

Examining the Physiological Effects of a SIT and Resistance Training Intervention on Sedentary Women with Metabolic Syndrome Risk Factors

by

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ABSTRACT

This study assessed the effects of a 10-week sprint interval training (SIT) and resistance training (RT) intervention on waist circumference (WC), blood pressure (BP), fasting plasma glucose (FPG), triglycerides (TG), high-density lipoproteins (HDL), body composition, $VO_2\max$, and strength in sedentary women. Thirty-eight females (Age = 38 ± 8 years, BMI = 33 ± 8 kg/m²) completed a 10-week, 30-session SIT and RT intervention. Paired samples t-tests compared pre and post BP, FPG, TG, HDL, MetS z-score and body composition. A repeated-measures ANOVA examined differences in the pre, mid (week 6) and post WC and three repetition maximum (3-RM) for the squat and bench press measures. Logistical regression was used to measure the dose response relationship between sessions attended and MetS z-score. The results showed significant decreases in systolic ($p=0.007$; pre = 129 ± 18 mm/Hg; post = 125 ± 12 mm/Hg), diastolic ($p=0.005$; pre = 81 ± 7 mm/Hg; post = 79 ± 6 mm/Hg), and mean arterial pressure ($p<0.001$; pre 81 ± 7 mm/Hg; post = 79 ± 6 mm/Hg). A significant decrease ($p=0.007$) in WC occurred from pre- (111 ± 18 cm) to post- (107 ± 16 cm). MetS z-score significantly ($p=0.001$) decreased from pre- (1.127 ± 3.696) to post- (-0.236 ± 3.216 mm/Hg). Fat mass decreased significantly ($p=0.004$; pre 41.6 ± 14.7 kg; post 40.1 ± 15.1 kg), and lean body mass increased significantly ($p<0.001$; pre 46.4 ± 14.9 ; post 47.6 ± 7.1 kg). $VO_2\max$ significantly increased ($p<0.001$; pre 23.7 ± 5.0 ml/kg/min; post 28.1 ± 6.5 ml/kg/min). Back squat significantly increased ($p<0.001$) from pre (27.7 ± 9.8 kg) to mid (46.9 ± 11.7 kg), pre to post (60.3 ± 13.5 kg), and mid to post training. Bench press significantly increased ($p < 0.001$) from pre (22.3 ± 7.6 kg) to mid (36.4 ± 7.6 kg), pre to post (41.5 ± 8.2 kg), and mid to post-training. Logistical regression showed that 24 sessions were needed to promote decreases in the odds of MetS. This study revealed that a 10-week SIT and RT intervention can significantly decrease BP,

WC, FM and MetS z-score while increasing LBM, VO₂max and strength in sedentary women who are at risk for metabolic syndrome.

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“One looks back with appreciation to the brilliant teachers, but with gratitude to those who touched our human feelings. The curriculum is so much necessary raw material, but warmth is the vital element for the growing plant and for the soul of the child.”- Carl Jung

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LIST OF ABBREVIATIONS

AT – Aerobic Training

BP – Blood Pressure

CDC – Centers for Disease Control and Prevention

CVD – Cardiovascular Disease

FPG – Fasting Plasma Glucose

HDL – High-Density Lipoprotein

HHS – Department of Health and Human Services

HIIT – High Intensity Interval Training

iDXA – Dual-Energy X-ray Absorptiometry

LDL – Low-Density Lipoprotein

MAP – Mean Arterial Pressure

MetS – Metabolic Syndrome

MICT – Moderate Intensity Continuous Training

MVPA – Moderate to Vigorous Physical Activity

NHLBI – National Heart, Lung, and Blood Institute

RM – Repetition Maximum

RT – Resistance Training

SIT – Sprint Interval Training

TG – Triglycerides

WC – Waist Circumference

I. INTRODUCTION

Introduction

Metabolic Syndrome (MetS) is defined as a cluster of risk factors that include elevated waist circumference, blood pressure (BP), fasting plasma glucose (FPG), high triglycerides (TG), and low high-density lipoproteins (HDL) (Alberti et al., 2009; Eckel et al., 2005; Grundy et al., 2005). According to the 2009 joint statement of the International Diabetes Federation Task Force on Epidemiology and Prevention, an individual must meet at least three of these criteria to be clinically diagnosed with MetS (Alberti et al., 2009; Table 1). Global estimates calculate approximately 100 million people in the world meet the criteria for MetS (Drebes et al., 2009), with more prevalence in first world countries (Levitt, 2008). In 2015, the prevalence of MetS in the United States alone was estimated to be almost 35% of all adults, and 50% for those 60 years and older (Aguilar et al., 2015).

Each risk factor for MetS puts an individual at an increased risk of premature death by 1.6 times, and increases the risk of developing comorbidities including cardiovascular disease (CVD), type II diabetes, and obesity (Alberti et al., 2009; O'Neill and O'Driscoll, 2015). Furthermore, individuals who do not meet the clinical diagnosis for MetS, but meet one of the criteria for MetS are also at an increased risk of developing comorbidities and premature death compared to risk free populations (de Carvalho et al., 2015). In addition to the health risks associated with MetS, there are accompanying financial costs to treat MetS and its associated risk factors. In 2015 alone, the Centers for Disease Control and Prevention (CDC) reported that the United States spent \$3.2 trillion on health-related expenses that include obesity and hypertension (risk factors associated with MetS). Those numbers were projected to rise to \$4 trillion in 2017 (CDC, 2016). To reduce the health and financial burden associated with MetS,

evidence-based studies should examine effective methods to reduce risks and poor health outcomes associated with MetS.

Lifestyle choices contributing to MetS include smoking, high fat diets, high carbohydrate diets, and sedentary or low physical activity (CDC, 2016; O'Neill and O'Driscoll, 2015). In recent years, a lack of physical activity has emerged as an impactful volitional behavior associated with MetS, and this is evident when examining countries with low MetS rates compared to the United States. For example, physically active African rural countries, such as Uganda and Malawi, reported less than 1% of MetS diagnosis (Drebes et al., 2009). Although the benefits of participating in physical activity are well known, a majority of adults in the United States do not meet physical activity recommendations. In 2018 updated physical activity recommendations were released by the Department of Health and Human Services (HHS) and stated that adults should engage in 150-300 min/week of moderate-intensity, or 75-150 min/week of vigorous-intensity aerobic physical activity, or a combination of moderate- and vigorous-intensity aerobic physical activity (MVPA). HHS also recommends that adults should engage in at least two days per week of muscle-strengthening activities in addition to aerobic MVPA. Currently, it is estimated that only 20% of adults in the United States meet current physical activity guidelines (Piercy et al., 2018). Not only does low physical activity participation contribute to risk factors leading to MetS, but sedentary behavior and physical inactivity is directly linked with an increased risk of weight gain, obesity, type II diabetes, hypertension, low HDL, and dyslipidemia (Alberti et al., 2009; Grundy et al., 2005; Matthews et al., 2008). A previous study monitoring 6,329 participants' behavior patterns reported that participants spent >54% of their monitored time being sedentary, with women showing less physical activity than men, and physical activity decreasing with age (Matthews et al., 2008).

In 2003, the HERITAGE Family Study published research on exercise as a means of treating MetS risk factors. Of the participants who completed the 20-week cycling study (3 days per week), 30% were no longer meeting MetS criteria (Katzmarzyk et al., 2003). The results showed exercise positively influences all five of MetS physiological risk factors. Specifically, the study reported 28% decreased waist circumference, 9% improved fasting plasma glucose (FPG), 38% decreased BP, 43% decreased triglycerides, and 16% improved HDL cholesterol (Katzmarzyk et al., 2003). The joint consensus among the National Heart, Lung, and Blood Institute; American Heart Association; World Heart Federation; International Atherosclerosis Society; and International Association for the Study of Obesity is that participating in physical activity is the most effective way of managing risk factors associated with MetS (Alberti et al., 2009). Data from a 2013 Canadian study utilizing accelerometers to observe the relationship between physical activity and MetS concluded that the amount of weekly MVPA correlated with the risk of developing risk factors associated with MetS. For this study physical activity guidelines consisted of 500 MET/minutes/week. Only 23.9% of the participants adhered to the physical activity prescription, with those who met the physical activity prescription showing significant ($p < 0.001$) decreases in waist circumference, triglyceride levels, and significant ($p < 0.001$) increases in HDL (Glazer et al. 2013). In 2018, a meta-analysis of exercise and MetS concluded that not only was MetS more prevalent in older women, but that women experienced more exercise benefits than their male counterparts. With exercise, women observed statistical ($p < 0.05$) decreases in all five of the MetS risk factor criteria while men observed ($p < 0.05$) decreases in two criteria (Wewege et al., 2018).

There have been several different approaches to physical activity interventions targeting MetS. This includes aerobic training (AT) only, resistance training (RT) only, and combined

aerobic and resistance training (AT+RT) (Bateman et al., 2011; Stensvold et al., 2010; Tjonna et al., 2008). AT, also known as cardiovascular training, is any exercise that increases the heart and breathing rate, and stresses the cardiovascular system to train the heart and lungs (Laursen & Jenkins, 2002). Aerobic-only training interventions typically promote decreases in body mass, TG, and BP while promoting increases in HDL (Bateman et al., 2011; Stensvold et al., 2010; Tjonna et al., 2008). Moderate-intensity continuous training (MICT), a specific type of aerobic training, is defined as exercising between 50-70% of maximum heart rate (HR_{max}) for ≥30 continuous minutes (Gibson, Wagner, and Heyward, 2018). MICT is associated with decreases in WC (Katzmarzyk et al., 2003; Mello et al., 2011), TG (Bateman et al., 2011; Katzmarzyk et al., 2003; Mello et al., 2011), BP (Katzmarzyk et al., 2003), HDL (Katzmarzyk et al., 2003), FPG (Katzmarzyk et al., 2003; Mello et al., 2011), and metabolic syndrome z score (Katzmarzyk et al., 2003). A metabolic syndrome z score (MetS z score) is a formula that utilizes the criteria of MetS to determine an individual's overall health status and risk for mortality. Bateman et al. (2011) conducted an exercise intervention for 8 months using MICT (65-80% VO_{2peak}). Exercise volume was calculated to ensure participants metabolized 14 kcal/kg of body mass/week (~12 miles/week) using treadmills, elliptical trainers, and cycle ergometers. Results showed significant ($p < 0.05$) decreases in body mass (-1.54 kg) and TG (-21.0 mg/dl). Additionally, WC numerically decreased (-1.12 cm), although this decrease was not significant. High intensity interval training (HIIT) is characterized by short repeated bouts (<5minutes) of vigorous exercise (70 to 90 percent HR_{max}), with short rests or active recovery in between bouts (Gibala, 2018; Kemi and Wisløff, 2010). HIIT is associated with decreases in WC (Stensvold et al., 2010), BP (Bonsu and Terblanche, 2016; Tjonna et al., 2008), HDL (Tjonna et al., 2008), FPG (Tjonna et al., 2008), and MetS z score (Tjonna et al., 2008). A HIIT training and detraining

study was conducted to measure changes in BP in 20 overweight/obese women. The findings after six HIIT sessions (~2 weeks) showed decreases in resting BP (>3 mmHg decrease) pre to post, and a return to baseline BP levels within 2 weeks of detraining (Bonsu and Terblanche, 2015). Sprint Interval Training (SIT) is a type of HIIT training characterized by short high intense sprints at maximal or near maximal intensity (~95 HRmax) followed by rest. Compared to HIIT, SIT consists of shorter active bouts, shorter rest periods, and takes less than 15 minutes to complete. Current research shows that SIT has similar physiological adaptations as HIIT including significant ($p < 0.05$) decreases in body mass (kg) and WC (Hazell et al., 2014), BP (Hazell et al., 2014), HDL (Gillen and Gibala., 2014), and FPG (Whyte et al., 2010). SIT has also resulted in increases in aerobic fitness (VO_{2max}) (Hazell et al., 2014). However, there is a gap in the literature as to the effects of SIT on sedentary women with risk factors for MetS (Gillen and Gibala., 2014; Hazell et al., 2014).

Resistance training (RT) is defined as any form of strength training used to resist or overcome force (Fleck and Kraemer, 2014). The American College of Sports Medicine (ACSM) further specifies that RT includes the use of concentric, eccentric, and isometric muscle actions using bilateral, unilateral, single-, and multiple-joint exercises (Ratamess et al., 2009). In terms of RT programs, a meta-analysis examined the effect of RT on risk factors related to MetS. Of the 13 studies reviewed, all observed a decrease in fat mass and increase in lean body mass. Specifically, for MetS, RT only interventions showed significant ($p < 0.05$) decreases in systolic BP (>6 mmHg decrease) (Strasser et al., 2010). Mixed findings are reported on changes in fasting insulin and glucose, diastolic BP, HDL, and TG levels in the literature on RT interventions in MetS populations and may be due to the type of RT intervention administered (Bateman et al., 2011; Stensvold et al., 2010; Tjonna et al., 2008). For example, Castaneda et al.

(2002) conducted a 16-week RT study and reported significant decreases in systolic BP ($p = 0.05$) in Latino older adults with type II diabetes (Castaneda et al., 2002). Training consisted of three sets of five repetitions on five pneumatic resistance training machines (chest and leg press, upper back, knee extension, and flexion). Bateman et al. (2011) conducted an 8-month RT intervention and reported no significant findings in the use of RT for MetS. Training consisted of 8-12 repetitions, 3 sets/day, 3 day/wk of 4 upper body and 4 lower body Cybex weightlifting machines, 2 free weight exercises, and crunches (Bateman et al., 2011). While both studies utilized exercise machines for ≥ 16 weeks, results from these studies make it difficult to conclude whether RT is, or is not, effective at changing MetS risk factors.

There is limited data on AT + RT interventions on metabolic outcomes in MetS participants. Two known studies used MICT (Bateman et al., 2011; Mello et al., 2011), while a third study utilized HIIT (Stensvold et al., 2010). Bateman et al. (2011) conducted an exercise intervention for 8 months using MICT (65-80% VO_{2peak}) + RT (3 day/wk, 3 sets/day, 8-12 repetitions) in 30 participants. Results for the AT + RT group showed a significant ($p < 0.05$) increase in VO_{2peak} (ml/kg/min) and strength (kg/session). There was also a significant ($p < 0.05$) decrease in body mass, TG, WC, FPG, diastolic BP, mean arterial BP, and MetS z score (Bateman et al., 2011). A cited barrier to the AT + RT intervention was the amount of time it took to complete exercise sessions, in particular MICT. While AT was ~ 117 minutes per week, AT + RT took 234-279 minutes per week to complete (Bateman et al., 2011). Mello et al. (2011) conducted a yearlong AT + RT study utilizing MICT (50-70% VO_{2max}) + RT (3 day/wk, 3 sets/day, 6-20 repetitions) ($n=15$). Results at 6 months showed a significant ($p < 0.05$) decrease in body mass, fat mass, visceral fat, WC, total cholesterol and LDL. From 6 months to 12

months, FPG and WC continued to decrease ($p < 0.05$) demonstrating long term exercise has continued benefits.

Based on a synthesis of the literature, it appears that an AT + RT intervention would provide the overall best results to combat risk factors of MetS. However, there are current gaps in the literature examining this exercise modality. Results showed a significant ($p < 0.05$) decrease in WC and fat mass, but not a significant difference in systolic BP and diastolic BP. Huffman et al. (2019) examined the effects of SIT +RT on sedentary women over 40 and found significant changes ($p < 0.05$) in VO₂max. However, criteria for MetS were not examined. As time is a cited barrier to combined training for this population (Bateman et al., 2011), SIT + RT offers a time efficient method of training that may effectively control MetS, however, this type of training has not been investigated for sedentary women with risk factors for MetS.

In summary, previous literature suggests that utilizing an exercise intervention consisting of both AT interval and RT would optimize health benefits and decrease risk factors associated with MetS (Bateman et al., 2011; Stensvold et al., 2010; Tjonna et al., 2008). A population that engages in the greatest amount of sedentary behavior are women ≥ 30 years old, which may increase their risk for developing MetS (Matthews et al., 2008). In addition, women have a significantly higher prevalence of MetS compared to men (Women 35.6% vs Men 30.3%, $p < 0.001$) (Aguilar et al., 2015). As physical activity is the most effective way of managing risk factors associated with MetS (Alberti et al., 2009), women over the age of 25 years old displaying even one MetS risk factor may benefit from an exercise intervention. To the best of the author's knowledge, there is no known study to observe the effects of a SIT and RT (AT+RT) intervention on individuals with MetS risk factors. With previous research contending that AT+RT elicit the greatest response and benefits to participants with MetS risk factors, the

goal of this study was to implement a 10-week combined SIT and RT intervention on sedentary women with at least one metabolic syndrome risk factor.

Purpose of the Study and Study Objectives

The purpose of this study was to examine the physiological effects of a SIT and resistance training intervention on sedentary women with at least one metabolic syndrome risk factor.

Primary Objective: Determine the effects of a SIT and RT intervention on waist circumference, blood pressure, fasting plasma glucose, triglycerides, and low high-density lipoproteins, body composition, physical and sedentary activity, aerobic fitness, and muscular strength.

Research Questions (RQ) and Hypotheses

a. RQ 1: What is the effect of a 10-week SIT and resistance training intervention on risk factors (waist circumference, blood pressure, fasting plasma glucose, high triglycerides, and high-density lipoproteins) associated with metabolic syndrome in sedentary women?

i. H1: MetS risk factors: waist circumference (measured with a tape measure), blood pressure (measured with a sphygmomanometer and blood pressure cuff), fasting plasma glucose (measured with a finger prick blood analysis), triglycerides (measured with a finger prick blood analysis) will decrease, and high-density lipoproteins (measured with a finger prick blood analysis) will increase, following a 10-week SIT and resistance training intervention for sedentary women with at least one metabolic syndrome risk factor.

b. RQ2: What is the effect of a 10-week SIT and resistance training intervention on body composition in sedentary women with at least one metabolic syndrome risk factor?

- i. H2: Total body mass, fat mass and percent body fat will decrease following 10-week SIT and resistance training intervention for sedentary women with at least one metabolic syndrome risk factor. Body composition was measured with the iDXA.
- ii. H3: Lean body mass will increase following 10-week SIT and resistance training intervention for sedentary women with at least one metabolic syndrome risk factor.

c. RQ3: What is the effect of a 10-week SIT and resistance training intervention aerobic fitness in sedentary women with at least one metabolic syndrome risk factor?

- i. H4: Aerobic fitness (ml/kg/min) will increase following 10-week SIT and resistance training intervention for sedentary women with at least one metabolic syndrome risk. Aerobic fitness will be estimated using a graded exercise test (GXT).

d. RQ4: What is the effect of a 10-week SIT and resistance training intervention on muscular strength in sedentary women with at least one metabolic syndrome risk factor?

- i. H5: Muscular strength, assessed with a three-repetition max for back squat and bench press will increase following a 10-week SIT and resistance training intervention for sedentary women with at least one metabolic syndrome risk factor.

Delimitations

The following study will be delimited to participants who meet the following criteria:

1. Females between 25-55 years of age
2. Low risk for medical complications from exercise as determined by the Physical Activity Readiness questionnaire (PARQ)

3. Currently not engaging in a regularly schedule of exercise
4. Displays at least one symptom of metabolic syndrome
5. Not pregnant
6. Currently not taking any medications that will increase the risk of participation or interfere with testing variables
7. Able to attend exercise sessions at Auburn University three times per week for 10 weeks

Limitations

The current study did not utilize a control group but instead examined a dose response relationship between the number of exercise sessions and changes in MetS risk score. In addition, the current study did not include the effects of menstrual cycle and oral contraceptives. We did not include control for diet; rather, we encouraged participants to maintain their current diet. Finally, VO₂max was estimated with a GXT (Bruce Protocol), instead of indirect calorimetry via metabolic cart. Utilizing a GXT is less risky for sedentary individuals and is an acceptable form of testing by ACSM (ACSM, 2017). Reliability testing for the GXT was done to assess reliability between GXT measures at baseline data collection.

II. LITERATURE REVIEW

Definition of Metabolic Syndrome

Metabolic Syndrome (MetS) is a condition comprised of multiple risk factors that contribute to comorbidities such as cancer, type II diabetes, obesity, cardiovascular disease (CVD) and increased risk of premature death (Grundy et al., 2005; O'Neill and O'Driscoll, 2015; Tibana et al., 2013). Patients with MetS are clinically diagnosed by meeting at least three of the criteria which include: elevated waist circumference (WC), blood pressure (BP), fasting plasma glucose levels (FBG), triglycerides (TG), and low high density lipoprotein (HDL) (Alberti et al., 2009; Grundy et al., 2005). While MetS is a commonly used descriptor, the National Heart, Lung, and Blood Institute (NHLBI) states that meeting this criteria can also be labeled as Dysmetabolic syndrome, Hypertriglyceridemia waist, Insulin resistance syndrome, Obesity syndrome, and Syndrome X. Individuals with one MetS risk factor are at an increased risk of developing comorbidities and possible premature death, and risk continues to increase with each additional risk factor (Katzmarzyk et al., 2003).

Since the 1990's, the prevalence of MetS in the United States has increased to almost 35% for adults, with a rate of 50% for adults aged 60 years and older (Aguilar et al., 2015). Of those adults, the highest increases in MetS prevalence are observed in non-Hispanic black men (55%), non-Hispanic white women (44%), non-Hispanic black women (41%), non-Hispanic white men (31%), and Hispanic men (12.5%). The smallest increase in MetS has been observed among Mexican American women (2%) (Moore et al., 2017). Moore et al. (2017) reported that the prevalence of MetS for all racial/ethnic groups increased from 10% (18 to 29 years) to almost 70% among women (≥ 70 years). In addition, the authors reported that for every 10-year increase in age, the risk of being diagnosed with MetS increased by 50-73% (Moore et al., 2017). In 2007,

a meta-analysis of 37 different studies examining MetS and the risk of CVD found there to be a 1.8-fold increased risk for CVD in those with MetS (Gami et al., 2007).

Wewege et al. (2018) conducted a meta-analysis of exercise and MetS and concluded that MetS is more prevalent in women. Specifically, women have a significantly higher prevalence (Women 35.6% vs Men 30.3%, $p < 0.001$) of MetS compared to men (Aguilar et al., 2015). With almost 35% of all adults in the United States estimated to meet criteria for MetS, and women at a greater risk of developing MetS risk factors. Therefore, it is essential to reduce associated risk factors of MetS in this population (Aguilar et al., 2015; CDC, 2016).

Clinical Diagnosis of Metabolic Syndrome

Clinical diagnosis of MetS includes elevated body weight (WC), BP, FPG, TG profile, and low HDL (Alberti et al., 2009; Grundy et al., 2005). The criteria have been updated over the years beginning with the World Health Organization (WHO) in 1998. In 2009, the NHLBI; American Heart Association (AHA); World Heart Federation; International Atherosclerosis Society; and International Association for the Study of Obesity came together to establish a joint consensus on defining criteria for clinically diagnosing MetS which is located in Table 1 (Alberti et al., 2009). The major additions to the criteria included specific WC measures for different genders and ethnic populations (Table 2), and adding medications as a qualification to TG, HDL, BP, and FPG measures (Table 1). If a specific ethnic population was not included, their country of origin was used as the criteria to establish WC measures. This is currently the standard clinical criteria used to diagnose MetS.

