EFFECT OF MENTOR-LED VIGOROUS AEROBIC EXERCISE PROGRAM ON BODY COMPOSITION, PEAK VO_2, AND INSULIN SENSITIVITY IN OVERWEIGHT AND OBESE ADOLESCENTS

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In the past few decades obesity rates in the US have reached epidemic proportions in both adults and children. Nearly one-third of American adults are obese, and since 1980, the obesity rates for children 6-11 years and 12-19 have nearly tripled (Centers for Disease Control and Prevention, 2012). Obesity in adults and children is associated with abnormal lipid profiles, insulin resistance and low cardiorespiratory endurance (CRE). The link between disease risk and low CRE has been well established in adults and to a lesser extent in children and adolescents. The **PURPOSE** of this study was to evaluate the effect of a mentor-led vigorous aerobic exercise program on insulin resistance, body composition, and peak VO_2 in overweight and obese adolescents. **METHODS** Subjects (n=23) for the study were randomly assigned to two groups. Eleven participants were assigned exercise mentors and exercised approximately three times per week for 45 to 60 minutes each session. An additional 12 adolescents were randomly assigned to a control group. Body composition, Peak VO_2, and HOMA-IR levels were assessed at pre-, post-, and follow-up testing. A 2 (control vs. experimental) x 3 (pre-, post-, follow-up) repeated measures analyzes of variance (ANOVA) was used to analyze the data using the MANOVA procedure in JMP®. **RESULTS** No significant intervention effect was observed for body

composition measures. Significant effects were observed in Peak VO_2max (p = 0.0066) and total treadmill time (p = 0.0116). In the experimental group, effect size, measured by Cohen's d, showed a high effect size (d = 0.88) for Peak VO_2max from pre to post test and a moderate decrease in effect size (d = -0.44) from post to follow-up. Similar findings were shown with total treadmill time with a small positive effect size from pre to post (d = 0.29) and a small decrease from post to follow-up (d = -0.33). No significant between group differences were found in HOMA-IR. However, the intervention group's HOMA-IR, improved between baseline and post testing period. The current findings show that independent of weight loss and change in body composition, positive changes in fitness were significantly different from the control group, and the fitness improvements were maintained throughout the duration of the study. Insulin resistance improved for the experimental group from baseline to post testing and was maintained over the 12 week non-intervention follow-up period. **CONCLUSION** A mentor-led exercise intervention does have potential to be effective at increasing health outcomes independent of weight loss, which can be sustainable after the cessation of the program.

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CHAPTER 1: INTRODUCTION

Over the past 30 years, obesity rates have more than tripled in the United States. One in every three adults is obese (Ogden, Carroll, McDowell, & Flegal, 2007) and almost 20% of our youth between the ages of 6 and 19 is obese (Ogden, Carroll, & Flegal, 2008). Since 1980, the obesity rate for children 6-11 years and 12-19 years has increased from 7%-20% and 5%-18%, respectively (Centers for Disease Control and Prevention, 2012). Childhood obesity tracks into adulthood as there is a 70% chance an obese adolescent will become overweight or obese as an adult. This percentage increases to 80% if the child has one or more parents who are overweight or obese (Surgeon General, 2012). Today, one-third of children and adolescents in the United States are at risk for developing weight-related health problems (Centers for Disease Control and Prevention, 2012).

Excess body weight is a risk for premature morbidity and mortality. Diseases once viewed as "diseases of aging" are now appearing in children: type 2 diabetes, dyslipidemia, hypertension, cardiovascular disease, sleep apnea, and orthopedic problems (Stoler, 2012). Type 2 diabetes mellitus (T2DM) is a common disease that tracks along with the obesity epidemic. Studies over the past years have noted that 80% of individuals with type 2 diabetes mellitus are either overweight or obese. With just an 11-18 pound weight gain, an individual increases his or her risk of developing T2DM increases to twice that of an individual who has not gained weight. (Surgeon General, 2012).

In the United States 1 in every 400 children and adolescents has type 2 diabetes mellitus (American Diabetes Association, 2012). And while excess weight is associated with increased diabetes risk, a sedentary lifestyle also predicts diabetes risk. Exercise is a proven intervention that improves the action of insulin thus affecting glucose levels. Exercise, independent of weight

loss, has shown to be an effective strategy for improved insulin sensitivity and diabetes avoidance (American Diabetes Association, 2012).

Cardiovascular disease (CVD) is another common health consequence of obesity. Having one or more of the following risk factors puts an individual at a higher risk for developing CVD. These risk factors include: age, family history, cigarette smoking, sedentary lifestyle, obesity, hypertension, dyslipidemia, and impaired fasting glucose (America College of Sports Medicine, 2014). Approximately 70% of obese children, ages 5-17 years, reportedly have at least one risk factor associated with CVD (Centers for Disease Control and Prevention, 2012).

A regular progressive exercise program increase cardiorespiratory fitness (VO_{2max}) in adolescents (Rynders et al, 2012). With improvements in VO_{2max}, other health related components such as blood glucose, insulin action, and body composition can improve lowering one's disease risk (Rynders et al, 2012).

According to a review conducted by Boutcher, high intensity exercise (70% of VO_{2max} or higher) has the potential to be a cost-effective and successful means for reducing fat mass in individuals. Recently a study involving overweight and obese children and adolescents evaluated the effects of high intensity exercise over an 8-week in-patient treatment program (Karner-Rezek et al, 2013). There was a decrease in percent fat for girls and boys and weight loss was mainly attributed to loss of fat mass. And while body fat levels can be influenced by higher intensities activities, in a review of literature described in the new edition of American College of Sports Medicine Guidelines, a positive dose-response relationship has been shown to lessen disease risk and improve (American College of Sports Medicine, 2014

Exercise is an important factor to consider when dealing with obesity in all ages. Vigorous exercise (> 60% of VO_2max) has been shown to increase health benefits more so than

lesser intensity exercise (< 60% of VO_2max). Physical activity interventions have been shown to benefit adolescents, however, recent studies have not explored vigorous intensity exercise (Rynders et al, 2012 & Shalitin et al, 2009).

A potential intervention method to help adolescents maintain vigorous intensity levels is a peer mentoring approach. According to Ricer, mentoring is "a personal process that combines role modeling, apprenticeship, and nurturing" (Ricer, 1998). In other words, a mentor is more experienced in training and helps to encourage and promote training for the less experienced mentee. It is suspected that with the implementation of a mentor in a vigorous aerobic exercise intervention positive outcomes should occur (Ricer, 1998).

Obesity is a universal problem. Obesity rates for children and adults have sky rocketed over the past three decades. Obesity is a risk factor for a variety of diseases and conditions. Weight loss is a practical intervention for health enhancement, unfortunately short and long term weight loss and maintenance, for many, is difficult. Exercise has long been promoted as an effective intervention to improve health outcome. Improvements in fitness, independent of weight loss, are associated with decreased mortality and morbidity (Rynders et al, 2012).

Statement of the Problem

The purpose of this study was to evaluate the effect of a mentor-led vigorous aerobic exercise program on insulin resistance, body composition, peak VO_2 in overweight and obese adolescents.

Research Hypotheses

Compared to a control group, a mentor-led vigorous aerobic exercise training will:

1.) Improve insulin resistance in overweight and obese adolescents.

2.) Promote the loss of fat mass and increase of lean body mass in overweight and obese adolescents.

3.) Lead to an increase in the fitness level, as determined by Peak VO_2 in overweight and obese adolescents.

4.) Increase the likelihood of adolescents maintaining exercise related improvements following the termination of the mentor-led program.

Delimitations

This study includes the following delimitations:

1.) Overweight and obese boys and girls between the age of 12 and 18 years.

2.) Participants able to participate in exercise sessions three times a week on days between Monday and Thursday.

3.) Participants do not have medical problems that would prohibit their active participation in a vigorous exercise training program.

Limitations

This study is limited by the following:

1.) While the protocol for the study was to have the adolescents exercise three times per week for 12 weeks, attendance to weekly sessions was determined by their parent/care givers willingness to get them to the FITT center for training.

2.) By the time of program implementation. Due to the university academic schedule, there were times (Thanksgiving, Christmas, spring break) when the mentors were not available to train the adolescents thus potentially impacting on the magnitude of change over time.

Definitions

For the purpose of this study, the following terms were defined:

Adolescent — period of adolescents is most associated with teenage years

Adult Obesity — If the individual's body mass index is ≥ 30.0 $kg \bullet m^{-2}$ they are classified as obese. Adult obesity is divided into three subcategories: Grade I (BMI of 30.0-34.9 $kg \bullet m^{-2}$), Grade II (BMI 35.0-39.9 $kg \bullet m^{-2}$), and Grade III (BMI ≥ 40 $kg \bullet m^{-2}$)

Adult Overweight — A BMI of 25.0-29.9 $kg \bullet m^{-2}$ generally classifies an individual as overweight in adults

Aerobic Exercise — Aerobic exercise is the capacity to exercise in aerobic activities for a prolonged period where the amount of activity depends on aerobic capacity and cardiorespiratory endurance (American College of Sports Medicine, 2009)

Blood Glucose — The amount of glucose in the bloodstream

Body Mass Index (BMI) — A ratio to calculate a person's weight relative to their height, by dividing the individuals weight in kilograms by their height in meters squared

Body Mass Index Z-score (BMI-Z) — Standardizes BMI for age and gender through Z-scores

Cardiovascular Disease (CVD) — Class of diseases that affect the heart or circulatory system (American College of Sports Medicine, 2014)

Childhood Obesity — If a child's BMI is at or above the 95th percentile for their same sex and age group they are classified as obese

Childhood Overweight — A child is considered overweight if their BMI is at or above the 85th percentile and below the 95th percentile for their specific age and sex group

Dual-energy X-ray absorptiometry (DXA) — A 3 compartment model for determining: fat, lean body, and bone mass

Exercise — Exercise is planned, structured, and repetitive bodily movement done to improve or maintain one or more physical fitness components (American College of Sports Medicine, 2014)

Fat mass — Adipose tissue

Insulin Resistance — A condition where the body produces insulin, but the action of the insulin has been attenuated causing a build up of glucose in the blood

Lean Body Mass (LBM) — The accumulation of everything in the body such as bones, organs, muscles, and skin, with the exception of fat

Percent Body Fat (% BF) — Adipose tissue devoid of bones, organs, muscle, and skin

Type 2 diabetes mellitus (T2DM) — Formerly called adult onset diabetes mellitus, the most common type of diabetes. In type 2 diabetes, either the body does not produce enough insulin or the cells ignore the insulin (American Diabetes Association, 2012)

Vigorous Exercise — Determined by an individual's percent of VO2 max to stay above 60%.

VO_2max — The maximal amount of oxygen consumed when an individual reaches maximal exercise capacity typically expressed in milliliters of oxygen consumed per kilogram of body weight per minutes (ml/kg/min)

VO_2 Peak — the greatest about of oxygen attained in a given test (American College of Sports Medicine, 2014)

Acronyms and Abbreviations

BMI — Body mass index

BMI Z-score — Body mass index Z-score

CHF — Congestive heart failure

CVD — Cardiovascular disease

DXA — Dual-Energy X-Ray Absorptiometry

I_S — Insulin sensitivity

LBM — Lean body mass

MANOVA — Multivariate analysis of variance

T2DM — Type 2 diabetes mellitus

CHAPTER 2: LITERATURE REVIEW

Research pertaining to obesity in children, adolescents, and adults was examined in this review. This chapter is divided into four sections: 1.) defining obesity in children and adults, 2.) the prevalence of obesity and health-related consequences associated with obesity, 3.) the effect of exercise training as it pertains to 3a.) body composition, 3b.) VO_2max, 3c.) insulin resistance, and 4.) the use of mentors to promote and encourage sustainable exercise related effects following the termination of the program.

Defining Obesity

Obesity is defined as an excessive accumulation of adipose tissue resulting from a chronic imbalance of energy intake and energy expenditure. There are several classifications to determine whether an individual is considered obese, overweight, normal, or underweight. Currently the most common method for establishing weight-related risk, for both children and adults, is body mass index (BMI) (Flegal, Tabak, & Ogden, 2006). Body mass index is a ratio that calculates a person's weight relative to their height by dividing their weight in kilograms by height in meters squared (Roche, Siervogel, Chumlea, & Webb, 1981).

To define overweight and obesity in adults (18+ years), the cutoffs are based on fixed BMI values related to health risks (National Institutes of Health, 1998). These values are standardized for ages 18+ and both sexes. A BMI of 25.0-29.9 kg• m^{-2} classifies an individual as overweight. If the individual's BMI is ≥ 30.0 kg•m^{-2} they are classified as obese. Adult obesity is further divided into three subcategories: Grade I (BMI of 30.0-34.9 kg• m^{-2}), Grade II (BMI 35.0-39.9 kg• m^{-2}), and Grade III (BMI ≥ 40.0 kg• m^{-2}).

When defining overweight and obesity in children, there are no risk-based fixed values of BMI. It is unclear as to what risk-related criteria are used with children (Flegal et al, 2006).

Instead, typically age and sex specific percentiles are used to classify children as underweight, normal, overweight, or obese. A child is considered overweight if their BMI is at or above the 85th percentile and below the 95th percentile for their specific age and sex group (Flegat et al, 2006). If BMI is at or above the 95th percentile for their same sex and age group the child is classified as obese. (Chen, Roberts & Barnard, 2006). Since children continue to grow, they cannot fit into the same BMI classifications scheme as adults. When the child's height is constantly increasing it results in a change in height to weight ratio. (Chinn, 2006).

To examine the changes in BMI over time BMI Z-scores are calculated. BMI Z-score standardizes BMI for age and gender through Z-scores. For every BMI that is calculated, a BMI Z-score can also be calculated. When comparing an individual's BMI at two time points, the lower the Z-score represents a decrease in BMI. If the BMI Z-score was higher when comparing two time points, it shows that there was an increase in BMI.

