breast cancer survivors have significantly lower physical and mental health scores, compared with their adult counterparts (Robb, 2007). These scores include physical functioning, role-physical (accomplishing fewer or having difficulty completing tasks), bodily pain, general health, vitality, social functioning, and role-emotional (carelessness and cutting down time) scores. They also report more interference with their daily function due to fatigue, as well as higher state depression and lower levels of spiritual well-being (Robb, 2007). The prevalence of moderate to severe cases of anxiety has been found to be up to 38% and depression (moderate to severe) up to 22% from the time of initial breast cancer diagnosis (Mehnert & Koch, 2008).

Some significant predictors of psychological co-morbidity in breast cancer survivors include: cancer progression, detrimental social interactions, lower levels of social support, and lower educational levels (Mehnert & Koch, 2008).

Ethnicity may also impact the quality of life in breast cancer survivors. For example, African Americans typically report lower quality of life scores in relation to their Caucasian counterparts. Forty-seven percent of African Americans with breast cancer are diagnosed in advanced stages of breast cancer. Survival rates are lower in African Americans (75%) than Caucasians (89%). The major symptoms experienced by African Americans are hot flashes and body image concerns, but also energy loss, sensory and sleep issues, pain, and mental distress. Several factors were found to be linked directly to quality of life in African Americans, including symptom distress, family functioning, cancer recurrence, life stress, general health perception, partnership status, and income (Powe, 2007). There is limited information regarding Latinas and quality of life, but they often report more breast cancer related symptoms than any other group, as well as decreased mental health (Giedzinska, Meyerowitz, Ganz, & Rowland, 2004). They also report increased negative feelings, social avoidance, distress about family's future, and distress about cancer recurrence (Carver, 2006).

In addition to ethnicity, education and income level may also impact quality of life in breast cancer survivors. Higher education has been associated with decreased fatigue, financial problems, and distress about the family's future, as well as an increase in pain and less perceived benefit from having had breast cancer (Carver et al., 2006). Other studies have shown little to no relationship between education level and quality of life (Ashing-Giwa et al., 1999; Ganz et al., 2002). Strong evidence has been shown for the association of higher income levels with a better quality of life among long-term breast cancer survivors from five to eight years (Ashing-Giwa et

al., 1999; Ganz et al., 2002; Mols et al., 2005). Income has been shown to explain forty-five percent of the variance in quality of life scores in long-term breast cancer survivors, with an income level under $45,000 being negatively associated with quality of life scores (Ashing-Giwa et al., 1999; Ganz et al., 2002). These findings suggest differences in quality of life based on ethnicity, education, and income. Thus, it is important to also study lower socioeconomic status and minority populations given these findings in order to find a means to improve quality of life in these populations.

Physical Activity and Improving Quality of Life

Physical activity has shown to be effective in improving health-related quality of life and reducing cancer-related symptoms in breast cancer survivors on- and post-treatment (McNeely et al., 2006). One study found that higher post-diagnosis sports/recreational activity is related to less severe reports of physical symptoms of fatigue and greater physical health-related quality of life, especially in the ability to be physically active in the daily lives of breast cancer survivors (Alfano et al., 2007). Following general public health recommendations for physical activity has also been associated with better psychosocial outcomes, including vitality, social functions and overall quality of life (Smith, Alfano, & Reeve, 2009). These improvements in quality of life can be seen in as little as six weeks (Bicego et al., 2009). Pre-diagnosis physical activity has shown benefits among breast cancer survivors and can lead to higher physical health-related quality of life and specifically the physical functioning subscale post diagnosis (Alfano et al., 2007). Physical activity is safe and feasible for this population and improves cardiorespiratory fitness, fatigue, physical functioning, and overall quality of life (McNeely et al., 2006). New data suggests that physical activity can reduce the risk of cancer recurrence and decrease all-cause

mortality in breast cancer survivors, further supporting the importance of physical activity for cancer survivors (Holick et al., 2008).

Improvements in quality of life have been associated with a variety of physical activity and exercise modalities across breast cancer survivors in different disease phases. Some of the modalities that have been studied include tai chi chuan, chair exercises, dance and movement, resistance training, and aerobic exercises, such as walking and recumbent cycling (Basen-Engquist et al., 2006; Campbell, Mutrie, White, McGuire, & Kearney, 2005; Courneya et al., 2003; Headley, Ownby, & John, 2004; Herrero et al., 2006; McKenzie & Kalda, 2003; Mustian et al., 2004; Ohira, Schmitz, Ahmed, & Yee, 2006; Sandel et al., 2005; Segal et al., 2001). These modalities had a significant impact on factors that are related with quality of life, such as self-esteem (Mustian et al., 2004), body image, mental health, physical function (Basen-Engquist et al., 2006; Sandel et al., 2005), bodily pain, role limitations due to physical problems such as accomplishing fewer or having difficulty completing tasks (Basen-Engquist et al., 2006), psychosocial scores (Ohira et al., 2006), and happiness (Herrero et al., 2006). Results have also shown attenuation in fatigue and a slower decline in physical quality of life, suggesting that exercise may slow the effects of treatment and disease process in women with advanced breast cancer (Headley et al., 2004).

In addition to more aerobic exercise types, upper extremity exercise, such as resistance training and arm cycling, may benefit breast cancer survivors with lymphedema. McKenzie et al. showed improvements in physical function, general health, vitality, and mental health in an eight week program incorporating upper extremity exercises in stage I and II breast cancer survivors who had completed treatment more than six months prior to the study with unilateral lymphedema. Although there were no volume changes in the affected arm, participants reported

softening of hardened areas, reduced pain and swelling, and the reappearance of hand tendons (McKenzie & Kalda, 2003). A six month lifestyle physical activity intervention including post-treatment breast cancer survivors within seven years of diagnosis focused primarily on walking and increasing daily step counts. This study reported that walking positively impacted general health, as well as physical aspects of quality of life, such as physical functions, role limitations due to physical problems, and bodily pain (Basen-Engquist et al., 2006). While the current research suggests that a variety of modalities may be beneficial to the overall quality of life in breast cancer survivors, walking may be optimal because it is accessible and universal to the general population of breast cancer survivors.

Physical Activity Recommendations and Levels in Breast Cancer Survivors

The American Cancer Society recommends that cancer survivors engage in thirty to sixty minutes of moderate-to-vigorous physical activity at least five days per week (Doyle et al., 2006; Schmitz, 2010). Most breast cancer survivors do not meet these recommendations (70.4%), and engage in less physical activity than the general population (63.4% inactive) (Bellizzi et al., 2005; Coups & Ostroff, 2005). Physical activity levels are lower in low socioeconomic individuals than in the general population and therefore this subgroup of breast cancer survivors may also be less active than other subgroups within this population (United States Department of Health and Human Services, 1999).

Physical activity levels may also vary based on ethnicity. A study by Smith et al. (2009) examined physical activity and quality of life two years post-diagnosis in stage 0-IIIa breast cancer survivors and reported that meeting general recommendations for physical activity is associated with higher quality of life scores, including vitality, social functioning, and global quality of life in Black and non-Hispanic White survivors (Smith et al., 2009). However, this was

not the case for Hispanic survivors, where physical activity was not associated with improved quality of life and even showed a non-significant negative relationship. Black survivors often report lower quality of life scores than their White and Hispanic counterparts. Although fewer Black survivors reported meeting physical activity recommendations, those that did meet recommendations reported higher levels of quality of life which reinforces the importance of physical activity in low socioeconomic and minority individuals (Smith et al., 2009). Although this study may give some insight into how physical activity impacts quality of life across different ethnic groups, more research is warranted in this area before generalizing these results.

Physical Activity Counseling Interventions

Despite having low physical activity rates, cancer survivors are interested in receiving physical activity counseling and programming (Feurerstein, Courneya, Karvinen, & Vallance, 2007), but there are few exercise-related services (e.g., counseling, programming, exercise facilities) available to them at clinics and hospitals (Stevinson & Fox, 2005). Opportunities for accessing any kind of physical activity counseling or programming may be diminished in low socioeconomic survivors due to barriers such as perceptions of high costs and lack of transportation (Kamphuis, van Lenthe, Giskes, Brug, & Mackenbach, 2007). The importance of finding enjoyable physical activity counseling interventions that increase physical activity and improve quality of life in breast cancer survivors is crucial. It is equally important to ensure that physical activity counseling interventions are accessible and culturally and educationally appropriate for all breast cancer survivors including low socioeconomic individuals.