Table 1. Criteria for Clinical Metabolic Syndrome

Measure (any 3 of 5 constitute diagnosis of metabolic syndrome)	Variable Cutoffs
Elevated WC	Population and country specific
Elevated TG	≥ 150 mg/dL (1.7 mmol/L) or On drug treatment for elevated triglycerides
Reduced HDL-C	≤ 50 mg/dL (1.3 mmol/L) in women or On drug treatment for reduced HDL-C
Elevated BP	≥ 130 mm Hg systolic blood pressure or ≥ 85 mm Hg diastolic blood pressure or On antihypertensive drug treatment in a patient with a history of hypertension
Elevated FPG	≥ 100 mg/dL or On drug treatment for elevated glucose

Table 2. Current Recommended Waist Circumference Thresholds for Abdominal Obesity in Women

Population	Waist Circumference
Asians	≥ 80 cm
Canada	≥ 88 cm
Caucasians	≥ 80 cm
Ethnic Central and South American	≥ 80 cm
European	≥ 88 cm
Middle East, Mediterranean	≥ 80 cm
Sub-Saharan African	≥ 80 cm
United States	≥ 88 cm

Treatment of Metabolic Syndrome

Lifestyle Changes

Currently, several lifestyle changes are known to influence the development and/or management of MetS. For individuals with one or more MetS risk factors the first line of defense are lifestyle changes, followed by medication if necessary (Grundy et al., 2005; Alberti et al., 2009; Tavares et al., 2015). Lifestyle choices such as smoking, diet, and sedentary behavior and/or low physical activity are listed as major predictors contributing to MetS (CDC, 2016; O’Neill and O’Driscoll, 2015). Therefore, to minimize risk for developing MetS, individuals are

recommended to avoid smoking, maintain healthy diets, and not engage in a sedentary lifestyle (Aguilar et al., 2015; CDC, 2016; O'Neill and O'Driscoll, 2015; Wewege et al., 2018).

Smoking has been suggested as a modifiable lifestyle factor affecting MetS risk factors. In 2012, a meta-analysis on the association of smoking and MetS was conducted to quantify the risk of this lifestyle choice (Sun, K., Liu, J., & Ning, G. 2012). The meta-analysis included 13 studies (56,691 participants) and concluded that there is a 26% increased risk of MetS for active smokers compared to nonsmoking individuals. Only four studies included females, and were inconclusive as to the risks of smoking on MetS risk factors. The authors reasoned that the prevalence of heavy smoking is lower in females, and/or females were less likely to reveal their smoking habits makes it difficult to analyze the effects of smoking on MetS risk factors in this population (Sun, K., Liu, J., & Ning, G. 2012). This conclusion is further corroborated in a study that observed the relationship of smoking and BP in young male and female Greek adults (Papathanasiou et al., 2015). While smoking prevalence of the participants was 35.2%, and heavy smoking (≥ 21 cigs/day) was 15.3%, there was no difference in smoking prevalence between sexes. Papathanasiou et al. (2015) concluded that there were no significant changes in systolic and diastolic BP for smokers, heavy smokers, and non-smokers (Papathanasiou et al., 2015).

A lifestyle factor affecting MetS risk factors that has been highly studied is diet (Yamaoka & Tango, 2012). For example, the Mediterranean diet has been associated with decreases in MetS risk factors (Kastorini et al., 2011; Yamaoka & Tango, 2012). The Mediterranean diet is composed of daily consumption of monosaturated fatty acids (olives, olive oil), fruits, vegetables, whole grains, and low-fat dairy products. In addition, this diet

recommends weekly consumption of fish and poultry, while limiting red meat and alcohol. Kastorini et al. (2011) conducted a systematic review of 50 studies (534,906 participants) researching the effects of MetS risk factors when adhering to a Mediterranean diet. The authors concluded that the combined data of adherence to the Mediterranean diet showed an overall decrease in WC (-0.42 cm), TG (-6.14 mg/dl), systolic BP (-2.35 mmHg), diastolic BP (-1.58 mmHg), FPG (-3.89 mg/dl) and an increase in HDL (+1.17 mg/dl). While diet alone has shown beneficial effects on MetS risk factors, diet combined with exercise is suggested to be the most beneficial form of lifestyle modifications (CDC, 2016). However, if research is looking to isolate the effects of a certain type of exercise on MetS risk factors, limiting adjustments to diet is a necessary component of a study. Therefore, at times participants may be asked to maintain their current eating/drinking patterns, regardless of the MetS benefits, to control for changing parameters of research being conducted.

Although sedentary behavior is not listed as a criterion for MetS, a sedentary lifestyle has implications for MetS criterion. Sisson et al. (2009) reported sedentary behavior negatively affects MetS risk factors in women. Specifically, that women who spent ≥ 4 hours of sedentary time/day were 54% more likely to have and/or develop MetS. Previous studies report decreasing sedentary behavior and participating in moderate-to-vigorous physical activity (MVPA) result in decreases in BP (>3 mmHg decrease), decrease in FPG ($\sim 9\%$), decrease in WC (0 to 5.6 cm), and TG levels (229 ± 25 mg/dL to 150 ± 15 mg/dL, $p = .001$) (Alberti et al., 2009; Cauza et al., 2005; Dalzill et al., 2014; Grundy et al., 2005; Katzmarzyk et al., 2003; Matthew et al., 2008; Owen et al., 2010; Pattyn et al., 2013). Owen et al. (2010) and Healy et al. (2008) agree that while light physical activity (1.9-2.9 METS) contributes to daily energy expenditure and a healthy lifestyle; metabolic benefits associated with regular MVPA should be promoted for

decreasing risk factors associated with MetS. In 2003, research on exercise (consistent, regular MVPA) as a means of treating MetS reported that of the participants who completed the 20-week study, 30% were no longer meeting MetS criteria (Katzmarzyk et al., 2003). The results showed exercise positively influences all five of MetS physiological risk factors. Specifically, the study reported 28% decrease in WC, 9% improvement in FPG, 38% decrease in BP, 43% decrease in TG, and 16% improvement in HDL. These results show that exercise positively affects all five-criteria used to diagnose MetS, and is an effective treatment strategy (Grundy et al., 2005; Owen et al., 2010). Although research supports participation in MVPA to positively influence all five of MetS physiological risk factors (Grundy et al., 2005; Owen et al., 2010), only 20% of adults in the United States meet physical activity recommendations (Matthews et al., 2008; Wewege et al., 2018), with women reporting less physical activity than their male counterparts (Matthews et al., 2008).

Exercise Interventions

Several different approaches to address MetS via exercise have been studied (Bateman et al., 2011; Cauza et al., 2005; Dalzill et al., 2014; Stensvold et al., 2010; Tjonna et al., 2008). These exercise interventions are categorized as aerobic training (AT) only, resistance training (RT) only, and combined aerobic and resistance training (AT+RT). A 2018 meta-analysis of exercise and MetS risk factors examined different participant characteristics in response to the exercise interventions across 16 interventions (12 AT, 4 RT) and 588 participants (Wewege et al., 2018). The meta-analysis revealed that of the 12 AT interventions reviewed, women experience more exercise benefits than their male counterparts. Women experienced statistical ($p < 0.05$) decreases in risk for all five of the MetS criteria while men saw statistical ($p < 0.05$)

decreases in only two criteria. The effect of resistance training was not able to be reviewed due to a lack of data (4 RT studies). Although the study concluded that MetS is more prevalent in women ≥ 30 years old, women who are ≥ 25 -29 years old that have at least one MetS risk factor would also benefit from an exercise intervention (Wewege et al., 2018). With the increased risk of developing MetS, and the benefits of possible statistical ($p < 0.05$) improvements in all five of the MetS criteria, women ≥ 25 years old are a population that warrants exercise intervention research for the purposes of decreasing risk factors related to MetS.

Currently, there is no consensus on the most effective and beneficial form of exercise to lower risk factors associated with MetS. With regards to preventative and intervention treatment, research on the most effective form of exercise for MetS risk factors deserves more attention as MetS patient numbers continue to grow.

Aerobic Interventions

Aerobic (AT) only interventions can be done on a variety of equipment and are labeled into three different categories: moderate intensity continuous training (MICT), high intensity interval training (HIIT), and sprint interval training (SIT). MICT is defined as exercising between 50-70% of maximum heart rate for ≥ 30 continuous minutes (Gibson, Wagner, and Heyward, 2018). HIIT is characterized by short repeated bouts (< 5 minutes) of vigorous exercise (70 to 90 percent HRmax), with short rests or active recovery in between bouts (Gibala, 2018; Kemi and Wisløff, 2010). Finally, SIT consists of repeated “all-out” bouts (< 40 seconds) at ~ 95 HRmax, followed by short rests or active recovery intervals (Åstrand et al., 1960; Hazell et al., 2014). The SIT protocol takes the least amount of time (< 15 minutes).

Bateman et al. (2011) conducted an exercise intervention for 8 months using MICT (~120 minutes/week at 65-80% VO_2peak). Exercise was calculated to ensure participants metabolized 14 kcal/kg of body mass/week (~12 miles/week) using treadmills, elliptical trainers, and cycle ergometers. Results for MICT (n=30) showed significant ($p < 0.05$) decreases in body mass (-1.5 kg) and TG (-21.0 mg/dl), while WC decreased but not significantly (-1.12 cm). Mello et al. (2011) utilized MICT (60 minutes/day, 3 days/week at 50-70% ventilatory threshold) in a 16-week exercise intervention for 15-19-year-old adolescents with MetS. Results for the MICT group (n=15) at 6 months showed a significant ($p < 0.05$) decrease in body mass, fat mass, visceral fat, FPG, WC, and TG. In addition, TG continued to show significant decreases from 6 months to the one-year post assessment (Mello et al., 2011). These findings indicate that MICT is effective at lowering risk factors associated with MetS.

When looking closer between the different types of AT for MetS risk factors, a difference in adaptations is observed between MICT and HIIT training groups. Tjonna et al. (2008) conducted a 16-week pilot study, revealing significant ($p < 0.05$) differences between the MICT and HIIT groups physiological changes (Tjonna et al., 2008). Participants exercised 3 sessions a week using a treadmill. The HIIT group completed four 4-minute intervals at 90% of HRmax with a 3-minute active recovery at 70% of HRmax in between bouts. The MICT group exercised for 47 minutes at 70% of HRmax. Both MICT and HIIT aerobic training MetS participants experienced a significant ($p < 0.05$) decrease in total body mass (3-4% kg), WC (>5 cm), systolic (~10 mmHg) and diastolic BP (~ 6 mmHg), and MetS z score (Tjonna et al., 2008). However, the HIIT group had a significantly ($p < 0.05$) greater decrease in risk factor variables that contributed to MetS. Specifically, a significantly ($p < 0.05$) greater decrease in FPG (HIIT 46% and MICT 37%), HDL (HIIT 25% and MICT ~0%), and VO_2max (HIIT 35% and MICT 16%; Tjonna et al.,

2008). Similar findings have been reported in other studies utilizing similar HIIT and MICT protocols (Bateman et al., 2011; Stensvold et al., 2010). Stensvold et al. (2010) performed a HIIT 12-week intervention consisting of 4 x 4 minutes of treadmill bouts at 90-95% HRpeak, three days/week. Results for the HIIT group (n=11) showed a significant ($p < 0.05$) decrease in WC, fat mass, and a non-significant reduction of systolic (~6 mmHg) and diastolic (~4 mmHg) BP. Taken together, these studies suggest that HIIT may have a greater physiological benefit to MetS risk factors than MICT.

Sprint interval training (SIT) is a type of HIIT training consisting of repeated “all-out” bouts (<40 seconds) at ~95 HRmax, followed by short rests or active recovery intervals. Previous literature has shown that SIT results in similar physiological benefits as MICT (Smith-Ryan., 2015; Stensvold et al., 2010) and HIIT (Gillen and Gibala., 2014; Hazell et al., 2014) including decreases in body mass, body fat, WC, resting systolic and diastolic BP. SIT training is at near maximal intensity with shorter bouts and shorter rest periods compared to HIIT and takes less than 15 minutes to complete. An example of SIT training would be three clusters of three sets of 40-second sprints (~95% HRmax) wherein each set is separated by 20 seconds of rest, and each cluster is separated by 60 seconds of passive recovery. Although, SIT has not been conducted in a clinical MetS population, other populations have shown changes in MetS risk factors. Hazell et al. (2014) conducted a 6-week SIT protocol (4x30 seconds max effort with 4 min active recovery between bouts, 3x/wk) in women with MetS risk factors and reported a significant ($p < 0.05$) decrease in body mass, body fat, and WC. Results also showed a significant ($p < 0.05$) increase in fat-free mass and VO₂max. These results are impressive due to significant changes from the short duration (6 weeks) of the study and the short amount (45 minutes total) of exercise necessary per week (Hazell et al., 2014). Sloth et al. (2013) conducted a meta-analysis of aerobic

exercise performance on 13 studies utilizing SIT protocols. The authors reported that 2–8 weeks of SIT performed 2–3 times/week resulted in improved FPG (28%). In summary, SIT training is associated with significant ($p < 0.05$) decreases in body mass, body fat, WC, FPG, systolic and diastolic BP and increases in fat-free mass and VO_{2max} (Hazell et al., 2014; Sloth et al., 2013). With similar physiological benefits and an even shorter exercise duration, SIT training is a possible replacement to MICT and HIIT for women with MetS risk factors.

Resistance Training Interventions

Resistance training (RT) alone has benefits in terms of decreases in WC (Stensvold et al., 2010), decrease in FPG (Conceição et al., 2013), decreases in systolic BP (Castaneda et al., 2002), and increases in strength (Bateman et al., 2011; Castaneda et al., 2002; Conceição et al., 2013; Levinger et al., 2007; Tibana et al., 2013). However, there have been several studies that found no significant changes in fasting FPG and TG in RT only MetS participants (Bateman et al., 2011; Levinger et al., 2007; Stensvold et al., 2010; Tibana et al., 2013). Studies finding significant and non-significant findings that were comparable in time increments ranged from eight weeks to four months (Castaneda et al., 2002; Conceição et al., 2013).

Conceição et al. (2013) conducted a 16-week study on RT and reported significant ($p < 0.05$) decreases in FPG levels with postmenopausal MetS women. Training consisted of 10 exercises (leg press, leg extension, leg curl, bench press, lat pulldown, lateral raise, triceps pushdown, arm curl, and basic abdominal crunch) with three sets of 8–10 maximum repetitions three times/week. Castaneda et al. (2002) conducted another 16-week RT study and reported significant decreases in systolic BP ($p = 0.05$), plasma glycosylated hemoglobin levels ($p < 0.01$) and muscle glycogen stores ($p < 0.04$) in Latino older adults with Type II Diabetes (Castaneda et

al., 2002). Training consisted of three sets of five reps on five pneumatic resistance training machines (chest and leg press, upper back, knee extension, and flexion; Keiser Sports Health Equipment, Fresno, CA). Where Conceição et al. (2013) used free weights, Castaneda et al. (2002) used resistance training machines. Both studies utilized largest to smallest muscle lifting order, however the studies differed in the number of sets, reps, and choice of exercise type. Although both studies consisted of 16 weeks, there is a possibility that these studies may have found different results from one another due to the different type of resistance training design chosen in these studies.

Currently, there is conflicting evidence on the effect of RT alone on risk factors for MetS. The literature does report the benefits of RT on decreasing WC and BP which are risk factors associated with MetS (Bateman et al., 2011; Bonsu and Terblanche, 2016; Castaneda et al., 2002; Conceição et al., 2013; Levinger et al., 2007; Stensvold et al., 2010; Tibana et al., 2013).

Aerobic and Resistance Interventions

Only a handful of studies have researched the effects of a combined aerobic and resistance training (AT+RT) intervention on physiological risk factors in participants with MetS (Bateman et al., 2011; Mello et al., 2011; Stensvold et al., 2010). These existing studies included AT+RT, AT alone and/or RT alone groups into their experimental design to compare different training program effects. RT alone did not show any significant changes on MetS risk factors (Bateman et al., 2011; Mello et al., 2011; Stensvold et al., 2010). Two of the studies used MICT as their form of AT (Bateman et al., 2011; Mello et al., 2011). Bateman et al., randomly assigned 196 participants into three groups: RT (3 sets/day at 8-12 reps/set, 3 days/week), AT (~120 minutes/week at 75% VO₂max), and AT + RT (exact combination of AT and RT protocols) for

eight months of training (Bateman et al., 2011). Results for the AT +RT group (n=30) showed a significant ($p < 0.05$) increase in VO_2 peak and strength (kg/session). There was also a significant ($p < 0.05$) decrease in body mass, TG, WC, FPG, diastolic BP, mean arterial BP, and MetS z score for the AT + RT group (Bateman et al., 2011). Although AT + RT resulted in the greatest decrease in risk factors associated with METS, Bateman et al. (2011) concluded that AT was the most beneficial form of training due to AT showing similar results as AT + RT, with AT having a lower weekly time commitment to observe positive changes. While AT was ~ 130 minutes per week, AT + RT took ~185 minutes per week to complete (Bateman et al., 2011). It could be speculated that had this study utilized a less time-consuming form of AT for the combined group that AT + RT would have been reported as the most beneficial form of training. Mello et al. (2011) utilized 30 (15-19 years) participants to randomly split into AT (60 minutes/day, 3 days/week at 50-70% ventilatory threshold) and AT + RT (30 minutes of AT at 50-70% ventilatory threshold + 30 minutes of RT, 3 days/week, RT load adjusted weekly to meet maximal repetition) groups for 1 year of training. Mello et al. (2011) concluded that AT +RT to be superior to AT alone due to greater decreases in risk factors associated with MetS. Results for the AT + RT group (n=15) at 6 months showed a significant ($p < 0.05$) decrease in body mass, fat mass, visceral fat, WC, and TG. In addition, all previously mentioned variables continued to show significant decreases from six months to the one-year post assessment (Mello et al., 2011). These studies showed that AT+RT may be beneficial, but further research to determine the effect of combining AT and RT in a time efficient manner is necessary to determine the effect of this type of training program on participants with MetS.

Time commitment is a commonly cited problem to the lack of exercise adherence (Bateman et al., 2011), which makes SIT and HIIT protocols attractive given that it takes a

fraction of the time to complete compared to long-slow distance cardiovascular exercise. Previous literature has reported similar physiological benefits in SIT, HIIT and MICT (Hazell et al., 2014; Tjonna et al., 2008). Research has shown that SIT provides similar health benefits as MICT and HIIT at a fraction of the time needed to commit per week. Although identified as HIIT, Stensvold et al. (2010) is the closest example of the effects of a SIT and RT combined study on risk factors for MetS. Stensvold et al. (2010) had participants do AT (four intervals of 4 min at 90–95% of HRpeak) once per week, and RT (three sets of low row, bench press, and hack lift for 8–12 repetitions) twice per week for 12 weeks. To the best of the authors knowledge, there is only one known study to specifically observe the effects of a SIT and resistance (SIT+RT) protocol on sedentary women, however, MetS criteria were not examined. Huffman et al. (2019) conducted a 10-week SIT and RT intervention on 53 (52.7 ± 7.1 years) sedentary women. Results showed significant ($p < 0.05$) improvements in VO_{2max} after 10 weeks of training. Results from the study did not evaluate risk factors for MetS, however this study does show opportunity for future research utilizing this intervention in a wider age group of sedentary women focusing on MetS risk factors.

In summary, women ≥ 30 years old, engage in the greatest amount of sedentary behavior and have a significantly higher prevalence (Women 35.6% vs Men 30.3%, $p < .001$) of MetS compared to men (Aguilar et al., 2015). Previous literature suggests that utilizing an exercise intervention consisting of both interval and RT would optimize health benefits and decrease risk factors associated with MetS (Bateman et al., 2011; Stensvold et al., 2010; Tjonna et al., 2008). As physical activity is the most effective way of managing risk factors associated with MetS (Alberti et al., 2009) women ≥ 25 years old, diagnosed with MetS and/or having at least one MetS risk factor, may benefit from an exercise intervention. With previous research contending that

AT+RT elicit the greatest response and benefits to patients with MetS risk factors, the purpose of this study was to examine the physiological effects of a SIT and RT intervention on sedentary women with at least one metabolic syndrome risk factor.

II. METHODOLOGY

Human Subjects Approval

To begin recruiting participants for this exercise intervention, a full-board research protocol document was submitted to the Auburn University Institutional Review Board for Research Involving Human Subjects (IRB). Following the regulations set forth by Auburn University IRB, this study protocol was approved for use from 09/24/2018 to 08/14/2019 under the following protocol number 18-323 AR 1809 (Appendix A).

Participants

Female participants were recruited by health fairs, word of mouth, e-mail, flyers, and social networks from the Auburn/Opelika community (Appendices B and C). Participants were included in the study if they met the following qualifications:

1. Between the age of 25-55
2. Met at least one of the criteria for clinical metabolic syndrome based on the 2009 Joint Interim Statement of the International Diabetes Federation Task Force on Epidemiology and Prevention (Alberti et al., 2009; Table 1; Table 2).
3. Aside from risk factors for metabolic syndrome, healthy as determined by the Physical Activity Readiness Questionnaire plus (PAR-Q+; Jamnik, Warburton, Makarski, McKenzie, Shephard, Stone and Gledhill 2011) (Appendix D),
4. Not pregnant
5. Agreed and able to complete a 10-week combined SIT and RT program,
6. Not currently engaged in any structured physical activity program.

Participants were grouped based on time preference/availability and were assigned based on participant preference to either morning, afternoon or evening sessions with a 1:1 researcher/participant ratio.

Study Protocol

This intervention consisted of one experimental group, a SIT and RT combined group attending 10 weeks of exercise training for 30 sessions. Prior to baseline testing, participants arrived at the lab and completed the informed consent and PAR-Q+. Baseline measures included a finger prick blood draw to measure fasting plasma glucose (FPG), triglycerides (TG), high-density lipoproteins (HDL), in addition to blood pressure (BP) and waist circumference (WC) (Table 1; Table 2). Participants that qualified for the study continued baseline testing which included height, weight, body composition, physical activity, sedentary behavior, dietary recall (Appendix E) aerobic fitness and 3-RM for the squat and bench press (Appendix F). Baseline measures were done over the period of one week. Post-testing occurred at week 11 (1 week of baseline, followed by 10 weeks of training) and consisted of baseline testing variables. Body composition was assessed with the iDXA. Physical activity and sedentary behavior were evaluated with a waist worn accelerometer at baseline, and week 11 for seven days. Appendix G contains the accelerometer log participants were asked to complete. In addition, a MetS z score was calculated at baseline and week 11 using the results from baseline and week 11 measurements of WC, BP, FPG, TG, and HDL. MetS z score was calculated pre- and post- exercise intervention based on the metabolic syndrome z score for women: $\{[(50\text{-HDL})/11.8] + [(TG-150)/66.2] + [(FBG-100)/10.4] + [(WC-88)/9.2] + [(MAP-100)/8.7]/100\}$ (Tibana et al., 2014). An outline of the study protocol is shown in Figure 1.

