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The Effect of Run Sprint Interval Training on Prediabetic Adults: Health Related Quality

of Life, Perceived Enjoyment, and Exercise Adherence

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A thesis submitted to the Graduate Faculty of

JAMES MADISON UNIVERSITY

In

Partial Fulfillment of the Requirements

for the degree of

Master of Science

Kinesiology

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Dedication

This manuscript is dedicated to my mother, Anne Gilbertson, who has taught me the value of education and achieving your goals. Thank you for always believing in me no matter the circumstance. I can never repay you for all that you have done for me but know that I will love you forever.

Acknowledgements

I would like to express my appreciation and thanks to my committee chair Dr. Elizabeth Edwards, you have been an incredible mentor for me. I would like to thank you for supporting me throughout the past year in my research and educational endeavors. Your advice and guidance means the world to me. I would also like to thank Dr. Jeremy Akers, Dr. David Wenos, and Dr. Trent Hargens for serving as my committee members. Thank you for your responsiveness to questions and willingness to help me grow as a researcher. I would especially like to thank my research team, including Katie Hilovsky and Joan Mandelson, for everything we have accomplished with the RSIT study and your friendship over the past two years.

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Abstract

Purpose: The purpose of this study is to determine if Health Related Quality of Life (HRQOL) and perceived exercise enjoyment are greater in a run sprint interval training (RSIT) group compared to a moderate intensity training (MIT) group in sedentary, prediabetic adults after an 8-week intervention.

Methods: Over 8-weeks, subjects in the RSIT group progressed from 4 to 6 30-second sprints per session, and the MIT group progressed from 30 to 60 minutes of continuous moderate intensity exercise. Participants in both groups completed 8-weeks of the Centers for Disease Control and Prevention (CDC) Diabetes Prevention Program educational classes. HRQOL (assessed by the CDC 4-item Healthy Days Core Module), perceived exercise enjoyment (assessed by the physical activity enjoyment scale, PACES), exercise adherence, VO_{2max} , and body composition were assessed in both groups.

Results: There was no significant difference from baseline to 8-weeks in Healthy Days in the RSIT group (p = 0.833) or the MIT group (p = 0.080). There were also no significant differences between or within groups at baseline or 8-weeks for self-reported days of negative physical health, mental health, or affected usual days scores. There was no significant difference in exercise adherence between the MIT (20.75 ± 2.71 sessions) and RSIT (20.57 ± 1.40 sessions) groups. There was no significant difference between groups in perceived enjoyment, however there was a significant increase from baseline to 8-weeks in the MIT group (11.88 ± 12.38 ; p = 0.030). 8-weeks of MIT significantly improved body composition measures including body weight (- 9.35 ± 6.21 ; p = 0.004), % body fat (- 2.015 ± 1.88 ; p = 0.019), body mass index (- 1.21 ± 1.07 ; p = 0.015), and % lean

mass (2.05±1.84; p = 0.016). RSIT significantly improved VO_{2max} (mL/kg/min) (1.84±1.70; p = 0.028) over 8-weeks.

Discussion: The practical implications of there being no significant difference between RSIT and MIT in perceived exercise enjoyment, exercise adherence, or HRQOL shows participants can choose their exercise preference. A significant improvement in PACES scores for the MIT may be a result of stronger social relationships formed. 8-weeks may have proven to not be long enough to see significant between or within group differences in HRQOL scores.

Chapter I

Introduction

The incidence of prediabetes is rising and expected to continue rising over the next several decades (ADA, 2014). Prediabetes is characterized by an elevated blood glucose concentration, which is higher than normal but not high enough for a diabetes diagnosis (defined as: fasting blood glucose level between 100-125 mg/dl, blood glucose between 140-199 mg/dl two hours after an oral glucose tolerance test (OGTT), or hemoglobin A1C of 5.7-6.4%) (CDC, 2011). Approximately 35% of the United States population, aged 20-years or older has prediabetes, and without intervention prediabetes often progresses to Type 2 Diabetes Mellitus (T2DM) within 10-years (ADA, 2014; CDC, 2011). Prediabetes is associated with being overweight or obese, sedentary, older in age, genetically predisposed, and elevated blood parameters including triglycerides, total cholesterol, low-density lipoprotein, plasma insulin, and plasma glucose (Pan et al., 1997 & Tuomilehto. et al., 2001). T2DM causes complications including heart disease, stroke, kidney disease, neuropathy, retinopathy, amputations, and early mortality (CDC, 2011). However, increasing physical activity and exercise in prediabetics can impede the progression of the disease to T2DM and its associated negative health complications including a reduced quality of life.

Quality of Life (QOL) is a multidimensional subjective evaluation of positive and negative aspects of life. Overall several domains including jobs, relationships, culture, religion, environment, and health affect QOL. Health-related QOL (HRQOL) includes the aspects of overall QOL, which clearly affects physical or mental health. Individually, HRQOL encompasses health risk and conditions, functional status, social support, and

socioeconomic status using a multidimensional subjective evaluation. HRQOL questionnaires are an important aspect of health surveillance and are also a powerful predictor of mortality and morbidity (CDC, 2011). HRQOL and QOL are lower in individuals who have diabetes than overall healthy individuals (Sparring et al., 2013; Venkataraman et al., 2013). In a recent study, both men and women with diabetes reported lower HRQOL at every time point of the study compared to healthy controls. Lower HRQOL was found to be due to differences in mobility, self-care, usual activities, and pain/discomfort (Sparring et al., 2013). Stewart et al. (1989), found that of 776 T2DM, 44% had physician-reported diabetes complications of the eye, foot, or kidney and/or had heart disease or hypertension; these comorbid conditions significantly impacted HRQOL. The presence of diabetic complications significantly influences the individual's well-being (Saatci, 2010). Indicated in HRQOL studies, physical functioning, role functioning, social functioning, health perception, mental health and bodily pain scores were lower in those with diabetes than average scores in those with no chronic conditions (Stewart, 1989 & Glasglow, 1997).

Many prediabetics are overweight or obese; QOL is lower in individuals who are overweight and obese (ADA, 2014; Imayama et al., 2011; Baillot et al., 2013). However, physical activity and losing weight improves QOL scores in this population (Wolin et al., 2007 & Kaplan et al., 1987). The SHIELDS longitudinal study proved that as BMI linearly increased, Physical Component Summary, determined by a QOL survey, significantly decreased (Grandy et al., 2012; Green et al., 2011). Similarly in the SHIELDS study, as Physical and Mental Component Summary scores decreased, body weight of respondents increased (Green et al., 2011). An exercise intervention of 45-60 minutes of walking at a target heart rate (HR) of 60-70% for 10-weeks caused an average weight loss of 1.42 kg and a significant improvement in QOL (Kaplan et al., 1987). Kempf et al. (2013) found that 30-minutes a day of Wii Fit Plus over 12-weeks caused a significant reduction in body weight and body mass index (BMI), as well as a significant, albeit modest (2.4%), increase in QOL. Finally, in a study of overweight and obese T2DM patients, individuals with a BMI > 40 kg/m² had a lower physical component score than those with a BMI between 25-35 kg/m² (Green et al., 2011). QOL is lower in those who are overweight and obese, however exercise may be able to improve physical and mental HRQOL (Nicolucci et al., 2011).

Physical activity has been shown to improve HRQOL and HbA1c in diabetics (Saatci et al., 2010 & Li et al., 2013). Li et al., (2007) gave questionnaires on healthy lifestyle habits and found that people with diabetes who are physically active report two fewer days per month of feeling physically unhealthy, mentally unhealthy, or impaired in activities. HbA1c has a significant correlation to improved QOL, along with diet and exercise (Kaplan et al., 1987). A questionnaire-based study in T2DM showed that diabetics taking medicine, exercising, and dieting had a lower HbA1c and higher QOL score than those who did not (Huang et al, 2012). In the aforementioned Wii Fit Plus intervention by Kempf et al. (2013), HbA1c was significantly reduced, even after adjustment for confounding variables, while diabetes dependent impairment scores and quality of life scores were both improved. Similarly, 50-minutes of aerobic training at 50% of target HR for 8-weeks has been found to elicit significant improvements in both mental component summary score and HbA1c in T2DM patients (Ng et al., 2011). Physical activity has not only the ability to improve HbA1c but also QOL by improving

physiological measures like VO_{2max} and percent body fat (Ng et al., 2011; Wiesinger et al., 2001).

Maximal oxygen consumption, VO_{2max} , has been associated with QOL scores in many populations (Adamsen et al., 2005; Sutbeyaz et al., 2007). A study including 28 obese individuals with arthritis of the knees and 28 obese control subjects with no knee arthritis showed that those with subjects with knee arthritis had lower VO_{2max} scores and reduced QOL scores in all domains compared to controls (Sutbeyaz et al., 2007). VO_{2max} was significantly correlated to improvements in physical role limitations, bodily pain, and general health in obese individuals with knee arthritis. Similarly, in a study of 82 cancer patients, 42 with no evidence of remaining cancer and 40 with cancer, underwent an intervention including high intensity physical training involving resistance training and 10-minute intervals of 60-100% HR max on a cycle ergometer. Significant improvements in VO_{2max} and all subscales of QOL were observed for both groups, and a correlation between improved VO_{2max} and reduced bodily pain was determined in both groups (Adamsen et al., 2005). Additionally, a 4-month aerobic training program in Type I diabetics significantly improved VO_{2max} by 27% and improved all subscales of HRQOL with significantly higher social functioning and vitality scores (Wiesinger et al., 2001). Thus, exercise is a power tool in improving VO_{2max} and QOL.