There have been a total of nine studies that test physical activity counseling methods and how they affect quality of life in cancer survivors (Basen-Engquist et al., 2006; Bennett, Lyons,

Winters-Stone, Nail, & Scherer, 2007; Demark-Wahnefried et al., 2006; Ligibel et al., 2010; Morey et al., 2009; Pinto, Frierson, Rabin, Trunzo, & Marcus, 2005; Rogers et al., 2009; Vallance, Courneya, Plotnikoff, Yasui, & Mackey, 2007; Vallance, Courneya, Plotnikoff, Dinu, & Mackey, 2008). Studies that have used counseling and intervention methods include in-person counseling (Bennett et al., 2007; Rogers et al., 2009), telephone counseling (Demark-Wahnefried et al., 2006; Ligibel et al., 2010; Morey et al., 2009; Pinto et al., 2005; Vallance et al., 2007), home-based intervention (Basen-Engquist et al., 2006; Demark-Wahnefried et al., 2006), print materials (Vallance et al., 2007), and group discussions (Basen-Engquist et al., 2006; Rogers et al., 2009). Of the studies that have been conducted, only three were effective at increasing physical activity levels and improving quality of life (Rogers et al., 2009); Pinto et al., 2005; Vallance et al.; 2007), three studies showed mixed evidence of effectiveness (Ligibel et al., 2010; Bennett et al., 2007; Basen-Engquist et al., 2006) and two studies did not impact either physical activity or quality of life (Demark-Wahnefried et al., 2006; Morey et al., 2009).

Pinto et al. (2005) executed a successful home-based intervention in eighty-six women who had completed treatment for stage 0-II breast cancer. The researchers spoke on the phone with the participants every week and helped identify barriers and health problems, as well as reinforce being physically active. The researchers also helped the participants set goals and encouraged them to increase their physical activity throughout the duration of the study. Weekly tip sheets and letters with feedback and the participant's progress were sent four times over the course of twelve weeks to each participant. Physical activity was measured objectively using an accelerometer. Results revealed a significant increase in the self-reported total minutes of weekly exercise in the intervention group (119 minutes) as compared to the control group (about 5 minutes). The intervention group also decreased their time in the one-mile walk test and

significantly increased in vigor, decreased overall mood disturbances, decreased fatigue, and increased in body esteem (Pinto et al., 2005).

Ligibel et al. (2010) implemented a telephone-based intervention very similar to Pinto et al.'s home-based intervention and produced significant improvements in both physical activity and quality of life. Participants included sedentary, stage I-III breast cancer survivors who were currently undergoing adjuvant therapy (any treatment after completing primary therapy). This telephone-based intervention was twelve-weeks long with a goal of 150 minutes per week of aerobic activity. Participants recorded daily minutes, average heart rate, and total steps per day in a seven-day daily activity log. After one face-to-face session with an exercise specialist, all other sessions were completed by telephone weekly and included topics such as goal setting, self-efficacy, self-monitoring, barriers, symptoms of treatment, and review of the daily activity logs. While participants did not reach the 150 minutes per week goal of the intervention, there was a significant increase in weekly minutes of physical activity from baseline (13 minutes) to the end of the intervention (116 minutes). Cardiorespiratory fitness also significantly increased as determined by a Bruce Modified Ramp Protocol Treadmill test. Significant improvements were also seen in quality of life as compared with baseline data and decreased fatigue that approached but did not reach statistical significance (Ligibel et al., 2010).

Vallance et al.'s (2007) study showed an increase in self-reported physical activity and improvement in quality of life under three different intervention conditions. The three intervention groups consisted of the following: a) a breast cancer specific physical activity manual featuring different strategies for becoming more physically active, b) a pedometer with a twelve week step log, and c) a combination of both the physical activity manual and the pedometer (Vallance et al., 2007). The sample included 377 breast cancer survivors from stages

I-IIIa who had completed adjuvant therapy. This study measured physical activity with a pedometer and self-reported physical activity. Results indicated a significant increase in self-report physical activity and quality of life under all three intervention conditions as compared to a condition which received only standard recommendations for physical activity. There were no significant increases in steps as measured with a pedometer (Vallance et al., 2007). These findings suggest that the intervention did not actually result in physical activity improvements in the intervention groups, but perhaps a social desirability bias where the participants felt compelled to report greater physical activity and quality of life.

A follow-up study by Vallance et al. (2008) reported maintenance of the previous study six months after the intervention using print materials. There were no significant differences in health-related quality of life or fatigue from baseline to six-month follow-up or from three months post intervention to six-month follow-up, indicating that the participants' quality of life and fatigue levels were maintained after completing the intervention. From baseline to six months after the intervention, all groups reported increases in moderate-to-vigorous physical activity although none reached significance. In addition, the maintenance of physical activity decreased from three months to six months post-intervention in all groups for minutes of moderate-to-vigorous physical activity and self-reported brisk walking minutes, with the groups receiving the pedometer and/or print materials reporting higher levels of maintenance than the standard recommendation group. All groups were still engaging in more physical activity at six months after the intervention than they reported at baseline. Objectively measured physical activity with a pedometer was not measured for this follow-up study. This study suggests that pedometers and print materials related to breast cancer survivors may improve the possibility of

physical activity maintenance, but more interactive strategies may be needed post-intervention to support the maintenance of physical activity (Vallance et al., 2008).

Additionally, the twelve-week BEAT (Better Exercise Adherence after Treatment for Cancer) program by Rogers et al. (2009) showed significant increases in physical activity counts via the GT1M accelerometer. Participants included breast cancer survivors from stages I-IIIa and were currently receiving hormone therapy. The intervention was based on the social cognitive theory and its primary goal was to increase all participants to physical activity to 150 minutes per week. There were six discussion group sessions and fifteen individual sessions, twelve of which consisted of supervised exercise and the other three were face-to-face update counseling sessions. While there was a significant increase in physical activity counts among participants, there were no significant increases in moderate-to-vigorous activity minutes or self-reported physical activity. There were no significant improvements in quality of life except among the social well-being subscale. It was suggested by Rogers et al. (2010) that the significant improvements in physical activity counts and social well-being could be due to the staff's attention to the participants, rather than the intervention itself because staff contact time was not similar between the intervention and usual care groups (Rogers et al., 2009). Contact is an important component to consider between intervention and control groups and should be implemented in both the intervention and control groups to control for any improvements that may result from the contact alone.

Of the remaining studies investigating physical activity counseling interventions in breast cancer survivors, only one showed increases in physical activity but did not show an improvement in quality of life. Bennett et al. (2007) incorporated an intervention over six months that consisted of one in-person counseling session followed by two telephone calls using

motivational interviewing. Participants included sedentary and fatigued, breast cancer survivors who had completed adjuvant therapy at least six months prior to enrollment in the intervention. Physical activity was measured by the CHAMPS (Community Healthy Activitities Model Program for Seniors) Physical Activity Questionnaire for Older Adults, which asks about sedentary, low, moderate, and vigorous activities during the last four weeks. Quality of life was measured by several questionnaires that addressed physical health status, mental health status, fatigue, and self-efficacy for regular physical activities. The findings of this study demonstrated that while self-report physical activity participation increased as a result of the motivational interviews, there were no increases in aerobic fitness, physical health and mental health statuses, or improvements in fatigue. Although many home-based intervention studies have used self-reported measures of physical activity, the data collected could be increased simply due to over reporting on the behalf of the participants since there was no improvement in quality of life and other physical factors. Future studies may benefit by using both self-report and objective measures of physical activity (Bennett et al., 2007).

Two additional studies also used self-report methods but did not show improvements in either physical activity or quality of life (Demark-Wahnefried et al., 2006; Morey et al., 2009). Denmark-Wahnefried et al. (2006) incorporated telephone counseling and tailored print materials aimed at increasing exercise and improving overall diet in breast cancer survivors ≥65 years old and within eighteen months of diagnosis. The intervention took place over a six month period and included twelve bimonthly twenty to thirty minute counseling sessions. Physical activity was measured using the CHAMPS questionnaire and quality of life was measured using several questionnaires, including the Short Form 36 Physical Function Subscale (SF-36) and Functional Assessment of Cancer Therapy Breast/Prostate (FACT-GQOL). Improvements were seen in the

intervention group from pre to post intervention in energy expenditure (kcal/week), physical function score via the SF-36, and quality of life score via the FACT-GQOL, but none reached significance (Demark-Wahnefried et al., 2006).

Morey et al. (2009) had similar techniques to Denmark-Wahnefried et al. (2006) and used a home-based tailored program. The sample consisted of overweight, long-term (≥5 years) survivors of colorectal, breast, and prostate cancer. Fifteen telephone counseling sessions and mailed materials were administered over a twelve-month period. In addition, the participants were also provided with a two-page progress report every twelve weeks. This study also used the CHAMPS and SF-36 questionnaires to measure physical activity and physical function. Physical function actually decreased from pre to post intervention in both the intervention and control groups, with a larger decrease in the control group. There were significant differences between the intervention and control groups for all exercise behaviors, including duration of strength training and endurance exercise, and frequency of strength training exercise, and excluding endurance exercise frequency (Morey et al., 2009). These findings suggest that this particular intervention was not helpful due to improvements in both the intervention and control groups and the use of a self-report physical activity questionnaire.

