THE EFFECTIVNESS OF A 12-WEEK FITNESS INTERVENTION FOR PEOPLE WITH METABOLIC SYNDROME

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THE EFFECTIVNESS OF A 12-WEEK FITNESS INTERVENTION FOR PEOPLE WITH METABOLIC SYNDROME

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Title of Study: THE EFFECTIVNESS OF A 12-WEEK FITNESS INTERVENTION FOR PEOPLE WITH METABOLIC SYNDROME

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Abstract:

Purpose: To see the effectiveness of a 12-week fitness intervention for individuals with metabolic syndrome. **Methods:** The sample included 11 adults (6 females, 5 males) all of which were classified with metabolic syndrome. The intervention consisted of moderate intensity aerobic exercise 3 times a week (30 mins each session) for 12 weeks. Every 2 weeks the subjects HR Reserve would be increased by 5% until reaching 65% at the end of the 12 weeks. Cholesterol, HDL, LDL, glucose, triglycerides, weight, girth, risk factors of metabolic syndrome, blood pressure, resting heart rate, flexibility, and muscular endurance were measured before and after the 12 weeks. **Results:** Out of the 13 pre/post-intervention assessments, only 6 showed a significant difference ($p < 0.05$): pre/post weight (p =.003), pre/post girth (p =.000), pre/post risk factors for metabolic syndrome (p =.004), pre/post sit and reach test (p =.025), pre/post bench press test (p =.004) and pre/post resting heart rate (p =.015). There was not however a significant difference in (pre/post cholesterol (p =.386), pre/post HDL (p =.326), pre/post LDL (p =.102), pre/post triglycerides (p =.229), pre/post glucose (p =.332), pre/post systolic blood pressure (p =.636), and pre/post diastolic blood pressure (p =.873). The overall prevalence of metabolic syndrome in this study decreased from 100% pre-intervention to 63% post-intervention. After the 12-week fitness intervention 63% of the subjects reduced their risk factors associate with metabolic syndrome and 36% of those subjects were below the criteria for having metabolic syndrome (< 3 risk factors). C**onclusion:** In summary, this study showed evidence that exercise does in fact help reduce some of the risk factors associated with metabolic syndrome.

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CHAPTER I

INDRODUCTION

Keeping a consistent workout schedule is not one of the easiest things to do when people have a career, family or just a busy life in general. Physical activity can be tough to fit into the work day or it may be difficult to get the motivation to go exercise. Now; add high blood pressure, obesity and diabetes into the mix of trying to get to the gym. Those risk factors are just three out of five that someone needs to have in order to be diagnosed with metabolic syndrome. Metabolic syndrome is the terminology used for a group of risk factors that raises your risk for heart disease and other health problems, such as diabetes and stroke as stated by the National Heart Lung and Blood Institute (NHLBI).

The following factors constitute metabolic syndrome: abdominal obesity, elevated triglycerides, low HDL cholesterol, raised blood pressure, and insulin resistance. When three or more of these risk factors are present an individual is classified as having metabolic syndrome. Metabolic syndrome is a medical condition that is becoming more and more prevalent throughout our society. As a weight loss recommendation, it too has been discussed that moderate intensity interval training workouts may be better for weight loss than normal low intensity workouts that last for an hour or more (Stensvold et at., 2011), (Bird and Hawley. 2012). People with metabolic syndrome are usually overweight and have a large abdominal girth but previous studies (as shown

in the literature review) have shown there is almost always a decrease in weight and abdominal girth when exercise is added into the equation. This is why it's so important for people with metabolic syndrome to start exercising. Weight loss and abdominal girth loss are just two of the side effects associated with exercising. In a study by Mecca et al. (2012), they found that in just 10 weeks of exercising and increasing the subject's dietary fiber intake, they were able to decrease factors associated with metabolic syndrome. This just gives more evidence on how important it is to continue further research on the effects of exercise and metabolic syndrome.

The decline in physical activity levels in the past decades can be attributed to a combination of factors, including; jobs becoming less physically active and more 'desk based', the reliance on motorized transport rather than walking and cycling, and the growth in the popularity of sedentary past-times involving televisions and computers (Bird and Hawley. 2012). Physical activity is just as important as brushing your teeth every morning and night to prevent cavities. Just like brushing your teeth every day, people should do some kind of physical activity every day as a preventive measure for metabolic syndrome. People who live sedentary lives and have metabolic syndrome should be more informed about the effects physical activity has on metabolic syndrome. It's important to get the word out so people who are sedentary or have metabolic syndrome can start living healthier and more productive lives. This is why research on this topic should never stop.

When it comes to finding a cure for cancer or a preventative measure the first thing scientist do is research and trial and error. Well with metabolic syndrome, the surface has just been scratched when it comes to research and trial and error. The benefits of exercise towards people with metabolic syndrome should never be stopped just like research for a cure to cancer. The more research that is done and the more that is known can help expand the field greatly. That's why this study is so important because it will help increase the knowledge towards this

specific subject. This study is just a small puzzle piece to a big puzzle. Without this study or more like it there will never be a finished puzzle. The benefits of exercise towards people with metabolic syndrome are limitless. This study will help understand what works and what doesn't when it comes to exercise and metabolic syndrome.

The purpose of this study is to see the effectiveness of a 12-week fitness intervention for individuals with metabolic syndrome. Based on previous research there should be a significant difference between exercise and metabolic syndrome. The significance of this study is to figure out if a structured cardiorespiratory fitness program has an effect on reducing any of the factors that are associated with metabolic syndrome. This will help in the future to narrow down an effective exercise regimen for people with metabolic syndrome. This study will potentially provide us with information on how exercise and weight management can lower people's chances of getting metabolic syndrome. This study was limited to a 12 week period (August-November) were people with metabolic syndrome at a Midwest University were the sole participants.

Subjects were recruited from a pre-existing program for those with metabolic syndrome. We will also be attaining the pre and post-test data from this program for the use in statistical analysis. The hypothesis is that the 12-week fitness intervention will reduce risk factors associated with metabolic syndrome and decrease resting heart rate.

RESEARCH QUESTIONS

1. Will there be a decrease in resting heart rate over the fitness intervention?
2. Will there be a significant difference between pre-test and post-test measures?

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CHAPTER II

LITERATURE REVIEW

As mentioned above in the introduction, metabolic syndrome is a medical condition that is becoming more and more prevalent throughout our society. There are many studies out there that help corroborate the importance of physical activity and the effects it has on decreasing the risk factors for metabolic syndrome. Physical exercise either aerobic interval training or strength training or even a combination of both have beneficial effects on physiological abnormalities associated with metabolic syndrome (Mecca et al., 2012). This literature review will establish how important it is to conduct further research on physical activity and the effects it has on metabolic syndrome.

In the research article by Mecca et al. (2012), "Ten-week lifestyle changing program reduces several indicators for metabolic syndrome in overweight adults" they studied the effectiveness of physical activity and high fiber intake and its effects on metabolic syndrome. The pre-test evaluations measured weight, height, waist circumference, body mass index (BMI), and body fat percentage which was assessed by a bioelectrical impedance device. They also obtained blood samples to record their HDL (high-density lipoprotein), LDL (low-density lipoprotein), triglycerides and total cholesterol. Their subjects were 50 overweight-obese individuals (11 men and 39 women). The subjects were separated into two groups (G1) and (G2). G1 (general education group) were given dietary counseling at baseline and engaged in physical activity three times a week. G2 (high fiber nutrition group) who followed a high dietary fiber intake along with weekly dietary counseling and engaged in physical activity three times a week (Mecca et al,

2012). For the physical activity, all participants were submitted to supervised exercise of 80 minutes, including warm up (20min) walking (40 min) and stretching (20 min), 3 times a week complemented with 60 min (2 time a week) of strength training(40 min), stretching (10 min) and warm-up (10 min) at a gym (Mecca et al., 2012).

Out of the two groups in Mecca et al. (2012) study, G2 had significantly greater reductions for waist circumference, weight, BMI, and body fat mass over the 10-week study period. G2, unlike G1 had a high dietary fiber intake along with weekly dietary counseling. This could be the reason G2 showed greater reduction in those areas. In both groups dietary intake improved but with higher improvements in G2 Mecca et al., (2012). Overall the 10-week high dietary fiber intake intervention combined with physical activity was associated with a reduction in percent change of metabolic syndrome incidence from baseline to post-intervention (Mecca et al., (2012).

