INTERVENTION TO REDUCE SEDENTARY TIME AND IMPROVE CARDIOMETABOLIC RISK FACTORS AMONG SEDENTARY EMPLOYEES

By

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Background: More than half of the US adult population is sedentary and this type of behavior is known to increase an individual's risk for overweight/obesity, hypertension, cardiovascular disease, stroke, type 2 diabetes mellitus, anxiety, and depression. Few interventions have been conducted with the purpose of reducing sedentary time to improve cardiometabolic risk factors. The purpose of this study was to examine the efficacy of the worksite intervention program Pedal@Work in reducing daily sedentary time and improving risk factors for cardiometabolic diseases.

Methods: Forty sedentary, overweight/obese adults (21-65 years) working a minimum of 35 hours per week were recruited to participate in a 12 week intervention. Participants were randomly assigned to an intervention (N=23; 42.6 years; 86.9% females) or wait-list control (N=17; 47.6 years; 94.1% females) group. Sedentary time was measured objectively over seven days with a StepWatch activity monitor. Cardiometabolic risk factor measures included resting heart rate, blood pressure, height, weight, body mass index, waist circumference, percent body fat, estimated cardiorespiratory fitness, and fasting blood lipids. All measures were collected at baseline and 12 weeks. Two-way repeated measures analysis of variance (ANOVA) was used to test group and time differences in cardiometabolic risk factors.

Results: The intervention group significantly reduced daily minutes of sedentary time (P<0.01) and percent daily time spent sedentary (P=0.03) compared to the control group from baseline to 12 weeks. The intervention group also significantly increased percent daily time spent in moderate intensity activity (P=0.04) compared to the control group. There was a significant group x time interaction for waist circumference (P=0.03). No changes were observed for any other cardiometabolic risk factors.

Conclusion: The results from this study suggest the intervention group significantly reduced their sedentary time and improved their waist circumference compared to baseline and compared to their control counterparts. These findings are important considering the increasing number of sedentary occupations and the rising prevalence of obesity in the U.S.

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CHAPTER 1: INTRODUCTION

Physical activity is an important component of an individuals' overall health. According to the American Heart Association and American College of Sports Medicine, adults should participate in 30 minutes of moderate to vigorous physical activity on at least 5 days of the week (Haskell et al., 2007). This activity can be performed periodically throughout the day in bouts of 10 minutes or more to accumulate the time, and can be performed in a variety of ways (Haskell et al., 2007). It is known that participating in regular physical activity can improve a persons' health, quality of life, and reduce risk factors associated with disease and premature mortality (ACSM guidelines, 2009; pg. 5-6). Evidence suggests there is an inverse dose-response relationship between physical activity and obesity, hypertension, cardiovascular disease, stroke, type 2 diabetes mellitus, anxiety, and depression (Kesaniemi et al., 2001; Warburton et al., 2006).

It could be argued that the recent advancements in technology have contributed to the human population becoming more sedentary. More and more people have sedentary desk occupations, are more sedentary in the means of traveling to and from work, and are sedentary in their leisure time in part due to the increased use of computers, television, and video games (Brownson et al., 2008). Not participating in a physically active lifestyle, otherwise known as sedentary behavior, has been associated with an increased risk for heart disease, metabolic dysfunction, overweight/obesity, and some cancers (Morris and Crawford, 1958; Dunstan et al., 2004; Helmerhorst et al., 2009). On the contrary, much evidence is available indicating achieving the ACSM's recommendations for daily physical activity is associated with the reduction of the aforementioned adverse diseases (Kesaniemi et al., 2001). The workplace is an optimal setting to promote reducing sedentary time because of the large amount of time spent sitting in desk occupations.

Although physical activity has numerous health benefits, more than half of American adults do not meet the national recommendations (NCCDPHP, 2007). Because of the low participation rates in physical activity, researchers have begun to explore other approaches for improving individuals' health beyond promoting moderate to vigorous intensity physical activity. Recent cross-sectional evidence has suggested that replacing time spent sedentary with even light intensity physical activity may have a positive effect on cardiometabolic risk factors, quality of life, and mental wellness (Healy et al., 2008; Wijndaele et al., 2009, Dwyer et al., 2010, Buman et al., 2011). However, few studies have aimed to reduce sedentary time in an intervention study (Carr et al., 2011; Chau et al., 2010; Marshall et al., 2011). No studies have examined if reducing sedentary time reduces cardiometabolic risk factors. This study will therefore examine the efficacy of a worksite, internet-delivered program intervention (Pedal@Work) for decreasing daily time spent sedentary and improving cardiometabolic risk factors.

The following literature review will examine the association between cardiometabolic health and sedentary behavior. Sedentary behavior and cardiometabolic risk factors will be defined. Furthermore, the literature review will survey the evidence of reducing sedentary time to improve cardiometabolic health.

Aims of Study

Few studies to date have attempted to explore the relationship between changes in sedentary time and changes in metabolic health in an intervention study. The purpose of this study was to examine the effectiveness of the Pedal@Work program for decreasing daily sedentary time, and improving several cardiometabolic risk factors.

Hypothesis

We hypothesize that the participants randomized to the Pedal@Work intervention will reduce their daily sedentary time to a greater extent than those randomized to a wait-list control group. Furthermore, we hypothesize that the intervention group will see significant improvements in some cardiometabolic risk factors when compared to the wait-list control group.

Limitations

It was assumed that the participants in this study had an interest in increasing physical activity to decrease their health risks; therefore the generalizability of this study was limited to such individuals. In addition, the presumption was made that the subjects followed all instructions given to them by the authors of this study, such as directions to follow for using the internet-delivered program and the portable pedal machine. Given the intervention included several components including access to a pedometer, portable pedal machine, and internet-delivered program, we were not able to identify what pieces of the intervention were most effective in reducing daily sedentary time across the entire day. Dietary recall was not included in the study, therefore changes in risk factors that may be associated with diet change was not accounted for. Also, the authors did not control for premenopausal and postmenopausal women, which may affect the change in metabolic risk factors. Lastly, the Ebbeling submaximal treadmill test, which had been demonstrated as a reliable and valid test for estimating aerobic fitness in middle-aged adults, resulted in higher than normal heart rates for some which suggests this test may not have been an appropriate measure of aerobic fitness for this sample.

Delimitations

This study was delimited to 40 apparently healthy but sedentary, overweight or obese adults working in full time sedentary, desk dependent occupations between the ages of 21 and 65 years in the greater Greenville area of North Carolina. The study was delimited to 12 weeks in duration.

Definitions

- **Sedentary**—Using the StepWatch activity monitor, sedentary behavior is defined as 0 steps per minute.
- **Light—**Using the StepWatch activity monitor, light intensity behavior is defined as 1-45 steps per minute.
- **Moderate—**Using the StepWatch activity monitor, moderate intensity behavior is defined as 46-60 steps per minute.
- **Vigorous—**Using the StepWatch activity monitor, vigorous intensity behavior is defined as 61+ steps per minute.
- **Intervention Compliance—**Pedal machine compliance was measured in three ways: 1. the percent of days pedaled measured over the length of the intervention, 2. the total minutes pedaled during the intervention, and 3. the average minutes pedaled per day. Compliance was also measured by the total number of steps logged using the pedometer and internet-delivered program, and the average number of steps logged per day.

CHAPTER 2 - LITERATURE REVIEW

Definition of Sedentary Time

Pate and colleagues (2008) defined sedentary behavior as "activities that do not increase energy expenditure substantially above resting levels". When defined operationally, sedentary behavior involves energy expenditure of 1.0-1.5 metabolic equivalents (METs) (Pate et al., 2008). Examples of such activities include, but are not limited to, sleeping, sitting, lying down, watching television, and other forms of screen-based entertainment such as using a computer. There is much debate currently about the best method for measuring sedentary time objectively as many studies have measured sedentary time by self-report (Pate et al., 2008). Advancements in technology have made it possible to objectively measure sedentary time. Accelerometry is one such method to give researchers insight into total time spend sedentary and total time participating in light, moderate, and vigorous intensity events (Plasqui and Westerterp, 2007).