One remaining pilot trial of a lifestyle intervention reported significant findings in physical aspects of quality of life, but not significant improvements in physical activity (Basen-Engquist et al., 2006). This trial included sedentary breast cancer survivors within seven years of diagnosis and no longer receiving therapy. The intervention consisted of twenty-one ninety-minute group sessions every week for sixteen weeks and every other week for an additional eight weeks. These group sessions were used to teach cognitive behavioral skills related to exercise and to discuss breast cancer-related topics. The intervention encouraged walking as the primary

physical activity modality. Physical activity was measured using the seven-day physical activity recall questionnaire and no objective measure was used. The control group was assigned to a standard care condition. While the intervention group reported greater motivational readiness, there were no significant differences in physical activity minutes or the number of days they spent more than thirty minutes being physically active as compared to the control group. There were, however, significant improvements in the quality life subscales measuring physical function, role limitations due to physical problems, and bodily pain as compared to the control group. The non-significant physical activity findings are suggested to be due to the control group also participating in increased physical activity, which may have been a result of being assessed for physical performance and current level of physical activity at the time of enrollment (Basen-Engquist et al., 2006).

Interventions that were effective at increasing physical activity and quality of life contained in-person and telephone based counseling that addressed barriers to physical activity, goal setting, self-efficacy, self-monitoring, and health problems/symptoms (Pinto et al., 2005; Ligibel et al., 2010). In addition, Bennett et al. (2007) specifically implemented motivational interviewing, which showed promise in improving physical activity levels and quality of life in breast cancer survivors. Common limitations of the physical activity counseling studies to date are the lack of objective methods to measure physical activity (Bennett et al., 2007; Demark-Wahnefried et al., 2006; Ligibel et al., 2010; Morey et al., 2009), instruments used were unable to detect small increases in exercise (Demark-Wahnefried et al., 2006), and the participants of the studies tended to be highly educated, high income primarily Caucasian women and thus not representative of the general population of cancer survivors (Morey et al., 2009). The present study addressed these limitations by using pedometers (an objective measure of physical activity)

in addition to self-report physical activity and utilized a counseling method that was accessible to all breast cancer survivors regardless of education and income status. Additionally given the high percentage of African American breast cancer survivors in the area, it was expected that a large proportion will enroll in the study and thus provide a more heterogeneous population in terms of ethnicity.

CHAPTER 3: METHODS

Participants & Recruitment

Twenty post-treatment breast cancer survivors were recruited through post-treatment follow-up clinics at Leo W. Jenkins Cancer Center (n=13) and 21st Century Oncology (n=1) in Greenville, NC, and also at LifeStyles Medical Fitness Center in Washington, NC (n=1) and through a university listserv (n=3). Survivors were excluded from the study if they meet any of the following criteria: on treatment (radiation or chemotherapy) for breast cancer, cognitive impairments, under the age of 18, and/or possess medical contraindications for exercise as indicated by the Physical Activity Readiness Questionnaire (PAR-Q). Breast cancer survivors on treatment were excluded from this study to avoid treatment-related complications that may have resulted in their inability to complete the study. Survivors with cognitive impairments would not be able to participate satisfactorily in the study and were thus excluded. An adult-only population was desired and was the reason for excluding those under the age of 18. Those who possessed medical contraindications to exercise were excluded for the safety of the breast cancer survivors.

Typically, breast cancer survivors refer to all individuals with breast cancer who have sustained life from the point of diagnosis. Contraindications for exercise are clinical symptoms or circumstances indicating that the use of an otherwise advisable intervention would be inappropriate. These were indicated by the PAR-Q and included heart conditions, chest pain, loss of balance/dizziness, loss of consciousness, bone or joint problems, or on medication for either blood pressure or a heart condition.

Those breast cancer survivors eligible to participate in the study were introduced by the nurse on duty or oncologist to a member of the research team after the survivor's regularly scheduled appointment at the Leo W. Jenkins Cancer Center. Interested survivors from 21st Century Oncology, LifeStyles Medical Fitness Center, or through a university listserv were referred by a staff member to a member of the research team to begin the study. The research team member met with the interested survivor in a private room and completed the PAR-Q to screen for medical contraindications. Four participants who were ineligible via the PAR-Q chose to obtain a doctor's note to give permission to enter the study. Once interested survivors were deemed eligible, the research team member described the study and the process of the informed consent. The participant signed the consent form at this time and completed the baseline questionnaire package.

Measures

The following measures were obtained during the study: medical and demographic information, quality of life, and physical activity.

Medical and Demographic Information

Medical and demographic information such as age, ethnicity, height, weight, and education were assessed by self-report questionnaires. Medical information pertaining to date of cancer diagnosis, stage, grade, and treatments received were obtained from medical records.

Quality of Life

Quality of life was measured using the Functional Assessment of Cancer Therapy-Breast (FACT-B) scale (Brady et al., 1997; D. F. Cella et al., 1993). This scale is a 37-item inventory

that assesses multidimensional health-related quality of life in breast cancer survivors. It is comprised of the Functional Assessment of Cancer Therapy-General (FACT-G) and the Additional Concerns Subscale. The FACT-G is multidimensional and consists of the following subscales: physical well-being, emotional well-being , social well-being , and functional well-being. The physical well-being subscale includes items such as lack of energy, nausea, meeting family needs, pain, side effects of treatment, feeling sick, and spending time in bed. Emotional well-being is comprised of items that include feeling sad, proud of coping with illness, losing hope from illness, nervousness, worry about dying, and worry condition will worsen. Feeling close to friends, emotional support from family and friends, family accepting illness, family communication, and feeling close to partner consist of the social well-being subscale. The functional well-being subscale encompasses ability to work, fulfillment in work, enjoying life, accepting illness, sleeping well, enjoying activities for fun, and content with quality of life.

The additional concerns subscale is comprised of ten items specific to quality of life in breast cancer but not already included in the FACT-G. These items include shortness of breath, self-consciousness, swollen or tender arms, attractiveness, hair loss, worry, effects of stress on illness, changes in weight, feeling like a woman, and significant pain. Each item for all subscales is rated on a scale from zero to four; 0) not at all, 1) a little bit, 2) somewhat, 3) quite a bit, and 4) very much. The FACT-B yields a total score, as well as scores for each subscale, with higher scores indicating better quality of life. The maximal scores for the FACT- G, FACT-B, and subscales (physical, emotional, social, and functional well-being, and additional concerns) are as follows: 108, 148, 28, 28, 28, 24, and 40, respectively (Holzner, 2004). It has been shown to be reliable, as it shares an expected pattern to similar measures and responds as predicted with change in clinical status (Brady et al., 1997).

Self- Report Physical Activity

Self-report physical activity was assessed by the International Physical Activity Questionnaire (IPAQ) (Craig et al., 2003) and physical activity log. The IPAQ is a self-report measure suitable for assessing population levels of physical activities across countries. There are eight versions of the questionnaire: four short and four long. The version of the questionnaire used for this study is the self-administered, short version that asks participants to recall the amount of time spent during the last seven days participating in vigorous and moderate activity, walking, and sitting. IPAQ correlations were 0.80 for reliability and 0.30 for validity compared to accelerometer data (Craig et al., 2003).

The physical activity log provided to the participants required information about the time spent wearing the pedometer, their total steps, whether they were sick or injured, and the type and amount of time spent participating in sports and/or exercise for each day. They also recorded in the physical activity log for five weeks total, four weeks of which were during the intervention phase and one week for the follow-up period. The physical activity log was mailed by participants to researchers post intervention and at follow-up.

Objectively Measured Physical Activity

Objectively measured physical activity was determined using Accusplit Eagle pedometers. Pedometers are small, light weight devices that are worn around the waist and measure the vertical displacement of the hips. This hip displacement is registered on the machine as a step count. While there is no reliability and validity data for the Accusplit Eagle pedometer, this pedometer has been tested in comparison with the Yamax SW-200 pedometer, which is statistically valid and accurate (Jordan, 2005). The Accusplit Eagle pedometer underestimates

steps by 3.1% compared to the Yamax SW-200 in post-menopausal women, an acceptable measurement error (Jordan, 2005). The participants wore the pedometers for four weeks during the intervention period and one week during the follow-up period. Daily step values were recorded in the physical activity log by participants.