In the study by Katzmarzyk et al. (2003) "Targeting the Metabolic Syndrome with Exercise: Evidence from the HERITAGE Family Study" they looked at how just exercise effects the factors connected with metabolic syndrome. The study included multiple schools where participants were recruited. The overall sample included 288 men and 333 women who fit the criteria of metabolic syndrome. Measurements that were taken at baseline and post-training were BMI (body mass index), waist circumference, triglycerides, HDL, blood pressure and fasting glucose. The subjects completed a 20-week standardized aerobic fitness training program (Katzmarzyk et al., 2003). The exercise training program involved three session per week of supervised exercise on a cycle ergometer. Participants started at 55% of their baseline VO_{2max} for 30 min per session and progressed in intensity or duration every 2 weeks after a standardized protocol until they were working at 75% VO_{2max} for 50 min per session for the final 6 weeks (Katzmarzyk et al., 2003). The results of this study showed the percentage of participants with risk factors associated with metabolic syndrome decreased following the exercise training. This

study indicates that physical activity can be used to manage/lessen the risk factors for metabolic syndrome.

Unlike the two studies listed above, a research paper written by Tim Church (Exercise in Obesity, Metabolic Syndrome, and Diabetes) describes the importance of exercise and how it plays an important role in decreasing the risk of developing both metabolic syndrome and type 2 diabetes. In the cross-sectional studies that examined the prevalence of metabolic equivalents across levels of physical activity, all found an inverse relationship between amount of physical activity and metabolic syndrome (Church, 2011). In simple terms, the more exercise someone preformed, the odds of having metabolic syndrome decreased. Church mentions that many studies have found that aerobic training along with resistance training is the best combination of physical activity to help decrease the factors of metabolic syndrome.

The 2008 federal physical activity guidelines suggest that individuals should strive to achieve at least 150 minutes per week of moderate-intensity physical activity, or for those that prefer to participate in vigorous-intensity physical activity, the minimal weekly goal is only 75 minutes or more per week (Church, 2011). In summary, physical activity has been shown in previous studies as a viable preventive measure for people with or without metabolic syndrome, diabetes and obesity.

In the study by Stensvold et al., (2011) "Effect of Exercise Training on Inflammation Status among People with Metabolic Syndrome" they look at how the effects of aerobic training versus strength training have on the circulation of proinflammatory markers in people with metabolic syndrome. The subjects in the study consisted of 10 women and 33 men who all had metabolic syndrome. Subjects were randomized to an aerobic interval training (AIT) group, strength training (ST) group, or a control group. The exercise program was a 12 week program with three exercise sessions per week. After the 12 week program there were no significant

differences between the groups in any of the five components defining the metabolic syndrome or in age or weight at baseline. The main finding in this study was that moderate-intensity exercise (AIT) and not strength training (ST) was associated with a more favorable inflammatory status among people with metabolic syndrome (Stensvold et al., 2011).

The Stensvold et al. (2011) study shows that with aerobic interval training (AIT) you can actually reduce the low-grade inflammation in people with metabolic syndrome. This is just another reason why physical activity (exercise training) needs to be researched further on how it effects the factors associated with metabolic syndrome. Physical activity has a wide range of health benefits that can be applied to many different aspects of life. Stensvold et al. (2011) improves the well-being/symptoms of people with metabolic syndrome due to the use of physical activity (exercise training).

Another article by Alberto da Silva et al. (2011) looked at the role of moderate-intensity aerobic training and the effects it has on improving endothelium-dependent vasodilatation in people with metabolic syndrome. The subjects underwent an initial clinical examination with a Cardiologist. The intervention lasted 6 weeks. This time period was considered enough to obtain changes in the endothelial function (Alberto da Silva et al., 2011). After the subjects initial test, they were randomized into specific groups for the exercise. The groups consisted of a low intensity group (50-60% of maximum heart rate), a moderate intensity group (75-85% of maximum heart rate) and a control group. There were a total of 31 subjects that met all the requirements, 10 in moderate intensity, 10 in low intensity and 11 in the control group. For the 6 week intervention the subjects trained 4 times a week for 50 minutes each time. The 6 weeks consisted of 2 weeks of a progressive adaptation phase and 4 weeks of training in the target intensity range predetermined by the maximum heart rate (Alberto da Silva et al., 2011).

The subjects were evaluated using supersonic sound waves and vascular software for bidimensional images of the brachial artery. They saw significant improvement for dependent endothelium dilation in the subjects after the 6 weeks of exercise training. The moderate intensity group showed the greatest improvements compared with the low intensity group. This study is different from the rest due to the fact that they were looking at trying to improve endothelial function, not just the risk factors associated with metabolic syndrome. This study helps restate the importance of physical activity as a treatment method for people with metabolic syndrome. Not only can you decrease the factors associated with metabolic syndrome but you can actually improve the functional capability and endothelium-dependent vasodilator response.

In an article by Dube et al. (2012), they talk about exercise dose and insulin sensitivity and how it relates to diabetes prevention. Even though they do not access metabolic syndrome, this article is still relevant. Diabetes is not one of the risk factors of metabolic syndrome but metabolic syndrome can eventually lead to diabetes. The more research out there that are about using exercise as a treatment for metabolic syndrome or diabetes the closer we are at helping people diminish metabolic syndrome or diabetes all together. In this article, they looked at 55 volunteers (21-men and 34-women) 25-75 years of age during a 16 week supervised exercise intervention. The subject were given a pre and post test where they measured glucose with a glucose clamp, height, weight, BMI, fat mass, fat free mass, physical fitness, HR, blood pressure and an electrocardiogram. Of the 16 week program, "The first 4 weeks, the intensity was 60-70% of peak HR for duration of 30 min. In weeks 5-8, intensity was kept similar, and exercise duration was increased to 40 min. During weeks 9-16, intensity was increased to 755 of peak HR and the duration to 45 min." (Dube et al., 2012).

They found a significant increase in insulin sensitivity with the intervention. They stated that "Further analyses revealed that this change was significantly related to the average kilocalories expended per week and to the average kilocalories expended per minute but not the

amount of sessions per week" (Dube et al., 2012). Dube et al. did find a significant improvement in only BMI and fat loss that were related to the amount of exercise sessions per week. If exercise can help insulin sensitivity in people with diabetes or prevent diabetes then it can help people with reducing factors associated with metabolic syndrome. The factors that make up metabolic syndrome can eventually increase the odds of that person getting diabetes. This study shows positive results in diabetes prevention which can in turn help with preventive measures for metabolic syndrome.

The article by Bird and Hawley (2012) "Exercise and type 2 diabetes: New prescription for an old problem" present evidence to demonstrate that appropriate exercise training is a clinically proven, primary intervention that delays and in many cases prevents the health burdens associated with MetS, and focus attention on a novel form of exercise prescription, moderate-intensity interval training, and show that interval training is a time-efficient and well-tolerated therapeutic intervention to improve cardio-metabolic health in a number of pre-clinical and clinical populations (Bird and Hawley, 2012). Physical inactivity and the rise of chronic metabolic diseases is nothing new in today's world. The decline in physical activity levels in the past five decades can be attributed to a combination of factors, including: jobs becoming less physically active and more 'desk based', the reliance on motorized transport rather than walking and cycling, and the growth in the popularity of sedentary past-times involving television and computers (Bird and Hawley. 2012). This is why physical activity is so important to incorporate into a daily routine. It has been proven to "delay and in many cases prevent health burdens associated with metabolic syndrome". The American College of Sports Medicine ACSM) states "Adults should get at least 150 minutes of moderate-intensity exercise per week. Exercise recommendations can be met through 30-60 minutes of moderate-intensity exercise (five days per week) or 20-60 minutes of vigorous-intensity exercise (three days per week)". Such guidelines are based on incontrovertible evidence from observational and randomized clinical trials

demonstrating that regular physical activity contributes to the primary and secondary prevention of T2DM (Type 2 Diabetes Mellitus) and CHD (Coronary Heart Disease) (Bird and Hawley. 2012).

