Determining the Effectiveness of the Cancer Phase Training Model in a Group Setting

Scott F. Eberhardt

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UNIVERSITY OF NORTHERN COLORADO

Greeley, Colorado

The Graduate School

DETERMINING THE EFFECTIVENESS OF THE CANCER PHASE TRAINING MODEL IN A GROUP SETTING

A Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Science

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ABSTRACT

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The role of exercise as a primary therapy has been well documented and has the capacity to act across multiple body systems to attenuate cancer-related toxicities. To date, the Cancer Phase Training Model is the only cancer rehabilitation intervention that includes recommended modes, intensity, frequency, and duration of exercise for cancer survivors. The one-on-one model has been shown to be the most effective method of cancer rehabilitation; however the largest perceived limitation of this model is the expense of the program and its lack of scalability. By creating a structured cancer-specific group model that can produce similar results to the one-on-one model, we can provide a feasible alternative rehabilitation program for cancer survivors. Purpose: To evaluate the effects of the Cancer Phase Training Model in a group setting, on cardiorespiratory endurance, muscular strength, and cancer related fatigue in cancer survivors. Methods: A total of 14 cancer survivors participated in the group model, with 12 participants completing the group model. The frequency of training was prescribed as two sessions per week for 12 weeks. The duration of each exercise session was 60 minutes with 20 minutes designated for cardiovascular exercise, 30 minutes for resistance exercise, 10 minutes for flexibility training, and with balance exercises incorporated throughout the entire session. Participants in the Group Model had a designated time in which they could exercise under the direct supervision of a Cancer
Exercise Specialist. Changes in peak volume of oxygen consumption (VO$_{2peak}$), muscular strength, and Cancer-Related Fatigue were observed once the 12 week intervention was completed. Percent change in VO$_{2peak}$, muscular strength, and fatigue from data collected in the Individual Phase Training Model were compared to the data collected in the Group Phase Training Model. **Results:** After completing a 12-week intervention in the Group Model, significant improvements (p<0.05) were observed in VO$_{2peak}$, leg press muscular strength (MS), chest press MS, seated row MS, and shoulder press MS, and fatigue. Although the GM was a pilot study and had a lower number of participants, similar results between GM and the IM Phase Training Model were observed in all variables. Participants completing the IM model resulted in an average 11% increase in VO$_{2peak}$, while the GM resulted in an average 9% increase. Participant’s leg press strength increased by an average of 9% in the IM compared to an average 10% increase in the GM. Participant’s chest press strength increased by an average of 16% in the IM, in comparison to an average 16% increase in the GM. The mean percent change in fatigue for participants completing the IM as a 21% decrease, while the GM experienced a 36% decrease in fatigue. **Conclusion:** This pilot study demonstrates that the Phase Training Model protocol can be safely and effectively administrated in a group setting. By offering the Phase Training Program in a group model, healthcare professionals can have a greater impact by providing services to more cancer survivors without placing the financial burden on the survivor or the program provider. By demonstrating its diversity, the Phase Training Model should be considered as a standard of care in the clinical cancer rehabilitation setting considering its success in both the group and individual model.
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CHAPTER I

INTRODUCTION

There are over 15 million cancer survivors in the United States today, with approximately 20 million survivors expected by 2026 (Miller et al., 2016). This increase in survival rate is attributed to improvements in early detection of cancer along with the advancement in cancer treatment. With an increase in survival rate, more cancer survivors are suffering from side-effects as a result of radiation, chemotherapy, and surgery. Although cancer treatments are effective in eliminating cancer, they lead to debilitating side effects in up to 96% of cancer survivors (Schneider, Dennehy, Roozeboom, & Carter, 2002). The toxicities from cancer treatment have detrimental side effects on physiological and psychological aspects of the cancer survivor’s life.

The negative physiological side effects from treatment affect the cardiovascular, immune, pulmonary, gastrointestinal, neuroendocrine, hepatic and musculoskeletal systems (Schneider et al., 2002). The debilitating physiological side effects have a significant impact on the negative psychological side effects, which include increased fatigue and depression, and a decrease in quality of life (QOL). The role of exercise as a primary therapy has been well documented and has the capacity to act across multiple body systems to attenuate cancer related toxicities (Schmitz et al., 2010; Schneider et al., 2002). Exercise training-induced improvements can be expected regarding aerobic
fitness, muscular strength, QOL, and fatigue in survivors with many types of cancer (Schmitz et al., 2010).

The beginning of cancer rehabilitation can be traced back to the National Cancer Act of 1971, which involved a multidisciplinary team of providers, including physiatrists, social workers, physical therapists and other medical personnel (Alfano, Ganz, Rowland, & Hahn, 2012; DeLisa, 2001). Today, cancer survivors are spending less time recovering in the hospital setting making these multidisciplinary services unnecessary for cancer rehabilitation. Recent research has demonstrated that a one-dimensional approach using exercise-based rehabilitation can affect the majority of the disabilities suffered by cancer survivors (Schneider, Dennehy, & Carter, 2003). The American College of Sports Medicine (ACSM) suggests that cancer survivors engage in 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity exercise per week and should avoid inactivity. Adding that prescriptive exercise should be individualized according to a cancer’s survivor’s aerobic fitness, medical co-morbidities, response to treatment, and negative side effects of treatment that are experienced at any given time (Schmitz et al., 2010). To date, the Cancer Phase Training Model introduced by Brown (2016) is the only established, structured, individualized model for cancer rehabilitation that includes mode, intensity, frequency and duration for cancer survivors throughout the cancer continuum.

Although group and one-on-one model have been reported to be safe and effective models for cancer rehabilitation (Dittus et al., 2015; Brown, 2016), current research is lacking in providing a consistent structure for a cancer-specific group model. Research shows that there are many benefits for cancer survivors working within a group,
including decreasing the financial burden and positively influencing the outcome results of a program offered (May et al., 2008, Midtgaard et al., 2005). The one-on-one model has been shown to be the most effective method of cancer rehabilitation; however the largest perceived limitation of this model is the expense of the program, not making it feasible to offer to the masses. By creating a structured cancer-specific group model that can produce similar results to the one-on-one model, we can provide a feasible alternative rehabilitation program for cancer survivors.

**Statement of Purpose**

The purpose of this study was to determine if the UNCCRI Phase Program was more effective in a group model setting or in a one-on-one setting. Effectiveness was evaluated by determining changes in cardiorespiratory endurance, muscular strength, and cancer-related fatigue. Establishing a cancer rehabilitation model that can be administrated in an individual and group setting could provide adaptability for clinics and hospitals administrating a cancer rehabilitation program. By creating a structured cancer-specific group model that can produce results similar to the one-on-one model, a feasible rehabilitation program for the large number of cancer survivors could be provided. It was hypothesized that the Cancer Phase Training Rehabilitation Program is more effective with a one-on-one model when compared to a group model.
CHAPTER II
REVIEW OF LITERATURE

Introduction

Cancer is a disease characterized by the uncontrolled growth and spread of abnormal cells, affecting any organ or body part. This disease is the leading cause of death in 22 states and second most common cause of death in the United States (US), exceeded only by heart disease, and accounts for nearly 1 of every 4 deaths (Siegel, Miller, & Jemal, 2016). The American Cancer Society (ACS) estimates that over 1.5 million new cancer cases are expected to be diagnosed in 2016, with nearly 600,000 people expected to die of cancer in 2016 (Siegel, Miller, & Jemal, 2016). The most common types of cancer are prostate cancer among men and breast cancer among women. Although the 2016 diagnostics number is higher than ever before, cancer survival rates continue to increase each year. The 5-year survival rate for all cancers diagnosed during 2005-2011 was 69%, which is up 20% from the 49% survival rate during 1975-1977 (Siegel, Miller, & Jemal, 2016). There are over 15.5 million cancer survivors in the US today; with 18 million survivors expected by 2022 (Miller et al., 2016). This increase in survival rate is attributed to the increase in early detection of cancer along with advancements in cancer treatment.

With an increase in survival rate, more cancer survivors are suffering from toxicities as a result from treatments such as radiation, chemotherapy, and surgery. Although cancer treatments are effective in eliminating cancer, they lead to debilitating
side effects in up to 96% of cancer survivors (Schneider et al., 2002). The toxicities from cancer treatment have harsh side effects on physiological and psychological aspects of the cancer patient’s life. The negative physiological side effects from treatment affect the cardiovascular, immune, pulmonary, gastrointestinal, neuroendocrine, hepatic and musculoskeletal systems (Schneider et al., 2002). The debilitating physiological side effects have a large influence on the psychological side effects, which include increased fatigue, increased depression, and a decrease in quality of life (QOL). Although there are specific risks associated with cancer treatment that need to be considered when cancer survivors exercise, there is dependable evidence that exercise is safe during and after treatment (Schmitz et al., 2010). Due to this, millions of cancer survivors in the US today can benefit from a structured exercise program administered by a trained Cancer Exercise Specialist. As the cancer rehabilitation field continues to grow, hospitals and outpatient clinics are beginning to establish different types of exercise interventions including, home-based exercise, group-based exercise, and one-on-one-based exercise interventions. To date there is only one exercise intervention that is specifically designed with precise prescriptive exercise involving all the basic principles of exercise and standardization of exercise-based model for cancer patients, which is known as the Cancer Phase Training Model (Brown, 2016).