Design & Procedures

This study was a randomized controlled trial. Randomization occured after participants completed the informed consent and baseline questionnaire package during recruitment. They were assigned to the cancer center based physical activity counseling program (CCB) condition or the attention control (AC) condition. A computer generated block design was used to generate the allocation sequence. A trained research assistant from outside the research team generated the group assignments in sequentially numbered and sealed opaque envelopes. The envelopes were opened by the research team recruiter who assigned participants to groups. After randomization, the intervention phase began and lasted for four weeks. Participants enrolled in the study and started the intervention phase as they became available.

Participants randomized to the CCB condition received a 20-30 minute face-to-face physical activity counseling session using Motivational Interviewing with a trained fitness consultant. Three fitness consultants were trained for two sessions lasting two hours by several professors at East Carolina University in a group setting. These sessions focused on the techniques used in Motivational Interviewing and included practice scenarios. Handouts were provided to the trained fitness consultants as a reference. In addition to this training, two of the three trained fitness consultants completed an exercise and psychology course that contained Motivational Interviewing and included practice scenarios as well.

Motivational Interviewing is a directive, client-centered counseling approach that is designed to enhance intrinsic motivation and explore ambivalence to elicit change behavior (Karzenowski et al., 2011). It is based on the Transtheoretical Model of Change, which states that behavior change progresses through six stages, including: pre-contemplation, contemplation, planning, action, maintenance, and termination. When implementing motivational interviewing, the interviewer must work with the client at their present stage to promote collaboration and reduce resistance to change. The five basic principles of motivational interviewing include: expressing empathy towards the client, avoiding arguments, supporting self-efficacy, rolling with resistance, and developing discrepancy. Trained motivational interviewers are persuasive and supportive and contain skills that include reflective listening, asking open ended questions, affirming the client, and summarizing the client's thoughts, needs, and emotions (Karzenowski et al., 2011).

The physical activity counseling session with the trained fitness consultant occurred immediately after randomization and took place at the site of recruitment. The focus of the session was to gain commitment to change in part by exploring the benefits of physical activity and recommendations for different home-based activities. Participants were also given a step pedometer and instructed on the proper use of the pedometer and when to record daily steps in the physical activity log. Participants were provided with a package of print materials tailored for breast cancer survivors outlining many physical activity topics, including specific exercises and motivational strategies, such as benefits and barriers of exercise, setting goals, support from others, and planning an exercise program (Vallance, Courneya, Taylor, Plotnikoff, & Mackey, 2008). Participants were telephoned weekly by a trained fitness consultant for the duration of the four-week intervention phase. The 20-30 minute telephone calls using motivational interviewing

were designed to provide motivation for continued participation in physical activity by exploring topics such as goal setting, overcoming barriers, relapse prevention, giving feedback on step counts and the usage of the physical activity log, and providing participants a chance to ask questions. This format of physical activity counseling has advantages over other methodology (e.g., print materials only or telephone only) because it is accessible to all breast cancer survivors and is based on previously determined physical activity preferences in this population (Karvinen, Raedeke, Arastu, & Allison, In Press).

Participants randomized to the AC condition received instruction on how to use the pedometer and when to record daily steps. Participants were also given the same package of print materials as the CCB condition. AC condition participants were telephoned every week and asked about pedometer and physical activity log use so that they were contacted an equal amount of times as the participants in the CCB group. The telephone calls lasted no longer than five minutes and specific strategies to increase motivation were not discussed with the participants of the AC condition.

All participants wore the pedometer and record steps/activities in the physical activity log daily during the course of the intervention and again during the eighth week after the start of the intervention during the follow-up phase.

At the end of the intervention, all participants completed the FACT-B and IPAQ questionnaires. During the follow-up phase (four weeks after the end of the intervention), the FACT-B and IPAQ questionnaires were completed once again by the participants. All follow-up questionnaires and physical activity logs were mailed by the participants to the researchers.

Data Analysis

Descriptive and frequency analyses were conducted to evaluate the demographic and medical information on all participants. The mean and standard deviation were computed for age, height, and weight of each group. A one-way between-groups analysis of variance (ANOVA) was conducted to find any differences in age, height, and weight between groups. The remaining categorical demographics underwent chi-square analyses to determine any differences between groups at baseline. An additional analysis was also conducted to evaluate the presence of outliers among the demographic and medical variables.

Two (group) x three (time) repeated measures analysis of variance (RM ANOVA) were conducted on the following dependent variables: self-reported vigorous, moderate, walking, and moderate-to-vigorous minutes per week. In addition, a two (group) x five (time) RM ANOVA was conducted on average steps per day by week. For all analyses, effect sizes were determined by partial eta squared values and interpreted by the recommendations of Cohen (i.e., small effect = .01, medium = .06, large = .14) (Cohen, 1988).

Quality of life was interpreted based on guidelines for judging the clinically important differences (CID) on the FACT-B scale, which was a seven to eight point difference in the overall score (D. Cella, Eton, Lai, Peterman, & Merkel, 2002; D. Cella, Hahn, & Dineen, 2002; Eton, 2004). Changes in quality of life were assessed using a two (group) x three (time) RM ANOVA. These analyses were conducted for overall quality of life and the subscales, which included physical, functional, emotional, and social well-being, and additional concerns.

Independent sample t-tests were also used to examine the differences in change scores from pre-intervention to follow-up (week 5 – week 1) and from pre-intervention to post-

intervention (week 4 – week 1) between the two conditions for the following dependent variables: average steps per day by week, self-reported vigorous, moderate, walking, and moderate-to-vigorous minutes per week, overall FACT-B score, and each of the FACT-B subscales.

Missing Data

Missing pedometer data was handled as follows: if daily steps were not recorded for one or more days in one week, the average daily steps for that week were calculated and was used for the days with missing data. FACT-B data was handled in a similar manner. For each subscale, the average score was calculated and used for the items with missing data in that particular subscale.

Two participants, one randomized to the CCB condition and one to the AC condition, failed to return follow-up questionnaires and physical activity logs. For these two participants, the last observation was carried forward for pedometer, IPAQ, and FACT-B data.

CHAPTER 4: RESULTS

Participant Characteristics

Twenty participants were randomized for this study, ten of which were randomized to the CCB and ten to the AC condition. Seventeen out of twenty participants were included in analyses due to three of the subjects failing to complete the post-intervention and follow-up questionnaires, as well as physical activity logs, two of which were assigned to the CCB condition and one from the AC condition. Demographic and medical variables are summarized in Tables 1 and 2. One-way between-groups ANOVAs revealed that the two groups were significantly different in age [$F(1,15) = 7.44$, $p = .02$], with the CCB condition having a higher mean age (Table 1). Chi-square analyses indicated that the groups were also significantly different in menopausal status [$\chi^2(1, N=17) = 5.13$, $p = .02$], with the majority of the participants in the CCB condition being post-menopausal (Table 1). There were no significant differences between groups on any of the other demographic variables and medical variables. The analysis of outliers yielded one outlier in the height and weight categories, which were randomized to the CCB and AC conditions, respectively. No other outliers were found for any of the other variables.

Table 1. Descriptive Statistics of Demographic Variables

	Total Mean(SD) or Frequency(%)	CCB Mean (SD) or Frequency(%)	AC Mean(SD) or Frequency(%)	F-value or χ^2	Sig.
Weight (kg)	91.3(21.4)	83.0(12.5)	98.6(25.4)	2.46	.14
Height (cm)	162.5(8.7)	160.8(11.2)	164.0(6.1)	.54	.47
Age (yrs)	53.5(10.9)	60.0(7.6)	47.8(10.4)	7.44	.02

Ethnicity					
Caucasian	14(82.4)	7(87.5)	7(77.8)	.28	.60
African American	3(17.6)	1(12.5)	2(22.2)		
Marital Status					
Not Married	4(23.5)	2(25.0)	2(22.2)	.02	.89
Married/Common Law	13(76.5)	6(75.0)	7(77.8)		
Education Level					
Completed High School	1(5.9)	1(12.5)	0(0.0)	1.20	.27
Completed University/College	16(94.1)	7(87.5)	9(100.0)		
Income Level					
<60,000	4(36.4)	1(25.0)	3(42.9)	.35	.55
>60,000	7(63.6)	3(75.0)	4(57.1)		
Employment Status					
Not Working	5(29.4)	3(37.5)	2(22.2)	.48	.49
Working	12(70.6)	5(62.5)	7(77.8)		
No. of Co-morbidities					
≤1	14(82.4)	7(87.5)	7(77.8)	.28	.60
≥2	3(17.6)	1(12.5)	2(22.2)		
Menopausal Status					
Pre-menopausal	7(41.2)	1(12.5)	6(66.7)	5.13	.02
Post-menopausal	10(58.8)	7(87.5)	3(33.3)		

Note: All participants reported to be non-smokers.