Bird and Hawley state how interval training may over-come some of the barriers to compliance typically associated with traditional exercise prescriptions, thereby facilitating sustainable changes in lifestyle and promoting the associated health benefits. They discuss that time is one of those barriers in which an interval training workout can fix that. Shorter (1-5min) bouts of intense (.75% of VO_{2max}) exercise may be the most effective strategy to improve metabolic health and reduce the risk for metabolic syndrome (Bird and Hawley. 2012). People with metabolic syndrome that do not have an hour to spend in the gym can perform interval training workouts and get a moderate intensity workout in about half the time it takes for a moderate intensity workout. Moderate-volume interval training has been shown to improve metabolic fitness to the same or even a greater extent than continuous moderate-intensity training in a range of populations including individuals with coronary artery disease and/or congestive heart failure, middle age adults with metabolic syndrome and obese individuals (Bird, Hawley. 2012). In general this article describes the importance of interval training and its effects it has on metabolic syndrome, coronary heart disease and obese individuals. The more research that is done on exercise and its effects on metabolic disease the better we can understand its health benefits.

In the research article by Crist et al. (2012), they proposed whether a change in aerobic fitness could significantly change the odds of metabolic syndrome. This study was to look at the prevalence of metabolic syndrome over an 18 month period. They looked at 810 subjects that were found over 4 clinical sites: John Hopkins University, Pennington Biomedical Research Center, Duke University Medical Center and Kaiser Permanente Center for Health Research. The subjects were randomly assigned into 1 of 3 groups. Group 1 was an advice-only control group

(AO), group 2 was a comprehensive lifestyle intervention group, termed the Established Group (EST) and group 3 was a comprehensive lifestyle intervention plus Dietary Approaches to Stop Hypertension (DASH) diet group, EST+DASH (Crist et al., 2012).

The AO group was given advice on weight loss, dietary intake and regular physical activity. Group EST and EST+DASH were given a multicomponent lifestyle intervention. This intervention consisted of an 18 month program that was based on the most current clinical practice guidelines for blood pressure control and cardiovascular health (Crist et al., 2012). The Subjects had to accumulate 180 minutes per week of moderate-intensity physical activity, limit their alcohol intake to 1oz or less per day, weight loss of at least 15lb at 6 months and limit their daily sodium intake. Since both of these groups had the same exercise goals, there were combined to form the Combined Lifestyle Treatment (CLT). All 3 groups took assessments at baseline, 6 months and 18 months. Each assessment consisted of an aerobic fitness test using a sub-maximal treadmill exercise test, blood pressure, waist circumference, triglycerides, HDL and glucose.

The results of the study showed that prevalence of metabolic syndrome decreased to 34% at 6 months and 32% at 18 months in the control group and 31% at 6 months and 33% at 18 months in the combined lifestyle treatment group (Crist et al., 2012). When both groups (AO, CLT) were combined, change in aerobic fitness significantly affected the odds of having metabolic syndrome at follow-up, a 1-beat-per-minute reduction in heart rate was associated with a 4% reduction in prevalence of metabolic syndrome (Crist et al., 2012). Overall Crist et al. (2012) concluded increased aerobic fitness may reduce prevalence of metabolic syndrome. This study just like the others show how important it is to continue further research on the effects exercise has on metabolic syndrome. Metabolic syndrome according to the 2003-2006 National Health and Nutrition Examination Survey shows the prevalence of the US is approximately 34% (Crist et al., 2012)

Metabolic syndrome in adults can be decreased with physical activity as it has been proven in almost all of the studies listed above but what about the elderly? In this study by Wang et al. (2012) they look at the "Effects of a 12-Month Physical Activity Intervention on Prevalence of Metabolic Syndrome in Elderly Men and Women." The prevalence approaches 47% and 57% for men and women older than 70 years in the United States (Wang et al., 2012). For this study Wang et al. looked at a population of 361 elderly adults from 70-89 years of age. The subjects were then divided into two different groups. Group 1 was physical activity (PA) which had 180 subjects and group 2 was successful aging (SA) which had 180 subjects. The PA intervention consisted of a combination of aerobic, strength, balance and flexibility exercises (Wang et al., 2012). The SA intervention included weekly small group meeting for the first 24 weeks and monthly thereafter (Wang et al., 2012). For the baseline, 6, and 12 month assessments they took body weight, height, waist circumference and blood samples.

The results found that there were no differences between groups in the prevalence of metabolic syndrome. Wang et al. also found that there were no group differences in individual metabolic syndrome components. In the end they suggested that medication usage may override any beneficial metabolic effects on PA in this age group (Wang et al., 2012). This study gives evidence why there needs to be more research done on the effects of physical activity and metabolic syndrome. Just because one study didn't show significant findings for physical activity and metabolic syndrome in the elderly doesn't mean this should be the end. The more research there is about this, the more we will be able to understand how to fight metabolic syndrome.

CHAPTER III

METHODOLOGLY

The purpose of this study is to record and analyze data from a fitness intervention with the help of the Campus Wellness employees and their metabolic syndrome program consisting of faculty and staff at a Midwestern University. This chapter will explain the details of the research study including subjects, research design, instrumentation, and procedures.

Subjects

Faculty and Staff at a Midwestern University that have been selected for the metabolic syndrome program will be the primary subjects of this study. The subjects were pre-selected as long as they met the criteria of metabolic syndrome. The metabolic syndrome program had a total of 12 people that met the criteria of which 11 (6 males and 5 females) agreed to participate in the study after reading the email recruitment script (Appendix 1A). The subjects' age range was from 30-64 years old. The subjects gave written consent (Appendix 2A) to participate in the study, which was approved by the universities Institutional Research Board (Appendix 3A). This study will give us the opportunity to see how a cardiorespiratory intervention will affect different age groups and its effects on the symptoms of metabolic syndrome.

Research Design

The experimental design for this study will be a convenience sampling. The subjects were already part of the metabolic syndrome program in which we recruited for this study. This allowed easy access to previously recorded data of the pre-existing program.

Instrumentation

Polar FT4-

The Polar FT4 is a watch that monitors a person's heat rate via a strap that goes around the subjects' sternum. The strap is fit and wrapped around the subjects' chest where the device is on top of their sternum. The device will relay the heart rate to the watch and also display it on the treadmills/bikes. This makes it convenient so the subject doesn't have to look at the watch while on the treadmill and lose balance or injure themselves.

Accu-Chek Compact-

Accu-Chek Compact is an all-in-one compact blood sugar monitor that will be used to measure the following (total cholesterol, HDL cholesterol, LDL cholesterol, fasting blood glucose and triglycerides).

Sit and Reach Test-

Using a ruler, the subject will sit with legs fully extended on the ground and feet flat up against a wall. They will reach as far forward as possible in a smooth motion three consecutive times recording all three measurements. This will help in determining the flexibility of the subject.

YMCA Bench Press Test-

Using a standard bench press males will use an 80 lb. barbell and women will use a 35 lb. barbell. Using a metronome, the subject will move the barbell up and down (bench-pressing) to

the beat of the metronome (set at 60 beats per minute). The test will be terminated when the subject is unable to reach full extension of the elbows or the subject breaks cadence and cannot keep up with the rhythm of the metronome.

Naughton Treadmill Protocol-

The Naughton protocol as stated by the ACSM's Guidelines for Exercise Testing and Prescription starts with a 2 minute warm-up. The speed is set to 1 mph and the incline is set to 0. After the warm-up, the speed is set at 2 mph and does not change for the remainder of the test. The test consists of six, 2 minute intervals. The grade starts at 0 for the first interval, and increases by 3.5 percent every 2 minutes. The test will be terminated when the subject cannot keep up with the speed or exceeds their max heart rate.

Karvonen Formula-

The Karvonen formula is a mathematical formula that helps determines a person's target heart rate zone. This method of calculating a person's exercising heart rate is considered the gold standard. The Karvonen formula is (Heart Rate Zone= [(Max Heart Rate – Resting Heart Rate) X % intensity] + Resting Heart Rate.

Heart Rate Reserve-

Heart Rate Reserve is the difference between resting and maximal Heart Rate.