Prevalence and Health-Related Consequences Associated with Obesity

An epidemic that has more than tripled in the last 30 years, obesity continues to impact individuals of all ages. One in every three adults is obese (Ogden et al, 2007). For children between the ages of 6 and 19 years, almost 20% are obese (Ogden et al, 2008). According to the Surgeon General, overweight adolescents have a 70% chance at becoming overweight or obese as an adult. Obesity risk increases to 80% when both parents are overweight or obese. Today an astonishing one-third of children and adolescents in the United States are at risk for developing weight-related health problems (Centers for Disease Control and Prevention, 2012).

Previous studies have shown that being overweight or obese as a child or adolescent predicts adult morbidity and mortality risk (Himes & Dietz, 1994). Diseases that have been viewed as "diseases of aging" are now appearing in children: type 2 diabetes, high cholesterol,

hypertension, cardiovascular disease, sleep apnea, and orthopedic problems (Stoler, 2012). As an individual's weight increases it elevates their risk for health consequences and numerous diseases associated with obesity.

The Surgeon General states that with just an 11-18 pound weight gain, an individual's risk for developing type 2 diabetes mellitus (T2DM) increases to twice that of an individual who has not gained weight. T2DM is possibly the largest health burden associated with obesity (Bell et al, 2007). In the adult population worldwide, approximately 246 million people are affected by diabetes, which represents 7.1% of the world's adult population (Praet & van Loon, 2007). Data from the American Diabetes Association show about 1 in every 400 children and adolescents in the United States suffer from T2DM.

Type 2 diabetes mellitus, a disease that was previously thought to be found in adults only, is now increasing in children. T2DM is characterized by a combination of progressive pancreas beta-cell failure and severe insulin resistance (Savoye et al, 2007). The American Diabetes Association states that 22-25% of children and adolescents with severe obesity (BMI $\geq 99^{th}$ percentile) are prediabetic (Fasting Plasma Glucose 100 mg/dL to 125 mg/dL). The development of T2DM in children, like adults, is related to obesity (American Diabetes Association, 2012).

Not only is type 2 diabetes mellitus a major health burden associated with obesity, it is also associated with increased cardiovascular disease (CVD) risk. (Bell et al, 2007). One or more of the following risk factors put an individual at a higher risk for suffering from cardiovascular disease: increased blood pressure, high cholesterol, elevated triglycerides and a decreased HDL (Centers for Disease Control and Prevention, 2012). As the level of obesity in children increases, the number of risk factors for CVD also increases (Farris et al, 2011). The Centers for Disease Control and Prevention reports that an estimated 70% of obese 5-17 year olds have at least one

risk factor associated with CVD. High levels of BMI relative to an individual's age and sex are likely to result in multiple risk factors for CVD (Freedman, Mei, Srinivasan, Berenson, & Dietz, 2007).

According to Farris et al, obese children have a greater risk of developing adult CVD when compared to their normal weight peers. Though cardiovascular disease and type 2 diabetes mellitus are the most common health consequences associated with obesity, there are still several other diseases that affect these individuals (Farris et al, 2011).

Effects of Exercise

A.) Body Composition

Exercise is defined as planned, structured, and repetitive bodily movements done to improve or maintain one or more physical fitness components (American College of Sports Medicine, 2014). Troiano et al. found that only 8% of youth, age 12-19 years old meet the physical activity recommendation of 60 or more minutes a day of either moderate- or vigorous-intensity aerobic physical activity. Older male children spend less than 20 minutes per day in structured physical activity of moderate or greater intensity and for older females less than 10 minutes per day is accumulated (Troiano et al, 2008).

The relationship between low levels of physical activity and obesity has been firmly established (Shalitin et al, 2008, Rynders et al, 2012, & Watts, Jones, Davis, & Green, 2005). Farris et al, conducted a twelve-week interdisciplinary intervention program for obese children. The interdisciplinary program was composed of specialists from medicine, exercise and fitness, physical therapy, and nutrition. Subjects were 6-12 year of age and had a BMI greater than the 95th percentile. Individuals were divided into two groups. The exercise intervention consisted of participation in 2 days per week of one-hour sessions of exercise and activities that were led by a

certified personal trainer. Exercise sessions consisted of a brief warm up, resistance exercises, floor exercises, aerobic activity, and ended with stretching exercises. On a 10 point scale, children were encouraged to exercise between a 6 and 7. BMI, waist circumference, skin-fold, and percent fat all showed a significant decrease between pre- and post-intervention. BMI values at preintervention and postintervention were 30.31±4.56 and 27.80±4.54 respectively, with a p value of < 0.001. BMI Z-score values at preintervention and postintervention were 2.65±0.27 and 2.39±0.39 with a p value of 0.026. Both variables showed a significant decrease from pretest to posttest. Based on these findings a positive intervention effect was found between body composition measures and a 12-week interdisciplinary intervention (Farris et al, 2011).

While changes in BMI are associated with positive health outcomes in adults and youth, BMI alone does not provide specific information relative to changes that can occur with exercise such as decreases in fat mass and increases lean body mass. To determine specific exercise induced changes, other assessment methods are needed. One relatively recent advancement is the use of dual-energy x-ray absorptiometry (DXA) in determining exercise induced body composition changes.

Several studies have evaluated whether exercise can improve body composition in children ages 7-16 years old. Ferguson et al noted that fat-free mass increased significantly ($p < 0.05$) as well as showed a significant decrease ($p < 0.05$) in percent body fat in the exercise group versus the control group. This four-month study consisted of 43 children, from 7-11 years of age, who were approximately at the 85th percentile for BMI. The exercise portion of the study consisted of five days per week of 40 minutes of aerobic exercise (heart rate greater than 150 beats per minute) (Ferguson et al, 1999). Gutin et al examined a similar study design. Twelve obese boys and 23 obese girls, age 7-11 years participated in a four-month long study. Gutin and

colleagues had similar finds as Ferguson and colleagues, which showed a decrease in percent body fat. At baseline percent fat was 47.2 for the experimental group, following the intervention fat levels digressed by 4.1% (Gutin, Owens, Slavens, Riggs, & Treiber, 1997).

Owens et al observed a decrease in percent body fat, fat mass, and subcutaneous abdominal adipose tissue, as well as an increase in fat-free mass in the exercise group. The study involved, 74 obese children, 7-11 years of age. Subjects were randomly assigned into a physical training group or control group. The exercise group's program consisted of 4-months of aerobic exercise, five days per week, for 40 minutes. Intensity was to be held between 70%-75% of the individual's maximal heart rate (Owens et al, 1999).

The above three studies show an intervention effect between vigorous aerobic exercise and a decrease in body composition measures. Though a relationship between exercise and body composition has been made, it is still unclear as to which exercise intensity, duration, and type will produce the greatest positive effects.

The previous studies have primarily focused on children, few studies have evaluated exercise-induced changes in adolescents. More studies need to be conducted to examine the changes in this age group. If an adolescent is obese, the trend tends to track into adulthood. Because of this, the age group preceding adulthood needs to be focused on since the majority of research lies in adult and childhood obesity.

B.) VO_2max

Maximal oxygen consumption (VO_2max) is a measure of cardiorespiratory fitness, which is a strong predictor of CVD risk in both children and adults (Rynders et al, 2012). Few studies have examined an intervention and its effects on VO_2max in adolescents (Rynders et al, 2012). A test designed to allow the exerciser to reach his or her maximum level of cardiovascular and

muscle fatigue is known as exercise testing (Calzolari & Pastore, 1999). Exercise tests can be administered on various machines. Typical assessment methods include: treadmills, cycle ergometer or arm ergometer. Obtaining a maximal effort for children and adolescents can be difficult. The most reliable results can be obtained when using a treadmill for youth, Calzolari and Pastore found that children tend to stop making a maximal effort too early on the cycle ergometer because their legs become tired (Calzolari & Pastore, 1999).

A study conducted by Rynders et al, found that moderate to vigorous intensities of exercise effectively improved aerobic fitness, independent of weight loss in adolescents. Subjects completed a VO_2max protocol on a bicycle ergometer at baseline testing and at post testing. There were no differences between diet and exercise and diet, exercise, and metformin as far as markers for diabetes. Consequently, exercise and diet education were as effective as the metformin group. (Rynders et al, 2012).

According to the National Health and Nutrition Examination Survey data, VO_2max is lower in overweight and obese adolescents when compared to their lean counterparts. A study examined improvements of early vascular changes and its impact of cardiovascular risk factors (Meyer, Kundt, Lenschow, Schuff-Werner, & Kienast, 2006). Meyer et al found that after 6 months of an exercise intervention in obese adolescents, vascular changes improved significantly. Improvements in CVD risk factors were also shown. Exercise intensity was not noted, however, there was an increase exercise intensity as the individual could tolerate it (Meyer et al, 2006).

Studies indicate that an increase in fatness in overweight adolescents may predict elevated health-risk and increase adult mortality (Himes & Dietz, 1994). A higher VO_2max is associated with lower risks for cardiovascular disease development, however, few studies have

examined VO_2max in obese adolescents as is pertains to an exercise intervention (Eisenmann, Welk, Ihmels, & Dollman, 2007). And there are limited studies that focus on aerobic exercise improvements and clinical outcomes in adolescents (Rynders et al, 2012).

C.) Insulin Resistance

One of the most prevalent diseases associated obesity is type 2 diabetes mellitus. An individual's pancreas produces insulin to be used by the skeletal muscle; however, the body becomes resistant to insulin and is less effective at using insulin in the body. Since muscle needs glucose, the pancreas continues to produce more insulin to transport glucose from the bloodstream, which in turn creates an abundance of insulin. This is known as insulin resistance. Insulin resistance precedes the development of T2DM, which results in high insulin levels and a gradual development of impaired glucose tolerance (Whitelaw & Gilbey, 1998). Since populations at risk for T2DM are now well established, an increase in physical activity levels can prevent or delay the progression toward type 2 diabetes mellitus (Praet & van Loon, 2007).

Past studies have examined the effect of exercise and diet on insulin resistance in obesity, however few have focused on exercise alone, especially in adolescents. A recent study investigated if exercise alone reduces insulin resistance in obese children independent of change in body composition (Bell et al, 2007). Obese individuals, age 9-11 who had high fasting insulin levels participated in the study. The exercise intervention consisted of 8 weeks of circuit training, which lasted 1 hour. Subjects exercised three days per week. A euglycemic-hyperinsulinemic clamp test was performed on each subject. Fasting insulin and glucose samplings were taken at baseline and end of intervention. Bell and team noted no significant difference in weight, BMI, or percent fat over the 8 weeks. Insulin resistance improved after the 8-week intervention conduced. There was no significant interaction found between a decrease in insulin resistance

and gender, age, improvement in fitness, change in weight or BMI. This study concluded that insulin resistance in obese children improved with exercise independent of change in weight, fitness, and body composition (Bell et al, 2007).

Praet and van Loon conducted a review of therapeutic benefits of exercise in type 2 diabetes in the adult population and concluded that endurance-type exercise, 3-5 days per week reduces insulin resistance. It was found that more vigorous intensity exercise would further improve insulin resistance and enhance cardiorespiratory fitness (Praet & van Loon, 2007). High-intensity interval training (HIT), consisting of brief repeated burst of relatively intense exercise separated by periods of recovery, was examined as a way to decrease insulin resistance (Gillen et al, 2012). In this study Gillen and colleagues concluded that a single session of low-volume high-intensity interval training totaling only 10 minutes, reduced hyperglycemia in adult patients with T2DM.

A dose-response relationship was observed in a randomized control trial in obese children 7-11 years old to note the effect of an aerobic training program on insulin resistance (Davis et al, 2012). Subjects were divided into two groups, the high-dose exercise group were offered two 20-minute exercise bouts each day after school and the low-dose exercise group were offered one 20-minute exercise bout and then taken into another room for 20 minutes of sedentary time. Davis and team noted a significant downward trend across fasting insulin levels, but no significant effect of exercise was detected for the secondary outcome of fasting glucose in both groups. Like the previous two studies, the high-dose exercise intervention demonstrated a significant benefit in response to the oral glucose tolerance test relative to insulin resistance (Davis et al, 2012).

A review study showed significant evidence that exercise training of 30-60 minutes of

moderate intensity exercise 5-7 days per week is an effective intervention for those at high risk for the development of T2DM (Bird & Hawley, 2012). Because we know how crucial it is to improve insulin resistance in obese adolescents, appropriate exercise interventions need to be established. Exercise training has a positive impact on insulin resistance, glucose disposal, and insulin secretion in normal glucose-tolerant subject, which leads us to believe that exercise can have a beneficial impact on insulin resistance in obese individuals (O'Gorman & Krook, 2011).

Previous studies have been done to examine what intensity, duration and type of exercise are needed to achieve substantial benefits in improving insulin resistance in obese individuals. The majority of the studies are conducted in healthy weight and obese adults and children (Manson et al, 1991, Manson et al, 1992, & O' Gorman & Krook, 2011). There is a lack of studies in the adolescent age group.

Use of Mentors to Promote and Encourage Sustainable Exercise Related Effects

Previous studies have shown increased health benefits with the adoption of vigorous intensity exercise. In order to promote and encourage sustainable exercise related effects from vigorous exercise a mentor-led intervention might provide the necessary motivation to help adolescents achieve exercise success.

Successful mentoring is characterized by long-term relationships that provide support, knowledge, and facilitate success for the mentee (Selwa, 2003). Smith conducted a pilot study using teen mentors to help promote physical activity and a healthy diet among children. About 100 third and fourth graders participated in an after-school program. The program was designed to help increase and promote awareness of healthy eating and physical activity by the way of physical activity games and discussion based learning and information. Smith concluded that teen mentoring for children was an effective means to increase knowledge, attitude, and decrease

BMI (Smith, 2011).

There are other studies that involve adults and the use of peer mentors for physical activity. A study conducted by Dorgo et al, showed high participation and retention rate, as well as an increase in fitness scores when using peer mentors. Eighty-eight older adults (60+) participated in a 14-week exercise training program. Fitness tests were assessed pre- and post- and showed a significant increase in post-testing (Dorgo, King, Bader, & Limon, 2013). From this study it was concluded that because older adults lack exercise guidance and social support that prevent physical activity, the implementation of a peer mentor was beneficial to exercise success (Dorgo et al, 2013).