CCB: Cancer-center based physical activity counseling

AC: Attention control

Table 2. Descriptive Statistics of Medical Variables

	Total Frequency(%) or Mean(SD)	CCB Frequency(%) or Mean(SD)	AC Frequency(%) or Mean(SD)	F-value or χ^2	Sig.
Breast Cancer Stage				2.46	.48
0	4(23.5)	3(37.5)	1(11.1)		
Ia/Ib	4(23.5)	1(12.5)	3(33.3)		
IIa/IIb	6(35.3)	2(25.0)	4(44.4)		
IIIa	2(11.8)	1(12.5)	1(11.1)		
Missing Data	1(5.9)	1(12.5)	0(0)		
Treatment					
Surgery	16(94.1)	7(87.5)	9(100.0)		
Chemotherapy	9(52.9)	3(37.5)	6(66.7)	.91	.34
Radiation	13(76.5)	6(75.0)	7(77.8)	.16	.69
Missing Data	1(5.9)	1(12.5)	0(0)		
Months Since Diagnosis	21.6(18.6)	20.0(22.7)	22.9(16.1)	1.58	.77

Note: Most participants underwent more than one type of treatment.

CCB: Cancer-center based physical activity counseling

AC: Attention control

Physical Activity Data

Pedometer Data

The average number of days participants wore the pedometers was 33.4 days (SD = 3.0) out of a total of 35 days. A two (group) x five (week) RM ANOVA with the average number of steps participants took each day by week as the dependent variable showed a non-significant increase in the main effect for week [F (1,60) = 2.29, p = .07] (Figure 1). The magnitude of the

differences in the average steps per day by week approached a large effect size (partial eta squared = .13). Likewise, there was not a week by group interaction [F (1,60) = 1.38, p = .25] (Figure 1). While the group interaction did not approach significance, the effect size was moderate (partial eta squared = .08). In addition, an independent samples t-test yielded a significant difference in change scores from pre-intervention to follow-up [t(15)= 2.22, p = .04] between the CCB and AC conditions, with the CCB condition having a larger change score. There was a non-significant difference from pre-intervention to post-intervention [t(15)= 1.22, p = .24] between the CCB and AC conditions (Table 3).

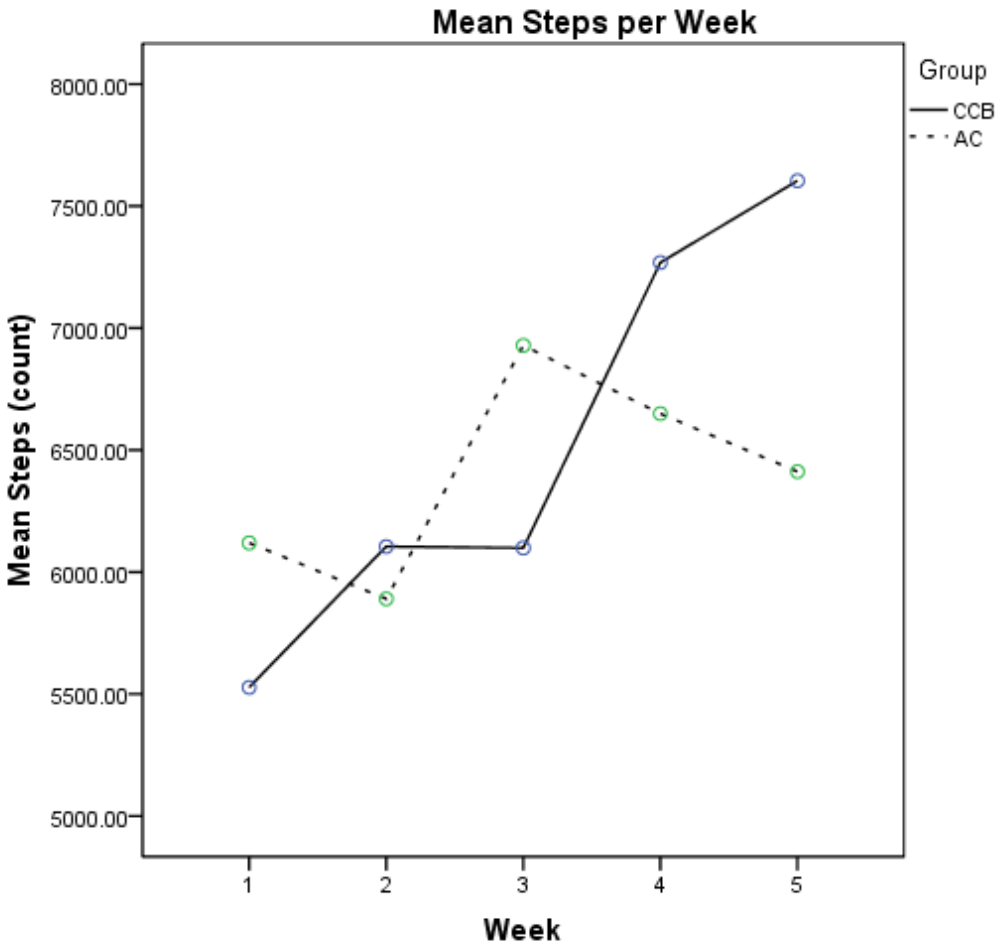
Table 3. Mean Steps per Day by Week and Group

	Week 1 M(SD)	Week 2 M(SD)	Week 3 M(SD)	Week4 M(SD)	Week 8 M(SD)	Change Scores Post - Pre / Follow-up - Post
CCB	5527.2	6104.8	6098.9	7268.8	7603.8	1741.6 / 2076.6
	(2851.4)	(2579.2)	(2130.6)	(2528.1)	(3346.7)	
AC	6119.4	5890.3	6929.3	6649.3	6411.8	529.9 / 292.4
	(3611.4)	(3364.2)	(2973.6)	(3441.7)	(3308.3)	

CCB: Cancer-center based physical activity counseling

AC: Attention control

Figure 1. Mean Steps per Week



CCB: Cancer-center based physical activity counseling

AC: Attention control

Self-Report Physical Activity

Minutes of vigorous physical activity per week were evaluated by RM ANOVA with the total number of self-reported minutes of vigorous activity as the dependent variable. A non-significant main effect was found by time [F (1,30) = .50, p = .61]. The magnitude of the differences in the average vigorous minutes per week was small (partial eta squared = .03) (Table 4). There was also a non-significant interaction between groups [F (1,30) = .09, p = .92] with a

small effect size (partial eta squared = .006) (Table 4). Further analysis of an independent samples t-test yielded a non-significant difference in change scores from pre-intervention to follow-up [t(15) = -.285, p = .78] and pre-intervention to post-intervention [t(15) = .20, p = .84] between the CCB and AC conditions (Table 4).

Table 4 shows the results of self-reported moderate minutes by group. Moderate minutes per week were evaluated by RM ANOVA with the total number of self-reported minutes of moderate activity as the dependent variable. A significant main effect was found by time point [F (1,30) = 4.16, p = .03]. The effect size of the magnitude of the differences in the average moderate minutes per week was large (partial eta squared = .22).There was a non-significant interaction between groups [F (1,30) = 1.42, p = .26], with a moderate effect size (partial eta squared = .09). Further analysis of an independent samples t-test yielded a non-significant difference in change scores from pre-intervention to follow-up [t(15) = 1.30, p = .21] and pre-intervention to post-intervention [t(15) = 1.28, p = .22] between the CCB and AC conditions.

Table 4 shows the summary of self-reported walking data.The amount of self-report minutes spent walking per week was evaluated by RM ANOVA with the total number of self-reported minutes of walking as the dependent variable. A non-significant main effect was found by time point [F (1,30) = 1.51, p = .24] with a moderate effect size (partial eta squared = .09). There was also a non-significant interaction between groups [F (1,30) = .37, p = .70] with a small effect size (partial eta squared = .02). In addition, an independent samples t-test yielded a non-significant difference in change scores from pre-intervention to follow-up [t(15) = .41, p = .69] and pre-intervention to post-intervention [t(15) = -.51, p = .62] between the CCB and AC conditions.

Moderate-to-vigorous minutes per week were evaluated with the total number of self-reported minutes of vigorous-to-moderate activity as the dependent variable. A significant main effect was found by time [F (1,30) = 3.57, p = .04] (Table 3). The effect size of the magnitude of the differences in the average vigorous-to-moderate minutes per week was large (partial eta squared = .19). There was a non-significant interaction between groups [F (1,30) = .77, p = .47] with a small-to-moderate effect size (partial eta squared = .05). In addition, an independent samples t-test yielded a non-significant difference in change scores from pre-intervention to follow-up [t(15) = .64, p = .53] and pre-intervention to post-intervention [t(15) = 1.22, p = .24] between the CCB and AC conditions (Table 4).