Procedures

We implemented a fitness intervention which consisted of an aerobic exercise session 3 times a week for 12 weeks where each subject's heart rate was recorded and monitored with wrist heart rate monitors (Polar FT4). Each exercise session was 30 minutes in duration. If the subjects do not want to wear the heart rate monitors, we took their radial pulse. To figure out their pulse we counted the number of beats for 10 seconds and multiply that number by 6. This gave us the subjects' heart rate without using the heart rate monitors. To figure out the subjects HR max we used the following formula (220-subjects age). During the intervention we increased the subjects HR Reserve by 5% every two weeks until they reach 65%. (Heart Rate reserve is the difference between resting and maximal Heart Rate). Thus, the subjects started off at 40% of their HR Reserve and ended at 65% of their HR Reserve. During the aerobic exercise session the subjects exercised in their designated heart rate zone determined by their HR Reserve via heart rate monitors. We used the Karvonen formula (listed above) to calculate each subjects target heart rate zone. We did this by subtracting their max HR from their resting HR then multiplying it by the percent intensity we wanted for that workout. After that we add resting HR to the total and got their target heart rate zone. The intensity will consist of low to moderate walking on a treadmill (Primary) or peddling on a recumbent bike (Secondary). This fitness intervention replaced the cardio session in the metabolic syndrome program. The metabolic syndrome program is a well-established fitness program that gives people with metabolic syndrome a chance to decrease their symptoms associated with metabolic syndrome.

We looked at the pre-test and post-test data that was collected during the metabolic syndrome program, which included the following: gender, height, age, pre- and post-intervention

body weight, body mass index (which is a measurement based on weight and height), waist girth, and blood pressure (using a blood pressure cuff and a stethoscope). Accu-Chek Compact was used to measure their total cholesterol, HDL cholesterol, LDL cholesterol, fasting blood glucose and triglycerides. A finger prick (Lance) was all that was needed for the measurement of cholesterol, blood glucose and triglycerides. The lance was disposed of in a biohazard trash can which was later disposed of properly. Plastic gloves were worn during the finger prick, rubbing alcohol was used to wipe down the finger before using the lance and a band aid was placed on the puncture site.

Flexibility (Sit and Reach Test), muscular endurance (YMCA Bench Press Test), and cardiorespiratory fitness (Naughton Treadmill protocol) was also measured. Subjects were under the supervision of certified personal trainers that work at the campus wellness center. All the certified personal trainers have been certified through either ACE (American Council on Exercise) or ACSM (American College of Sports Medicine).

Analysis

All statistical data was analyzed using SPSS (Version 21) statistics. 13 separate compared sample t-test were used to figure out the significant differences between pre-intervention and post-intervention. The *P* value was set at < 0.05. Some statistical data (2 people from girth and 1 person from triglycerides) was left out of the calculations so the outliers would not skew the data.

CHAPTER IV

FINDINGS

Results

The overall prevalence of metabolic syndrome in this study decreased from 100% pre-intervention to 63% post-intervention as seen in Fig. 1. After the 12-week fitness intervention 63% of the subjects reduced their risk factors associate with metabolic syndrome and 36% of the subjects were below the criteria for having metabolic syndrome (< 3 risk factors) as show in Fig. 1. Out of the 13 pre/post-intervention assessments, only 6 showed a significant difference ($p < 0.05$): pre/post weight (p =.003), pre/post girth (p =.000), pre/post risk factors for metabolic syndrome (p =.004), pre/post sit and reach test (p =.025), pre/post bench press test (p =.004) and pre/post resting heart rate (p =.015). There was not however a significant difference in (pre/post cholesterol (p =.386), pre/post HDL (p =.326), pre/post LDL (p =.102), pre/post triglycerides (p =.229), pre/post glucose (p =.332), pre/post systolic blood pressure (p =.636), and pre/post diastolic blood pressure (p =.873). Even though there was a significant difference in pre/post resting heart rate, there was not a decrease but actually a slight increase in resting heart rate.

As shown in Fig. 2. you can see the individual risk factor changes along with the age and how it correlates. Also shown are the individuals who are no longer classified as having metabolic syndrome identified with an asterisk.

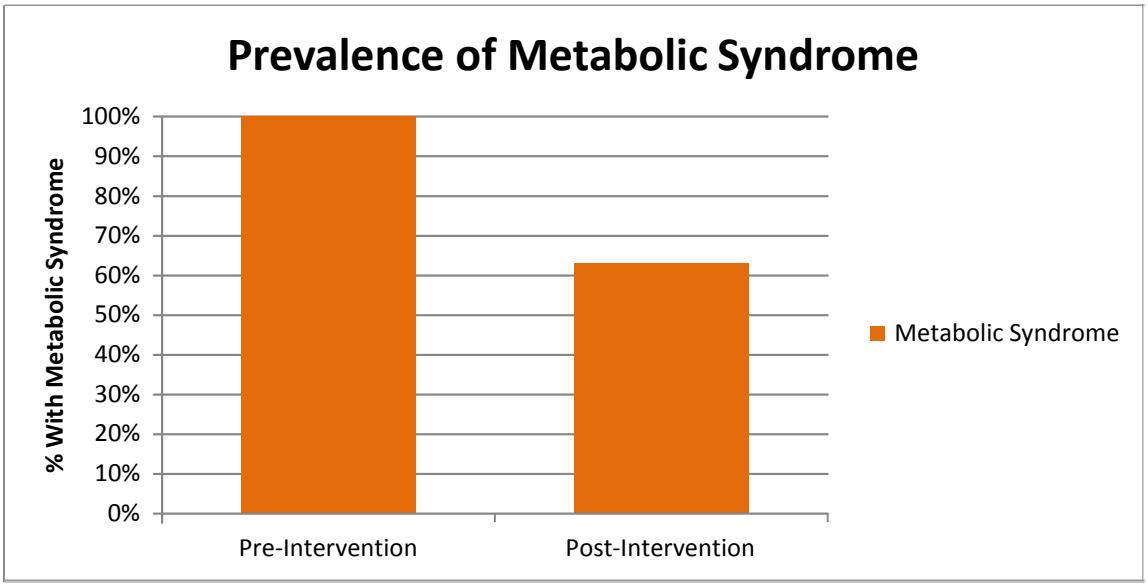

Figure 1.-Prevalence of metabolic syndrome before and after a 12 week fitness intervention.

***P* < 0.05 pre-intervention versus post-intervention**

Of the subjects who were no longer classified as having metabolic syndrome (36%) after the intervention, 50% reduced their CHO, LDL and blood glucose, 50% increased their HDL, 75% decreased their triglycerides and 100% reduced their girth (waist circumference). This put them all below the values used to diagnose metabolic syndrome. As shown in Fig. 3A-M. you can see the means and standard deviation for all 13 pre/post-test measurements. This figure shows that even though some did not have a significant difference, there still was a positive result in some of the measures at the end of the 12-week fitness intervention.

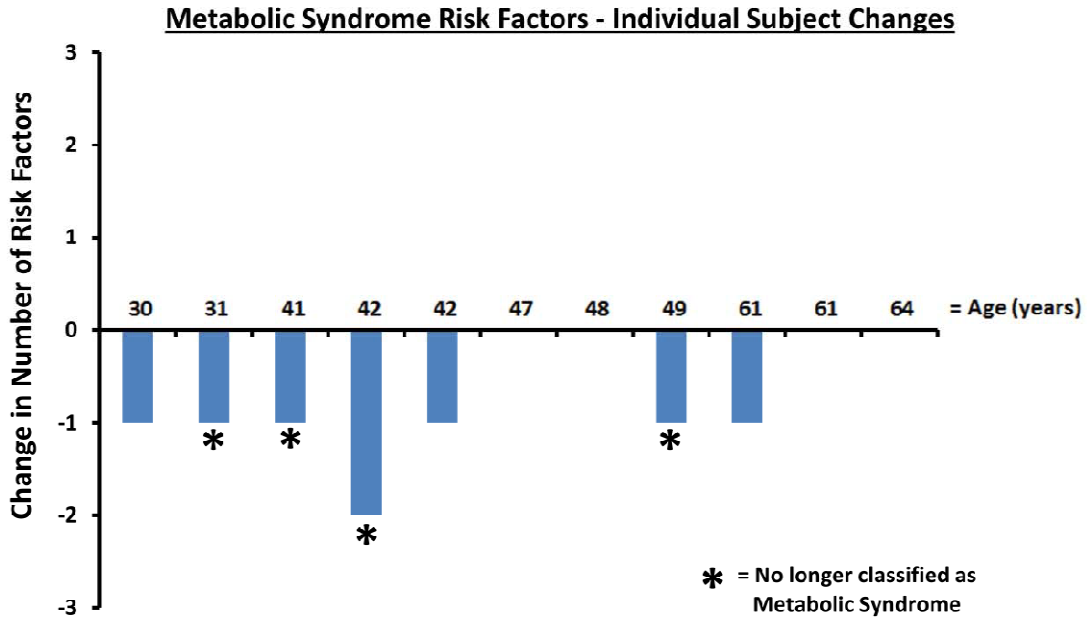

Fig. 2. Metabolic syndrome risk factor changes in individual subjects plus age. * indicates subjects no longer classified with metabolic syndrome.