The literature shows that mentor-led exercise programs do indeed work and are beneficial to the individual. However, there is a lack of research examining the effects on overweight and obese adolescents and how they response to mentor-led interventions. A conclusion can be drawn from the previous studies that if children and adults both had success using a mentor, then adolescents should experience the same success.

Summary

Substantial evidence has been provided as an insight to the epidemic of obesity, especially pertaining to children. The rate of obesity continues to escalate not only nationally, but also worldwide. New labor saving technology devices, energy-dense foods with low nutritional value, an increase in a sedentary lifestyle, and lack of physical activity all contribute to an increase risk for becoming overweight and obese. Evidence suggests that non-physically active children are more likely to become sedentary adults (Watts et al, 2005). The likelihood of an overweight or obese youth or adolescent becoming obese adults has been well documented (Surgeon General, 2012). Therefore it is imperative to develop creative intervention programs

aimed directly at adolescents to help prevent and decrease the risk for developing obesity as well as attenuating obesity co-morbidities.

Previous obesity-centered research has focused primarily on children and adults. Studies targeting adolescents are rare. Of those programs that have targeted adolescents, weight loss and health improvement results are inconclusive. While it appears exercise intervention can promote positive health outcomes, it is difficult for groups (adults, adolescents, and children) to achieve sustainable exercise-related health improvements. The use of exercise mentors appears to have merit in providing exercise success in the short and long term for adults, adolescents, and children.

CHAPTER 3: METHODS

Participants

Participants in this study were 23 overweight and obese adolescents, ranging from 12-18 years of age. The participants were above the 85th percentile for BMI relative to their age and sex. Subjects were excluded from the study if they had any physical disabilities or medical conditions determined by a physician that would prohibit them from participating in a mentor led vigorous exercise training program. The East Carolina University Institutional Review Board approved this project for use of human participants.

Procedures

Recruitment and Screening

Participants were recruited through various strategies. Subjects were obtained by sending an electronic email via East Carolina University's email server, advertisements placed in the local Pitt County newspaper, and personal recruitment at local pediatric offices. Following study recruitment, a telephone screening took place. The subject's height, weight, age, gender, BMI, medical history, and current medications were recorded. The subject was included if all inclusion criteria was met, however, subjects were eliminated if they met any of the exclusion criteria. Following a meeting time was set up for the parent or legal guardian and adolescent to come into the FITT building if the adolescent was interested in study participation. A medical history form, informed consent, and assent forms were completed. An initial baseline testing date and meeting time was discussed and agreed upon by both the parent or guardian and the adolescent.

Baseline Testing

Participants came in during a scheduled date and time to perform a series of baseline tests. The tests performed were: height, weight, DXA, insulin profiles, VO_2max treadmill test

and physical activity assessment. Following a 12-hour fast, blood samples were obtained to determine insulin and glucose levels. On the next scheduled date, the other tests were performed. Adolescents were instructed to fill out a DXA questionnaire prior to their scan and reminded that a small dose of radiation exposure was associated with the procedure. Participants then had their resting blood pressures and heart rates taken and recorded. Prior to the beginning of the VO_2max treadmill test, subjects were familiarized with the equipment and testing protocol. Each participant received an accelerometer to use for a week to determine his or her baseline physical activity.

Once baseline tests were completed, participants were assigned to a mentor based on the compatibility of availability for exercise. After following a 3-week ramping period, subjects exercised three days a week, for 45-60 minutes, at an intensity of 70-85% peak VO_2max, which was determined after the treadmill test was completed. Heart rates were monitored, maintained, and recorded by having the subjects wear a Polar T31 heart rate monitor and watch throughout each exercise session.

Training Program

The intervention program included 11 adolescents, 12-17 years of age with a BMI greater than the 85th percentile relative age and sex. After baseline testing was completed, the 12-week exercise intervention began. A ramp protocol was used during the first three weeks to allow for subjects to work up to maintaining intensity between 70% and 85% of peak VO_2. Because participants may have not been used to exercising for 45-60 minutes at a vigorous intensity, the ramp protocol allowed the subjects to gradually increase their intensity. This helped to keep participants from wanting to stop in the beginning weeks because they weren't used to high intensity exercise. For the first week, subjects exercised between 50%-55% of peak VO_2max.

The second week intensity was set for 55%-60% of peak VO_2 and the third week 60%-65% of peak VO_2. Starting on week four, subjects participated in 45-60 minutes of aerobic training at 70%-85% peak VO_2. After the first three weeks were complete intensity stayed between the previously stated intensity for the duration (9 weeks) of the intervention.

During the 12-week intervention, subjects participated in three exercise sessions per week, lasting approximately one hour in duration. The hour session consisted of a 5 to 7-minute warm-up, 45 minutes of aerobic training, and 5 to 7- minute cool down. Dynamic stretches and moderate activity exercise such as jumping jacks, brisk walking, and light biking made up the warm-up portion of the exercise session. The 45-minute aerobic training session included activities such as running, biking, elliptical, soccer, basketball, tennis, racquetball, and other various outside games. In order to maintain the intensity through down time during games, a variety of games and activities were used to keep heart rates at prescribed levels. When switching between different activities throughout the 45-minute session, subjects were instructed and encouraged to race their mentor, jump rope, play tag, or other various activities to keep their intensity level at 70-85%. Once the 45-minute aerobic training portion of the exercise session was concluded, subjects had the option to participate in various strength training exercises if interested. The 5-minute cool down session consisted of light dynamic stretches, static stretches, and walking or biking.

Mentor Training

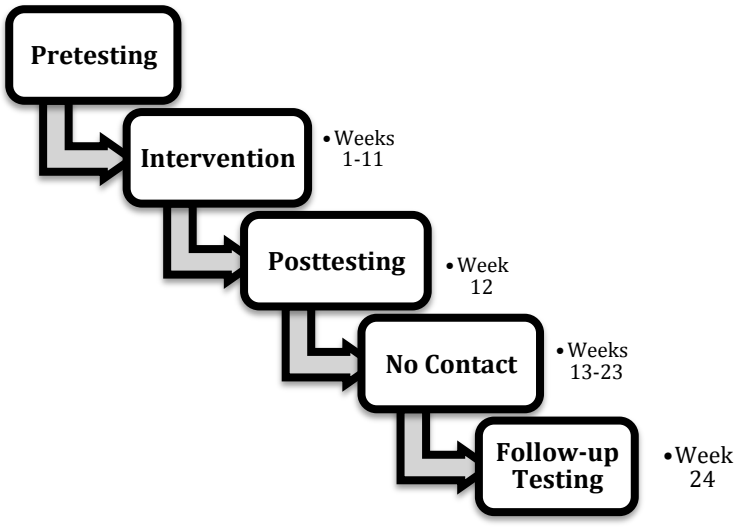
Mentors participated in a two-hour weekly training meeting. These meetings covered physical activity habits, motivational interviewing and behavioral strategies. Exercise physiology and exercise psychology graduate students conducted such meetings to help mentors better assist the participants they were paired with.

Design

Subjects who met the above criteria were randomly assigned to one of two groups: wait list control or experimental. Each participant in the intervention condition was assigned an exercise mentor. The mentor was responsible for training his/her mentee for approximately 12 weeks (spring semester of academic year). The adolescents, under the direction of their exercise mentor, met with their mentor three days per week for approximately one hour per exercise session. The control group did not receive any formal exercise training during the intervention program.

Both groups (control and experimental) were tested at pretest and approximately 12 weeks later for post-testing (end of spring semester). Both control and intervention groups had a 12-week no contact phase during the summer and both were brought back for follow-up testing. Outcomes measures included percent body fat assessed by Dual-Energy X-Ray Absorptiometry (DXA), insulin sensitivity using HOMA, and maximal oxygen uptake (VO_2max).

Figure 1. Outline of Major Time Points



Instrumentation and Measures

Each participant's height (meter), weight (kg), and BMI were determined while wearing typical exercise clothing, excluding shoes. Height was measured and recorded to the nearest .25 inch, using a Detecto™ scale that was attached to the wall. Each subject was instructed to stand with their backs against the wall without shoes. Using a calibrated medical scale, weight was measured and recorded to the nearest .1 lb. Subjects were instructed to take shoes off and step on the scale once zeroed. Pounds were converted to kilograms and inches were converted to meters in order to calculate BMI. BMI was determined using height and weight measures entered into the following calculation:

$$\text{BMI } (kg/m^2) = \frac{\text{weight in kilograms}}{\text{height in meters}^2}$$

Once BMI was calculated, BMI Z-score was calculated using the following website: http://stokes.chop.edu/web/zscore/.

Dual-Energy X-Ray Absorptiometry

Duel-Energy X-Ray Absorptiometry (DXA) measures bone density, fat mass, and fat free mass. These measurements were taken with a Lunar Prodigy Advance Dual Energy X-ray Absorptiometry, General Electric, Madison WI. DXA is associated with a small dose of radiation exposure. Subjects were required to complete a DXA questionnaire prior to the scan in the presence of a trained technician (Appendix C). The questionnaire helped the technician screen whether participants had any metal on or in their bodies that could potentially interfere with the scan. The back section of the questionnaire was to ensure female subjects were not pregnant.

Prior to using the DXA machine, a calibration was completed to ensure the machine would deliver a precise and accurate scan. Before the scan, the technician entered the subjects

weight, height, ethnicity, and gender into the software. Participants were instructed to lay inside the rectangular reference box. If the subject did not fit into the reference box, they were instructed to have the entire right side of their body in the box so the body could be duplicated for a total body scan. Subjects' ankles and legs were strapped together while hands and arms were placed as close to their sides as possible making sure not to overlap onto their body. Subjects were instructed to stay as still as possible during the scan. Typical scan time was 6-12 minutes. DXA is used as the primary way to determine body composition, due to its ability to show the smallest amount of change in total body fat that could result from the intervention.

Maximal Oxygen Consumption (VO_2max)

Subjects completed a maximal treadmill test to exhaustion to determine maximal oxygen consumption (VO_2max). Heart rate, rate of perceived exertion, and expired gases were monitored throughout the test. A TrueOne™ 2400 metabolic measuring system, Parvo Medics, Sandy UT was calibrated prior to testing according to the manufacturer's instructions. The calibration gas tank consisted of 16% oxygen, 4% carbon dioxide, and a nitrogen balance. A 3-liter syringe was used to calibrate flow rate and flow meter prior to each test. Height (in) and weight (lbs) was taken prior to start of the treadmill test in workout clothes, excluding shoes. Seated blood pressures and heart rates were also recorded.

A standard baseline treadmill protocol was established for all participants to ensure measurement accuracy (Appendix D). The speed started at 2.0 mph, with a grade of 0% and remained constant for the first two minutes. Starting at minute three, the grade was increased by two percent each minute and the speed remained at 3.0 mph until minute seven. At minute eight, speed was increased by .2 mph and 1% each minute until the subject could no longer exercise. Once the test was terminated, subjects continued to walk for five minutes at a zero percent grade

at 1.5 mph, recovery heart rates were assessed each minute.

Every minute the subject's heart rate was recorded, including the recovery stage using a Polar T31 heart rate monitor. Participants wore a heart rate monitor band, which was placed snug around their chest and a watch, which displayed heart rate. Fifteen seconds before each stage concluded, subjects were asked to point to the appropriate number on the rate of perceived exertion (RPE) scale. The scale is based on how the participant feels and ranges from 1 to 10; where 1 corresponds to no activity (example sitting on a couch) and 10 is to the point of exhaustion. During the test, subjects wore headgear that was designed to hold the mouthpiece in place. A nose clip was placed on the participant's nose to ensure no air was lost. Every 20 seconds, expired gases was collected and analyzed by the Parvo Medics TrueMax 2400 metabolic cart.

Subjects were instructed to continue exercising until exhaustion and maximal effort was achieved. To determine whether the participant achieved maximal effort, adolescents must meet at least two of the following criteria: a heart rate within 10-15 beats of the subject's age-predicted maximal heart rate (220-age), a rating of perceived exertion (1-10 scale) ≥ 8, a respiratory exchange ration > 1.10, or a point of leveling off of VO_2 (<50 ml/min) with increasing workload.

Blood Measures

Participants from both groups (control and experimental) came in for a pre-, post-, and follow-up blood draw. All subjects were instructed to fast for 12-hours prior to their appointment time. The only thing subjects were allowed to have during the fast was water to stay hydrated. Fasting status was determined prior to each blood draw. After the subjects' blood was drawn, the Uni Cel DxC 600i, Beckman Coulter (Indianapolis, IN) was used to determine fasting glucose

and fasting insulin levels. The homeostasis model assessment for insulin resistance (HOMA-IR) was used to estimate insulin action (QU, Li, Rentfro, Fisher-Hoch, & McCormick, 2011). HOMA-IR levels were calculated by multiplying fasting plasma insulin (FPI) by fasting plasma glucose (FPG), then dividing by the constant of 22.5 (HOMA-IR= (FPIxFPG)/22.5 (Wallace, Levy, & Matthew, 2004).

Statistical Analysis

A series of 2 (control vs. experimental) x 3 (pre-, post-, follow-up) repeated measures analyzes of variance (ANOVA) was used to analyze the data using the MANOVA procedure in JMP®. The MANOVA procedure was used to evaluate the difference between control vs. experimental and changes across the pre-, post-, and follow-up assessment on body composition, Peak VO_2max, and insulin resistance. In addition to significance testing, effect size, using Cohen's *d*, was used to evaluate the magnitude of change.

Chapter 4: Results

Descriptive statistics

At baseline, participants were randomly assigned to an experimental or control group. Dependent variables were assessed at three time points (Pre, Post, and Follow-up). Descriptive statistics for dependent variables (body composition, aerobic time, blood results) can be found in Tables 1 through 3 for experimental and control groups. An examination of the mean values of the variables indicated that the values varied across time and that the variability was related to group membership.

Table 1

Examination of Mean Scores and Standard Deviations for Body Composition Measures

	Experimental					
	Pre		Post		FU	
Variable	M	SD	M	SD	M	SD
BMI Z-score[a]	2.06	(.48)	1.93	(.48)	1.97	(.45)
DXA R%F[b]	42.39	(6.70)	40.79	(7.14)	42.12	(6.63)
DXA FM[c]	35.62	(10.33)	33.98	(9.90)	36.45	(10.03)
DXA FFM[d]	48.24	(13.78)	49.05	(13.13)	50.06	(13.66)
	Control					
	Pre		Post		FU	
Variable	M	SD	M	SD	M	SD
BMI Z-score[a]	2.30	(.33)	2.22	(.36)	2.28	(.39)
DXA R%F[b]	45.50	(5.92)	45.47	(6.14)	45.40	(5.46)
DXA FM[c]	44.31	(12.07)	46.75	(10.95)	46.27	(11.36)
DXA FFM[d]	51.91	(7.59)	54.52	(9.80)	55.18	(8.48)

[a]Body Mass Index Z score (BMI Z-score). [b]Dual energy X-ray absorptiometry regional percent body fat (DXA R%F). [c]Dual energy X-ray absorptiometry fat mass (DXA FM). [d]Dual energy X-ray absorptiometry fat free mass (DXA FFM).

Table 2

Examination of Mean Scores and Standard Deviations for Aerobic Capacity Measures

	Experimental					
	Pre		Post		FU	
Variable	M	SD	M	SD	M	SD
VO_2max[a]	27.20	(7.31)	33.41	(6.84)	30.42	(6.78)
TIME[b]	647.00	(115.99)	683.55	(132.39)	639.91	(130.10)
	Control					
	Pre		Post		FU	
Variable	M	SD	M	SD	M	SD
VO_2max[a]	24.47	(5.92)	24.15	(7.84)	22.96	(6.56)
TIME[b]	604.58	(120.33)	553.67	(103.71)	497.17	(93.59)

[a]Maximum Oxygen Consumption (VO_2max). [b]Total treadmill time (TIME).

Table 3

Examination of Mean Scores and Standard Deviations for Blood Measures

	Experimental					
	Pre		Post		FU	
Variable	M	SD	M	SD	M	SD
GLU[a]	86.10	(8.75)	84.10	(10.96)	87.25	(6.13)
INSUL[b]	20.91	(12.59)	17.92	(7.55)	17.63	(8.65)
HOMA-IR[c]	4.45	(2.58)	3.69	(1.60)	3.84	(1.90)
	Control					
	Pre		Post		FU	
Variable	M	SD	M	SD	M	SD
GLU[a]	79.82	(15.23)	79.00	(9.84)	87.67	(9.29)
INSUL[b]	15.26	(9.44)	16.88	(11.28)	22.17	(17.43)
HOMA-IR[c]	2.99	(1.79)	3.30	(2.22)	4.77	(3.56)

[a]Blood glucose (GLU). [b]Insulin (INSUL). [c]Homeostatic model assessment insulin resistances.

MANOVA Procedure

The response variables were analyzed individually using a MANOVA procedure to examine the effect of both between-subject (experimental and control) and within-subject (pretest, posttest, and follow-up) effects. The analyses were done using the MANOVA procedure because is does not require an assumption of sphericity. The assumption of sphericity is that the variances of differences between all possible pairs of groups are assumed equal. Univariate analyses were also calculated using subjects nested within groups as the source for the error term but are not reported because the results were almost identical to the results obtained from the

MANOVA procedure and because the univariate procedure has the additional assumption of sphericity. The data analysis was conducted using JMP 10®. The details of conducting the analysis and the assumptions of the statistical test are reviewed in Chapter 11 of Lehman, O'Rourke, Hatcher, and Stepanski (2013). The MANOVA technique can also be used to produce a univariate F test for the within-subject (time) variable but it was decided that using an exact F based on the MANOVA procedure was more appropriate.

Missing Data

Missing data are inevitable when dealing with human subjects. Equipment Malfunction and subject compliance issues occurred during the study. And while the amount of lost testing data was small, it was important to treat missing data conservatively. If a subject was missing pre test values, posttest values were substituted. For missing posttest values, pre test values were substituted. If follow-up testing values were missing, post testing values were substituted.

Body Composition Measures

BMI Z-score, regional percent fat, fat free mass, and fat mass were all examined using the MANOVA procedure to examine group effect, time effect, and time by group effect. BMI Z-score showed significance in time ($p = 0.0028$), however, the interaction between groups ($p = 0.1164$) and group over time ($p = 0.6658$) was not significant (See Table 4). The experimental group started at a lower BMI Z-score than the control group, which can be seen in Figure 2. Both groups stayed consistent with BMI Z-score over time.

Table 4

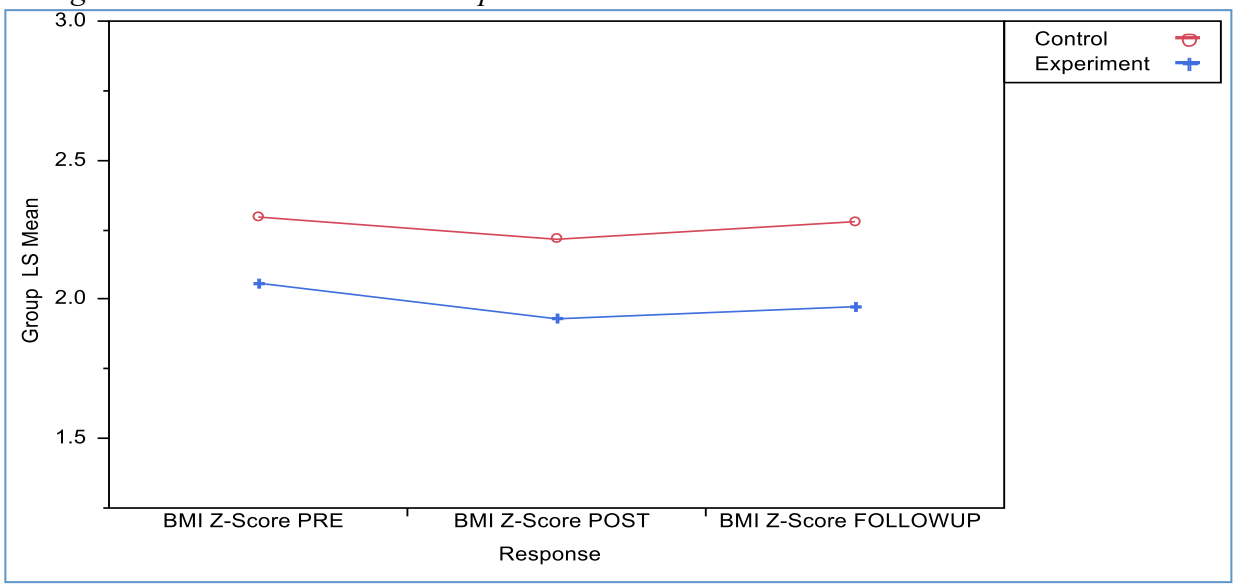
MANOVA procedure for BMI Z-score

Test	Exact F	*DF*	*p*
Group	2.681	21	.1164
Time	7.997	20	.0028*
Time X Group	.415	20	.6658

*Significance in time ($p < .05$) but interaction not significant.

Figure 2

Changes in BMI Z-score across time points



To examine meaningfulness of change from pretest to posttest and posttest to follow-up throughout the intervention, Cohen's *d* was calculated (see Table 5). As a rule of thumb, <.3 is a small effect, .5 is a moderate effect, and >.8 is a large effect. Inspection of mean scores at pre and post testing for BMI Z-score revealed effect sizes of -.27 and -.23 for experimental group, and control groups, respectively. To examine whether the intervention effects were maintained over the no contact phase, effect sizes were also measured. The experimental and control group both groups had an effect size of close to 0.00, which indicates no effect. When looking from pre to post and post to follow-up it is apparent that the decrease in BMI Z-score was maintained over time (see Table 5).

Table 5

Comparison of Body Composition Measures Effect Sizes (Cohen's d) between Groups

	Experimental			Control		
	Pre	Post		Pre	Post	
Variable	M	M	*d*	M	M	*d*
BMI Z-score[a]	2.06	1.93	-.27	2.30	2.22	-.23
DXA R%F[b]	42.39	40.79	-.23	45.50	45.47	-0.005
DXA FM[c]	35.62	33.98	-.16	44.31	46.75	.21
DXA FFM[d]	48.24	49.05	.06	51.91	54.52	.30
	Experimental			Control		
	Post	Follow-up		Post	Follow-up	
Variable	M	M	*d*	M	M	*d*
BMI Z-score[a]	1.93	1.97	.09	2.22	2.28	.16
DXA R%F[b]	40.79	42.12	.19	45.47	45.40	-.01
DXA FM[c]	33.98	36.45	.25	46.75	46.27	-.04
DXA FFM[d]	49.05	50.06	.08	54.52	55.18	.07

[a]Body Mass Index Z score (BMI Z-score). [b]Dual energy X-ray absorptiometry regional percent body fat (DXA R%F). [c]Dual energy X-ray absorptiometry fat mass (DXA FM). [d]Dual energy X-ray absorptiometry fat free mass (DXA FFM).

Other measures of body composition include the three measures obtained from DXA, which are regional percent fat, fat free mass, and fat mass. No significant difference was found in any of the three tests examining regional percent fat (Figure 3). Since significant differences were not found in regional percent fat; examining fat free mass and fat mass gave a better indication of changes in body composition.

Figure 3

Changes in Regional Percent Fat across time points

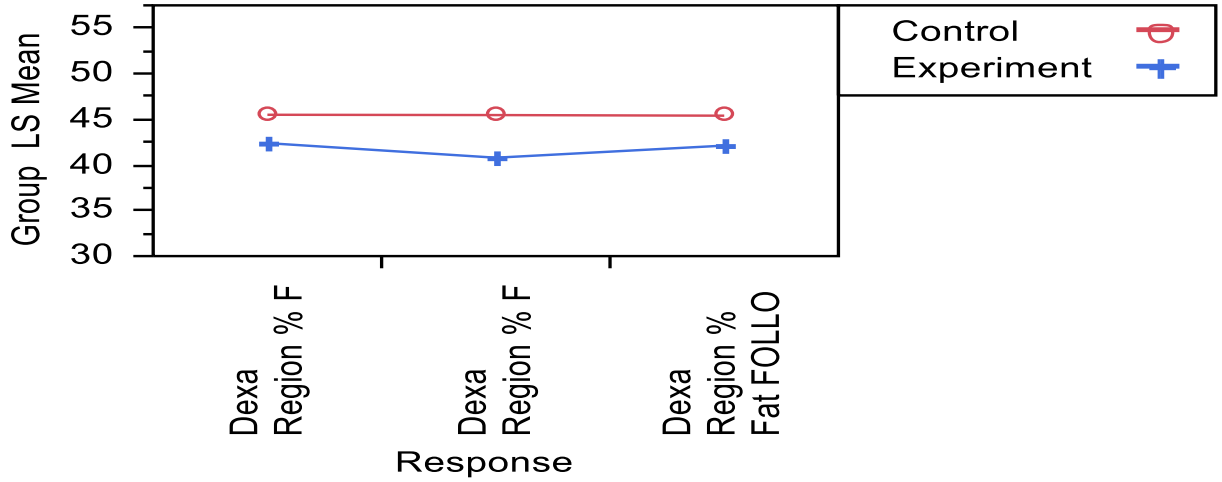


Table 6 shows a significant effect across time (p = .0066) for fat free mass, however the effect was similar for both groups (See Figure 4). The experimental group showed a slight increase from pretesting to post testing and they continued to increase from post to follow-up testing. The control also increased from pre to post testing, however plateaued at when values were assessed at follow-up. An increase in fat free mass is a positive interaction over time.

Table 6

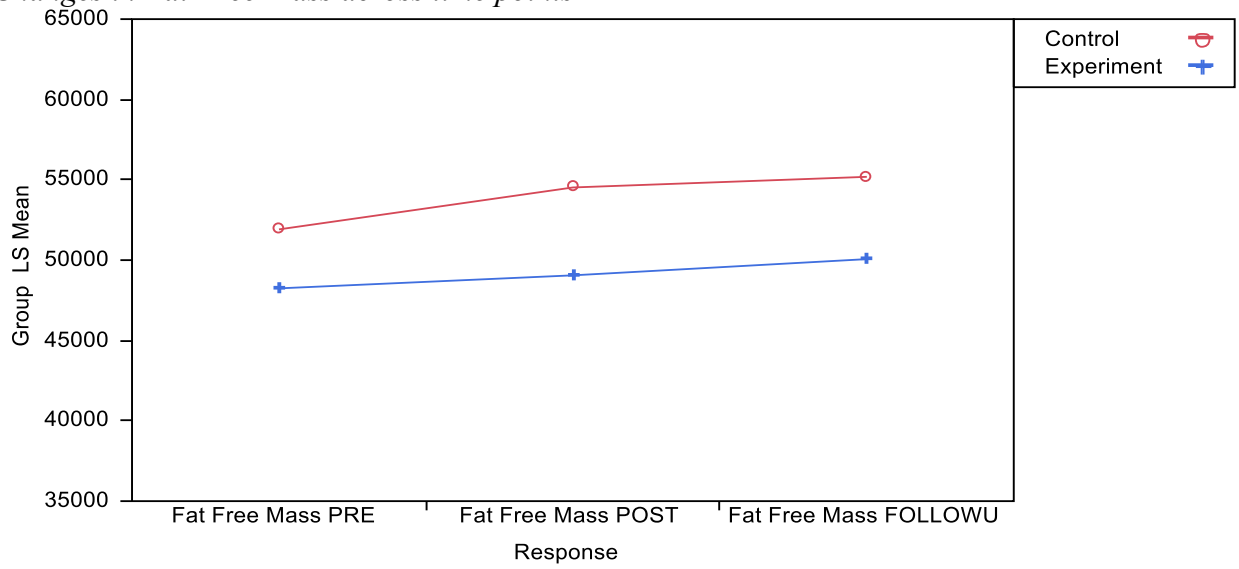
MANOVA procedure for Fat Free Mass

Test	Exact F	*DF*	*p*
Group	1.0602	21	.3149
Time	6.5107	20	.0066*[a]
Time X Group	.7192	20	.4993

*Significant change across time (p < .05) [a]but similar for both groups.

Figure 4

Changes in Fat Free Mass across time points



A significant interaction was found in fat mass between groups (p =0.0296) and groups over time periods (p = 0.0182), however there was no treatment effect was observed (p = 0.0709) (See Table 7). A decrease in fat mass over time would show that there was a positive treatment effect for this variable. As with in BMI Z-score and fat free mass, fat mass was lower to start with in the experimental group (See Figure 5). Cohen's d was calculated to assess effect size in the

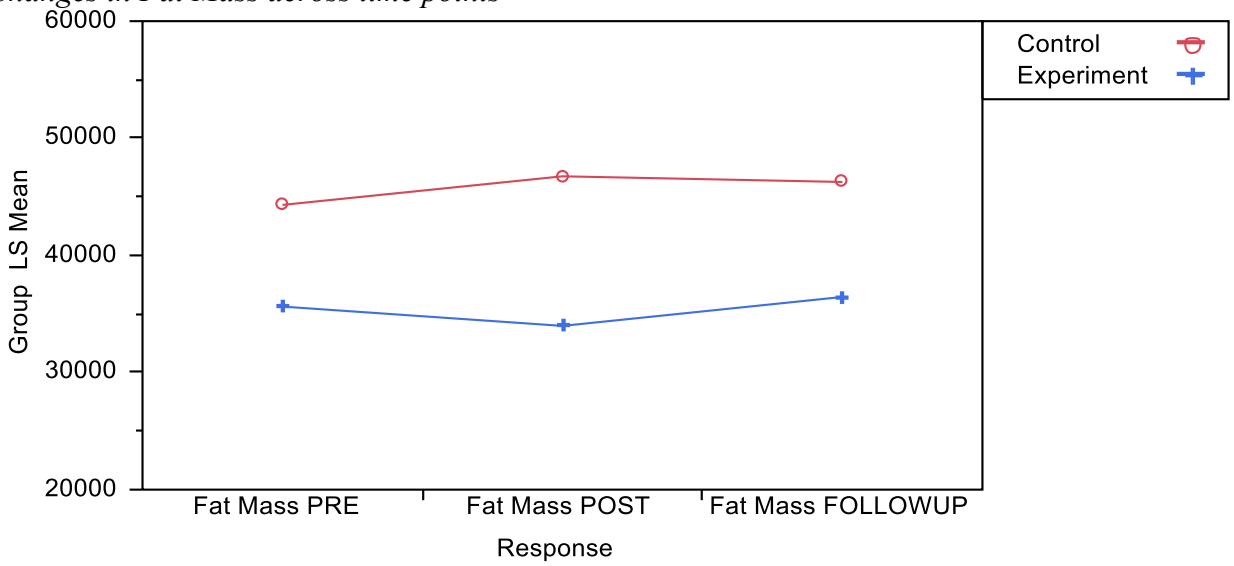
DXA measurements. In the experimental group, a decrease in DXA regional percent fat and fat mass was found from pre to post test (see Table 5). To evaluate whether maintenance was obtained from post to follow-up testing, Table 5 shows the experimental group returned back to baseline values.

Table 7
MANOVA procedure for Fat Mass

Test	Exact F	*DF*	*p*
Group	5.4478	21	.0296*
Time	3.0305	20	.0709
Time X Group	4.9253	20	.0182*

*Significant interaction ($p < .05$) but no treatment effect.

Figure 5
Changes in Fat Mass across time points



Aerobic Capacity Measures

Aerobic capacity was examined at all three time points by a VO_2max treadmill test specifically designed for the participants in the study. To evaulate which percentile subjects were at for age and gender they were compared to the 50th percentile for boys (45.7) and girls (38.0). The average Peak VO_2 for the expermintal at pretest was 33.41 and 24.15 for the control (Eisenmann, Laurson, & Welk, 2011). It is obvious to see that both groups were below the 50th

percentile at pretesting. Results revealed a significant group effect ($p = 0.0463$), followed by a time effect which was significant ($p = 0.0033$). Also, a significant effect was found in group over time ($p = 0.006$) (See Table 8). A positive intervention effect was found in Peak VO_2max. At baseline the experimental group and the control groups' peak VO_2max were similar. After the 12 week intervention, experimental group (Figure 6) increased their VO_2max, while the control group decreased slightly. At follow-up testing the experimental group did decrease from posttest, however, it was a slight decrease, but the decrease was not significant. Over time the control group steadily declined in peak VO_2max.

Table 8

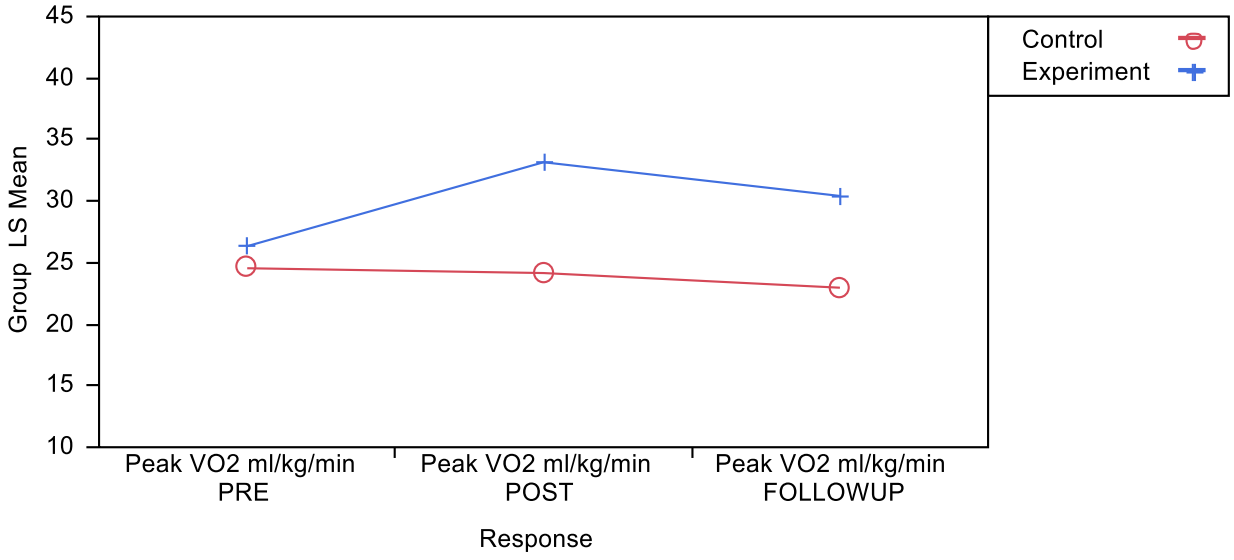
MANOVA procedure for Peak VO_2max

Test	Exact F	*DF*	*p*
Group	4.5460	19	.0463*
Time	8.0054	18	.0033*
Time X Group	6.7261	18	.0066*

*All effects were significant (p < .05).

Figure 6

Changes in Peak VO_2max across time points



A strong effect size of .88 from pre to post test in the experimental group for peak VO_2max was found. To examine whether the positive effect from the intervention was maintained, a moderate effect size of -.44 was observed. The experimental group increased their VO_2max throughout the intervention and they decreased or maintained their $VO2_2$max at follow-up. The experimental group increased VO_2max throughout the intervention period and decreased slightly at follow-up. However, improvement in peak VO_2max was maintained over baseline.

Table 9

Comparison of Aerobic Capacity Measures Effect Sizes (Cohen's d) between Groups

	Experimental			Control		
	Pre	Post		Pre	Post	
Variable	M	M	*d*	M	M	*d*
VO_2max[a]	27.20	33.41	.88	24.47	24.15	-.05
TIME[b]	647.00	683.55	.29	604.58	553.67	-.45
	Experimental			Control		
	Post	Follow-up		Post	Follow-up	
Variable	M	M	*d*	M	M	*d*
VO_2max[a]	33.41	30.42	-.44	24.15	22.96	-.17
TIME[b]	683.55	639.91	-.33	553.67	497.17	-.57

[a]Maximum Oxygen Consumption (VO_2max). [b]Total treadmill time (TIME).

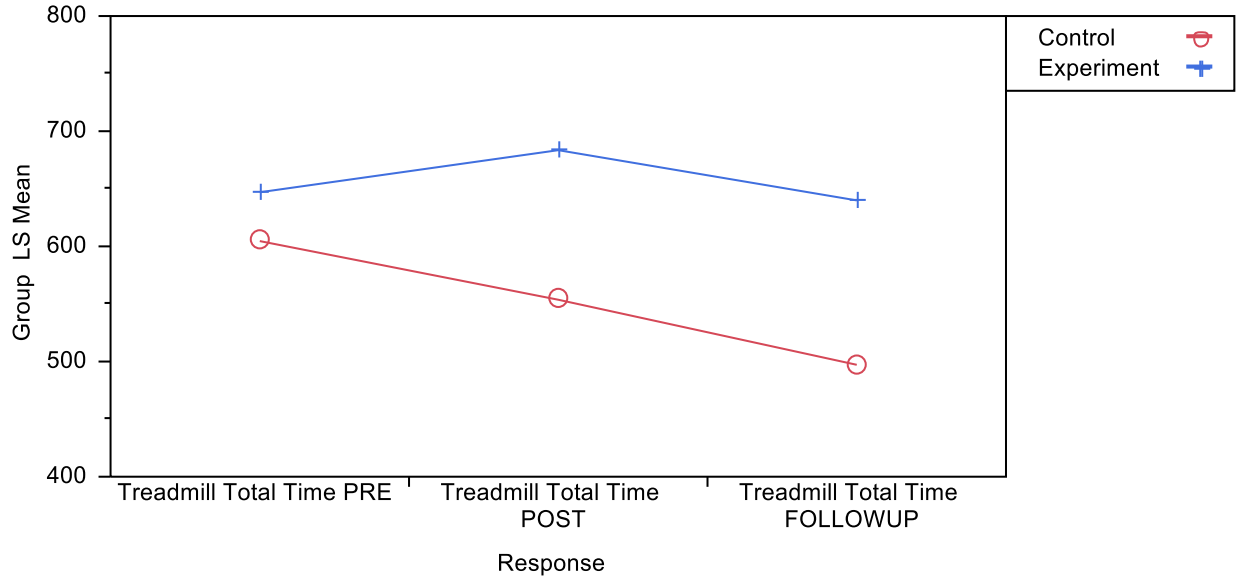
Not only is it important to assess peak VO_2max as a predictor of increased aerobic capacity, but the examination of total treadmill time is also a predictor of the treatment effect. Significant results were noted between groups, over time and by group over time (Table 10). Total treadmill time did not vary greatly (Figure 7). Over the three time points, the control group's performance decreased, while the experimental group increased at posttest and decreased slightly or maintained total treadmill time at follow-up. The experimental group showed an increased, which was a low effect size of .29 from pre to post test. From post to follow-up testing there was a decrease, which was a low effect size of -.33 (Table 9). This trend is consistent with the MANOVA findings for treadmill time.

Table 10
MANOVA procedure for Total Treadmill Time

Test	Exact F	*DF*	*p*
Group	5.3609	21	.0308*
Time	8.0615	20	.0027*
Time X Group	5.6182	20	.0116*

* All effects were significant (p < .05).

Figure 7
Changes in Total Treadmill Time across time points



Blood Measures

Glucose and insulin levels were examined at all three time points, which was used to calculated HOMA-IR. All values for group interaction, time interaction, and time and group interaction are presented in Table 11.

Table 11
MANOVA procedure for Blood Measures

	Group			Time			Time X Group		
Variable	Exact F	DF	*p*	Exact F	DF	*p*	Exact F	DF	*p*
GLU[e]	.9751	19	.3358	6.2147	18	.0089*	2.1685	18	.1433
INSUL[f]	.0376	19	.8484	.4818	18	.6254	2.0095	18	.1630
HOMA-IR[g]	1.393	19	.7131	.9445	18	.4073	2.3815	18	.1209

[a]Blood glucose (GLU). [b]Insulin (INSUL). [c]Homeostatic model assessment insulin resistances.
*Significance was found at p < .05.

Table 12

Comparison of Blood Measures Effect Sizes (Cohen's d) between Groups

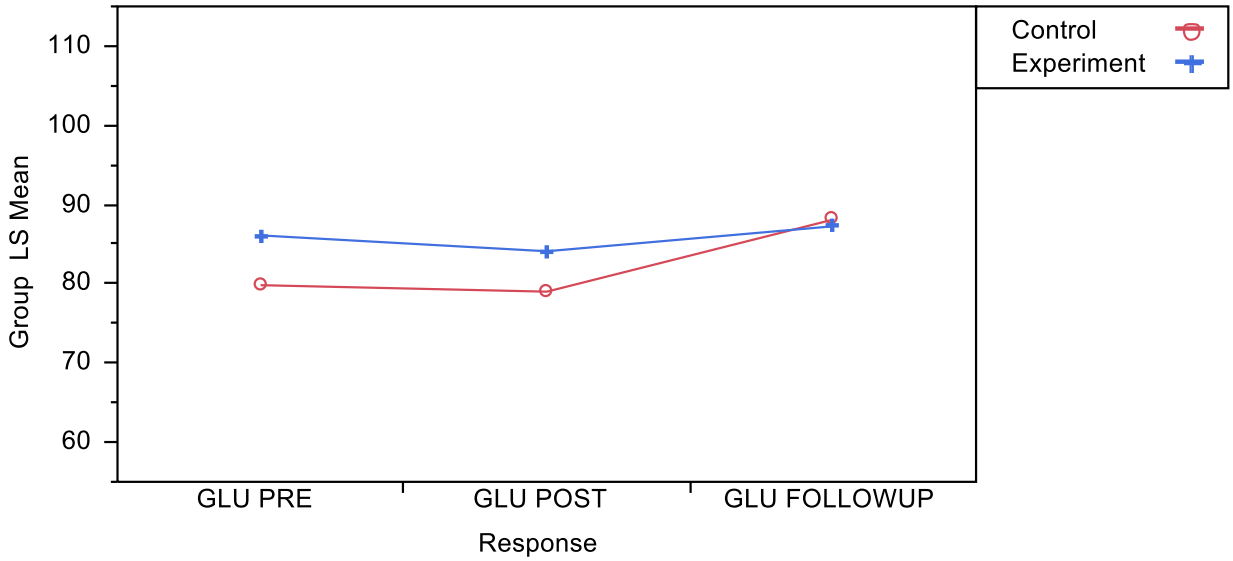
	Experimental			Control		
	Pre	Post		Pre	Post	
Variable	M	M	*d*	M	M	*d*
GLU[e]	86.10	84.10	-.20	79.82	79.00	-.07
INSUL[f]	20.91	17.92	-.30	15.26	16.88	.16
HOMA-IR[g]	4.45	3.69	-.36	2.99	3.30	.15
	Experimental			Control		
	Post	Follow-up		Post	Follow-up	
Variable	M	M	*d*	M	M	*d*
GLU[e]	84.10	87.25	.37	79.00	87.67	.91
INSUL[f]	17.92	17.63	-.04	16.88	22.17	.37
HOMA-IR[g]	3.69	3.84	.09	3.30	4.77	.51

[a]Blood glucose (GLU). [b]Insulin (INSUL). [c]Homeostatic model assessment insulin resistances.

A significant time effect (p =0.0089) was observed for glucose. Glucose level for the experimental group (figure 8) stayed relatively consistent over the three time points. From posttest to follow-up for the control, glucose levels increased to that of the experimental group at follow-up. In the experimental group there was a small effect of -.20 from pre to post test. From post to follow-up the experimental group had a small effect of .37, which shows an increase back to baseline. The control group from pre to post test showed almost no change (d = -.07), however from post to follow-up test there was a high effect of .91 showing the increase.

Figure 8

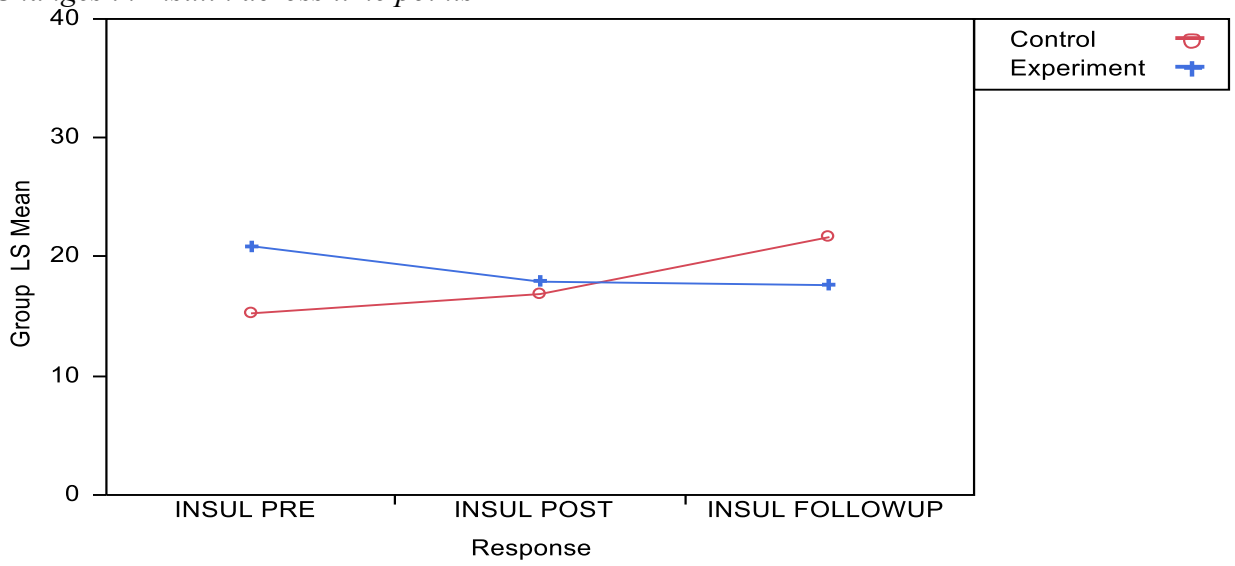
Changes in Glucose across time points



Insulin on the other hand showed no effect when a MANOVA approach was used. Insulin values for the experimental group decreased from pre to post testing as continued to decrease over the 12-week no contact phase (Figure 9). The control group started with a lower value than the experimental group at pretest, however, increased over the intervention. Insulin values continued to increase from post to follow-up testing in the control group.

Figure 9

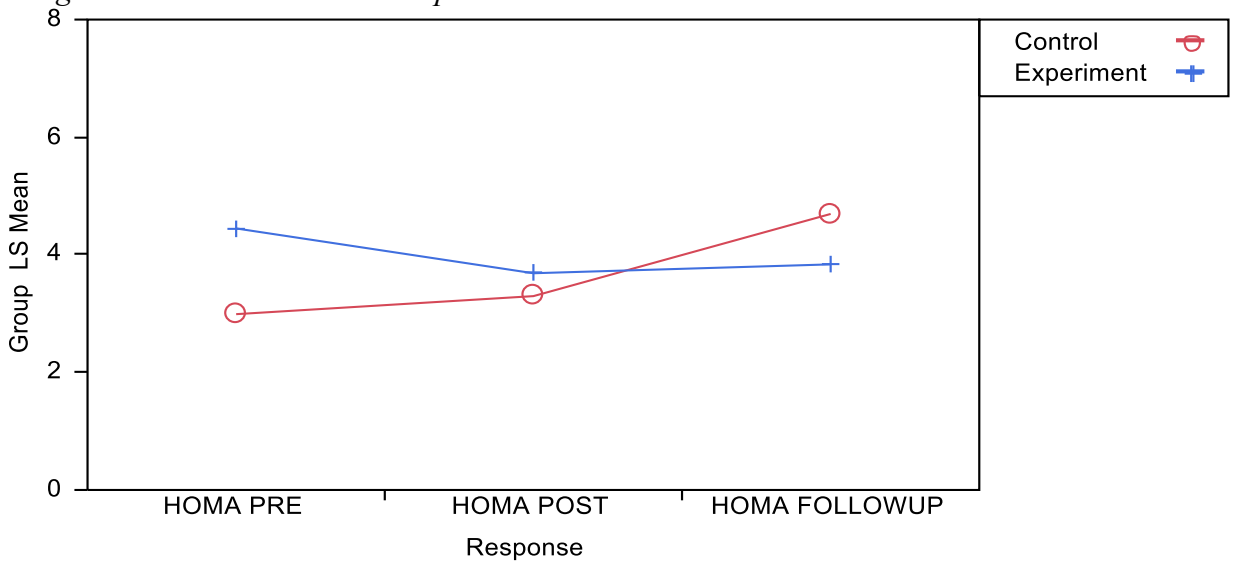
Changes in Insulin across time points



HOMA-IR is an assessment model that multiplies glucose levels and insulin levels and divides the total by 405. This assessment model examines insulin resistance in an individual. Table 11 shows that there were no effects on this variable when analyzed using a MANOVA approach. The lower the HOMA-IR value the less insulin resistant the participant became and the higher the HOMA-IR values the more insulin resistant the participant became. Figure 10 shows that at pretest the experimental group had a higher HOMA-IR value to start than the control group. However, it is important to note that while the experimental group had a higher value to start, over the three time points their values decreased which shows a positive intervention effect. Over the 12-week intervention the participants became less insulin resistant and seemed to maintain HOMA-IR values over the non-contact phase. The control group on the other hand did have a lower HOMA-IR at pretest than the experimental group; however, over the three time points it is apparent that the control group showed no change. Though significance wasn't found in this variable, a positive intervention effect is suggested when examining Figure 10. From this variable it gives insight that the intervention did in fact have a positive effect on HOMA-IR values.

Figure 10

Changes in HOMA-IR across time points



Chapter 5: Discussion

The purpose of this study was to evaluate the effect of a mentor-led vigorous aerobic exercise program on insulin resistance, body composition, and peak VO_2 in overweight and obese adolescents. The study also examined whether or not exercise induced changes were sustainable after cessation of a direct mentor-led exercise programming.

To determine the impact of the exercise training program, body composition, peak VO_2, and insulin sensitivity were evaluated. The study also evaluated if changes that were made by the intervention group were maintained 12 weeks later. The follow-up testing time point was necessary to assess if changes made during the intervention were maintained after the conclusion of the intervention.

Overall, results revealed the mentor-led exercise intervention showed significant effects in Peak VO_2max and total treadmill time. Effect size, measured by Cohen's *d*, showed a high effect size ($d > 0.80$) for Peak VO_2max from pre to post test and a moderate decrease in effect size from post to follow-up. Similar findings were shown with total treadmill time with a small positive effect size ($d < 0.30$) from pre to post and a small decrease from post to follow-up. Both of these variables show an increase in the intervention group from baseline to post test and a small decrease from post to follow-up, which shows evidence for maintenance after the 12 weeks of no contact. When the control group was evaluated at baseline they had similar baseline Peak VO_2max values as the experimental group. However, unlike the experimental group, the control group showed decreases in Peak VO_2max throughout the 12-week intervention and continued to decrease over the 12-week non-contact phase. Total treadmill time for the control group decreased significantly from pretest values to posttest values. These results support the

hypothesis that a mentor-led exercise intervention would increase fitness level, as determined by VO_2max in overweight and obese adolescents, is correct.

Previous research provides further supports that exercise can increase, although not significantly, cardiorespiratory endurance in adolescents (Rynders et al, 2012 & Meyer et al, 2006). A higher VO_2max is associated with lower risks for the premature development of cardiovascular disease and a reduction in cardiovascular disease risk factors. However, few studies have examined VO_2max in obese adolescents as it pertains to an exercise intervention (Eisenmann et al, 2007). Rynders et al found that VO_2max relative to body mass was not different between groups at baseline or after the 6 month intervention. In addition, no statistical change in VO_2max was found within group (Rynders et al, 2012). The findings by Rynders and colleagues were dissimilar to the current findings of our study. The dissimilarities may be caused due to the different intervention designs (exercise verses exercise/diet and exercise/diet/metformin). There are still limited studies that focus on adolescent intervention and the effect of VO_2max concerning clinical outcomes (Rynders et al, 2012).

The results found in our study are important because they give support to the previous research and also show that changes in aerobic capacity can be maintained over a 12 week no contact phase after the intervention was concluded. It appears that the inclusion of mentor-led training has the potential to have a longer-term impact on exercise related behaviors following the cessation of structured exercise.

When examining insulin resistance, HOMA-IR was used as a way to analyze the impact the exercise intervention had on the components of insulin and glucose. No significances between group differences were found in HOMA-IR. However, the intervention group's HOMA-IR significantly improved between baseline and post testing period. From posttest to follow-up

the intervention group showed maintenance of their level at posttest. Our hypothesis for this was variable is that from the mentor-led vigorous aerobic exercise intervention there would be an increase in insulin sensitivity in overweight and obese adolescents. HOMA-IR cut-off values for insulin resistance in adults are accepted as 2.5; however, these values do not correspond in children and adolescents (Matthews et al, 1985). Insulin resistance cut off values were determined in adolescent males and females (Kurtoğlu et al, 2010), values below 5.22 and 3.82 for male and females, respectively were associated with not being insulin resistant. Pretesing HOMA-IR values were less than both cut offs in the experimental and control groups. Experimental and control subjects at baseline, using these standard values, were considered not to be insulin resistant. Over the course of the study, the experimental group's HOMA-IR values decreased whereas the control group's values increased. A decrease in HOMA-IR does lead us to believe that there was a positive intervention effect in this variable.

Up until now there have been an insufficient number of studies that have examined the independent effect of exercise on insulin resistance. After a thorough examination of literature, only two studies were found that focused on exercise interventions in overweight and obese children and its effects on insulin resistance (Bell et al, 2007 & Davis et al, 2012). Bell et al, examined exercise alone as a way to reduce insulin resistance in obese children, independently of changes in body composition. Results showed that after the cessation of an 8-week training program insulin sensitivity improved (Bell et al, 2007). Though significance was not found, this exercise program did show improvements in insulin resistance in obese children with the absence of changes in body composition (Bell et al, 2007). The results that Bell and colleagues found were similar to ours in that we also found that the intervention group became less insulin resistant, however, it was not statistically significant. While our findings were similar in regards

to decreases in insulin resistance, our study provided a follow-up period to see if changes were maintained 12-week after the intervention. Maintenance was found in the intervention group, however the control group tended to trend more towards insulin resistance. Though the findings of our study did not show a statistically significant intervention effect on insulin resistance, it is important to note that the exercise intervention used in this study appears to have a positive effect on HOMA-IR in the experimental group over the 12-week intervention in overweight and obese adolescents as well as show maintenance of these changes.

Differences in regional percent fat, fat free mass, and fat mass as measured by DXA were not significantly different between the experimental group and the control group. Fat free mass for both groups did increase slightly throughout the intervention. Fat mass stayed relatively consistent throughout the intervention. Rynders et al found that subjects who increased their VO_2max throughout a 6-month intervention (exercise/diet or exercise/diet/metformin) had significant reductions in percent body fat, BMI, and weight. These results were different from ours in the fact that we did not show significant decreases in percent body fat, BMI, and weight (Rynders et al, 2012). Having a larger sample may attribute to the differences in findings between Rynders et al and ours. Another study that showed significant decreases in BMI and percent body fat mass was Meyer et al. This study's intervention was similar to the design of Rynders et al, in that they were both 6-month exercise interventions. However, Meyer et al started with 50 subjects in the intervention group and finished with 33. This larger sample size may lead to a reason why they showed positive decreases in percent body fat mass and BMI. Even though we did not find significant decreases in any measure of body composition, we did see increased fitness outcomes and maintenance.

The findings of the recent study are dissimilar to studies that examined percent fat and fat mass using exercise interventions in children (Ferguson et al, 1999 & Owens et al, 1999). Farris et al showed a significant decrease in BMI and BMI Z-score from pretest to posttest, however this study used an interdisciplinary intervention program, which consisted of exercise and fitness, nutrition, and physical therapy (Farris et al, 1999). Our study focused primarily on exercise; however mentors did discuss small dietary changes with the intervention subjects. The focus on exercise alone as an intervention could lead to our hypothesis being incorrect. The hypothesis that a mentor-led exercise program would promote the loss of fat mass and increase of lean body mass in overweight and obese adolescents was not supported by the findings. However, BMI Z-score did slightly decrease during the intervention phase but did increase when assessed at follow-up. The same trend was observed with the control group. It is also important to note that the control group and the experimental group were different at baseline and throughout the intervention as well as follow-up. Showing no significance in BMI Z-score could be attributed to group randomization errors.

The current findings show that independent of weight loss and change in body composition, positive changes in fitness were significantly different from the control group, and the fitness improvements were maintained throughout the duration of the study. Insulin sensitivity improved from the experimental group from baseline to post testing; however, these improvements were not maintained over the 12 week non-intervention follow-up period.

There are three main limitations that are notable factors to take into consideration. The first is the small sample size. The total sample included 23 overweight and obese adolescents. Of the 23 subjects, 11 were assigned to the intervention group and 12 were assigned to the control group. Although we had a small sample size, positive sustainable changes occurred in most

variables.. Further studies need to be conducted using a larger sample size to examine if the intervention effects that were found with this current study will remain the same or show increased significance and better findings.

Another limitation of this study is not being able to accurately evaluate whether an hour of vigorous aerobic exercise was obtained during each session following the completion of the 3-week ramping phase. Subjects wore heart rate monitors every session and recorded the highest heart rate achieved, as well as the average heart rate throughout the session. Though using the heart monitors is a good tool to assess how hard the subject is working, it does not show the intensity that the subject is at throughout the session. Since our subjects were overweight and obese the majority of them were extremely deconditioned at the start of the intervention. The disadvantage of using heart rate monitors to measure intensity in deconditioned individuals is that their heart rate peaks from participating in short durations, high intensity activities can remain elevated when they stop moving. It would be advantageous to use accelerometers or another type of intensity tracking instrument that will accurately measure intensity throughout the exercise sessions. Stating that the subjects have to maintain a certain heart rate throughout each session does not take into consideration the deconditioned population at hand (Ferguson et al, 1999 & Gillen et al, 2012).

When considering which tool should be used to examine intensity throughout the exercise intervention it is important to be aware of how the subject will react the specific tool. Heart rate monitors are relatively easy to require 12-18 year olds to wear due to the fact that they are simply wearing a watch and the heart rate strap is easily concealed under a shirt. The problem with accelerometers is that they can be more noticeable, and for adolescents, being required to wear

something that brings attention to them reduces compliance (Mann, Hosman, Schaalma, & de Vries, 2004).

The last limitation was participant attendance. While the protocol for the study was to have the adolescents exercise three times per week for 12 weeks, attendance to weekly sessions was determined by their parent/care givers willingness to get them to the weekly training sessions.

When examining the results of this study it was obvious there were differences in each group at baseline. Pre-evaluation prior to group assignment might provide more opportunities to evaluate a treatment effect. It would also be important to ensure that all subjects that are recruited can be 100% committed to the requirements of the study. Once the commitment was established it would allow for baseline measurements to be taken. All subjects at this point would believe they are going to participate in the study until they are randomly assigned after pretesting.

The current study extends previous literature by showing the success of mentoring in an exercise intervention with adolescents (Dorgo et al, 2013). The majority of current literature on peer mentoring in an exercise intervention is demonstrated in adults (Dorgo et al, 2013), however no studies were found on peer mentoring in an exercise intervention with overweight and obese adolescents. Kahn et al indicated that with adequate social support, exercise participation, retention, and level of fitness might be improved in adults. Since no current research examines the effect of mentor with adolescents in an exercise intervention, we can only assume that adolescents would have the same results as adults. The use of undergraduate college students majoring in exercise science as mentors for an exercise intervention has the potential to positively influence exercise/activity decisions the adolescents make. Not only do the college

students have a background in exercise, they are also receiving benefits from mentoring an overweight or obese adolescent. The students gain experience that will help them in their careers as health/fitness professionals as well as the ability to form one-on-one bonds with their mentee.

Another strength of the study was evaluating three different measurements through the use of an exercise intervention alone. Most studies examine body composition and aerobic capacity measures (Eisenmann et al, 2007, Meyer et al, 2006, & Rynders et al, 2012), however there were no studies found that examine body composition, aerobic capacity, and HOMA-IR in overweight and obese adolescents with an exercise intervention. Studies have selectively examined different components when using an exercise intervention, however ours is the first to examine body composition, aerobic capacity, and HOMA-IR in overweight and obese adolescents.

While this study showed limitations and strengths, it is important to evaluate the next step in continuing the growth of this body of research. Further studies need to examine the use of a two-semester, or 28 week, intervention to assess if there is better success of maintenance at follow-up testing. The use of a longer intervention will perhaps help subjects create a lifestyle changes as far as exercise is concerned once direct mentor contact ceases. It would also be beneficial to assist each subject in designing and implementing at home activities and planning how they are going to maintain their success after the completion of the intervention.

This study was designed to examine the effect of a mentor-led vigorous aerobic exercise intervention in overweight and obese adolescents. The findings show that a mentor-led exercise intervention does have the potential to be effective in increasing health outcomes independent of weight loss, however after cessation of the program, the majority of the markers for improved health status were not maintained. Positive outcomes were found in fitness even with the

conclusion of the program. At the follow-up portion of the program fitness changes were not as positive as they were at posttest, however they still remained higher than at baseline. This shows that some residual effect was maintained in fitness, independent of changes in body composition. Further interventions should focus on increasing the length of the intervention as well as the maintenance for long-term success.

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APPENDIX A: IRB APPROVAL

EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board Office
4N-70 Brody Medical Sciences Building· Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834
Office **252-744-2914** · Fax **252-744-2284** · www.ecu.edu/irb

Notification of Continuing Review Approval

From: Biomedical IRB
To: Thomas Raedeke
CC:

Date: 7/25/2013
Re: CR00001165
UMCIRB 10-0362
[IMPORTED] Project MENTOR: Exercise and Sport Science Students as the Agent of Change in an Adolescent Weight Management Intervention.

I am pleased to inform you that at the convened meeting on 7/24/2013 of the Biomedical IRB, this research study underwent a continuing review and the committee voted to approve the study. Approval of the study and the consent form(s) is for the period of 7/24/2013 to 7/23/2014.

The Biomedical IRB deemed this study Greater than Minimal Risk.

Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The investigator must adhere to all reporting requirements for this study.

Approved consent documents with the IRB approval date stamped on the document should be used to consent participants (consent documents with the IRB approval date stamp are found under the Documents tab in the study workspace).

The approval includes the following items:

Document	Description
AASP grant_final.doc(0.01)	Study Protocol or Grant Application
Barriers to Physical Activity Questionnaire & Social Anxiety Scale for Adolescents(0.01)	Surveys and Questionnaires
Assent_child(0.02)	Consent Forms
informed_consent_18years1.doc_rev_7_16_13_no-track.doc(0.01)	Consent Forms
informed_consent_7_16_2013_parent_no-Track_changes.doc(0.01)	Consent Forms
Demographics(0.01)	Surveys and Questionnaires
Doctor letter.pdf(0.01)	Additional Items

DXA Risk Statement and Questionnaire.pdf(0.01)	Surveys and Questionnaires
Fall 2013 Flyer.docx(0.01)	Recruitment Documents/Scripts
Final Revised Flyer.pub(0.01)	Recruitment Documents/Scripts
Flier(0.01)	Recruitment Documents/Scripts
iMedical_history.pdf(0.01)	Surveys and Questionnaires
Mentor survey.pdf(0.01)	Surveys and Questionnaires
Multidimensional Scale of Perceived Social Support(0.01)	Surveys and Questionnaires
PARTS(0.01)	Surveys and Questionnaires
RDA 2010-11_template.pdf(0.01)	Study Protocol or Grant Application
RecruitmentVideo.mov(0.01)	Recruitment Documents/Scripts
Revised protocol Sept 29, 2010(0.02)	Study Protocol or Grant Application
SDTneeds(0.01)	Surveys and Questionnaires
SocialCognitive(0.01)	Surveys and Questionnaires
VideoPermission.doc(0.01)	Recruitment Documents/Scripts

The following UMCIRB members were recused for reasons of potential for Conflict of Interest on this research study:

None

The following UMCIRB members with a potential Conflict of Interest did not attend this IRB meeting: None

APPENDIX B: INFORMED CONSENT

East Carolina University

Consent to Participate in Research that is Greater than Minimal Risk
Information to Consider Before Taking Part in This Research

Title of Research Study: Project Mentor- Kinesiology Students as the Agents of Change in an Adolescent Weight Management Intervention.
Principal Investigator: Thomas Raedeke, Ph.D.
Institution/Department or Division: Kinesiology, East Carolina University
Address: Minges Coliseum
Telephone #: 252 737-1292 (Raedeke)

This consent document may contain words that you do not understand. You should ask the study investigator or the study coordinator to explain any words or information in this consent form that you do not understand.

Introduction

Your child has been invited to participate in a research study designed to evaluate the effectiveness of an exercise intervention that includes mentoring from undergraduate students in Kinesiology. This project is a joint effort by faculty members in Kinesiology (Thomas Raedeke, Ph.D., Michael McCammon, MA) as well as Psychology (Lesley Lutes, Ph.D.) from East Carolina University.

Plans and Procedures

We will study 20-30 adolescents between the ages of 12-18 over the course of a 12-month period. Adolescents who volunteer to participate will engage in a mentoring program that involves vigorous exercise, some resistance exercise training, and lifestyle coaching. They will also be asked to participate in health and fitness related assessments four times over a12-month period.

If your child participates in the mentoring program, he or she will be asked to exercise at least three times per week for one hour per session and participate in a weekly lifestyle counseling session. A college student majoring in exercise physiology will be assigned to work with your child. The college student will be the primary exercise trainer and lifestyle counselor for your child. The college students will be supervised by faculty and graduate students from the Department of Kinesiology. You will be asked to attend a monthly meeting designed to provide information to facilitate your child's success at lifestyle improvement.

Plans and Procedures

If your child is interested in participating, and you consent to his or her involvement, you will be asked to complete a medical history questionnaire pertaining to your child to help ensure that participation is safe and does not result in elevated health risk due to exercise or any of the testing procedures. To qualify for the project, your child has to be classified as being physically inactive and be overweight.

All of the following procedures will be administered four times over a 12-month period including (a) before training, (b) the end of the fall semester, (c) end of the spring semester (c) and after a 12-week follow-up period.

Determination of body composition using DXA (dual energy x-ray absorptiometry), skinfolds and measurement of your waist, hip, and thigh circumferences. These methods will determine how much of your child's body is fat and how much is muscle. Your child will have his or her body composition determined by a method known as DXA. DXA is the emerging gold-standard in determining the amount of bone, fat and lean tissue amounts in the body. DXA is non-invasive and works somewhat like an X-ray. The scan takes about 5 minutes to complete. No anesthesia is required. The procedure is painless and radiation exposure is minimal. Your child's body composition will also be assessed using a skinfold caliper. Your child's skin will be lightly pinched at eight different body sites. This is a painless procedure and it is another way to assess percent body fat. During the same visit, circumference measurements around the waist, thigh and hip will be taken using measuring tape.

Wearing a motion sensor (accelerometer). Your child will be asked to wear a motion sensor (accelerometer) which is about the same size as a pager for one week at each of the four testing periods.

Maximal oxygen uptake stress test. Your child will walk, maybe run, on a treadmill until he/she has to stop. During the test he/she will breathe through a long plastic tube connected to a box that measures the amount of oxygen used during the exercise test.

Lipid Profile. Fasting venous blood samples (approximately 10 ml of blood will be obtained) to evaluate lipid, cholesterol, and insulin levels. Sterile techniques will be employed. Blood samples will be stored in freezers at the Human Performance Laboratory. You can can request their destruction (discarded into biohazard containers and disposed of by ECU biohazard personnel) at any time.

Survey Completion. Your child will be asked to complete questionnaires that examine their thoughts and feelings about exercise, health, self-concept, and exercise motivation. Completing the surveys will take approximately 30 minutes at each assessment point. There are no right or wrong to the survey items and answers will be kept completely confidential.

Potential Risks and Discomforts

Participation in this study is completely voluntary and refusal to participate in any of the assessments does not have any negative consequences. Although potential risks are very unlikely, there are certain risks and discomforts that may be associated with this research.

Potential risks of maximal exercise testing include dizziness, ventricular arrhythmias (abnormal heart function), and remote chance of death. These risks are very small, with an incidence of fewer than 1 in 10,000 deaths in patients who are known to, or suspected of, having heart disease. The risk is expectedly much smaller in adolescents. To minimize this risk even further, faculty and students that have been extensively trained in administering maximal exercise tests will administer the assessments. If during a test a subject complains of dizziness, chest discomfort, or other signs of exertional intolerance, the test will be promptly terminated. In the event a test is terminated, the subject will be evaluated and, if necessary, CPR and AED administration will be initiated and Greenville Fire/Rescue will be notified via 911. Members of the research team have over 25 years of maximal exercise testing experience and have supervised over 10,000 maximal stress tests.

To complete a DXA scan, your child will simply lie still on the DXA table while the scanning arm of the machine passes over him/her. The DXA procedure is painless and radiation exposure is minimal. Any time an individual is exposed to radiation there is potential health-related risk. However, the amount of radiation that your child will be exposed to is quite minimal. Every person is exposed daily to natural background radiation from sources like soil, rocks, radon, and natural radiation in our bodies, the sun, and outer-space. The amount of radiation exposure from a DXA scan is substantially less than what your child gets daily from normal background radiation and what your child would receive during a cross country flight. Thus, the amount of radiation your child is exposed to through DXA is small. The effects of DXA upon an unborn fetus are not known. Thus, if there is any chance of pregnancy, a person should not participate in DXA.

The risk of infection and bruising is slight from blood draw. To minimize risk, trained individuals will obtain the blood samples.

Although there are minimal risks associated with completing the surveys, not all risks are predictable. If your child experiences any emotional discomfort when answering the survey items or wants to stop completing the questionnaire for any reason, he/she will be free to discontinue at any time. To further minimize risk, a member of the research team will be available to answer any questions your child may have regarding the survey items. Dr. Lesley Lutes, a licensed clinical psychologist or a Ph.D. student in clinical health psychology will be available for consultation in event of the survey resulting in extreme emotional distress.

If your child has any discomfort or adverse effects associated with these any of these tests, you will need to immediately notify the study investigators at the contact numbers provided on the last page of this consent form under ("Persons to Contact").

Potential Benefits

Excess body weight is a major health concern in our country. Overweight individuals are at an increased risk for a variety of health problems. Vigorous exercise is an effective weight loss intervention, improves physical health, and can enhance psychological well-being. Fitness improvements associated with vigorous exercise are associated with a reduction in heart disease risk factors, high blood pressure and diabetes risk. Exercise participation can also enhance psychological well-being. As a token of appreciation, participants will receive $20 for involvement in each testing period.

Confidentiality

Only the investigators associated with this study will have access to the data obtained. The identity of the subjects will be protected by numeric coding. No identifying information will be released.

Termination of Participation

The principal investigator reserves the right to terminate your child's participation in the study. Reasons for termination can include (but not limited to) risk of adverse reaction to the protocol, unreliability and/or failure to adhere to the protocol.

Costs and Compensation

There are no costs associated with the evaluations performed in the study. You will be responsible for getting your child to and from the FITT building.

Compensation and Treatment for Injury

The policy of East Carolina University and/or Pitt County Memorial Hospital does not provide for payment or medical care for research participants because of physical or other injury that result from this research study. Every effort will be made to make the facilities of the School of Medicine and Pitt County Memorial Hospital available for care in the event of injury.

Voluntary Participation

Participating in this study is voluntary. If your child decides not to be in this study after it has already started, he or she may stop at any time without penalty.

Persons to Contact with Questions

A member of the research team will be available to answer any questions concerning this research, now or in the future. You may contact Thomas Raedeke at 252-737-1292; raedeket@ecu.edu. If you have questions about you rights as a research participant, you

may call the Chair of the University and Medical Center Institutional Review Board at phone number 252 744-2914 (days) and/or the University Risk Management Office at 252 328-6858.

Research Participant Authorization to Use and Disclose Protected Health Information

The purpose of the information to be gathered for this research study is to better understand the effects of an exercise mentoring program on health, fitness and body composition. The individuals who will use or disclose your identifiable health information for research purposes include members of the research team and the Human Performance Laboratory. Individuals who will receive your identifiable health information for research purposes include members of the research team and the Human Performance Laboratory. The type of information accessed for this research study includes the assessments described previously in this informed consent document. The information will be used and disclosed in such a way as to protect your identity as much as possible; however, confidentiality cannot be absolutely guaranteed. Someone receiving information collected under this Authorization could potentially re-disclose it, and therefore it would no longer be protected under the HIPAA privacy rules (federal rules that govern the use and disclosure of your health information). There is not an expiration date for this Authorization.

You may not participate in this study if you do not sign this Authorization form. You may revoke (withdraw) this Authorization by submitting a request in writing to Thomas Raedeke or Peter Farrell. However, the research team will be able to use any and all of the information collected prior to your request to withdraw your Authorization.

To authorize the use and disclosure of your health information for this study in the way that has been described in this form, please sign below and date when you signed this form. A signed copy of this Authorization will be given to you for your records.

Consent to Participate

You have read all of the above information, asked questions and have received satisfactory answers in areas you did not understand. If you consent to your child participating in this study, you will be asked to sign a copy of this form. A second copy will be given to you for your records. Your child will also be asked to complete an assent form to indicate that he or she volunteers and wants to participate in this study.

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

Participant's Name (Print)

Authorized Representative's Name (Print) – Parent/Guardian

Authorized Representative Signature – Parent/Guardian Date

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

Name (Print)

Signature Date

APPENDIX C: ASSENT FORM

East Carolina University

1907-2007 CENTENNIAL

Assent Form

Things You Should Know Before You Agree To Take Part in this Research

Title of Research Study: Project Mentor- Kinesiology Students as the Agents of Change in an Adolescent Weight Management Intervention.
Person in Charge of the Study: Thomas Raedeke.
Where they Work: Kinesiology, East Carolina University
Other people who work on this study: Mike McCammon, Lesley Lutes, and students from ECU

Study contact phone: 252 737-1292 (Raedeke)
Study contact E-mail address: raedeket@ecu.edu

Introduction

You have been asked to participate in a 12-month research project that involves exercise and lifestyle coaching. We are evaluating whether an exercise and lifestyle change program results in improved health and fitness. What makes this program unique is that college students majoring in kinesiology will serve as exercise leaders or mentors. This project is being conducted by faculty members of East Carolina University. It is important for you to understand that even though your parents have given permission for you to participate you don't have to. For this program to help you become more physically active, you have to want to be a part of it.

Plans and Procedures

We will study 20-30 males and females between the ages of 12-18 over the course of a 12-month period. If you volunteer to participate, you will be asked to participate in the exercise and lifestyle change program. The program will involve vigorous exercise, some resistance exercise training, and lifestyle coaching. You will also be asked to participate in health and fitness related assessments four times over a12-month period.

If you volunteer to participate in this project, you will be asked to exercise at least three times a week with your college exercise mentor and participate in a weekly lifestyle counseling session at the FITT building at ECU. We will also want you to increase the amount you exercise on your own. A college student majoring in Kinesiology will be there to help you.

If you are interested in participating, you will be asked to complete a medical history questionnaire with the help of your parent(s)/guardian to help ensure that it is safe for you to exercise and be involved in this study. If there are medical or health related reasons why you should not exercise or if you are pregnant, then you should not participate in this study. If you want to participate, we will ask you to be involved a variety of health and fitness assessments four times over a 12-month period including the (a) before training, (b) end of the fall semester, (c) end of the spring semester (c) and after a 12-week follow up period. These assessments are described in the next section.

Risks and Discomforts

Sometimes things we may not like happen to people in research studies. These things may even make them feel bad. These are called "risks." Although potential risks are very unlikely, there are certain risks associated with this research.

We will have you do an exercise test. For this test you will walk and maybe run on a treadmill until you have to stop. During the test you will breathe through a mouthpiece connected to a machine that measures how much oxygen you use. This is a safe test; however, you will be tired and out of breath and you might feel a little dizzy at the end of it. These are normal responses. Potential risks of exercise testing include a negative heart rate response and a very remote chance of death. These risks are very small. In fact, less than 1 in 10,000 deaths occur in adult patients who likely have heart disease. The risk is much smaller in youth. To minimize this risk, members of the research team have conducted more than 10,000 of these tests in a safe way.

To measure how much physical activity you typically get, you will be asked to wear a motion sensor which looks like a pager. Four times during the study, you will be asked to wear the motion sensor for a week at each time. We can show you what one of these look like.

Your height, weight, and percent body fat will be measured. One way we will measure how much of your body weight is muscle and how much is fat is through DXA (duel energy x-ray absorptiometry). DXA works somewhat like an X-ray. You will lie on a table and have the machine scan your body. The scan takes about takes about 5 minutes to complete. You won't feel a thing during it. Like an X-ray, you will be exposed to a very small amount of radiation. However, the radiation is much less than an X-ray. However, if there is any chance you are pregnant, you should not have a DXA scan as we don't know what impact it has on a fetus. Another way we will evaluate your weight is by using a skinfold caliper. Your skin will be lightly pinched at eight different body sites. You will feel a very light pinch but it won't hurt. During the same visit, we will also use a tape measure the distance around your waist, hip, and thigh.

Another test involves us taking a small amount of blood. You may have had a similar test done at a doctor's office. Through this test, we will learn about your cholesterol level. There is small chance of infection and bruising, but those chances are small.

Finally, we will ask you to complete a survey that examines your thoughts and feelings about exercise, health, self-concept, and sadness/depression. It will take about 30 minutes to complete at each testing period. However, the survey is not a test and there are no right or wrong answers. Rather, we are interested in your opinions and viewpoints. We won't share your answers with anyone. If you feel uncomfortable completing the questionnaire, you can stop at any point. You can also tell us what made you uncomfortable so we can help. Dr. Lesley Lutes, a licensed clinical psychologist, will be available on request to provide additional help if you have any concerns based on the questionnaire items.

Potential Benefits

If you are assigned to the exercise and lifestyle counseling condition, this project is focused on helping you learn how to manage your weight effectively, eat healthier and to increase your fitness and physical activity level. Exercise and lifestyle counseling are good ways to lose or maintain weight as well as improve physical health and psychological well-being.

Confidentiality

Your personal information and samples collected will be kept private and safe in a locked room for 5 years. The information we gather will be identified by a code rather than your real name. We won't tell others you were involved in this project without permission. Only members of the research team will have access to your data. If you decide that you want your samples thrown out, your samples will be gotten rid of properly by workers at ECU. Although your information is private, your parents will be able to see the results from the medical history questionnaire as they will help you complete it.

Persons to Contact with Questions

If you have questions about this study, you can ask to person going over this form with you. If you have questions at a later time, you can contact the people listed on the first page. If you have questions about you rights as a research participant, you may call the Chair of the Institutional Review Board at 252 744-2914.

Assent to Participate

If you decide to take part in this research, you should sign your name below. It means that you agree to participate in this study. Participating in this study is voluntary. It is your decision. If you decide not to be in this study after it has already started, you may stop at any time. You will also be given a copy of this form to keep.

_____ _____

Print your name here if you want to be in this study

_____

Sign your name here if you want to be in this study Date

Printed name of person obtaining assent

Signature of person obtaining assent Date

APPENDIX D: DXA QUESTIONNAIRE

DXA Risk Statement and Subject Questionnaire
Human Performance Laboratory
Body Composition / Bone Mineral Density Analysis

During this visit, my body composition will be measured using dual energy x-ray absorptiometry (DXA) technology, a state-of-the-art method that uses very low intensity x-rays. The x-ray exposure from DXA is minimal and comparable to a round-trip airplane flight from Chicago to Paris. I will need to remove metal clothing accessories, jewelry and my shoes as these can affect the scan results; however, I will otherwise remain fully clothed. The DXA will scan my entire body very slowly; so, I will need to lie on a table without moving for almost 5 minutes, while the DXA is passed over my entire body. I will feel no discomfort associated with this test. There are no restrictions to my normal activity following this procedure. This test will determine the amount of fat, muscle and bone that I have. I have been informed that females with ANY chance of being pregnant should NOT undergo DXA scanning.

If I have further questions about the risks of DXA I may contact David Rushing, Clinical Radiation Safety Officer, Brody School of Medicine at East Carolina University, 252-744-2236.

Please complete the following questions to the best of your ability. If you have any questions, please ask the DXA technician for assistance.

Have you had any X-ray procedures within the last 3 days which use:	Iodine	Yes ☐	No ☐
	Barium	Yes ☐	No ☐
	Nuclear Medicine Isotopes	Yes ☐	No ☐
Do you have any of the following Medical devices in your body:	Ostomy devices	Yes ☐	No ☐
	Prosthetic Devices	Yes ☐	No ☐
	Surgical Devices	Yes ☐	No ☐
	Pacemaker leads	Yes ☐	No ☐
	Radioactive seeds	Yes ☐	No ☐
	Radiopaque catheters or tubes	Yes ☐	No ☐
Are you wearing any of the following Jewelry or clothing	Metal buttons	Yes ☐	No ☐
	Zippers	Yes ☐	No ☐
	Snaps	Yes ☐	No ☐
	Jewelry	Yes ☐	No ☐
Do you have any of the following Foreign Objects in your body:	Shrapnel, Buckshot	Yes ☐	No ☐
	Metal of any sort	Yes ☐	No ☐
	Other: Specify	Yes ☐	No ☐

Females of child bearing age only…. *(Bolded answers contraindicate DEXA)*

Are you currently	Pregnant or Lactating	**Yes** ☐	No ☐
	Using birth control	Yes ☐	No ☐
Circle type of birth control	Condoms or diaphragm; birth control pill; depo-provera; IUD; partner has vasectomy		
When did your last normal period start?	Date: _____/_____/_____		
Have you has unprotected intercourse since your last period?	Note: if you are using some form of birth control, this means that you did not use birth control or you experienced a problem with your birth control method?	**Yes** ☐	No ☐

I certify that the information given above is true and correct to the best of my knowledge and that I have read all of the above information, asked questions and have received satisfactory answers in areas I did not understand. (A copy of this signed and dated consent form will be given to the person signing this form as the subject or as the subject's authorized representative.)

_____ _____
Subject/Authorized Representative (Sign) Date

_____
Subject/Authorized Representative (Print)

Witnessed:

_____ _____
Technician, Human Performance Laboratory Date

I hereby certify that I have reviewed the pregnancy information given by this subject and the indication was that:

☐ -there was a very low risk of pregnancy. DXA was performed.

☐ -there was an unacceptably high risk of pregnancy. DXA was not performed pending further tests.

_____ _____
Technician, Human Performance Laboratory Date

_____
If this is for a research study, please print the name of the Primary Investigator above.

APPENDIX E: TREADMILL PROTOCOL

MENTOR TREADMILL PROTOCOL

ID#:_____ Date of Birth: _____ Date: _____
Height: _____ Weight: _____ Sitting BP: _____ Sitting HR: ___
Medications: _____ Metabolic Cart#: _____ Treadmill: _____

Minute	Speed	Grade	Heart Rate	RPE	Comments
1	2.0	0	_____	____	_____
2	2.0	0	_____	____	_____
3	3.0	2	_____	____	_____
4	3.0	4	_____	____	_____
5	3.0	6	_____	____	_____
6	3.0	8	_____	____	_____
7	3.0	10	_____	____	_____
8	3.2	11	_____	____	_____
9	3.4	12	_____	____	_____
10	3.6	13	_____	____	_____
11	3.8	14	_____	____	_____
12	4.0	15	_____	____	_____
13	4.2	16	_____	____	_____
14	4.4	17	_____	____	_____
Recovery					
1	1.5	0	_____		_____
2	1.5	0	_____		_____
3	1.5	0	_____		_____
4	1.5	0	_____		_____
5	1.5	0	_____		_____

Comments:

_____
_____
_____
_____