**Cancer Treatments**

The most common treatments for cancer are chemotherapy, radiation, hormonal treatment, and surgery. Alternative treatments involve immunotherapy, hyperthermia and stem cell transplant (Siegel, Miller, & Jemal, 2016). The advancement in cancer treatments is one of the crucial contributors to the increased survivorship of cancer
patients. Cancer treatments can be used independently, but are often used in conjunction with one another to help increase the chances of treating cancer.

Chemotherapy is the administration of antitumor drugs that destroy malignant tumor cells. The goal of chemotherapy is to destroy tumor cells and minimize the destruction of normal cells while limiting the disruption of normal cell function. Chemotherapy is usually administrated orally in pill, capsule, or liquid form, or via vein or artery infusion, having an effect on the entire body. The antineoplastic effects of chemotherapy are most pronounced in cells during the proliferation phases of the cell cycle. Because cancer cells proliferate faster than normal cells, chemotherapy drugs destroy a higher percentage of cancer cells than normal cells (Schneider, Dennehy, & Carter, 2003). There are different classifications of chemotherapy that attack cancer cells differently. The classes of chemotherapy include alkylating agents, antimetabolites, antitumor antibiotics, and alkaloids (Greenhalgh & Symonds, 2014).

Radiation therapy uses high-energy X-rays, electron beams, or radioactive isotopes to damage and destroy malignant cancer cells (Schneider et al., 2003). Unfortunately, like chemotherapy, radiation cannot differentiate between normal cells and cancer cells, negatively affecting both cancerous and normal cells that come in contact with the radiation. The response to radiation in normal and cancer cells depends on the rate of cell proliferation (Kerr, Winterford, & Harmon, 1994). The two most common types of radiation therapy used are internal and external radiation. External radiation aims beams of radiation from a source outside the body at the targeted tissue within the body; while internal radiation places radioactive isotopes near the tumor within
the body (Greenhalgh & Symonds, 2014). The main use of radiation is to target small areas of the body and would not be used for metastasizing cancers (Kerr et al., 1994).

Surgery can be a safe and effective method of removing cancer in patients with solid tumors that are confined to one tissue of organ (Schneider et al., 2003). Not only can surgery be effective in removing cancer but is also used for prevention and diagnosis of cancer. Surgical treatment aims to remove the cancerous tumor cells and some surrounding healthy tissue while causing minimal injury to normal functioning of the affected area (Schneider et al., 2003).

**Treatment Side Effects**

The adverse effects of cancer treatment may be immediate, resolving during a period of days or weeks, or may be persistent, lasting years after the completion of treatment (Schmitz et al., 2010). Treatment side effects are patient-dependent, meaning that even though two different patients may have the same diagnosis and treatment, their side effects to can differ greatly. The impact of cancer treatment is not limited to cancer cells but also causes deleterious effects on healthy tissues that result in physiological and psychological negative side effects in cancer survivors (Schneider, Hsieh, Sprod, Carter & Hayward, 2007a). The side effects from cancer treatment can affect the cardiovascular, pulmonary, immune and musculoskeletal systems, which can lead to fatigue, depression, and decreased QOL.

**Cardiovascular Toxicities**

Both chemotherapy and radiation therapy have adverse effects on the cardiovascular system. Chemotherapy directly damages cardiac myocytes, resulting in a loss of myocardial fibrils, mitochondria changes, and cellular destruction within the
cardiac tissue (Camp-Sorrel, 2006). Chemotherapy-induced cardiovascular toxicities may include cardiomyopathy with or without overt congestive heart failure, endothelial dysfunction, and arrhythmias (Carver et al., 2007). Radiation has a large effect on the cardiovascular system when external beam radiation is used on the thoracic region. Radiotherapy-induced cardiovascular toxicity may include coronary artery disease, valvular heart disease, chronic pericardial disease arrhythmias and conduction disturbances cardiomyopathy or carotid artery stenosis (Carver et al., 2007). These cardiovascular toxicities can result in left ventricular dysfunction, increased time to peak filling of the left ventricle, lower left ventricular ejection fraction, abnormal left ventricular contractility, reduced cardiac output and stoke volume, which may lead to lower oxygen and nutrient delivery (Schneider et al., 2007a). The incidence of abnormal cardiac function appears to increase with accumulation of time after treatment, and in patients with a higher total cumulative dose of chemotherapy and radiotherapy (Carver et al., 2007).

Pulmonary Toxicities

Cancer patients undergoing cancer treatment may experience acute or chronic pulmonary toxicities. Pulmonary toxicities include radiation pneumonitis, pulmonary fibrosis, and an overall decrease in pulmonary function (Carver et al., 2007). Chemotherapy causes its initial damage to endothelial cells, causing extensive alterations of the pulmonary parenchyma, with changes in the connective tissue, obliteration of alveoli, and dilation of air spaces (Camp-Sorrel, 2006). Radiation destroys the cells lining alveoli, and the alveoli become inflamed with accumulated exudative fluid (Camp-Sorrel, 2006). Patients may experience coughing, dyspnea, and a low grade fever as a
result of pulmonary toxicity (Schneider et al, 2002). These changes in pulmonary
function result in shortness of breath, decrease total lung capacity, decrease diffusion
capacity, which in turn compromises oxygen delivery and carbon dioxide removal
(Schneider et al., 2007a). These pulmonary toxicities may present as symptoms such as
fatigue, low exercise tolerance, and restlessness.

**Musculoskeletal Toxicities**

The side effects from cancer treatment have negative impacts on the muscular
system, which can be a direct effect of the cancer treatment itself along with other side
effects from treatment. Cancer and cancer treatment can induce lean tissue degradation
and abnormalities in the metabolic system in skeletal muscle, resulting in muscle wasting
and a decrease in muscular strength in cancer survivors. This loss in lean muscle occurs
due to a decline in protein synthesis in conjunction with enhanced protein catabolism
(Schneider, Hsieh, Sprod, Carter & Hayward, 2007b). The decrease in protein synthesis
and protein degradation reduces muscle mass and muscle fiber cross-sectional area, it
results in the loss of muscle extensibility, and it decreases proteins necessary for
metabolism. Cancer survivors with reduced protein synthesis and enhanced muscle
degradation experience muscle weakness, decrease functional work capacity, decreased
flexibility, and reduced mobility (Schneider et al., 2007b). Radiation has also been found
to alter the sarcolemma, sarcoplasmic reticulum, and mitochondrial membrane, leading to
the disturbances in generating muscle force. This loss of muscle force is a result of the
abnormalities in the recycling of calcium (Ca\(^{2+}\)) by the sarcoplasmic reticulum and
abnormalities in the calcium-adenosine triphosphatase (Ca\(^{2+}\)-ATPase) system (Schneider
et al., 2002).
**Fatigue**

Fatigue is recognized as the most pervasive and debilitating adverse effect in cancer survivors (Hofman, Ryan, Figueroa-Moseley, Jean-Pierre, & Morrow, 2007; Lawrence, Kupelnick, Miller, Devine, & Lau, 2004). Cancer-related fatigue (CRF) varies greatly from fatigue of everyday life, which is usually temporary and is relieved by rest. The definition of CRF is an overwhelming, draining, whole-body tiredness that is unrelated to activity or exertion, and negatively impacts overall well-being and activities of daily living, that are not alleviated by rest (Brown 2016). Hofman et al. (2007) reported that 40% of patients at diagnosis, up to 90% of patients treated with radiation and 80% of patients treated with chemotherapy experience cancer related fatigue.

Cardiotoxicity, pulmonary toxicity, musculoskeletal toxicity, and other physiological toxicities resulting from treatment may all result in CRF (Schneider & Hayward, 2013). Cardiovascular toxicities may reflect a decreased stroke volume and cardiac output, which would cause a decrease in oxygen and nutrient delivery to tissues and organs, placing more stress on the heart, leading to fatigue. Pulmonary toxicities have a similar effect causing a decrease the amount of oxygen diffusion and lung capacity due to pulmonary fibrosis. The decrease in oxygen diffusion also contributes to the decrease in oxygen delivery throughout the body. A decrease in protein synthesis may contribute to muscle toxicities, resulting in a decrease in cross-bridge formation and muscle contraction, contributing to a decrease in strength and an increase in the sensation of fatigue. Fatigue not only affects physiological systems, it also has a significant impact on cancer survivor’s psychological state of mind, including mood, anxiety, and depression (Curt et al, 2000).
Depression

Depression is one of the most common psychological side effects of cancer and cancer treatment, affecting 10% to 25% of all cancer survivors (Pirl, 2004). The most common symptoms of depression are negative mood along with low energy, poor concentration, loss of interest, memory disturbances, low self-esteem, guilty feeling, hypochondriac preoccupation, sleep and appetite disturbances and hopelessness (Pasquini & Biondi 2007). The severity of depression fluctuates depending on the type of cancer, the stage of cancer, cancer treatment, and coping strategies of the patient (Schneider et al., 2002). Depression in cancer survivors should be monitored carefully because it can affect the patient’s QOL, it can exacerbate inactivity, and it can influence the outcome of treatment (Pirl, 2004).

Quality of Life

Quality of life is a term used widely to describe an individual’s assessment of their own well-being, including symptoms and functioning in physical, psychological, social, and spiritual domains (Hewitt, Greenfield, & Stovall, 2005). Multiple studies have documented that cancer diagnosis and cancer treatments have negative effects on patients overall QOL both during and after treatment (Hendren et al., 2012). These effects can be attributed to the cardiovascular, pulmonary and musculoskeletal toxicities that result in an inability to complete basic activites of daily living.