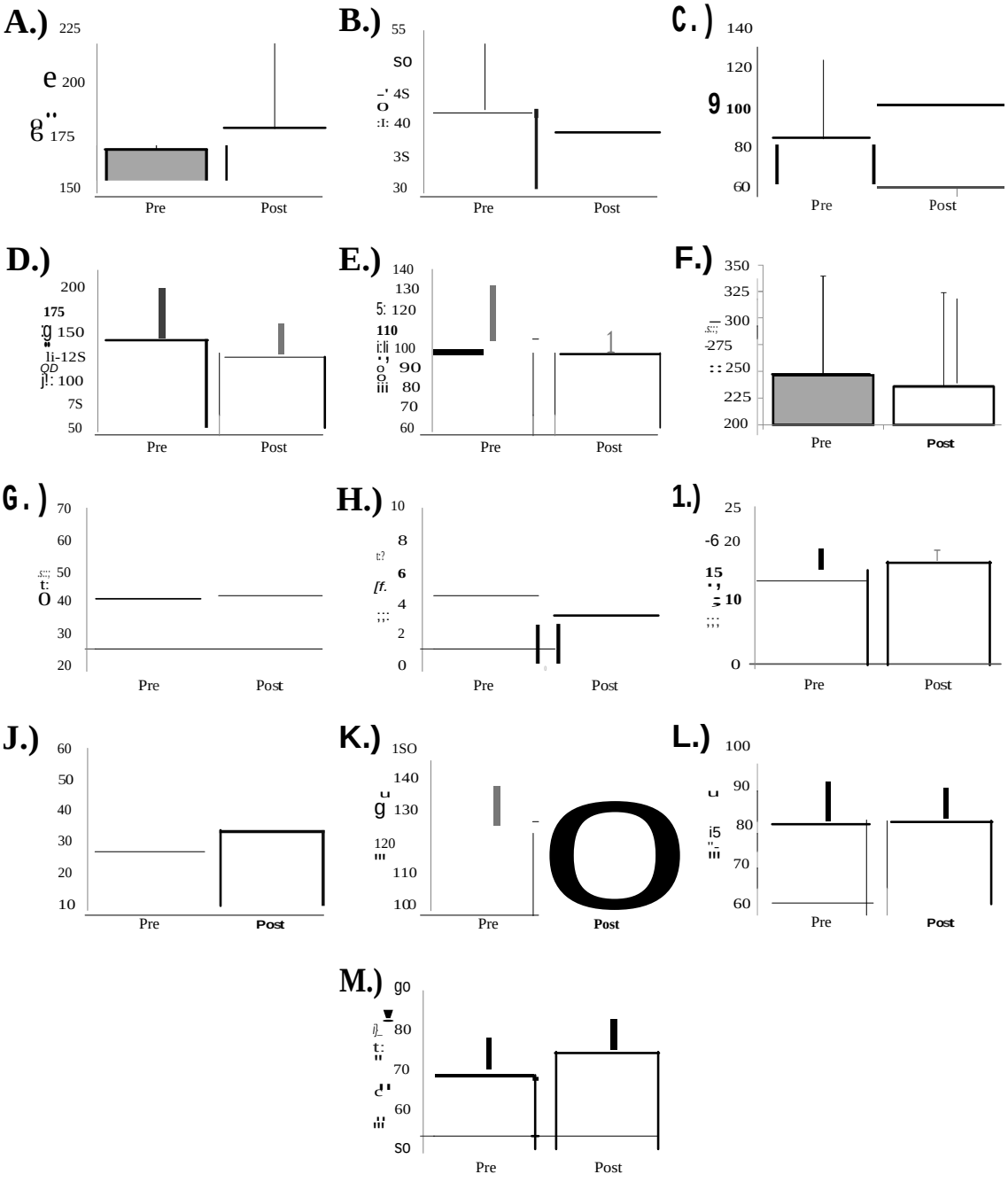

Fig. 3A-M. The means and SD of all13 Pre/Post measurements

Discussion

This study focused on how a 12 week fitness intervention would affect people with metabolic syndrome. The findings suggest that aerobic training mixed with weight training did cause a decrease in metabolic syndrome risk factors and 36% of subjects are now cleared of metabolic syndrome. Showing improvements in some of the factors that make up metabolic syndrome due to exercise training is encouraging but not all risk factors were improved. There is good evidence that aerobic exercise training has a beneficial effect on individual cardiovascular disease risk factors such as high blood pressure, dyslipidemia (particularly low HDL and high TG), and glucose intolerance (Katzmarzyk et al., 2003). These findings have the potential to impact the sedentary people who might not know the health benefits of physical activity and its effects on metabolic syndrome.

As stated in the results section earlier, there were findings of significant differences in a number of measurements (girth, weight, risk factors for metabolic syndrome, sit and reach test, bench press test and resting heart rate) between pre-intervention and post-intervention. The ones that did not show a significant difference could have been affected by the low population for this study. If more subjects were in this study there might be more measures that were significantly significant. The one that really stands out is the resting heart rate pre/post-test measures. Resting heart rate actually increased by the end of the intervention. This could be explained by high stress at work or medications they might be taking. These findings suggest that the fitness intervention did succeed in improving certain aspects of the metabolic syndrome spectrum just like it did in the HERITAGE Family Study (Katzmarzyk et al., 2003). Even though not all of the risk factors were affected, this fitness intervention was successful. The effects of exercise training seen in this

study play an important role in the prevention of metabolic syndrome because the subjects involved were at a high risk of future diseases due to the presence of multiple risk factors (Katzmarzyk et al., 2003). The current recommendation for physical activity and health are that all adults should be active for at least 150 mins of moderate-intensity aerobic activity per week or 75 mins of vigorous-intensity aerobic activity per week as stated by the Centers for Disease Control and Prevention (CDC. 2011, Dec. 1). With this exercise intervention, the subjects had to complete at least 150 mins of moderate-intensity aerobic activity per week. The subjects went from a sedentary lifestyle to a physically active lifestyle for 12 weeks and the majority of subjects saw significant improvements in their overall health. The statistical analysis only shows small changes in the risk factors associated with metabolic syndrome but other studies have reported that improved results with exercise training and metabolic syndrome. More research needs to be performed in order to better understand the effects of exercise training on people with metabolic syndrome.

Age will always be a factor that has to be considered into the equation. As you can see in Fig.3. age is show in correlation to the total loss in risk factors associated with metabolic syndrome. Fig. 3. shows that everybody below the age of 45 had a decrease in risk factors but the 4 subjects that didn't decrease their risk factors at all were all about the age of 45. This age range difference in risk factors might be explained by the amount of energy they have. The younger subjects might have had more energy and will power than the older subjects when it came to how hard they were going to work out that day. Another reason that might explain this is the older subjects might be set in their ways and not willing to fully change their sedentary ways. Where the younger subjects might be more willing to try new things and change their sedentary ways. In

the study by Wang et al. they found that physical activity had little to no beneficial effects on people with metabolic syndrome (Aged 70-89) due to medication use. This coincides with the results of this study as seen in Fig.3. of the 4 subjects that had no change in risk factors associated with metabolic syndrome (all over the age of 45). Age might play a bigger role in metabolic syndrome than we know. This is an interesting find considering the majority of the subjects in this study were on some kind of medication because of metabolic syndrome. It would be interesting to see more research done on the effects of physical activity on specific age ranges of people with metabolic syndrome while limiting the usage of medication.

Limitations

In this study there were several limitations one of which was the actual intervention. Starting the subjects at 40% of their HR Reserve and increasing 5% every two weeks had them walking on the treadmill where their heart rate was just slightly increased. The subjects were not getting the workout intensity they need to be able to see results in the end. This would have produced little to no change in the risk factors associated with metabolic syndrome. Another limitation in this study is the reliability of the subjects and completing 150 mins of exercise per week. The number of subjects in the study greatly decreases the power. If there were more subjects to this study we might have seen more pre/post-test measures be significantly different.