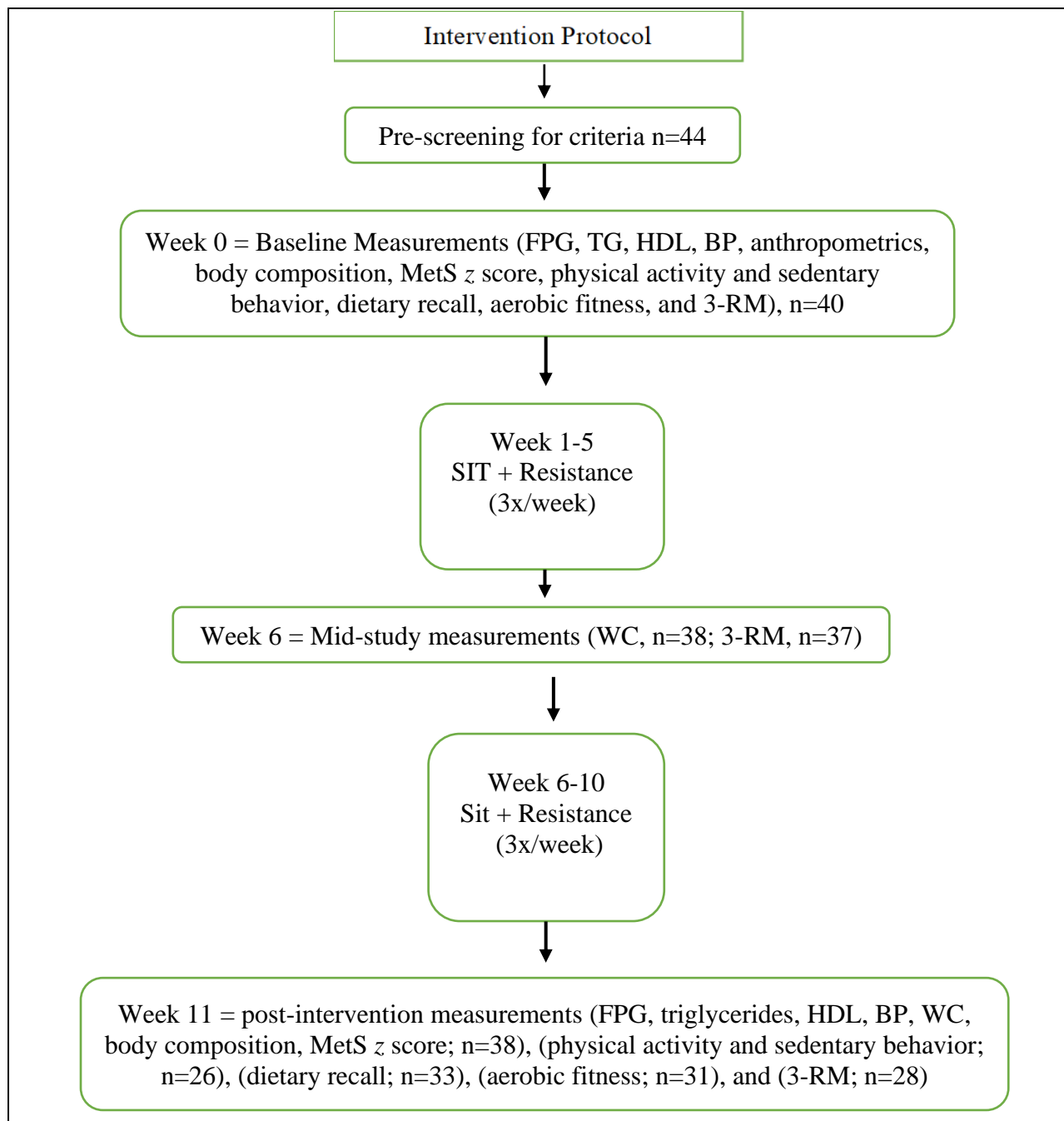


Figure 1: Study Protocol

Table 1 summarizes the criteria for Clinical Metabolic Syndrome.

Table 1. Criteria for Clinical Metabolic Syndrome

Measure (any 3 of 5 constitute diagnosis of metabolic syndrome)	Variable Cutoffs
Elevated WC	Population and country specific
Elevated TG	≥ 150 mg/dL (1.7 mmol/L) or On drug treatment for elevated triglycerides
Reduced HDL-C	≤ 50 mg/dL (1.3 mmol/L) in women or On drug treatment for reduced HDL-C
Elevated BP	≥ 130 mm Hg systolic blood pressure or ≥ 85 mm Hg diastolic blood pressure or On antihypertensive drug treatment in a patient with a history of hypertension
Elevated FPG	≥ 100 mg/dL or On drug treatment for elevated glucose

Table 2. Current Recommended Waist Circumference Thresholds for Abdominal Obesity in Women

Population	Waist Circumference
Asians	≥ 80 cm
Canada	≥ 88 cm
Caucasians	≥ 80 cm
Ethnic Central and South American	≥ 80 cm
European	≥ 88 cm
Middle East, Mediterranean	≥ 80 cm
Sub-Saharan African	≥ 80 cm
United States	≥ 88 cm

Measurements

Blood Collection

Fasting capillary blood was drawn after an 8-hour fast and was assayed for FPG, HDL, LDL, and TG at baseline and week 11 by a trained phlebotomist. Participants were asked to sit comfortably in the blood collection chair for blood to be drawn (5 microliters (μL)) from a fingerstick using a 28-gauge lancet (Unistick 3 comfort, Owen Mumford, Marietta, GA) which was collected in a lithium heparin-coated capillary tube. This capillary tube transported blood to a cassette loaded into the Alere Cholestech LDX (Alere San Diego, inc. San Diego, CA) for analysis. Specifically,

the tester stated, “*You will feel a slight prick on the fourth finger of your non-dominant hand. The needle and supplies used are sterile and similar to what is used by your physician’s office to draw blood.*” The tester then drew blood using standard phlebotomy techniques.

Blood Pressure

To measure BP participants were instructed to wear loose clothing, sit quietly, and keep both feet flat on the floor. Systolic BP and diastolic BP were measured at baseline and week 11 with a sphygmomanometer and blood pressure cuff (Welch Allyn Inc, Skaneateles, NY, USA). Mean arterial Pressure (MAP) was calculated for use in the MetS *z* score with the following formula: Calculation for MAP = Systolic BP + 2(Diastolic BP)/3. Cuff size was adapted to the arm circumference of the participant. To standardize the process, the cuff was attached to the left arm, two fingers’ width above the bend in the elbow, and in line with the brachial artery (Thompson et al., 2013). Participants already on BP medication were noted as meeting criteria for MetS but were measured at baseline and week 11 without BP medicine taken on measurement day to determine a true resting BP.

Metabolic Syndrome Z Score

MetS *z* score is a continuous risk score that is calculated from the individuals MetS risk factor results. MetS *z* score was calculated using the results from baseline and week 11 measurements of WC, BP, FPG, TG, and HDL. MetS *z* score was calculated pre- and post- exercise intervention based on the metabolic syndrome *z* score for women: $\{[(50\text{-HDL})/11.8] + [(TG\text{-}150)/66.2] + [(FBG\text{-}100)/10.4] + [(WC\text{-}88)/9.2] + [(MAP\text{-}100)/8.7]/100\}$ (Tibana et al., 2014).

Anthropometrics

Height was measured to the nearest 0.25 cm, and weight was assessed using a using a stadiometer (SECA Model 769, Seca gmbh & Co.kg., Hamburg, Germany) to the nearest 0.1 kg. Waist circumference was measured at the top of the right iliac crest and placing a Gulick tension rod measuring tape in a horizontal plane around the abdomen and level of the iliac crest. Before reading the tape measure we ensured that the tape was snug but did not compress the skin and was parallel to the floor. Measurements were made at the end of a normal expiration (Grundy et al., 2005).

Body Composition

Body composition was assessed by dual-energy X-ray absorptiometry (iDXA) (GE Healthcare Lunar, Madison, WI), which provides accurate data related to body composition in terms of BMI, fat mass (FM), lean body mass (LBM), bone mineral density, and exact data from sections of the body if necessary. iDXA body composition analysis provides precise high-resolution images on measuring fat mass, lean mass, and bone mineral density of each segment of the body. It measures the diffusion of X-rays through the body at high and low energies. The X-ray beam energy is diminished with the passage through the three human body components that are distinguishable by their X-ray attenuation properties: bone mineral, fat tissue, and lean soft tissue (Toombs, Ducher, Shepherd, & De Souza, 2012). This measurement takes between 7 to 14 minutes depending on the thickness of a person's body mass. According to previous studies the precision error for total body mass 0.9%, total body lean mass 0.4 to 0.5%, total bone mineral content 0.6%, fat mass 0.7 to 0.8%, and percent body fat 0.6 to 0.9% (Hind, Oldroyd, & Truscott, 2011; Rezzi, Ginty, Beaumont, & Ergun, 2009; Rothney et al., 2012). Percent body fat

(%Fat) lean body mass (LBM), fat mass (FM), and body weight (BW) were measured in kilograms by iDXA. All iDXA measurements were carried out by certified personnel.

Physical Activity and Sedentary Behavior

To measure physical activity and sedentary behavior outside of the 30 sessions a waist worn Actigraph wGT3X-BT was attached on the waist of each participant to assess changes regarding sedentary, light, moderate, and vigorous physical activity. Each participant wore the accelerometer for 7 days at baseline and week 11. Based on previous studies (Cain & Geremia, 2012; Ward, Evenson, Vaughn, Rodgers, & Troiano, 2005), an epoch length of 60 seconds was chosen as the standard for the current study with a sampling rate of 30 Hz. Additional criteria for analysis include a minimum of 10-hour daily wear time and 3-5 days of monitoring. A minimum of 10 hours per day of wear time was needed for sampling wake-time behavior with 3-5 days of monitoring required to achieve 80% reliability for total and moderate-to-vigorous intensity physical activity (Hart, Swartz, Cashin, & Strath, 2011; Matthews et al., 2008; Trost, McIver, & Pate, 2005). Non-wear time was identified based on the algorithm from Choi et al. (2011) and removed from the analysis (Choi et al., 2011). After each assessment, accelerometers were collected, and the data was downloaded to the Actigraph Actilife software. Previously validated cut points classified accelerometer data as sedentary (<100 counts/minute), light (100-2019 counts/minute), moderate (2020-5998 counts/minute), and vigorous (≥ 5999 counts/minute) (Freedson, 1998). Based on these accelerometer cut points, data was divided into four activity categories: sedentary, light, moderate, and vigorous. Participants were asked not to change physical activity outside of the study over the course of the study.

Aerobic Fitness

Aerobic fitness was measured with a Bruce Protocol that exercised the participants to volitional fatigue. Participants' heart rates were recorded at the end of each stage and heart rate and time were recorded at volitional fatigue. This exercise stress test is commonly used to estimate aerobic (cardiovascular) fitness with a reported standard error of estimates (SEEs) range from ± 2.7 to ± 4.7 ml/kg/min (ACSM, 2017). In this test, VO_{2max} is estimated by asking the participant to walk- jog, and/or run on a treadmill at stages of three minutes each one, beginning at:

1. 10% of incline and 1.7 miles per hour (MPH)
2. 12% incline and 2.5 MPH
3. 14% incline and 3.4 MPH
4. 16% incline and 4.2 MPH
5. 18% incline and 5.0 MPH

Once the participant reached volitional fatigue the test was stopped and VO_{2max} was estimated by using a standardized and validated formula (Bruce, Kusumi, & Hosmer, 1973). Formula to predict VO_{2max} :

$$VO_2 \text{ (ml/kg/min)} = 6.7 - 2.82(2) + .056 \text{ (time in seconds)}$$

$$VO_2 \text{ (ml/kg/min)} = 1.06 + .056 \text{ (time in seconds) (WOMEN)}$$

Even though, submaximal exercise testing is not as precise as indirect calorimetry, it provides an estimate of a person's aerobic fitness. The advantages to the Bruce Protocol are that it is easily administered, low cost, reduces risk of negative events, needs less time and effort on the part of

the subject, and assumptions related to submaximal tests are easily met (Fletcher et al., 2001). According to ACSM (ACSM, 2017) when a repeated submaximal GXTs are applied over a period of weeks or months and with a HR response decreasing over time with a fixed workload, it is likely that the cardiorespiratory fitness of that person can be improved. Thus, we chose to validate our submaximal test by having randomly selected participants (n=5) repeat the test within 2 days of the initial test to ensure reliability for the GXT protocol. All tests were performed under the supervision of appropriately trained personnel.

Muscular Strength

Lower extremity muscular strength was assessed with the back squat using a 3-RM, while upper extremities strength was gauged through the bench press. Study participants were instructed on and practiced proper lifting techniques and were spotted during all resistance lifting tasks. Initial back squat 3-RM assessment began with 10 repetitions of a body weight squat followed by 5 back squats using a 45 lb. barbell. Foam barbell covers were available for the convenience of participants. After a 2-minute break, 5 additional repetitions were completed at 50% of the participant's estimated 1-RM for the back squat. After an additional 2-minute rest period, 3 repetitions were completed at an estimated 70% of 1-RM. Subsequent sets of progressively heavier weight were completed until three repetitions were performed with proper form at near maximal weight. Each of these sets was separated by a recovery period of 3 minutes. A similar protocol was utilized for the bench press. Three RM values were utilized to estimate 1-RM values through the Wathen equation (McNair et al., 2011). Three RM were assessed at baseline, week 6, and week 11 after the program. Resistance training was performed under the supervision of appropriately trained personnel.

Dietary Recall

To determine that the effects of the study were not due to dietary changes, participants were asked to complete a 3-day diet recall (two weekdays and one weekend day) during baseline of the intervention and at week 11 (one week after the intervention). Energy intake and diet components were analyzed by using open-sourced software (www.nutritiondata.com). Average kcals over the three days is reported at baseline and at week 11.

Intervention

The 10-week intervention consisted of 30 sessions, 3 times a week (Monday, Wednesday, and Friday). Each session all participants completed a SIT and RT protocol. Prior to each exercise session the participants completed five minutes of dynamic warm-up exercises and after each exercise sessions participants completed five to ten minutes of static stretching and range of motion activities.

SIT Protocol

The SIT running protocol consisted of two (first 5 weeks) -to- three (last 5 weeks) sets of three 40-second sprints with 20 seconds of passive recovery between each sprint and one additional minute of recovery after each set. For example, at the beginning of minute 3, 4, and 5 the participant would sprint for 40 seconds, followed by 20 seconds of passive rest by straddling the treadmill belt. The participant would then rest for a full minute (minute 6), followed by one to two more sets of sprints. Sprint sets were preceded by a warming up phase of three minutes at 3.0 mph. At the end of the sprint participants walked on the treadmill at 3.0 mph for 3 minutes to cool down. The SIT program was set to induce cardiovascular responses ~95% of maximal heart

rate achieved during the VO₂max test, therefore speed and grade was adjusted throughout the program to maintain this intensity.

Resistance Protocol

For all participants, two different resistance training protocols were utilized and alternated every day throughout the study. These were denoted as protocol A and protocol B. Both protocols began with a dynamic warm-up. Protocol A consisted of back squat, bench press, and bent-over row. Protocol B consisted of squat jumps, walking lunges, standing shoulder press, and back extensions. Both protocols ended with abdominal exercises, followed by cool down stretches. The resistance exercise training program, based on undulating periodization, was set to impose fluctuating stimuli and in turn, neuromuscular overload. Undulating training model targets volume based on two principles, accumulation which meets high volume training: higher repetitions, more sets, more exercises, and so on; and intensification, the opposite, based on heavier weights, lower repetitions, and emphasis on adding more weight to the workout. Prior to beginning the training program, one week of orientation was used to familiarize participants with the SIT protocol and lifting techniques. The order of the training model utilized in this study was: two week of conditioning, two weeks of hypertrophy, two weeks of muscular strength, two weeks of hypertrophy, and two weeks of muscular strength. The conditioning phase encompassed three sets of 10 repetitions at 55%, 65% and 70% of each participant's 3-RM for the back squat and bench press with the emphasis on proper form. For example, if the participants form failed at rep seven, then the participant would stop that set at rep seven, rest and pick up at the next set. The hypertrophy phase encompassed three sets of 10 repetitions at 65%, 70% and 75% of each participant's 3-RM for the back squat, bench press, bent over row,

and overhead press, while the muscular strength phase was composed of three sets of six repetitions at 75%, 80%, and 85% of participant's 3-RM for each of the lifts.

Statistical Analyses

Descriptive statistics were used to present participants' physical characteristics. Normal distribution was checked using a Shapiro-Wilk normality test. A Power analysis was conducted to determine sample size. A minimum of 34 participants was necessary to achieve a power of 0.80 (effect size set to 0.5; significance level set to 0.05). A correlation was utilized to validate the reliability of using a GXT to measure VO_2max . The pre- and post- intervention variables were analyzed using paired samples t-tests to determine whether changes within each risk factor were significant. In addition, MetS z score for women was measured pre and post to assess if overall MetS changes occurred. Statistical significance was set at $p \leq 0.05$. A Bonferroni correction ($0.010 = 1 - (1 - .05)^{1/5}$) of $p \leq 0.01$ was utilized to account for multiple comparisons. A Cohen's d_s was used to measure the effect size of any variables that were between p 0.01 and 0.05. A repeated measures ANOVA was used to individually analyze waist circumference, 3-RM squat, and 3-RM bench press. Bonferroni post hoc tests were used to determine which points were significantly different. A logistical regression assessed the probability of a decrease in MetS z score following the intervention based on the number of sessions attended out of 30. To analyze data, the IBM Statistical Package for the Social Sciences (SPSS) System (version 24.0) for Windows® was used. Intention to treat analysis was used therefore, any participants who completed testing regardless of the number of sessions attended were included in the analysis.

IV. RESULTS

The purpose of this study was to examine the physiological effects of a SIT and RT intervention on sedentary women with at least one metabolic syndrome risk factor. Initially, 44 women from the local community volunteered to participate. Prior to beginning of the exercise intervention one participant withdrew due to becoming pregnant, two withdrew due to time constraints, and one withdrew due to a heart arrhythmia identified during baseline testing. A total of 40 participants met the criteria and completed baseline measures. During the intervention one participant voluntarily dropped from the study during the exercise intervention due to time constraints, and a second participant dropped due to the loss of family members from a natural disaster. These individuals were returned their materials and excluded from the study. A total of 38 females (Age = 38 ± 8 years old, BMI = 33 ± 8 kg/m²) completed pre- and post- MetS measures. Not all 38 participants made every training session and all testing measures. Four participants became sick with pneumonia/flu and had to discontinue training in the second half of the study. Two participants noted pain from previously undisclosed injuries and were asked to discontinue the study for safety and ethical concerns. Two participants developed knee pain that made them unable to complete part of the protocol and were required to discontinue the study. Due to the fact that we were also examining a dose-response relationship, participants that missed sessions were included in analysis. However, participants that were unable to complete all three measurements for the GXT (31 completed) and/or maximal strength testing (28 completed) were excluded from that analysis. One participant moved away, and several participants had scheduling conflicts that made them unable to make the post- GXT and/or maximal strength testing. Participant flow and dropout is displayed in figure 2.

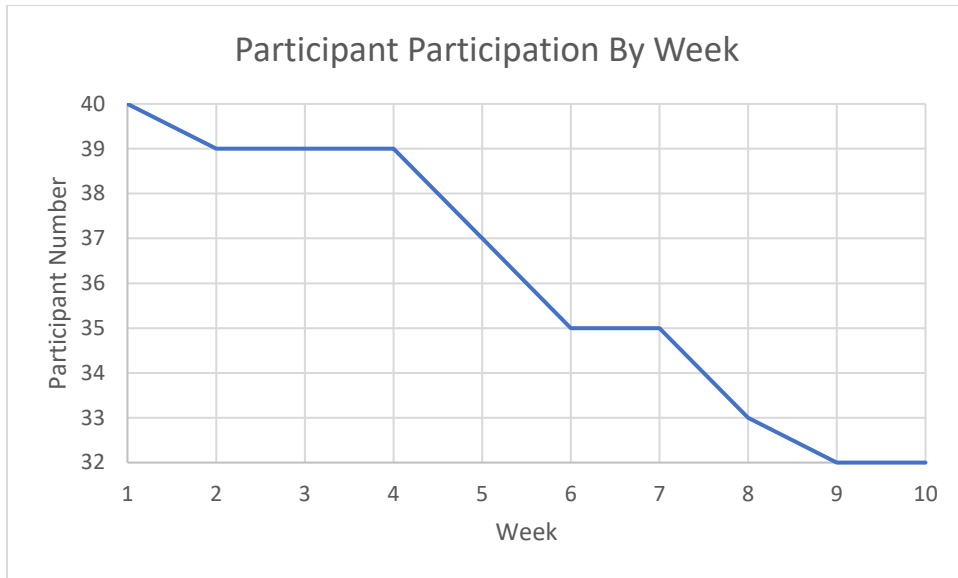


Figure 2. Participant Flow and Dropout by Week.

Descriptive statistics for the remaining 38 participants are presented in Table 3.

Table 3. Descriptive Characteristics

Variable	Mean \pm SD
Age (Y)	40 \pm 9
Caucasian	23
Black	14
Asian	1
Height (cm)	164 \pm 7
Weight (kg)	90 \pm 44
BMI (kg/m ²)	33 \pm 8

Table 4. Changes in the Number of Participants Qualifying Risk Factors for MetS

Variable	Pre-	Post-	Change
Waist Circumference	38	35	-3
Triglycerides	11	8	-3
High-density Lipoprotein	21	21	0
Fasting Plasma Glucose	2	4	+2
Blood Pressure	20	9	-11

Metabolic Syndrome Risk Factors

All data was found to have a normal distribution for the MetS criteria. All 38 women completed all MetS measurements. A repeated-measures ANOVA assessed changes in waist circumference at three different times: pre-, mid-, and post- exercise intervention and a paired t-test assessed changes at pre and post for all other measures. A Bonferroni correction ($p < 0.01$) was used to account for multiple comparisons when analyzing the paired samples t-test. Metabolic Syndrome Risk Factors, Mean Arterial Pressure, and Metabolic Z-score results are presented in Table 5.

Table 5. Metabolic Syndrome Risk Factors, Mean Arterial Pressure, and MetS Z-score, Mean \pm SD (N=38)

Variable	Pre-	Mid-	Post-	Sig.
Waist Circumference (cm)	111 \pm 18	108 \pm 16	107 \pm 16	0.005
Triglycerides (mg/dl)	155 \pm 92	N/A	118 \pm 69	0.033
High-density Lipoprotein (mg/dl)	52 \pm 17	N/A	51 \pm 15	0.669
Fasting Plasma Glucose (mg/dl)	90 \pm 8	N/A	88 \pm 8	0.369
Systolic Blood Pressure (mm/Hg)	129 \pm 18	N/A	125 \pm 12	0.007
Mean Arterial Pressure (mm/Hg)	97 \pm 7	N/A	94 \pm 7	< 0.001
Diastolic Blood Pressure (mm/Hg)	81 \pm 7	N/A	79 \pm 6	0.005
Metabolic Z-score	1.127 \pm 3.696	N/A	-.236 \pm 3.216	0.001

A significant effect of time was found for WC ($F(1.628, 60.230) = 3.872, p < 0.034$). Follow-up post-hoc testing revealed no significant changes for WC from ($p = 0.180$) pre (111 \pm 18 cm) to mid (108 \pm 16 cm), and ($p = 1.000$) mid to post- (107 \pm 16 cm) testing. However, there was a significant decrease ($p = 0.005$) in WC from pre (111 \pm 18 cm) to post (107 \pm 16 cm) testing. Waist circumference changes are presented in Figure 3.