Exercise interventions have been proven to decrease the incidence of prediabetes progressing to T2DM. A study by Pan et al., (1997) found that in subjects with impaired glucose tolerance that 30-minutes of mild exercise or 20-minutes of moderate exercise a day was associated with a reduced incidence of T2DM diagnosis (8.3 cases per 100 person-years), as compared to the sedentary controls (15.7 cases per 100 person-years).

Similarly, lifestyle interventions in accordance with the Finnish Diabetes Prevention Study, including diet and 30-minutes of moderate exercise a day, significantly reduced waist circumference, fasting plasma glucose concentration, and serum insulin (Uusitupa, et al., 2003 & Tuomilehto, et al., 2001). The Finnish Diabetes Prevention Study intervention also improved insulin sensitivity index and reduced the overall incidence of diabetes by 58% (Uusitupa, et al., 2003 & Tuomilehto, et al., 2003 & Tuomilehto, et al., 2001). Unfortunately, Taylor et al. (2010) found that only 38% of prediabetics were meeting ACSM physical activity guidelines, but those meeting guidelines had significantly higher mental and physical health than those who did not.

The Diabetes Prevention Program (DPP) is an intensive lifestyle intervention designed to prevent or delay the development of T2DM for prediabetics at high risk for progression of the disease compared to standard lifestyle recommendations combined with metformin or a placebo drug. The intensive lifestyle intervention included training in diet, exercise, and behavior modification as well as support from case managers with the goal of losing 5-10% of their initial weight and increasing activity levels to 30-minutes a day, 5-days per week (DPP Research Group, 1999). In 2.8-years, the DPP showed that an intensive lifestyle intervention had the greatest proportion of participants who met the physical activity goal, had the greatest weight loss, and lowest incidence of diabetes compared to the standard lifestyle recommendations coupled with metformin or a placebo drug (DPP Research Group, 2002). A secondary aim of the DPP was to assess the change in HRQOL (DPP Research Group, 1999). Florez et al. (2012) found that in the DPP, HRQOL worsened in all three treatment groups, however the intensive lifestyle intervention had a significantly slower decline in HRQOL than the placebo and

metformin group. The study also found that those in the intensive lifestyle intervention who gained weight had a significant worsening of HRQOL aspects including physical function, general health, body pain, and vitality compared to those in the intensive lifestyle intervention who lost weight (Florez et al., 2012). The DPP study by Marrero et al. (2014) also found that HRQOL declines in all three treatment groups whether or not they were diagnosed with diabetes throughout the study, but those in the intensive lifestyle intervention group with no diabetes diagnosis had a slight improvement in HROOL from baseline to one year. However, this study found that those in the intensive lifestyle intervention who develop diabetes report a more significant decline in HROOL aspects including role physical score and role emotional score compared to those who developed diabetes in the standard lifestyle recommendations coupled with metformin or placebo drug group (Marrero et al., 2014). These studies made no correlation between the diagnosis of T2DM and those in the intensive lifestyle intervention who did or did not follow diet, exercise, and behavior modification instructions (Marrero et al., 2014 & Florez et al., 2012). However, as previously discussed, exercise interventions in prediabetics can be a powerful tool in not only inhibiting the progression of prediabetes to T2DM but may also aide in maintaining or improving QOL in individuals (Taylor et al., 2010).

Physical activity levels in diabetics are significantly associated with self-efficacy, social support, and perceived barriers. (Adeniyi et al., 2012). In T2DM, low social support increases the risk of physical inactivity by four times, while high perception of barriers doubles of the risk of physical inactivity. In diabetics, commonly reported barriers to physical activity include holidays, time management, thought and mood,

illness, low self-efficacy, and motivation (Venditti et al., 2014 & Stewart et al., 2002). However, the most commonly reported barriers to physical activity are internal barriers, specifically lack of time and lack of enjoyment (Mullen et al., 2011 & Slutts, 2004). Designing an exercise intervention, which can reduce time commitment and increase enjoyment, is crucial in the prediabetic population to halt the progression of the disease.

High Intensity Interval Training (HIIT) is a time efficient alternative to traditional aerobic exercise, which elicits the same physiological responses (Metcalfe et al., 2012). There have been several different protocols used to classify HIIT. Sijie et al. (2012) compared a non-exercise control group to a moderate intensity control group and a HIIT intervention group for five training sessions a week for 12-weeks. Participants ran five 3minute intervals at 85% of VO_{2max} followed by a 3-minute recovery at 50% VO_{2max}. The HIIT groups significantly decreased fat mass and significantly increased stroke volume, left ventricle ejection fraction, VO_{2max}, and ventilatory threshold compared to the control group, which did no exercise. In another study, individuals following the HIIT protocol ran at 100% VO₂R for one minute followed by a three minute recovery at 20% VO₂R (Terada et al., 2013). Both the HIIT and moderate-intensity groups significantly reduced total percent body fat while changes in positive well-being, psychological distress, and task-efficacy were not significant (Terada et al., 2013). Little et al. (2011) conducted a study in which 8 T2DM subjects completed HIIT for six sessions on a cycle ergometer with ten 60-second cycling intervals at 90% HR max, with a weekly total commitment equaling 75 minutes/week. The subjects reported an average perceived enjoyment of all sessions as 7.9 out of 9, or enjoyable (Little et al., 2011). Similarly, Bartlett et al. (2011) found perceived enjoyment of an acute bout of HIIT running was significantly higher

than an acute moderate intensity bout. HIIT elicits similar physiological responses in 75 minutes/week as moderate intensity training does in 150 minutes/week, cutting the ACSM recommendation in half. (ACSM; Metcalfe et al., 2012). HIIT has been found to be a successful intervention for individuals who are physically inactive due to lack of time and lack of enjoyment (Little et al., 2011; Lunt et al., 2014). However, sprint interval training (SIT) has recently been studied and findings suggest similar physiological adaptations occur with a thirty minute less time commitment compared to HIIT protocols (Lunt et al., 2014).

Sprint interval training involves a 30-second "all out" exercise effort, typically on a cycle ergometer (Hazell et al., 2013). Although SIT has been found to induce physiological adaptations similar to moderate intensity training, access to a cycle ergometer is often not feasible, thereby creating another barrier (Hazell et al., 2013 & Macpherson et al., 2010). More recently, studies have been performed to see the benefits and adaptations of running sprint interval training (RSIT). Macpherson et al. (2010), conducted a 6-week training intervention, with sprints progressing from 4 to 6 sprints by the final week, for three sessions per week, resulting in significant improvements in fat mass and VO_{2max} of 12.4% and 11.5%, respectively. Hazell et al. (2014), had similar findings with the same 6-week, three sessions per week, protocol, which was associated with improvements in fat mass, body fat percent, waist circumference, and VO_{2max} increased. Similarly, 8-weeks of RSIT, with a progressive increase in the number of sprints per session, was shown to elicit a significant increase in VO_{2max} (Sandvei et al., 2012). This protocol was also associated with a significant reduction in fasting glucose in healthy adults, which is of particular interest for application in the prediabetic population

(Sandvei et al., 2012). Despite the reduced exercise volume in each the studies, the results produced were similar to what would be expected with moderate intensity training.

Sprint interval training has been a successful protocol to address the barrier of lack of time. However, limited data has evaluated perceived enjoyment in RSIT. Crisp et al. (2012) conducted a protocol similar to SIT on a cycle ergometer in which healthy and overweight boys completed 4-seconds of maximal sprints on a cycle ergometer followed by a 2-minute active recovery. After a 30-minute exercise period all normal weight boys and 7 of 9 overweight boys preferred the sprint intervals more than moderate intensity exercise, however significance was not reached. If the SIT protocol increases exercise enjoyment as well as reduces a time commitment, then participation in exercise and adherence to training may increase.

SIT elicits physiological benefits similar to traditional moderate intensity aerobic exercise in a fraction of the time. SIT has been proven to decrease fat mass, increase VO_{2max}, and improve fasting blood glucose (Hazell et al., 2014 & Sandvei et al., 2012). These physiological adaptations have been found to improve QOL in several populations including prediabetics, using more traditional exercise interventions (Kaplan et al., 1987; Ng et al., 2011; Sutbeyaz et al., 2007). If decreased time commitment, increased enjoyment, and improved QOL can increase exercise participation and adherence, then prediabetics may find RSIT appealing. However, no studies have been completed to report perceived enjoyment and QOL in relation to RSIT training in the prediabetic population.

Purpose

The purpose of this study is to determine if health related quality of life (HRQOL) and perceived exercise enjoyment are greater in an RSIT experimental group compared to a moderate intensity group in sedentary, prediabetic adults during and after a 16-week intervention.

Hypothesis

It is hypothesized that HRQOL, evaluated using the CDC HRQOL – 4 questionnaire, will improve in the R-SIT group and moderate intensity group after 16-weeks. It is also hypothesized that HRQOL will be greater at 16-weeks than baseline and be maintained from week 16 to the 3-months post intervention in both the R-SIT and moderate intensity groups.

It is hypothesized that perceived enjoyment, evaluated by the Physical Activity Enjoyment Scale, will be greater in R-SIT than the moderate intensity group at 8-weeks and 16-weeks. It is also hypothesized that perceived enjoyment will be greater at 16weeks than 8-weeks and greater at 8-weeks than baseline in R-SIT and moderate intensity groups.