CHAPTER V

CONCLUSION

This study looked at the effects of a 12 week fitness intervention on people with metabolic syndrome and it has shown promising results. The two questions that were proposed at the beginning were: 1.) Will there be a decrease in resting heart rate over the fitness intervention? and 2.) Will there be a significant difference between pre-test and post-test data? The hypothesis was that the 12-week fitness intervention will reduce risk factors associated with metabolic syndrome and decrease resting heart rate. To figure out these questions and see if the hypothesis is correct, measurements were taken at the beginning and end of the 12 week fitness intervention. The data was then run through SPSS (version 21, a statistical program) to see if there were any significant differences. The results showed that there was not a decrease in resting heart rate and that there was a significant difference in some of the pre/post-test measurements.

Finding more about how exercise can be used as a preventative measure is just a small section of the big picture. There are studies out there that prove exercise is beneficial: (Crist et al., 2012), The HERITAGE Family Study (Katzmarzyk et al., 2003) and (Dube et al., 2012) just to name a few. These studies all look at exercise and metabolic syndrome as a single group. The bigger picture is looking at how to apply this knowledge of exercise towards the general population, not just people with metabolic syndrome. This study proved that with 12 weeks of exercise you can lose weight and gain strength. Yes, we know exercise is beneficial towards

people with metabolic syndrome but what about people in the general population? Informing them could help improve their daily life. This study and the ones listed earlier have the potential not only to change the lives of people with metabolic syndrome but the lives of people who don't know the benefits of exercise.

In summary, this study showed evidence that exercise does in fact help reduce some of the risk factors associated with metabolic syndrome but does not decrease resting heart rate. There needs to be more research done to further prove the benefits of exercise on people with metabolic syndrome. Seeing how exercise helped these people in this study, it would be interesting to see how the same fitness intervention would affect sedentary people (general population) vs. people with metabolic syndrome. This would be a great idea for future research in this field.

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APPENDICES

Appendix 1A.

Verbal/Email Recruitment Script

Hello, my name is Andrew Hall, and I am a master's student in the Department of Health and Human Performance here at Oklahoma State University. I would like to conduct a research study with my advisor Dr. Dough Smith, an associate professor in the department, on the effectiveness of an aerobic fitness intervention on the factors contributed with Metabolic Syndrome. The title of the study is "The Effectiveness of a 12-week Fitness intervention for Individuals with Metabolic Syndrome". We will be analyzing changes in the variables: gender, age, height, body weight, body mass index, waist girth, blood pressure, total cholesterol, HDL cholesterol and LDL cholesterol, fasting blood glucose and triglycerides from pre-intervention to post-intervention.

The records of this study will be kept private. Any written results will discuss group findings and will not include information that will identify you. Research records will be stored securely and only researchers and individuals responsible for research oversight will have access to the records.

You will be required to sign an informed consent document showing that you are willing to participate in this study and allow your data to be collected and used for research purposes. Your participation will greatly benefit the research community and clinicians by identifying effective exercise interventions aimed at improving the health of individuals with metabolic syndrome. I would be happy to answer any additional questions that you may have about the study. Do you think you might be interested in participating?

Thank you.

Andrew Hall
Masters Student
Seretean Wellness Center
Department of Health and Human Performance
Oklahoma State University
Seretean Wellness Center
Stillwater, OK 74078
Email: Andrew.hall10@okstate.edu
Phone: (817) 692-7655

Appendix 2A

Informed Consent Form

Project Title: The Effectiveness of a 12-week Fitness intervention for Individuals with Metabolic Syndrome

Investigators:

Andrew Hall

Masters Student

Seretean Wellness Center

Department of Health and Human Performance

Oklahoma State University

Seretean Wellness Center

Stillwater, OK 74078

Email: Andrew.hall10@okstate.edu

Phone: (817) 692-7655

Dr. Doug Smith Ph.D.

Associate Professor

Applied Musculoskeletal and Human Physiology Lab

Department of Health and Human Performance

Oklahoma State University

180 Colvin Recreation Center

Stillwater, OK 74078

Email: doug.smith@okstate.edu
Phone: (405) 744-5500

Purpose: The purpose of this consent form is to obtain your permission to use data that will be collected during the 12-week Met-S program for research purposes. The data will include the following: gender, age, height, body weight, body mass index, waist girth, blood pressure, total cholesterol, HDL cholesterol and LDL cholesterol, fasting blood glucose and triglycerides. The data will not include identifiers (i.e. names of participants); each individual's personal data will be recorded on paper and entered into a computer spreadsheet and coded by a subject number. After this has been done, all records with personal identifiers will be returned to the Seretean Wellness Center. Any written results will discuss group findings and will not include information that will identify you.

Procedures: There will be a pre and post-test collecting the following from all of the subjects participating in this study: gender, height, and age, and pre- and post-intervention body weight, body mass index, waist girth, blood pressure, total cholesterol, HDL cholesterol and LDL cholesterol, fasting blood glucose and triglycerides, flexibility, muscular endurance, and cardiorespiratory fitness. There will be a 30 min. aerobic session three times a week where your heart rate will be monitored with heart rate monitors during the 12 week program. The aerobic session will consist of using a treadmill or recumbent bike while exercising in your calculated heart rate zone using the heart rate monitors. This is for research purpose only.

Risk of Participation: Associated with physical exercise there might be some muscle soreness and/or fatigue that will be short term. You will be under constant supervision of a personal trainer at the Seretean Wellness Center gym/Colvin gym to insure safety during the workouts.

Benefits: The benefits of this study will help in figuring out if a structured cardiorespiratory fitness program has an effect on reducing any of the factors that are associated with metabolic syndrome.

Confidentiality: The records of this study will be kept private. The records will be stored securely within room 108 in the Seretean Wellness Center and only researchers and individuals responsible for research oversight will have access to the records. It is possible that the consent process and data collection will be observed by research oversight staff responsible for safeguarding the rights and wellbeing of people who participate in research. All data will be kept for a period of 3 years, whereupon paper data will be shredded and electronic data will be removed from the computer it is stored on.

Contacts: If you have questions about the research please feel free to contact Andrew Hall at 817-692-7655 and/or Dr. Doug Smith at 405-744-5500. If you have questions about your rights as a research volunteer, you may contact Dr. Shelia Kennison, IRB Chair, 219 Cordell North, Stillwater, OK 74078, 405-744-3377 or irb@okstate.edu

Signatures:

I have read and fully understand the consent form. I sign it freely and voluntarily. A copy of this form has been given to me.

_____ _____

Signature of Participant Date

I certify that I have personally explained this document before requesting that the participant sign it.

_____ _____

Signature of Researcher Date

I certify that I have personally explained this document before requesting that the participant

Sign it.

_____ _____

Signature of Researcher Date

Appendix 3A.

Application for Review of Human Subjects Research **Submitted to the** **Oklahoma State University Institutional Review Board** Pursuant to 45 CFR 46	IRB Number FOR OFFICE USE ONLY
Title of Project: The Effectiveness of a 12-week Fitness intervention for Individuals with Metabolic Syndrome	
Is the Project externally funded? Yes No If yes, complete the following: Private State Federal Agency: Grant No: OSU Routing No:	
☐ ☒ ☐ ☐ ☐ Type of Review Requested: Exempt Expedited Full Board	
Principal Investigator(s): *I acknowledge that this represents an accurate and complete description of my research. If there are additional PIs, provide information on a separate sheet.*	

☐ ☒ ☐

Andrew Hall		4/16/13
Name of Primary PI (typed)	Signature of PI	Date
SAHEP/HHP	COE	
Department	Col ege	
Seretean Wellness Center	817 692 7655	andrew.hall10@okstate.edu
PI's Address (Street, City, State, Zip)	Ph ne	E-Mail

Required IRB Training Complete: Yes No

(Training must be completed before application can be reviewed)

	☐ ☐	
Name of Co-PI (typed)	Signature of Co-PI	Date
Department	College	
I's Address	Phone	E-Mail

Required IRB Training Complete: Yes No

(Training must be completed before application can be reviewed)

Adviser (complete if PI is a student): *I agree to provide the proper surveillance of this project to ensure that the rights and welfare of the human subjects are properly protected.*

Doug Smith Ph.D		4/16/13
Adviser's Name (typed)	Signature of Adviser	Date

SAHEP/HHP	COE	
Department	College	
196 Colvin Recreation Center	405-744-5500	Doug.smith@okstate.edu
Adviser's Address	Phone	E-Mail

Required IRB Training Complete: ☒ Yes ☐ No

(Training must be completed before application can be reviewed)

1. Describe the purpose and the research problem in the proposed study. *Your response in this section will enable the reviewers to determine whether the project meets the criteria of research with human participants and also the extent to which the research may produce new generalizable knowledge that may benefit the participants and/or society.*

The purpose of this study is to record and analyze data from a fitness intervention with the help of the Seretean Wellness employees and their program (Balance Program) consisting of faculty and staff at OSU with metabolic syndrome. Metabolic syndrome is a constellation of risk factors that increases a person's risk of developing cardiovascular disease. The following factors constitute metabolic syndrome: abdominal obesity, elevated triglycerides, low HDL cholesterol, raised blood pressure, and insulin resistance. When three or more of these risk factors are present an individual classified as having metabolic syndrome. This study will help us show that with proper exercise and weight management people can lower their chances of getting metabolic syndrome.