Table 4. Self-Reported Vigorous, Moderate, Walking, and Moderate-to-Vigorous Minutes by Group

	Pre-Intervention M(SD)	Post-Intervention M(SD)	Follow-Up M(SD)	Change Score Post - Pre / Follow-up - Post
Vigorous Min/Wk				
CCB	56.3 (126.7)	97.5 (120.8)	92.8 (147.0)	41.2 / 36.5
AC	105 (130.8)	130.0 (150.0)	166.7 (289.0)	25 / 61.7
Moderate Min/Wk				
CCB	57.5(124.1)	278.8(576.1)	446.3(721.0)	221.3 / 388.8
AC	71.1(145.9)	93.3(127.7)	177.8(272.8)	22.2 / 106.7
Walking Min/Wk				
CCB	258.1(429.6)	187.5(288.1)	573.1(695.8)	-70.6 / 315.0
AC	175.6(264.4)	230.6(399.4)	339.4(676.6)	55 / 163.8
Vig-Mod Min/Wk				
CCB	115.0(163.9)	376.3(551.0)	539.1(751.2)	261.3 / 424.1
AC	176.1(255.3)	223.3(230.0)	344.4(530.5)	47.2 / 168.3

CCB: Cancer-center based physical activity counseling

AC: Attention control

*p<.05 denotes a significant finding

Quality of Life Data

FACT-B Data

Two (group) by three (time) RM ANOVAs were conducted for the FACT-B and its subscales: physical well-being, social well-being, emotional well-being, functional well-being, and additional concerns. For the FACT-B, a non-significant main effect was found for time [F

(1,30) = 1.29, p = .29] (Table 5). The magnitude of the differences in the average total FACT-B score from pre-intervention to follow-up was moderate (partial eta squared = .08). There was also a non-significant interaction between groups [F (1,30) = 1.02, p = .37] with a moderate effect size (partial eta squared = .06). In addition, an independent samples t-test yielded a non-significant difference in change scores from pre-intervention to follow-up [t(15) = -.56, p = .58] and pre-intervention to post-intervention [t(15) = -1.43, p = .17] between the CCB and AC conditions (Table 5).

For physical well-being, a non-significant main effect was found by time point [F (1,30) = 2.95, p = .07], with a large effect size (partial eta squared = .16). There was also a non-significant interaction between groups [F (1,30) = 2.79, p = .08] but a large effect size (partial eta squared = .16). Further analysis of an independent samples t-test yielded a non-significant difference in change scores from pre-intervention to follow-up [t(15) = -.56, p = .58] and approached significance from pre-intervention to post-intervention [t(15) = -1.98, p = .07] between the CCB and AC conditions (Table 5).

For social well-being, a non-significant main effect was found by time [F (1,30) = 2.55, p = .10] with a large effect size (partial eta squared = .15). There was also a non-significant interaction between groups [F (1,30) = 1.04, p = .37] with a moderate effect size (partial eta squared = .07). In addition, an independent samples t-test yielded a non-significant difference in change scores from pre-intervention to follow-up [t(15) = -.26, p = .80] and pre-intervention to post-intervention [t(15) = -1.15, p = .27] between the CCB and AC conditions (Table 5).

A non-significant main effect was found for emotional well-being across time [F (1,30) = .259, p = .77] with a small effect size (partial eta squared = .02). There was also a non-significant

interaction between groups [F (1,30) = .645, p = .53] also with a small effect (partial eta squared = .04). Further analysis of an independent samples t-test yielded a non-significant difference in change scores from pre-intervention to follow-up [t(15) = -.84, p = .41] and pre-intervention to post-intervention [t(15) = -.04, p = .97] between the CCB and AC conditions (Table 5).

For functional well-being, a non-significant main effect was found by time [F (1,30) = .220, p = .80] with a small effect size (partial eta squared = .01). There was also a non-significant interaction between groups [F (1,30) = .645, p = .53] with a small effect (partial eta squared = .04). In addition, an independent samples t-test yielded a non-significant difference in change scores from pre-intervention to follow-up [t(15) = -.62, p = .55] and pre-intervention to post-intervention [t(15) = -1.07, p = .30] between the CCB and AC conditions (Table 5).

A non-significant main effect was found for the Additional concerns subscale over time [F (1,30) = .935, p = .40]. The magnitude of the differences in the average additional concerns score was moderate (partial eta squared = .06). There was also a non-significant interaction between groups [F (1,30) = .332, p = .72] with a small effect size (partial eta squared = .01). Further analysis of an independent samples t-test yielded a non-significant difference in change scores from pre-intervention to follow-up [t(15) = .68, p = .51] and pre-intervention to post-intervention [t(15) = .70, p = .50] between the CCB and AC conditions (Table 5).

Table 5. Mean Scores for Overall FACT-B and Subscales by Group

	Pre-Intervention M(SD)	Post-Intervention M(SD)	Follow-Up M(SD)	Change Scores Post - Pre / Follow-up - Post
Overall FACT-B				
Overall	112.9(18.1)	110.5(17.1)	112.5(18.5)	

CCB	116.8(14.0)	111.9(14.0)	115.4(14.5)	-4.9 / -1.4
AC	109.3(21.3)	109.2(20.3)	110.0(22.0)	-0.1 / 0.7
Physical				
Overall	22.0(4.3)	22.5(4.4)	23.5(4.4)	
CCB	23.0(2.9)	22.0(4.3)	24.0(3.2)	-1.0 / 1.0
AC	21.1(5.3)	23.0(4.7)	23.1(5.5)	1.9 / 2.0
Social				
Overall	22.0(2.7)	20.9(3.1)	21.3(2.7)	
CCB	22.2(2.3)	20.4(3.5)	21.4(2.6)	-1.8 / -0.8
AC	21.8(3.19)	21.3(2.8)	21.2(2.9)	-0.5 / -0.6
Emotional				
Overall	19.7(3.3)	19.4(3.7)	19.4(4.3)	
CCB	20.0(4.4)	19.6(4.7)	19.1(5.7)	-0.4 / -0.9
AC	19.4(2.1)	19.1(2.8)	19.7(2.9)	-0.3 / 0.3
Functional				
Overall	22.9(4.3)	22.5(3.5)	22.7(4.7)	
CCB	23.5(3.7)	22.3(1.9)	22.9(4.5)	-1.2 / -0.6
AC	22.3(5.0)	22.7(4.6)	22.6(5.1)	0.4 / 0.3
Additional Concerns				
Overall	26.3(7.6)	25.2(8.1)	25.6(7.8)	
CCB	28.1(4.3)	27.6(5.5)	28.0(4.5)	-0.5 / -0.1
AC	24.7(9.6)	23.1(9.6)	23.4(9.6)	-1.6 / -1.3

CCB: Cancer-center based physical activity counseling

AC: Attention control

CHAPTER 5: DISCUSSION

Findings

Minimal research has evaluated whether physical activity counseling interventions are effective in increasing physical activity and improving quality of life in breast cancer survivors. This particular study implemented a cancer center based intervention lasting four weeks that included motivational interviewing, self-monitoring using a pedometer, and a physical activity manual specific to breast cancer survivors. Results from this study suggest that while significant differences between the CCB condition and the AC condition were not found in the results of the RM ANOVAs, effect sizes were moderate to large in favor of positive changes in some of the physical activity indices. Moreover, significant differences were found in change scores for pedometer steps in favor of the CCB condition compared to the AC condition. There were no improvements in the overall FACT-B scores or its subscales within all participants or by group based on the RM ANOVAs and change score analyses, and the clinically important difference guidelines per Eton et al. (2004). Thus, the findings of this study partially met the hypotheses that the CCB condition would show greater improvements in (a) quality of life indicated by higher scores on the FACT-B questionnaire and (b) physical activity levels compared to the AC condition.

Effects on Physical Activity

Significant Change Scores for Pedometer Steps and Self-Report Physical Activity

Significant differences in changes scores for pedometer steps pre-intervention to follow-up were in favor of the CCB condition. This is different from the findings of Vallance et al.

(2007), who reported significant improvements in self-reported moderate-to-vigorous activity, but no significant improvements in step counts. Motivational interviewing and weekly contact with the participants of the CCB condition are the likely cause of the difference in results from the intervention implemented by Vallance et al. (2007), whose participants were given the same package of print materials tailored of breast cancer survivors.