Assumptions

It is assumed that subjects in this study will be able to run on a treadmill. It is also assumed that subjects will give maximal exertion during sprint intervals of exercise.

Limitations

Limitations of this study are we are only studying prediabetic, sedentary adults, and so our results can only apply to the specific population.

Delimitations

Delimitations of this study are we are only studying prediabetics. Also, we are using a treadmill, not a cycle ergometer.

Definition of Terms

Sedentary - Not meeting ACSM guidelines of 150 minutes of physical activity per week Prediabetic - American Diabetes Association guidelines of a fasting blood glucose level between 100-125 mg/dl, blood glucose between 140-199 mg/dl two hours after an oral glucose tolerance test (OGTT), or a hemoglobin A1C of 5.7-6.4%

Chapter II

Methods

Research Design

This study is a 16-week, randomly controlled study designed to compare the effects of run sprint interval training protocol to a moderate intensity control exercise protocol in sedentary, prediabetic men and women diagnosed according to the American Diabetic Association (ADA). HRQOL, perceived enjoyment, VO_{2max} , body composition, and HbA1c will be measured at baseline, 8-weeks, 16-weeks, and 3-months post intervention.

Subjects

For the study, 75 men and women will be recruited by flyers and referrals from local physicians in the Harrisonburg, VA area. Study subjects will be prediabetic (as defined by the ADA), have no other known diseases or comorbidities limiting physical activity (assessed with the PAR-Q), and be sedentary (as defined by the ACSM and assessed using the IPAQ). The IPAQ consists of subject's self-reporting activity levels for the past 7 days to determine low, moderate, or high activity levels (Craig et al., 2003). Subjects will be excluded if they are Type 1 or Type 2 Diabetics, women who are currently pregnant, demonstrate signs or symptoms of Cardiovascular Disease according to the ACSM, or taking medication for prediabetes. However, subjects will be included in the study if they are seeing a physician or seeking education for prediabetes. The study and its procedures will be approved by James Madison University (Harrisonburg, VA) according to ethical standards of the Institutional Review Board.

Familiarization:

Subjects will be brought to the Human Performance Lab in Godwin Hall at James Madison University for a familiarization session. Subjects will be informed about testing procedures and familiarized with the treadmill.

Physical Activity Enjoyment and Quality of Life

Subjects will fill out CDC HRQOL-4 and Physical Activity Enjoyment Scale (PACES) questionnaires. Finally, body composition (assessed by iDXA), resting HR, and blood pressure will be measured in all subjects.

- CDC HRQOL-4 identifies health disparities and tracks population trends and has been validated (Gold et al., 2001). The questionnaire will include the 4-item Healthy Days Core Module. The 4-item Healthy Days Core Module will range from 0-30, with a higher score indicating worse perceived health. Item one assesses self-rated general health with a range of 5 answers from excellent to poor. Questions 2 and 3 assess the number of days mental and physical health were impaired, while question 4 assesses recent limitations to activities due to impairments. The maximum score assigned is 30 (CDC, 2011).
- **PACES** assesses physical activity enjoyment utilizing a 18 statement questionnaire. The questionnaire will be used scoring subjects on a seven point Likert Scale ranging from 1 ("Disagree a lot") to 7 ("Agree a lot). Each question beginning with "When I am active" (Kendzuerski et al., 1991). A higher score on PACES will be associated with a higher perceived enjoyment.

Clinical Measures:

Body Composition and Resting Heart Rate: Body composition will be assessed in the Human Performance Lab in Godwin Hall, at James Madison University, using a GE Lunar Prodigy iDXA (GE Health Care). After a 10-minute rest period laying supine on the iDXA, resting heart rate and blood pressure will be obtained. Procedures for obtaining resting heart rate using a polar watch are in conjunction with another study.

HbA1c: Participants will have their blood drawn by a certified phlebotomist after an all-night fast at a laboratory associated with the regional hospital.

Fitness Measures:

Subjects will return to the lab for VO_{2max} testing. VO_{2max} will be measured on a treadmill, and will assess maximal oxygen uptake and cardiovascular fitness. After a three minute warm up, VO_{2max} will be measured utilizing a modified ramp protocol. Subjects will self-select a speed they can comfortably maintain for the test. Grade will begin at 0% grade and will be increased by 2.5% every three minutes until volitional exhaustion as assessed by a metabolic cart. Strong verbal encouragement will be provided. Maximal effort will be determined by a respiratory exchange ratio (RER) greater than 1.1, a rating of perceived exertion (RPE) of 19 or 20 on the Borg Scale, and/or a HR max within 10 beats per minute of age expected HR max.

Adherence:

Exercise adherence will be determined by calculating the total number of sessions attended by each subject out of a total of 48 sessions.

Exercise and Lifestyle Interventions:

Subjects will be randomly separated into two different groups including a run sprint interval training protocol (RSIT) or a moderate intensity control training protocol (MIT). All training sessions for RSIT and MIT will be supervised and conducted in Godwin Hall at James Madison University 3-days a week, for 16-weeks. Training volume will progress every 4-weeks. Each exercise session will begin and end with a 5-minute walk at 2.5 mph and 0% grade.

- Run Sprint Interval Training (RSIT) Initially, subjects in the RSIT group will run four 30-second maximal "all out" sprints at a self-selected maximum speed at a grade of 3-5%. The grade allows subjects to reach a maximal effort while reducing required speed as well as reducing orthopedic stress (Ehlen et al., 2010). HR and RPE will be recorded after each interval to ensure maximal effort. HR is expected to be as close to max as possible and RPE range should reach 19-20 on the Borg Scale. Following the 30-second sprint, subjects will have a 4-minute active rest of walking at a speed of 2.5mph and 0% grade. Every four weeks the number of sprints will increase by two so that at the end of the study, subjects in the RSIT group will be doing 10 maximal sprints. By the end of the training RSIT will be doing 15 minutes of vigorous physical activity per week.
- Moderate Intensity Training (MIT) Initially, subjects will walk or jog on a treadmill for 30-minutes at 45-55% of their heart rate reserve (HRR), defined as moderate intensity according to the ACSM. Every four weeks the length of training will increase by 10-minutes so that at the end of the study, subjects in the MIT group will be participating in 60-minute sessions. By the end of training the MIT group will be doing 180-minutes of moderate intensity physical activity per week.

Statistical Analysis

CDC HRQOL – 4, PACES, VO_{2max} , HbA1c, and body fat percentage will be analyzed using a repeated measures two-way ANOVA. Correlations will be determined

between CDC HRQOL-4 and VO_{2max}, CDC HRQOL-4 and HbA1c, CDC HRQOL-4 and body fat percentage, and CDC HRQOL-4 and PACES using a Pearson's Produce Moment Coefficient of correlation. Significance is set at p < 0.05.

Chapter III

Journal Manuscript

Manuscript Title: The Effect of Run Sprint Interval Training on Prediabetic Adults: Health Related Quality of Life, Perceived Enjoyment, and Exercise Adherence

Abstract

Purpose: The purpose of this study is to determine if Health Related Quality of Life (HRQOL) and perceived exercise enjoyment are greater in a run sprint interval training (RSIT) group compared to a moderate intensity training (MIT) group in sedentary, prediabetic adults after an 8-week intervention.

Methods: Over 8-weeks, subjects in the RSIT group progressed from 4 to 6 30-second sprints per session, and the MIT group progressed from 30 to 60 minutes of continuous moderate intensity exercise. Participants in both groups completed 8-weeks of the Centers for Disease Control and Prevention (CDC) Diabetes Prevention Program educational classes. HRQOL (assessed by the CDC 4-item Healthy Days Core Module), perceived exercise enjoyment (assessed by the physical activity enjoyment scale, PACES), exercise adherence, VO_{2max} , and body composition were assessed in both groups.

Results: There was no significant difference from baseline to 8-weeks in Healthy Days in the RSIT group (p = 0.833) or the MIT group (p = 0.080). There were also no significant differences between or within groups at baseline or 8-weeks for self-reported days of negative physical health, mental health, or affected usual days scores. There was no significant difference in exercise adherence between the MIT (20.75±2.71 sessions) and RSIT (20.57±1.40 sessions) groups. There was no significant difference between groups in perceived enjoyment, however there was a significant increase from baseline to 8weeks in the MIT group (11.88±12.38; p = 0.030). 8-weeks of MIT significantly improved body composition measures including body weight (-9.35±6.21; p = 0.004), % body fat (-2.015±1.88; p = 0.019), body mass index (-1.21±1.07; p = 0.015), and % lean mass (2.05±1.84; p = 0.016). SIT significantly improved VO_{2max} (mL/kg/min) (1.84±1.70; p = 0.028) over 8-weeks.

Discussion: The practical implications of there being no significant difference between RSIT and MIT in perceived exercise enjoyment, exercise adherence, or HRQOL shows participants can choose their exercise preference. A significant improvement in PACES scores for the MIT may be a result of stronger social relationships formed. 8-weeks may have proven to not be long enough to see significant between or within group differences in HRQOL scores.