2. (a) Describe the subjects of this study:

   1) Describe the sampling population: Faculty and staff at OSU

   2) Describe the subject selection methodology(i.e. random, snowball, etc.): Convenience sample

   3) Describe the procedures to be used to recruit subjects. Include copies of scripts, flyers, advertisements, posters or letters to be used. **If recruitment procedures will require access to OSU System email addresses you will need to include Appendix A of this application**:[7] Subjects will be recruited through the use of informational flyers in the Seretean Wellness Center.

   4) How many subjects are expected to participate?: 12 subjects will participat in the MET-S program.

   5) What is the expected duration of participation for each segment of the sampling population? If there is more than one session, please specify the duration of each session: This is a 14 week program requiring each particapant to exercise at least 150 min. each week.

   6) Describe the calendar time frame for gathering the data using human subjects: The time frame for gathering the data will be upon final IRB approval – Aug 2014.

   7) Describe any follow-up procedures planned: There will be no follow-up procedures with this study. The subjects will be finished with this study after the 14 week program is over.

   (b) Are any of the subjects under 18 years of age? ☐ Yes ☒ No

   If Yes, you must comply with special regulations for using children as subjects. Please refer to IRB Guide.

3. Provide a detailed description of any methods, procedures, interventions, or manipulations of human subjects or their environments and/or a detailed description of any existing datasets to be accessed for information. Please indicate the physical location where the research will take place (if applicable). Include copies of any questionnaires, tests, or other written instruments, instructions, scripts, etc., to be used.

We will be implanting a fitness intervention which will consist of an aerobic exercise session 3 times a week for 12 weeks where each subject's heart rate will be recorded and monitored with wrist heart rate monitors (Polar FT4). If the subjects do not want to wear the heart rate monitors, we will take their pulse (either from their neck or wrist). To figure out their pulse we will count the number of beats for 10 seconds and multiply that number by 6. This will give us the subjects' heart rate without using the heart rate monitors. To figure out the subjects VO_2 max we will use the following formula (220-subjects age). During the intervention we will increase the subjects VO2 Reserve (VO_2 Reserve-difference between resting and maximal VO2), (VO_2-measurement of oxygen use: a factor used in

measuring the maximum amount of oxygen used by an athlete or exerciser while performing at peak intensity.) by 5% every two weeks until they reach 65%. The subjects will start off at 40% of their VO_2 Reserve and end at 65% of their VO_2 Reserve. During the aerobic exercise session the subjects will exercise in their designated heart rate zone determined by their VO_2 Reserve via heart rate monitors. We will use the Karvonen formula to calculate each subjects target heart rate zone (HeartRateZone= [(MaxHeartRate – RestingHeartRate) X % intensity] + RestingHeartRate). The intensity will consist of low to moderate walking on a treadmill (Primary) or peddling on a recumbent bike (Secondary). This fitness intervention will replace the cardio session in the Balance Program. The Balance Program is a well-established fitness program that gives people with metabolic syndrome a chance to decrease their symptoms associated with metabolic syndrome. We will also be looking at the pre-test and post-test data that will be collected during the Balance Program, which will include the following: gender, height, age, pre- and post-intervention body weight, body mass index (which is a measurement based on weight and height), waist girth, blood pressure (using a blood pressure cuff and a stethoscope). Accu-Chek Compact (all-in-one compact blood sugar monitor) will be used to measure the following (total cholesterol, HDL cholesterol and LDL cholesterol, fasting blood glucose and triglycerides). A finger prick (Lance) will be all that is needed for the measurement of cholesterol, blood glucose and triglycerides. The lance will be disposed of in a biohazard trash can which will later be disposed of properly. Plastic gloves will be worn during the finger prick and rubbing alcohol will be used to wipe down the finger before using the lance. Flexibility (Sit and Reach Test; using a rule the subject will sit with legs fully extended on the ground and feet flat up against a wall. They will reach as far forward as possible in a smooth motion three consecutive times recording all three measurements), muscular endurance (YMCA Bench Press Test; Using a standard bench press males will use a 80 lb. barbell and women will use a 35 lb. barbell. Using a metronome, the subject will move the barbell up and down (bench-pressing) to the beat of the metronome (set at 60 beats per minute). The test will be terminated when the subject is unable to reach full extension of the elbows or the subject breaks cadence and cannot keep up with the rhythm of the metronome), and cardiorespiratory fitness (Naughton Treadmill protocol; The Naughton protocol starts with a 2 minute warm-up. The speed is set to 1 mph and the incline is set to 0. After the warm-up, the speed is set at 2 mph and does not change for the remainder of the test. The test consists of six, 2 minute intervals. The grade starts at 0 for the first interval, and increases by 3.5 percent every 2 minutes. The test will be terminated when the subject cannot keep up with the speed or exceeds their max heart rate.) will also be analyzed. They will be under the supervision of certified personal trainers that work at the Colvin/Seretean Wellness Center. All the certified personal trainers have been certified through either ACE (American Council on Exercise) or ACSM (American College of Sports Medicine).

4. Will the subjects encounter the possibility of stress or psychological, social, physical, or legal risks that are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests? ☒Yes No

☐

If Yes, please justify your position: The subjects will participate in a fitness intervention program consisting of at least 150 mins. a week. They will be under the supervision of certified personal trainers that work at the Colvin/Seretean Wellness Center. All the certified personal trainers have been certified through either ACE (American Council on Exercise) or ACSM (American College of Sports Medicine).

5. Will medical clearance be necessary for subjects to participate because of tissue or blood sampling, administration of substances such as food or drugs, or physical exercise conditioning? Yes No

If Yes, please explain how the clearance will be obtained: The subjects will need clearance from their primary doctor and sign and date the consent forms.

☒ ☐

6. Will the subjects be deceived or misled in any way? Yes No

If Yes, please explain:

☐ ☒

7. Will information be requested that subjects might consider to be personal or sensitive? Yes No

If Yes, please explain: Subjects will be asked for such personal information as; age, height, body weight, blood pressure, cholesterol (HDL and LDL), triglycerides, fasting glucose, and eating behaviors via self report on a food log. This is consistent with previous groups that have participated in this program.

☒ ☐

8. Will the subjects be presented with materials that might be considered to be offensive,

threatening, or degrading? Yes No

If Yes, please explain, including measures planned for intervention if problems occur.

☐ ☒

9. Will any inducements be offered to the subjects for their participation? Yes No

If Yes, please explain:

☐ ☒

NOTE: If extra course credit is offered, describe the alternative means for obtaining additional credit available to those students who do not wish to participate in the research project.

10. Describe the process to be used to obtain the consent/assent of all subjects including (as appropriate); who will seek the consent/assent, steps to minimize coercion or undue influence, and the method(s) to be used to document the consent.

Please provide copies of all consent documents with your application

Permission to analyze data from the intervention will be requested via the attached consent form. Subjects will be contacted by the PI (myself) during the initial meeting. I have attached a copy of the consent form.

13. Will the data be a part of a record that can be identified with the subject? Yes No

If Yes, please explain: The subjects will have a folder with their ID # and recorded date in it to be used in the analysis later. These will be stored in a locked file box at the front desk of the Colvin/Seretean Wellness Center gym where the PI and the certified personal trainers will be the only ones who have access. ☒ ☐

14. Describe the steps you are taking to protect the confidentiality of the subjects and how you are going to advise subjects of these protections in the consent process. Include information on data storage and access. If data will not be reported in the form of group

means, please explain how the data will be reported.