Benefits of Exercise

Through the advancement in cancer detection and treatment the multidisciplinary services of the National Cancer Act of 1971 (Alfano et al., 2012) may no longer be necessary for cancer rehabilitation. Recent research has demonstrated that a
unidimensional approach using exercise-based rehabilitation can affect the majority of the disabilities experienced by cancer survivors. The role of exercise as a primary therapy has been well documented and has the capacity to act across multiple body systems to attenuate cancer-related toxicities (Schmitz et al., 2010; Schneider et al., 2002).

Although there are specific risks associated with cancer treatment that need to be considered when survivors exercise, there is consistent evidence that exercise is safe and effective during and after cancer treatment (Schmitz et al., 2010). Exercise has been established as a successful method of rehabilitation for improving both physiological and psychological side effects cancer survivors’ experience. Exercise training-induced improvements can be expected in aerobic fitness, muscular strength, QOL, and fatigue in many types of cancer survivors (Schmitz et al., 2010).

When analyzing the effects of exercise on cancer toxicities, cardiovascular and pulmonary toxicities are usually group into one category, cardiorespiratory. Acute and chronic exercise can enhance the cardiorespiratory system. The physiological changes that occur through exercise reduces stress on the heart and blood vessels, thus enhancing the ability of the heart and lungs to more efficiently deliver oxygen to the working tissues (Schneider et al., 2002). These changes improve cardiovascular efficiency, increase cardiac output and stroke volume, decrease resting heart rate, lower exercise heart rate and improve ventilation and transport of oxygen (Schneider et al., 2007a). Improvements in the pulmonary system include an increase in forced vital capacity, forced expiratory volume, predicted maximal oxygen consumption, and the length of time on the treadmill (Schneider et al., 2007a). These benefits of exercise have the potential to reverse or
attenuate the cardiorespiratory toxicities experienced by cancer patients. Research indicates that relatively short-term, structured, moderate-intensity exercise training significantly improves VO$_{2\text{peak}}$ in cancer patients both during and following adjuvant therapy (Jones et al., 2011).

Exercise improves the efficiency of skeletal muscle cells to perform contractions, alleviating the effects of muscle wasting and decreased strength experienced by cancer patients (Schneider et al., 2003). The changes occur through an increase in the number and size of mitochondria, increased ability to resynthesize adenosine triphosphate (ATP), increased myoglobin, increased protein synthesis, and increased muscle fiber cross-sectional area (Schneider et al., 2007a).

The positive physiological outcomes from a proper exercise intervention have a large effect on increasing patient’s psychological variables including fatigue, depression and QOL. Regular physical exercise improves mood, body image, self-concept, and sleep patterns, resulting in decreased anxiety, depression and feeling of helplessness in cancer patients (Schneider et al., 2003). Research indicates that cancer patients participating in a supervised exercise intervention have significantly reduced levels of fatigue when compared to a control group (Carayol et al., 2013; Puetz & Herring, 2012) with one study reporting 32-39% decreases in fatigue scores (Schneider, & Hayward, 2013). With a strong correlation between fatigue and depression severity, improvements can also be seen in depression following an exercise intervention. Patients who exercise during treatment can experience a 43% decrease in depression, while participants exercising following treatment report a 25% decrease. With an increase in physiological variables along with a decrease in fatigue and depression, QOL significantly increases.
Blanchard et al. (2003) reported that promoting exercise three days per week is suggested in order to experience optimal increases in QOL.

**Physical Activity vs. Prescribed Exercise**

Research indicates that physical activity or an exercise intervention can positively affect the physiological and psychological side effects of cancer treatment and inactivity should be avoided (Schmitz et al., 2010). When reviewing the exercise programs created for cancer patients, programs should be split up into physical activity and prescriptive exercise. Physical activity is defined as any body movement produced by skeletal muscles that requires more energy expenditure than resting (Caspersen, Powell, & Christenson, 1985), such as walking, running, swimming, yoga and gardening. The American College of Sports Medicine (ACSM) suggest that cancer survivors engage in 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity exercise per week (Schmitz et al., 2010). However, these guidelines are very broad and fall within the definition of physical activity. ACSM added that prescriptive exercise should be individualized according to a cancer survivor’s aerobic fitness, medical comorbidities, response to treatment, and negative side effects of treatment that are experienced at any given time (Schmitz et al., 2010). These considerations emphasize the need for prescriptive exercise interventions when working with cancer patients. Prescriptive exercise refers to specific exercise guidelines prescribed for an individual that are designed for a specific purpose or purposes.

If one is to expect specific outcomes from therapeutic exercise interventions, it is necessary to prescribe exercise using the fundamental principles of exercise such as specificity, progression, overload, initial values, reversibility and diminishing returns.
(Winter-Stone, Neil, & Campbell, 2013). When comparing different types of exercise interventions designed for cancer patients, it is very important that programs follow these principles to take into account the cancer patients physiological and psychological alterations during and after treatment. The most popular exercise interventions for cancer patients include home-based interventions, group interventions, and individual one-on-one interventions (Blaney et al., 2010). Unfortunately, there are only a hand-full of exercise models that address the majority of the principles of exercise. Of the hand full of exercise interventions, all but one lacks the appropriate assessment, prescription, and interventions needed to directly target the toxicities caused by cancer treatments. Home-based exercise interventions for cancer patients often recommend modes of physical activity such as walking or yoga, and do not fall within the principles of exercise. Although home-based exercise interventions may have positive effects on the physiological and psychological aspects of a cancer survivor’s life, not adhering to the principles of exercise does not make it a valid unidimensional mode of cancer rehabilitation. The only possible way to properly administer a prescriptive exercise intervention is under the supervision of a Cancer Exercise Specialist (CES) in either a group or individual setting. With the increasing number of possible exercise interventions available, it is important to determine whether a group or individual model is more effective when administering a rehabilitation program in a hospital or outpatient setting.

In the apparently healthy population, group exercise means having one exercise professional leading a group through a series of exercises performed all together throughout a session. The group class is not specifically designed for every individual in
the group but focuses on increasing general physiological aspects of fitness. Most group classes are held at certain times and participation is not mandatory. However, the term “group” has a different meaning in exercise-based cancer rehabilitation when compared to the general public’s view of group exercise. A group-based cancer rehabilitation intervention is classified as two or more participants that are able to attend a reserved time in a facility where cancer patients can come in and complete a specifically designed individual workout under supervision of an exercise professional or physical therapist. Not only do cancer survivors have an individual workout but frequency, intensity and time are all prescribed in each workout. Cancer group exercise is also a prescribed amount of time to complete the program. After a cancer survivor has completed their program they will be re-tested and prescribed a new exercise regimen with new frequencies, intensities, and time, based on their assessment results. During the allotted time for group exercise cancer survivors are encouraged to complete as many exercises as possible during their allotted time.

The group-based cancer rehabilitation intervention has been a popular model in many hospitals and clinics. While both group and one-on-one exercise interventions have been established as safe and effective for cancer patients, there are many benefits that come from working within a group. Not only can a group model decrease the financial burden on cancer survivors, it may also result in positive program outcomes (May et al 2008, Midtgaard et al, 2005). Braney et al. (2010) conducted a qualitative study illustrating that most participants would prefer exercising with other patients with cancer within a clinic or hospital setting, as they would have similar cancer experiences and comparable fitness levels.
The University of Vermont recently published parameters for a group-based cancer rehabilitation intervention that is based off a cardiac rehabilitation model. Dittus et al. (2015) proposed a three phase program that separates cancer survivors whether they are in or out of treatment and the time in which they have completed cancer treatment. Phase 1 addresses range of motion defects and deconditioning after surgery while receiving cancer treatment, working one-on-one with a physical therapist transitioning to independent exercise. Phase 2 consisted of structured group, medically supervised exercise immediately after cancer treatment, addressing persistent side effects and deficits, supervised exercise progression, and lifestyle improvements. Phase 3 was characterized as independent group exercise to improve fitness and lifestyle interventions to improve chronic disease management. In this study the only phase that can be classified as cancer rehabilitation group exercise is Phase 2. In this phase patients are prescribed specific frequency, intensity and time, based off of the cancer survivor’s fitness assessment. Phase One of this program is working with a physical therapist to make sure the survivor has normal range of motion, while Phase 3 in this study is classified as apparently healthy group exercise, neither Phase 1 or Three incorporate the principles of exercise. Phase 2 of this program was a cancer rehabilitation group design with individuals exercising in a less supervised fashion, with an exercise physiologist available if needed. The group intervention for Phase 2 consisted of two days a week of aerobic and resistance training. The training program included twenty minutes of aerobic training at 70%-80% peak heart rate or between a RPE of twelve and fourteen. The resistance training included upper and lower extremity exercises with the intensity set at 60%-70% of one repetition maximum or able to complete eight repetitions with good
form. Data collected from Phase two throughout the 12 week program showed an 8% increase in \( \text{VO}_{2\peak} \), 22% increase in chest press one rep max, 22% increase in leg press one rep max, 36% decrease in fatigue, 25% decrease in depression and 19% decrease in anxiety (Dittus et al. 2015). Throughout their prescriptive exercise they adhered to all principles of exercise. The limitations of this program are the methods used to obtain baseline results and that the design of the program was developed for cardiac patients rather than cancer survivors. However, this program illustrated that group-based cancer rehabilitation is safe for cancer patients to perform and has positive effects on the physiological and psychological side effects of cancer treatment.

In contrast, the University of Northern Colorado Cancer Rehabilitation Institute (UNCCRI) created the first individual one-on-one model designed specifically for cancer survivors (Schneider et al., 2002). This model utilizes a four phase program that is classified by what point on the cancer continuum the cancer survivor falls in. Phase 1 individuals are classified as patients currently in treatment (chemotherapy and/or radiation). Phase 2 individuals are patients who have never received chemotherapy or radiation, who have completed chemotherapy or radiation treatment, or have completed Phase 1. Phase 3 are patients who have completed phase two, and phase four are patients completed with phase three. The Cancer Phase Training Model uses cancer-specific physiological and psychological assessments to create specific, individualized prescriptive exercise interventions. Each Phase has different exercise intensities and goals that are based off of the initial assessment of each participant. Phase 1 intensities may be classified as low, ranging between 30-45% heart rate reserve (HRR) and estimated one repetition maximum (EST 1-RM). Phase 2 intensities may be classified as
low to moderate ranging 40-60% HRR and EST 1-RM. Phase 3 intensities may be classified as moderate to high and range between 60-85% HRR and EST 1-RM. The frequency of training was prescribed as three sessions per week for twelve weeks. The duration of each exercise session was sixty minutes with twenty minutes designated for cardiovascular exercise, thirty minutes for resistance exercise, ten minutes for flexibility training, and with balance exercises incorporated throughout the entire session. From the data collected, Phase 1 participant’s results showed a 13% increase in VO_{2peak}, 8% increase in leg press one rep max, 16% increase in chest press one rep max, and a 27% decrease in fatigue. Phase 2 participants results showed a 15% increase in VO_{2peak}, 16% increase in leg press one rep max, 23% increase in chest press one rep max, and 27% decrease in fatigue. Phase 3 participants results showed a 5% increases in VO_{2peak}, 4% increase in leg press one rep max, 8% increase in chest press one rep max, and a 8% decrease in fatigue (Brown, 2016). As previously mentioned this is the first exercise program that included all the basic principles of exercise and cancer specific assessments to properly prescribe a therapeutic exercise intervention tailored specifically for cancer patients.

The purpose of this study was to determine if the UNCCRI Phase Program was more effective in a group model setting or in a one-on-one setting. Effectiveness was evaluated by determining changes in cardiorespiratory endurance, muscular strength, and cancer-related fatigue. Establishing a cancer rehabilitation model that can be administrated in an individual and group setting could provide adaptability for clinics and hospitals administrating a cancer rehabilitation program. By creating a structured cancer-specific group model that can produce results similar to the one-on-one model, a feasible
rehabilitation program for the large number of cancer survivors could be provided. It was hypothesized that the Cancer Phase Training Cancer Rehabilitation Program is more effective with a one-on-one model when compared to a group model.
CHAPTER III
METHODOLOGY

Participants

Data were obtained from subjects participating in the Cancer Phase Training Group Model (GM) from during the 2016 calendar year. All participants were eligible for participating in the group study if they were cleared to participate in an exercise program through a referral by his/her oncologist or primary care physician. Participants had to be able to move freely around the facility with minimal assistance and did not require spotting while walking. Participants that required a walker to move around the facility were excluded from the group study.

Participants were both male and female cancer survivors who were currently undergoing or had completed cancer treatment including surgical intervention, chemotherapy, radiation therapy, immunotherapy, hormonal therapy, and/or other types of unconventional treatment. Safety of the participants was ensured throughout all data collection, exercise testing, and exercise training through supervision by a CES. Along with the referral from the physician or oncologist, a detailed medical and cancer history of each participant was provided. Prior to any data collection, all participants were informed that they were volunteers and could terminate their involvement in the study at any time. Subjects entered into the program with a rolling enrolment, meaning they could start their twelve week program once they signed up and did not have to wait for a specific start date. After a thorough explanation of the group program, each participant
agreed to participate and signed an informed consent. All protocols used for the study were approved by the University of Norther Colorado’s (UNC) Institutional Review board (Appendix A). All exercise testing and training took place at UNCCRI on the University of Northern Colorado campus in Greeley, Colorado.

Recruitment

Participants were recruited into the group study from cancer patients that were referred by their oncologist or primary care physician to participate in an exercise intervention at UNCCRI. Participants were notified about the GM in the initial call from UNCCRI after receiving their referral to schedule their initial assessment. One incentive of a subject to participate in the GM was that the price for a twelve week intervention was reduced compared to participating in the individual protocol. Another incentive for subjects was that they would be exercising with other cancer survivors that they could socialize with throughout the program. The GM was only offered at UNCCRI on Tuesday and Thursday at 8 am and 11 am. Once a participant signed up for the group model they were asked to pick either of the designated times to attend throughout the 12-week program. If participants had a scheduling conflict for treatments or medical appointments they were given the opportunity to attend an alternate time during those days. One limitation to the GM was the schedule was that the times offered had to fit within the participants’ schedule in order to participate in the GM.

Patient Screening and Paperwork

After receiving the participant’s physician referral and signed consent form, each subject was asked to complete questionnaires evaluating their psychological function, lifestyle, behavior, and medical information. All questionnaires were completed at the
subject’s home prior to their initial assessment. The questionnaires included: Medical History, Revised Piper Fatigue Scale, Beck Depression Inventory questionnaire, and Ferrans and Powers Quality of Life Index Version III.

**Medical History**

Participants’ medical information was obtained via this self-reported worksheet detailing present medical history, family medical history, medications, allergies, and cancer diagnosis. If needed, further medical information was requested from the participants’ oncologist or primary care physician.

**Revised Piper Fatigue Scale**

Fatigue was measured via the Piper Fatigue Inventory, which evaluates total cancer-related fatigue, as well as four subscales of fatigue: behavior/severity, affective meaning, sensory, and cognitive/mood. These individual subscales comprise 22 questions to help calculate each subscale and a score representing total fatigue. In order to calculate fatigue on each subscale the sum of each subscale is taken and divided by the number of items on that subscale. To calculate the total fatigue, all twenty questions were added together and divided by twenty two. The fatigue scale ranges from zero to ten, a score of zero indicates that the participant shows no sign of fatigue, a score from one to three indicates mild fatigue, four to six indicates moderate fatigue, and a score greater than or equal to seven indicates severe fatigue (Piper et al, 1998).

**Beck Depression Inventory**

This questionnaire is a valid and reliable (Vodermaier, Linden, & Siu, 2009) 21-question index that assessed symptoms such as, but not limited to hopelessness, feelings of being punished, weight loss, and guilt. Each question is rated on a four point scale
ranging from zero to three based on the severity of each item. The sum all the rated questions are taken to determine the individual’s depression, with a maximum total score of 63. The higher the score indicate more severe depression with 0 indicating no depression and >40 indicating extreme depression.

**Ferrans and Powers Quality of Life Index Version III**

This 66-question questionnaire is designed to evaluate social, psychological, family and health satisfaction as well as total QOL. Higher scores indicate greater satisfaction in QOL (Ferrans & Powers, 1985).

Prior to the initial assessment and each subsequent reassessment, a detailed medical and cancer screening was recorded on the Client Summary form. The Client Summary listed all pertinent cancer information, including type, stage and diagnosis date, cancer treatments received or currently receiving, additional medications concerns that may affect training, disease concerns, including family health history, current medications, current and past physical activity level, and short and long term goals.

**Assessment Protocols**

Prior to the design of the participants’ prescriptive exercise, each participant completed an Initial Assessment. Each assessment measured vitals, body composition, cardiovascular endurance, muscular strength, and flexibility and range of motion (ROM). Results from the assessment were recorded on the Data Collection Sheet for the corresponding Phase. Reassessment occurred after each twelve week exercise intervention completed by the participant.
**Vital Measurements**

Prior to and following the completion of exercise testing, participants’ heart rate (HR), oxygen saturation (SpO₂), and blood pressure (BP) were assessed via heart rate monitors around the chest, pulse oximeter, and sphygmomanometer and stethoscope, respectively.

**Body Composition**

Body fat percentage was first assessed via the three-site skinfold (SKF) test using a Lange skin fold caliper. The three-site SKF locations for men were: the chest, abdomen, and thigh. The three-site SKF locations for women were: the triceps, suprailiac, and thigh. Two measurements, in a rotational order, were taken; a third was taken at any site that differed by more than two millimeters. Waist-to-hip ratios were measured in inches using a tape measure at the slimmest point on their waist and the widest point on their hip.

**Cardiovascular Endurance**

Cardiovascular endurance was evaluated using the cancer-specific UNCCRI Treadmill Protocol, which yields VO₂peak values. This protocol was found to be the most accurate and appropriate for the cancer population (Shackelford, Brown, Peterson, Schaffer, & Hayward, 2015). The goal of this test was for the participant to reach self-perceived maximal exertion or fatigue. The highest measurement of oxygen consumption was calculated. This protocol consists of one minute stages, which increased speed and/or incline at the conclusion of every stage. During the test, HR and SpO₂ were collected at the end of every minute. BP was recorded at the end of every three minutes, as well as the participant’s rating of perceived exertion (RPE) on the modified Borg Scale. This RPE
scale consisted of numbers zero to ten which correlates to the participants’ perceived intensity of the test. An RPE of zero correlates with the intensity of a stroll in the park, and a RPE of ten signifies the patient has reached his or her maximal effort and cannot continue. The use of handrails was discouraged, but was allowed if deemed necessary. If necessary, handrail usage was required throughout the entire test in order to stay consistent. Termination criteria of the test were: participant reached volitional fatigue or asked to stop for any reason, failure to increase systolic BP or HR with increased intensity, fluctuation of more than 10 mmHg from resting measures in diastolic BP, or oxygen saturation drops below 80 on the pulse oximeter. Once the testing ended, each subject completed a cool-down period, where all of the aforementioned variables were measured in the same manner as during the test. Final treadmill time, BP, HR, and RPE was recorded. Peak volume of oxygen consumption was estimated using ACSM’s walking and running equations, which have been found to be valid in determining VO$_2$peak (Shackelford et al., 2015).

**Muscular Strength Assessment**

Muscular strength was assessed via the estimated 1-repetition maximum protocol (EST 1-RM) using the Brzycki equation. This test used Cybex Eagle resistance machines (Cybex Inc., Medway, MA), and specifically utilized the following machines: chest press, lat pulldown, seated row, shoulder press, leg press, leg curl, and leg extension. The goal of this test was to have the participant lift as much weight as possible between one and ten repetitions. RPE values were asked at the end of every set. The test was performed in six steps as follows: (1) before the participant began the test, the CES demonstrated how to perform each machine correctly with proper form, and adjusted the machine to ensure
a proper fit for each participant. (2) The participant was then asked to perform a warm-up set, which consisted of five repetitions at a low intensity. (3) After the warm-up set, the weight was increased accordingly to elicit muscular failure or fatigue between 1 and 10 repetitions. (4) The participant then attempted to lift the weight deemed appropriate to elicit failure between one to ten repetitions. (5) If the weight appeared to be too light to elicit failure between one to ten repetitions, the set was stopped immediately and the weight increased. If the weight was too heavy for even one full repetition, the weight was reduced accordingly. (6) After a two to three minute rest, steps four and five may have been repeated up to two times per machine to elicit a weight that resulted in muscular fatigue between one and ten reps. The EST 1-RM values, as pounds (pounds) lifted, were recorded for each machine.

**Flexibility and Range of Motion Assessment**

The modified sit-and-reach (SR) test, back scratch test, and reaching tests were used to assess flexibility and range of motion. For the modified SR test, the participant was instructed to sit on the floor with his or her shoulders, head, and hips against a wall. The legs were extended in front of them, with their feet flat against a twelve inch SR box. The participant then extended his or her arms out, with one on top of the other. The end of the arm of the SR box was positioned so it was at the end of the participant’s fingertips. The participant was instructed to bend forward at the hips and slide the fingertips along the arm of the SR box until no further extension was possible. The value was recorded in inches. This procedure was conducted two additional times, and the highest value recorded.
The back scratch test required the patient to reach up and behind their back with the dominant hand, palm facing the back. They were asked to reach the other arm down and behind the back as far as possible, with the palm facing away from the back. Both wrists were kept as straight as possible. The distance between each middle finger was used as landmarks and the distance in inches recorded. If the fingertips touched without overlapping, the score was recorded as zero inches. If they did not touch, the score was recorded as a negative value in centimeters, and if they overlapped it was recorded as a positive value in centimeters.

For the reaching tests, the participant was asked to reach as far as possible with both arms in the anterior plane, and then the sagittal plane. Arms were kept as straight as possible. The highest score in each plane (anterior: 1 to 4; sagittal: 1 to 8) was recorded.

**Phase Training Model: Prescriptive Exercise**

Prescriptive exercise took place following the assessment and was created using the Client Overview document. The Client Overview indicated the starting Phase, and starting target intensity of both the aerobic and resistance training components of the program. The participant screening, which was recorded on the Client Summary, and the data collected from each assessment protocol, which was recorded on the Data Collection Sheet, were used together to create the prescriptive exercise for each participant. If the subject was currently undergoing chemotherapy and/or radiation therapy, he or she was placed in Phase I. If treatment had ended at entry into the program or if the subject underwent surgical intervention and/or other treatments (hormonal, immune, etc.), he or she was placed in Phase II. The assessment results and specifically the classifications achieved by the participant during each assessment were utilized to begin the process of
selecting the appropriate target intensity of the intervention. The Client Summary further assisted the prescription of intensity as the principles of individualization and specificity were utilized in relation to each patient’s specific goals and desired outcomes from the program.

**Exercise Intervention**

All exercise sessions were completed at UNCCRI under supervision of a CES. There was one CES working with the group throughout its duration, who recorded all physiological data. In the healthy population, group exercise means having one exercise professional leading a group through a series of exercises performed all together throughout a session. The group class is not specifically designed for every individual in the group but focuses on increasing general physiological aspects of fitness. However, the term “group” has a different meaning in exercise-based cancer rehabilitation when compared to the general public’s view of group exercise. A group-based cancer rehabilitation intervention is classified as two or more participants that are able to attend a reserved time in a facility where cancer patients can come in and complete a specifically designed individual workout under supervision of an exercise professional or physical therapist. The beginning of a group-based intervention includes an orientation, where participants are introduced to the exercises and proper use of the equipment for the first week. Once the intervention begins the exercise professional takes more of a supervising role only helping to increase intensity and assist if there are any questions. Cancer survivors are encouraged to complete as many exercises as possible during their allotted time.
The frequency of training was prescribed as two sessions per week for twelve weeks. The duration of each exercise session was sixty minutes with twenty minutes designated for cardiovascular exercise, thirty minutes for resistance exercise, ten minutes for flexibility training, and with balance exercises incorporated throughout the entire session. Participants used the following modes for the aerobic portion of the exercise session; treadmill, recumbent cycle ergometer, upright cycle ergometer and NuStep. For the resistance training, each session focused on a full body workout targeting all the major muscle groups including, chest, back, lower body, and core, and utilized three sets of ten repetitions for each exercise. By participating in the group model the majority of all the resistance training was performed on Cybex resistance machines, additional exercises were prescribed to each participant individually which included Thera band, dumbbells, body weight, and resistance tubing. The flexibility portion used straps, chairs, and steps to help focus on targeting all major muscle groups that were used during the exercise session.

The intensity of the prescriptive exercise was directly based off of the individual’s treatment status, assessment results and the starting Phase. Participants who were still in treatment would enter the phase program in Phase I. The goal of Phase I was to maintain or slightly increase the participant’s physiological and psychological values. Participants, who have completed chemotherapy or radiation, or who had never received either of these treatments, were prescribed to Phase II. Phase II is also the next Phase for participants who have completed Phase I. Participants enter into Phase III only by completing Phase II.
The GM did not use heart rate monitors to record intensity during the aerobic session, due to only having one CES accounting for multiple participants. Instead the revised RPE scale (0-10) was used to prescribe intensity for the aerobic portion. The starting intensity for Phase I was low, ranging between 30-45% EST 1-RM and an RPE of 4-6. Phase 2 starting intensity was low to moderate, ranging between 40-60% EST 1-RM and a RPE of 5-7. The starting intensity for Phase 3 was moderate to high, with intensities ranging between 60-85% EST 1-RM and a RPE of 6-8. Phase 4 starting intensity was moderate to near maximal, ranging between 65-95% EST 1-RM and a RPE of 6-9. To ensure the principles of progression and overload were met throughout each phase, participants were educated about these two key factors of the intervention and were taught how to apply them to their intervention. Through this education, participants were given the freedom to increase their weight and aerobic intensities and report back to the CES to record the increases. If the CES did not receive self-reported increases from a participant after three weeks of new intensities for their strength or aerobic training, the CES would encourage the participant to increase their weight on the strength machines or the speed or grade on the aerobic equipment.

**Exercise Intervention Orientation**

The first two days of the GM, survivors participated in an orientation of their exercise program. Lacking the direct supervision of a CES for each participant, the main goal of orientation was to understand the intensity and progression of their intervention as well as the proper use and safety precautions of all equipment being used. Day One Orientation: The first part of day one of the orientation had the participant and Cancer Exercise Specialist review initial results along with the intensity in
which the Cancer Exercise Specialist has prescribed for the participant. The understanding of RPE scale was explained to make sure the participant had a clear understanding for both cardiovascular RPE and muscular strength RPE. Progressive overload was explained to the participant to make sure progress is accomplished throughout the twelve weeks. Participants were given the freedom to increase their weight throughout the twelve weeks; if the CES did not see any progress the CES would suggest an increase in intensity in either cardiovascular endurance or muscle strength. The second part of orientation consisted of machine orientation of the cardiovascular equipment. During this time the participant was shown all the available options to perform the cardiovascular aspect of the workout. How to properly get on and off the machine, changing intensity and how to stop the machine immediately in case of an emergency was reviewed.

Day Two Orientation: Day two consisted of a review of the cardiovascular machines, as well as the muscular strength machine orientation. During the machine orientation participants were shown how to properly use each piece of machine along with the proper seat position on every machine. During this time, participants were able to go over their prescribed weights on each machine and report to the CES if they felt like it was an accomplishable weight to begin with. If participants were not able to safely complete the prescribed weight the CES was able to make adjustments to determine the appropriate starting weight. After completion of the two days of orientation, the participant began their twelve week intervention.
**Statistical Analysis**

Two related samples Wilcoxon Signed-Rank Test was utilized to examine if significant differences occurred in cardiovascular endurance, muscular strength, and fatigue. The following dependent variables were assessed: VO$_2$peak, EST 1-RM of leg press, EST 1-RM chest press, EST 1-RM seated row, EST 1-RM lat pull down, EST 1-RM shoulder press and fatigue. With the low number of participants, pre and post results of all completed phases were compared. Statistical analyses were performed using the Statistical Package for the Social Science software package (SPSS, Chicago, IL). Significance levels were set at $p < 0.05$. 
CHAPTER IV

DETERMINING THE EFFECTIVENESS OF THE CANCER PHASE TRAINING MODEL IN A GROUP SETTING

Contribution of Author

Manuscript in Chapter IV

Author: Scott Francis Eberhardt

Contributions: Conceived the study topic, developed and implemented the study design, Generated and analyzed data. Wrote first and edited draft of the manuscript.
Introduction

There are over 15.5 million cancer survivors in the United States today; with 20 million survivors expected by 2026 (Miller et al., 2016). This increase in survival rate is contributed to the increase in early detection of cancer along with the advancement in cancer treatment. With an increase in survival rate, more cancer survivors are suffering from toxicities as a result of radiation, chemotherapy, and surgery. Although cancer treatments are effective in eliminating cancer, they lead to debilitating side effects in up to 96% of cancer survivors (Schneider, Dennehy, Roozeboom, & Carter, 2002). The toxicities from cancer treatment have detrimental side effects on physiological and psychological aspects of the cancer survivor’s life.

The negative physiological side effects from treatment affect the cardiovascular, immune, pulmonary, gastrointestinal, neuroendocrine, hepatic and musculoskeletal systems (Schneider et al., 2002). The debilitating physiological side effects have a large influence on the negative psychological side effects, which include increased fatigue and depression, and a decrease in quality of life (QOL). The role of exercise interventions as a primary therapy has been well documented and has the capacity to act across multiple body systems to attenuate cancer related toxicities (Schmitz et al., 2010; Schneider et al., 2002). Exercise training-induced improvements can be expected regarding aerobic fitness, muscular strength, QOL, and fatigue in many types of cancer survivors (Schmitz et al., 2010).

The beginning of cancer rehabilitation can be traced back to the National Cancer Act of 1971, which involved a multidisciplinary team of providers, including physiatrists, social workers, physical therapists and other medical personnel (Alfano, Ganz, Rowland,
& Hahn, 2012; DeLisa, 2001). Through the advancement in cancer detection and treatment, cancer survivors are spending less time recovering in the hospital setting making these multidisciplinary services unnecessary for cancer rehabilitation. Recent research has demonstrated that a one-dimensional approach using exercise-based rehabilitation can affect the majority of the disabilities suffered by cancer survivors (Schneider, Dennehy, & Carter, 2003). The American College of Sports Medicine (ACSM) suggests that cancer survivors engage in 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity exercise per week and should avoid inactivity. Adding that prescriptive exercise should be individualized according to a cancer’s survivor’s aerobic fitness, medical co-morbidities, response to treatment, and negative side effects of treatment that are experienced at any given time (Schmitz et al., 2010). To date, the Cancer Phase Training Model introduced by Brown (2016) is the only established structured individualized model for cancer rehabilitation that includes mode, intensity, frequency and duration for cancer survivors throughout the cancer continuum.

Although the group and one-on-one model have been established as safe and effective models for cancer rehabilitation (Dittus et al., 2015; Brown, 2016), to date research is lacking in providing a consistent structure for cancer specific group model. Research shows that there are many benefits for cancer survivors working within a group, including decreasing the financial burden on cancer survivors and positively influencing the outcome results of a program offered (May et al., 2008, Midtgaard et al., 2005). The one-on-one model has been proven to be the most effective method of cancer rehabilitation; however the largest perceived limitation of this model is the expense of the program, not making it feasible to offer to the masses. The purpose of this pilot study is
to evaluate the effects of the Cancer Phase Training Model in a group setting, on
cardiorespiratory endurance, muscular strength, and cancer related fatigue in cancer
survivors. By creating a structured cancer specific group model that can produce similar
results to the one-on-one model, we can provide a feasible alternative rehabilitation
program for cancer survivors.

Methodology

Subjects

Data were obtained from subjects participating in the Phase Training Group
Model (GM) during the 2016 calendar year. Participants were both male and female
cancer survivors who were currently undergoing or had completed cancer treatment
including surgery, chemotherapy, radiation therapy, immunotherapy, hormonal therapy,
and/or other types of unconventional treatment. All participants were eligible for
participation in the group study if they were cleared to participate in an exercise program
through a referral by his/her oncologist or primary care physician. Participants had to be
able to move freely around the facility with minimal assistance and did not require
spotting while walking. Participants that required a walker to move around the facility
were excluded from the group study.

Participants were recruited into the group study from referrals by their oncologist
or primary care physician to participate in an exercise intervention at the University of
Northern Colorado Cancer Rehabilitation Institute (UNCCRI). Participants were notified
about the GM in the initial call from UNCCRI after receiving their referral to schedule an
initial assessment. The GM was only offered at certain times during UNCCRI’s daily
operations, and must have fit within the participants schedule to participate. Subjects
entered into the program with a rolling enrolment, meaning they could start their twelve-week program once they signed up and did not have to wait for a certain start date. All protocols used for the study were approved by the University of Northern Colorado’s (UNC) Institutional Review Board (see Appendix A). All exercise testing and training took place at UNCCRI on the University of Northern Colorado campus in Greeley, Colorado.

**Patient Screening and Paperwork**

After receiving the participant’s physician referral and signed consent form, each subject was asked to complete questionnaires evaluating their psychological function, lifestyle, behavior, and medical information. All questionnaires were completed at the subject’s home prior to their initial assessment. The questionnaires included: Medical History, Revised Piper Fatigue Scale, Beck Depression Inventory questionnaire, and Ferrans and Powers Quality of Life Index Version III.

**Physiological Assessments**

Prior to the design of the participants’ prescriptive exercise, each participant completed an Initial Assessment. Each assessment measured vitals, body composition, cardiovascular endurance, muscular strength, and flexibility and range of motion (ROM). Prior to and following the completion of exercise testing, participants’ heart rate (HR), oxygen saturation (SpO₂), and blood pressure (BP) were assessed via heart rate monitors around the chest, pulse oximeter, and sphygmomanometer and stethoscope, respectively. Cardiovascular endurance was evaluated using the cancer-specific UNCCRI Treadmill Protocol which yields VO₂peak values (Shackelford et al., 2015). Muscular strength was assessed via the estimated 1-repetition maximum protocol (EST 1-RM) using the Brzycki
equation. This test used Cybex Eagle resistance machines (Cybex Inc., Medway, MA), and specifically utilized the following machines: chest press, lat pulldown, seated row, shoulder press, leg press, leg curl, and leg extension.

**Exercise Prescription**

Prescriptive exercise took place following the assessment and was created using the Client Overview document. The Client Overview indicated the starting Phase, and starting target intensity of both the aerobic and resistance training components of the program. The participant screening, which was recorded on the Client Summary, and the data collected from each assessment protocol, which was recorded on the Data Collection Sheet, were used together to create the prescriptive exercise for each participant. If the subject was currently undergoing chemotherapy and/or radiation therapy, he or she was placed in Phase I. If treatment had ended at entry into the program or if the subject underwent surgical intervention and/or other treatments (hormonal, immune, etc.), he or she was placed in Phase II. Once a subject had completed Phase II and the reassessment, subjects were then moved into Phase III of the Phase Training Model. The assessment results and specifically the classifications achieved by the participant during each assessment were utilized to begin the process of selecting the appropriate target intensity of the intervention. Table 1 describes the criteria for the entry and transition in the Phase Training Model and Phase intensity.
Table 1

*Phase Transitions and Intensities*

<table>
<thead>
<tr>
<th>Phase</th>
<th>Entry Criteria</th>
<th>Intensity</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Participants who are still in treatment</td>
<td>30-45% EST 1-RM and an RPE of 3-5</td>
</tr>
<tr>
<td>2</td>
<td>Have completed cancer treatment or receiving hormonal treatment, or after the completion of Phase 1</td>
<td>40-60% EST 1-RM and a RPE of 5-7</td>
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<tr>
<td>3</td>
<td>By completing Phase 2</td>
<td>60-85% EST 1-RM and a RPE of 6-8</td>
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**Exercise Intervention**

There was one Cancer Exercise Specialist (CES) working with the group throughout its duration, who recorded all physiological data. The frequency of training was prescribed as two sessions per week for twelve weeks. The duration of each exercise session was 60 minutes with 20 minutes designated for cardiovascular exercise, 30 minutes for resistance exercise, 10 minutes for flexibility training, and with balance exercises incorporated throughout the entire session. The intensity of the prescriptive exercise was directly based on the individual’s treatment status, assessment results and the starting Phase. The GM did not use heart rate monitors to record intensity during the aerobic session, due to only having one CES accounting for multiple participants. Instead, the revised RPE scale (0-10) was used to prescribe intensity for the aerobic portion.

**Orientation**

The first two days of the GM, survivors participated in an orientation of their exercise program. Lacking the direct supervision of a CES for each participant, the main goal of orientation was to understand the intensity and progression of their intervention as
well as the proper use and safety precautions of all equipment being used. All orientations were performed one-on-one with the CES who was overseeing the group.

Day One Orientation: The first part of orientation reviewed the results of the Initial Assessment along with the intensities in which the CES has prescribed for the participant. Following this, each participant underwent an orientation of to the cardiovascular equipment. During this time the participant was shown all the available options to perform the cardiovascular aspect of the workout, this included treadmill, upright and recumbent bike, and Nustep. How to properly get on and off the machine, changing intensity and how to stop the machine immediately in case of an emergency was reviewed. While on the cardiovascular machine RPE was reviewed in order for participants to determine the speed and resistance of the appropriate intensity.

Day Two Orientation: Consisted of a review of the cardiovascular machine, as well as the muscular strength machine orientation. During the machine orientation participants were shown how to properly use each piece of machine along with the proper seat position on every machine. After completion of the two days of orientation, the participant began their twelve week intervention

**Statistical Analysis**

A two related samples Wilcoxon Signed-Rank Test was utilized to examine if significant differences occurred in cardiovascular endurance, muscular strength, and fatigue. The following dependent variables were assessed: VO$_{2peak}$, EST 1-RM leg press, EST 1-RM chest press, EST 1-RM seated row, EST 1-RM lat pull down, EST 1-RM shoulder press and fatigue. With the low number of participants, pre and post results of all completed phases were compared. Statistical analyses were performed using the
Statistical Package for the Social Science software package (SPSS, Chicago, IL). Significance levels were set at p < 0.05.

**Results**

The purpose of this study was to determine if the UNCCRI Phase Program was more effective in a group model setting or in a one-on-one setting. Effectiveness was evaluated by determining changes in cardiorespiratory endurance, muscular strength, and cancer-related fatigue. Establishing a cancer rehabilitation model that can be administrated in an individual and group setting could provide adaptability for clinics and hospitals administering a cancer rehabilitation program. By creating a structured cancer-specific group model that can produce results similar to the one-on-one model, a feasible rehabilitation program for the large number of cancer survivors could be provided. It was hypothesized that the Phase Training Cancer Rehabilitation Program is more effective with a one-on-one model when compared to a group model.

Table 2 summarizes the demographic characteristics of study participants. A total of 14 cancer survivors were recruited to participate in the group study. Of the fourteen, 12 completed the program (seven males and five females). The treatments the participants received prior to or during the program included: surgery only, radiation only, combination of surgery and chemotherapy, combination of surgery and radiation, and the combination of surgery, radiation, and chemotherapy. The attendance rate for the exercise programs sessions throughout the study was 71%. After participants completed a Phase there was a 75% retention rate for continuing the Phase Training Model GM. On average each participant completed eight strength exercises during each exercise session.
This number of completed exercises meets the ACSM recommendations of completing eight to ten different exercises within a session.

Table 2

<table>
<thead>
<tr>
<th>Participant Characteristics</th>
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<tr>
<td>Age (years)</td>
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<tr>
<td>Male, n (%)</td>
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<tr>
<td>Female, n (%)</td>
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<table>
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<tr>
<th>Phase</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>2 (17)</td>
</tr>
<tr>
<td>Phase 2</td>
<td>6 (50)</td>
</tr>
<tr>
<td>Phase 3</td>
<td>4 (33)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Prostate</td>
<td>4 (34)</td>
</tr>
<tr>
<td>Colorectal</td>
<td>3 (25)</td>
</tr>
<tr>
<td>Uterine</td>
<td>3 (25)</td>
</tr>
<tr>
<td>Melanoma</td>
<td>1 (8)</td>
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</table>

<table>
<thead>
<tr>
<th>Cancer Stage</th>
<th>N (%)</th>
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</thead>
<tbody>
<tr>
<td>I</td>
<td>1 (8)</td>
</tr>
<tr>
<td>II</td>
<td>4 (34)</td>
</tr>
<tr>
<td>III</td>
<td>3 (25)</td>
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<tr>
<td>IV</td>
<td>3 (25)</td>
</tr>
<tr>
<td>Unknown/not staged</td>
<td>1 (8)</td>
</tr>
</tbody>
</table>

Changes in Peak Volume of Oxygen Consumption, Muscular Strength, and Fatigue in Group Model

Table 3 depicts absolute values (pre-to-post) for the GM for $\text{VO}_{2\text{peak}}$ (mL$\cdot$kg$^{-1}$$\cdot$min$^{-1}$), leg press MS (pounds lifted), chest press MS, seated row MS, shoulder press MS, and fatigue. Figure 1 depicts mean percent change in $\text{VO}_{2\text{peak}}$ and fatigue. Figure 2
depicts pre to post strength differences for lower and upper body, while figure 3 depicts mean percent changes in lower body and upper body strength.

After completing a twelve week intervention in the GM, significant improvements (p<0.05) were observed in VO$_2$peak (mL·kg$^{-1}$·min$^{-1}$), leg press MS, chest press MS, seated row MS, and shoulder press MS, and fatigue. Non-significant improvements (p>0.05) were observed in lat pull down MS, leg extension MS, and leg curl MS. Figure 8 depicts the percent change for each variable was as follows: VO$_2$peak (9%), leg press MS (10%), chest press MS (16%), seated row MS (11%), shoulder press MS (18%) and fatigue (-36%).

Table 3

*Improvements in Physiological Values and Fatigue*

<table>
<thead>
<tr>
<th>Group Model</th>
<th>N=12</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strength Variables</strong></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>Post</td>
</tr>
<tr>
<td><strong>VO$_2$peak</strong></td>
<td>19.1 ± 4.0</td>
</tr>
<tr>
<td><strong>Leg Press MS</strong></td>
<td>172 ± 66</td>
</tr>
<tr>
<td><strong>Leg Curl MS</strong></td>
<td>80 ± 33</td>
</tr>
<tr>
<td><strong>Leg Extension MS</strong></td>
<td>114 ± 27</td>
</tr>
<tr>
<td><strong>Chest Press MS</strong></td>
<td>64 ± 33</td>
</tr>
<tr>
<td><strong>Seated Row MS</strong></td>
<td>90 ± 33</td>
</tr>
<tr>
<td><strong>Lat Pull down MS</strong></td>
<td>108 ± 35</td>
</tr>
<tr>
<td><strong>Shoulder Press MS</strong></td>
<td>45 ± 16</td>
</tr>
<tr>
<td><strong>Fatigue</strong></td>
<td>4.9 ± 1.1</td>
</tr>
</tbody>
</table>

*Note. N = number of participants, VO$_2$peak = peak volume of oxygen consumption (mL·kg$^{-1}$·min$^{-1}$); MS = muscular strength (pounds lifted), * denotes a p value < 0.05 between pre and post values.*
Figure 1. Mean percent change in VO\textsubscript{2}peak and fatigue pre to post each phase transition in the GM. *p < 0.05

Figure 2. Muscular strength changes with each Phase transition in the GM.
Figure 3. Mean percent change in upper and lower body strength between each Phase transition; *p < 0.05

Individual vs. Group Phase Training Models

The twelve participants of the GM completed Phase 1, Phase 2 and Phase 3 of the GM. When comparing the results of the Individual Phase Training Model (IM) to the GM we evaluated all of the Phase transitions completed by the participants. The GM had a significantly lower N than the compared IM making the IM results more significant than the GM. Figure 4 depicts the mean percent change in VO$_2$peak and strength between the IM compared to the GM. Figure 5 depicts the mean percent change in fatigue between the IM and GM Phase Training Model. When determining the mean values for the IM, the average was determined from the combining the average percentages from each phase transition, Phase I to Phase II, Phase II to Phase III, and Phase III to completion of the program.
Although the GM was a pilot study and had drastically lower number of participants, similar results between GM and the IM Phase Training Model were observed in all variables. When observing the changes in fatigue classification, five participants stayed within the moderate category although their fatigue score decreases, six participants went from moderate to mild, and one participant went from mild to none in fatigue classification.

![Figure 4](image_url)

*Figure 4*. Comparison between the individual and group model in percent change in VO2peak and Strength.
To date, the Phase Training Model introduced by Brown (2016) is the only established structured model for cancer rehabilitation that includes mode, intensity, frequency and duration for cancer survivors. The main attributes to the success of the Phase Training Model is the cancer specific fitness assessments utilized to create a detailed and individualized exercise prescription for each participant. This study indicates that the Phase Training Model can be effectively administered in an individual or group model. The GM produced significant improvements in cardiovascular fitness, upper and lower body muscular strength, and fatigue throughout all phases of the program. An important take away from this study is that a group design is safe, effective, and well tolerated for all cancer patients regardless of diagnosed cancer stage and treatment status. In this study, six participants were able to complete one or more Phases of the group program with cancer stage diagnosis of three or four. The group model also
shows to be well-tolerated for patients who are currently undergoing treatment. This supports Brown (2016) findings that Phase one’s intensity is safe and effective in producing significant psychological and physiological improvements, and should become the standard intervention for patients undergoing treatment. This study indicates that when using the same assessments and guidelines for exercise prescription as the Phase Training Model protocol, it is safe and well tolerated for any cancer patient whether the program is administrated individually or in a group.

**Group vs Individual**

The GM yielded similar results to the other group studies as well as the IM Phase Training Model. With the small number of participants in the pilot study of the GM, Phase-to-Phase transitions could not be compared to the IM Phase Training Model. Comparing the IM Phase Training Model to the GM the results are very similar when evaluating the overall improvements of the total program. When comparing the mean percent change in VO$_{2\text{peak}}$ and strength in participants completing Phase one and two, the results are very similar between the participants completing the IM and GM. Participants completing the IM resulted in an average 10.8% increase in VO$_{2\text{peak}}$, while the GM resulted in an average 9.4% increase. Participant’s leg press strength increased by an average of 8.9% in the IM compared to an average 10.3% increase in the GM. Participant’s chest press strength increased by an average of 15.6% in the IM, in comparison to an average 16.5% increase in the GM. The mean percent change in fatigue for participants completing the IM was a 20.7% decrease, while the GM experienced a 36% decrease in fatigue. The only outcome that was lower in the GM than the IM was cardiovascular endurance. The smaller increase in cardiovascular endurance,
although still significant, can be attributed to two main disadvantages of the GM. One disadvantage is not having the ability to use heart rate in the participants exercise prescription. The disadvantage of using RPE for the cardiovascular portion of the exercise session is that it can change daily within cancer patients depending on the side effects cancer treatment toxicities that can have an impact on fatigue, pain, and mental state. The second disadvantage of the GM is the lack of constant encouragement, motivation, and supervision of the CES which is provided in the IM. In some cases the prescribed intensity for an individual to reach their target heart rate and RPE can be quite challenging. Without a CES by their side to help push them to the prescribed intensity participants have a hard time reaching the prescribed heart rate zone. Due to this a participant suffering from severe cardio toxicities would benefit greater in the IM Phase Training Model than the GM. The greatest difference in the results between the IM and the GM was fatigue. With administrating the same exercise intensity ranges for participants in each Phase, the greater decrease in fatigue seen in GM can be attributed to working within the group. Although the GM had a smaller N than the IM compared to, the similar results between the IM and the GM, demonstrates how versatile the Phase Training Model can be for clinics and hospitals.

In recent studies group exercise models have included additional services such as support groups or team activities to the exercise program to enhance group cohesion (Dittus et al 2015; May et al. 2008, Midtgaard et al 2006). It has been established that group cohesion can produce positive effects on program outcomes (May et al. 2008). This is the first study where the group model is only based on exercise prescription and does not include any additional services. Although the study did not include additional
services and only focused on exercise, there were still significant improvements seen in participant’s psychological factors, such as cancer related fatigue. This indicates that group exercise alone may have a positive effect on the negative psychological effects of cancer diagnosis and treatment. Although there were no additional services offered to the participants in the Phase Training Group Model, participants had the opportunity to socialize throughout their exercise intervention, where they were able to get to know each other and create a sense of group cohesion. This indicates that group cohesion may not need to be administered in additional services but rather having cancer survivors working out in the same facility creates a group aspect all on its own.

The largest limitation of this study was the number of participants allowing us to only present this study as a pilot. UNCCRI plans to continue this study to collect enough data to be able to compare the Phase Training Model side by side to the UNCCRI Group Model. One limitation the GM experienced from the IM was not being able to use heart rate percentages in the exercise prescription. Without the use of heart rate monitors participants were asked to exercise at a prescribed RPE. This type of prescription is less accurate than heart rate because RPE can differ greatly in cancer survivors on a day-to-day basis. This difference in prescription could be the primary reason the IM resulted in better cardiovascular endurance results than the GM.

The largest barriers for cancer patients to receive rehabilitation through exercise interventions are the cost and the lack of exercise facilities tailored to the cancer population (Blaney et al. 2010). With patients unable to receive re-imbursement from insurance, the financial burden is put on the cancer survivor needing these services. Research has indicated that exercise can have powerful effects on decreasing the negative
side effects experienced after and during cancer treatment. By establishing a group exercise rehabilitation program created specifically for cancer patients during any aspect of the survivor continuum, more cancer patients can have access to a valuable one-dimensional rehabilitation program through exercise interventions without the financial burden. By demonstrating the Phase Training Model protocol can be safe and effective within a GM, it should be established as the standard rehabilitation program for cancer patients within the hospital and clinical setting.

Conclusion

To date, the Cancer Phase Training Model is the only cancer rehabilitation intervention that includes recommended modes, intensity, frequency, and duration of exercise for cancer survivors. Through the precise cancer-specific pretreatment screening, baseline fitness assessment, and individualize exercise prescription, the Cancer Phase Training Model has been shown to attenuate the negative physiological and psychological effects of cancer treatment. This pilot study indicates that the Phase Training Model protocol can be safely and effectively administrated in a group model. Through administrating the Phase Training Program in a group model, professionals can have a greater impact by providing services to more cancer survivors without placing the financial burden on the survivor or the program provider. By demonstrating its diversity, the Phase Training Model should be considered as a standard of care in the clinical cancer rehabilitation setting considering its success in both the group and individual model.
REFERENCES


APPENDIX A

INFORMED CONSENT FOR PARTICIPATION
IN RESEARCH
INFORMED CONSENT
[FOR PARTICIPATION IN RESEARCH AT UNCCRI]  

NAME

DATE

PROJECT TITLE: Exercise Interventions to Attenuate the Negative Side-Effects of Cancer Treatments

University of Northern Colorado Cancer Rehabilitation Institute

Reid Hayward, Ph.D., Director
Phone Number: 970-351-1821
reid.hayward@unco.edu

Michael Lazio, M.S., Clinical Coordinator
Phone Number: 970-351-1724
michael.lazio@unco.edu

The University of Northern Colorado Cancer Rehabilitation Institute (UNCCRI) and the School of Sport and Exercise Science support the practice of protection of human subjects participating in research. The following information is provided for you to decide whether you wish to participate in either the standard UNCCRI program or if recruited, specific research investigations. You should be aware that even if you agree to participate, you are free to withdraw at any time without affecting opportunities for participation in other programs offered by this department.

This program is involved with the assessment of your body composition, pulmonary function, cardiovascular endurance, muscular strength and endurance, range of motion and flexibility. Skinfold calipers will be used to measure body composition (body fat percentage). The pulmonary function test will be measured through maximum exhalation into a sterile mouthpiece. Measuring oxygen consumption on a motor-driven treadmill will assess your cardiorespiratory capacity. Assessment of muscular strength and endurance will occur through the use of weights, dumbbells, a handgrip dynamometer, and other established tests. Flexibility and range of motion will be measured by the modified sit-and-reach test and the reaching test. Baseline measurements such as: heart rate, blood pressure, height, weight, and circumference measurements will be taken for risk stratification and safety during your participation. Forms to be completed for the program include cancer history, medical history, lifestyle activity questionnaire, and psychological tests such as depression scales. Quality of life, fatigue and cognitive functioning. Blood may be drawn with your permission at various time points during your participation. Once all of the tests are completed, the results will be analyzed and an exercise prescription will be written. You may then have the option of participating in a three-month exercise intervention based on your testing results. The expected benefits associated with your participation in this program include information regarding your level of physical fitness and recommended fitness and lifestyle changes necessary to improve your quality of life and health.

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If you are recruited, and agree to participate in a specific research investigation, additional exercise, psychological, and/or cognitive tests may be administered. Your optional three month exercise intervention may also differ, but the expected benefits should still include improved quality of life and health. All participants at UNCCRI will be under the direction of the UNCCRI Director and Clinical Coordinator but other persons will be associated or assist with the data collection. Your participation is solicited, although strictly voluntary. The obtained data may be used in reports or publications but your identity will not be associated with such reports. We at UNCCRI take mental distress that may accompany health issues seriously and will attempt to support you with counseling referrals and information on local cancer support groups if this is an issue. Our staff is required to report evidence of clear and imminent danger.

This research should not result in physical injury, however, some soreness may occur and some of the fitness tests can be uncomfortable. Additionally, with the blood draws you may feel temporary discomfort. The duration of the discomfort is short. Please give your consent with full knowledge of the nature and purpose of the procedures, the benefits that you may expect, and the discomforts and/or risks which may be encountered. We appreciate your assistance.

Participation is voluntary. You may decide not to participate in this study and if you begin participation, you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Having read the above and having had an opportunity to ask any questions, please sign below if you would like to participate in this research. A copy of this form will be given to you to retain for future reference if requested. If you have any concerns about your selection or treatment as a research participant, please contact Sherry May, IRB Administrator, Office of Sponsored Programs, Kepner Hall, University of Northern Colorado Greeley, CO 80639; 970-351-1910.

The University of Northern Colorado Cancer Rehabilitation Institute would like to share your contact information with the UNC Foundation and Development Office for purposes of marketing and communication. By signing below you agree to allow us to share your contact information with the UNC Foundation and Development Office. NO MEDICAL INFORMATION WILL BE SHARED. If you would like to opt out, please check this box \( \square \).

_____________________________  ______________________________
Signature of Subject Agreeing to Participate  Date
By signing this consent you certify you are at least 18 years of age.

_____________________________  ______________________________
Signature of Researcher  Date

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APPENDIX B

INSTITUTIONAL REVIEW BOARD
APPROVAL
DATE: March 27, 2017

TO: Reid Hayward, PhD
FROM: University of Northern Colorado (UNCO) IRB

PROJECT TITLE: [573297-5] Exercise Interventions to Attenuate the Negative Side-Effects of Cancer Treatments
SUBMISSION TYPE: Continuing Review/Progress Report

ACTION: APPROVED
APPROVAL DATE: March 27, 2017
EXPIRATION DATE: March 26, 2018
REVIEW TYPE: Expedited Review

Thank you for your submission of Continuing Review/Progress Report materials for this project. The University of Northern Colorado (UNCO) IRB has APPROVED your submission. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on applicable federal regulations.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require that each participant receives a copy of the consent document.

Please note that any revision to previously approved materials must be approved by this committee prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office.

Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of March 26, 2018.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact Sherry May at 970-351-1910 or Sherry.May@unco.edu. Please include your project title and reference number in all correspondence with this committee.
Thank you for the clear documentation of updated protocols following the situation in April 2016. The continuation application materials are approved for continued participant recruitment and data collection. Best wishes with this continued work.

Sincerely,

Dr. Megan Stellino, UNC IRB Co-Chair

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Northern Colorado (UNCO) IRB's records.