It was recently discovered that adults spend an average of 9.3 hours per day engaged in sedentary behaviors (Healy et al., 2007). Among the same sample, an average of 6.5 hours per day were spent in light intensity physical activity, leaving only 0.7 hours per day spent in moderate to vigorous physical activity (Healy et al., 2007). Similar results were found in the US National Health and Nutrition Examination Survey (NHANES) in 2009 when physical activity was measured via accelerometer for 7 days (CDC: NHANES, 2009). Sedentary time comprised 58% of waking hours, while 39% of waking hours were spent in light intensity physical activity. This leaves a remaining 3% in moderate to vigorous physical activity. Changes in technology in the areas of transportation, communications, the workplace, and domestic entertainment are a major reason for such elevated levels of sedentary behavior (Brownson et al., 2008). In this age, humans spend much of their time being sedentary or performing low intensity physical activity.

Owen and colleagues (2010) recently posed an interesting research question: are adverse health effects caused by too much sitting or from participating in too little light, moderate, and/or vigorous physical activity? The authors believe that too much sitting is distinct from too little exercise. They define sedentary behaviors as television viewing, computer and game console use, workplace sitting, and time spent in automobiles. These behaviors involve both sitting and low levels of energy expenditure.

Distinct from sedentary behaviors, moderate to vigorous intensity physical activities require an energy expenditure of 3-8 METs, and include bicycling, swimming, walking, or running (Ainsworth et al., 2000). In the Owen and colleagues study, the authors question whether light intensity physical activity plays a substantial role in overall daily energy expenditure, and whether increasing the amount of time spent in these light intensity behaviors will improve cardiometabolic risk. Therefore, more work is needed to determine the relationship of decreasing sedentary behaviors to improve cardiometabolic health.

Cardiometabolic Risk Factors

Cardiometabolic risk is determined by a variety of risk factors such as high blood pressure, abnormally high triglycerides, abnormal levels of low and high density lipoproteins, high total cholesterol, increased adiposity, smoking, and sedentary behavior. The combination of at least three risk factors may lead to an increase risk of developing chronic cardiometabolic diseases such as type II diabetes and cardiovascular disease. An estimated 47 million US residents have cardiometabolic risk, which includes 43.5% of adults ages 60-69 (Ford et al., 2002). A major contributor to such high levels of cardiometabolic risk is the rise in obesity rates, which has doubled over the past twenty-five years, resulting in an estimated two-thirds of American adults either overweight or obese (Eckel et al., 2006; CDC: Overweight and Obesity, 2010). Identifying interventions that are successful at reducing cardiometabolic disease risk is an important field of research.

Low-density Lipoprotein and High-density Lipoprotein Cholesterol

Low-density lipoprotein (LDL) cholesterol is directly related to cardiovascular disease. Data made available by the National Cholesterol Education Program provides evidence that elevated levels of LDL cholesterol are a major cause of cardiovascular disease (NCEP, 2001). Lowering LDL cholesterol substantially lowers cardiovascular disease risk (ACSM guidelines, 2009, pg.48-49). Optimal levels of LDL cholesterol are less than 100 mg/dL. LDL cholesterol has an atherogenic effect, meaning it enhances plaque formation on the arterial walls (Brown and Goldstein, 1983). LDL cholesterol can be thought of as a plaque-like substance that circulates in the blood. Excessive LDL cholesterol promotes a build-up of plaque on the walls of the arteries. This can cause hardening of the arteries, a condition known as atherosclerosis. Atherosclerosis has a direct effect on developing cardiovascular disease. Atherosclerosis prevents smooth flow of blood through the arteries, further damaging the arterial wall. If the plaque were to dislodge from the arterial wall and become lodged downstream, this would be known as a blood clot, or embolism.

Conversely, high-density lipoprotein (HDL) cholesterol has a strong inverse association with cardiovascular disease. HDL cholesterol levels less than 40 mg/dL places an individual at an elevated risk for cardiovascular disease, while increasing HDL cholesterol levels may reduce the risk for cardiovascular disease (ACSM guidelines, 2009, pg. 49). HDL cholesterol is a substance that “removes” LDL cholesterol from the blood (Carew et al., 1976). The higher the level of HDL cholesterol, the more LDL cholesterol it can remove, thus reducing plaque build-up.

Strong evidence suggests that aerobic physical activity reduces LDL cholesterol and increases HDL cholesterol values (Thompson et al., 2003). The authors present the findings from a meta-analysis of 52 exercise training trials. Each of these physical activity interventions lasted longer than 12 weeks. A 4.6% increase was noted in HDL cholesterol values after training. Also, a 5.0% reduction was noted in LDL cholesterol values. Thompson and colleagues (2003) also provided the findings from the exercise trial, the Health, Risk Factors, Exercise Training, and Genetics (HERITAGE) study. In this study, participants underwent 5 months of exercise training. On average, HDL cholesterol increased by 1.1 mg/dL (3%), and LDL cholesterol decreased 0.9 mg/dL (0.8%) in men. In women, HDL cholesterol increased 1.4 mg/dL (3%), and LDL cholesterol decreased by 4.4 mg/dL (4%). This data supports the idea that regular physical activity reduces LDL cholesterol and improves HDL cholesterol values, thus reducing one's risk of developing cardiovascular disease.

Triglycerides

Although the relationship is not directly known, elevated triglyceride levels are thought to increase the risk for developing cardiovascular disease as well (ACSM Guidelines, 2009, pg. 49). Triglyceride values less than 150 mg/dL are considered normal. Triglycerides are thought to have an atherogenic effect similar to that of LDL cholesterol. Meta-analysis evidence suggests that physical activity interventions reduced triglyceride concentrations by 3.7%, (Thompson et al., 2003). The HERITAGE study noted a decrease in triglyceride values of 5.9 mg/dl (2.7%) in men, and 0.6 mg/dL (0.6%) in women (Thompson et al., 2003) with exercise training.

Blood Pressure

Blood pressure is extremely important to measure in individuals. Increased blood pressure puts a greater stress on the heart and arterial walls which will eventually weaken the arterial walls and promote plaque build-up. Blood pressure is recorded as systolic pressure over diastolic pressure. Systolic blood pressure is the pressure exerted by the blood on the arteries when the heart contracts. Diastolic blood pressure is the pressure exerted by the blood on the arteries when the heart is relaxed. Blood pressure greater than 140/90 mmHg is associated with an increased risk for cardiovascular disease (ACSM guidelines, 2009, pg. 47). Keeping blood pressure values less than 120/80 mmHg can reduce atherosclerotic plaque build-up, thus reducing the chance for cardiovascular disease. Thompson and colleagues (2003) analyzed the results from 44 randomized control trials that studied the effects of exercise training on resting blood pressure. There was an average reduction in systolic blood pressure of 3.4 mmHg, and a 2.4 mmHg reduction in diastolic blood pressure. Furthermore, subjects were divided into normotensive or hypertensive categories. An average decrease of 2.6 mmHg in systolic blood pressure and 1.8 mmHg in diastolic blood pressure were noted in the normotensive individuals. A greater reduction was noted in hypertensive individuals, with an average decrease in systolic blood pressure of 7.4 mmHg and 5.8 mmHg in diastolic blood pressure.

Adiposity

Adiposity is the amount of fat an individual has in relation to their total body weight. Individuals that are either overweight or obese are at an increased risk for developing hypertension, cardiovascular disease, hyperlipidemia, type 2 diabetes mellitus, stroke, and the metabolic syndrome (National Institutes of Health, 1985). Adiposity can be measured in a number of different ways including absolute body mass, waist circumference, body mass index

(BMI), and percent body fat. BMI is calculated by dividing weight in kilograms by height in meters squared. A BMI of 18.5-24.9 is considered normal; 25.0-29.9 is considered overweight; and greater than 30.0 is considered obese. Percent body fat can be measured in a number of different ways including skin fold measurements, hydrodensiometry, dual energy x-ray absorptiometry, and bioelectrical impedance analysis. Men ages 40-59 years that have a percent body fat of 11 to 21% are considered to have normal weight. Percent body fat of 22-27% is considered elevated, and greater than 28% is considered high. Women ages 40-59 years that have a percent body fat of 23-33% are considered normal weight. Percent body fat of 34-39% is considered elevated, and greater than 40% is considered high. Waist circumference is a horizontal measure of girth taken with a flexible yet inelastic tape measure at the most narrow part of the torso above the umbilicus and below the xiphoid process. It is important the individual is standing upright, with arms at the side and the abdomen relaxed. The ACSM recommends women to have a waist circumference less than 88 cm and men to have a waist circumference less than 102 cm. Individuals that possess more fat on the trunk (abdominal fat) are at an increased risk for hypertension, cardiovascular disease, and other metabolic disorders, when compared to individuals who have more fat around the hip and thigh region (ACSM guidelines, 2009, pg. 64).

Cardiorespiratory Fitness

Cardiorespiratory fitness can be defined as the ability of the lungs and cardiovascular system to transport and utilize oxygen in the muscles during physical activity. Cardiorespiratory fitness can be directly measured, or estimated using regression equations and heart rate responses from submaximal exercise tests. It is important to assess cardiorespiratory fitness because low levels of cardiorespiratory fitness are associated with increased risk of all-cause mortality, and specifically, cardiovascular disease mortality (ACSM Guidelines, 2009, pg. 71). One cause of low cardiorespiratory fitness is an impaired ability of working muscles to use oxygen brought in by the lungs and transported to the muscles by the cardiovascular system. Muscles use the oxygen as a fuel source to sustain physical activity. If the muscles cannot use the oxygen as a fuel sources, lactic acid will build up in the muscles, likely resulting in discontinuation of the physical activity. Improvement in cardiorespiratory fitness reduces the risk for mortality and increases health status (Blair et al., 1995).

Association between Sedentary Time and Cardiometabolic Health

It is well established that moderate to vigorous physical activity (MVPA) is beneficial to one's health by lowering the risk for obesity, cardiovascular disease, type II diabetes mellitus, and all-cause mortality (ACSM, 2009, pg. 5-8; Healy et al., 2008; Wijndaele et al., 2009; Dwyer et al., 2010, and Buman et al., 2011). When most people think of MVPA, they think of activities such as jogging, using an elliptical machine or stair climbing machine, bicycling, and other activities that are most frequently performed at gyms. However, everyday activities such as occupational activities performed at work, yard work, and house cleaning activities can be performed at moderate and vigorous intensities as well (Dong et al., 2004).

In a seminal study conducted in 1958 by Morris and Crawford, it was observed that men whose jobs involved sitting for prolonged periods of time (bus drivers) had a significantly higher risk of cardiovascular disease compared to men whose jobs required moderate levels of physical activity (conductors of double decker bus). Sedentary workers had a larger percentage of non-coronary related deaths compared to their more active counterparts. This same trend was also observed for coronary related deaths (hypertension, diabetes, and other vascular disorders) with a larger percentage of coronary related deaths observed among the sedentary bus drivers (Morris and Crawford, 1958).

The Morris and Crawford (1958) study was the foundation for the field of physical activity promotion and as a result many studies have since studied the effect of increasing physical activity for improving health. Most interventions conducted to date have focused specifically on promoting MVPA which is consistent with the recommended physical activity guidelines. More recently, however, researchers have begun to look at the deleterious effects of prolonged sedentary behavior such as sitting.

In 2008, Katzmarzyk and colleagues studied the relationship between sitting time and all-cause mortality, cardiovascular disease, and cancer. In particular, they wanted to look at the effect of excessive sitting time in individuals who met the physical activity recommendations of 30 minutes of moderate intensity physical activity on 5 days per week, or 20 minutes of vigorous intensity physical activity on 3 or more days per week. Participants included 7278 men and 9735 women, 18-90 years old, who took part in the 1981 Canada Fitness Survey. Baseline data were collected during home visits through the use of a detailed lifestyle questionnaire, anthropometric measures, and an extensive recall of physical activity. A physical activity questionnaire asked participants to specify the amount of time per day spent sitting during work, school, and other activities (Katzmarzyk et al., 2008). Leisure time physical activity was estimated by adding together the products of the metabolic costs of each activity (METs), its duration, and the average number of sessions per week over the previous 12 months. Individuals completed the Physical Activity Readiness Questionnaire (PAR-Q) and the research team calculated their BMI. There were 951 deaths in men and 881 deaths in women during the 12.9 years of follow-up. Statistical analysis showed that deceased individuals were significantly older, had a higher BMI, and had higher levels of sedentary time (Katzmarzyk et al., 2008). All-cause mortality was plotted against categories of daily sedentary time, and it was found that there was an inverse relationship between survival rate and time spent sitting. In other words, individuals who are sedentary "almost none of the time" had the highest chance of survival, while sitting "almost all of the time" had the lowest chance of survival. After researchers adjusted for age, sex, smoking status, alcohol consumption, leisure time physical activity and the PAR-Q, the elevated risk for all-cause mortality remained positive with greater time spent sitting. Furthermore, in individuals who met the recommendations for being physically active, there was still a strong association between sitting and risk of death, suggesting sedentary time is an independent risk factor for all-cause mortality. The highest risk of mortality was in people who have a BMI greater than 30 $kg \cdot m^{-2}$, categorizing them as obese, who spend most of their day sitting.

Dunstan and colleagues (2010), analyzed results from the Australian Diabetes, Obesity, and Lifestyle Study (AusDiab) to determine the relationship between television viewing time and mortality. A total of 8,800 adults older than 25 years were examined, who had no previous history of cardiovascular disease. Total television viewing time was self-reported for the previous 7 days. Leisure time physical activity was assessed by the Active Australia questionnaire. Blood pressure, waist circumference, fasting triglycerides, total cholesterol, and HDL cholesterol levels were obtained. Mortality status and causes of death were obtained from the National Death Index as described by Barr and colleagues (2007). Participants were characterized by viewing television less than 2 hours per day (<2), greater than or equal to 2 hours per day but less than 4 hours per day (≥2 to <4), and greater than or equal to 4 hours per day (≥4). Deaths were followed over an average of 6.6 years. The authors concluded that each additional hour of watching television resulted in an 11% increased risk of all-cause mortality, and 18% increased risk of cardiovascular disease mortality. These results were independent of smoking status, blood pressure, cholesterol, diet, leisure-time physical activity, and waist circumference (Dunstan et al., 2010). It can be concluded that television time is directly associated with an increased risk of mortality.

Individuals who participate in no physical activity or who have low-activity occupations have a higher likelihood of being overweight or obese (King et al., 2001). In 2004, Steeves and colleagues aimed to determine if non-occupational physical activity and occupational physical activity are related to abdominal obesity. The researchers used the information previously attained from the NHANES (1999-2004). There were 3539 participants over the age of 20 years, who worked in one of 17 occupational categories identified as low occupational activity (LOA) or high occupational activity (HOA). Abdominal obesity was defined as a waist circumference greater than 102 cm (40 inches) in men and greater than 88 cm (35 inches) in women. Gender, age, race/ethnicity, education, household income, and smoking status were also assessed. A physical activity questionnaire assessed three areas of physical activity: daily transportation, domestic, and leisure-time activity. Participants were asked to identify the number of times, and duration, in the past 30 days they participated in such activities, and activities lasting <10 minutes in duration were excluded. Steeves and colleagues (2004) found that abdominal obesity was greater in those with LOA (47.8%) compared with HOA (41.8%). Furthermore, in individuals who were in the LOA group but achieved 500 or more MET-minutes (this corresponds with current physical activity recommendations), had a 42% lower chance of having abdominal obesity. This supports the claim that individuals who engage in physical activity, regardless of occupational activity, have lower rates of adiposity.

In 2008, Healy and colleagues studied the association of breaks in sedentary time and several cardiometabolic risk factors such as adiposity, lipids, blood pressure, and glucose measures. One hundred sixty eight participants (65 men and 103 women) without type II diabetes mellitus were recruited from the AusDiab Study. Participants underwent biochemical, anthropometric, behavioral assessments, and oral glucose tolerance tests. Participants wore a uniaxial accelerometer during all waking hours for 7 days to measure physical activity. They also recorded all activity duration, type, and intensity accumulated throughout the day. A break in sedentary time was defined as the accelerometer count rising above 100 counts/min. It was observed that more breaks in sedentary time were beneficially associated with the metabolic risk variables of waist circumference, body mass index, and triglycerides. The authors noted that those individuals who had the highest number of breaks in sedentary time had, on average, a 5.95 cm lower waist circumference (p=0.027) than those individuals who did not take as many breaks in sedentary time. A similar trend was found for BMI with a p value of 0.026, and triglycerides with a p value of 0.029 (Healy et al., 2008).

Wijndaele and colleagues (2009) aimed to evaluate the association between sedentary behavior and leisure time physical activity with a continuous metabolic syndrome risk score in adults. Metabolic syndrome is a clustering of risk factors (e.g. possessing at least three of the following cardiovascular disease risk factors: abdominal obesity, elevated triglycerides, low HDL cholesterol, elevated blood pressure, or elevated fasting glucose) which predicts the development of type II diabetes, cardiovascular disease, and all-cause mortality (ACSM guidelines, 2009; pg. 250-251). The authors also aimed to determine the relationship of sedentary behavior and leisure time physical activity with each of the continuous risk factors of the metabolic syndrome, and the extent to which obesity is related. The Flemish Policy Research

Centre Sport, Physical Activity and Health collected data from 559 men and 433 non pregnant women between October 2002 and April 2004. The subjects underwent a fasting blood draw to determine triglycerides, HDL cholesterol, and plasma glucose. Waist circumference and blood pressure were also taken. Sedentary behavior and lifestyle physical activity were assessed using the Flemish Physical Activity Computerized Questionnaire. Sedentary behavior was associated with a higher risk for metabolic syndrome independent of total leisure-time physical activity ($p<0.05$ in men, and $p<0.01$ in women). Furthermore, being active in leisure time was associated with a lower metabolic risk independent of sedentary behavior ($p<0.01$ in men, and $p<0.05$ in women). The authors found that a higher level of sedentary behavior was associated with a higher waist circumference and less HDL cholesterol in men ($p<0.05$), and higher waist circumference and blood pressure in women ($p<0.05$).

Reducing Cardiometabolic Risk by Reducing Sedentary Time

Evidence for improving/reducing cardiometabolic disease risk factors through interventions aimed at reducing sedentary time is minimal. There has, however, been interventions conducted that explore whether increasing MVPA is effective at reducing cardiometabolic disease risk.

The relationships between physical activity, metabolic risk factors, adiposity, and fitness has yielded contrasting results in previous studies. Ekelund and colleagues (2007) assessed whether associations between change in physical activity energy expenditure, metabolic risk factors, and clustered metabolic risk are independent of change in aerobic fitness and adiposity. Participants were selected from the Medical Research Council Ely Study, which studied type II diabetes and related metabolic disorders. Between 1994 and 1996, baseline measures were taken on 739 participants who provided complete data on anthropometric and body composition variables and physical activity energy expenditure data. Of this, 393 volunteers (176 males and 217 females) were re-evaluated at follow up between 2001 and 2003, where physical activity energy expenditure data was obtained again. At both baseline and follow up, resting energy expenditure was measured by indirect calorimetry. The authors found that an increase in physical activity energy expenditure over 5.6 years was associated with improvements in insulin sensitivity, glucose tolerance, fasting triglycerides, and clustered metabolic risk in a middle-aged population of white men and women, independent of changes in adiposity and aerobic fitness. Ekelund and colleagues (2007) also concluded that changes in physical activity energy expenditure and adiposity were independently associated with multiple metabolic risk factors.

In 2008, Carr and colleagues conducted a randomized controlled trial to test the efficacy of a theory-based, internet delivered physical activity program aimed at increasing lifestyle physical activity (Active Living Every Day (ALED)). Specifically, the researchers aimed to determine if the program increased physical activity and improved cardiometabolic risk factors in a sedentary, overweight/obese adult population. The ALED program is based on the transtheoretical model (Prochaska and DiClemente, 1983) and the social cognitive theory (Bandura, 1986). This program identified each participant's level of readiness to change and the participants were provided the opportunity to identify barriers to physical activity participation. The program then gave the participants examples of activities they could do to replace their sedentary time with physical activity. Participants were non-smokers, had no ambulatory or exercise limitations, free from cardiovascular, metabolic, respiratory, or neurological diseases, and females were pre-menopausal (Carr et al., 2008). Furthermore, all participants were sedentary and had a BMI between 18-40 kg/m^2. The ALED intervention lasted 16 weeks and has been previously explained by Carr and colleagues (2008). Physical activity was measured by pedometer (Yamax Digiwalker SW200®) and step log for seven consecutive days prior to baseline and post-intervention. At baseline and post-intervention, height, weight, blood pressure, and waist circumference were measured, as well as percent body fat using dual energy X-ray absorptiometry. Also, individuals were asked to fast overnight before a venous blood sample was collected to determine lipid/lipoprotein, glucose, insulin, and C-reactive protein (CRP) concentrations. Cardiovascular risk score was calculated by entering in age, systolic blood pressure, total cholesterol, HDL and CRP concentrations into a cardiovascular algorithm. Aerobic fitness was estimated by a one-mile walk test, during which individuals wore a heart rate monitor. The authors found that the ALED program effectively increased physical activity in sedentary, overweight adults by 17%. In addition, the ALED program decreased abdominal adiposity as measured by waist circumference by 4.0 cm or 4% in the participants.

In 2010, Dwyer and colleagues researched the relationship between change in physical activity and BMI, waist to hip ratio, and insulin sensitivity over a five year follow up period. Five hundred ninety two participants, who took part in the AusDiab study and were 25 years and older and free of type II diabetes mellitus, were analyzed in this study. In 2000 and 2005, individuals completed the active Australia questionnaire to report the frequency and duration of physical activity in the previous week. Omron HJ-003 and Omron HJ-002 pedometers were used to objectively measure physical activity for two consecutive days. Measures of adiposity included BMI and waist to hip ratios. Participants were categorized as normal weight, overweight, or obese with a corresponding BMI of <25, 25-29.9, or >30 $kg \cdot m^{-2}$, respectively. Dwyer and colleagues (2010) found that higher daily step counts in 2000, and higher steps in 2005 than in 2000, were associated with a lower BMI and a lower waist to hip ratio. This was an inverse dose-response relationship.

To date, most research has been conducted to increase the amount of moderate to vigorous physical activity in participants. There have been few interventions conducted to reduce sedentary time as a primary outcome to improve cardiometabolic risk factors. There is some evidence to suggest that such studies are effective in reducing time spent sedentary, resulting in improvements in some cardiometabolic risk factors (Carr et al., 2008; Dwyer et al., 2010). Therefore, more research needs to be conducted to reduce sedentary time as a primary outcome to improve cardiometabolic risk factors.

Worksite Interventions

Physical activity interventions conducted in the worksite to reduce sedentary time and improve health is an emerging field of study (Dugdill et al., 2008; Owen et al., 2011). The idea of worksite physical activity interventions is fairly new but its importance is increasing (Engbers et al., 2005) as occupational sedentary behavior is growing (Shields et al., 2008; Healy et al., 2008). Recent evidence suggests adults spend more than half of their waking hours in an occupational setting highlighting the need for worksite interventions to reduce daily sedentary time (Dugdill et al., 2005). While advances in technology have led to declines in occupational activity, technology can also be used to reduce occupational sedentary time. Besides increased physical activity levels, health promotion efforts conducted in the workplace have demonstrated other important outcomes including reduced absenteeism among employees, reduced back pain, increased productivity, increased stress tolerance and improved decision-making (Kreis et al., 2004). These findings are important as they appeal to employers who must first provide clearance for employees interested in participating in such programs. Worksite physical activity interventions may be a viable solution to decrease sedentary time for improved health.

CHAPTER 3 - METHODS

Participants

We recruited 49 participants between the ages of 21 and 65 years for this study who were sedentary, overweight or obese, but apparently healthy. A sedentary and overweight/obese population was recruited because these individuals are considered to be at an elevated risk for developing cardiovascular disease and other metabolic disorders. These individuals were full-time employees of East Carolina University who worked a minimum of 35 hours per week. Participants were classified as sedentary if they reported engaging in less than 60 minutes of moderate to vigorous physical activity per week and reported a minimum of 75% of their working hours spent sedentary. This was determined by using the phone screen. The criteria for overweight or obese were selected according to a BMI between than 25.0 and 40.0 kg/m^2. Participants were recruited on a rolling basis using: 1) posted fliers; and 2) electronic mailing list serves. Before participating in the study, participants had the study described to them and were asked to sign an informed consent document.

Inclusion Criteria: Participants were screened for eligibility by answering questions on an eligibility survey that was administered via telephone. Adult participants were included if they: 1) engaged in less than 60 minutes per week of moderate to vigorous activity; 2) worked 35+ hours/week at a sedentary, desk-dependent occupation; 3) were determined to be healthy as assessed by the health history screening; 4) were without evident cardiovascular, metabolic, respiratory, psychological, or neurological diseases, both acute and complicated; 5) were under the care of a primary physician for cardiovascular, metabolic, respiratory, or psychological disease condition in which the condition was controlled; 6) were free from ambulatory and exercise limitations; and 7) were between the ages of 21 and 65 years. Participants completed the Par-Q and were deemed ‘apparently healthy’ if they had no heart, metabolic, respiratory, psychological, or neurological conditions; no chest pain at rest or with physical activity; no balance or dizziness problems; and no joint or bone problems that may limit physical activity participation.

Furthermore, participants had to have no pending surgeries scheduled in the next 6 months, never been treated for heart disease by bypass or valvular surgery or interventional procedures (angioplasty, pacemaker, or other implantable device to control heart rate or rhythm), no history of stroke or transient ischemic attacks, no abnormal electrocardiograms, no kidney problems, no peripheral vascular disease, no heart murmurs, no chronic infections diseases such as HIV or hepatitis, no chronic liver disease, no cystic fibrosis, no asthma, no chronic bronchitis or emphysema, no seizures in the past year, and no current cancer of any kind. Participants were asked to disclose any medications they were taking and the reason for taking the medication.

In addition, participants were asked about their psychological health via phone screen. Participants were asked if they had ever been diagnosed with anxiety or depression and if there were undergoing treatment for such disorders. They were also asked if they had been bothered by any of the following in the last 2 weeks: little interest or pleasure in doing things; feeling down, depressed, or hopeless; trouble falling or staying asleep, or sleeping too much; feeling tired or having little energy; poor appetite or overeating; feeling bad about oneself—or that they are a failure and have let themselves or someone else down; trouble concentrating on things; moving or speaking so slowly that other people could have noticed, or being so fidgety, restless, or moving around more; or thoughts of hurting oneself or thoughts of suicide.

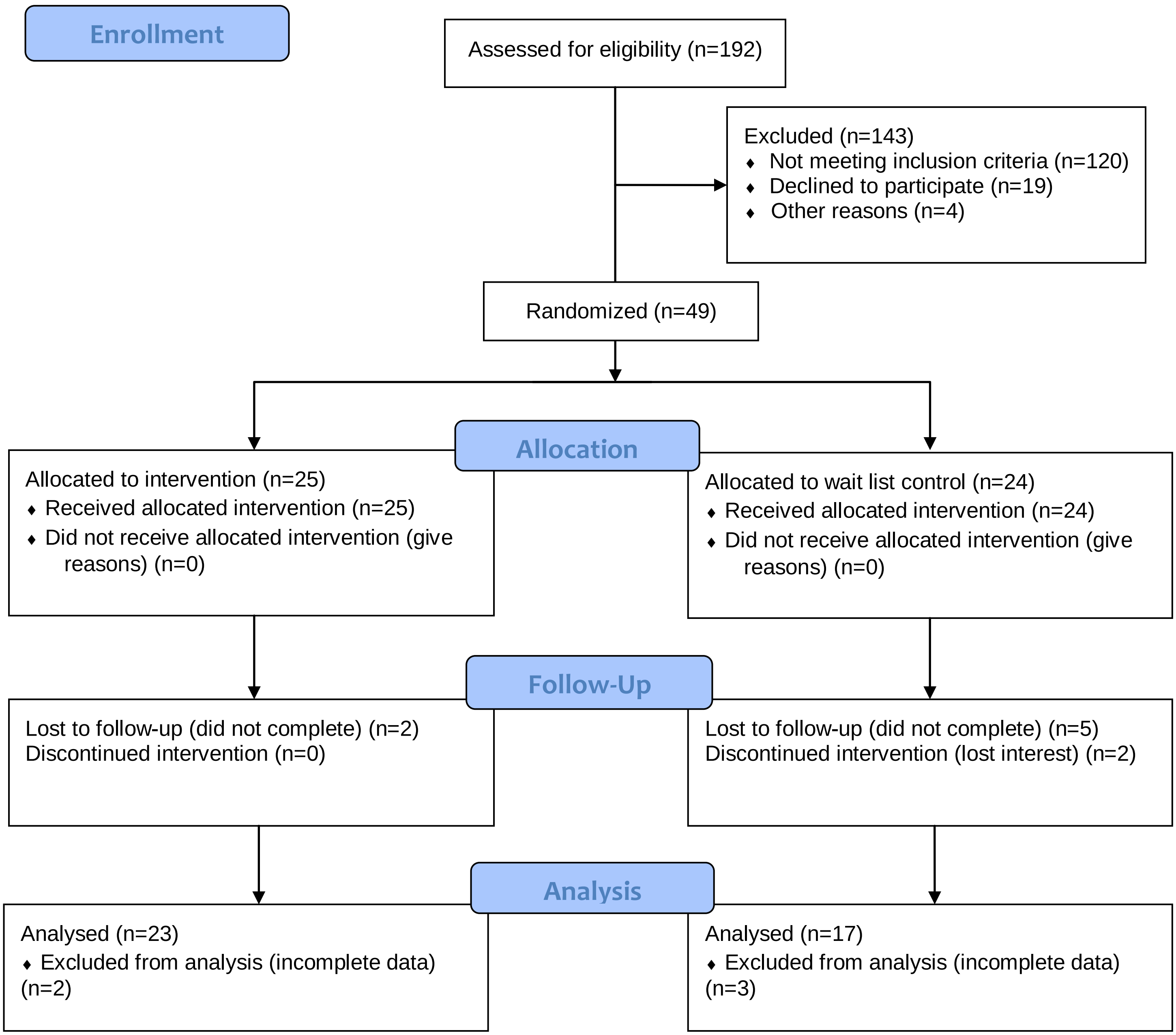
Importantly, male participants 45 years and older and female participants 55 years and older were required to authorize or provide approval for participation in the proposed study from a licensed health care practitioner (medical doctor, nurse practitioner, or physician’s assistant) prior to enrollment in the study. Participants had access to a computer that has a USB port and operates with Windows XP-2000, Vista or Windows 7 in order to be compliant with software to be used in the intervention. The participants had clearance from their supervisor to participate in the study and allow the research team to download all software that accompanies a portable pedal exercise machine. Furthermore, participants must have planned to be at the current job for at least the next 6 months and must have had room underneath their desks to place a pedal exercise machine.

Groups

Eligible and interested participants were randomly assigned to an intervention (N=23) or wait list control group (N=17) (Figure 1). The intervention group was provided access to a MagneTrainer portable pedal machine and its corresponding FitXF software for 12 weeks. In addition, the intervention participants received an Omron HJ150 pedometer and access to a motivational website designed to increase physical activity/reduce sedentary time known as WalkerTracker. Prior to this study, the WalkerTracker website had not yet been tested in a research setting. The wait list control group was asked to maintain their current physical activity habits over the first 12 weeks, and then had the option of receiving the intervention for an additional 12 weeks.

Figure 1. Participant recruitment schematic

CONSORT Flow Diagram



Measures

Baseline and 12 week follow-up measures on both the intervention and control groups included resting heart rate and blood pressure, height, weight, waist circumference, percent body fat and percent lean mass, cardiorespiratory fitness and daily time spent sedentary. All participants also completed several behavioral surveys to get background information on demographics, work environment, physical activity history, and recent illnesses and/or infections, although these measures will not be discussed in this document.

Body mass (nearest 0.1 kg) and height (nearest 0.5 cm) were measured using a calibrated digital scale and a wall mounted stadiometer. Body mass index (BMI; kg/m^2) was calculated as weight (kg) divided by height (m) squared. Waist circumference (inches) was measured using a Gulick measuring tape that was tension regulated, and measurements will be taken twice to verify accuracy. Researchers measured the circumference of the waist half way between the inferior portion of the sternum and the umbilicus. Percentage body fat and lean body mass was determined by bioelectrical impedance analysis (BIA) machine (Valhalla Scientific) previously demonstrated as accurate in overweight women (Heyward et al., 1992). Also, a fasting finger stick was conducted to test the blood for total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides using a point of care Cholestech LDX analyzer previously demonstrated as meeting National Cholesterol Education Program guidelines (Panz et al., 2005).

Blood pressure was measured with a stethoscope and sphygmomanometer using standard techniques. Heart rate was monitored at rest and throughout a submaximal walking test by using a Polar™ heart rate monitor and watch. The chest strap was arranged to fit snuggly against the skin at the level of the sternum. Participants completed a previously validated 12-minute submaximal walking test developed by Ebbeling, et al in 1990. Fifty to seventy percent of the age-predicted maximum heart rate was calculated on each participant before the test begins. The test was performed on a treadmill, and consisted of three, four-minute stages, with each stage increased in grade by 5% while the speed was kept constant throughout all stages. Resting heart rate was recorded before the test began. Individuals began with a warm-up to get familiar with walking on the treadmill. Once the participant felt ready to begin, the researcher allowed the participant to walk at a speed between 2.5-4.0 miles per hour (mph), at which the individual felt comfortable. This stage was performed at 0% grade, for 4 minutes, and 50-70 % of age-predicted maximum heart rate was met during this stage. The speed was then kept constant, while the grade increased to 5% in stage 2. The second stage lasted for 4 minutes as well. Still keeping the speed constant, the grade was then increased to 10% in stage 3 for the remaining 4 minutes. Heart rate was recorded every 2 minutes of each stage, while blood pressure and rating of perceived exertion (RPE) was evaluated every 4 minutes, at the end of each stage. Researchers used the 6-20 Borg RPE scale. After 12 minutes of walking, the grade was lowered to 0% to allow the participant to cool down. The speed was adjusted as well, if needed. Heart rate was recorded every minute, and blood pressure was recorded after 2 minutes of cool down. Participants cooled down until heart rate returned to less than 100 bpm and blood pressure returned to near resting values.

Time spent sedentary was continuously measured on all participants at both baseline and follow up for seven continuous days using the StepWatch™ 3.0 accelerometer. Evidence of the accuracy and validity of the StepWatch has previously been demonstrated during controlled laboratory settings for measuring walking behavior and estimating energy expenditure (Bowden et al., 2007 and Foster et al., 2005). Accuracy of the StepWatch for estimating sedentary and light intensity has also been recently established by Carr and Mahar et al, 2011 (in press). The authors found that the StepWatch monitor accurately identified sedentary activity (lying down, sitting watching television, sitting at the computer, and standing) more than 90% of the time and correctly coded the activity as sedentary. Carr and Mahar and colleagues (2011) found that the StepWatch monitor identified 88.8% of slow walking time as light intensity. The StepWatch monitor was the most accurate method of recording pedaling activity compared to the other methods because the StepWatch is worn around the ankle instead of at the waistline (Carr and Mahar, 2011). The StepWatch monitor recorded pedaling at 7.0 mph as light intensity 54.4% of the time, and recorded pedaling at 15.0 mph as light intensity 39.2% of the time. The StepWatch correctly coded pedaling at 7.0 mph and 15.0 mph as “nonsedentary” 100% of the time. However, 45.6% of pedaling at 7.0 mph was incorrectly identified as sedentary. Participants were instructed to wear the accelerometers for a minimum of 10 hours per day for 7 consecutive days on the right ankle. In addition to wearing the StepWatch, individuals filled out a daily log to record the time the monitor was put on and taken off each day. After seven days, the StepWatch was loaded onto the docking station and the number of steps and its corresponding intensity level were uploaded by the analysis software.

Intervention participants were provided a MagneTrainer pedal machine which was 18” in height and 20” in length, and setup either underneath or next to the individual’s office desks. The pedal machines were connected to the participants’ work computer using a USB drive and pedal activity was objectively tracked with its corresponding exercise tracking software (FitXF Exercise tracking software). This software also provided the user real-time biofeedback on time (minutes), average speed (miles per hour), maximum speed (miles per hour), distance (miles), and estimated energy expenditure (calories).

In addition to the pedal machine, intervention participants received an Omron HJ150 pedometer to track their number of steps per day. This pedometer was attached to the waistband at the hip as was used only as a self-monitoring tool. The pedometer was to be worn only during the intervention time, not during the assessment (StepWatch) time. Intervention participants also received access to a motivational website called WalkerTracker. This website allowed users to record the number of steps per day for the duration of 12 weeks. An activity converter was available on the website for individuals to enter time spent in various activities (such as pedal activity), and the website automatically converted that activity into steps. This calculated activity was added to the total number of steps per day. The intervention participants were also entered into a group competition in which participants were divided into five groups of five. The five groups as a whole tallied together the total number of steps taken by all participants and "Walked across the United States." At any given time, the individuals could view a map of the competition and see where they stood and how much progress their team was making in comparison to other teams.

Finally, the intervention group was provided regular emails which were sent out each week on Monday, Wednesday, and Friday, for 12 weeks. The emails focused on goal setting, self-efficacy for physical activity participation, and reshaping perceptions about the physical activity environment. Furthermore, daily reminders to log their daily activity on the WalkerTracker website were sent out automatically by the website. Participants were encouraged to use the pedal machine at work to decrease their time spent sedentary.

The control group was put on a wait list and asked to refrain from changing their exercise or dietary habits for the 12 week intervention period. The control group was then allowed to enter the treatment group after the conclusion of the study. Participants were allowed to terminate their involvement with the research study at any time, without penalty. All information gathered from the participants was kept confidential.

Statistical Analysis

Baseline descriptive and independent variables were analyzed by one-way analysis of variance (ANOVA). Change in sedentary time (baseline to post-intervention) and change in cardiometabolic risk factors (baseline to post-intervention) were the primary and secondary outcomes for this study, respectively. Change in sedentary time was the independent variable and change in cardiometabolic risk factors was the dependent variable. All outcome measures were evaluated before and after the 12-week experimental period within and between groups by two-way (Group x Time) repeated measures ANOVA. When indicated by a significant F value, post hoc procedures were performed (Tukey). Statistical significance was set a priori at $p<0.05$.

CHAPTER 4 - RESULTS

Mean baseline characteristics are presented in Table 1. A total of 40 participants completed the study (Control group N=17 and Intervention group N=23). Both groups had similar descriptive characteristics and were middle-aged (47.6 ± 9.9 (Control) vs. 42.6 ± 8.9 (Intervention) years of age). There was no significant difference in the ages of the participants. Participants in both groups were overweight or obese with a mean BMI of 33.2 ± 4.5 (Control) and 31.7 ± 4.9 (Intervention) kg/m^2. There was no significant difference in the average BMI of the two groups. Both groups were predominantly female (94.1% in control group vs. 86.9% in intervention group). The control group participants wore the StepWatch activity monitor for an average of 5.5 days while the intervention group participants wore the StepWatch for an average of 5.7 days at baseline. There were no significant differences between groups for other baseline characteristics such as height, weight, percent non-Hispanic white, percent college graduates, and percent of income greater than $40,000 per year. These results indicate that the participants of both groups were statistically the same at baseline.

Table 1. Baseline characteristics between groups (Mean ± S.D.).

	Control Group (N=17)	**Intervention Group (N=23)**	**P-value**
Age (years)	47.6 ± 9.9	42.6 ± 8.9	0.10
Female %	94.1%	86.9%	0.46
Height (in)	65.2 ± 3.2	65.4 ± 3.4	0.89
Weight (lbs)	201.3 ± 30.2	194.1 ± 34.9	0.50
Body Mass Index (BMI) (kg/m^2)	33.2 ± 4.5	31.7 ± 4.9	0.36
Non-Hispanic White (%)	76.5%	63.6%	0.40
College Graduate (%)	71.0%	86.0%	0.24
Income >$40,000 (%)	62.5%	63.6%	0.94
StepWatch Number Days	5.5 ± 2.0	5.7 ± 1.6	0.72
StepWatch Minutes Included/Day	829.6 ± 93.5	867.1 ± 142.8	0.35

Primary and secondary outcome measures were assessed twice; once at baseline and once at 12-week follow up. Table 2 depicts between group and within group two way repeated measures ANOVA for sedentary and physical activity behavior of both groups. Two-way repeated measures ANOVA showed that there were no significant differences found at baseline between the two groups for minutes of sedentary, light, moderate or vigorous activities or percent time spent in sedentary, light, moderate and vigorous behaviors. At time of follow up, participants in the intervention group significantly decreased minutes spent in sedentary activities (584.9 to 526.1 minutes) and this was significantly different compared to the control group ($p<0.05$). The control group increased the number of minutes spent in sedentary activities from 544.2 to 599.7, although this was not significant. The participants in the intervention group also significantly reduced the percent of time spent in sedentary behaviors (67.6% to 63.9%) compared to the control group ($p<0.05$).

The intervention group participants significantly increased the percent of time spent in moderate intensity behaviors compared to baseline ($p<0.05$). The intervention participants increased percent time spent in moderate intensity behavior from 1.5 to 2.8 percent from baseline to follow up (Table 2). Significant group x time relationships for minutes spent in sedentary activities ($p=0.007$), percent time spent in sedentary behaviors ($p=0.036$), and percent time spent in moderate intensity behaviors ($p=0.04$) were observed (Table 2).

Table 2. Two way repeated measures ANOVA for sedentary and physical activity behavior

	Control Group (N=17)		**Intervention Group (N=23)**		**P-value**
	Baseline	**12 Weeks**	**Baseline**	**12 Weeks**	**Group x Time**
Minutes Sedentary	544.2±76.9	599.7±106.6	584.9±136.1	**526.1±77.3*†**	**0.007**
% Time Sedentary	65.7±7.5	67.5±8.0	67.6±7.2	**63.9±7.9†**	**0.036**
Minutes Light	265.7±84.0	262.2±70.8	263.9±69.5	270.3±69.5	0.67
% Time Light	31.9±8.1	30.3±8.4	30.6±8.2	32.7±7.6	0.14
Minutes Mod	18.6±25.2	17.4±23.7	14.5±18.5	23.3±28.0	0.11
% Time Moderate	2.3±3.2	2.0±2.9	1.51±1.5	**2.8±3.4†**	**0.04**
Minutes Vigorous	1.2+2.6	1.5±2.7	2.7±6.4	4.9±10.9	0.51
% Time Vigorous	0.14+.32	0.17±0.30	0.27±0.60	0.60±1.3	0.38

Mean ± S.D.
*Significant difference between groups at same time point (p<0.05)
†Significant difference within groups compared to baseline (p<0.05)

Table 3 depicts two way repeated measures ANOVA between groups and within groups for cardiometabolic risk factors of both groups. Two way repeated measures ANOVA showed that there were no significant differences between groups at baseline for cardiometabolic risk factors. The analysis also showed that there were no significant differences between groups at follow up for cardiometabolic risk factors. There was a significant group x time interaction for waist circumference (p=0.03) with the intervention group slightly reducing their waist circumference and the control group slightly increasing their waist circumference (Table 3).

Table 3. Two way repeated measures ANOVA for cardiometabolic risk factors

	Control		Intervention		P-Value
	Baseline	**12 Weeks**	**Baseline**	**12 Weeks**	**Group x Time**
Weight (lbs)	201.4 ± 30.3	202.4 ± 30.5	194.2 ± 34.9	194.4 ± 34.5	0.63
BMI (kg/m^2)	33.2 ± 4.5	33.4 ± 4.6	31.8 ± 4.9	31.9 ± 5.0	0.76
Resting HR (bpm)	77.1 ± 9.3	74.1 ± 10.0	77.2 ± 10.0	80.3 ± 14.0	0.08
Systolic BP (mmHg)	117.1 ± 13.0	117.5 ± 12.8	120.0 ± 13.8	115.7 ± 10.8	0.19
Diastolic BP (mmHg)	72.8 ± 10.3	73.3 ± 10.6	78.17 ± 10.3	75.4 ± 7.4	0.34
Waist Circumference (cm)	92.9 ± 11.1	93.9 ± 10.8	92.6 ± 11.2	91.6 ± 11.3	**0.03**
Percent Body Fat	36.2 ± 3.9	36.7 ± 3.2	34.6 ± 6.1	36.2 ± 5.3	0.25
Estimated V02 (mL/kg/min)	29.6 ± 2.5	29.9 ± 2.6	30.8 ± 5.2	31.1 ± 4.6	0.86
Total Cholesterol (mg/dL)	188.9 ± 31.0	193.6 ± 30.1	191.4 ± 26.3	192.8 ± 30.3	0.68
Triglycerides (mg/dL)	130.6 ± 65.4	163.5 ± 108.9	120.2 ± 84.9	131.8 ± 85.3	0.49
HDL (mg/dL)	47.6 ± 18.5	46.7 ± 18.9	45.7 ± 17.7	43.7 ± 16.5	0.76
LDL (mg/dL)	115.2 ± 35.6	116.4 ± 29.0	119.4 ± 23.1	123.6 ± 36.2	0.99
TC/HDL Ratio	4.8 ± 3.1	5.0 ± 2.7	4.9 ± 2.4	5.4 ± 3.2	0.57

Mean ± S.D.
*Significant difference between groups ($p<0.05$)
** Significant difference within group compared to baseline ($p<0.05$)

Table 4 depicts Pearson correlations between intervention compliance and change in cardiometabolic risk factors amongst the intervention group (N=23). A significant correlation was found between total minutes pedaled over the duration of the intervention and both change in weight (p=0.03) and change in BMI (p=0.02) from baseline to 12-week follow-up amongst the intervention group. There was also a significant relationship between average minutes pedaled per day and both change in weight (p=0.03) and change in BMI (p=0.02) from baseline to follow-up amongst the intervention group. A significant relationship was observed between total steps logged over the duration of the intervention and change in weight (p=0.04), and average steps logged per day and change in weight (p=0.05) from baseline to follow-up amongst the intervention group. There were no other significant relationships between intervention compliance and changes in weight, BMI, and waist circumference.

Table 4. Pearson correlations between intervention compliance and change in cardiometabolic risk factors for Intervention participants (N=23)

	Δ Weight		**Δ BMI**		**Δ Waist Circumference**	
	R	P	R	P	R	P
Pedal Compliance (% Days Pedaled)	-0.20	0.34	-0.15	0.51	0.03	0.89
Total Minutes Pedaled	**-0.46**	**0.03**	**-0.48**	**0.02**	-0.20	0.35
Average Minutes Pedaled/Day	**-0.46**	**0.03**	**-0.47**	**0.02**	-0.20	0.35
Website Compliance (% Days Logged)	-0.28	0.20	-0.23	0.27	-0.26	0.24
Web Compliance (Total Web Logs)	-0.26	0.24	-0.22	0.30	-0.23	0.30
Total Steps Logged	**-0.43**	**0.04**	-0.38	0.07	-0.36	0.08
Avg. Steps Logged/Day	**-0.41**	**0.05**	-0.37	0.08	-0.32	0.13

CHAPTER 5 - DISCUSSION

The primary findings of this study are as follows. Participants in the intervention group significantly reduced the number of minutes spent in sedentary behaviors compared to baseline and compared to the control group. Also, participants in the intervention group significantly reduced the percent of time spent in sedentary activities compared to baseline and compared to the control group. Furthermore, intervention participants significantly increased the percent of time spent in moderate activities compared to baseline. There were no significant changes in time spent in light or vigorous physical activities for either group. Finally, of the cardiometabolic risk factors measured, the only group x time interaction found was for waist circumference suggesting minimal to no improvements in cardiometabolic health amongst the participants of this study.

The first primary finding in this study was the decrease in time spent sedentary and percent of time spent in sedentary activities in the intervention participants when compared to baseline and compared to the control group. To date, no intervention studies have aimed to reduce sedentary time as a primary outcome in adults (Chau et al., 2010 and Marshall et al., 2011). Chau and colleagues (2010) examined six studies that primarily aimed to increase physical activity, and secondly aimed to reduce sitting. Chau and colleagues (2010) found that none of these studies significantly reduced sitting in the intervention group when compared to the control or comparison group. Pedal@Work is the first study to effectively reduce sedentary time as a primary outcome. Future studies need to examine whether interventions aimed at reducing sedentary time can instill long-term changes as past interventions promoting moderate to vigorous intensity activity have struggled to demonstrate long term adherence (Carr et al., 2009).

Secondary findings in this study include a change in cardiometabolic risk factors. It was found that there was a significant group x time interaction for waist circumference. This finding is important considering past studies which have reported higher levels of sedentary behavior to be associated with a higher waist circumference in both men and women (Wijndaele et al., 2009). This finding is consistent with the finding of Healy and colleagues in 2008. Healy and colleagues (2008) found a cross-sectional association between self-reported number of breaks in sedentary time and waist circumference. Furthermore, Carr and colleagues (2008) found that an internet-delivered behavior change program that resulted in significant increases in light intensity lifestyle walking resulted in significant improvements in waist circumference when comparing the intervention group versus the control group. The limited changes in cardiometabolic risk factors may be due to the low intensity of the intervention as well as the limited duration of 12 weeks. Future studies are needed that test the effectiveness of reduced sedentary time over a longer duration on these same cardiometabolic risk factors.

Tertiary findings of this study include intervention compliance and changes in cardiometabolic risk factors. It was found that there was a significant relationship between total minutes pedaled over the 12 week intervention and changes in weight and BMI. A significant relationship also existed between average minutes pedaled per day and changes in weight and BMI. Similarly, a significant relationship was found between total steps logged over the 12 week intervention and change in weight. A significant relationship was also observed between average steps logged per day and change in weight. These findings indicate that while website use did not predict change in measures of adiposity, pedal use and pedometer use did predict improvements in measures of weight and BMI.

The results from the current study expand upon findings of a previous study conducted by Carr and colleagues in 2011. In that study, the research team tested the feasibility of the MagneTrainer pedal machine for reducing sedentary time in the workplace over a short duration. Specifically, eighteen healthy, adult, full-time employees who were sedentary were given access to the pedal machine for four weeks. There was no intervention accompanying access to the pedal machine. Carr and colleagues (2011) found that participants pedaled an average of 23 minutes per day on the days they used the pedal machines. In the present study, participants used the pedal machines an average of 29 minutes per day on the days they used the pedal machines. These findings suggest that the motivational intervention provided improved participant's adherence to the pedal machine each day and over a longer duration (12 weeks) when compared to just providing participants access to the device. This finding is important given past findings suggesting short term increases in physical activity predict longer-term adherence (Carr et al., 2009).

Strengths/Limitations

Strengths of this study include the objective measure of sedentary behavior and physical activity behavior by the use of the StepWatch monitor. Participants in both the intervention and control group wore the StepWatch for an average of 5 days which yields more accurate results of their sedentary and physical activity behaviors over a typical week. Access to the pedometer and biofeedback of the pedal machine were other strengths of this study. The instant feedback provided may have provided encouragement to continue physical activity participation. Methods for data collection were reliable and validated. For example, the submaximal walking test was generalizable to the population of interest in this study. The BIA machine was a valid method for measuring body composition and the Cholestech LDX analyzer was a valid method for determining blood lipids. Also, of the 49 participants that began the study, 40 participants completed follow up measures which shows a modest attrition rate of less than 20%.

Limitations of this study include that we did not control for diet—which is known to contribute to cardiometabolic health. We also were not able to control for the control group not beginning a diet regimen or exercise routine. The submaximal test may have been a maximal test for some participants in this study, therefore, other regression equations may have been more appropriate than the one used. Another limitation was the duration of the intervention. A longer duration may show different compliance or different changes in cardiometabolic risk factors. Lastly, the BIA machine used was from the 1990s and due to the age of the machine, may have resulted in some error in body composition calculation.

To improve this study, I would increase the duration of the study beyond 12 weeks to test the long term effects of this type of intervention. Twelve weeks may not have been long enough to see adequate changes in cardiometabolic risk factors. I would use a more up-to-date BIA machine so that we can confirm the body composition analysis is accurate. Also, I would incorporate a dietary recall into the study to provide more confidence that diet is not contributing to the cardiometabolic outcomes of the study. Lastly, I would try to recruit more men to be included in the study, so that the findings may be more generalizable to the public.

Conclusion

In conclusion, the Pedal@Work intervention was successful at decreasing minutes of sedentary time and percent time spent in sedentary behaviors in the intervention group when compared to the control at both baseline and follow up. Pedal@Work was also effective at increasing percent time spent in moderate intensity activities in the intervention group at follow up compared to baseline. This intervention did not result in overall improved cardiometabolic health. This study was among some of the first randomized controlled trials that aim to reduce sedentary time as a primary outcome (Wilmot et al., 2011).

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APPENDIX A – INSTITUTIONAL REVIEW BOARD APPOROVAL LETTER

EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board Office
1L-09 Brody Medical Sciences Building• 600 Moye Boulevard • Greenville, NC 27834
Office 252-744-2914 • Fax 252-744-2284 • www.ecu.edu/irb

TO: Lucas Carr, PhD, Dept. of EXSS, ECU—172 Minges Coliseum

FROM: UMCIRB *kck*

DATE: May 5, 2011

RE: Expedited Category Research Study

TITLE: "Pedal At Work"

UMCIRB #11-0227

This research study has undergone review and approval using expedited review on 4.6.11. This research study is eligible for review under an expedited category number 2, 4, & 7. The Chairperson (or designee) deemed this **Division of Research & Graduate Studies** sponsored study **no more than minimal risk** requiring a continuing review in **12 months**. 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.

The above referenced research study has been given approval for the period of **4.6.11** to **4.5.12**. The approval includes the following items:

- Internal Processing Form (received date 3.11.11)
- Informed Consent (dated 3.31.11)
- Pedal at Work Phone Screener
- Demographic Questionnaire
- Exercise Goals
- 24 Hour Sedentary Recall Questionnaire
- Satisfaction with Life Scale
- General Happiness Scale
- Physical Activity Self-Efficacy
- Treatment Self-Regulation Questionnaire
- Work Productivity and Activity Impairment Questionnaire
- Health Survey
- Social Support & Exercise Survey
- Qualitative Interview
- Predictive Submaximal Exercise Tests
- Operating and Safety Procedures for DXA Body Composition and Bone Densitometry
- COI disclosure form (dated 3.25.11)
- Flyer

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

IRB00000705 East Carolina U IRB #1 (Biomedical) IORG0000418
IRB00003781 East Carolina U IRB #2 (Behavioral/SS) IORG0000418
IRB00004973 East Carolina U IRB #4 (Behavioral/SS Summer) IORG0000418
Version 3-5-07

UMCIRB #11-0227
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APPENDIX B – INFORMED CONSENT

1907-2007
CENTENNIAL
East Carolina University

UNIVERSITY HEALTH SYSTEMS
of Eastern Carolina.

Informed Consent to Participate in Research

Information to consider before taking part in research that has no more than minimal risk.

Title of Research Study: Pedal@Work

Principal Investigator: Dr. Lucas J. Carr, Ph.D.
Institution/Department or Division: Department of Exercise and Sport Science
Address: 172 Minges Coliseum, Greenville, NC 2758
Telephone #: 252-328-0009

Researchers at East Carolina University (ECU) study problems in society, health problems, environmental problems, behavior problems and the human condition. Our goal is to try to find ways to improve the lives of you and others. To do this, we need the help of volunteers who are willing to take part in research.

Why is this research being done?
The purpose of this research is to test the efficacy of a behavioral intervention designed to reduce sedentary time and improve your health. The decision to take part in this research is yours to make. By doing this research, we hope to learn the best methods for reducing sedentary time and to improve the health of working adults.

Why am I being invited to take part in this research?
You are being invited to take part in this research because you are an apparently healthy volunteer and have indicated an interest in participating in this research study. If you volunteer to take part in this research, you will be one of about 60 people at East Carolina University to do so.

Are there reasons I should not take part in this research?
I understand I should not volunteer for this study if I: am not apparently healthy, not between the ages of 18 and 65 years, not working full time (40 hours/week) in a desk/computer occupation, do not have my supervisor's permission to participate in this study or have any type of disease, disability or health condition that would prohibit me from being regularly active.

What other choices do I have if I do not take part in this research?
You can choose not to participate.

Where is the research going to take place and how long will it last?
The research testing procedures will be conducted in the Minges Coliseum building in the Department of Exercise and Sport Science. You will need to come to Minges room 101 on three separate occasions during the study. The total amount of time you will be asked to volunteer for this study is 12-24 weeks.

What will I be asked to do?

UMCIRB Number: 11-0227
Consent Version # or Date: 3·31·11
UMCIRB Version 2010.05.01

UMCIRB
APPROVED
FROM 4·6·11
TO 4·5·12

Participant's Initials