All subject files with identifiers (such as names) will be returned to the Seretean Wellness Center once the data has been recorded. Subject numbers will replace subject names. Subject data, using subject numbers as identifiers instead of names, will be kept in hard copy in a locked cabinet and on a desktop computer in advisor Dr. Doug Smith's office for a period of 3 years; whereupon paper data will be shredded and electronic data will be removed from the computer it is stored upon. All written results will only discuss group findings and not individual identifiers such as names.

15. Will the subject's participation in a specific experiment or study be made a part of any record available to his or her supervisor, teacher, or employer? ☐Yes ☒No

If Yes, please describe:

16. Describe the benefits that might accrue to either the subjects or society. *Note that 45 CFR 46, Section 46.111(a)(2) requires that the risks to subjects be reasonable in relation to the anticipated benefits. The investigator should specifically state the importance of the knowledge that reasonably may be expected to result from this research.*

The benefits of this study will help in figuring out if a structured cardiorespiratory fitness program associated with a daily food log has an effect on reducing any of the factors that are associated with metabolic syndrome.

Appendix 4A.

Oklahoma State University Institutional Review Board

Date:	Monday, August 26, 2013
IRB Application No	ED13134
Proposal Title:	The Effectiveness of a 12-week Fitness Intervention for Individuals with Matabolic Syndrome
Reviewed and Processed as:	Expedited

Status Recommended by Reviewer(s): Approved Protocol Expires: 8/25/2014

Principal Investigator(s):

Andrew Hall
2326 N. Benjamin
Stillwater, OK 74075

Douglas Smith
180 CRC
Stillwater, OK 74078

The IRB application referenced above has been approved. It is the judgment of the reviewers that the rights and welfare of individuals who may be asked to participate in this study will be respected, and that the research will be conducted in a manner consistent with the IRB requirements as outlined in section 45 CFR 46.

The final versions of any printed recruitment, consent and assent documents bearing the IRB approval stamp are attached to this letter. These are the versions that must be used during the study.

As Principal Investigator, it is your responsibility to do the following:

1. Conduct this study exactly as it has been approved. Any modifications to the research protocol must be submitted with the appropriate signatures for IRB approval. Protocol modifications requiring approval may include changes to the title, PI, advisor, funding status or sponsor, subject population composition or size, recruitment, inclusion/exclusion criteria, research site, research procedures and consent/assent process or forms.
2. Submit a request for continuation if the study extends beyond the approval period of one calendar year. This continuation must receive IRB review and approval before the research can continue.
3. Report any adverse events to the IRB Chair promptly. Adverse events are those which are unanticipated and impact the subjects during the course of this research; and
4. Notify the IRB office in writing when your research project is complete.

Please note that approved protocols are subject to monitoring by the IRB and that the IRB office has the authority to inspect research records associated with this protocol at any time. If you have questions about the IRB procedures or need any assistance from the Board, please contact Dawnett Watkins 219 Cordell North (phone: 405-744-5700. dawnett.watkins@.okstate.edu).

Sincerely,

Shelia Kennison, Chair
Institutional Review Board

Informed Consent Form

Project Title: The Effectiveness of a 12-week Fitness intervention for Individuals with Metabolic Syndrome

Investigators:

Andrew Hall
Masters Student
Seretean Wellness Center
Department of Health and Human Performance
Oklahoma State University
Seretean Wellness Center
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Email: Andrew.hall10@okstate.edu
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Dr. Doug Smith Ph.D.
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Stillwater, OK 74078
Email: doug.smith@okstate.edu
Phone: {405) 744-5500

Purpose: The purpose of this consent form is to obtain your permission to use data that will be collected during the 12-week Met-S program for research purposes. The data will include the following: gender, age, height, body weight, body mass index, waist girth, blood pressure, total cholesterol, HDL cholesterol and LDL cholesterol, fasting blood glucose and triglycerides. The data will not include identifiers (i.e. names of participants); each individual's personal data will be recorded on paper and entered into a computer spreadsheet and coded by a subject number. After this has been done, all records with personal identifiers will be returned to the Seretean Wellness Center. Any written results will discuss group findings and will not include information that will identify you.

Procedures: There will be a pre and post-test collecting the following from all of the subjects participating in this study: gender, height, and age, and pre- and post-intervention body weight, body mass index, waist girth, blood pressure, total cholesterol, HDL cholesterol and LDL cholesterol, fasting blood glucose and triglycerides, flexibility, muscular endurance, and cardiorespiratory fitness. There will be a 30 min. aerobic session three times a week where your heart rate will be monitored with heart rate monitors during the 12 week program. The aerobic session will consist of using a treadmill or recumbent bike while exercising in your calculated heart rate zone using the heart rate monitors. This is for research purpose only.

Risk of Participation: Associated with physical exercise there might be some muscle soreness and/or fatigue that will be short term. You will be under constant supervision of a personal trainer at the Seretean Wellness Center gym/Calvin gym to insure safety during the workouts.

Benefits: The benefits of this study will help in figuring out if a structured cardiorespiratory fitness program has an effect on reducing any of the factors that are associated with metabolic syndrome.

Confidentiality: The records of this study will be kept private. The records will be stored securely within room 108 in the Seretean Wellness Center and only researchers and individuals responsible for research oversight will have access to the records. It is possible that the consent process and data collection will be observed by research oversight staff responsible for safeguarding the rights and wellbeing of people who participate in research. All data will be kept for a period of 3 years, whereupon paper data will be shredded and electronic data will be removed from the computer it is stored on.

Contacts: If you have questions about the research please feel free to contact Andrew Hall at 817-692-7655 and/or Dr. Doug Smith at 405-744-5500. If you have questions about your rights as a research volunteer, you may contact Dr. Shelia Kennison, IRB Chair, 219 Cordell North, Stillwater, OK 74078,405-744-3377 or irb@okstate.edu

Signatures:

I have read and fully understand the consent form. I sign it freely and voluntarily. A copy of this form has been given to me.

_____ _____

Signature of Participant Date

I certify that I have personally explained this document before requesting that the participant sign it.

_____ _____

Signature of Researcher Date

I certify that I have personally explained this document before requesting that the participant

Sign it.

_____ _____

Signature of Researcher Date

Verbal/Email Recruitment Script

Hello, my name is Andrew Hall, and I am a master's student in the Department of Health and Human Performance here at Oklahoma State University. I would like to conduct a research study with my advisor Dr. Dough Smith, an associate professor in the department, on the effectiveness of an aerobic fitness intervention on the factors contributed with Metabolic Syndrome. The title of the study is "The Effectiveness of a 12-week Fitness intervention for Individuals with Metabolic Syndrome". We will be analyzing changes in the variables: gender, age, height, body weight, body mass index, waist girth, blood pressure, total cholesterol, HDL cholesterol and LDL cholesterol, fasting blood glucose and triglycerides from pre-intervention to post-intervention.

The records of this study will be kept private. Any written results will discuss group findings and will not include information that will identify you. Research records will be stored securely and only researchers and individuals responsible for research oversight will have access to the records.

You will be required to sign an informed consent document showing that you are willing to participate in this study and allow your data to be collected and used for research purposes. Your participation will greatly benefit the research community and clinicians by identifying effective exercise interventions aimed at improving the health of individuals with metabolic syndrome. I would be happy to answer any additional questions that you may have about the study. Do you think you might be interested in participating?

Thank you.

Andrew Hall
Masters Student
Seretean Wellness Center
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Oklahoma State University
Seretean Wellness Center
Stillwater, OK 74078
Email: Andrew.hall10@okstate.edu
Phone: (817) 692-7655

VITA Andrew

C. Hall

Candidate for the Degree of

Master of Science

Thesis: THE EFFECTIVNESS OF A 12-WEEK FITNESS INTERVENTION FOR PEOPLE WITH METABOLIC SYNDROME

Major Field: Health and Human Performance

Biographical:

Education: Bachelor of Sciences in Health Promotion and Education

Completed the requirements for the Master of Science in Health and Human Performance at Oklahoma State University, Stillwater, Oklahoma in July, 2014.

Completed the requirements for the Bachelor of Science/Arts in Health Promotion and Education at Oklahoma State University, Stillwater, Oklahoma in 2010.

Experience:

Professional Memberships: