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Effectiveness of a Training Program Using an Alter-G Treadmill to Improve Physiological and Psychosocial Measures in Female Breast Cancer Survivors

Ciaran Fairman
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Effectiveness of a training program using an Alter-G treadmill to improve physiological and psychosocial measures in female breast cancer survivors

by

CIARAN FAIRMAN

(under the direction of Kristina Kendall)

ABSTRACT

Breast Cancer survivors often experience lower bone mineral density following treatment, and may be at a higher risk for osteoporosis and consequent falls and injuries. This study aimed to build on previous research using lower impact exercise programs by using an anti-gravity (Alter-G) treadmill to administer cardiovascular training. PURPOSE: The purpose of this study was to determine the effectiveness a physical activity program, including an anti-gravity (Alter-G) treadmill at improving physiological and psychosocial measures in female breast cancer survivors. METHODS: Five female breast cancer survivors were recruited to participate in the study. A 14-week intervention using an AB-AB study design was employed. Participants attended three 60-minute sessions per week, consisting of a combination of muscular strength/endurance, and cardiovascular endurance exercises. Consistent with current literature and guidelines, exercise interventions were individualized and tailored to suit individuals. RESULTS: Statistical analysis yielded no significant (P>0.0036) difference in measures of cardiovascular endurance, body composition, and quality of life between pre/post measurements. However, visual analysis of results found improvements in cardiovascular endurance and measures of body composition. Quality of life was maintained throughout the study. Finally, no adverse effects were reported from the participants. CONCLUSIONS: The results of this study
suggest that the use of an anti-gravity treadmill in combination with a physical activity program may be a safe, alternative means of improving cardiovascular endurance. Finally, an individualized physical activity program in combination with an anti-gravity treadmill may provide practical and meaningful improvements in measures of cardiovascular endurance and body composition.
Effectiveness of a training program using an Alter-G treadmill to improve physiological and psychosocial measures in female breast cancer survivors

by

CIARAN FAIRMAN

B.S. Kentucky Wesleyan College, 2012

A Thesis Submitted to the Graduate Faculty of Georgia Southern University in Partial Fulfillment of the Requirements for the Degree

MASTER OF SCIENCE

KINESIOLOGY

STATESBORO, GEORGIA

2013
EFFECTIVENESS OF A TRAINING PROGRAM USING AN ALTER-G TREADMILL TO IMPROVED PHYSIOLOGICAL AND PSYCHOSOCIAL MEASURES IN FEMALE BREAST CANCER SURVIVORS.

by

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Jim McMillan
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Electronic Version Approved:

Fall 2013
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Secondly, to Jay “6am” Stewart; you saw me go through this project from the start and listened to me nonstop complaining and picked me up whenever I was getting knocked down. I learned a lot from watching you and feel like I developed as a professional and as a person as a result. I appreciate everything you’ve done for me pal.

To my committee, Brandonn, Krissy, and Jimbo, I don’t think I could have asked for a better group of people to mentor me through this process. Quite frankly it scares me to move forward as I can’t see my dissertation committee being anywhere near as awesome.

Brandonn, I remember when I first came into your office, petrified of research and no direction. I came in with just an idea and over the course of an hour, you managed to turn it into a set plan with specific steps. I never would have gotten it off the ground as quick were it not for you.
Krissy, it’s hard to believe you haven’t strangled me yet. You have offered me unconditional support throughout this program, especially at times where I felt overwhelmed and couldn’t make it. I can’t thank you enough for all you have done me; holding me to as high as a standard as you have has strengthened the caliber of this study ten-fold than what it would have been.

Jimbo, I don’t think I have ever met a man more awesome to you; I have learned so much about leadership just from watching you and how you carry yourself. It’s been an absolute pleasure getting to know you, and I appreciate all the support, advice and resources you have given me.

The ability of the three of you as a team to keep this process as lighthearted as you have is nothing short of a miracle. I don’t think I could have made it this far without you guys.
Table of Contents

ACKNOWLEDGEMENTS .................................................................................................................. 6

List of Tables ................................................................................................................................... 11

List of Figures ................................................................................................................................. 12

CHAPTER I ........................................................................................................................................... 14

INTRODUCTION .............................................................................................................................. 14

Purpose ............................................................................................................................................. 17

Research Questions ......................................................................................................................... 17

Hypothesis ......................................................................................................................................... 17

Limitations ......................................................................................................................................... 18

Delimitations ..................................................................................................................................... 18

Assumptions ....................................................................................................................................... 18

Operational Definitions .................................................................................................................... 19

CHAPTER II ........................................................................................................................................ 21

REVIEW OF LITERATURE ................................................................................................................. 21

Quality of life ..................................................................................................................................... 21

Cancer related Fatigue (CRF)........................................................................................................... 22

Physiological functioning .................................................................................................................. 23

Anti-gravity training .......................................................................................................................... 26

CHAPTER III ...................................................................................................................................... 29

METHODS ......................................................................................................................................... 29
Participants .................................................................................................................................................. 29
Inclusion/Exclusion Criteria .......................................................................................................................... 29
Equipment ..................................................................................................................................................... 30
Measurements ................................................................................................................................................ 30
Procedure ....................................................................................................................................................... 31
Research Design .......................................................................................................................................... 32
Exercise prescription .................................................................................................................................... 35
Alter-G Protocol ........................................................................................................................................... 37
CHAPTER IV RESULTS ................................................................................................................................. 38
CHAPTER V .................................................................................................................................................... 81
DISCUSSION .................................................................................................................................................. 81
Cardiovascular functioning as measured by treadmill times ...................................................................... 81
Flexibility ....................................................................................................................................................... 82
Balance and Mobility .................................................................................................................................... 82
Weight ............................................................................................................................................................ 83
Waist-to-hip ratio .......................................................................................................................................... 84
Resting heart rate (RHR) and Blood Pressure (BP) .................................................................................... 84
Quality of life ................................................................................................................................................ 85
Adherence ...................................................................................................................................................... 86
Limitations ..................................................................................................................................................... 90
Conclusion & Implications ............................................................................................................................... 91
Bibliography ................................................................................................................................................... 91
List of Tables

Table 1: Inclusion/Exclusion criteria ................................................................. 27
Table 2: Sample Session .................................................................................. 33
Table 3: Subject Characteristics ....................................................................... 34
Table 4: Wilcoxon Signed Rank Test ............................................................... 78
List of Figures

Figure 1: Timing of Phases in AB-AB design........................................................................33
Figure 2: Balke Protocol (P1).................................................................................................38
Figure 3: Sit and Reach (P1).....................................................................................................39
Figure 4: Get Up and Go (P1)...................................................................................................40
Figure 5: Weight (P1)...............................................................................................................41
Figure 6: Waist to Hip Ratio (P1)............................................................................................42
Figure 7: Resting Heart Rate & Blood Pressure (P1).................................................................43
Figure 8: Quality of Life (P1)..................................................................................................45
Figure 9: Balke Protocol (P2)..................................................................................................46
Figure 10: Sit and Reach (P2).................................................................................................47
Figure 11: Get Up and Go (P2)................................................................................................48
Figure 12: Weight (P2)............................................................................................................49
Figure 13: Waist to Hip Ratio (P2)........................................................................................50
Figure 14: Resting Heart Rate & Blood Pressure (P2).............................................................51
Figure 15: Quality of Life (P2)...............................................................................................53
Figure 16: Balke Protocol (P3)................................................................................................54
Figure 17: Sit and Reach (P3)..................................................................................................55
Figure 18: Get Up and Go (P3)...............................................................................................56
Figure 19: Weight (P3)...........................................................................................................57
Figure 20: Waist to Hip Ratio (P3)........................................................................................58
Figure 21: Resting Heart Rate & Blood Pressure (P3).............................................................59
Figure 22: Quality of Life (P3)...............................................................................................61
Figure 23: Balke Protocol (P4)................................................................................................62
Figure 24: Sit and Reach (P4)...............................................................................................63
Figure 25: Get up and Go (P4) ................................................................. 64
Figure 26: Weight (P4) ................................................................. 65
Figure 27: Waist to Hip Ratio (P4) ................................................................. 66
Figure 28: Resting Heart Rate & Blood Pressure (P4) ................................................................. 67
Figure 29: Quality of Life (P4) ................................................................. 69
Figure 30: Balke Protocol (P4) ................................................................. 70
Figure 31: Sit and Reach (P5) ................................................................. 71
Figure 32: Get Up and Go (P5) ................................................................. 72
Figure 33: Weight (P5) ................................................................. 73
Figure 34: Waist to Hip Ratio ................................................................. 74
Figure 35: Resting Heart Rate & Blood Pressure (P5) ................................................................. 75
Figure 36: Quality of Life (P5) ................................................................. 77
CHAPTER I

INTRODUCTION

Cancer is a major health issue in the United States (U.S.) and breast cancer in particular is one of the more prevalent forms of the disease. An estimated 1,638,910 new cancer cases for 2012 with 226,870 cases of breast cancer were expected to occur for the year in 2012 (American Cancer Society, 2012).

Major risks of cancer are a combination of modifiable and non-modifiable risk factors. Modifiable risk factors include increased body weight and Body Mass Index (BMI), unhealthy diet (regular consumption of foods high in sugar and fat, and regular consumption of alcohol), and a sedentary lifestyle; whereas non-modifiable factors include gender (females are at greater risk than males), increasing age, family history and possibly an increased exposure to hormones testosterone and progesterone due to early menstruation (before 12 years old) or late menopause (after age 55) (CDC, 2012; Irwin a, 2012; ACS 2012).

The American Cancer Society also states that survival rates for breast cancer have risen from 63% in the early 1960’s to almost 90% today, with over 2.9 million survivors in the U.S. (American Cancer Society, 2012). This survival rate is most likely due to increased awareness, earlier detection, along with advances in treatment. Consequently, this means that more women are living with the negative effects of cancer (Sprod, 2009), either by the disease itself, or as a result of treatment (radiation, chemotherapy, hormonal therapy etc.). Some of the negative effects include cancer related fatigue (CRF), pain, irregular sleep pattern, and decreased cardiovascular and pulmonary function (Irwin b, 2012).
Physical activity (PA) has been concluded to be a safe and effective treatment to attenuate the aforementioned negative effects for breast cancer survivors both during and post treatment. (Sprod, 2009; Schmitz, Kathryn H., Kerry S. Courneya, Charles Matthews, et al, 2010; Irwin, 2012) However, despite the strong growing evidence of the health promoting effects of PA, and the subsequent recommendations for levels of PA for survivors (150 min/wk of moderate to vigorous physical activity following treatment) the majority of women reach insufficient levels of PA (Irwin, 2008). Harrison et al assessed the PA levels of 287 breast cancer survivors in 6 month intervals up to 18 months post-diagnosis. Although almost 80% of survivors reported some sort of PA during the testing intervals, only 45% were considered to have met national guidelines for survivors (defined as moderate-intensity activity on 5 or more days for at least 30 min or vigorous activity on 3 or more days for at least 20 min) (Harrison, Hayes and Newman, 2008)

Several researchers have found specific barriers to physical activity in cancer survivors. These barriers include the non-availability of insurance coverage, reluctance of oncologists to prescribe PA, a lack of prioritization of PA in healthcare settings, and some confusion of patients as to whether PA increases survival (Irwin, 2008). Blaney and colleagues found additional barriers including physical deconditioning, social isolation, lack of confidence due to self-image, lack of exercise facilities & programs directed at patients (Blaney et al, 2012). Thus it appears that the availability, promotion, and acceptance of exercise programs directed at survivors are all important factors to increase their levels of physical activity.

Previous research directed at breast cancer survivors typically involved a 12-16 week program including a combination of flexibility, resistance, balance and cardiovascular training.
Exercise programs have generally utilized a treadmill, elliptical or a stationary bike to provide the cardiovascular training. Recognizing the need for more low impact exercises with survivors, particularly with their increased risk of osteoporosis and fracture after treatment (Chen et al, 2005), researchers have examined the use of a water-based exercise programs to unweight the participant and lower the impact even further (Fernández-Lao, Cantarero-Villanueva, Ariza-Garcia, Courtney, Fernández-de-las-Peñas, and Arroyo-Morales, 2013). These studies provide important implications that lower impact exercises may be a feasible and well-tolerated alternative to load bearing activities such as treadmill training for breast cancer rehabilitation. This study aimed to build on studies with lower impact exercise programs by using an antigravity (Alter-G®) treadmill to administer cardiovascular training.

The antigravity treadmill (Alter-G®) is a relatively new piece of equipment used in a range of settings from physical therapy to sports performance. This treadmill uses a chamber attached to a pair of modified shorts at waist-level. The chamber calibrates to match air pressure to the patient’s body weight. After calibration, the treadmill can then increase air pressure inside the chamber to ‘unweight’ the participant to as low as 20% of their body weight (Alter-G, 2012). The Alter-G treadmill builds on the premise set forth by the aquaciser treadmill by using pressure to unweight the participant; the advantage of the Alter-G is that it allows the technician to modify the air pressure in the chamber, providing a range from 20-100% of the participants’ body weight. This range allows participants to start at a relatively low weight on their bones and joints. They can gradually increase the percentage throughout the duration of the program to eventually reach 100% body weight. While still a relatively new tool for physical therapy, several studies have found positive results that support its safety and efficacy in training stroke
patients, lower body injuries (Saxena & Granot, 2011; Tenforde et al, 2012), and obese patients (Simonson et al, 2011).

The goal of an exercise program for cancer survivors is to help them regain independence while improving physiological function. Supervised exercise programs may act to utilize social support from health professionals to improve the survivors’ quality of life and avoid physical inactivity (Schmitz, Kathryn H., Kerry S. Courneya, Charles Matthews, et al, 2010).

**Purpose**

The purpose of this study was to determine the effectiveness a physical activity program including an anti-gravity (Alter-G) treadmill in improving physiological and psychosocial measures in female breast cancer survivors.

**Research Questions**

The research questions for this study are:

- RQ1- Investigate if the physical activity intervention will improve quality of life among participants.
- RQ2- Evaluate the effectiveness of the intervention at improving physiological measures including resting heart rate and blood pressure, body composition, mobility & flexibility, and aerobic capacity.

**Hypothesis**

The hypotheses for this study are

- A 5 week physical activity program including resistance, balance, flexibility and cardiovascular training will illicit improvements in quality of life
• Participants will show improvements in measures of flexibility, balance/mobility, resting heart rate/ blood pressure and cardiovascular endurance (Compared to pre testing/baseline or during each of the treatment phases compared to baseline and return to baseline phases) following the program

_Limitations_

The following are limitations of the study:

• The small sample size of the study may have been a limitation of the study; however the design of the study allowed for participants to be their own control, which strengthened the design.

• Participants will have had different stages & duration of cancer, as well as different modes of treatment, which could affect generalizability.

• The AB-AB design may not have been sensitive enough to detect changes in physiological variables, which can have a delay in returning to baseline.

_Delimitations_

The following are delimitations of the study:

• Participants were recruited from a small rural area in the Southeast.

• Participants were all female between the ages of 18 and 65.

• Participants were at least 6 months post treatment.

_Assumptions_

The following are assumptions of the study:

• Equipment was properly calibrated and functioned properly for testing and training sessions.

• Participants gave 100% effort during training and testing.
• Participants did not change their dietary habits.
• Participants did not take part in external physical activity.
• Participants provided honest and accurate answers on surveys.

**Operational Definitions**

**Cancer:** “A group of diseases that cause cells in the body to change and grow out of control”

(Breast Cancer facts & figures, 2012)

**Cancer Related Fatigue (CRF):** “persistent subjective sense of physical, emotional or cognitive tiredness or exhaustion related to cancer & cancer treatment that is not proportionate to activity & interferes with normal functioning” (Blaney et al, 2010)

**Cancer Survivor:** “any individual that has been diagnosed with cancer from the time of discovery and for the balance of life” (Scmitz et al, 2005)

**Cachexia:** “A multifactorial syndrome characterised by an ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment.” (Fearon et al, 2010)

**Radiation:** A form of treatment typically used for localized tumors. It is used to kill cancer cells and shrink tumors. Radiation may come from outside the body (external beam) or using radioactive material place inside the body (internal radiation). (ACSM/ACS, 2013)

**Chemotherapy:** Treatment that kills cancer cells by stopping growth and division (ACSM/ACS, 2013). Chemotherapy attacks rapidly dividing cells; often times this results in damage to otherwise healthy cells (red/ white blood cells, cells that line mouth and intestines, and hair growth).
**Hormonal treatment**: treatment that is used to block the body’s natural hormones. Often used to lower estrogen levels and subsequent growth of breast cancer cells (Breast Cancer facts & figures, 2012)

**Post treatment**: Survivors that have completed all treatment (chemotherapy, radiation, hormonal therapy, targeted therapy etc.) for at least 6 months.

**Respiratory exchange ratio (RER)**: Ratio of oxygen consumption to carbon dioxide production. Often used as a measured of substrate utilization during exercise. A value of 1.0 is representative of 100% carbohydrates and .7 100% fat. (Powers, & Howley, 2001)
CHAPTER II

REVIEW OF LITERATURE

An increasing number of studies have emerged promoting exercise and PA as a means to attenuate the side effects and improve cancer related quality of life among survivors. Several studies have hypothesized, with relative success, that exercise can be used to prevent, attenuate, treat and rehabilitate the physiological and psychosocial challenges faced by survivors (Schmitz, Courneya, Matthews, et al, 2010; Schneider, Hseih, Sprod, Carter, & Hayward, 2007; Sprod et al, 2009).

Quality of life

Chen et al (2010) studied the effects of regular exercise on quality of life (QOL) (General Quality of Life Inventory-74) in cancer survivors from baseline to 36 months post treatment. Participants (n=1829) were interviewed about their PA levels at each stage of assessment and assigned a metabolic equivalent task (MET). QOL was measured 6 months and 36 months after treatment. Regular exercise was found to have a significant positive effect in both measurements (at 6 and 36 months) of QOL. Participants with ≥8.3 MET experienced higher total scores on physical, psychosocial measurements along with an increase in social well-being.

A systemic review of 9 studies by Bicego et al (2008) analyzed the effects of different PA interventions as a means to improve quality of life (QOL) among participants. The duration of studies reviewed was between 8 and 24 weeks. Interventions ranged from gentle seated exercises, Tai Chi to more intense aerobic and resistance training. The researchers noted a
significant increase in Quality of life among intervention groups in comparison to control groups (although further reviews to determine the effect of different lengths of an intervention on QOL in survivors is warranted).

Schneider, et al (2007) investigated prescriptive exercise to improve muscular fitness, depression and quality of life in cancer patients. 135 women diagnosed with breast cancer were recruited for the study. Participants joined in a 6 month exercise program; with two to three sessions per week of a combination of aerobic and resistance training.

Their results demonstrated significant improvements in muscular fitness (p=.006), depression and quality of life (p=.0012) among survivors. Their findings suggested that utilizing moderate individualized, prescriptive exercise is a safe and efficacious means to improve quality of life and physical function in cancer survivors.

*Cancer related Fatigue (CRF)*

Peutz and Herring noted that approximately 50%-90% of cancer patients experience fatigue during treatment. For the majority of patients this fatigue remains apparent even after treatment has concluded. The researchers carried out a meta-analysis of 70 studies during and post-treatment. They found that over 90% of the studies reviewed during treatment, and 85% of the studies that reviewed post treatment interventions significantly decreased CRF (Puetz, Herring, 2012). They also noted that larger reductions of CRF in the post treatment group and greater improvements witnessed in studies with a longer time between treatment and program initiation.
A study done by Hsieh et al (2008) investigated the effects of an exercise intervention on physiological functioning and levels of fatigue in breast cancer survivors undergoing numerous clinical treatments. Patients performed a combination of stretching and aerobic and resistance training, two to three days a week for six months. Researchers found a significant decrease in fatigue and a concurrent improvement in cardiopulmonary function regardless of type of treatment received.

Velthuis, Agasi-Idenburg, Aufdemkampe and Wittink (2010) conducted a review of 19 studies to determine the effects of PA on CRF. Studies were grouped into either home-based or supervised exercise programs. Of the 18 studies reviewed, 12 were with breast cancer survivors, with 6 being of other cancer types. Their analysis found home-based exercise programs showed no significant reductions in CRF, whereas the supervised exercise programs were more effective in significantly reducing CRF. Reviews concerning breast cancer survivors in particular found significant improvements during supervised aerobic programs.

Schneider et al (2007) divided 113 Breast cancer survivors into groups depending on whether they were receiving an exercise intervention during treatment, or post treatment. After a 6-month treatment period, the effectiveness of the intervention was analyzed. Both during and post treatment groups showed significant reductions in behavioral, sensory and total fatigue (on the Piper Fatigue Inventory).

**Physiological functioning**

PA has been shown to induce physiological benefits; however some survivors may be limited in their activity by cancer related fatigue (Stasi, R., Abriani, L., Beccaglia, P., Terzoli, E. & Amadori, S., 2003).
Twiss, Waltman, Berg, Ott, et. al (2009) conducted a 24 month long study to examine the effects of an intervention of strength and weight exercises on breast cancer survivors who had experienced bone loss. The study included both an exercising group (n=110) and a control group (n=113). The program comprised of home and fitness center based exercises, with measurements of strength (using Biodex ®) and balance (Timed Backward Tandem Walk) taken at baseline and every 6 months thereafter. After analysis of measurements, researchers found “meaningful gains in muscle strength and balance” (Twiss, Waltman, Berg, Ott, et. al, 2009, p 25).

The study also reported an adherence rate of almost 70% over 2 years. The researchers noted several reasons for participant dropout (lack of time, chronic pain, osteoarthritis and injury/fractures) that can help researchers navigate these in the future and aim to increase adherence rates.

In a previously mentioned study, Schneider et al (2007) also found significant improvements in physiological measurements in breast cancer survivors both during and post treatment following a 6 month supervised exercise intervention. The during treatment group also showed an increase in cardiopulmonary function (as measured by systolic blood pressure and time on treadmill) with the post treatment group showed reductions in blood pressure and resting heart rate.

A study done in 2009 by Sprod et al compared the physiological and psychological effects of three versus six months of exercise training in breast cancer survivors. Survivors either completed a 3-month (n=29), a 6-month (n=68) or no treatment (n=17) exercise intervention during the experiment. Pulmonary function was assessed via forced vital capacity (FVC) and forced expiratory volume in one-second (FEV₁). Muscular endurance was measured using a
battery of tests developed specifically for cancer survivors (weight lifted was determined by body weight and age of survivor, and repetitions were performed at a rate of 12.5 repetitions per minute until volitional fatigue). The results showed that 3 months of exercise improved symptoms of depression, fatigue and cardiovascular endurance. Further improvements in muscular endurance and pulmonary function were shown in the survivors who exercised for 6 months. This study highlights the efficacy of interventions of longer length to illicit further improvements in physiological variables and attests to importance of survivors to maintain an exercise program.

More recently, Saarto & colleagues (2012) examined the effects of a 12 month combined step aerobic and circuit-training program on bone mineral density (BMD) at the lumbar spine and femoral neck in pre and post-menopausal breast cancer survivors (n=498). The intervention consisted of one supervised session and two to three home based sessions a week. The supervised session alternated between a vigorous step aerobics session and a circuit training session weekly. Similar exercises were prescribed for home-based sessions to ensure a minimum of three sessions per week. Bone loss managed to be prevented in the intervention group for premenopausal women; with lumbar bone loss being unable to be prevented. Researchers found no significant effect of exercise on BMD at either femoral neck or lumbar spine. Bone loss in post-menopausal survivors was attributed to age, menopause, and even older participants lower physical performance and resulting lower level of training intensity to induce bone loading. Nonetheless, this study shows promise to the efficacy of supervised exercise programs at preventing bone loss in premenopausal survivors.
**Anti-gravity training**

Figueroa, Manning & Escamilla (2011) investigated the difference in metabolic work when using an anti-gravity treadmill, at different percentages of body weight (80%, 90%, & 100%) compared to jogging to maximal aerobic capacity. Testing of 10 subjects occurred on three separate days at three different percentages of their body weight. Each testing session was separated by two weeks. Maximal oxygen consumption (VO2 max) was measured using a modified Bruce Protocol. Additionally, caloric expenditure (kcals), substrate utilization (RER), rating of perceived exertion (RPE) and HR response of participants while jogging were all measured. Relative and absolute VO2max values were not significantly different at any body weight percentage compared to running regularly. Similarly, HR and RER were not significantly affected by the reduction in body weight. This study provides promising evidence in support of the use of unloading a participant to reduce ground reaction forces and subsequent impact on their bones and joints, yet maintaining the same metabolic responses to exercise. Future research may need to investigate the effects of reducing the percentage of body weight even further (70%, 60% & 50%). This line of research examining low impact exercises on physiological variables in breast cancer survivors is promising, yet further research is warranted to determine the most effective types of interventions.

The American College of Sports Medicine (ACSM) recently conducted a roundtable to review the current literature and ultimately conclude that exercise training is safe during and post- treatment and can result in improvements in cancer related fatigue, Quality of life, and physical functioning. (Schmitz, Courneya, Matthews, et al, 2010) The focus was on adult cancers
where most evidence had been assembled (breast, prostate, colon, adult hematologic, Adult HSCT & gynecologic).

These guidelines were developed based on existing ACSM, AHA, ACS and 2008 US department of Health and Human Services recommendations. The roundtable highlighted that the study of the safety and efficacy of exercise is an emerging one; consequently, literature should be reviewed frequently.

Detailed guidelines for prescription of exercise including pre assessment, contraindications, and progression for different types of cancer are provided in the roundtable (Schmitz, Courneya, Matthews, et al, 2010) but some of the key findings are outlined below.

- Exercise prescription should be individualized to each survivor based on their pretreatment physical assessment, medical history, response to treatment and apparent contraindications.

- Maintaining and increasing muscle mass is recommended for all survivors.

- 85 studies reviewed, with consistent evidence found on the safety and efficacy of exercise before and after treatment.

  - Some exercise induced improvements consistently found in reviewed studies:
    Quality of Life, fatigue, aerobic fitness, muscular strength, and endurance

The roundtable also emphasized two limitations of current research;

- This field of research is in its adolescent stages, thus studies have focused on the efficacy and feasibility of exercise as opposed to the effectiveness and generalizability
There is a need for greater specificity and consistency between studies on optimal dose-response and the effects of particular types of training before and after treatment.
CHAPTER III

METHODS

Participants

Participants of the study (n=6) were female breast cancer survivors (51±18 years old). One participant dropped out of the program due to an extended vacation taken towards the end of the study. Participants were recruited through a number of measures, primarily word of mouth and recruitment flyers. Each participant was given a numerical code to identify them objectively and protect their identity. Prior to participation, all participants were required to complete a cancer specific PAR-Q, a written statement of informed consent, and a form providing physicians’ release to participate in the study. This study was approved by the University’s Institutional review board (H13160).

Inclusion/Exclusion Criteria

The inclusion/exclusion criteria for participation in the study are outlined below:

<table>
<thead>
<tr>
<th>Table 1: Inclusion/Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inclusion Criteria</strong></td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Breast Cancer Survivor</td>
</tr>
<tr>
<td>At least 6 months post treatment</td>
</tr>
<tr>
<td>18-65 years old</td>
</tr>
<tr>
<td>Participant is willing and able to</td>
</tr>
<tr>
<td>complete the protocol</td>
</tr>
<tr>
<td>Participant has received physician’s</td>
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<tr>
<td>clearance</td>
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</table>


**Equipment**

- The Alter-G treadmill

This was a primary component of the aerobic training portion of the program. Participants began at a percentage of their body weight that they felt was comfortable (at least 50%). Progression to higher percentages was individualized, gradual and measured on a combination of the participant’s ability, and the exercise specialist’s assessment of their ability to progress.

- Other equipment used in the program included; free weights, Bosu™ balls, resistance bands, weight training machines.

**Measurements**

(Further detail & instructions provided to participant are outlined in the appendices)

- Resting Heart Rate (beats per minute, BPM) & Blood pressure (mmHg)

- Cardiovascular endurance via treadmill time

- Functional Balance- Timed “Get Up and Go” (in seconds)
  - Get Up and Go Test begins with the participant sitting in a chair. Their score is based on the time it takes them to rise from the chair, walk three meters, turn and return to the chair.

- Flexibility- modified sit and reach (cm)

- Body composition - circumference (cm), weight (kg)
Procedure

The Alter-G treadmill intervention closely followed interventions by Schneider et al, (2007) and guidelines recently released by the ACSM (Schmitz et al. 2010,) for safe and efficacious training with cancer survivors. The program included a screening week, where participants filled out informed consent forms and were given an overview of what the study would consist of. Participants were asked to sign a University research participation release form prior to beginning the program.

This study focused on recommendations for pre-exercise assessments, exercise prescription and programming adaptations from ACSM’s newly released Guide to Exercise and Cancer Survivorship (2012). The primary investigator was a certified professional with an extensive background working with cancer survivors. The investigator was able to modify, adapt and individualize exercise prescription as needed.

Exercise prescription was based on initial assessments of cardiorespiratory fitness, muscular strength and endurance, flexibility, range of motion and body composition (Sprod, 2009). Screening and training protocol closely followed the American College of Sports Medicine (ACSM) contraindications and precautions for exercise and testing patients with cancer (Schmitz et al. 2010).

Rate of perceived exertion (RPE) was monitored throughout each session (Sprod, 2009) using Borg’s modified RPE scale (Borg, 1982). The modified Borgs scale is a commonly utilized tool to evaluate perceived exertion of exercise sessions. This scale is numbered 1-10 (10 being the highest level of perceived physical exertion, 1 being the lowest); participants are asked how they felt the intensity of an exercise or session was on the scale of 1-10. The reliability of this scale
has been found to be high \((r = 0.80–0.90)\) (Chen, Xitao and Moe, 2002) and it’s validity to be high \((r= ~64)\) (Karavatas and Tavakol, 2005).

**Research Design**

A single case AB-AB designed was employed (Kazdin, 1982). The design consisted of four phases: (A) a baseline testing phase to establish initial conditions and performance, followed by (B) an intervention phase (4 weeks) followed by (A) a return to baseline (2-3 weeks) and (B) a final replication phase. This design is unique in that it employs multiple baselines, allowing for each participant to serve as their own control. Continuous testing was performed three times a week throughout the program. The result of each assessment for each variable was plotted along a graph. Using ocular statistics, these scores were observed and evaluated to determine if the treatment was effective.

Below is an outline of sessions and visits with the program:

**Week 1 – Visit 1**

- Consisted of initial screening and testing. Participant’s physician clearance form was reviewed, along with PAR-Q. Participants were given an orientation into the study, a demonstration of some of the equipment, particularly the Alter-G treadmill, and an overview of the timeline of the study.

**Week 1 – Visit 2: Baseline Testing (BT)**

- Regular testing (RT) was performed prior to each session. Participants resting heart rate and blood pressure were taken along with assessments of flexibility & balance/mobility.
Baseline testing was performed once a week and consisted of the regular testing outlined above, with additional measurements of body composition, Quality of Life and cardiovascular endurance.

**Balance/Mobility**

- Functional balance was measured with a timed “Get-up-and-Go” (GUG) test. The GUG test consisted of time measurements of the participants starting from a seated position, standing without the help from their hands, walking forward three meters, turning around, walking back to the chair, and sitting down without use of their hands. Time was measured in seconds.

**Flexibility**

- A modified sit and reach test was used to measure flexibility. Participants sat in a chair with one leg outstretched. They then slid their hands as far down their outstretched leg as possible. Flexibility was measured by the distance between the participant’s fingertips and their toes.

**Body composition**

- Body composition was tracked using a combination of circumference, waist-to-hip ratio, and weight.

**Quality of Life**

- Measured using Ferrans and Powers QUALITY OF LIFE INDEX© CANCER VERSION – III. This is a survey used to establish a client’s satisfaction in various areas of their
The survey is a 6-point Likert-type scale determining participants’ satisfaction & perceived importance of different aspects of their life.

**Cardiovascular endurance**

Cardiovascular endurance was measured through the use of a modified Balke protocol (Appendix F). This test was administered on a traditional treadmill as no protocols have been established for use on the Alter-G treadmill. Participants were asked to walk until volitional fatigue. Total time on the treadmill was recorded.

**Week 1 - Visit 3**

Training sessions began on the third visit. Sessions consisted of a combination of flexibility, balance and resistance exercises.

**Week 2 – Visit 4-6**

-These visits included the same procedure as the third visit; sessions comprised of flexibility, balance and resistance training.

**Weeks 3-7 – Visits 7-21**

-These visits included the training sessions as interventions. RT was performed at the beginning of each session, followed by a combination of resistance, aerobic and flexibility training. The Alter-G treadmill was introduced in the program. Participants all began at a percentage of their bodyweight they felt they could comfortably walk at (at least 50%).

**Weeks 8-9 - Visit 22-28**
- This “return to baseline” phase included the removal of the Alter-G treadmill. There was no structured cardiovascular training performed during this time. However, resistance, flexibility and balance training were all maintained during this period.

*Weeks 10-14 - Visit 29-45*

- Return to treatment. The Alter-G treadmill was reintroduced. Procedure for this phase was the same as visits 7-21.

Below is a visual outline of the timing of the phases during the study.

**Figure 1: Timing of Phases in AB-AB Design**

<table>
<thead>
<tr>
<th>Behavior/physiological condition</th>
<th>Baseline (A Phase)</th>
<th>Intervention (B Phase)</th>
<th>Return to Baseline (A)</th>
<th>Final replication (B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase</td>
<td>Weeks 1-2</td>
<td>Weeks 3-7</td>
<td>Weeks 8-9</td>
<td>Weeks 10-14</td>
</tr>
</tbody>
</table>

*Exercise prescription*
The program consisted of muscular strength and endurance, and cardiovascular endurance exercises. Consistent with current literature and guidelines, exercise interventions were individualized and tailored to suit individuals.

General standards of exercise intervention included:

- 60-minute sessions 2 days per week (a minimum of 24 hours rest was required between training days). A third day each week was used for testing.

- Warm-up, followed by bouts of aerobic, resistance, balance and flexibility training, followed with a cool down.

- RPE was used to monitor & adjust levels of intensity for both aerobic and resistance training

- Participants began with 1-2 sets of 12-15 repetitions; gradually increasing to 3 sets of 8-10 repetitions.

**Table 2: Sample Session**

<table>
<thead>
<tr>
<th>Tests</th>
<th>Set 1</th>
<th>Set 2</th>
<th>Set 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Rate/Blood Pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GUG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flexibility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercises (weight/reps)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Push ups</td>
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<td></td>
<td></td>
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<tr>
<td>Pull ups</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Body weight squats</td>
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<td></td>
<td></td>
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<tr>
<td>Exercise</td>
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<td></td>
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<tr>
<td>Leg Press</td>
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<td></td>
<td></td>
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<tr>
<td>Leg Extension</td>
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<td></td>
<td></td>
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<tr>
<td>Leg Curls</td>
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<td></td>
<td></td>
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<tr>
<td>Curls</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Tricep Extension</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foam pad timed leg stand</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bosu ball balance throw</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PNF stretching</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Alter-G Protocol**

Participants began the aerobic training at a percentage of their body weight they felt comfortable (at least 50% of their body weight). The percentage of body weight was increased as participants’ improved and progressed throughout the program. Aerobic exercise was performed for a minimum of 30 minutes each session. Intensity was manipulated by increasing the percentage of weight the participants worked at, and/or the speed of the treadmill.
CHAPTER IV

RESULTS

Data Analysis

Visual inspection was used to analyze changes in magnitude (mean and level) and the rate of change (trend and latency) (Kazdin, 1982).

Mean: The mean of each phase was calculated. Using the mean from baseline, we can predict the future performance of the participant if no change were to occur and from this compare the mean determined from the intervention to infer the magnitude of change.

Level: The level of each refers to the difference between the last measurement of one phase to the first measurement of the following phase. Essentially, this allows one to infer how great of a change occurred when a phase shift occurred.

Trend: The trend refers to the direction of the data throughout the intervention. Through visual inspection, one can look at the trend of measurements either increasing or decreasing concurrent with each appropriate phase, which may add strength to the hypothesis that the change is a result of the presence or lack of an intervention.

Latency: Latency refers to how quickly after a change of phase does a change in measurement occur. An immediate increase of decrease in measurements, for example, would suggest that it was a phase change that caused the different measurements than a change that happened later.
Table 3 – Subject Characteristics (n=5).

Participant 1 (P1)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>(mean ±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>51±18</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>166.12±17.78</td>
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<tr>
<td>Weight (kg)</td>
<td>73.12±45.8</td>
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<td>Cancer stage</td>
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<td>Radiation</td>
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<tr>
<td>Chemotherapy</td>
<td>5</td>
</tr>
<tr>
<td>Hormonal Therapy</td>
<td>2</td>
</tr>
<tr>
<td>Surgery</td>
<td>5</td>
</tr>
</tbody>
</table>

Figure 2 – Balke Protocol (P1)
The mean treadmill time for the first baseline phase was 9.25 minutes; 12.04 minutes for the return to baseline phase and 13.99 for the second intervention phase 12.03 minutes followed the mean for the final replication phase. There was an increase in mean between the first baseline and first intervention phases, followed by a stable mean between the first intervention and the return to baseline phase, with a subsequent increase in mean in the replication phase from the return to baseline phase. There was little change in level between phases although there was evidence of an increasing trend in treadmill time in both intervention phases. The latency of change was not immediate although evident in both intervention phases with respect to the preceding baseline phases.
The average score for baseline one was 4.17cm, with the first intervention having a mean of -5.34cm, return to baseline mean of -7.08cm and a final replication mean of -6.28cm. There was a slight change in level between the first baseline phase and the first intervention phase, and another slight change in level seen between the return to baseline phase and final replication phase. There was an apparent trend in increase of flexibility from the first baseline to the first intervention phase, followed by a leveling of scores from the return to baseline to final replication. The latency of change was evident in the first baseline to the first intervention (although there was already a downward trend in scores during the first baseline phase) and a subsequent change in latency evident in the return to baseline to final replication phase.

Figure 3 – Sit and Reach (P1)
The first baseline phase exhibited a mean of 9.2 seconds (s), with the first intervention phase displaying a mean of 6.14s, followed by a mean of 5.89s in the return to baseline phase and a mean of 5.33s in the final replication stage. There was little to no apparent change in level between each of the four phases. There was evidence of a trend with a slight improvement of scores across baseline and the first intervention phase followed by an apparent plateau in scores. There was slight evidence of a change in latency at the onset of the first intervention phase from baseline and then again in the final replication phase from the return to baseline phase.

Figure 4 – Get up and Go (P1)
The mean weight for the first baseline phase was 119.6kg; the mean for the first intervention phase was 118.6kg. The means for the return to baseline and final replication were 119kg and 119kg, respectively. There was little change in level across the four phases of the study. There was a relatively stable trend in both baseline phases with a trend of a decrease in weight in both intervention stages. Finally, the latency of change was apparent, although not immediate in both intervention stages.
Figure 6 – Waist to Hip Ratio (P1)
The mean waist to hip ratio (W/H) was .91 for the first baseline phase, .87 for the first intervention phase and the return to baseline phase, and .84 for the replication phase. There were slight changes in level evident between the first baseline phase and the first intervention phase, the first intervention and return to baseline phase, and finally the return to baseline phase and final replication phase. There was a stable trend in the first baseline phase, followed by a decreasing trend in the first intervention phase. There was a stable trend in the return to baseline phase with no apparent trend in the final baseline phase. The latency of change was evident, although slightly delayed in both intervention phases with respect to the preceding baseline phases.

Figure 7 – Resting Heart Rate & Blood Pressure
The mean RHR for Baseline 1 was 69.5 bpm, followed by a mean of 70.3 bpm for the first intervention phase, 70.3 bpm for the return to baseline phase, and 67.4 bpm for replication phase. There was relatively little change in level between each phase. There was no obvious change in trend throughout the study. The latency of change was not obvious between phases.

The mean systolic blood pressure (SBP) for the first baseline phase was 127.67 mmHg, with a mean of 125.13 mmHg for the first intervention phase. The mean blood pressure for the return to baseline phase was 127.5 mmHg with a mean of 125.8 mmHg for the final replication phase. There was little evidence of change in level between phases with the exception of the baseline 2 and final replication phase. There was evidence of a slight increasing trend in SBP in baseline, followed by a slight decrease in the intervention phase, a relatively stable return to baseline phase, and a curvilinear decrease in the final replication phase.

The mean diastolic blood pressure was 77.6 mmHg for the first Baseline phase, followed by a mean of 81.78 mmHg for the first intervention phase, 77.4 mmHg for the return to baseline phase and 76.06 mmHg for the final replication phase. There is little change in level between each phase. There is no apparent trend throughout the phases. The latency of change is not evident between phases.
The mean total quality of life for the first baseline phase was 20.70, 24.86 for the first intervention phase, 25.06 for the return to baseline phase. The mean for the final replication phase was 26.23. There was a slight change in level between the first baseline phase and the first intervention phase, with little change across the subsequent phases. There was no apparent change in trend across phases. There was no latency of change evident between any phase with the exception of an immediate change apparent between the first baseline phase and the first intervention phase.

Figure 8 – Quality of Life (P1)
Participant 2 (P2)

Figure 9 – Balke Protocol (P2)

There was a change in mean time for the Balke protocol across all phases. The mean time was 6.3min in baseline one, 12.8 minutes in intervention one, 14.04min in baseline two and 19.51min in intervention two. There was a slight change in level between baseline one and intervention one. The latency of change is evident in both intervention stages. There was a trend of increasing times in baseline one, intervention one and intervention two with a stable trend in baseline two. The latency of change was evident, although slightly delayed in both intervention phases.
There was a change in mean of sit and reach scores across all phases. The mean for baseline one was -6 cm, the mean for intervention one was -9.7 cm, with the mean for baseline two and intervention two being -13.75 cm and -14.94 cm, respectively. A change in level was evident from baseline two to intervention two. There was a trend of decreasing scores (increasing flexibility) across all phases. The latency of change was not evident between any of the phases.
The mean scores for the GUG test were 5.1s for baseline one, 4.31s for intervention one, 4.29s for baseline two, and 4.27s for baseline two. There was a slight change in level between baseline one and intervention one with a decrease in time, with no change in level in any other phase. While there was a trend of decreasing time in baseline one, there was no change in trend across the other phases. There was no latency of change between each phase.
The mean weight for baseline one was 85.6kg, for intervention one was 82.8kg, for baseline two was 80.9kg, and a mean of 81.6kg for intervention two. There was a slight change in level between baseline two and intervention two. There was a trend of decreasing weight in intervention one and a curvilinear increase in intervention two. The latency of change is evident in both intervention phases. In both phases, the change seemed occur almost immediately with the introduction of the intervention.
The mean for the first baseline phase was .84; the mean for the first intervention phase was .80. The means for the return to baseline and final replication were both .78. Thus, there was a .04 reduction in the mean waist-hip ratio between the first baseline and first intervention phase, and a subsequent reduction of .02 between the first intervention and the return to baseline phase. There was no evidence of a change in level between any of the phases. There was a trend of a slight decrease in W/H in baseline one. There was also evidence of a slight decrease in scores in intervention one, with an apparent increase in scores in intervention two. The latency of trend was not immediately apparent in any of the phases.
The mean resting heart rate for the first baseline phase was 73 bpm, the mean for the first intervention phase was 73 bpm, with means of 69 bpm and 74 bpm for the return to baseline phase and final replication phase, respectively. There was relatively little change in level between each phase. There was also no obvious change in trend, nor evidence of latency of change between the phases.

The mean systolic blood pressure for the first baseline phase was 121 mmHg, with a mean of 121 mmHg for the first intervention phase. The mean SBP for the return to baseline phase was 124 mmHg with a mean of 119 mmHg for the final replication phase. There was little evident of change in level between phases with the exception of a slight increase between the first
intervention phase and the return to baseline phase. There was little evidence of change of trend between phases. There was also little evidence of latency of change between phases.

The mean diastolic blood pressure for the first baseline phase was 78mmHg, with a mean of 78mmHg for the first intervention phase. The return to baseline phase and final replication phase had means of 78mmHg and 77mmHg respectively. Similarly, there was little change in level between phases. There was no obvious change in trend between phases. The latency of change was not obvious between phases.
The mean quality of life for the first baseline phase was 24, with a score of 27 for the first intervention phase. There was a mean of 27.7 for the return to baseline phase and 27.65 for the final replication phase. There was a trend a slight increase in scores across the baseline phase and the first intervention phase. There was no change in level apparent across phases. There was also little evidence of latency of change across each phase.

Figure 15 – Quality of Life (P2)
Participant 3 (P3)

There was a change in mean time for the Balke protocol across all phases. The mean time was 7.8 min in baseline one, 14.19 min in intervention one, 20.9 min in baseline two and 28.4 min in the final replication phase. There was a slight change in level between baseline one and intervention one. There was a trend of increasing times in both intervention phases with stable trend in both baseline phases. The latency of change was evident, although slightly delayed in both intervention phases.
Figure 17 – Sit and Reach (P3)

There was a change in mean of sit and reach scores across all phases. The mean for baseline one was -25cm, the mean for intervention one was -26cm, with the mean for baseline two and intervention two being -28cm and -29cm, respectively. There was no obvious trend in the first baseline phase, with a trend of decreasing scores (increased flexibility) in the first intervention phase. The return to baseline phase and final replication phase showed a stable trend. There was no obvious change in level across any phase. There was a slight delay in the latency of change between the first baseline phase and the first intervention phase, with no evidence of latency of change in the remaining phases.
Figure 18 – Get Up and Go (P3)

The mean scores for the GUG test were 6.02 sec for baseline one, 4.75 seconds for intervention one, 4.6 sec for baseline two, and 4.2 sec for the final replication phase. There was a downward trend in the first baseline phase, with a slight downward trend in the final replication phase. There was no apparent change in level between phases. The latency of change was not evident between phases.
There was a change in mean between phases. The mean weight for the first baseline phase was 46.2kg the mean for the first intervention phase was 47.86kg. The mean weight for the return to baseline phase and final replication phase were 48.6kg and 47.5kg, respectively. There was a change in level between the first baseline phase and first intervention phase and again between the return to baseline phase and final replication phase. There was a trend of increase in weight in the first intervention phase and a subsequent trend of a curvilinear decrease in weight in the final replication phase. The latency of change was evident in both the first intervention phase and final replication phase as changes in weight occurred almost immediately.

Figure 19 – Weight (P3)
The mean W/H was .73 for the first baseline phase, with a mean of .74 for the first intervention phase. The means for the return to baseline phase and final replication phase were .73 and .73 respectively. There was no change in level or trend between each phase. The latency of change was not obvious in this phase.
The mean resting heart rate for the first baseline phase was 101 bpm, the mean for the first intervention phase was 105 bpm, with means of 107 bpm and 104 bpm for the return to baseline phase and final replication phase, respectively. There was no obvious change in level between phases. There was no evidence of a change in trend between phases. There was also no latency of change in any phase.

The mean systolic blood pressure for the first baseline phase was 124 mmHg, with a mean of 125 mmHg for the first intervention phase. The mean SBP for the return to baseline phase was 127 mmHg with a mean of 122 mmHg for the final replication phase. There was no evidence of a
change in level or trend between phases. A latency of change between phases was also not apparent.

The mean diastolic blood pressure for the first baseline phase was 79.5Hg, with a mean of 76mmHg for the first intervention phase. The return to baseline phase and final replication phase had means of 74mmHg and 73mmHg, respectively. There was no obvious change in level or trend between phases. There was also no obvious latency of change between phases.
The mean for the first baseline phase was 15.33, followed by a mean of 17.5 for the first intervention phase. The mean quality of life for the return to baseline phase was 20.1 with a score of 24.88 for the final replication phase. There was a trend of an increase in quality of life score across all phases, with the exception of the first intervention phase, which appeared to have an unstable trend. There were changes in level between the first baseline phase and the first intervention phase, the first intervention phase and the return to baseline phase and a slight change between the return to baseline phase and the final replication phase. The latency of change was evident between the first baseline phase and the first intervention phase and between the first intervention phase and return to baseline phase.
Participant 4 (P4)

The mean time for the first baseline phase was 18.83min, with a mean of 34.93min for the first intervention phase. The mean times for the return to baseline and final replication phase were 50min and 54.2min, respectively. There was an increasing trend in the first baseline phase, first intervention phase, and final replication phase. There was no obvious change in level between phases. The latency of change was apparent and immediate in both intervention phases.

Figure 23 – Balke Protocol (P4)
The mean sit and reach scores for the first baseline and first intervention phase were -1.3cm and -14.5cm, respectively. The mean for the return to baseline phase was -14.3cm with a mean of -16.3cm for the final replication phase. There was a decreasing trend (increased flexibility) in the first baseline phase, and again in the first intervention phase. There was a stable trend apparent in the two final phases. There was a change in level between the first baseline phase and the first intervention phase and again between the return to baseline phase and the final replication phase. The latency of change was not apparent between phases.
The mean scores for the GUG test were 4.5s for the first intervention phase, 3.8s for the first baseline phase, 3.6s for the return to baseline phase, and 3.6s for the final replication phase. There was a slight trend of increasing scores in the first baseline phase, with no apparent trend in the other three phases. There was a change in level between the first baseline phase and the first intervention phase. The latency of change was also evident between the first baseline phase and the first intervention phase.

**Figure 25 – Get Up and Go (P4)**
The mean weight for the first baseline phase was 80kg with a mean of 78.1kg in the first intervention phase. The mean weight for the return to baseline phase and final replication phase was 78.1kg and 76.8kg, respectively. There was a stable trend apparent in both baseline phases, with a trend of decreasing weight in both intervention phases. The was a slight change in level between the first baseline phase and first intervention phase, and between the return to baseline phase and final replication phase. The latency of change is apparent, and immediate in both intervention phases.
The mean W/H for the first baseline phase was .83, with a mean of .80 for the first intervention phase. The mean for the return to baseline phase was .78 with a mean of .80 for the final replication phase. There was a decreasing trend of waist-hip ratio in the first baseline phase, with no apparent trend in the first intervention phase. There was no trend in the return to baseline phase, with a slight increasing trend in the final replication phase. There was a change in level between the first baseline phase and the first intervention phase, the first intervention phase and return to baseline and finally the return to baseline phase and final replication phase. There was a latency of change in between the first baseline phase and first intervention phase, and the first baseline phase and return to baseline phase. The latency of change was also evident in between the return to baseline phase and final replication phase.
The mean resting heart rate for the first baseline phase was 68 bpm, the mean for the first intervention phase was 70bpm, with means of 75bpm and 71bpm for the return to baseline phase and final replication phase, respectively. There was a slight change in level between the first intervention phase and the return to baseline phase. There was no obvious change in trend between phases. The latency of change was also not evident between phases.

The mean systolic blood pressure for the first baseline phase was 118mmHg, with a mean of 117mmHg for the first intervention phase. The mean SBP for the return to baseline phase was 123mmHg with a mean of 118mmHg for the final replication phase. There was no evidence of a
change in level or trend between phases. A latency of change between phases was also not apparent.

The mean diastolic blood pressure for the first baseline phase was 81mmHg, with a mean of 76mmHg for the first intervention phase. The return to baseline phase and final replication phase had means of 78mmHg and 76mmHg respectively. There was no obvious change in level or trend between phases. There was also no obvious latency of change between phases.
The mean scores for quality of life were 24.81 in the first baseline phase, 29.13 in the first intervention phase, 29.65 in the return to baseline phase and 27.87 for the final replication phase. There was a trend of increasing scores in the first baseline phase, with stable trend across the first intervention phase and return to baseline phase, with a relatively stable trend in the final replication phase. There was a slight change in level between the first baseline phase and the first intervention phase. There latency of change was apparent between the first baseline phase and the first intervention phase.

Figure 29 – Quality of Life (P4)
The mean times for the Balke protocol were 12.16 min for the first intervention phase, 21.88 min for the first baseline phase, 31 min for the return to baseline phase and 34.2 min for the final replication phase. There was a trend of increasing time in the first intervention phase and final replication phase. There was a change in level between the first baseline phase and the first intervention phase. The latency of change was immediately evident between the first baseline phase and first intervention phase.
The mean sit and reach score for the first baseline phase was -11.5cm, with a mean of -18.1cm for the first intervention phase. The means for the return to baseline phase and final replication phases were -18.2cm, and -17.9cm respectively. There was a change in level between the first baseline phase and the first intervention phase, and again between the return to baseline phase and final replication phase. There was a trend of a curvilinear decrease (increase in flexibility) in the first intervention phase; all other phases had stable trends. The latency of change was evident between the first baseline phase and the first intervention phase, and again between the return to baseline phase and final replication phase, with immediate responses to the intervention.
The means for the GUG test were 4.9s for the first baseline phase, 3.9s for the first intervention phase, 4.0s for the return to baseline phase, and 4.0s for the final replication phase. There was a trend of decreasing time in the first baseline phase, and a slight decrease in the first intervention phase. There was a slight change in level between the first intervention phase and the return to baseline phase. The latency of change was not evident across the phases.
The mean weight for the first baseline phase was 81.1kg, with a mean weight of 80.2kg for the first intervention phase. The mean for the return to baseline phase was 80.4kg with a mean or 80.5kg for the final replication phase. There was a decreasing trend in the first baseline phase, a curvilinear decreasing trend in the first intervention phase, a stable trend in the return to baseline phase and no obvious trend in the final replication phase. There was a change in level between the first baseline phase and the first intervention phase, and between the first intervention phase and the return to baseline phase. The latency of change was immediately evident between the first baseline phase and the first intervention phase.
The mean W/H for the first baseline phase was .71, with a mean of .71 for the first intervention phase. The means for the return to baseline and final replication phase were .70 and .69, respectively. There was evidence of a decreasing trend in both baseline phases, and the final replication phase. There was a change in level between the first baseline phase and the first intervention phase, and again between the first intervention phase and return to baseline phase. The latency of change was apparent, although slightly delayed in the first intervention phase.
Resting Heart Rate & Blood Pressure

The mean for resting heart rate was 78bpm for the first baseline phase, 84bpm for the first intervention phase, 88.5bpm for the return to baseline phase, and 83bpm for the final replication phase. There was no obvious trend across each phase. There was no evidence of a change in level between each phase. The latency of change was not apparent between phases.

The mean for systolic blood pressure was 127mmHg for the first baseline phase, 125mmHg for the first intervention phase, 127mmHg for the return to baseline phase, and 125mmHg for the final replication phase. There was no obvious change in level or trend across phases. There latency of change was not apparent between phases.

Figure 34 – Resting Heart Rate & Blood Pressure (P5)
The mean for diastolic blood pressure was 79 mmHg for the first baseline phase, 82 mmHg for the first intervention phase, 76 mmHg for the return to baseline phase, and 76 for the final replication phase. There was no apparent change in trend or level between phases. The latency of change was not apparent between phases.
The mean quality of life for the first baseline phase was 25.13, with a mean of 24.65 for the first intervention phase. The mean for the return to baseline phase was 25.07 with a score of 26.63 for the final replication phase. There was a relatively stable trend across all phases, with a curvilinear increasing trend in the final replication phase. There was a slight change in level between the first baseline phase and first intervention phase. The latency of change was evident between the first baseline phase and the first intervention phase.
Statistical Analysis

A Wilcoxon signed-rank test was used to compare the mean score of each phase to determine if they were statistically significantly different. This test is a non-parametric version of a dependent t-test. Seven variables were compared at two different time points for a total of 14 tests. This complex analysis increases the risk of making a type one error. To reduce this error, a Bonferroni correction was performed and the alpha level of .05 divided by the total number of tests performed (14) to reach a new alpha level of .0036. This new alpha level ensured the risk of making a type one error is reduced.

Table 4 – Wilcoxon signed rank test

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre Mean</th>
<th>Pre SD</th>
<th>Post Mean</th>
<th>Post SD</th>
<th>z-score</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balke</td>
<td>9.688</td>
<td>4.46</td>
<td>33.9</td>
<td>15.24</td>
<td>-2.023</td>
<td>0.031</td>
</tr>
<tr>
<td>S/R (cm)</td>
<td>-2.55</td>
<td>14.1</td>
<td>-17.2</td>
<td>8.14</td>
<td>-2.023</td>
<td>0.031</td>
</tr>
<tr>
<td>GUG (secs)</td>
<td>6.95</td>
<td>2.36</td>
<td>4.14</td>
<td>0.61</td>
<td>-2.023</td>
<td>0.031</td>
</tr>
<tr>
<td>Weight</td>
<td>181.24</td>
<td>57.24</td>
<td>177.14</td>
<td>55.04</td>
<td>-1.753</td>
<td>0.063</td>
</tr>
<tr>
<td>W/H</td>
<td>0.81</td>
<td>0.08</td>
<td>0.76</td>
<td>0.09</td>
<td>-1.841</td>
<td>0.063</td>
</tr>
<tr>
<td>QOL</td>
<td>20.85</td>
<td>4.46</td>
<td>29.5</td>
<td>3.26</td>
<td>-2.023</td>
<td>0.031</td>
</tr>
</tbody>
</table>

*S/R = Sit and Reach, GUG = Get up and Go, W/H = Waist to Hip ratio, QOL = Quality of life

**Alpha level was set to .0036
CHAPTER V

DISCUSSION

The purpose of this study was to determine if using a physical activity program, including an anti-gravity (Alter-G) treadmill, would aid in improving physiological and psychosocial measures in female breast cancer survivors.

It was hypothesized that using a physical activity program including an Anti-gravity treadmill would improve physiological and psychological measures in the participants. Based on our results, we can conclude that a fifteen-week exercise program with a combination of resistance, flexibility, balance and cardiovascular training with an Alter-G treadmill at least maintained, and in some cases, improved these measures outlined below.

**Cardiovascular functioning as measured by treadmill times**

The Wilcoxon signed rank test, using an adjusted alpha cut off of $p=0.0036$ (Bonferroni correction), showed no statistically significant improvements between pre and post measurements. However, visual interpretation of the results suggests that all participants experienced improvements in treadmill times during both the intervention phase and the final replication phase. A plateau in times across both baseline phases suggests signs of decreased cardiovascular functioning as a result of detraining (Neufer 1989). Sprod et al. (2010) noted similar findings with significant improvements in cardiovascular functioning as reported by treadmill times in both a 3-month and 6 month exercise group. Other researchers have found comparable results with exercise interventions of different lengths, demonstrating significant
improvements in cardiovascular function in female breast cancer patients, both during and post treatment (Hseih et al, 2008; Schneider et al, 2007, Sprod et al, 2010). These results partially support the hypothesis that using the anti-gravity treadmill as part of an exercise program can improve cardiovascular endurance.

Flexibility

The Wilcoxon signed rank test showed no significant improvements in flexibility as measured by the sit and reach. However, the visual interpretation of the graphs suggests that all participants improved flexibility throughout the duration of the program. Burnham and Wilcox (2002) have noted similar increases in lower body flexibility following a 10-week protocol with breast cancer survivors. Cheema and Gaul (2006) further supported this finding with improvements in lower body flexibility found in breast cancer survivors following an eight-week study. The results from this study help to strengthen previous research highlighting the efficacy of a supervised exercise program carried out three times a week for 15 weeks at increasing flexibility in breast cancer survivors. An increase in flexibility may aid in restoring “normal” function, range of motion and improve physical functioning needed for activities of daily living (Stathokostas, Little, Vandervoory & Paterson, 2012). Thus, the inclusion of flexibility training as a component in a training program is warranted.

Balance and Mobility

No statistically significant improvements in the Get Up and Go (GUG) test were found in the present study. Visual interpretation suggested that 3 of the 5 participants showed a slight improvement in the GUG test. Further improvement in balance and mobility may have been
shown with the selection of a different test. All participants had strong baseline measurements (compared to norms of similar age, (Bohannon, 2006; Isles, Low Choy & Steer, 2004)) on the GUG, leaving the room for improvement marginal. Use of a different testing protocol may have yielded more improvement among the participants. Twiss et al (2009) utilized a timed backward tandem walk test in a study of 223 postmenopausal breast cancer survivors. The researchers found that survivors in an exercise intervention group had statistically (p=0.010) significant improvements in balance and mobility. It is apparent that the efficacy of an exercise program at improving balance and mobility is unclear; although we can suggest that with the contribution of muscle strength to balance control (Winters-stone et al, 2012), an exercise program utilizing resistance training in breast cancer survivors can at least maintain, and in some cases improve measures of balance and mobility.

Weight

The Wilcoxon signed rank test yielded no significant changes in weight. However, visual inspection of the graphs showed that all participants at least maintained if not experienced a favorable weight change. Participant one for example, lost 2.7kg throughout the program, which a reduction from 120 to 117 can yield important health improvements, such as a reduced risk of recurrence, increase in longevity and quality of life as a result. Cachexia is prevalent condition following treatment, and patients often have trouble maintaining weight as a result. Participant four was able to gain 1.5kg throughout the program, which again can have important health implications including prevention of weight loss, particularly in a population at risk of mortality (Morley, Thomas & Wilson, 2006). However, further research is needed to investigate the effects of an exercise intervention on weight and body composition with survivors diagnosed with
cachexia. The results of this study are consistent with previous literature noting improvements in body fat percentage and lean body mass (Irwin et al, 2009, Battaligni et al, 2007) following training interventions.

**Waist-to-hip ratio**

Waist to hip ratio (W/H) yielded no significant improvements through the Wilcoxon signed rank test. Visual interpretation of the graphs showed a slight improvement in some cases. For instances Participant one experienced a decrease of almost a decimal point throughout the program. Several other researchers have noted significant improvements in waist and hip measurements (Cheema & Gaul, 2006; Nuri et al, 2012). There are important clinical implications of lowering W/H in breast cancer survivors as evidenced by Borugian et al (2003). These authors noted each decimal increase in W/H represented a 50% increase in postmenopausal breast cancer mortality. Thus, a lower W/H may be associated with increased longevity in survivors and could be a practical tool of assessment in field settings where laboratory measurements are not available. Participants in the present study experienced modest improvements in W/H; further research is needed to determine if a longer protocol might illicit favorable body composition changes.

**Resting heart rate (RHR) and Blood Pressure (BP)**

The Wilcoxon signed rank test yielded no significant differences for either RHR or BP for the intervention. Visual inspection also yielded little variance or improvement in RHR or BP among the participants. It is possible that the intervention of 20-30 minutes of cardiovascular training three times a week may not have been sufficient to illicit changes in RHR and BP.
However, this does partially support the ability of a physical activity intervention to at least maintain RHR and BP in breast cancer survivors.

**Quality of life**

There were no statistically significant improvements found from analysis of the Wilcoxon signed rank test. Visual interpretation of the results suggests that quality of life (QOL) can at least be maintained, if not improved in some cases.

The effects of training interventions and levels of physical activity and QOL among breast cancer survivors have been well researched. Mandelblatt et al (2011) assessed physical activity levels of 2,279 breast cancer survivors between 2006 and 2009. The researchers found a significant, positive correlation with QOL and physical activity. Chen et al (2010) found similar results with participants achieving higher levels of activity being associated with a higher QOL. Work by Schneider further supports this, with a 6-month exercise program demonstrating significant improvements in QOL ($p = .0012$) in breast cancer survivors.

Gupta, Grutsch and Lis (2008) recently highlighted an important note about the use of QOL surveys. The European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire (QLQ-C30) and the Ferrans and Powers Quality of Life index (QLI) were compared and found to have poor to modest correlations among the subscales of each survey (0.6 for QLQ-C30 physical and QLI health, 0.6 for QLQ-C30 role and QLI health, and 0.2 for QLQ-C30 social and QLI social). The authors concluded that the two instruments measure different and unrelated aspects of QOL and may yield different results and conclusions. This study utilized the QLI, which has four subscales: health and physical, social and economic,
psychological and spiritual and family. Future studies may be strengthened by using instruments to measure QOL that include functional aspects such as the QLQ-C30 (functional scales include physical, role cognition, emotional and social, along with symptom scales including fatigue, pain and insomnia). This may provide a better insight as to the mechanisms of improving QOL through physical activity.

**Adherence**

Six participants started the study; however due to an extended vacation towards the end of the study, one participant dropped out (although this participants adherence rate to the protocol up until dropout was 100%). For the participants who completed the study, the intervention consisted of three sessions a week for fifteen weeks, yielding a total of 45 sessions for each participant to attend. Overall, a total of 7 sessions were missed between the participants, yielding a 97% adherence rate for this intervention. This adherence rate is higher than seen in previous studies; Courneya et al (2008) found an adherence rate to a supervised exercise program to be 70.2%. Interestingly, these same researchers found significant associations between exercise adherence and the location of the center (closer), disease stage (lower disease stage), and physical fitness (higher levels of fitness). Daley et al (2007) found similar results with a reported 77% adherence rate observed over an 8-week exercise program with breast cancer survivors. In a more recent study, Courneya et al (2012) found an adherence rate similar to the one found in this study with participants attending 95% of supervised exercise sessions. Courneya and colleagues also found that the unsupervised portion of the exercise program had a lower adherence rate, a trend that is evidenced in other literature (Halle, 2013; Lemanne, Cassileth & Gubili, 2013). While the high adherence rate in our study is most likely due to the lower number of participants;
all six participants had been previously inactive for at least 6 months prior to the study. This period of inactivity suggests that they most likely would have remained sedentary or at least refrained from performing structured physical activity prior to enrollment in this study.

Use of visual interpretation and single subject design are rare in the literature (Kinugasa, Cerin & Hooper, 2004). However its use in the field can be supported by its ability to assess a participant’s individual response to a stimulus. It is also important to note the difference between statistical significance and practical significance in the field of applied research. Statistical significance speaks to the probability that an intervention had an effect on a dependent variable (Kinugasa, Cerin & Hooper, 2004). Conversely, practical significance refers to the practical meaningfulness or value of the effect of an intervention in an applied setting (Kinugasa, Cerin & Hooper, 2004).

The practical implications of this study are two-fold. Firstly, the simplicity of visual analysis provides practitioners and health professionals a quick and straightforward method of analyzing a participant’s response to training. Of course, error of measurement must be taken into account with visual analysis, and the use of statistical analysis may help strengthen the interpretation. Nevertheless, this type of design may be warranted in an applied setting where larger participant numbers are not available or individual responses to training are of interest. This is advantageous with a population such as breast cancer survivors where special considerations need to be included in exercise prescription and response to an exercise program may not represent that of an apparently healthy individual. This design allows for consistent monitoring of response and if needed, modification to the program to enhance its effectiveness.
Secondly, throughout the course of this study, all participants were meeting national guidelines for physical activity (moderate-intensity activity on 5 or more days for at least 30 min or vigorous activity on 3 or more days for at least 20 min (Harrison, Hayes, Newman, 2008)). Despite strong evidence supporting regular physical activity in reducing breast cancer risk and recurrence, as few as 32% of breast cancer survivors were meeting the recommended levels of physical activity (150 min/week of moderate to vigorous-intensity sports/recreational physical activity) Irwin et al, 2004). This study attests to the efficacy of a supervised physical activity study at increasing physical activity levels in breast cancer survivors. This study adds strength to the growing body of research supporting the safety and efficacy of physical activity interventions at increasing levels of physical activity, adherence and improving physical functioning in breast cancer survivors (Holmes, Chen, Feskanich, Kroenke, & Colditz, 2005; Sprod, 2009; Schmitz, Kathryn H., Kerry S. Courneya, Charles Matthews, et al, 2010; Irwin, 2012; Halle, 2013; Lemanne, Cassileth & Gubili, 2013).

Cancer survivors often experience reduced bone mineral density following treatment, and are consequently at a greater risk for falls and injury (Chen et al, 2005). Furthermore, researchers have utilized aqua aerobics with cancer survivors with the premise that the buoyancy of water will reduce axial loading and allow participants to perform exercises they may not be able to on land (Fernández-Lao, Cantarero-Villanueva, Ariza-Garcia, Courtney, Fernández-de-las-Peñas, & Arroyo-Morales, 2013). This study adds to previous research suggesting that low-impact exercise may reduce the load experienced on participants’ bones and joints, and can be a well-tolerated and feasible alternative to regular treadmill training.
This study is the first of its kind to examine the inclusion of an Alter-G treadmill in a physical activity program directed at breast cancer survivors. The ability of the treadmill to “unload” the participants and lower the pressure on their bones and joints may provide a novel alternative to higher impact activities to improve cardiovascular functioning. This low-impact activity may also reduce the risk of falls and fractures that may occur during traditional treadmill training among breast cancer survivors who are at an increased risk following treatment (Chen et al, 2005). Finally, the ability to gradually increase the percentage of bodyweight a participant can run at, may contribute to the gradual strengthening of bones, and bone ossification.

The nature of breast cancer rehabilitation research is progressing to a more individualized method of exercise prescription based on survivors’ treatment, level physical functioning, limitations etc. Stout & colleagues (2012) recently presented a “Progressive Surveillance Model (PSM)” for female breast cancer survivors. The primary goal of a PSM is to consistently monitor and periodically assess progress of participants’ progress through an exercise program to modify if needed, and fully optimize the exercise prescription. By monitoring levels of physical functioning before, during, and after treatment, health professionals are able to prescribe individualized and effective programs to optimize progress. This model allows for physical limitations and impairments to be addressed consistently and exercises prescribed to expedite the rehabilitation process and restore physical functioning.

Brown, Shackleford & Schneider (2013) presented a similar presence at the 2013 American College of Sports Medicine annual meeting. The researchers developed an outpatient phase model to attempt to individualize exercise prescription for survivors based on their progress with treatment (pre, during, post etc.) and physical functioning. Consistent with
previous literature (Binkley et al, 2012) the researchers advocated the need for an educational aspect about the side effects of treatment and realistic expectations for physical functioning and Quality of Life following treatment, to be included in an intervention.

This type of AB-AB design supports the aforementioned models of individualized prescription and adds to the recommendations for consistent and periodical surveillance and assessment of participants’ progression through an exercise intervention and attempt to optimize prescription. All testing used well-utilized field methods that could be easily replicated. Testing time was minimal with the excepting for cardiovascular testing which was simultaneously used as an exercise session. Health professional may find use from this model of consistent assessment to provide the participant with visual encouragement, provide third party payers and physicians with simple and easy to interpret visual analysis of progress, and finally as a means of assessing the effectiveness of the program.

Limitations

This study had several limitations. The small sample size makes it difficult to generalize to a larger population of survivors. However, the benefit of this type of study design allows for each participant to be his or her own control. This gives the unique advantage of being able to analyze individual results rather than as a group. Research of this nature highlights the individual response to exercise and supports the idea that variability in treatment received, duration of treatment, age, time since diagnosis, severity of disease, among others, may affect the response of breast cancer survivors to exercise (Schmitz, Kathryn H., Kerry S. Courneya, Charles Matthews, et al, 2010; Irwin, 2012).
Lengths of the baseline phases were two weeks apiece. Future studies may be strengthened by administering longer baseline phases between intervention phases to allow for a longer period of deconditioning. This in turn may make it easier to infer that it was the intervention that caused changes. This study took place in a small southeastern rural town and thus may not be generalizable to other geographical areas. The lack of laboratory tests may also be a limitation, particularly methods of assessing cardiorespiratory fitness and body composition. Future studies may be strengthened by more robust methods of assessment such as gas exchange analysis to determine VO2max and Dual X-ray absorptiometry to evaluate changes in fat mass and lean body mass.

**Conclusion and Implications**

In conclusion, the results of this study suggest that participation in a 15-week supervised intervention with the inclusion of an Anti-gravity treadmill may provide practical and meaningful improvements in physiological and psychosocial variables in female breast cancer survivors. Further research should include a larger population more representative of the general breast cancer population. The use of longer baseline periods may give a better indication of the effects of the intervention.

There is a growing body of literature supporting physical activity as a means to attenuate the negative side effects of cancer treatment such as pain, fatigue, lymphedema, weakness, restricted range of motion, neuropathy, & reduced bone density (Sprod, 2009; Irwin, 2012; Siegal, R., DeSantis, C., Virgo, K., Stein , K. et al, 2012). Despite this, there remains to be a low level of survivors meeting the National guidelines for minimal physical activity. The apparent inconsistency of physician recommendations for physical activity, as well as lack of third party
compensation for rehabilitation programs may provide a possible reason for survivors’ lack of physical activity and participation in supervised exercise programs (Blaney, Lowe-Strong, Campbell, Allen et al, 2010). Thus it is imperative to establish a collaborative relationship between exercise specialists and physicians to increase awareness of current guidelines and programs available. Furthermore, there is a need for more studies contributing to the current body of literature supporting physical activity as a primary component of cancer care and rehabilitation. Future research will help support the inclusion of physical activity as a primary component of cancer treatment and recovery (Irwin, 2008) and provide policy makers and third party payers with the sufficient evidence for reimbursing cancer survivors for treatment and counseling (Irwin, 2008; Schmitz, 2010).
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The effects of an individualized exercise intervention on body composition in breast

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Physician Approval Form.

Date_____

Dear Doctor:

Your patient ____________________________ wishes to take part in a physical activity program with concurrent assessments. The program may include progressive resistance training, flexibility exercises, and a cardiovascular program; increasing in duration and intensity over time depending on the participant’s ability. The fitness assessment will include a sub-maximal cardiovascular fitness test and measurements of body composition, flexibility, and mobility. (Details of the program are in the attached information packet.)

Please indicate if there are any special precautions or considerations for this individual to limit his/her participation in the program. (i.e. current medical condition: risk of bone metastases or osteoporosis, presence of lymphedema, hematological parameters etc.)

____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

For physician signature only:
I, ____________________________, have reviewed the proposed program and approve of my patient ______________________________ participating in the above-described program while undergoing chemotherapy, radiation therapy, or other active cancer treatments. I recommend the aforementioned adaptations for my patient’s safety.

Print Name ___________________ Signature _____________________

**Program Details:**

The purpose of this study is to determine if using an anti-gravity (Alter-G) treadmill in combination with a physical activity program will aid in improving physiological and psychosocial measures in female breast cancer survivors.

The program will include a screening week where participants will fill out informed consent forms and be given an overview of what the study will consist of.

Participation in this research will include completion of a training program administered by specialized health professionals. It will consist of 16 total weeks of participation. The first 2 weeks will comprise of testing to establish an initial evaluation of baseline performance. Following this will be a 4 week period of an exercise program compromising of cardiovascular, resistance and flexibility training. Following this period there will be a 2-3 week return to baseline phase where the participant will not participate in the exercise program but will be continuously assessed throughout the period. The final 4 week phase represents a return to exercise phase where participants will take part in the same exercise program as before. (A detailed outline of sessions is provided below). The intervention will be modified to each individual based on medical history, prior history of exercise, any physical limitations as a result of treatment along with any physician notes about a participant.
The Alter-G treadmill operates in a similar fashion to a regular treadmill with the exception of a chamber surrounding the participant at waist-level. This chamber attached to specially modified shorts worn by the participant & calibrates to match air pressure to the patient’s body weight. After calibration, the treadmill can then increase air pressure inside the chamber to decrease the load on the participant. Participants will be asked to walk or run at a percentage of their body weight for a specified period of time. The treadmill will be used in each training phase. The treadmill is FDA approved, covered by many health insurance plans along with being used at physical therapy facilities, and collegiate & professional sports teams nationwide.

**Visit 1- Week 1**
- Will consist of initial screening and testing. Participants will be given an orientation into the study and an overview of the timeline.

**Visit 2- Week 1**
- Baseline testing will consist of measuring resting heart rate & blood pressure at the beginning of the session.

**Balance**
- Functional balance will be measured with a timed “Get-up-and-Go” (GUG) test. The GUG test consists of time measurements of the participants starting from a seated position, standing without the help from their hands, walking forward three meters, turning around, walking back to the chair, and sitting down without use of their hands. Time will be measured in seconds.

**Flexibility**
- A modified sit and reach test will be used to measure flexibility. Participants sit in a chair with one leg outstretched. They the slide their hands as far down their outstretched leg as possible. Flexibility will be measured by the distance between the participant’s fingertips and their toes.

**Body composition (Skinfold Calipers)**
- A Skinfold Caliper is a specially designed piece of equipment used for taking measurements of subcutaneous tissue. Measurements are obtained from either a 3-fold or a 7-fold site. These measurements are inputted into an equation to estimate body fat percentage.

**Quality of Life**
- Measured using Ferrans and Powers QUALITY OF LIFE INDEX® CANCER VERSION – III. This is a survey used to establish a client’s satisfactions in various areas of their life.
**Visit 3- Week 1**
- This will comprise of the same testing measures as Baseline Testing (BT) with the addition of an estimated VO2 max test designed to measure oxygen consumption and aerobic capacity.

**Visit 4-6- Week 2**
- These visits will have the same procedure as baseline testing.

**Visit 7-19 Weeks 3-7**
- These visits will include the training sessions as interventions. BT will be performed at the beginning of each session, followed by a combination of resistance, aerobic and flexibility training.

**Visit 20-29 Weeks 8-11**
- Intervention will be removed and in a ‘return to baseline phase’ BT will be carried out through each visit throughout this phase.

**Visit 30-42 Weeks 12-16**
- Return to treatment. Training protocol will be reintroduced. Procedure for this phase will be the same as visits 7-19.
B. Informed Consent

COLLEGE OF (HEALTH AND HUMAN SERVICES)

DEPARTMENT OF (KINESIOLOGY & HEALTH PROMOTION)

INFORMED CONSENT

- The purpose of this research is to examine the effects of a physical therapy program including an anti-gravity treadmill in improving physical functioning and Quality of Life in female breast cancer survivors.

- Participation in this research will include completion of a training program administered by specialized health professionals. The training program is being provided as a substitute to the normal physical therapy program. Participation in this research will be done as a SUBSTITUTE to a regular physical therapy, NOT in addition to. However, this program is designed following the latest research and guidelines on the safety and efficacy of training cancer survivors. Thus you will expect to see improvements in physical functioning, mood, self-esteem and possibly overall quality of life. One dissimilarity between this program and what typically may be seen in a regular therapy program is the presence of two baseline phases (6 weeks total) where the participant will be not be given any intervention with the exception of baseline testing (detailed below). This represents a phase of physical deconditioning not seen in typical programs. However the initial baseline phase will allow the participant to become acclimated with the setting, exercises and modes of testing; the return to baseline may provide a period of lower activity to provide the participant with a “break before resuming the final replication stage.” It will consist of 16 total weeks of participation. The first 2 weeks will comprise of testing to establish an initial evaluation of baseline performance. Following this will be a 4 week period of an exercise program compromising of cardiovascular, resistance and flexibility training. Following this period there will be a 2-3 week return to baseline phase where the participant will not participate in the exercise program but will be continuously assessed throughout the period. The final 4 week phase represents a return to exercise phase where participants will take part in the same exercise program as before. The Alter-G treadmill operates in a similar fashion to a regular treadmill with the exception of a chamber surrounding the participant at waist-level. This chamber attached to specially modified shorts worn by the participant & calibrates to match air pressure to the patient’s body weight. After calibration, the treadmill can then increase air pressure inside the chamber to
decrease the load on the participant. You will be asked to walk or run at a percentage of your body weight for a specified period of time. The treadmill will be used in each training phase.

- **Discomforts and Risks:**
  By participating in this research, there exists a remote possibility of some adverse changes during the study. These include dizziness, abnormal blood pressure, irregular heartbeat, fainting, stroke, or death. I understand that every effort will be made to minimize these risks by evaluating preliminary health information prior to testing. An initial fitness assessment will allow for an individualized training program which will be monitored closely by trained exercise specialists to ensure risks are optimally minimized. Emergency equipment is available and personnel trained in CPR, AED and first aid will be available to deal with any unusual situations. “I understand that medical care is available in the event of injury resulting from research but that neither financial compensation nor free medical treatment is provided. I also understand that I am not waiving any rights that I may have against the University for Injury resulting from negligence of the University or investigators.” Further information can be obtained by consulting the Principal Investigator, Ciaran Fairman, who can refer you to the appropriate health services.

- **Benefits:**
  It is possible that you will receive some benefit from this study which may include: improved physical functioning, improved outlook on life, & reduced risk of recurrence. This study may also show results that will pave the way for future research to evaluate the efficacy and significance of using an anti-gravity treadmill in a rehabilitation program for Breast Cancer survivors.

- The program will consist of training & testing 3 days a week for 14 weeks.

- **Statement of Confidentiality** All data and information provided will remain private and confidential. Only the principal investigator, Ciaran Fairman, and the faculty advisor, will have access to your information. Data will be stored in a secure location for 7 years.

- **Right to Ask Questions:** Participants have the right to ask questions and have those questions answered. If you have questions about this study, please contact the principal investigator, Ciaran Fairman, at 912-536-2096 or the faculty advisor, Jim McMillan whose contact information is located at the end of the informed consent. For questions concerning your rights as a research participant, contact Georgia Southern University Office of Research Services and Sponsored Programs at 912-478-0843.

- You are under no obligation to participate in this research and may end your participation by letting the person in charge of your decision.

- There is no penalty from deciding not to participate in the study. At any point if you feel you don’t want to participate further in the study you may withdraw without penalty or retribution. **Withdrawing from this study does not exclude you from participating in other available physical therapy programs as recommended by your physician or physical therapist**

- You must be 18 years of age or older to consent to participate in this research study. If you consent to participate in this research study and to the terms above, please sign your name and indicate the date below.
You will be given a copy of this consent form to keep for your records. This project has been reviewed and approved by the GSU Institutional Review Board under tracking number H13160.

Title of Project: **Effectiveness of a training program using an Alter-G treadmill to improve physiological and psychosocial measures in female breast cancer survivors**
Principal Investigator: Ciaran Fairman, 212 A Nature Way, Statesboro, GA, 30458. 912-536-2096. cf02129@georgiasouthern.edu

Other Investigator(s): Brandonn Harris, c/o Department of Health & Kinesiology, Georgia Southern University, 1332 Southern Drive, Statesboro, Georgia 30458, (912) 478-7900 and bharris@georgiasouthern.edu
Kristina Kendall, c/o Department of Health & Kinesiology, Georgia Southern University, 1332 Southern Drive, Statesboro, Georgia 30458,

Faculty Advisor: (Jim McMillan, c/o Department of Health & Kinesiology, Georgia Southern University, 1332 Southern Drive, Statesboro, Georgia 30458, (912) 478-0200, jmcmillan@GeorgiaSouthern.edu)

____________________________________________________________________________________
Participant Signature                                          Date

I, the undersigned, verify that the above informed consent procedure has been followed.

____________________________________________________________________________________
Investigator Signature                                          Date
Volunteers needed for a study to evaluate the effects of a physical activity program on female breast cancer survivors

The purpose of this study is to examine the effectiveness of a physical activity program in improving Quality of Life. Body composition and some other physiological measures in breast cancer survivors.

Who is eligible?
- Female breast cancer survivors between the ages of 18-65 are eligible to participate.
- Eligibility also requires you to have completed treatment (chemotherapy, radiation, etc.) for at least 6 months prior to start of study

What will I be asked to do?
Participate in a 14-16 week long physical activity program. Your progress will be monitored throughout the duration of the study using standard testing protocols.

Participants will receive a free individualized physical activity program under the supervision and guidance of trained professionals.

Where?
Study will take place at Southern Wellness and Rehab facility. Some testing visits will be held at Georgia Southern University’s human performance lab.

For more information please contact the primary researcher:
Claran Fairman
Tel: 912-536-8416
Email: df02129@georgiasouthern.edu

(This study has been approved by the Georgia Southern institutional review board; ref #: H13160)
D. QUALITY OF LIFE SCALE

Ferrans and Powers
QUALITY OF LIFE INDEX®
CANCER VERSION - III

PART 1. For each of the following, please choose the answer that best describes how satisfied you are with that area of your life. Please mark your answer by circling the number. There are no right or wrong answers.

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<th>HOW SATISFIED ARE YOU WITH:</th>
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<th>Slightly Satisfied</th>
<th>Moderately Satisfied</th>
<th>Very Satisfied</th>
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<tr>
<td>1. Your health?</td>
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<td>2</td>
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<tr>
<td>2. Your health care?</td>
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<td>2</td>
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<td>6</td>
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<tr>
<td>3. The amount of pain that you have?</td>
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<td>4. The amount of energy you have for everyday activities?</td>
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<tr>
<td>5. Your ability to take care of yourself without help?</td>
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<td>6</td>
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<tr>
<td>6. The amount of control you have over your life?</td>
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<tr>
<td>7. Your chances of living as long as you would like?</td>
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<tr>
<td>8. Your family’s health?</td>
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<td>9. Your children?</td>
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<tr>
<td>10. Your family’s happiness?</td>
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<tr>
<td>11. Your sex life?</td>
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<td>12. Your spouse, lover, or partner?</td>
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<td>13. Your friends?</td>
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<td>14. The emotional support you get from your family?</td>
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<tr>
<td>15. The emotional support you get from people other than your family?</td>
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(Please Go To Next Page)

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109
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<tr>
<td>16. Your ability to take care of family responsibilities?</td>
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<tr>
<td>17. How useful you are to others?</td>
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<tr>
<td>18. The amount of worries in your life?</td>
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<td>19. Your neighborhood?</td>
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<td>20. Your home, apartment, or place where you live?</td>
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<td>22. Not having a job (if unemployed, retired, or disabled)?</td>
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<tr>
<td>23. Your education?</td>
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<tr>
<td>24. How well you can take care of your financial needs?</td>
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<tr>
<td>25. The things you do for fun?</td>
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<tr>
<td>26. Your chances for a happy future?</td>
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<tr>
<td>27. Your peace of mind?</td>
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<tr>
<td>28. Your faith in God?</td>
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<tr>
<td>29. Your achievement of personal goals?</td>
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<td>30. Your happiness in general?</td>
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<td>31. Your life in general?</td>
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<tr>
<td>32. Your personal appearance?</td>
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<tr>
<td>33. Yourself in general?</td>
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</tbody>
</table>
**PART 2.** For each of the following, please choose the answer that best describes how **important** that area of your life is to you. Please mark your answer by circling the number. There are no right or wrong answers.

**HOW **_**important**_ **TO YOU IS:**

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<th>Moderately Unimportant</th>
<th>Slightly Unimportant</th>
<th>Slightly Important</th>
<th>Moderately Important</th>
<th>Very Important</th>
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<td>1. Your health?</td>
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<td>2. Your health care?</td>
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<tr>
<td>3. Having no pain?</td>
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<td>6. Having control over your life?</td>
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<th>HOW IMPORTANT TO YOU IS:</th>
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<tr>
<td>21. Your job (if employed)?</td>
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<td>6</td>
</tr>
<tr>
<td>24. Being able to take care of your financial needs?</td>
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<td>2</td>
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<td>6</td>
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<tr>
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<td>6</td>
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<td>26. Having a happy future?</td>
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<td>2</td>
<td>3</td>
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<tr>
<td>27. Peace of mind?</td>
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<td>29. Achieving your personal goals?</td>
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<td>6</td>
</tr>
<tr>
<td>31. Being satisfied with life?</td>
<td>1</td>
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<tr>
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<td>33. Are you to yourself?</td>
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# E. BALKE TREADMILL PROTOCOL

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### F. Contraindications to Exercise

**TABLE 5.2 Absolute and Relative Contraindications for Exercise Testing**

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<th>Absolute</th>
<th>Relative</th>
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<tr>
<td>Acute myocardial infarction (3-5 days)</td>
<td>Left main coronary stenosis or its equivalent</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>Moderate stenotic valvular heart disease</td>
</tr>
<tr>
<td>Uncontrolled arrhythmias causing symptoms or hemodynamic compromise</td>
<td>Severe untreated arterial hypertension at rest (&gt;200 mg Hg systolic, &gt;120 mm Hg diastolic)</td>
</tr>
<tr>
<td>Syncope</td>
<td>Tachyarrhythmias or bradyarrhythmias</td>
</tr>
<tr>
<td>Active endocarditis</td>
<td>High-degree atrioventricular block</td>
</tr>
<tr>
<td>Acute myocarditis or pericarditis</td>
<td>Hypertrophic cardiomyopathy</td>
</tr>
<tr>
<td>Symptomatic severe aortic stenosis</td>
<td>Significant pulmonary hypertension</td>
</tr>
<tr>
<td>Uncontrolled heart failure</td>
<td>Advanced or complicated pregnancy</td>
</tr>
<tr>
<td>Acute pulmonary embolus or pulmonary infarction</td>
<td>Electrolyte abnormalities</td>
</tr>
<tr>
<td>Thrombosis of lower extremities</td>
<td>Orthopedic impairment that compromises exercise performance</td>
</tr>
<tr>
<td>Suspected dissecting aneurysm</td>
<td>Untreated anemia (hemoglobin level between 8 and 11 gm/dL)</td>
</tr>
<tr>
<td>Uncontrolled asthma</td>
<td></td>
</tr>
<tr>
<td>Pulmonary edema</td>
<td></td>
</tr>
<tr>
<td>Room air desaturation at rest ≤ 85%</td>
<td></td>
</tr>
<tr>
<td>Respiratory failure</td>
<td></td>
</tr>
<tr>
<td>Acute noncardiopulmonary disorder that may affect exercise performance or be aggravated by exercise (i.e., infection, renal failure, thyrotoxicosis)</td>
<td></td>
</tr>
<tr>
<td>Mental impairment leading to inability to cooperate</td>
<td></td>
</tr>
<tr>
<td>Evidence of extensive visceral or skeletal metastases, or both</td>
<td></td>
</tr>
</tbody>
</table>

Adapted from American Thoracic Society/American College of Chest Physicians, 2003, "ATS/ACCP Statement on cardiopulmonary exercise testing."