Of the remaining studies to incorporate pedometers in their intervention (Ligibel, 2010; Pinto, 2005), neither reported pedometer data as part of their results. Like Vallance et al. (2007), Bennett et al. (2007) also found significant differences in self-report physical activity as assessed by the CHAMPS Physical Activity Questionnaire, but found no significant improvements in objectively measured aerobic fitness. In addition to significant improvements in pedometer change scores, a significant main effect for self-reported moderate and moderate-to-vigorous physical activity was found in both the CCB and AC conditions. It is speculated that these results may be due to both groups of participants perceiving that they were receiving an intervention; therefore a social-desirability bias and over-reporting of physical activity may have taken place, which has shown to be common and a major limitation in self-report measures (Sallis, 2000).

Significant Differences in Change Scores at Follow-up

The major findings of this study suggest that the CCB condition did have an impact on increasing physical activity in breast cancer survivors at follow-up better than the AC condition. While both groups significantly improved in self-report physical activity, only the CCB condition significantly improved in objectively measured physical activity from pre-intervention to follow-up. It is suggested by literature that wearing pedometers may increase motivation for achieving more steps in a day (Bassett, 2000), however, these findings seem to suggest that the

participants in the CCB condition were better able to maintain their improvements in pedometer steps because of the skills they had acquired due to the intervention, and not due to the effects of wearing a pedometer. Most studies only look at changes in physical activity and do not look at maintenance of physical activity, which is a strength of this study. However, Wilcox et al. (2009) conducted a similar counseling intervention that included behavior change strategies in which participants were able to maintain their physical activity six months post-intervention. Thus, behavior change strategies like those implemented in this study (i.e., goal setting, overcoming barriers, and relapse prevention) are beneficial skills for the maintenance of physical activity compared to simply providing a physical activity manual.

No Changes in Vigorous Activity

There were no significant differences in self-reported vigorous activity for either the CCB or AC conditions in this study. Of those aforementioned studies that incorporated self-report physical activity measures, only Pinto et al. (2005) reported findings for self-report vigorous physical activity. The findings of Pinto et al. (2005) report significant results in "hard-to-very hard intensity exercise", which was assessed with the Seven-Day Physical Activity Recall. Our findings may be due to a focus on participating in moderate activities, especially walking, and increasing one's daily steps. Moderate activities were described as movement that takes moderate physical effort and makes one breathe somewhat harder than normal, and one is able to talk comfortably. Although Pinto et al. (2005) also reports that their program focused on moderate activities, their participants were taught to monitor their heart rates and they were prescribed a range of 55% to 65% of maximum heart rate. This may have resulted in higher reported levels of "hard-to-very hard intensity exercise" based on their perception of how hard

they felt they were exercising and may have also motivated them to work at more vigorous levels. Thus it is not surprising that there were no significant changes in vigorous intensity physical activity in the present study.

No Changes in Walking Activity

There were also no significant differences in self-reported walking for either the CCB or AC conditions in this study, which does not mirror the significant differences in change scores for step counts from pre-intervention to follow-up in the CCB condition. Reliability and validity of the IPAQ in assessing walking has been assessed with data from nine countries. Test-retest reliability correlations of the IPAQ walking question had moderate to high reliability (0.69 to 0.91), however, the validity correlations as compared with an accelerometer was relatively poor (0.18 to 0.39) (Van der Ploeg, 2010). These findings by Van der Ploeg et al. (2010) suggests that the IPAQ was not a sufficient method of measuring self-reported walking and may explain why changes in self-reported walking did not mirror changes in pedometer step counts.

Effects on Quality of Life

Physical activity interventions have been shown to increase quality of life in breast cancer survivors (Pinto, 2005; Vallance, 2007; Ligibel, 2010), however, there were no significant improvements found in overall FACT-B scores and its subscales in all participants, by group, or by change scores in this study. Although moderate-to-large effect sizes were observed, the differences in these scores were not clinically important per the guidelines by Eton et al. (2004), which are a seven to eight point difference in the overall score (D. Cella, Eton, Lai, Peterman, & Merkel, 2002; D. Cella, Hahn, & Dineen, 2002; Eton, 2004)..

Although normative data on the FACT-B scale has not been published, normative data on the FACT-G scale (Functional Assessment of Cancer Therapy-General) indicates that the participants in this study are similar to their peer cancer survivors in the general population and fall in the 90th percentile for overall quality of life (Holzner, 2004). Participants in this study also had similar baseline FACT-B scores to that of Rogers et al. (2009), who reported "relative high quality of life scores at baseline" in their participants, which may suggest a ceiling effect in the results of this study (Rogers, 2009; Linden, 2007). Thus, since study participants reported fairly high quality of life at baseline, they may not have had much room for improvement.

Although the literature on the topic is sparse, it is possible that longer interventions are required to see changes in quality of life. A more intense intervention may have generated significant differences in quality of life, which might include a longer intervention with more frequent counseling with the participants (Bennett, 2007). This particular study included an intervention lasting four weeks, which may not have been long enough to produce any effects (Valenti, 2008). In comparison with other studies that successfully resulted in significant differences in quality of life, the interventions were much longer and lasted twelve weeks (Ligibel, 2010; Pinto, 2005; Vallance, 2007).

Limitations

There are several limitations that could be improved upon for future implementation of cancer center based interventions similar to this one. Several barriers arose that impacted the recruitment of participants for this study. Resignations of some of the oncologists at the cancer center resulted in a lack of support of the study. The oncologists would typically introduce the prospective participant to the researcher following their appointment so that the prospective

participant may be more receptive and comfortable with the researcher at the time of recruitment. In addition, during the months after the oncologists resigned, patients were not attending their appointments at the cancer center and thus recruitment was a slow process.

Given a longer time frame, more subjects should be recruited and complete the intervention through the follow-up phase. This study included twenty participants, while other studies similar to this one included a range from forty-one to 641 participants (Rogers, 2009; Morey, 2009; Ligibel, 2010). The small sample may have resulted in the lack of findings since some analyses approached significance, but did not reach it.

Like Morey et al. (2009), the participants recruited to this study were mostly highly educated, high income, and primarily Caucasian women, and not representative of the general population of cancer survivors. With more participants recruited, a higher number of African American participants should be included given the high percentage of African Americans in the area (34.1% of the population in Pitt County) (U.S. Census Bureau, 2011). However, barriers in recruiting African Americans are not uncommon. Study design and distrust of researchers are among the most prevalent barriers to recruiting African Americans and other minority individuals (Yancey, 2006). Minorities are less likely to participate in a study design that includes interventions as compared with an observational study design. Randomization of participants is also viewed negatively by minority participants (Yancey, 2006). Distrust of the researchers is a significant barrier to recruiting minorities, especially among African Americans (Yancey, 2006). Research has shown that as much as 32% of African American women reported a lack of trust in researchers as compared with 4.1% in Caucasian women (Kelley, 2011). African Americans have also reported significantly more cultural beliefs that discourage seeking

care, as well as a lack of knowledge about the seriousness of breast cancer (Kelley, 2011). Thus, future efforts should recognize barriers in recruiting African Americans and strategies to overcome these barriers in order to recruit more African Americans for breast cancer research.

Lastly, this four-week intervention was much shorter than other similar interventions, which ranged from as little as twelve weeks to one year (Morey, 2009; Pinto, 2005; Ligibel, 2010; Rogers, 2009; Vallance, 2007). A longer intervention may result in improvements in quality of life and a better chance in increasing and maintaining physical activity, as seen in interventions conducted by Pinto et al. (2005), Vallance et al. (2007) and Ligibel et al. (2010).

Conclusion

In conclusion, this study demonstrates that breast cancer survivors participating in a four-week cancer center based physical activity counseling intervention post-treatment increased self-report moderate and moderate-to-vigorous physical activity, as well as maintained quality of life scores as assessed by the FACT-B in both conditions. Participants in the CCB condition had significant differences in change scores in pedometer steps from pre-intervention to follow-up as compared with the AC condition. Thus, the results of this study partially support the hypothesis that those in the CCB condition would show greater improvements in their physical activity, but not in quality of life. Future efforts should include larger sample size that better represents the general population of breast cancer survivors and a longer intervention to better determine the effectiveness of this particular intervention.

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APPENDIX A: INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

University and Medical Center Institutional Review Board
East Carolina University • Brody School of Medicine
600 Moye Boulevard • Old Health Sciences Library, Room 1L-09 • Greenville, NC 27834
Office **252-744-2914** • Fax **252-744-2284** • **www.ecu.edu/irb**
Chair and Director of Biomedical IRB: L. Wiley Nifong, MD
Chair and Director of Behavioral and Social Science IRB: Susan L. McCammon, PhD

TO: Kristina Karvinen, PhD, Department of EXSS, ECU, 173 Minges Coliseum

FROM: UMCIRB

DATE: December 29, 2009

RE: Expedited Category Research Study

TITLE: "Effectiveness of a Cancer Center Based Physical Activity Intervention"

UMCIRB #09-0887

This research study has undergone review and approval using expedited review on 12/19/09. This research study is eligible for review under an expedited category because it is research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
The Chairperson (or designee) deemed this **Research and Creative Activity Grant/ECU** sponsored study **no more than minimal risk** requiring a continuing review in **12 months**. Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The investigator must adhere to all reporting requirements for this study.

The above referenced research study has been given approval for the period of **12/19/09** to **12/18/10**. The approval includes the following items:

- Internal Processing Form
- Informed Consent (received 12/7/09)
- Grant Proposal
- Baseline questionnaire
- One month questionnaire
- Two month questionnaire

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

APPENDIX B: INFORMED CONSENT

1907-2007 CENTENNIAL

UNIVERSITY HEALTH SYSTEMS of Eastern Carolina.

East Carolina University

Informed Consent to Participate in Research

Information to consider before taking part in research that has no more than minimal risk.

Title of Research Study: Effectiveness of a cancer center based physical activity intervention.
Principal Investigator: Kristina Karvinen, PhD
Institution/Department or Division: Department of Exercise and Sport Science
Address:173 Minges Coliseum
Telephone #: 252-328-5193

Researchers at East Carolina University (ECU) study problems in society, health problems, environmental problems, behavior problems and the human condition. Our goal is to try to find ways to improve the lives of you and others. To do this, we need the help of people who are willing to take part in research.

The person who is in charge of this research is called the Principal Investigator. The Principal Investigator may have other research staff members who will perform some of the procedures. The person explaining the research to you may be someone other than the Principal Investigator. Qualified research assistants may be asking you to take part in this study.

You may have questions that this form does not answer. If you do, feel free to ask the person explaining the study, as you go along. You may have questions later and you should ask those questions, as you think of them. There is no time limit for asking questions about this research.

You do not have to take part in this research. Take your time and think about the information that is provided. If you want, have a friend or family member go over this form with you before you decide. It is up to you. If you choose to be in the study, then you should sign the form when you are comfortable that you understand the information provided. If you do not want to take part in the study, you should not sign this form. That decision is yours and it is okay to decide not to volunteer.

Why is this research being done?
The purpose of this research is to find out what kind of strategy is best for helping breast cancer survivors become more active. The decision to take part in this research is yours to make. By doing this research, we hope to learn what is the best strategy for helping breast cancer survivors become more active.

Why am I being invited to take part in this research?
You are being invited to take part in this research because you have been diagnosed with breast cancer in the past five years. If you volunteer to take part in this research, you will be one of about 50 people to do so.

Are there reasons I should not take part in this research?
I understand that I should not volunteer for this study if I am under 18 years of age.

UMCIRB
APPROVED
FROM 8-3-10
TO 12-18-10

What other choices do I have if I do not take part in this research?
You have the choice of not taking part in this research study.

Where is the research going to take place and how long will it last?
The research procedures will be conducted at Leo Jenkins Cancer Center or 21st Century Oncology. You will be asked to remain at Leo Jenkins Cancer Center or 21st Century Oncology after your regularly scheduled appointment today. This is the only time you will be required to meet with the researchers of this study. The visit today will take about 30 minutes if you are randomly selected for the print materials group and 60 minutes if you are randomly selected for the face to face group. You will also be telephoned at home on a weekly basis. Each telephone call will last approximately 10 to 15 minutes. The total amount of time you will be asked to volunteer for this study is 2-3 hours over the next month.

What will I be asked to do?
You are being asked to do the following:

- Meet with an exercise specialist at Leo Jenkins Cancer Center or 21st Century Oncology after your regularly scheduled appointment. At the meeting you will complete a questionnaire asking you about your current physical activity level, thoughts about physical activity and quality of life. You will also have your height and weight taken. Afterwards you will be randomly assigned to either a "Print Materials" group or a "Face to Face" group.
    - If assigned to the "Print Materials" group you will be given an exercise manual, pedometer and the physical activity logs.
    - If assigned to the "Face to Face" group you will be give approximately 30 minutes of face-to-face physical activity counseling by the exercise specialist. You will also receive an exercise manual, pedometer and physical activity logs.
- Wear a pedometer (step counter) every day for one month. At the end of each day you will be asked to record the number of steps you took that day. You will be asked to mail your logs back to the researchers every week.
- Receive a weekly telephone call from an exercise specialist providing study related support.
- Complete a questionnaire at the end of the study (one month after your meeting at Leo Jenkins Cancer Center or 21st Century Oncology). The questionnaire will ask you about your current physical activity level, thoughts about physical activity and quality of life. You will be asked to mail the questionnaire back to the researchers.
- Wear the pedometer again for one week one month after the study has ended (two months after your meeting at Leo Jenkins Cancer Center or 21st Century Oncology). You will be asked to record the number of steps you took in a log. You will also be asked to complete a questionnaire asking you about your current physical activity levels, thoughts about physical activity and quality of life. You will be asked to mail the questionnaire and log back to the researchers.

What possible harms or discomforts might I experience if I take part in the research?
There are always risks (the chance of harm) when taking part in research. It has been determined that the risks associated with this research are no more than what you would experience in a normal life. However, some people react to things differently so it is important for you to tell us as quickly as possible if you experience any negative feelings, or feel sick.

Are there any reasons you might take me out of the research?
During the study, information about this research may become available that would be important to you. This includes information that, once learned, might cause you to change your mind about wanting to be in the study. We will tell you as soon as we can.

There may be reasons we will need to take you out of the study, even if you want to stay in. We may find that you are not or cannot keep sending us your logs and doing the questionnaires as scheduled. If this is found to be true, we will need to take you out of the study.

What are the possible benefits I may experience from taking part in this research?
Other people who have participated in this type of research have experienced increased physical activity and sometimes quality of life. By participating in this research study, you may also experience these benefits.

Will I be paid for taking part in this research?
A pedometer and guidebook will be provided by the study with no cost to you and will be yours to keep after the study has ended.

What will it cost me to take part in this research?
It will not cost you any money to be part of the research. The sponsor of this research will pay the costs of:

- **Physical activity counseling**
- **Pedometers**
- **Physical activity guidebooks**
- **Postage**

Who will know that I took part in this research and learn personal information about me?
To do this research, ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- Any agency of the federal, state, or local government that regulates human research. This includes the Department of Health and Human Services (DHHS), the National Cancer Institute, the North Carolina Department of Health, and the Office for Human Research Protections
- The University & Medical Center Institutional Review Board (UMCIRB) and its staff, who have responsibility for overseeing your welfare during this research, and other ECU staff who oversee this research.
- People designated by PCMH and University Health System;

How will you keep the information you collect about me secure? How long will you keep it?
All information about you will be kept in a locked filing cabinet in the locked office of the Principal Investigator or qualified research assistant. All electronic files will be stored in a secured computer in the Principal Investigator's office or in the research assistant's office. Hard copies of your information will be shredded after 5 years. Computer files with your information will be deleted after 5 years.

What if I decide I do not want to continue in this research?
If you decide you no longer want to be in this research after it has already started, you may stop at any time. You will not be penalized or criticized for stopping. You will not lose any benefits that you should normally receive.

What if I get sick or hurt while I am in this research?
This study does not involve any risk greater than what you experience in everyday life. Therefore, we do not expect you to become sick or hurt as a result of being part of this research. However, people respond differently to things and sometimes accidents do happen. Therefore, if you need emergency care call 911 for help. If possible, take a copy of this consent form with you when you go.

Call the principal investigator as soon as you can. He/she needs to know that you are hurt or ill. Call Dr. Kristina Karvinen at 252-328-5193 or Dr Katrina DuBose at 252-328-1599.

If you believe you have been hurt or if you get sick because of something that is done during the study, you should call Dr. Kristina Karvinen at 252-328-5193 immediately. There are procedures in place to help provide care for you. Costs associated with this care will be billed in the ordinary manner, to you or your insurance company. However, some insurance companies will not pay bills that are related to research costs. You should check with your insurance about this. Costs that result from research-related harm may also not qualify for payments through Medicare, or Medicaid. You should talk to the Principal Investigator about this, if you have concerns.

Who should I contact if I have questions?
The people conducting this study will be available to answer any questions concerning this research, now or in the future. You may contact the Principal Investigator at 252-328-5193 (days, between 9am and 5pm).

If you have questions about your rights as someone taking part in research, you may call the UMCIRB Office at phone number 252-744-2914 (days, 8:00 am-5:00 pm). If you would like to report a complaint or concern about this research study, you may call the Director of UMCIRB Office, at 252-744-1971.

I have decided I want to take part in this research. What should I do now?
The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I understand that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

Participant's Name (PRINT)	**Signature**	**Date**

Person Obtaining Informed Consent: I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above, and answered all of the person's questions about the research.

Person Obtaining Consent (PRINT)	**Signature**	**Date**