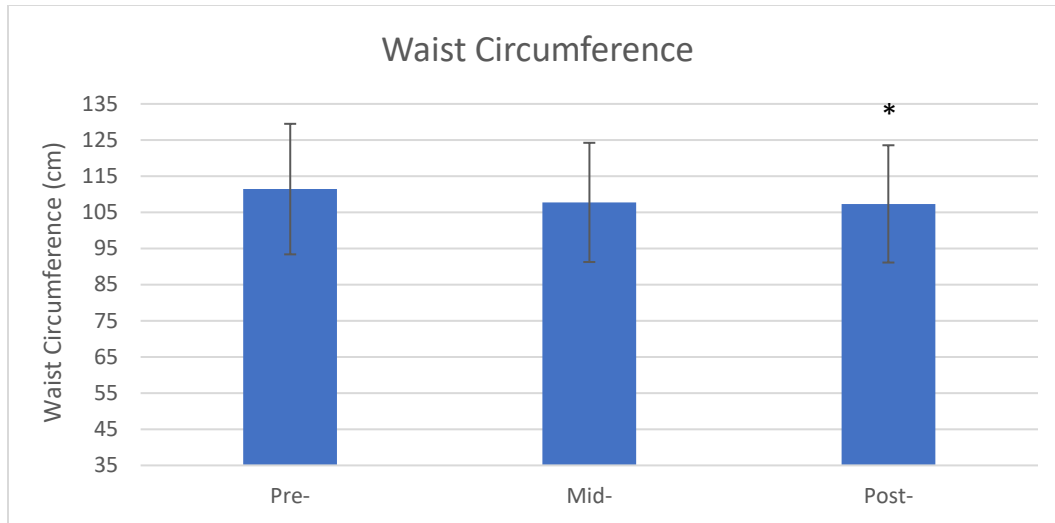


Figure 3. Waist Circumference Measurements. * Significantly different from pre- to post- ($p < 0.01$)

A paired-samples t-test was used to compare pre- and post- intervention means of TG, HDL, FPG, and BP.

Serum triglycerides showed a non-significant decrease ($t(37) = 2.214$, $p = 0.033$) from pre (155 ± 92 mg/dl) to post (118 ± 69 mg/dl) intervention. A Cohen's d_s showed a large (0.72) effect size. Triglyceride changes are presented in Figure 4.

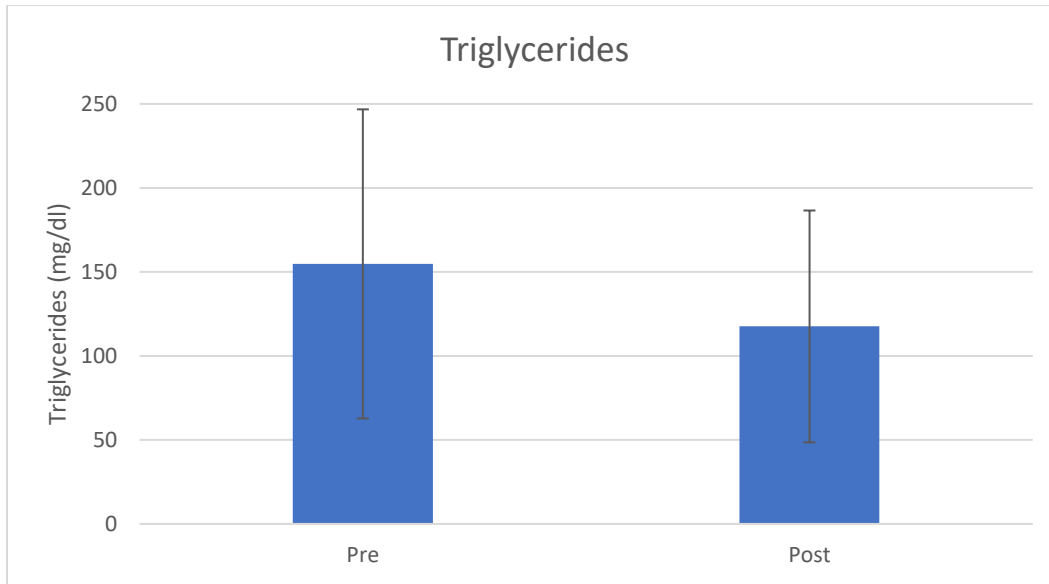


Figure 4. Serum Triglycerides Measurements.

There were no significant ($t(37) = .431, p > 0.05$) changes in HDL from pre (52 ± 17 mg/dl) to post (51 ± 15 mg/dl) intervention. Changes for HDL are presented in Figure 5.

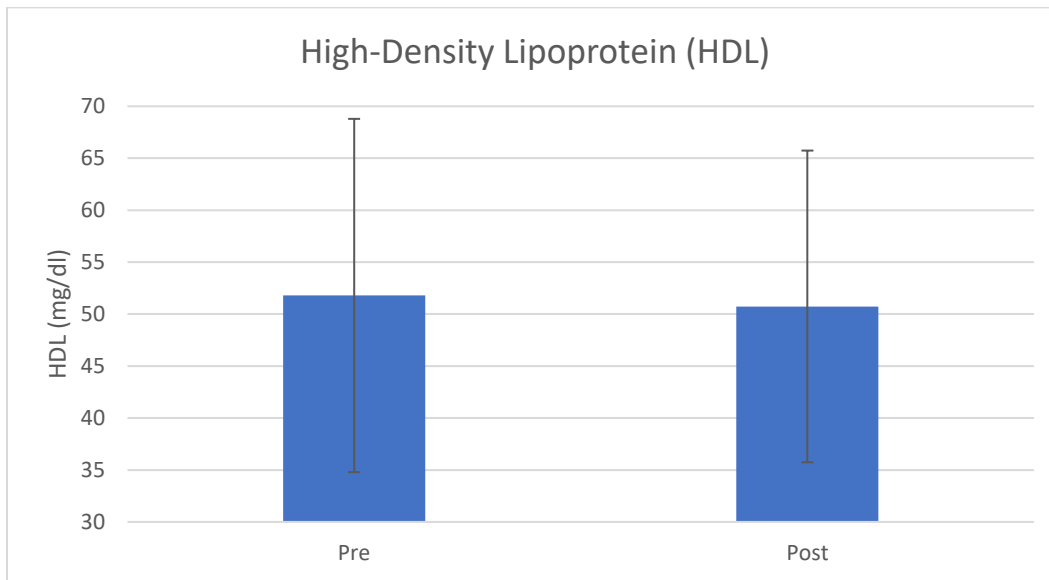


Figure 5. High-Density Lipoprotein Measurements.

FPG did not significantly ($t(37) = .909, p > 0.05$) change from pre (90 ± 8 mg/dl) to post (88 ± 8 mg/dl) intervention. Change in FPG are presented in Figure 6.

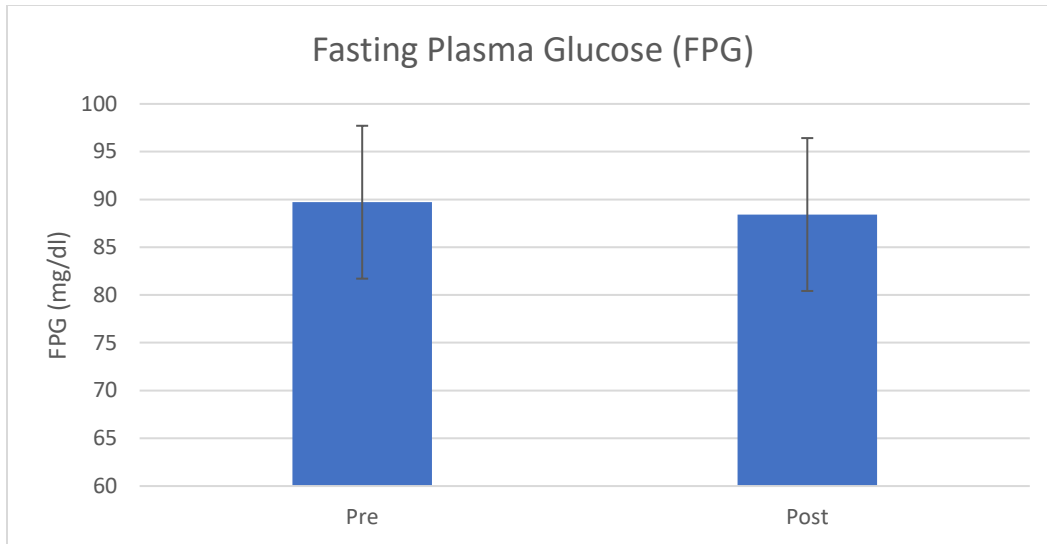
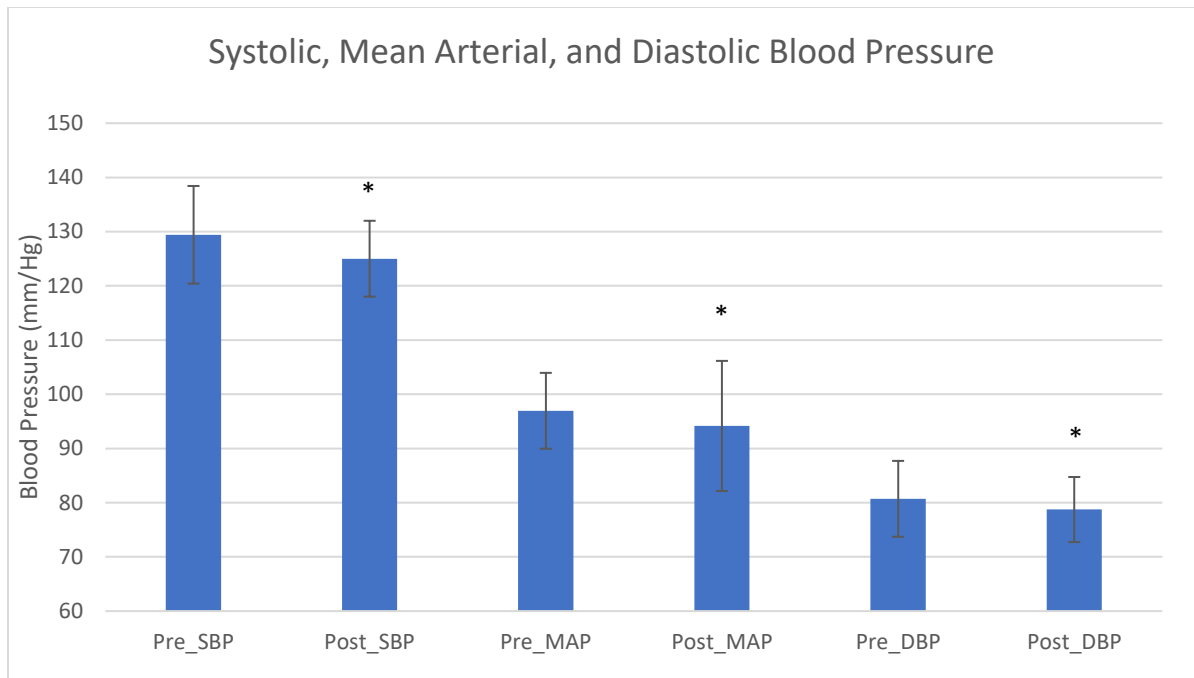


Figure 6. Fasting Plasma Glucose Measurements.

Blood pressure showed a significant ($p < 0.05$) decreases in systolic, diastolic, and mean arterial pressure. Systolic BP decreased significantly ($t(37) = 2.877, p = 0.007$) from pre (129 ± 18 mm/Hg) to post (125 ± 12 mm/Hg), MAP decreased significantly ($t(37) = 4.197, p < 0.001$) from pre (97 ± 7 mm/Hg) to post (94 ± 7 mm/Hg), and diastolic BP decreased significantly ($t(37) = 2.999, p = 0.005$) from pre (81 ± 7 mm/Hg) to post (79 ± 6 mm/Hg) intervention. Blood Pressure changes are presented in Figure 7.



*Figure 7. Blood Pressure Measurements. * Significantly different from pre- to post- (p<0.01)*

A paired-samples t-test compared pre and post intervention changes in calculated MetS z-score. Overall MetS z-score calculated for women significantly ($t(37) = 3.641, p = 0.001$) decreased from pre (1.127 ± 3.696) to post ($-.236 \pm 3.216$) intervention. A decrease represents a decrease in risk of all-cause mortality. This includes going below zero and continuing with a more negative z-score. Therefore, we can interpret that the change in participants MetS z-score from pre to post in this study have significantly lowered their risk for cardiovascular diseases, and premature death. The changes in overall metabolic syndrome z score are shown in Figure 8.

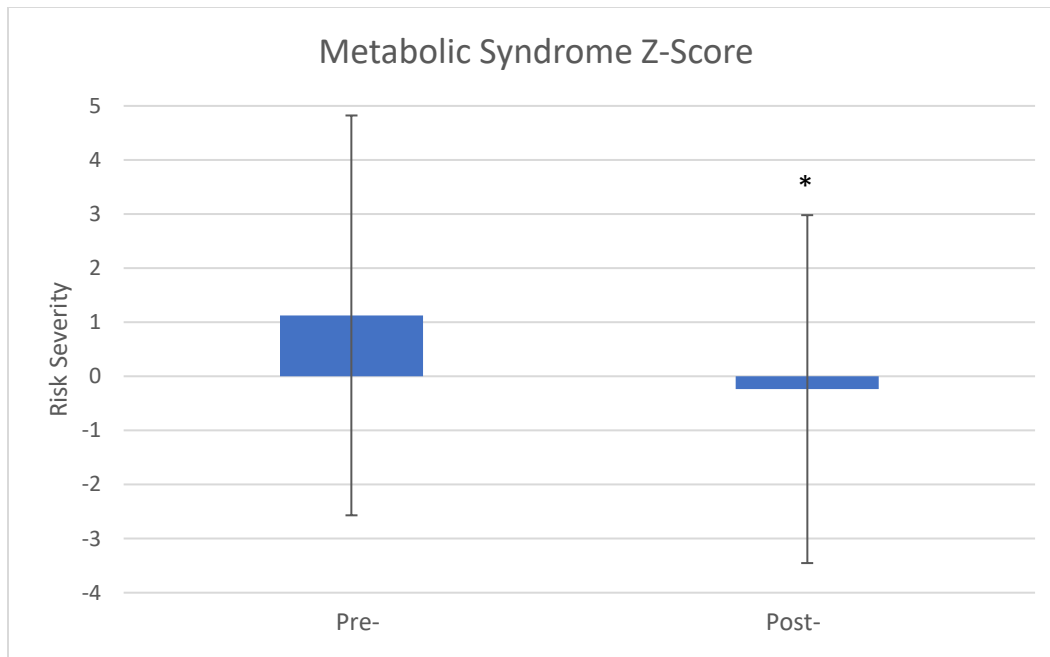


Figure 8. Metabolic Syndrome Z-Score. * Significantly different from pre- to post- ($p < 0.01$)

Body Composition

A paired-samples t-test was conducted to compare the means of pre and post intervention body weight, FM, and LBM.

Although no significant difference was found in pre to post body weight ($t(37) = -.256, p = 0.799$), both FM ($t(37) = 3.103, p = 0.004$) and LBM ($t(37) = -4.877, p < 0.001$) showed significant changes. FM decreased significantly from pre (41.6 ± 14.7 kg) to post (40.7 ± 15.1 kg), and LBM significantly increased from pre (46.4 ± 14.9) to post (47.6 ± 7.1 kg). Body composition measurements are reported in Figure 9. BMI changes by ethnicity are reported in Table 6.

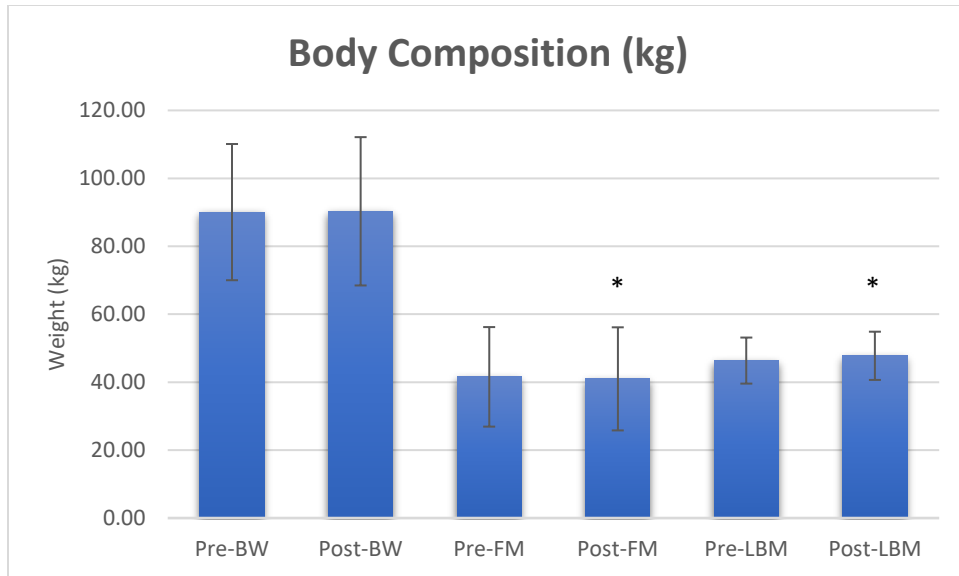


Figure 9. Body Composition Measured by iDXA. * Significantly different from pre- to post- ($p < 0.01$)

Table 6. Changes in BMI Status by Ethnicity (n=38)

Variables (n)	Total	Normal	Overweight	Obese	Extremely Obese
Pre-Caucasian	23	4	6	11	2
Post Caucasian	23	4	6	11	2
Pre-Black	14	1	2	4	7
Post-Black	14	1	2	4	7
Pre-Asian	1			1	
Post-Asian	1			1	

Aerobic Fitness

Five participants (randomly chosen) volunteered to do a second graded exercise test (GXT) at baseline to determine reliability for estimating VO_{2max} . Reliability testing between

GXTs for these five participants showed a strong correlation of .705, indicating the GXT to be a consistent measure for this sample. Mean estimated VO₂max for initial baseline testing (pre-1) was 25.9 ± 2.6 ml/kg/min and 26.4 ± 2.7 ml/kg/min for the second test completed at baseline (pre-2).

A total of 31 participants completed pre- and post- measures for aerobic fitness. Only participants that completed both measures were included in the analyses. A paired-samples t-test was conducted to compare the means of pre and post estimated VO₂max scores. A significant increase ($t(30) = -5.659, p < 0.001$) in VO₂max was observed from pre (23.7 ± 5.0 ml/kg/min) to post (28.1 ± 6.5 ml/kg/min) exercise intervention. In regard to VO₂max, according to the ACSM Guidelines for Exercise Testing and Prescription, the participants on average remained in the “fair” category at post-testing. Reliability and VO₂max testing measures are presented in Figure 10.

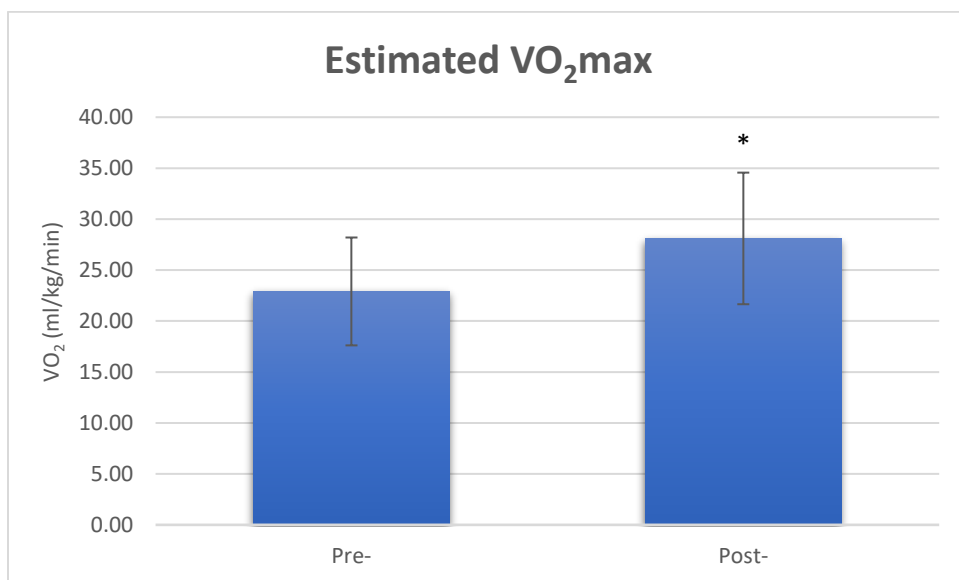
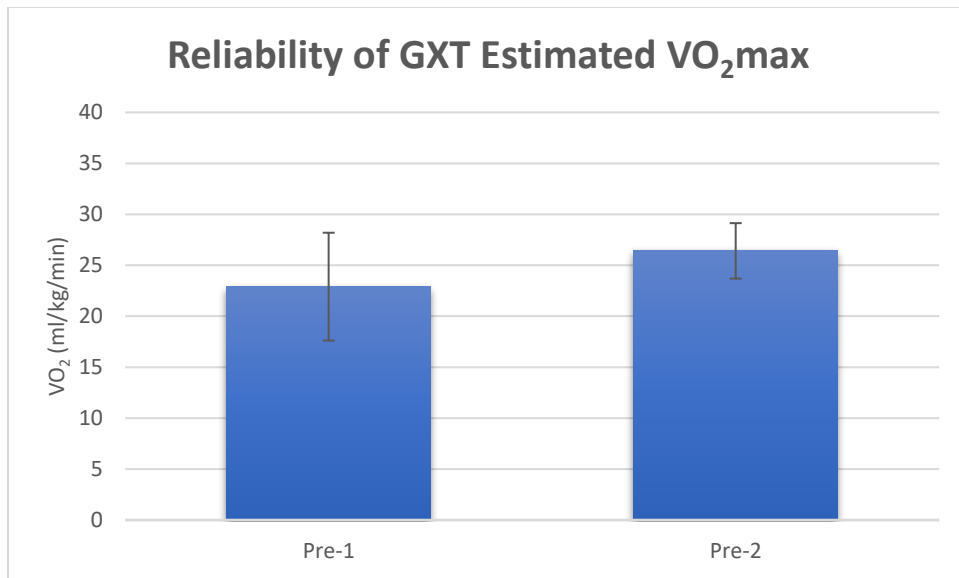


Figure 10. Reliability and VO₂max Measured by GXT. * Significantly different from pre- to post- ($p < 0.01$)

Muscular Strength

A total of 28 participants completed pre, mid, and post measures for muscular strength. Only participants that completed all three measures were included in the analyses. A repeated-measures ANOVA was used to evaluate changes in muscular strength.

A significant effect of time in muscular strength was found for both the back squat ($F(2,54) = 122.401, p < 0.001$) and the bench press ($F(2,54) = 102.972, p < 0.001$). Back squat showed significant ($p < 0.001$) increases from pre (27 ± 10 kg) to mid (47 ± 12 kg), pre to post (60 ± 13 kg), and mid to post exercise intervention. Bench press showed significant ($p < 0.001$) increases from pre (22 ± 8 kg) to mid (36 ± 8 kg), pre to post (42 ± 8 kg), and mid to post exercise intervention. Muscular strength measures are presented in Figure 11.

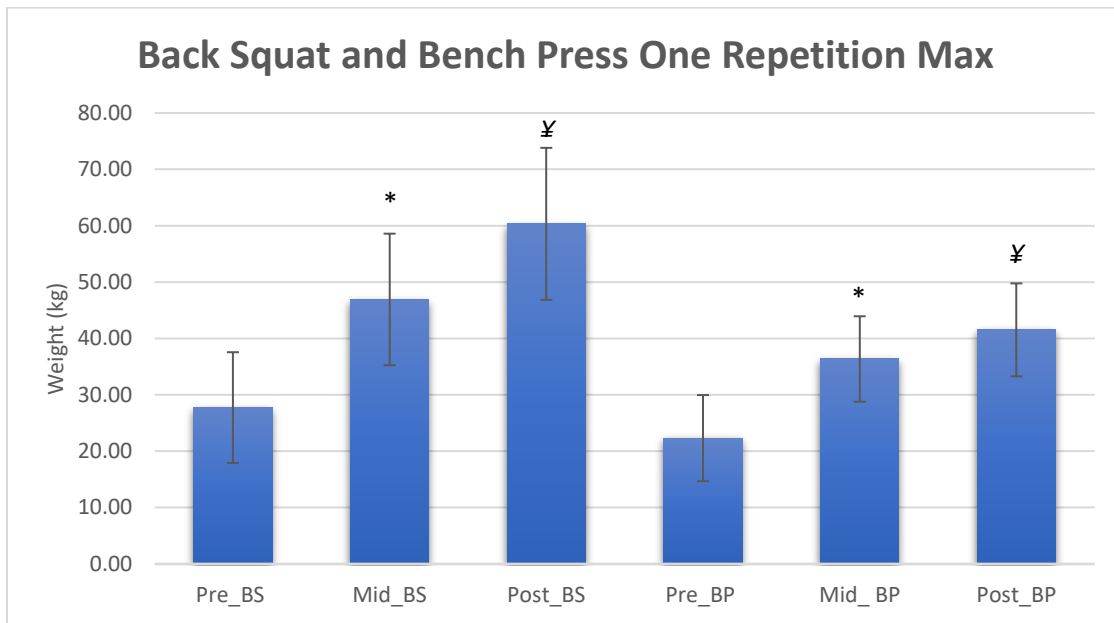


Figure 11. Back Squat and Bench Press Strength. Symbols denote significantly different:

* pre- to mid-; ¥ pre- to post- and mid- to post-, ($p < 0.01$)

Accelerometer

Paired-samples t-tests were used to compare percentage of daily time spent in sedentary, light, moderate, and vigorous physical activity at pre and post. A minimum of 10 hours per day of wear time was needed for sampling wake-time behavior with 3-5 days of monitoring required to achieve 80% reliability for total and moderate-to-vigorous intensity physical activity (Hart, Swartz, Cashin, & Strath, 2011; Matthews et al., 2008; Trost, McIver, & Pate, 2005). Of the 38

participants that completed the intervention, 26 of the participants at both pre and post met the wear time criteria set in the methods to be analyzed.

Sedentary activity ($t(25) = 0.333, p = 0.742$) did not significantly change from pre ($68.5 \pm 8.6\%$) to post ($67.7 \pm 9.1\%$) intervention. Light activity ($t(25) = -0.398, p = 0.694$) did not significantly change from pre ($29.7 \pm 8.1\%$) to post ($30.1 \pm 8.5\%$) intervention. Moderate activity ($t(25) = 0.390, p = 0.700$) did not significantly change from pre ($2.3 \pm 1.1\%$) to post ($2.1 \pm 1.1\%$) intervention. Vigorous activity ($t(25) = -1.274, p = 0.215$) did not significantly change from pre ($0.12 \pm 0.02\%$) to post ($0.05 \pm 0.03\%$) intervention. This data suggests that participant activity patterns outside of the intervention did not change over the course of the study. Physical activity measures are presented in Figure 12.

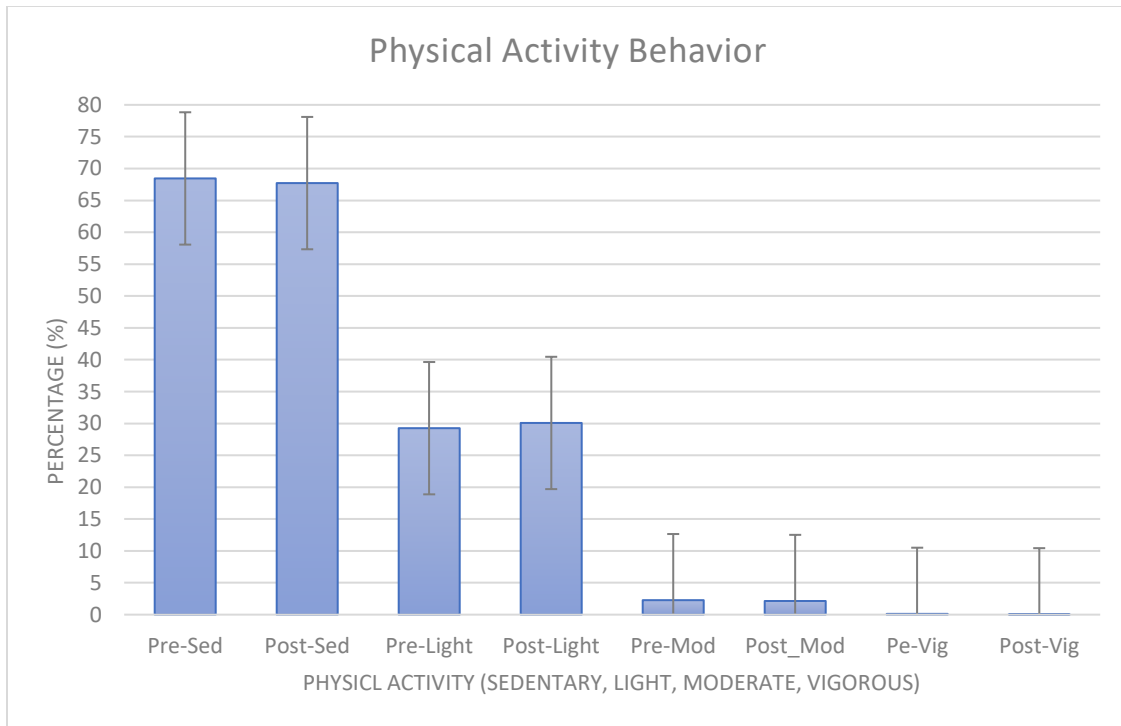


Figure 12. Physical Activity Behavior Measured by Accelerometer

3-day dietary recall

To determine that the effects of the study were not due to dietary changes, participants were asked to complete a three-day diet recall (two weekdays and one weekend day) during baseline and post testing. Of the 38 participants, only 33 returned pre and post completed dietary logs. A paired t-test showed that there were no changes in overall caloric intake from pre (1938 ± 483) to post (1932 ± 479 ; $t(32) = .159, p = 0.875$).

Dose Response Relationship

A logistic regression determined the relationship between number of exercise sessions participants attended out of the 30 sessions and changes in overall MetS z-score. Participants who decreased their MetS z-score and participants who maintained or increased their MetS z-score served as the dependent variable and number of exercise sessions served as the independent variable. The omnibus test of model coefficients showed a significant ($p = 0.006$) model. The Hosmer and Lemeshow test had a significance of $p = 0.610$, indicating that the model fits the data and supports further interpretation. This model was observed to be accurate 68.4% of the time. The logistic regression concluded that a minimum of 24 sessions was needed to see decreases in MetS z-score. The odds of showing a decrease in MetS z-score at post intervention increased by .788 for every additional training session. A flow chart of the number of sessions attended by participants is displayed in Figure 13.

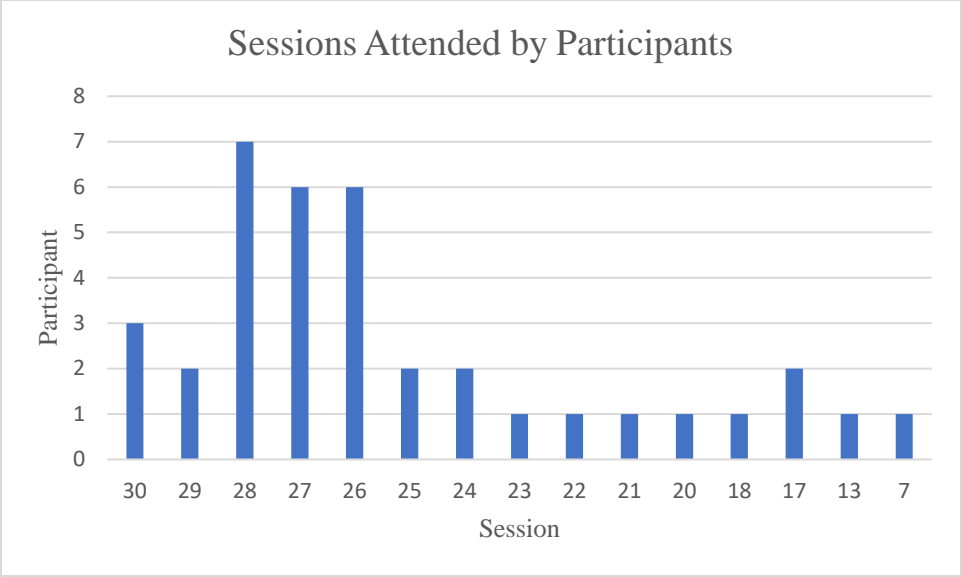


Figure 13. Number of Sessions Attended by Participants

V. DISCUSSION

The purpose of this study was to examine the effect of a 10-week SIT and RT exercise intervention on metabolic syndrome (MetS) risk factors in sedentary women. Huffman et al. (2019) examined the effects of SIT + RT on sedentary women over 40, however criteria for MetS were not examined. To the best of this authors knowledge no studies have specifically examined a SIT and RT combined exercise intervention for sedentary women aimed at reducing MetS risk factors. In addition, there is limited research on exercise interventions in the 10-week range for this population.

It is important to point out that this study looked beyond clinical MetS, which requires at least three of the five mentioned criteria (Aguilar et al., 2015; Grundy et al., 2005; Table 1; Table 2). Our approach was to target individuals with at least one criteria for MetS to offer a preventive behavioral lifestyle approach to targeting those at risk for developing MetS. Aguilar et al. (2015) concluded that women ≥ 30 years old have a significantly higher prevalence (Women 35.6% vs Men 30.3%, $p < .001$) of MetS compared to men. Therefore, the age for the study was lowered to women ≥ 25 years old, with at least one MetS risk factor. As physical activity is the most effective way of managing risk factors associated with MetS (Alberti et al., 2009), an exercise intervention was utilized in this population for the purpose of examining applied homeopathic preventative measures. Previous literature suggests that utilizing an exercise intervention consisting of both interval and RT would optimize health benefits and decrease risk factors associated with MetS (Bateman et al., 2011; Stensvold et al., 2010; Tjonna et al., 2008). This data adds to the limited literature on suggested exercise modalities for sedentary women with MetS. In addition, the wide age range (25-55) of participants involved shows that this exercise intervention produces similar MetS benefits across multiple generations of women.

According to the International Diabetes Federation, of the five MetS risk factors, WC is considered the central risk factor for determining MetS. The present study observed a significant decrease in WC which has also been noted in previous studies examining combined exercise intervention in participants with MetS risk factors (Bateman et al., 2011; Mello et al., 2011; Stensvold et al., 2010; Wewege et al., 2018). This suggests that the mode of exercise chosen in the present study is effective in reducing WC, which is a central risk factor in MetS. It is important to note that although the current study went with the updated WC guidelines (Alberti et al., 2009; Table 2), that none of the participants ethnicities went outside of the United States which includes the previous criteria of 88 cm (Grundy et al., 2005). Therefore, this study could not add to the literature of international and Asian ethnic individuals with MetS risk factors.

According to the new ACSM guidelines the threshold criteria for hypertension has recently changed from 140/90 mm/Hg to 130/80 mm/Hg. This increases those qualifying for hypertension in the US from 32% to 46% according to ACSM (Piercy et al., 2018). As MetS criteria has not yet changed to the new hypertension guidelines, the current study used the threshold of 130/85 mm/Hg (Alberti et al. 2009), which is the MetS criteria. Observed BP decreased significantly for the current study in systolic (~4 mm/Hg), diastolic (~2 mm/Hg), and mean arterial pressure (~2 mm/Hg). This type of exercise modality seems promising as previous literature has cited 5-10 mm/Hg decreases in systolic and diastolic BP to lower risk of heart disease (Piercy et al., 2018). It is suggested that future research using combined exercise interventions should evaluate both the current MetS and ACSM hypertension thresholds to observe differences in MetS outcomes (Alberti et al. 2009; Piercy et al., 2018).

As there are a limited number of studies on combined exercise interventions on MetS risk factors, it is difficult to make comparisons (Bateman et al., 2011; Mello et al., 2011; Stensvold et

al., 2010; Wewege et al., 2018). Literature does point to conflicted outcomes for MetS variables. Bateman et al. (2011) found significant decreases in TG, and non-significant changes in HDL and FPG. This closely parallels the current studies results as a trend in decreasing TG was observed, along with no significant changes in HDL and FPG. Stensvold et al. (2010) found no significant changes in TG, HDL, and FPG. O'Neill and O'Driscoll (2015) have discussed the important contribution that TG, HDL, and FPG, play on obesity. These results are comparable to previous studies utilizing MICT and HIIT training for eight weeks to four months (Bateman et al., 2011; Mello et al., 2011; Stensvold et al., 2010). It could be possible that a longer intervention with a higher dose of SIT might prove advantageous for these variables. It is important to note that overall TG (pre 155 ± 92 mg/dl to post 118 ± 69 mg/dl) decreased below the risk factor threshold into an acceptable range. In addition, for the current study overall means for HDL (pre 52 ± 17 mg/dl to post 51 ± 15 mg/dl) and FPG (pre 90 ± 8 mg/dl to post 88 ± 8 mg/dl) began and ended in an acceptable range for MetS risk factors. This may have been a contributing factor to why these variables did not significantly change. While these studies did not find any significant negative changes to these variables, future research into increasing positive changes is a point of interest (Bateman et al., 2011; Mello et al., 2011; Stensvold et al., 2010; Wewege et al., 2018).

The current study found significant decreases in MetS z score. This is an important observed change because as the overall MetS z score decreases, so does the risk of comorbidities and premature death. To clarify, even as the MetS z score becomes negative, the further below zero the score goes, the lower your risk becomes (Wewege et al., 2018). Bateman et al. (2011) compared RT, AT, and AT+RT combined training for four months on MetS risk factors and z score. Of the three different types of exercise intervention, only AT+RT showed a significant

($p=.004$) decrease in MetS z score. It is important to point out that while there were significant decreases, the MetS z-score for Bateman et al. (2011) AT+RT stayed in a healthier range the entire study (baseline -1.07 ± 3.06 ; Change -1.10 ± 1.70). This is curious as the current 10-week study began in an unhealthy range at pre- (1.127 ± 3.696) and decreased to a healthier range at post ($-.236 \pm 3.216$). Although starting at different MetS health points, the change for the current study was similar to Bateman et al. (2011). In addition, Bateman et al. (2011) found that RT only and AT only interventions increased or maintained MetS z score. The current study supports AT+RT as the optimal mode of exercise to lower overall MetS z score and decrease health risks associated with MetS. In addition to AT+RT as optimal in general, these results show that the current study's intervention is able to replicate MetS z-score changes in approximately half the time that previous study have reported.

In the current study there was not a significant change in body weight. While total weight was maintained, there was a change in body composition. Both fat mass (FM) and lean body mass (LBM) changed significantly with FM decreasing (~ 1.99 kg) and LBM increasing (~ 2.62 kg). Stensvold et al. (2010) reported significant increases in LBM (1.4 kg) but no significant differences in FM (0.8 kg). In comparing the two studies, the current study observed double the FM decreases and LBM increases than Stensvold et al. (2010). This is curious as Stensvold et al. (2010) did combine exercise for 3 times/week for 12 weeks, which was two weeks longer than the current study. However, the training program was different with HIIT AT done two days/week and RT done once/week (Stensvold et al., 2010). The current study utilized a specific exercise modality of combined SIT and RT for all three sessions. The increase in repetitive cardiovascular and RT may have contributed to the increase in fat loss that resulted in significant decreases in FM. This is an important observation as finding an optimal modality of exercise is

important towards improving body composition. Changes in FM and LBM may have contributed to changes in WC in this study.

Previous literature on combined exercise interventions reports an increase in cardiovascular fitness measures (Stensvold et al., 2010). In addition, there are limited combined (SIT+RT) exercise interventions to compare data for this population which makes this study novel. The closest protocol to the current study is from Stensvold et al. (2010). Stensvold et al. (2010) reported ~10-11% increases in VO_{2peak} from pre to post exercise intervention after 12 weeks of training. In the current study, cardiovascular fitness increased ~15-16% from pre- (23.7 ± 5.0 ml/kg/min) to post (28.1 ± 6.5 ml/kg/min) intervention after only 10 weeks. When looking closer at the protocol differences, the current study showed greater increases in cardiovascular fitness in two weeks less training, and shorter bouts of cardiovascular training. While Stensvold et al. (2010) utilized HIIT (~43 minutes per session), the current study utilized SIT (~15 minutes per session). In addition, another difference in protocol is the set-up of training. While the participants from Stensvold et al. (2010) performed AT two times/week and RT once/week, the current study combined SIT and RT for all three exercise sessions each week. These results show the possibility of the current study's mode of exercise capable of obtaining significant increases in cardiovascular health with less time commitment.

Muscular strength does play a role in MetS (Volaklis et al., 2015). Of the 23 studies reviewed by Volaklis et al. (2015), only four utilized maximal leg strength and maximal bench press as their measure of strength (Artero et al., 2011; Fitzgerald et al., 2004; Ruiz et al., 2008; Ruiz et al., 2009). Volaklis et al. (2015) concluded that in addition to combating sarcopenia, that increased muscular strength provides a combination of factors (i.e. improved BP and body fat, decreased risk of fall, prevention of bone loss) that positively affect mortality. The current study

showed significant increases in both upper and lower body maximal strength. For upper body maximal strength, the bench press increased by ~ 38-39% from week one to week five. At the conclusion of the study (week 10) the bench press had increased an additional 12-13%. For lower body maximal strength, the back-squat increased by ~40-41% from week one to week five. By week 10 the back squat had increased an additional 22-23%. These results provide supporting evidence that SIT+ RT is effective in increasing muscular strength in as little as five weeks, with added increases in strength seen through 10 weeks of training. Muscular strength training is important for decreasing the risk of injury due to weak muscles, increasing/maintaining optimal levels of bone mineral density, and maintaining a healthy body composition.

Physical activity outside of the intervention did not change from pre to post testing. It is important to note that we asked participants to not change activity outside of the study throughout the intervention. This lack of change demonstrates that our protocol may be the only change in physical activity. Without continued monitoring, we are unable to determine adherence to the study. This is an area of future study we are following up with. Linke et al. (2011) noted physical activity as being a modifiable lifestyle choice for prevention of disease and premature death. Of the 14 studies examined, Linke et al. (2011) concluded that there is a large gap in the literature on research examining adherence to exercise in previously sedentary individuals. Of the research that has been conducted, an unfortunate low to moderate adherence rate (mean ~66%) has been reported. One study suggests that ~50% of participants are shown to dropout within six months of discontinuing an exercise study (Linke et al., 2011). Of the 40 participants that began the exercise intervention, 32 participants continuously attended sessions for the whole 10 weeks of intervention. This translates to a dropout rate for the current study of ~20%.

Continuing to engage in physical activity post intervention is important to maintain the physiological changes obtained in the present study.

Although diet is listed as a lifestyle factor that can be modified to improve an individual's health, the researchers from the present study wanted to focus on the effects of the specific type of exercise intervention used (SIT + RT) on MetS risk factors and human performance variables. To control for diet participants were asked to complete a three-day diet recall (two weekdays and one weekend day) during pre and post testing. Based on the non-significant changes in overall caloric intake from pre (1938 ± 483 kcals) to post (1932 ± 479 kcals), we posit that changes in dietary intake did not play a role in the changes of MetS risk factors, MetS z-score, body composition, VO_2 max, and muscular strength. However, it is notable that dietary intakes were assessed using recalls and this presents a limitation to these findings given that substantial reporting error has been previously reported (Grandjean, 2012).

Previous literature has suggested that long-term (>12 weeks) exercise benefits individuals with MetS risk factors (Wewege et al., 2018). There is a gap in the literature examining a dose response relationship in short-term (<12 weeks) exercise interventions on MetS risk factors. Results from the current study concluded that a minimum of 24 sessions over 10 weeks was needed to observe significant changes in MetS z score. At three days/week, the current study provides support towards significant improvements in MetS risk factors when exercising at three days/week for a minimum of eight weeks. Specifically, in a 10-week intervention, significant improvements can be seen in WC, BP and MetS z score. In addition, there were moderate improvements in TG, and overall HDL (>50 mg/dL) and FPG (<100 mg/dL) remained in a healthy range with regards to MetS. The current study provides novel data that counters the

implications that a minimum of 12 weeks of continuous exercise (at 3-4 days per week) is necessary to observe beneficial changes in MetS risk factors (Wewege et al., 2018).

In addition to the dose-response at 24 sessions, these results clarified limitations from previous research on examining physiological changes in individuals with MetS participating in a combined exercise intervention (Bateman et al., 2011; Cauza et al., 2005; Dalzill et al., 2014; Stensvold et al., 2010; Tjonna et al., 2008). Specifically, Bateman et al. (2011) discussed the robust improvements made in their combined exercise intervention. However, the AT utilized in the Bateman et al. (2011) utilized moderate intensity continuous training and stated that a limitation to their study was the unanswered question as to whether or not the significant benefits for the combined AT/RT group were due to the longer exercise duration (128 ± 27 AT and 56 ± 11 RT min/week; ~ 185 min/week). Participants from the current study exercised for 12-15 AT minutes and 30 RT minutes per session (~ 126 -135 total min/week) and showed similar significant improvements in MetS risk factors and MetS z score. This may indicate that the combined AT/RT modality and not specifically exercise time were responsible for the significant changes in MetS risk factors and MetS z score. Overall, the observed changes challenge current literature on the suggested timeframe and optimal modality of exercise to benefit from improvements in MetS risk factors (Bateman et al., 2011; Cauza et al., 2005; Dalzill et al., 2014; Stensvold et al., 2010; Tjonna et al., 2008; Wewege et al., 2018).

The practical application of this exercise program for a clinician could include an exercise prescription in lieu of medication and costly invasive procedures. Currently, the American College of Sports Medicine has taken the stance that exercise is medicine (Gibson et al., 2018). The current study provides data that supports the use of an exercise program to lower risk factors associated with MetS. Risk factors, that if left untreated, can lead to increased risk of

premature death and developing comorbidities including cardiovascular disease, Type II Diabetes, and obesity (Alberti et al., 2009; O'Neill and O'Driscoll, 2015).

In conclusion, this study showed that participating in a combined SIT and RT exercise program can show improvements in metabolic health in as little as 10-weeks, for sedentary women. Our findings suggest that SIT and RT is a time-efficient alternative to utilize with comparable benefits to other forms of combined training. Finally, this study has shown the practical application that a wide age range of sedentary women can successfully engage in this type of exercise program and see improvements in metabolic health.

VI. REFERENCES

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APPENDICES

APPENDIX A: IRB PROTOCOL

**AUBURN UNIVERSITY INSTITUTIONAL REVIEW BOARD for RESEARCH INVOLVING HUMAN SUBJECTS
RESEARCH PROTOCOL REVIEW FORM
FULL BOARD or EXPEDITED**

For information or help contact **THE OFFICE OF RESEARCH COMPLIANCE (ORC)**, 115 Ramsay Hall, Auburn University
Phone: 334-844-5966 e-mail: IRBAdmin@auburn.edu Web Address: <http://www.auburn.edu/research/vpr/ohs/index.htm>

Revised 2.1.2014 Submit completed form to IRBsubmit@auburn.edu or 115 Ramsay Hall, Auburn University 36849.

Form must be populated using Adobe Acrobat / Pro 9 or greater standalone program (do not fill out in browser). Hand written forms will not be accepted.

1. PROPOSED START DATE of STUDY: 08/20/2018

PROPOSED REVIEW CATEGORY (Check one): FULL BOARD EXPEDITED

SUBMISSION STATUS (Check one): NEW REVISIONS (to address IRB Review Comments)

2. PROJECT TITLE: Effect of interval and resistance exercise on physiological and psychological parameters

3. Danielle Wadsworth Assoc KINE wadswdd
PRINCIPAL INVESTIGATOR TITLE DEPT AU E-MAIL
301 Wire Road 844-1836
MAILING ADDRESS PHONE ALTERNATE E-MAIL

4. FUNDING SUPPORT: N/A Internal External Agency: _____ Pending Received

For federal funding, list agency and grant number (if available). _____

5a. List any contractors, sub-contractors, other entities associated with this project:

None

b. List any other IRBs associated with this project (including Reviewed, Deferred, Determination, etc.):

None

PROTOCOL PACKET CHECKLIST

All protocols must include the following items:

- Research Protocol Review Form (All signatures included and all sections completed)
(Examples of appended documents are found on the OHSR website: <http://www.auburn.edu/research/vpr/ohs/sample.htm>)
- CITI Training Certificates for all Key Personnel.
- Consent Form or Information Letter and any Releases (audio, video or photo) that the participant will sign.
- Appendix A, "Reference List"
- Appendix B if e-mails, flyers, advertisements, generalized announcements or scripts, etc., are used to recruit participants.
- Appendix C if data collection sheets, surveys, tests, other recording instruments, interview scripts, etc. will be used for data collection. Be sure to attach them in the order in which they are listed in # 13c.
- Appendix D if you will be using a debriefing form or include emergency plans/procedures and medical referral lists
 (A referral list may be attached to the consent document).
- Appendix E if research is being conducted at sites other than Auburn University or in cooperation with other entities. A permission letter from the site / program director must be included indicating their cooperation or involvement in the project.
NOTE: If the proposed research is a multi-site project, involving investigators or participants at other academic institutions, hospitals or private research organizations, a letter of IRB approval from each entity is required prior to initiating the project.
- Appendix F - Written evidence of acceptance by the host country if research is conducted outside the United States.

FOR ORC OFFICE USE ONLY

DATE RECEIVED IN ORC: _____ by _____ PROTOCOL # _____
DATE OF IRB REVIEW: _____ by _____ APPROVAL CATEGORY: _____
DATE OF IRB APPROVAL: _____ by _____ INTERVAL FOR CONTINUING REVIEW: _____
COMMENTS: _____

The Auburn University Institutional Review Board has approved this Document for use from 09/24/18 to 08/14/2019
Protocol # 18-323 AR 1809

6. GENERAL RESEARCH PROJECT CHARACTERISTICS

6 A. Research Methodology

Please check all descriptors that best apply to the research methodology.

Data Source(s): New Data Existing Data

Will recorded data directly or indirectly identify participants?
 Yes No

Data collection will involve the use of:

- | | |
|--|---|
| <input checked="" type="checkbox"/> Educational Tests (cognitive diagnostic, aptitude, etc.) | <input checked="" type="checkbox"/> Internet / Electronic |
| <input checked="" type="checkbox"/> Interview | <input checked="" type="checkbox"/> Audio |
| <input type="checkbox"/> Observation | <input type="checkbox"/> Video |
| <input type="checkbox"/> Location or Tracking Measures | <input type="checkbox"/> Photos |
| <input checked="" type="checkbox"/> Physical / Physiological Measures or Specimens (see Section 6E.) | <input type="checkbox"/> Digital images |
| <input checked="" type="checkbox"/> Surveys / Questionnaires | <input type="checkbox"/> Private records or files |
| Other: _____ | |

6 B. Participant Information

Please check all descriptors that apply to the target population.

Males Females AU students

Vulnerable Populations

Pregnant Women/Fetuses Prisoners Institutionalized
 Children and/or Adolescents (under age 19 in AL)

Persons with:

Economic Disadvantages Physical Disabilities
 Educational Disadvantages Intellectual Disabilities

Do you plan to compensate your participants? Yes No

6 C. Risks to Participants

Please identify all risks that participants might encounter in this research.

Breach of Confidentiality* Coercion
 Deception Physical
 Psychological Social
 None
 Other: _____

*Note that if the investigator is using or accessing confidential or identifiable data, breach of confidentiality is always a risk.

6 D. Corresponding Approval/Oversight

• Do you need IBC Approval for this study?
 Yes No

If yes, BUA # _____ Expiration date _____

• Do you need IACUC Approval for this study?
 Yes No

If yes, PRN # _____ Expiration date _____

• Does this study involve the Auburn University MRI Center?
 Yes No

Which MRI(s) will be used for this project? (Check all that apply)
 3T 7T

Does any portion of this project require review by the MRI Safety Advisory Council?
 Yes No

Signature of MRI Center Representative: _____
 Required for all projects involving the AU MRI Center

Appropriate MRI Center Representatives:
 Dr. Thomas S. Denney, Director AU MRI Center
 Dr. Ron Beyers, MR Safety Officer

7. PROJECT ASSURANCES Effect of interval and resistance exercise on physiological and psychological parameters

A. PRINCIPAL INVESTIGATOR'S ASSURANCES

1. I certify that all information provided in this application is complete and correct.
2. I understand that, as Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the Auburn University IRB.
3. I certify that all individuals involved with the conduct of this project are qualified to carry out their specified roles and responsibilities and are in compliance with Auburn University policies regarding the collection and analysis of the research data.
4. I agree to comply with all Auburn policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects, including, but not limited to the following:
 - a. Conducting the project by qualified personnel according to the approved protocol
 - b. Implementing no changes in the approved protocol or consent form without prior approval from the Office of Research Compliance
 - c. Obtaining the legally effective informed consent from each participant or their legally responsible representative prior to their participation in this project using only the currently approved, stamped consent form
 - d. Promptly reporting significant adverse events and/or effects to the Office of Research Compliance in writing within 5 working days of the occurrence.
5. If I will be unavailable to direct this research personally, I will arrange for a co-investigator to assume direct responsibility in my absence. This person has been named as co-investigator in this application, or I will advise ORC, by letter, in advance of such arrangements.
6. I agree to conduct this study only during the period approved by the Auburn University IRB.
7. I will prepare and submit a renewal request and supply all supporting documents to the Office of Research Compliance before the approval period has expired if it is necessary to continue the research project beyond the time period approved by the Auburn University IRB.
8. I will prepare and submit a final report upon completion of this research project.

My signature indicates that I have read, understand and agree to conduct this research project in accordance with the assurances listed above.

Danielle Wadsworth
Printed name of Principal Investigator

Danielle Wadsworth
Principal Investigator's Signature

08/03/2018
Date

B. FACULTY ADVISOR / SPONSOR'S ASSURANCES

1. I have read the protocol submitted for this project for content, clarity, and methodology.
2. By my signature as faculty advisor/sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.
3. I agree to meet with the investigator on a regular basis to monitor study progress. Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
4. I assure that the investigator will promptly report significant incidents and/or adverse events and/or effects to the ORC in writing within 5 working days of the occurrence.
5. If I will be unavailable, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the ORC by letter of such arrangements. If the investigator is unable to fulfill requirements for submission of renewals, modifications or the final report, I will assume that responsibility.

Printed name of Faculty Advisor / Sponsor

Faculty Advisor's Signature

Date

C. DEPARTMENT HEAD'S ASSURANCE

By my signature as department head, I certify that I will cooperate with the administration in the application and enforcement of all Auburn University policies and procedures, as well as all applicable federal, state, and local laws regarding the protection and ethical treatment of human participants by researchers in my department.

Mary Rudisill
Printed name of Department Head

Mary Rudisill
Department Head's Signature

08/03/2018
Date

8. PROJECT OVERVIEW: Prepare an abstract that includes:

(350 word maximum, in language understandable to someone who is not familiar with your area of study):

a) A summary of relevant research findings leading to this research proposal:

(Cite sources; include a "Reference List" as Appendix A.)

b) A brief description of the methodology, including design, population, and variables of interest

A) Metabolic Syndrome (MetS) is defined as a cluster of risk factors that include elevated waist circumference, blood pressure, blood glucose, high triglycerides, and low high-density lipoproteins (HDL) (Eckel et al., 2005). The combination of these risk factors put an individual at a higher risk of developing cardiovascular disease (CVD), Type II Diabetes, obesity, and premature death (Alberti et al., 2009). It was estimated in 2009 that 20-25% of the world's population has developed MetS (Alberti et al., 2009). Although sedentary behavior is not included in the criteria for MetS, sedentary behavior has been directly linked with an increased risk of weight gain, obesity, Type II Diabetes, hypertension, dyslipidemia, and MetS (Alberti et al., 2009; Grundy et al., 2005). According to multiple authorities (ACSM, AHA, CDC etc.) engaging in physical activity is an effective method to reduce and/or manage risk factors associated with MetS (Alberti et al., 2009). For example, a high intensity interval training (HIIT) training study was conducted to measure changes in blood pressure on 20 overweight/obese women. The findings after six HIIT sessions showed decreases in BP (>3mmHg decrease) pre to post, and a return to baseline BP levels within 2 weeks of detraining (Bonsu and Terblanche, 2016). The American Diabetes Association formed the Diabetes Prevention Program Research Group (DPPRG) has conducted research on the effects of physical activity and exercise on Type II diabetes. According to the DPPRG, physical activity interventions reduced the incidence of Type II Diabetes by 48 to 66% (Diabetes Prevention Program Research Group, 2002). Data from a 2013 study utilizing accelerometers to observe the relationship between physical activity and MetS concluded that there was a strong association with the amount of weekly moderate to vigorous physical activity and the prevalence of MetS with only 23.9% of the participants adhering to the physical activity guidelines. Those who met the physical activity guidelines had significant health improvements and decreased risk factors for MetS including a decrease in waist circumference, triglyceride levels, and an increase in HDL (Glazer et al. 2013). However, which type of exercise is most effective to reduce the risk for MetS is not conclusive. In addition, exercise programs which combine HIIT training and resistance training are deficient in the literature.

B) Therefore the purpose of this project is to determine how concurrent training including HIIT and resistance training effects risk factors associated with MetS. We will also examine changes in body composition, blood vessel function, HbA1c, sedentary behavior, physical activity, adherence to exercise, self-regulation and perceived stress. Following baseline assessments participants will engage in 30 sessions of supervised exercise training (3 sessions per week for 10 weeks). Participants will be reassessed at week 13 and week 26. During weeks 13-26 participants will participate in self-regulation and motivational interviewing via phone and text to support exercise adherence.

9. PURPOSE.

a. Clearly state the purpose of this project and all research questions, or aims.

1. What is the effect of HIIT and resistance training on markers of MetS (waist circumference, blood pressure, blood glucose, high triglycerides, and low high-density lipoproteins) at week 13 and week 26.
2. What is the effect of HIIT and resistance training on body composition, blood vessel function, HbA1c, sedentary behavior, physical activity, adherence to exercise, self-regulation and perceived stress at week 13 and week 26.
3. What are participants experiences with HIIT and resistance training?

b. How will the results of this project be used? (e.g., Presentation? Publication? Thesis? Dissertation?)

Dissertation, Presentation and Publication

10. **KEY PERSONNEL.** Describe responsibilities. Include information on research training or certifications related to this project. **CITI is required.** Be as specific as possible. (Include additional personnel in an attachment.) *All key personnel must attach CITI certificates of completion.*

Principle Investigator Danielle Wadsworth Title: Assoc E-mail address wadswdd
Dept / Affiliation: KINE

Roles / Responsibilities:

Oversee the research project in its entirety including: consenting process, data collection, data reduction and preparation for publication and presentation

Individual: Michael Brown Title: Professor E-mail address mdb0075
Dept / Affiliation: KINE

Roles / Responsibilities:

Oversee Ultrasound data collection; store blood samples; analyze blood samples

Individual: James McDonald Title: Assoc Prof E-mail address j_rm00_1_3
Dept / Affiliation: KINE

Roles / Responsibilities:

Assist in the consenting process; Assist in data collection, data reduction and preparation.

Individual: Dave Pascoe Title: Professor E-mail address pascodd
Dept / Affiliation: KINE

Roles / Responsibilities:

Assist in data collection and manuscript preparation

Individual: Marilyn Cornish Title: Assist Prof E-mail address mac0084
Dept / Affiliation: Special Ed-Reha Counseling

Roles / Responsibilities:

Assist in data collection and interpretation of perceived stress variables

Individual: Geetha Thangiah Title: Assoc Prof E-mail address thangee
Dept / Affiliation: Dept. Nutrition, Dietetics and Hospitality Management

Roles / Responsibilities:

Collect blood samples

11. **LOCATION OF RESEARCH.** List all locations where data collection will take place. (School systems, organizations, businesses, buildings and room numbers, servers for web surveys, etc.) Be as specific as possible. Attach permission letters in Appendix E. (See sample letters at <http://www.auburn.edu/research/vpr/ohs/sample.htm>)

Kinesiology building 301 Wire Road: Epidemiology Lab (Room 144), Fitness Optimization Lab (Room 136), TigerFit Lab (room 126), i DEXA (Room 125).

Additional Key Personnel

1. Graduate Students
 - a. Kameron Suire (kbs0041) - assist in data collection, data reduction and manuscript preparation
 - b. Ashley Peart (azh0078) - assist in data collection, data reduction and manuscript preparation
 - c. Maitha Aldokhayyil (maa0076) – assist in ultrasound data collection

12. PARTICIPANTS.

- a. Describe the participant population you have chosen for this project including inclusion or exclusion criteria for participant selection.

Check here if using existing data, describe the population from whom data was collected, & include the # of data files.

For this particular cohort we are purposefully recruiting women aged 25-55 who are at risk for or have metabolic syndrome.

This population consists of: females, aged 25-55, who are: sedentary (not reporting a regular schedule of exercise over the last 3 months), and have at least one of the following criteria for metabolic syndrome: Elevated waist circumference, elevated triglycerides, reduced HDL-C, elevated blood pressure and/or elevated fasting glucose. If a participant is currently being treated for one of these conditions (i.e. taking medication for blood pressure, elevated triglycerides, glucose or triglycerides) then they meet the criteria for "elevated" for that category (See additional pages for a complete chart for criteria for metabolic syndrome). For example, if a participant is currently taking medication for high blood pressure then they are considered to meet the criteria for elevated BP. Please note as per ACSM guidelines for exercise prescription, any participant with a blood pressure over a systolic of 200mmHG or diastolic of 110mmHG will be excluded from the study and referred to a physician. Participants who do not qualify will be notified during the screening process and verbally explained why they do not meet the study criteria.

- b. Describe, step-by-step, in layman's terms, all procedures you will use to recruit participants. Include in Appendix B a copy of all e-mails, flyers, advertisements, recruiting scripts, invitations, etc., that will be used to invite people to participate. (See sample documents at <http://www.auburn.edu/research/vpr/ohs/sample.htm>.)

Participants will be recruited by word of mouth, e-mail blasts, flyers, and social network blasts. See Appendix B. No deceptive language will be used in recruiting participants, and any potential questions regarding the study will be honestly answered to the best of our ability.

- c. What is the minimum number of participants you need to validate the study? 20
How many participants do you expect to recruit? 40
Is there a limit on the number of participants you will include in the study? No Yes - the # is 50

- d. Describe the type, amount and method of compensation and/or incentives for participants.

(If no compensation will be given, check here:)

Select the type of compensation: Monetary Incentives
 Raffle or Drawing incentive (Include the chances of winning.)
 Extra Credit (State the value)
 Other

Description:

13. PROJECT DESIGN & METHODS.

- a. Describe, step-by-step, all procedures and methods that will be used to consent participants. If a waiver is being requested, check each waiver you are requesting, describe how the project meets the criteria for the waiver.

- Waiver of Consent (including using existing data)
- Waiver of Documentation of Consent (use of Information Letter)
- Waiver of Parental Permission (for college students)

Before any testing familiarization or data collection, potential participants will be provided with the study approved informed consent document and have any of their questions answered by the principal investigator Dr. Danielle Wadsworth or Dr. James McDonald. If the potential participant decides to volunteer for the study, she will sign the consent form and will be asked to complete a Physical Activity Readiness Plus Questionnaire (PAR-Q+). In order to participate in the study, participants will be sedentary, aged 25-55, have at least one criteria for MetS and must answer no to all questions in section 2-chronic medical conditions or have approval from a physician. Approval from a physician will be in the form of a letter stating that the participant can participate in the study. Participants will then be screened for MetS criteria including waist circumference and blood pressure. If they qualify for MetS by one of those criteria and/or are taking medication for blood pressure, glucose, cholesterol and triglycerides we will proceed with a venous blood draw. If they do not meet the criteria we will utilize a finger prick to assess eligibility. A small amount of blood (5 microliters (µL)) will be drawn via finger prick and analyzed with the cholestech system. If the subject meets the criteria for the study, then a venous blood draw will occur. If the participant does not meet inclusion criteria, the PAR-Q, consent form and cholestech results will be returned and the reason why they did not meet the study criteria explained.

- b. Describe the research design and methods you will use to address your purpose. Include a clear description of when, where and how you will collect all data for this project. Include specific information about the participants' time and effort commitment. (NOTE: Use language that would be understandable to someone who is not familiar with your area of study. Without a complete description of all procedures, the Auburn University IRB will not be able to review this protocol. If additional space is needed for this section, save the information as a .PDF file and insert after page 7 of this form.)

Procedures and methods are provided in the following pages.

Day 1 - 60 minutes

Participants will arrive to the KINE building in a fasting state (nothing by mouth except water for 8 hours) and perform the consenting procedures described in 13a. Those that meet study criteria will receive a venous blood draw, idexa scan, blood pressure measurement, complete questionnaires (self-regulation, intrinsic motivation, mental well-being, emotional distress, perceived stress) and provide demographic information. An ultrasound may be preformed at this baseline measurement or the following two-weeks based on menstruation.

Venipuncture

Participant will then be asked to lay (face up) on a treatment table for blood to be drawn from an antecubital vein. Specifically, the tester will state, *“You will have approximately 18 milliliters (four teaspoons) of blood drawn from a vein located in the area in front of your elbow, and collected into two red-top tubes called serum separator tubes. The needle and supplies used are sterile and similar to what is used by your physician’s office to draw blood.”* The tester will then draw blood using standard phlebotomy techniques based on Lippincott standardized procedures. The standard techniques include: 1) sanitize hands and put gloves on, 2) visual inspection of the antecubital area and apply the tourniquet 2 to 3 inches above the puncture site, 2) disinfect the area surrounding the puncture site with an alcohol wipe, 3) puncture the skin at a 30-degree angle using the 21G needle, 4) attach the data collection tube until filled, 5) once tube is filled release the tourniquet and remove the needle, 6) apply gauze over the wound and ask patient to hold the gauze and apply pressure to the wound, 7) place the needle in the sharps material disposal container, 8) check the wound to ensure that the bleeding has stopped and apply the bandage, 9) discard all waste into appropriate containers, 10) monitor the patient for a minimum of 10 minutes and provide subsistence. The purpose of this blood draw is to determine general health markers (i.e. cholesterol, glucose, and triglycerides) and molecular markers related to inflammation (i.e. TNF alpha, IL6 and C-reactive protein).

In the event the subject becomes uneasy or nauseous during or following the blood draw, the technician performing the blood draw will allow the subject to continue lying on the table or assist the subject back to the table to allow the response to subside. Only once the subject feels comfortable will the process continue. After the venipuncture is complete, a light snack and water will be given to the participant.

iDexa

iDexa measures body composition and bone density by dual energy X-ray absorptiometry. Participants will be asked to lie flat face-up on the iDexa table within the scanning area. The arm of the scanner will pass over the individual to assess body composition and bone density. The scan will take approximately 7-13 minutes depending on the size of the individual. All iDXA measurements will be carried out by certified and trained personnel.

Blood pressure will be measured manually with standardized blood pressure techniques.

Questionnaire and demographic information forms are located in the appendix.

Ultrasound (*Endothelial function assessment*):

Endothelial function is measured as flow-mediated dilation (FMD) of the brachial artery. FMD is a non-invasive vascular function test that measures the change in artery diameter in response to reactive hyperemia. Baseline artery diameter and blood flow velocity are measured using high-resolution Doppler ultrasound. An occlusion cuff is then inflated to decrease venous return to the lower arm for 5 minutes. Ischemia in the tissue distal to the cuff causes the distal vessels to dilate which decreases vascular resistance. This reduction in downstream resistance dramatically increases blood flow to the arm. The endothelium responds to the resulting increase in flow shear stress by releasing the vasodilator, nitric oxide, which cause dilation in the artery (Vanhoutte, et al., 1982). FMD is an established method of predicting future cardiovascular disease risk. Low brachial artery FMD predicts cardiovascular event risk in healthy people and in patients with cardiovascular disease (Green et al., 2011; Shechter, et al., 2009; Shechter et al., 2009; Yeboah et al., 2007). The rationale for measuring FMD in the proposed study is because endothelial-dependent dilation reflects the health of the endothelium

FMD will be assessed in a dedicated ultrasound room (Room 149 in KINE). All studies will be performed, after overnight fasting, in a quiet, dimly lit, air-conditioned room (constant temperature of 22-25°C) according to established guideline methods of Corretti et al. and Deanfield et al. Subjects will be asked to refrain from coffee, vitamin E and/or C supplementation until after the test. In addition, the increased endogenous production of estrogen, concurrently with progesterone, across the menstrual cycle has been documented to improve endothelial function (Hayashi et al., 1995). Measurements must be performed at the same time of the menstrual cycle. To minimize the impact to these hormonal changes, menses (days 1-7 of the menstrual cycle) offers the lowest attainable levels of both estrogen and progesterone in women and is therefore the optimum time for FMD studies (Hashimoto et al., 1995). If a female does not have a menstrual cycle (menopause, hysterectomy) FMD will be assessed on Day 1. In addition, participants will need to refrain from taking pain medication and decongestants the day before the test and take heart rate medication and blood pressure medication after the test. Therefore, this test may occur on Day 1 if these conditions are met, during the familiarization week or during the first week of training due to menstruation. If training is occurring after the ultrasound a snack and water will be given prior to exercise.

Dr. Brown has performed hundreds of these assessments and one of his trained technicians will perform the tests using a Hitachi Arietta 7 ultrasound machine using Duplex Mode. Duplex mode allows the simultaneous acquisition of B-mode and Doppler for determination of vessel diameter and blood velocity, respectively. After 15 minutes of quiet supine rests, the subject's non-dominant arm is placed at an 80° angle from the torso and maintained in the position with positioning pillows. An integrated ECG machine will be connected to electrodes placed on the subject's left and right upper torso and lower left torso in order to perform ECG gating. The reason for this is that depending upon pulse pressure and vascular stiffness, arterial diameter may vary quite considerably across a single cardiac cycle (15). ECG gating allows for the assessment of diameter according to the cardiac cycle (e.g. end-diastole). A blood pressure cuff will then be placed around the forearm and inflated to 200mmHg.

The brachial artery will be scanned longitudinally 5-10 cm above the antecubital fossa using a high-resolution linear artery transducer (13 MHz) coupled to computer-assisted analysis software (e-TRACKING system, Hitachi Co) that uses an automated edge detection system for measurement of brachial artery diameter. When the clearest B-mode image of the anterior and posterior intimal interfaces between the lumen and vessel wall is obtained, the transducer will be held at the same point throughout the scan by a special probe holder to ensure consistency of the image. Depth and gain setting are set to optimize the images of the arterial lumen wall interface. When the tracking gate is placed on the intima, the artery diameter is automatically tracked and the waveform of diameter changes over the cardiac cycle is displayed in real time using the FMD-mode of the e-TRACKING system. This allows the ultrasound images to be optimized at the start of the scan and the transducer position to be adjusted immediately for optimal tracking performance throughout the scan. Pulsed Doppler flow is assessed at baseline and during peak hyperemic flow, which is confirmed to occur within 15 seconds after cuff deflation. The Doppler flow signals are captured and blood flow velocity is calculated from the color Doppler data and displayed as a waveform in real time. The baseline longitudinal image of the artery is acquired for 30 seconds and then the blood pressure cuff is inflated to 50 mm Hg above systolic pressure for 5 min. The longitudinal image of the artery is recorded continuously until 5 minutes after cuff deflation. Pulsed Doppler velocity signals are obtained for 20 seconds at baseline and for 10 seconds immediately after cuff deflation. FMD is automatically calculated as the percent change in peak vessel diameter from the baseline value. %FMD (peak diameter - baseline diameter/baseline diameter) is used for analysis. Reactive hyperemia is calculated as the maximum percentage increase in flow after cuff deflation compared with baseline flow.

Day 2-7 - 45 to 60 minutes per visit

Participants will return to the lab on three separate occasions (familiarization days 1, 2 and 3) to become familiar with the testing procedures and complete baseline testing. During these three visits participants will complete a VO₂max test (an incremental treadmill walking/running test to determine aerobic fitness), practice the resistance training and treadmill protocols, receive an accelerometer to measure physical activity outside of the lab and complete a dietary assessment. If an ultrasound has not been performed then one will be performed during this week or the following week based on menstruation. An ultrasound and a VO₂max will not be performed on the same day because an ultrasound requires a fasting state. Data collection will be as follows:

Familiarization Day 1: VO₂ max, familiarize with resistance training, receive accelerometer and dietary log

Familiarization Day 2: Familiarize with resistance training and treadmill protocol

Familiarization Day 3: Familiarize with resistance training and treadmill protocol, perform 3 RM for bench press, back squat and standing press.

VO₂ max testing

During this test the participant will walk/jog using predetermine speeds and inclines until maximum fatigue. VO2max is estimated by asking the participant to walk/jog on a treadmill at stages of three minutes. The stages are:

1. 10% of incline and 1.7 miles per hour (MPH)
2. 12% incline and 2.5 MPH
3. 14% incline and 3.4 MPH
4. 16% incline and 4.2 MPH
5. 18% incline and 5.0 MPH

Once the participant reaches maximum fatigue tolerance the test is stopped and the VO2max is estimated by using a standardized and validated formula (Bruce, Kusumi, & Hosmer, 1973). Formula to predict VO2 max:

$$\text{VO}_2 (\text{mL} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}) = 1.06 + .056(\text{time in seconds}) (\text{WOMEN}).$$

Heartrate is monitored throughout the test for safety and to determine proper training ranges during the exercise training. This test is low risk and is common place in exercise and clinical settings to determine fitness. After maximum fatigue is reached, participants will begin a walking cool-down. Prior to the test the following script will be read: *"We are going to test your fitness level by walking/jogging on the treadmill. Every three minutes the treadmill will increase in speed and elevation. We ask that you continue the test until volitional fatigue. When you reach fatigue you will straddle the belt (demonstration will be given) and we will slow down the belt to a walking speed for you to cool down until your heartrate has returned to 130 bpm. If you begin to feel faint, pain in your chest and/or trouble breathing please let us know immediately. Do you have any questions?"* At this time the test will begin. Of note, the test will also be stopped by the tester according to the recommendations of the American College of Sports Medicine if:

1. There is chest pain suggestive of ischemia
2. Signs of dizziness occur
3. Signs of respiratory failure occur
4. There is sudden pallor (loss of face color), or blue flushness in the face indicative of lack of oxygen
5. The subject requests to stop the test
6. The tester deems the subject unsafe i.e. signs of fainting

In the extraordinarily rare event that a person faints and is unconscious due to a cardiovascular event, then the emergency plan (attached) will be executed by laboratory personnel.

Assessment of muscular strength: Please note that prior to the strength assessments, participants will have been trained and evaluated on proper form. If proper form cannot be maintained or executed the exercise will be modified. For example, some participants may not have the shoulder range of motion to place a bar on their upper back for a squat and may have to utilize hand weights to do the back squat.

3- RM Back squat - Participants will warm-up; followed by a set of 5 air squats (squats with just body weight). The participant will then preform up to 5 squats with the bar (35

pounds). If needed, weight will be added until the participant can only perform 3 squats with proper form. 3 RM will be obtained in no more than 4 attempts.

3 RM Standing Press - Participants will warm-up; followed by a set of 5 standing presses with a 9 pound bar. If needed, weight will be increased until the participant can only perform 3 standing presses with proper form. 3 RM will be obtained in no more than 4 attempts.

3 RM Bench Press - Participants will warm-up; followed by a set of 5 bench presses with a 35 pound bar. If needed, weight will be increased until the participant can only perform 3 bench presses with proper form. 3 RM will be obtained in no more than 4 attempts.

Accelerometer

An accelerometer is a small device (1" by 1.5") validated to record activity counts and step counts. The number of counts accumulated over a minute are used to determine sedentary, light, moderate, or vigorous activity based on previously validated cut-off values. For this study an accelerometer will be worn on the hip or wrist over 7 days at baseline, week 13 and week 26. The accelerometer will be given to the participants and verbal instructions will be given. An accelerometer log will be given to the participants to record wear times.

Dietary Recall

A 3-day dietary recall will be given to the participants to determine nutrition intake over two weekdays and one weekend day. Participants will be asked to record all food and beverages consumed and approximate the amount consumed.

Training weeks 2-12: Time commitment 2.5 – 3.5 hours per week.

It is important to note that over 150 individuals have completed this protocol with no adverse outcomes. This includes a cohort of females aged 40-64 and obese females aged 30-55. In addition, it is important to understand that the terms “high intensity and sprint” are relative to the individual performing the exercise. Many of these participants will “sprint” at 2.5 mph and a 6% grade based on their heart rate baseline parameters. All exercise are tailored to the individuals at each exercise session.

Training will take place three days per week: Monday, Wednesday, and Friday. Each day participants will participate in a treadmill and resistance training protocol. Each session will start with a dynamic warm-up and conclude with a cool-down. Participants will be asked to consume at least 1 pint of water before reporting for the workout and have eaten prior to exercising.

Before each training session, participants will be asked the following questions to determine if

there have been any changes in health status:

- Have you consumed at least 1 pint of water today?
- Have you eaten today?
- Have you started taking any new medications since the last session?
- Do you know of any reason that would increase the risk of exercise today?
- Are you ill?

Resistance Training Protocol

- General dynamic flexibility warm-up will be completed before each training session. These will be slightly different for each training protocol and will remain constant throughout the training program
- Two different training protocols will be utilized throughout the study and will be alternated every day, protocol A and protocol B
- Every two weeks each training protocol will be completed 3 times: Week 1 sequence – A, B, A; Week 2 sequence – B, A, B. An undulating periodization model will be used over the 10 weeks and consists of:
 - Initial load will be 70% of 3-RM max
 - Number of sets, reps, and load will be altered every 6th training session
 - Will follow the general pattern of:
 - Weeks 3-5 3 (sets) x 10 (Reps)
 - Weeks 6-7 4 (sets)x 5 (Reps)
 - Weeks 8-9 3 (sets) x 10 (Reps)
 - Weeks 10-12 4 (sets)x 5 (Reps)
 - A rest period of between 1 and 2 minutes will be allowed between sets

Treadmill Protocol

- Warm-up will consist of 3 minute walk or jog at 50% of VO₂ max along with dynamic flexibility.
- Participants will complete intervals at 40 seconds work to 20 seconds rest at a heartrate that is 90-95% of maximal heart rate observed during their VO₂ max test for a total of 4 minutes of exercise (total time including warm-up, cool-down and rest cycles is 12 minutes). Based on past cohorts, that are similar to this cohort in terms of sedentary individuals, this constitutes a walk at 2.5-3 mph at 6% grade. After three sprints a full minute recovery will occur, followed by 3 more sprints. At week 8, three additional sprints will be added for a total of 9 sprints and of 6 minutes of exercise (total time including warm-up, cool-down and rest cycles is 15 minutes). Each participant's speed is based on their baseline data and adjusted based on their response to the training program.
- Throughout the 10 weeks speed will be adjusted to maintain 90-95% of heart rate max. Grade will remain at 6% throughout the 10 weeks.
- If fewer than 6 intervals are able to be completed in a given training session then the intensity will be decreased by 1 % for the following training session and progression will continue.

Post-testing Week 13: Time commitment for the week is 3.5 hours.

We will retest of all variables examined in week 1. Testing schedule is found below:

Monday: 3- RM testing for back squat and standing press.

Wednesday: Fasting blood collection, iDexa, anthropometric data, Blood flow (may be adjusted based on menstration)

Friday: questionnaire and VO2 max

Debriefing Week 14: 30 minutes

Participants will participate in a brief interview (see appendix) to determine their experience with the study. This interview will be audio recorded, transcribed and analyzed for themes. Participants will be identified with their participant identifier on the audio recording. The recorder will be turned off after the interview and then each participant will receive their results from the program.

Adherence to protocol -Weeks 15-26 – Time Commitment = 30 minutes per week

Upon the conclusion of lab training participants will receive reinforcement to continue exercising via text messages or phone calls. Participants will receive a maximum of three messages and one phone call each week. Participants will be informed that they are responsible for any charges associated with texts and calls.

Retention measures – Week 26 – Time commitment = 60 minutes

The following baseline measures will be repeated: anthropometric data, questionnaire, iDexa, venous blood draw, blood flow and interview.

In the event of an emergency, the emergency action plan is followed. This includes notification of EMS, administration of first aid/CPR procedures, direction of EMS in the building and follow-up procedures. The complete emergency action procedures are located in the appendix. All study personnel are trained in the emergency procedures prior to the start of the study.

13. PROJECT DESIGN & METHODS. *Continued*

- c. List all data collection instruments used in this project, in the order they appear in Appendix C. (e.g., surveys and questionnaires in the format that will be presented to participants, educational tests, data collection sheets, interview questions, audio/video taping methods etc.)

Informed Consent; Par-Q+; iDexa for body composition; Scale for weight; Stadiometer for height; measuring tape for waist circumference; Woodyway treadmill for VO2 max; Accelerometer; Questionnaire (demographics dietary recall, self-regulation questionnaire, intrinsic motivation, perceived stress, mental well-being and emotional distress); Ultrasound; Blood Pressure Cuff, stethoscope, sphygmomanometer;

- d. Data analysis: Explain how the data will be analyzed.

Data will be examined over time within individuals to determine the effect of the intervention at 13 and 26 weeks. Differences between variables will be examined to determine which variables predict adherence at 13 and 26 weeks.

14. RISKS & DISCOMFORTS: List and describe all of the risks that participants might encounter in this research. If you are using deception in this study, please justify the use of deception and be sure to attach a copy of the debriefing form you plan to use in Appendix D. (Examples of possible risks are in section #6D on page 2)

- 1) The most extreme potential risk during the maximal effort exercise in this study is death. However, the American College of Sports Medicine cites a survey that determined the risk of death to be 0.5 per 10,000 individuals. Other risks of exercise include nausea, fainting, dehydration, dizziness, muscle strain/pull, heart arrhythmia, and abnormal blood pressure response.
- 2) During blood draws there is a risk of infection, bruising, bleeding, irritation at injection site, fainting, and/or contact with blood-borne pathogens.
- 3) Some participants may experience psychological or emotional discomfort from completing the new questionnaires that assess perceived stress, mental well-being, and emotional distress.
- 4) There may be some discomfort during the blood flow measurement where the hand can become numb and tingly from the occlusion of the vein.
- 5) As participants will likely be relatively new to resistance training, there is the potential additional risk for musculoskeletal injuries to occur.
- 6) Muscle Soreness is a possibility especially during the first several weeks. This is a greater risk with a relatively untrained population.
- 7) A small amount of radiation from the DEXA scan.
- 8) Since we will be using human subjects and will not be collecting data anonymously, breach of confidentiality is always a risk.

15. **PRECAUTIONS.** Identify and describe all precautions you have taken to eliminate or reduce risks as listed in #14. If the participants can be classified as a "vulnerable" population, please describe additional safeguards that you will use to assure the ethical treatment of these individuals. Provide a copy of any emergency plans/procedures and medical referral lists in Appendix D. (Samples can be found online at <http://www.auburn.edu/research/vpr/ohs/sample.htm#precautions>)

1. All participants will be screened by the Parq+. The VO2 test will be conducted by trained personnel and exercise testing are commonplace in the exercise science literature and Dr. Wadsworth Lab (hundreds of participants). Participants will also be able to freely terminate any test or exercise session whenever they wish. For this cohort in which aerobic capacity is low (approximately 20ml/kg/min), most subjects will terminate the test between minutes 3-6 which is 12% grade and 2.5 mph.
2. The chance of infection from a blood draw is minimal due to the use of aseptic blood drawing procedures, sterile needles, and a trained phlebotomist taking the blood sample. Only trained phlebotomists (Dr. Thanigah) will conduct the blood draws. After the blood draw is complete participants will be provided with a snack and water, as well as, advised to drink extra fluids throughout the day.
3. The likelihood of psychological or emotional distress from completing the new questionnaires is low. The measures selected are well-established measures commonly used in psychological research. As a precaution, a Referral List of local mental health provided has been compiled, to be offered to participants at each questionnaire assessment timepoint.
See additional pages

If using the Internet or other electronic means to collect data, what confidentiality or security precautions are in place to protect (or not collect) identifiable data? Include protections used during both the collection and transfer of data.

None

16. **BENEFITS.**

- a. List all realistic direct benefits participants can expect by participating in this specific study.

(Do not include "compensation" listed in #12d.) Check here if there are no direct benefits to participants.

Participants will benefit from the physiologic training and testing conducted during this study that would not normally be available to them. Both pre and post testing results will be given and explained to the participants. This information gives participants information on their strength, power, anaerobic capacity, blood profile and body composition. Participants will have the opportunity to have their training program designed monitored by trained professionals for no cost.

Participants will also benefit from the increases in health and physical fitness associated with regular exercise, such as decreased risk of death, reduced risk of cardiovascular disease, reduced risk of diabetes, increased bone and muscle health, reduced feelings of anxiety and depression, and better control of body weight.

- b. List all realistic benefits for the general population that may be generated from this study.

The results of this study could provide the general population with a template to maximize gains from training aimed at both strength and endurance improvements at the same time. This template could apply to both recreationally active and untrained individuals. Methods to maintain exercise behavior are limited in women, this study will provide methods on how to best intervene with this population.

Precautions Continued

4. The numbness from the blood pressure cuff will be alleviated when the cuff is deflected. This technique is commonplace in the literature and Dr. Brown's lab. If an abnormality is found (which is unusual at the brachial artery) the participants will be referred to their physician. The participant will verbally informed privately that we have found an abnormality in the ultrasound and we recommend that you see your primary physician.
5. All exercise sessions will be overseen by trained researchers staff, tailored to each individual's needs and progression will occur based on the individual. In addition, each session will begin with a dynamic warm-up and end with a cool-down that includes static stretching. This protocol has been completed with over 150 participants with no adverse outcomes.
6. Radiation from the idexa is equivilant to walking outside for approximately 10 minutes. All procedures used for the idexa are standardized and follow radiation safety.
7. Even though data will not be collected anonymously, it will be recorded anonymously, with the code list linking the participants kept confidential in a locked filing cabinet until the end of the study when it will be destroyed.

17. PROTECTION OF DATA.

a. Data are collected:

- Anonymously with no direct or indirect coding, link, or awareness of who participated in the study (Skip to e)
- Confidentially, but without a link of participant's data to any identifying information (collected as "confidential" but recorded and analyzed as "anonymous") (Skip to e)
- Confidentially with collection and protection of linkages to identifiable information

b. If data are collected with identifiers or as coded or linked to identifying information, describe the identifiers collected and how they are linked to the participant's data.

We will know the identity of the participants as we collect the data, but the data will be recorded by participant identifier only. After data collection and collation, the master list linking participant to numbered data will be destroyed.

c. Justify your need to code participants' data or link the data with identifying information.

Identity of participants is necessary to link baseline and follow-up data.

d. Describe how and where identifying data and/or code lists will be stored. (Building, room number?) Describe how the location where data is stored will be secured in your absence. For electronic data, describe security. If applicable, state specifically where any IRB-approved and participant-signed consent documents will be kept on campus for 3 years after the study ends.

An electronic copy of the code list will be stored on a password protected laptop in Dr. Wadsworth office 165 @ 301 Wire Road. The consent forms will also be stored in this office. The office remains locked when not in use. In the event of Dr. Wadsworth's absence, Dr. McDonald will maintain the code list and consent forms in his office, room 169.

e. Describe how and where the data will be stored (e.g., hard copy, audio cassette, electronic data, etc.), and how the location where data is stored is separated from identifying data and will be secured in your absence. For electronic data, describe security

Hard copies of data will be stored in a locked filing cabinet in Room 144. The room remains locked when not in use. Electronic data formats will be stored on a password protected encrypted computer in room 144. This computer is maintained by the Auburn Office of Information technology. A back-up copy of the data will be stored on a password protected google drive cloud based software, which utilizes a 256-bit AES encryption and cipher.

f. Who will have access to participants' data?

(The faculty advisor should have full access and be able to produce the data in the case of a federal or institutional audit.)

Dr. Wadsworth will have full access to the data. Only the research personnel identified in this IRB will have any access to the data.

g. When is the latest date that identifying information or links will be retained and how will that information or links be destroyed? (Check here if only anonymous data will be retained)

Dr. Wadsworth will keep the informed consent for three years (as required). The master list will be deleted from the computer once all data have been collected and collated, which is typically 6 months after the final data (week 26) is collected.



AUBURN UNIVERSITY

COLLEGE OF EDUCATION

School of Kinesiology

Informed Consent for a Research Study Entitled

“Effect of interval and resistance exercise on physiological and psychological parameters in women”

Project Overview: You are invited to participate in a research study that will examine the effect of a concurrent training program including aerobic and strength training, on body composition, metabolic syndrome, motivation, physical activity, blood flow, perceived stress and exercise adherence in females aged 25-55. We are recruiting participants to complete a 26 week study. Participants will participate in a concurrent strength training and sprint high intensity interval training (HIIT) for 10 weeks. We will follow-up with your changes up to 26 weeks.

Purpose: The purpose of this investigation is to examine changes in body composition, metabolic syndrome, motivation, physical activity, blood flow, perceived stress and exercise adherence following a 10-week concurrent training program.

Participation Requirements: To be eligible, you must be:

1. Female participant between 25 and 55 years of age.
2. Low risk for medical complications from exercise (as determined by physical activity readiness questionnaire (PARQ+).
3. Neither currently engaging in exercise nor consistently over the last three months.
4. Displays at least one symptom of metabolic syndrome, or is taking medication for metabolic syndrome risk factors. Metabolic syndrome includes elevated waist circumference (≥ 35 inches), elevated triglycerides (≥ 150 mg/dL), reduced HDL (≤ 50 mg/dL), elevated blood pressure (≥ 130 mm Hg systolic blood pressure and < 200 mmHG or ≥ 85 mm Hg diastolic blood pressure and < 110 mmHG), and/or elevated fasting glucose (≥ 100 mg/dL). We will screen for these symptoms during your first visit.
5. Not pregnant.
6. Currently not taking any medications that will increase the risk of participation, or interfere with testing variables. Note that taking certain medications may cause you to be excluded from participation in this study including those that cause increases in heart rate or blood pressure. Medications may include bronchodilators or amphetamines.

You must meet all of the requirements to be eligible for participation in this study

Time commitment for participation in this study will be approximately 40 hours. Lab training time will last 12 weeks with follow-up on weeks 19 and 26.

Page 1 of 5

Initials _____

301 Wire Rd., Auburn, AL 36849-5323; Telephone: 334-844-4483; Fax: 334-844-1467

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Day 1: On the first visit to the lab, you will complete the PARQ+ Questionnaire, complete the questionnaire (self-regulation, mental well-being, emotional distress, perceived stress, demographic data), and read and sign the University-approved informed consent form. Dr. Danielle Wadsworth or Dr. Jim McDonald will be present for all informed consent briefings. The PARQ+ is a screening tool that helps us determine if you are ready for physical activity. You will need to arrive to the lab in a fasting state (i.e. no food for eight hours prior to your lab visit). In order to qualify for the study we will need to assess your blood chemistry for markers of metabolic syndrome. These markers include: fasting blood glucose, cholesterol and triglycerides, and will be initially assessed via a finger prick. You may qualify if taking medication for these markers. If you qualify, we will further assess your blood via a venous blood draw. A total of 18 ml (4 teaspoons) will be drawn. Blood collection will be repeated again on weeks 13 and 26 of the study, for a total of 54 ml (12 teaspoons). The blood will be taken from your arm. The risks of taking blood include pain, a bruise at the point where the blood is taken, redness, swelling of the vein, infection, and a rare risk of fainting. Following your blood draw you will complete an iDEXA body composition scan. The scan is an x-ray that measures the amount of muscle and fat in your body. The radiation you are exposed to during this scan is equal to walking outside on a sunny day for 10 minutes. After the scan you will be given a snack or juice prior to leaving the lab. You will repeat this scan on week 13 and week 26. We may also measure blood flow on Day 1. In order to accurately measure blood flow we will need to know the timing of your menstrual cycle. If you are currently menstruating and/or do not have a menstrual cycle we will measure blood flow on this day. If not, we will measure it on another day. In addition, we will also ask you to avoid any pain medicines such as Advil or Motrin the day before the test, and to take your heart and blood pressure medication after the test. If you have taken any of this medication, we will plan to do the test on another day. To measure blood flow, you will be asked to lie down on a table in a dimly lit, quiet room. We will use an ultrasound machine to measure your blood vessels. Specifically, we will measure how well the artery in your upper left arm is able to expand using the ultrasound. First, we will place 3 sticky pads on your upper body in order to measure your heartbeat during the test. Then, the probe of the ultrasound machine will be placed on your skin, over the blood vessel, on the inside of your upper left arm. A small amount of clear gel will be on the probe. This allows for better contact between the probe and the skin. We will then place a blood pressure cuff on your lower arm. Next, we will inflate (pump up) the cuff to 200 mmHG (what a doctor usually inflates a blood pressure cuff to when measuring a person's blood pressure in the doctor's office). This may cause slight discomfort (similar to when your hand or foot has "fallen asleep"). After 5 minutes, we deflate the cuff and measure how the size of the artery changes. In addition, on the first day you will complete a questionnaire to measure self-regulation, mental well-being, emotional distress, perceived stress, demographic data (height, weight, and waist circumference), and we will measure your blood pressure.

Total time for Day 1 is 60 minutes.

If ineligible for participation for any reason (participation requirements or PAR-Q+) all forms will be returned to the subject, and no record will be kept by the researchers.

Day 2 – Day 7: Over this 5 day period, you will return to the lab on three separate occasions to become familiar with testing procedures including the back squat, standing press, bench press, and treadmill walking/running protocol as needed. A member of the research team will verbally describe the exercise and allow you time to practice with correct form.

We will also complete a VO₂max test (an incremental treadmill walking/running test designed to determine your maximal oxygen uptake). We will monitor you closely and ensure that you complete a thorough cool-down by walking for several minutes at a comfortable pace.

Additional familiarization opportunities will be provided as needed. On the last familiarization day you will perform supervised three repetition max (3RM) tests for the back squat, standing press and bench press. **Total time commitment for each visit is 45 to 60 minutes.**

You will be given a dietary log on Monday to record throughout the week. Logs will be collected on the following Monday by the researchers. You will also be asked to wear an accelerometer on your wrist or waist. These measures allow us to determine how much exercise you do outside of the lab.

Monday: VO2 max, Practice for back squat, standing press, bench press, receive accelerometer and diet log

Wednesday: Blood flow, if not already completed. Practice training protocol to include treadmill walking/running and resistance training (back squat, standing press, bench press)

Friday: 3 RM testing for back squat, standing press, bench press

Time commitment for the week = 3.5 hours

After testing you will begin your training protocol. The exercise protocol is described below:

Training Weeks 2 – 12

- Training will take place three days per week: Monday, Wednesday, and Friday
- Participants will be asked to consume at least 1 pint of water before reporting for the workout
- Time commitment 2.5 – 3 hours per week.

Strength Training Protocol -

- General warm-up will be completed before each session
- Two alternating training days will be used
- Sets, reps, and intensity will be altered after every six training sessions
- Each program will be individualized based on your testing variables
- All training will be overseen by a certified strength and conditioning coach
- Time commitment = 2.0 hours/week

Sprint HIIT Protocol -

- 3 minute warm-up will be completed consisting of a walk/jog at 50% your VO2 max
- Participants will be allowed to actively stretch as needed prior to intervals
- HIIT training will consist of intervals (3 intervals for the first five weeks building to 9 intervals for the last 5 weeks of the study) each interval lasting 40 seconds walking/running, with 20 seconds passive recovery
- 3 minute cool-down will be completed at 50% of VO2 max
- Speed of the walk/run will be individualized and based on testing outcomes
- Time commitment = 1 hour / week

Post Testing – Week 13 – Will be a retest of all variables examined in week 1. Dietary logs will be returned to participants on Friday of week 12, and you will be asked to replicate dietary intake from the first week as closely as possible. Testing schedule is found below:

Monday: 3 RM testing for back squat and standing press, anthropometric data

Wednesday: Fasting blood collection, iDexa, Blood flow

Friday: VO2 Max, questionnaire

After you have completed all of your post-testing you will be asked to return to the lab for a brief interview. The interviewer will ask you questions about your experience with our program, such as your enjoyment and intentions to continue with the training. This interview will be audio recorded with your individual subject identifier. The audio tapes will be destroyed after the transcription is complete, which is typically 6-months after your interview. At this time you will receive all of your results thus far.

Time commitment for the week = 3.5 hours

Total time commitment for lab participation = 12 weeks – approximately 40 hours

Adherence to protocol -Weeks 14-26 – Upon the conclusion of your lab training you may receive reinforcement messages or phone calls to help you maintain your activity levels. You may receive up to three messages each week. You are responsible for any costs occurred via text.

Retention measures – Week 26 – There will be follow-up testing, where you will be asked to you to return to the lab and complete an iDexa scan, blood flow, blood draw, questionnaire, and interview.

Time commitment for the week = 3.5 hours

Test Descriptions:

VO₂Max – Walk and/or jog on the treadmill at a pre-set speed and incline. Each three minutes the speed and incline will be increased until you terminate the test. This test allows us to determine your fitness levels.

3 repetition max (RM) – We will assess how strong you are when completing a back squat, bench press, and shoulder press. We will monitor your form and gradually increase weight until you can only complete three repetitions, or terminate the test.

iDexa – An x-ray that assesses your body composition in terms of percent fat mass and lean mass. It also assesses your bone mineral density.

Blood Flow – We will use an ultrasound to take pictures of your blood vessels to understand how well your blood vessels expand.

Accelerometer – A small device worn on the hip or wrist to measure physical activity outside of the lab.

Blood Draw – We will collect venous blood by inserting a needle into your arm and gathering a small amount of blood into a tube.

Finger Prick – If necessary, we will screen your blood by pricking one of your fingers with a lancet and gather a small amount of blood.

Potential Risks:

1. While performing any exercise there is a chance of muscle strains, sprains, pulls, and even death. The American College of Sports Medicine estimates the risk of sudden cardiac death 1 per 36.5 million hours of exertion or 1 in 10,000.
2. Due to the high intensity nature of some of the exercises, you may feel sore or tired after completing the exercises.
3. With any blood collection procedure there is a risk of infection, bleeding, bruising, irritation at injection site, and/or fainting.
4. It is possible that completing questionnaire items about psychological wellbeing and distress may bring up some degree of psychological or emotional discomfort.
5. There may be some discomfort during the blood flow measurement where the hand can become numb and tingly from the occlusion of the vein.
6. A small amount of radiation from the iDexa scan.

“Note” Although injuries are not anticipated in this protocol, it is important for you to acknowledge that the investigators have no plans for compensation in the event of an injury you experience.

Precautions:

1. Although the training for this trial is of a higher intensity, it is of short duration, at a comfortable environmental temperature, and humidity level. In addition, the training is tailored to you and your fitness levels. Heart rate will be recorded throughout the trial. We will also collect data on your daily activity using a wrist accelerometer to monitor free living exercise behavior.
2. We have additionally employed the use of the PARQ+ to assist in eliminating participants that have potential medical or orthopedic identified risks. During the trials you will always be accompanied by researchers who maintain current CPR Certifications.
3. After each exercise bout you will be monitored and be given a chance to cool-down.
4. Investigators participating in blood data collection have completed NIH approved phlebotomy training. Only new sterile blood-gathering equipment, and aseptic techniques, will be utilized throughout all data collection and analysis processes.
5. The training program was designed by Dr. Rich Laird, PhD, and Certified Strength and Conditioning Coach. It has been used safely and effectively in previous Auburn Studies. Proper lifting technique, volume and intensity manipulation, and spotting will be employed to decrease the risk of injury.
6. Should an emergency arise, we will call 911 and follow our emergency action plan. You are responsible for any cost associated with medical treatment.
7. Should you experience psychological or emotional discomfort from completing the questionnaires, you may inform the researchers about your concerns. In addition, counseling referral information is available from the researchers should you determine you may want to seek counseling for any concerns identified in this study. You are also allowed to skip any questionnaire item that you do not wish to answer, or that makes you too uncomfortable.
8. Discomfort associated with the blood pressure cuff will dissipate after the cuff has been deflated.
9. The iDexa scan radiation is the equivalent to walking outside in the sun for 10 minutes. We utilize standard procedures approved by radiation safety.

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Benefits: You will receive 12 weeks of organized and supervised training, along with performance assessments including: body composition, bone density, VO₂max, 3 RM, and blood chemistry. In addition, you will receive reinforcements to help you transition to exercising on your own.

Your participation is completely voluntary. If you change your mind about participating, you can withdraw at any time during the study. If you choose to withdraw, you can request to have your data withdrawn. Your decision about whether or not to participate or to stop participating will not jeopardize your future relations with Auburn University, the School of Kinesiology, or any of the researchers. Your privacy will be protected. Any information obtained in connection with this study will remain anonymous.

If you have any questions, we invite you to ask us now. If you have questions later, you can contact Danielle D. Wadsworth (wadswdd@auburn.edu; 334-750-1642), James R. McDonald (jrm0013@auburn.edu), or call 334-844-1836. You will be provided with a copy of this document for your records.

For more information regarding your rights as a research participant, you may contact the Auburn University Office of Human Subjects Research, the Institutional Review Board phone number (334) 844-5966, or by email at hsubjcc@auburn.edu or IRBChair@auburn.edu.

HAVING READ THE INFORMATION PROVIDED, YOU MUST DECIDE WHETHER OR NOT YOU WISH TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES YOUR WILLINGNESS TO PARTICIPATE.

Participant's signature	Printed Name	Date
_____	_____	_____
Investigator obtaining consent	Printed Name	Date
_____	_____	_____
Co-Investigator	Printed Name	Date
_____	_____	_____

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APPENDIX B: RECRUITMENT SCRIPT

Social Media Recruitment Script

Research Study: Exercise Training for Women. You are invited to participate in a research study that will examine the effect of a concurrent training program including aerobic and strength training, on body composition, metabolic syndrome, motivation, blood flow, perceived stress and exercise adherence in females aged 25-55. We are recruiting participants to complete a 26 week study. To be eligible you must be: Female participant between 25 and 55 years of age, Low risk for medical complications from exercise (as determined by physical activity readiness questionnaire (PARQ+), Currently not engaging in exercise, Display at least one symptoms of metabolic syndrome (Metabolic syndrome includes elevated waist circumference, elevated triglycerides, reduced HDL, elevated blood pressure and/or elevated fasting glucose. We will screen for these symptoms during your first visit), Not pregnant and, Currently not taking any medications that will increase the risk of participation, or interfere with testing variables. Please contact Danielle Wadsworth via e-mail at wadswdd@auburn.edu or telephone at 334-844-1836 for more information.

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APPENDIX C: MEDIA RECRUITMENT

RESEARCH STUDY: EXERCISE TRAINING STUDY FOR WOMEN

Effect of high intensity exercise training on
physiological, psychosocial and exercise adherence



Purpose: You are invited to participate in a research study that will examine the effect of a concurrent training program including aerobic and strength training, on body composition, metabolic syndrome, motivation, blood flow, perceived stress and exercise adherence in females aged 25-55. We are recruiting participants to complete a 26 week study. Participants will participate in a concurrent strength training and sprint high intensity interval training (HIIT) for 10 weeks. We will follow-up with your changes up to 26 weeks.

Participation Requirements: To be eligible, you must be:

1. Female participant between 25 and 55 years of age.
2. Low risk for medical complications from exercise (as determined by physical activity readiness questionnaire (PARQ)).
3. Currently not engaging in exercise.
4. Displays at least one symptoms of metabolic syndrome. Metabolic syndrome includes elevated waist circumference, elevated triglycerides, reduced HDL, elevated blood pressure and/or elevated fasting glucose. We will screen for these symptoms during your first visit.
5. Not pregnant.
6. Currently not taking any medications that will increase the risk of participation, or interfere with testing variables. Note that taking certain medications may cause you to be excluded from participation in this study including those that cause increases in heart rate, or other drugs that may increase the risk of participation.

Benefits: You will receive free exercise training (i.e. strength training, cardiovascular) for 12 weeks and follow up testing for two additional weeks. In addition you will receive detailed feedback on your training and nutritional intake, as well as, all of your results including a full body fat analysis. Previous benefits from this study have shown an increase in lean body mass.

YOUR PARTICIPATION IS COMPLETELY VOLUNTARY!

Contact Information: Please contact Danielle Wadsworth via e-mail at wadswdd@auburn.edu or telephone at 334-844-1836 for more information.

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APPENDIX D: FLYER


2018 PAR-Q+






The Physical Activity Readiness Questionnaire for Everyone

The health benefits of regular physical activity are clear; more people should engage in physical activity every day of the week. Participating in physical activity is very safe for MOST people. This questionnaire will tell you whether it is necessary for you to seek further advice from your doctor OR a qualified exercise professional before becoming more physically active.

GENERAL HEALTH QUESTIONS

Please read the 7 questions below carefully and answer each one honestly: check YES or NO.	YES	NO
1) Has your doctor ever said that you have a heart condition <input type="checkbox"/> OR high blood pressure <input type="checkbox"/> ?	<input type="checkbox"/>	<input type="checkbox"/>
2) Do you feel pain in your chest at rest, during your daily activities of living, OR when you do physical activity?	<input type="checkbox"/>	<input type="checkbox"/>
3) Do you lose balance because of dizziness OR have you lost consciousness in the last 12 months? Please answer NO if your dizziness was associated with over-breathing (including during vigorous exercise).	<input type="checkbox"/>	<input type="checkbox"/>
4) Have you ever been diagnosed with another chronic medical condition (other than heart disease or high blood pressure)? PLEASE LIST CONDITION(S) HERE: _____	<input type="checkbox"/>	<input type="checkbox"/>
5) Are you currently taking prescribed medications for a chronic medical condition? PLEASE LIST CONDITION(S) AND MEDICATIONS HERE: _____	<input type="checkbox"/>	<input type="checkbox"/>
6) Do you currently have (or have had within the past 12 months) a bone, joint, or soft tissue (muscle, ligament, or tendon) problem that could be made worse by becoming more physically active? Please answer NO if you had a problem in the past, but it <i>does not limit your current ability</i> to be physically active. PLEASE LIST CONDITION(S) HERE: _____	<input type="checkbox"/>	<input type="checkbox"/>
7) Has your doctor ever said that you should only do medically supervised physical activity?	<input type="checkbox"/>	<input type="checkbox"/>

 **If you answered NO to all of the questions above, you are cleared for physical activity. Please sign the PARTICIPANT DECLARATION. You do not need to complete Pages 2 and 3.**

-  Start becoming much more physically active – start slowly and build up gradually.
-  Follow International Physical Activity Guidelines for your age (www.who.int/dietphysicalactivity/en/).
-  You may take part in a health and fitness appraisal.
-  If you are over the age of 45 yr and NOT accustomed to regular vigorous to maximal effort exercise, consult a qualified exercise professional before engaging in this intensity of exercise.
-  If you have any further questions, contact a qualified exercise professional.

PARTICIPANT DECLARATION
If you are less than the legal age required for consent or require the assent of a care provider, your parent, guardian or care provider must also sign this form.


I, the undersigned, have read, understood to my full satisfaction and completed this questionnaire. I acknowledge that this physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if my condition changes. I also acknowledge that the community/fitness centre may retain a copy of this form for records. In these instances, it will maintain the confidentiality of the same, complying with applicable law.




NAME _____ DATE _____

SIGNATURE _____ WITNESS _____

SIGNATURE OF PARENT/GUARDIAN/CARE PROVIDER _____





 **If you answered YES to one or more of the questions above, COMPLETE PAGES 2 AND 3.**

 **Delay becoming more active if:**





-  You have a temporary illness such as a cold or fever; it is best to wait until you feel better.
-  You are pregnant - talk to your health care practitioner, your physician, a qualified exercise professional, and/or complete the ePARmed-X+ at www.eparmedx.com before becoming more physically active.
-  Your health changes - answer the questions on Pages 2 and 3 of this document and/or talk to your doctor or a qualified exercise professional before continuing with any physical activity program.

2018 PAR-Q+

 **If you answered NO to all of the FOLLOW-UP questions (pgs. 2-3) about your medical condition, you are ready to become more physically active - sign the PARTICIPANT DECLARATION below:**

-  It is advised that you consult a qualified exercise professional to help you develop a safe and effective physical activity plan to meet your health needs.
-  You are encouraged to start slowly and build up gradually - 20 to 60 minutes of low to moderate intensity exercise, 3-5 days per week including aerobic and muscle strengthening exercises.
-  As you progress, you should aim to accumulate 150 minutes or more of moderate intensity physical activity per week.
-  If you are over the age of 45 yr and **NOT** accustomed to regular vigorous to maximal effort exercise, consult a qualified exercise professional before engaging in this intensity of exercise.

 **If you answered YES to one or more of the follow-up questions about your medical condition:**
You should seek further information before becoming more physically active or engaging in a fitness appraisal. You should complete the specially designed online screening and exercise recommendations program - the **ePARmed-X+** at www.eparmedx.com and/or visit a qualified exercise professional to work through the ePARmed-X+ and for further information.

-  **Delay becoming more active if:**
-  You have a temporary illness such as a cold or fever; it is best to wait until you feel better.
 -  You are pregnant - talk to your health care practitioner, your physician, a qualified exercise professional, and/or complete the ePARmed-X+ at www.eparmedx.com before becoming more physically active.
 -  Your health changes - talk to your doctor or qualified exercise professional before continuing with any physical activity program.

- You are encouraged to photocopy the PAR-Q+. You must use the entire questionnaire and NO changes are permitted.
- The authors, the PAR-Q+ Collaboration, partner organizations, and their agents assume no liability for persons who undertake physical activity and/or make use of the PAR-Q+ or ePARmed-X+. If in doubt after completing the questionnaire, consult your doctor prior to physical activity.

PARTICIPANT DECLARATION

- All persons who have completed the PAR-Q+ please read and sign the declaration below.
- If you are less than the legal age required for consent or require the assent of a care provider, your parent, guardian or care provider must also sign this form.

I, the undersigned, have read, understood to my full satisfaction and completed this questionnaire. I acknowledge that this physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if my condition changes. I also acknowledge that the community/fitness center may retain a copy of this form for records. In these instances, it will maintain the confidentiality of the same, complying with applicable law.

NAME _____ DATE _____

SIGNATURE _____ WITNESS _____

SIGNATURE OF PARENT/GUARDIAN/CARE PROVIDER _____

For more information, please contact
www.eparmedx.com
Email: eparmedx@gmail.com

Citation for PAR-Q+
Warburton DER, Jamnik VK, Bredin SSD, and Gledhill N on behalf of the PAR-Q+ Collaboration.
The Physical Activity Readiness Questionnaire for Everyone (PAR-Q+) and Electronic Physical Activity
Readiness Medical Examination (ePARmed-X+). Health & Fitness Journal of Canada 4(2):3-23, 2011.

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The PAR-Q+ was created using the evidence-based AGREE process (1) by the PAR-Q+ Collaboration chaired by Dr. Darren E. R. Warburton with Dr. Norman Gledhill, Dr. Veronica Jamnik, and Dr. Donald C. McKenzie (2). Production of this document has been made possible through financial contributions from the Public Health Agency of Canada and the BC Ministry of Health Services. The views expressed herein do not necessarily represent the views of the Public Health Agency of Canada or the BC Ministry of Health Services.

APPENDIX E: DIETARY RECALL

Three Day Food Log

1. Please write down everything you eat and drink for 3 typical days. Try to include at least one weekend day - Saturday or Sunday.
2. Record this in the column marked FOOD and BEVERAGES.
3. Record only amounts EATEN, not amount served.
4. Record the brand name and method of cooking in the "METHOD OF PREPARATION / BRAND NAME" column.
5. Under 'AMOUNT', record in 'teaspoons', 'cups', or fractions of these. You may use 'slices' or 'pieces' when necessary. If something eaten has a specific measurement on the label, record that amount. For example: Coke - 12 ounce can, Hershey bar 1.45 ounces.
6. It is important to remember the following while recording different types of food:

Milk: State if whole, skim, fortified, powdered, liquid, evaporated, or chocolate

Liquids: Record amount of milk and all beverages in 'cups' or 'ounces'.

Bread: Specify white, rye, whole wheat, raisin, etc.

Meats: Give the length, width and thickness of the portion, or its weight in 'ounces' after cooking.

Cereals, rice, and pasta: Record amount of cereals, rice, and pasta in 'cups' or fractions of cup. Do not record in 'BOWLS'. List anything added e.g. fruit, sugar

Fruits and Vegetables: Specify, fresh, frozen, canned, dried, or freeze dried.

Condiments: Record any jelly, butter, ketchup, mayonnaise or seasonings added.

Canned foods: Record what food is packed in – oil, water, syrup, etc.

Again, If you have any questions, please send me an email at wadswdd@auburn.edu or call 334-844-1836. I will be more than happy to answer your questions.

Danielle

24 Hour Diet Recall

Subject #: _____ Date: _____

Day of the week: Monday Tuesday Wednesday Thursday Friday Saturday Sunday

Does this day represent your typical eating habits? Yes No

Please be as specific and honest as possible for review with the Registered Dietitian. Thank you.

Day 1

Time	FOOD/BEVERAGES	Method of Preparation - (baked, fried, boiled, canned etc.) Brand Name	Amount/Serving Size

Day 2 24 Hour Diet Recall

Day of the week: Monday Tuesday Wednesday Thursday Friday Saturday Sunday
Does this day represent your typical eating habits? Yes No

Time	FOOD/BEVERAGES	Method of Preparation - (baked, fried, boiled, canned etc.) Brand Name	Amount/Serving Size

Day 3 24 Hour Diet Recall

Day of the week: Monday Tuesday Wednesday Thursday Friday Saturday Sunday

Does this day represent your typical eating habits? Yes No

Time	FOOD/BEVERAGES	Method of Preparation - (baked, fried, boiled, canned etc.) Brand Name	Amount/Serving Size

APPENDIX F: DATA COLLECTION SHEET

Data Collection Sheets

Subject #:			
Height:		Weight:	
Lifts:			
Bench Press:	Previous Max:	Warm-up set:	
1.	2.	3.	4.
Squat:	Previous Max:	Warm-up set:	
1.	2.	3.	4.
Treadmill:			
	Stage 1 HR:	Stage 2 HR:	Stage 3 HR:
	Stage 4 HR:	Stage 5 HR:	
	Treadmill Time:	Estimated VO2	
Blood:	Completed Date:		
DEXA:	Completed Date:		
Paperwork	Completed Date:		
Accelerometer	Completed Date:		
Blood Flow:	Completed Date:		
Nutrition:	Completed Date:		

The Auburn University Institutional
 Review Board has approved this
 Document for use from
09/24/18 to 08/14/2019
 Protocol # 18-323 AR 1809

Data Collection Worksheet

Day 1

Subject #		Date:
Cell Phone:	Cell Phone Provider:	E-mail:
DOB:	Height:	Weight:
Hydration:	iDexa	VO2:

	Date
Back Squat	
Bench Press	
Row	
Overhead Press	
Blood:	Completed Date:
DEXA:	Completed Date:
Paperwork	Completed Date:
Accelerometer	Completed Date:
Blood Flow:	Completed Date:
Nutrition:	Completed Date:

The Auburn University Institutional Review Board has approved this Document for use from 09/24/18 to 08/14/2019 Protocol # 18-323 AR 1809

APPENDIX G: ACCELEROMETER DATA COLLECTION

Subject# _____

Activity and Accelerometer Log

Device and Activity Log

Wear the devices for seven (7) consecutive days. If you are unable to wear the device for seven (7) consecutive days, add additional days at the end of the week. Please fill out the log daily. An example entry is provided. If you take the accelerometer off for more than 5 minutes, such as showering, record when you take it off and put it back on, and any activity you performed while not wearing.

Questions? Just call or text: 334-844-1836 or email: wadswdd@auburn.edu

Example	Time On:	Time Off:	Activity while not wearing:	Location:
	6:00 am	7:00 am	Showered and changed after walking in a.m.	Home
	7:30	9:30 pm		
Exercise performed: walked				

Day 1	Time On:	Time Off:	Activity while not wearing:	Location:
Exercise performed:				

Day 2	Time On:	Time Off:	Activity while not wearing:	Location:
Exercise performed:				

Day 3	Time On:	Time Off:	Activity while not wearing:	Location:
Exercise performed:				

Day 4	Time On:	Time Off:	Activity while not wearing:	Location:
Exercise performed:				

Day 5	Time On:	Time Off:	Activity while not wearing:	Location:
	Exercise performed:			

Day 6	Time On:	Time Off:	Activity while not wearing:	Location:
	Exercise performed:			

Day 7	Time On:	Time Off:	Activity while not wearing:	Location:
	Exercise performed:			