Introduction

Prediabetes is a major public health concern (CDC, 2011). In 2010, approximately 35% of the United States population, ages 20-years or older, were prediabetic. Prediabetes is characterized as an increased blood glucose concentration, which is higher than normal but not high enough for a diabetes diagnosis (CDC, 2011). Without intervention, prediabetes most likely progress to Type 2 Diabetes Mellitus (T2DM) within 10 years (CDC, 2011). However, increasing physical activity in prediabetics can impede the progression of the disease to T2DM (ADA, 2014; CDC, 2011). It has been shown that patients with diabetes and health related complications have a lower quality of life (QOL) (Venkataraman et al., 2013). QOL is a multidimensional subjective evaluation of positive and negative aspects of life. Overall several domains including jobs, relationships, culture, religion, environment, and health affect QOL. Health-related QOL (HRQOL) is important for overall QOL, and is linked to both physical and mental health (CDC, 2000). Individually, HRQOL encompasses health risk and conditions, functional status, social support, and socioeconomic status using a multidimensional subjective evaluation (CDC, 2011).

Health-related quality of life, including constructs such as physical functioning, role functioning, social functioning, health perception, mental health and bodily pain scores, is lower in people with diabetes than healthy people with no chronic conditions (Glasglow et al., 1997; Stewart et al., 1989). In a recent evaluation of HRQOL in diabetics aged 15-34 years versus healthy controls, both men and women with diabetes reported lower HRQOL at every time point of the study (Sparring et al., 2013). The

lower HRQOL scores were associated with differences in mobility, self-care, usual activities, and pain/discomfort (Sparring et al., 2013).

Multiple studies have indicated that physical activity can improve HRQOL in diabetics (Kaplan et al., 1987; Li et al., 2007; Saatci et al., 2010). Kaplan et al. (1987), found a diet plus exercise intervention of 45-60 minutes of walking at a target heart rate (HR) of 60-70% for 10-weeks caused a significant decrease in HbA1c, an important parameter in diabetes diagnostics and treatment. Additionally, a lower HbA1c had a significant correlation to a higher QOL (Kaplan et al., 1987). A questionnaire-based study in T2DM showed that diabetics taking medicine, exercising, and dieting had a lower HbA1c and higher QOL score than those who did not (Huang et al., 2012). A 4month aerobic training program in Type I diabetics significantly improved VO_{2max} by 27% and improved all subscales of HRQOL, including significantly higher social functioning and vitality scores. A similar impact of VO_{2max} on QOL has been seen in body weight and composition (Wiesinger et al., 2001). Green et al. (2011) showed as body mass index (BMI) increases, physical component scores significantly decreased (Green et al., 2011). However, Ng et al. (2011) found that in overweight T2DM 50minutes of aerobic training at 65% of their HR_{max} for 8-weeks elicited significant improvements in general health, vitality, and mental component summary score (Ng et al., 2011). Thus, exercise interventions in prediabetics may be a powerful tool in not only inhibiting the progression of prediabetes to T2DM but may also aide in maintaining or improving QOL (Li et al., 2007; Saatci et al., 2010).

Exercise interventions have proven to decrease the incidence of prediabetics progressing to T2DM. Lifestyle interventions in accordance with the Finnish Diabetes

Prevention Study, including diet and 30-minutes of moderate exercise a day, significantly reduced waist circumference, fasting plasma glucose concentration, and serum insulin, as well as reduced the overall incidence of diabetes by 58% (Tuomilehto et al., 2001; Uusitupa et al., 2003). Despite the clear benefits of exercise for T2DM, barriers stand in the way of exercise in the prediabetic population. 58-61% of individuals with T2DM do not meet the American Diabetes Association (ADA) or American College of Sports Medicine (ACSM) physical activity recommendations (Zhao et a., 2007.) The most commonly reported barriers to physical activity are internal barriers, specifically lack of time and lack of enjoyment (Mullen et al., 2011; Stutts, 2002). Designing an exercise intervention that addresses these barriers is crucial to the prediabetic population as an effort to slow the progression of the disease.

Sprint Interval Training (SIT) is a training protocol that has recently received attention in exercise science research (Crisp et al., 2012; Hazell et al., 2013 & Macpherson et al., 2010; Tritter et al., 2013). SIT is a time efficient training protocol that utilizes thirty-second maximal exercise efforts and has been shown to elicit the same physiological adaptations traditional aerobic exercise (Burgomaster et al., 2007; Hazell et al., 2013; Macpherson et al., 2010; Sandvei et al., 2012). Most SIT protocols involve a cycle ergometer, however access to a cycle ergometer is often not feasible creating another barrier to regular exercise (Hazell et al., 2014; Macpherson et al., 2010). More recently, studies have been performed to see the benefits and adaptations of running sprint interval training (RSIT). Macpherson et al. (2010), conducted a 6-week study comparing six weeks of endurance training at 65% of VO_{2max} progressing from 30 to 60-minutes to RSIT that progressively increased in the number of sprint intervals from four

to six. This intervention caused a significant decrease in fat mass (12.4%, 5.8%) and significant increase in VO_{2max} (11.5%, 12.5%) in both RSIT and MIT groups, respectively. There was no significant difference between groups (Macpherson et al., 2010). Other RSIT studies have reported significant decreases in body mass (-0.5 kg), body fat percent (-1.7%), and waist circumference (-2.8 cm) in just 6-weeks (Hazell et al., 2014). Sandvei et al., 2012 found that 8-weeks of RSIT was as equally successful at reducing fasting glucose as aerobic training at 70-80% of HR_{max}. Given that these improvements in fasting glucose were seen in a population with healthy fasting glucose levels, SIT training may prove to be a powerful tool in treating the prediabetic population in a time-efficient manner

SIT has been a successful protocol to improve physiological aspects of ones health (Burgomaster et al., 2007; Hazell et al., 2013; Macpherson et al., 2010; Sandvei et al., 2012). However, limited data has evaluated perceived enjoyment in RSIT. Crisp et al. (2012), conducted a protocol similar to SIT on a cycle ergometer in which healthy and overweight boys completed four seconds of maximal sprints on a cycle ergometer followed by a 2-minute active recovery. After a 30-minute exercise period all normal weight boys and 7 of 9 overweight boys preferred the sprint intervals more than moderate intensity exercise, however significance was not reached. If the SIT protocol increases exercise enjoyment as well as reduces a time commitment, then participation in exercise and adherence to training may increase.

As previously discussed, SIT elicits physiological benefits similar to traditional moderate intensity aerobic exercise, in a fraction of the time (Hazell et al., 2014; Macpherson et al., 2010; Sandvei et al., 2012). If decreased exercise time commitment,

increased enjoyment, and improved QOL can increase exercise participation and adherence, then prediabetics may find RSIT appealing. However, no studies have examined perceived enjoyment and QOL in the prediabetic population. Therefore, the purpose of this study is to determine if HRQOL, perceived enjoyment, and exercise adherence are greater in an RSIT experimental group compared to a moderate intensity control group in sedentary, prediabetic adults during and after an 8-week intervention. It is hypothesized that HRQOL will improve in both the RSIT and moderate intensity groups after 8-weeks. It is also hypothesized that perceived enjoyment will be greater in RSIT than the moderate intensity group after 8-weeks.

Methodology

Research Design

This study was an 8-week, randomly controlled study designed to compare the effects of RSIT protocol to a moderate intensity control exercise protocol (MIT) in sedentary, prediabetic men and women diagnosed according to the ADA. HRQOL, perceived enjoyment, exercise adherence, VO_{2max} , body composition, and HbA1c were measured at baseline and 8-weeks post intervention.

Subjects

For the study, 15 men and women, ages 18-71 years, were recruited by flyers, television commercials, newspaper and radio advertisements, and referrals from local physicians in the Harrisonburg, VA area. Study subjects were physician diagnosed prediabetic (as defined by the ADA as a fasting blood glucose level between 100-125 mg/dl, blood glucose between 140-199 mg/dl two hours after an oral glucose tolerance

test (OGTT), or hemoglobin A1C of 5.7-6.4%), had no other known diseases or comorbidities limiting physical activity (assessed with the PAR-Q), and were sedentary (defined as not meeting the ACSM physical activity recommendations and assessed using the international physical activity questionnaire, IPAQ). The IPAQ consists of subject's self-reporting activity levels for the past 7-days to determine low, moderate, or high activity levels (Craig et al., 2003). Subjects were excluded if they have a previous diagnosis of type 1 or type 2 diabetes, women who were currently pregnant, or demonstrated signs or symptoms of cardiovascular disease according to the ACSM. The study and its procedures were approved by James Madison University (Harrisonburg, VA) according to ethical standards of the Institutional Review Board.

Familiarization:

Subjects were brought to the Human Performance Lab in Godwin Hall at James Madison University. At baseline a physician approval form, confirming the subjects prediabetes diagnosis, was received and informed consent was obtained. At baseline and 8-weeks testing included subjects completing questionnaires, clinical measures, and fitness measures.

Questionnaires:

The CDC HRQOL-4 identifies health disparities and tracks population trends and has been validated (Gold et al., 2001). The questionnaire included the 4-item Healthy Days Core Module. Item one assessed self-rated general health with a range of five answers from excellent to poor. Questions two and three assessed the number of days mental and physical health were impaired over the past 30-days, while question four assessed recent limitations to activities due to impairments with a maximum of 30-days. To determine Healthy Days, reported scores for question two and three were added, so that the maximum score could be 30. The total number of days mental and physical health were impaired was subtracted from 30 to report Healthy Days. Healthy Days, impaired physical health, impaired mental health, and days affected due to usual activity impairment were reported and analyzed (CDC, 2011).

PACES assessed physical activity enjoyment utilizing a 16-statement questionnaire. The questionnaire scored subjects on a seven point Likert Scale ranging from one ("Disagree a lot") to seven ("Agree a lot). Each question began with "When I am active" (Kendzierski et al., 1991). A higher score on PACES was associated with a higher perceived enjoyment.

Clinical Measures:

Height, weight, body composition measures, resting HR, blood pressure, and blood parameters were measured in all subjects. Body Composition measures included BMI, waist and hip circumference, % body fat, and % lean mass. Percent body fat and lean mass was assessed using a GE Lunar Prodigy iDXA (GE Health Care). After a 10minute rest period laying supine on the iDXA, resting heart rate and blood pressure was obtained. At the end of testing participants were given a blood draw form to have their blood drawn by a certified phlebotomist after an all-night fast at a laboratory associated with the regional hospital. Blood parameters include blood glucose and HbA1c.

Fitness Measures:

Subjects returned to the lab for VO_{2max} testing (Parvo Medics) on a second day. VO_{2max} was measured on a treadmill, and assessed maximal oxygen uptake and cardiovascular fitness. After a three minute warm up, VO_{2max} was measured utilizing a modified ramp protocol. Subjects self-selected a speed they could comfortably maintain for the test. Grade began at 0% grade and increased by 2.5% every three minutes until maximal effort was reached according to the following criteria; a respiratory exchange ratio (RER) greater than 1.1, a rating of perceived exertion (RPE) of 19 or 20 on the Borg Scale, and/or a HR max within 10 beats per minute of age expected HR max.

Adherence:

At the familiarization session participants were informed that they were required to attend 80% of exercise sessions. Exercise adherence was determined by calculating the total number of sessions attended by each subject out of a total of 24 sessions (three sessions per week for 8-weeks). Individuals who dropped out from the exercise intervention were noted and rationale, if any, was noted.

Exercise and Lifestyle Interventions:

Subjects were randomly separated into two different groups including a RSIT protocol or a MIT protocol. All training sessions for RSIT and MIT were supervised and conducted in Godwin Hall at James Madison University, three days a week, for 8-weeks. Training volume progressed every four weeks. Each exercise session began and ended with a 5-minute walk at a self-selected, low-intensity speed and grade.

The RSIT group (n=7) initially ran four 30-second maximal "all out" sprints at a self-selected maximum speed and grade. The grade allowed subjects to reach a maximal effort while reducing required speed as well as reducing orthopedic stress (Ehlen et al., 2010). HR and RPE were recorded after each interval to ensure maximal effort. HR was expected to be as close to max as possible and RPE was expected to reach 19-20 on the Borg Scale. Following the 30-second sprint, subjects had a 4-minute active rest of

walking at a speed of 2.0-2.5 mph and 0% grade. Half way through the intervention, beginning week five, the number of sprints increased by two to six maximal sprints. By the end of the training, RSIT participants were completing 9-minutes of vigorous physical activity per week.

The MIT group (n=8) initially walked on a treadmill for 30-minutes at 45-55% of their heart rate reserve (HRR), defined as moderate intensity according to the ACSM. After four weeks the length of training increased by 10-minutes so that at the end of the study, subjects in the MIT group participated in 40-minute sessions. By the end of training, the MIT group completed 120-minutes of moderate intensity physical activity per week.

All participants attended the first 8-weeks of the 16-week CDC Diabetes Prevention Program (DPP) educational class (DPP Research Group, 1999). The DPP is an intensive lifestyle intervention designed to prevent or delay the development of T2DM for prediabetics at high risk for progression of the disease compared to standard lifestyle recommendations combined with metformin or a placebo drug. The intensive lifestyle intervention included training in diet, exercise, and behavior modification as well as support from case managers with the goal of losing 5-10% of their initial weight and increasing activity levels to 30-minutes a day, 5-days per week (DPP Research Group, 1999).

Statistical Analysis

Subject characteristics were assessed at baseline via independent samples t-tests. Between and within group differences for PACES, exercise adherence, VO_{2max} , HbA1c, and body composition measures from baseline to 8-weeks were analyzed using independents samples t-tests and paired samples *t*-tests, respectively. Within group differences from baseline to 8-weeks for the CDC HRQOL-4 questionnaire was analyzed using related-samples Wilcoxon signed rank test. Correlations were determined between all of the aforementioned variables using Spearman Rho's Coefficient of correlation. Significance was set at p < 0.05.

Results

Subject Characteristics

Baseline characteristics are presented in Table 1. There were no significant differences in age, height, weight, BMI, VO_{2max} , or fasting glucose. HbA1c was significantly lower in the RSIT group (-0.37±0.13; p = 0.015) at baseline.

Body Composition and Fitness

There were no significant differences between groups in subject characteristics, including HbA1c, at 8-weeks. Within group differences in fitness, body composition, fasting glucose and HbA1c measures from baseline to 8-weeks in the two training groups are reported in Table 2. There was no significant difference between groups in VO_{2max} at baseline and 8-weeks. There was a significant improvement in VO_{2max} (mL/kg/min) (1.84±1.70; p = 0.028) from baseline to 8-weeks in the RSIT group, however there was only a trend towards improvement seen in the MIT group (1.90±2.66; p = 0.083). There were no significant differences between groups in body weight, BMI, body fat percentage, lean muscle mass, or waist to hip ratio at baseline or 8-weeks. From baseline to 8-weeks, there was a significant decrease in body weight (-9.35±6.21; p = 0.004), body fat percentage (-2.02±1.87; p = 0.019), and BMI (-1.21±1.07; p = 0.015) and significant
increase in lean muscle mass percentage (2.05±1.84; p = 0.016), in the MIT group. There were no significant differences in body composition in the RSIT group, however there was a trend towards significance from baseline to 8-weeks in BMI (1.06±1.34; p = 0.081).

Perceived Exercise Enjoyment and Exercise Adherence

There was no significant difference in exercise adherence between groups, with the MIT group attendance at 86.5% (20.75±2.71 sessions) and the RSIT group attendance at 85.7% (20.57±1.40 sessions). Four participants in the RSIT group and three participants from the MIT group dropped out of the study prior to the 8-week mark due to injury and lack of time. There was no significant difference in perceived exercise enjoyment between groups at baseline or 8-weeks, however there was a significant improvement in perceived exercise enjoyment (11.88±12.38; p = 0.030) within the MIT group from baseline to 8-weeks.

Spearman's correlation coefficient showed that there was no association between baseline or 8-week perceived exercise enjoyment and exercise adherence in all participants or when separated by training groups. There was an association between baseline perceived exercise enjoyment and age in the MIT group (r = 0.76; p = 0.031).

Health-Related Quality of Life

Related-samples Wilcoxon signed rank test showed there was no significant difference from baseline to 8-weeks in Healthy Days in the RSIT group or the MIT group. There were also no significant differences between or within groups at baseline or 8-weeks for self-reported days of negative physical health, mental health, or affected usual days scores.

Spearman Rho's correlation coefficient determined associations between selfreported days of negative physical health, mental health, or affected usual activity scores and fitness, body composition, and 8-week adherence at baseline (Table 3) and 8-weeks (Table 4). In the RSIT group, there was a positive association between mentally unhealthy days and fasting glucose (r=0.085; p=0.015). There was an unusual negative correlation between HbAlc and mentally unhealthy days in the RSIT group (r=-0.89; p=0.008), likely due to the small sample size.

Discussion

The purpose of the study was to determine the differences in perceived exercise enjoyment, exercise adherence, and HRQOL between an RSIT and MIT exercise protocol over 8-weeks in sedentary, prediabetic adults. A primary finding of the study shows there was no significant difference in perceived exercise enjoyment, as measured by the PACES questionnaire, between groups after 8-weeks of training. However, there was a significant increase in PACES scores in the MIT group from baseline to 8-weeks. The findings in the present study contradict the hypothesis that stated perceived enjoyment would be greater in the RSIT than MIT group and that perceived enjoyment would be significantly greater from baseline to 8-weeks in the MIT and RSIT group, as perceived enjoyment was only significantly greater in the MIT group. Our findings contradict previous findings by Bartlett et al. (2011), which found that recreationally active men with a mean age of 25 scored an acute bout of high intensity interval running as significantly more enjoyable than an acute bout moderate intensity continuous running. The findings in Bartlett et al. (2011) differs from the present study in that a majority of participants were females, the mean age of all participants was 46, and all participants were physician-diagnosed prediabetic. Additionally, individuals in the present study only completed one exercise protocol for 8-weeks length instead of both exercise protocols for one acute bout. It should also be noted that participants in both training protocols had high, perceived exercise enjoyment scores at baseline (RSIT = 85.0; MIT=80.0). Both groups may have had a ceiling effect given their high baseline scores and the questionnaire may have failed to detect true growth in enjoyment scores over 8-weeks. Additionally, the high baseline PACES scores may not be true to the whole prediabetic population due to the self-selection bias of participants joining an exercise intervention study.

This is the first study, to our knowledge, that evaluated the difference of perceived enjoyment in RSIT versus MIT in physician-diagnosed prediabetics. Wininger and Pargman (2003) found that in female students participating in an aerobic dance classes, perceived exercise enjoyment was most strongly correlated with music, followed by satisfaction with the instructor, and finally self-identity. Additionally, in individuals at high risk for developing T2DM encouragement, social support from others, and exercising with individuals of a similar physical level were important factors reported for enjoying and remaining motivated to exercise (Korkiakangas et al., 2010). In the present study, participants were equally exposed to exercise instructors, similar music was played at all exercise sessions, and participants exercised with individuals of similar physical levels. Thus, variables causing a significant increase in perceived enjoyment scores in the MIT group may be attributable to self-identity, encouragement from individuals outside of the study, and social support from others.

Another primary finding of the study shows there was no significant difference from baseline to 8-weeks in self-reported Healthy Days in both the RSIT and MIT group. There was also no significant difference between self-reported days of negative physical health, mental health, or impaired activities days out of the past 30-days between the RSIT and MIT group. These findings contradict the hypothesis that stated HRQOL will improve in the RSIT and MIT group after 8-weeks of training.

To our knowledge this is the first study examining the effect of RSIT on HRQOL in prediabetics. Baillot et al. (2012) reported that in obese T2DM men completing an 8week aerobic training program, there was no significant change in QOL scores, in agreement with our findings for the MIT group. Alternately, Nicolucci et al. (2011) found that 12-months of aerobic training for 150 minutes/week caused improvements of QOL in domains including role limitations due to physical problems, bodily pain, general health perception, energy/vitality, social functioning, role limitations due to emotional problems, and mental health. The 16-week DPP program caused no significant changes in mental component summary scores but caused a significant increase in physical component scores from baseline to one-year (Marrero, 2014). Thus, it may be that 8weeks was not a long enough intervention to elicit significant changes in HRQOL selfreported unhealthy days. There was an association between HRQOL and BMI, body fat percentage, and lean mass in the MIT group. Given these changes, it is possible that a significant difference in HRQOL scores was not observed because the CDC Healthy Days Module asks for individuals to report effected days out of the past 30-days. Participants may have not had time in the 8-weeks to reflect on changes in HRQOL as

expected to see when there is a reduction in BMI and percentage of body fat (Imayama, 2011; Kaplan, 1987; Grandy, 2012).

Quality of life and glucose tolerance has been found to be bi-directional in which poor QOL can increase one's risk for developing T2DM, while developing T2DM can cause poor QOL (Tapp, 2006). Acceptance into the present study required a physician approval form confirming a prediabetes diagnosis. Knowledge of having prediabetes and a new health diagnosis could have played a role on HRQOL scores at baseline and 8weeks (Seppala, 2013). Furthermore, progression along the diabetes continuum from normal fasting glucose to a diabetes diagnosis is associated with lowering HRQOL scores (Seppala, 2013; Tapp, 2006; Vaatainen, 2014). Perhaps because there were no significant changes in fasting glucose or HbA1c from baseline to 8-weeks in either group, no change in HRQOL occurred. The association of 8-week mental health scores to HbA1c and fasting glucose in the present study support these positions. Finding of Saatchi et al. (2010) support the aforementioned findings in the present study as improvements in HbA1c was associated with improved mental health (p=0.046).

A greater number of self-reported negative mental health days and impaired activities days at baseline correlated to a lower exercise adherence in the present study. In 282 overweight and obese subjects, Mazzeschi et al. (2012) found that poor exercise adherence could be significantly predicted by poor HRQOL scores in the domains vitality, physical role functioning, social functioning, mental composite scores, and physical composite scores. In the present study, participant's baseline self-reported days out of the past 30 days for negative mental health (9.87 \pm 12.30) and impaired activities days (7.40 \pm 11.27) was less than 14-days. The CDC has found that 14 or more self-

reported negative days categorizes individuals as having frequent distress (CDC, 2000) and is associated with physical inactivity (Brown et al., 2003). To our knowledge no study has investigated the effect of having or not having frequent distress on exercise adherence, however HRQOL scores may be a predictor for exercise adherence. Additionally, mentally unhealthy days were correlated to 8-week adherence in all participants and the MIT group, and so mental health could be a greater influence on individuals adhering to an exercise program than other HRQOL subcomponents.

A greater number of self-reported days of impaired activities at baseline were associated with a lower VO_{2max} (L/min) in the MIT group at baseline. At 8-weeks in all participants and the MIT group, a higher VO_{2max} was associated with fewer reported mentally and physically unhealthy days. These findings are expected as increased physical activity improves HRQOL, and physical activity is associated with higher VO_{2max} (Brown et al., 2003; Green et al., 2011; Li et al., 2007). Higher VO_{2max} has been found to be associated with greater physical functioning, general health, exercise selfefficacy, mental and physical component scores, and physical role limitations (Adamsen et al., 2006; Imayama et al., 2013; Sutbeyaz et al., 2007). However, to our knowledge the present study is the first to find a correlation between the HRQOL subcomponents and VO_{2max} in the prediabetic population.

At baseline there was an unusual correlation in the RSIT group in that as VO_{2max} scores increased so did the number of reported mentally unhealthy days and negatively effected usual activity days. The researches noted one outlier who skewed that data as they had the highest VO_{2max} of all participants and also reported 30 mentally unhealthy days and 27 negatively effected usual activity days.

A final primary outcome of the present study shows there was no significant difference between groups in exercise adherence, measured by total number of sessions attended in 8-weeks. The MIT group attended 86.5% of exercise sessions and the RSIT group attended 85.7%. However, all participants were informed at the familiarization session that they were required to attend 80% of exercise sessions, or 19 out of 24 possible sessions, to remain in the study. Total exercise sessions attended could have been lower had participants not been required to attend 80%. Additionally exercise adherence has been found to be effected by factors including body mass, level of selfmotivation, occupational status, spousal and social support, and encouragement (Danielson & Wanzel, 1978; Wankel, 1985). Mullen et al. (2011) found that in sedentary older adults exercise enjoyment, measured by PACES, is associated with exercise adherence. The findings by Mullen et al. (2011) contradict the findings in the present study as there was no correlation between exercise enjoyment and exercise adherence in all participants or when participants were analyzed in their respective groups. A questionnaire on attitudes towards physical activity was not administered, however the researchers noted that many participants formed strong relationships with participants in their training group and DPP educational class. Wankel (1985) found that friendship in an exercise group was rated important for exercise adherence to a jogging/running training program at a university. A study by Carron et al. (1989) showed that fitness class and elite sport adherers were more personally attracted to the groups task and perceived the group as more integrated around social and task dimensions. The high adherence rates in the present study were then likely due to the 80% required adherence and friendships formed.

Past research shows that between 30% and 70% of participants drop out of exercise programs (Pollock, 1977; Ballantyne, 1978). 31.8% (7 out of 22) of participants in the present study dropped out prior to completing 8-weeks of training. Only a few participants gave reasons for dropping out of the study including injury, lack of time, or too many other commitments. Pollock et al. (1977) found that an exercise duration of 45minutes causes a 50% increased incidence of injury, primarily shin splints and knee problems, when compared to 30-minutes of exercise. In the present study, from week one to four total exercise time equaled 28-minutes in the RSIT group and 40-minutes in the MIT group. From weeks five to eight, total exercise time equaled 37-minutes for the RSIT group and 50-minutes for the MIT group. The initial exercise duration and the progressed exercise duration may have caused dropouts due to injury. Ingjer and Dahl (1979) found that in individuals participating in cross-country running three times a week, individuals who dropped out did not significantly improve their aerobic power in the first 2-weeks or have significant weight loss in the first 7-weeks like those who remained in the study. Additionally, Wankel (1985) reported that the most frequently reported reasons for dropping out of an exercise program included inconvenient times, loss of interest in the program, injury, dislike for a rigid schedule, and an inconvenient exercise location. Thus, any of the previous findings mentioned above could offer an explanation for individuals dropping out of the study.

Secondary findings of the present study include VO_{2max} , body composition, and HbA1c. The present study found a significant increase in VO_{2max} in the RSIT group but not the MIT group from baseline to 8-weeks. These findings are similar to a 6-week RSIT study in which healthy recreationally active women significantly increased their VO_{2max}

by 8.7% (Hazell et al., 2014). Sandvei et al. (2012) found that in healthy young subjects, RSIT improved VO_{2max} by 5.3±1.8% over 8-weeks of training. Unlike the present study, participants in the continuous endurance group study improved VO_{2max} by 3.8±1.6%, however in participants exercised as a higher percentage of max (70-80% of maximal heart rate) as compared to the present study (Sandvei et al., 2012). Additionally, past research in SIT are in agreement with our finding in which there was no significant difference in VO_{2max} (L/min and mL/kg/min) between MIT and RSIT groups after 8weeks of training (Lunt et al., 2014; Macpherson et al., 2010; Sijie et al., 2012). However, the past research involved healthy recreationally active men and women (Macpherson et al., 2010), sedentary overweight adults (Lunt et al., 2014), and female university students (Sijie et al., 2012) that lasted for 6-weeks (Macpherson et al., 2010) or 12-weeks (Lunt et al., 2014; Sijie et al., 2012) and differed in training protocols.

Body composition measures (including body weight, lean muscle, percent body fat, and BMI) were not significantly different between the MIT and RSIT groups after an 8-week intervention in the present study. These findings are similar to the findings of Macpherson et al. (2010) in which there was no significant difference in fat mass or lean muscle mass in an RSIT and endurance training group after a 6-week intervention. However, in the present study there was a significant decrease in body weight, percent body fat, and BMI and a significant increase in lean mass from baseline to 8-weeks in only the MIT group. Contradictory to the present findings, 20 recreationally active women who participated in six weeks of RSIT significantly decreased body mass and fat mass as well as significantly improved fat free mass. However, although a small period of time, 2-weeks of HIT in individuals with T2DM had no effect on body mass (Little et al., 2011). Furthermore, Macpherson et al. (2010) found that decreases in fat mass in the RSIT group were due to changes in men while decreases in fat mass in the endurance training group was due to decreases in both genders. Therefore, it is possible that because only one male completed the RSIT protocol in the present study, significant changes in body composition were not seen within that respective group.

 VO_{2max} (mL/kg/min) was correlated to several body composition measures at baseline and 8-weeks. A lower VO_{2max} was associated with a greater body weight, body fat percentage, and BMI. Additionally, a low VO_{2max} was correlated to a low lean body mass percentage. The aforementioned correlations have been supported in past research (Boreham, 2000; Carrick-Ranson, 2012; Venkata, 2004). In prediabetics, improvements in body composition measures through a training intervention can be expected to improve VO_{2max} .

The final secondary outcome of the present study was HbA1c. There was no significant difference between or within groups for HbA1c. In a study comparing HIIT to MIT in individuals with T2DM, after 12-weeks of training there was no significant difference in HbA1c between groups (Terada et al., 2013). In the present study there was a trend (p=0.089) from baseline to 8-weeks towards a reduction of HbA1c in the MIT group. A 12-week study of individuals with T2DM showed that 30-minutes a day of moderate intensity Wii Fit Plus causes a significant reduction in HbA1c. As HbA1c is a two to three month average of plasma glucose, 8-weeks may not have been long enough to see the effects of exercise and report a significant change.

There were a few limitations to the present study, the primary limitation being the small sample size. One of the major issues found was individual's lack of knowing their

fasting blood glucose or HbA1c. Additionally, many individuals did not have primary care physicians and so having the physician approval form filled out was a barrier to many. A second limitation includes the few number of men enrolled in the study compared to females. Teraslinna et al. (1969) found that men lose motivation to participate in an exercise program at the age when many coronary heart disease risk factors develop, roughly age 50. It is possible that the diagnosis of prediabetes resulted in some men to lose motivation to join the present study instead of join as expected. A final limitation of the present study is the use of a treadmill. Many participants complained of knee, shin, and joint pain as a result of the treadmill. The researcher's manipulated speed and grade to help offset pain, however obesity and sedentary behavior can result in injury when beginning an exercise program at moderate intensity (Ehlen et al., 2010). Additionally, many participants had not used a treadmill before and so the first few weeks were an adjustment period to improve comfort on the treadmill as many participants would hold onto the sides or go at a slower speed due to fear. Thus, the use of a treadmill to reduce barriers to exercise may have unintentionally become a barrier to exercise and physiological changes.

Future research is important to determine the physiological and psychological effects, as well as feasibility of sprint interval training in individuals with prediabetes. Additionally, cycle ergometer sprint interval training should be compared to RSIT to determine if one mode is perceived as more enjoyable and is associated with lower injury rates. Future research should also be conducted to determine the different physiological effects of RSIT along the fasting plasma glucose or HbA1c continuum as results may differ between individuals considered normal, prediabetic, or in those with T2DM.

In conclusion, the present study was designed to determine differences in sedentary, prediabetic adults in perceived enjoyment, exercise adherence, and HRQOL between a RSIT and MIT protocol over 8-weeks. The practical implication of there being no significant difference between groups in perceived enjoyment, exercise adherence, or HRQOL shows participants can choose their exercise preference. Although more research is needed, preliminary findings show that RSIT may be better for improving fitness and MIT may be better for improving body composition measures.

	RSIT (n=7)	MIT (n=8)
Age (yrs)	42.70 ± 19.92	48.87 ± 14.95
Height (cm)	64.66 ± 2.28	64.00 ± 3.32
Weight (lbs)	220.23 ± 69.67	236.00 ± 74.19
BMI (kg/m^2)	36.76 ± 9.79	40.59 ± 12.49
VO _{2max} (mL/kg/min)	24.27 ± 7.14	23.93 ± 7.55
Fasting Glucose (mg/dL)	93.71 ± 10.22	105.87 ± 16.08
HbA1c (%) *	5.54 ± 0.25	5.91 ± 0.26

Table 1- Baseline Characteristics of Prediabetics in Exercise Intervention Groups

Data are presented as mean ± SD. *Significant differences (p<0.05) between groups.

Measure		Baseline	8-Weeks		
	Weight (lbs)	220.23 ± 69.67	216.28 ± 69.64		
	BMI (kg/m ²)	36.76 ± 9.79	35.70 ± 9.50		
	% Body Fat	47.07 ± 9.66	46.23 ± 9.61		
	% Lean Mass	52.77 ± 9.39	53.77 ± 9.61		
RSIT	Waist:Hip	0.90 ± 0.11	0.89 ± 0.13		
	VO _{2max} (mL/kg/min)	24.27 ± 7.14	$26.11 \pm 6.74^*$		
	VO _{2max} (L/min)	2.29 ± 0.50	2.40 ± 0.67		
	Fasting Glucose	93.71 ± 10.22	94.29 ± 5.15		
	HbA1c	5.54 ± 0.25	5.34 ± 0.55		
	Weight (lbs)	236.00 ± 74.19	$226.65 \pm 73.02*$		
	BMI (kg/m^2)	40.59 ± 12.49	39.37 ± 12.45*		
	% Body Fat	47.31 ± 8.93	45.30 ±10.22*		
	% Lean Mass	52.67 ± 8.95	54.73 ± 10.22*		
MIT	Waist:Hip	0.94 ± 0.10	0.94 ± 0.07		
	VO _{2max} (mL/kg/min)	23.93 ± 7.55	25.83 ± 9.65		
	VO _{2max} (L/min)	2.44 ± 0.65	2.50 ± 0.77		
	Fasting Glucose	105.87 ± 16.08	103.63 ± 14.83		
	HbA1c	5.91 ± 0.26	5.75 ± 0.39		

Table 2- Physiological Measures at Baseline and 8-Weeks for RSIT and MIT groups

Data are presented as mean \pm SD. *Significant (p<0.05) from baseline to 8-weeks.

		VO _{2max} (mL/kg/min)	VO _{2max} (L/min)	Body Fat %	Lean Mass %	BMI (kg/m ²)	8-Week Adherence
	Physical Unhealthy Days	r = -0.36 p=0.211	r = 0.05 p = 0.879	r = 0.30 p = 0.298	r = -0.33 p = 0.245	r = 0.52 p = 0.051	r = -0.29 p = 0.322
All Participants	Mental Unhealthy Days	r = 0.02 p=0.938	r = -0.06 p = 0.846	r = -0.03 p = 0.913	r = 0.01 p = 0.972	r = 0.18 p = 0.524	r = -0.66* p = 0.007
	Negatively Effected Usual Activity Days	r = 0.01 p = 0.963	r = -0.27 p = 0.338	r = -0.034 p = 0.904	r = -0.04 p = 0.902	r = 0.05 p = 0.867	r = -0.62* p = 0.014
RSIT	Physical Unhealthy Days	r = 0.16 p=0.736	r = 0.51 p = 0.240	r = -0.20 p = 0.672	r = 0.02 p = 0.967	r = 0.39 p = 0.382	r = 0.33 p = 0.465
	Mental Unhealthy Days	r = 0.87* p = 0.010	r = 0.38 p = 0.398	r = -0.71 p = 0.074	r = 0.67 p = 0.098	r = -0.33 p = 0.474	r = -0.40 p = 0.369
	Negatively Effected Usual Activity Days	r = 0.90* p = 0.006	r = 0.36 p = 0.434	r = -0.75 p = 0.053	r = 0.69 p = 0.085	r = -0.43 p = 0.335	r = -0.60 p = 0.151
MIT	Physical Unhealthy Days	r = -0.69 p = 0.083	r = -0.31 p = 0.501	r = 0.55 p = 0.206	r = -0.55 p = 0.206	r = 0.69 p = 0.083	r = -0.39 p = 0.388
	Mental Unhealthy Days	r = -0.58 p = 0.131	r = -0.40 p = 0.332	r = 0.55 p = 0.115	r = -0.55 p = 0.155	r = 0.57 p = 0.142	r = -0.88* p =0.004
	Negatively Effected Usual Activity Days	r = -0.56 p = 0.151	r = -0.81* p = 0.014	r = 0.52 p = 0.190	r = -0.52 p = 0.190	r = 0.42 p = 0.302	r = -0.62 p = 0.099

Table 3 – The Correlation Between Baseline HRQOL Unhealthy Days and Fitness, Body Composition, and Adherence in Physician Diagnosed Prediabetics

*Significant (p<0.05) from baseline to 8-weeks.

		VO _{2max} (mL/kg/min)	VO _{2max} (L/min)	Body Fat %	Lean Mass %	BMI (kg/m ²)	8-Week Adherence
All Participants	Physical Unhealthy Days	r = -0.52* p = 0.047	r = -0.15 p = 0.606	r = 0.43 p = 0.114	r = -0.43 p = 0.114	r = 0.46 p = 0.083	r = -0.15 p = 0.594
	Mental Unhealthy Days	r = -0.27 p = 0.359	r = -0.25 p = 0.395	r = 0.03 p = 0.933	r = -0.03 p = 0.933	r = 0.17 p = 0.569	r = -0.68* p = 0.008
	Negatively Effected Usual Activity Days	r = -0.45 p = 0.105	r = -0.13 p = 0.662	r = 0.25 p = 0.391	r = -0.25 p = 0.391	r = 0.38 p = 0.177	r = -0.12 p = 0.692
RSIT	Physical Unhealthy Days	r = 0.06 p = 0.908	r = 0.62 p = 0.139	r = -0.06 p = 0.908	r = 0.06 p = 0.908	r = 0.47 p = 0.284	r = -0.29 p = 0.530
	Mental Unhealthy Days	r = 0.04 p = 0.937	r = 0.41 p = 0.359	r = -0.08 p = 0.873	r = 0.08 p = 0.873	r = 0.17 p = 0.718	r = -0.75 p = 0.051
	Negatively Effected Usual Activity Days	r = -0.20 p = 0.661	r = 0.61 p = 0.144	r = 0.61 p = 0.144	r = -0.61 p = 0.144	r = 0.61 p = 0.144	r = 0.43 p = 0.333
MIT	Physical Unhealthy Days	r = -0.91* p = 0.002	r = -0.72* p = 0.041	r = 0.95* p = 0.000	r = -0.95* p = 0.000	r = 0.80* p = 0.017	r = -0.24 p = 0.568
	Mental Unhealthy Days	r = -0.51 p = 0.248	r = -0.90* p = 0.006	r = 0.25 p = 0.585	r = -0.25 p = 0.585	r = 0.38 p = 0.403	r = -0.82* p = 0.024
	Negatively Effected Usual Activity Days	r = -0.52 p = 0.227	r = -0.52 p = 0.227	r = 0.08 p = 0.873	r = -0.08 p = 0.873	r = 0.19 p = 0.688	r = -0.60 p = 0.159

Table 4 – The Correlation Between 8-Week HRQOL Unhealthy Days and Fitness, Body Composition, and Adherence in Physician Diagnosed Prediabetics

*Significant (p<0.05) from baseline to 8-weeks.

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Appendix A

CDC HRQOL - 4

Health Related Quality of Life

CDC Healthy Days Core Module (CDC HRQOL – 4) ID # _____

1. Would you say that in general your health is:

- 1. Excellent
- 2. Very Good
- 3. Good
- 4. Fair
- 5. Poor
- 6. Don't know
- 7. Refuse to answer

2. Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?

- 1. Number of Days _____
- 2. None
- 3. Don't know/not sure
- 4. Refused

3. Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?

- 1. Number of Days _____
- 2. None
- 3. Don't know/not sure
- 4. Refused

4. During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?

- 1. Number of Days _____
- 2. None
- 3. Don't know/not sure
- 4. Refused

Appendix B

Physical Activity Enjoyment Scale (PACES)

When I am physically active: Agree a Disagre No e a lot lot opinion ? ? ? ? 1 I enjoy it ? ? ? 2 I feel bored ? ? ? ? ? ? ? ? ? ? ? ? 3 I dislike it ? ? 4 I find it pleasurable ? ? ? ? ? ? ? (same as 1) Agree a Disagre No e a lot opinion lot ? ? ? ? ? 5 It's no fun at all ? ? ? ? ? ? ? 6 It gives me energy ? ? ? ? ? ? ? 7 It makes me sad ? ? ? ? ? 8 It's very ? ? ? ? pleasant/fun Agree a Disagre No e a lot opinion lot

The Physical Activity Enjoyment Scale

Name _____ ID # ____ Date _/_/_

9	My body feels good	2	2	2	2	2	2	2
10	I get something out of it	?	?	2	?	2	2	2
11	It's very exciting	2	2	2	2	2	2	?
12	It frustrates me	2	2	2	2	?	2	?
		Disagre e a lot			No opinion			Agree a lot
13	It's not at all interesting	2	2	2	2	2	?	2
14	It gives me a strong feeling of success	2	2	2	2	2	2	2
15	It feels good	2	2	2	?	2	?	?
16	I feel as though I would rather be doing something else	2	2	2	2	2	2	2

Appendix C

Informed Consent

James Madison University Departments of Kinesiology and Health Sciences Consent for Investigative Procedure (Informed Consent)

You are being asked to participate in a research study conducted by Drs. Elizabeth Edwards, Jeremy Akers, Trent Hargens, David Wenos, and graduate students Katie Hilovsky, Jo Mandelson, and Nicole Gilbertson from the Departments of Kinesiology and Health Sciences at James Madison University. The purpose of this study is to determine the effect of low volume, high intensity training on physical fitness, physical activity enjoyment, and physical activity adherence, along with factors known to increase risk for chronic disease (blood lipids, etc.) by conducting an experimental study in a cohort of prediabetic men and women.

Research Procedures. The study will consist of a 16-week supervised exercise program. The research study will consist of three groups. Each participant will be randomized to a control, low volume, high intensity training, or moderate intensity training group. Prior to beginning the study, at the mid-point of the study (8 weeks), upon completion of the study (16 weeks), and at three-month and six-month follow-up, you will complete various supervised tests and questionnaires to measure the physical fitness, health status, lifestyle behaviors, body composition, blood lipids, insulin, and blood glucose levels.

Note: In the event you discover that any of the following information is not clear, please ask one of the researchers to explain immediately.

Blood Pressure. Blood pressure measurements will be taken using a sphygmomanometer and stethoscope. A blood pressure cuff will be placed over the upper portion of your right arm, slightly above the elbow. The cuff will be inflated to approximately 200mmHg and then slowly released, while a researcher uses a stethoscope to listen to sounds of blood flow through the vein on this inside of your elbow.

Blood Draws. A fasted (8-10 hour) blood sample will be obtained by a butterfly needle in a vein in your mid arm. All blood draws will be taken from Sentara Rockingham Memorial Hospital (SRMH). In order to minimize the transfer of blood-borne pathogens, the trained person taking your blood will wear latex gloves at all times during blood sampling and testing. All values will be sent to researchers in a sealed envelope. Per SRMH protocol you will be required to provide a medical provider's information at each blood draw session. If blood values are outside normal/optimal ranges the blood values will be sent to your primary medical provider. For each blood draw, we will be measuring several different substances in the blood related to health and disease risk.

Preparation for Blood Draw. You will be asked to fast for 8-10 hours before the session. This includes coffee, tea, alcohol, or tobacco products.

Body Composition and Bone Mineral Density. Your height and weight will be measured and used to calculate body mass index BMI (kg/m²). Additionally, the size of your waist and hips will be measured with a cloth tape measure. Your waist measurement is important in determining your risk for cardiovascular disease and diabetes. Dual-energy x-ray absorptiometry (DXA) will be used to estimate body composition data and bone mineral density through the whole body

scan. For the DXA scan, you'll be asked to lie on your back and remain still for the whole scan; the scan will last approximately 6-10 minutes.

Maximal Exercise Test. The purpose of the maximal graded exercise test, also known as the VO₂max test, is to measure cardiorespiratory fitness. Cardiorespiratory fitness is the ability to engage in dynamic moderate- to high-intensity exercise for a prolonged period of time. Cardiorespiratory fitness is an important consideration when health risks and overall exercise capability are assessed. High levels of cardiorespiratory fitness are correlated with reduced risk coronary artery disease.

Preparation for Exercise Testing. Prior to exercise testing, we will ask you to not <u>eat</u> or <u>drink</u> anything, except water for three hours prior to the test. Please note that this includes caffeinated beverages – such as coffee or tea! Use of tobacco products should be avoided at least three hours prior to testing as well. Please avoid heavy exercise on the testing day. Try to get to get at least six hours of sleep the night before, to ensure that you are well rested. Wear clothing that is comfortable and allows you to move freely, such as shorts, a t-shirt, and comfortable running shoes. Be aware that the test is fatiguing, so you may wish to be fully hydrated before the test.

Procedure for Exercise Testing. Resting heart rate and blood pressure will be taken prior to testing. The treadmill test follows a predetermined protocol to obtain a maximal oxygen uptake. You will run on a treadmill, with the speed and/or grade increasing as the test progresses, until you're working as hard as you can. You will be fitted with a heart rate monitor chest strap and a pulmonary facemask. Nonverbal cues will be used to communicate during the test. Hand signals include "yes," "no," and/or "stop the test." It is important to realize that you may stop the test when you wish because of feelings of fatigue or any other discomfort. Additionally, we may stop the test at any time due to signs of fatigue or abnormal physiological responses. These may include failure for heart rate increase with increased workload, dizziness, chest pains, or muscular fatigue. Please note that both protocols and procedures are in adherence with the guidelines set forth by the American College of Sports Medicine for exercise testing.

You will be permitted to leave once post exercise heart rate drops below 100 beats per minute or resting heart rate levels. Avoid a hot shower and a heavy meal for at least an hour after the exercise test.

At-Home Sleep Assessment: The at-home sleep assessment will be utilized to screen for possible obstructive sleep apnea (OSA), a frequent co-morbid condition with diabetes, and a condition that may confound data analysis without accounting for. Research staff will instruct the you on the proper setup and use of the ApneaLink[™] at-home screening device. The ApneaLink device is composed of a pulse oximeter, which is worn on the end of an index finger, and a nasal cannula, which is worn over the face, and into the nose to measure airflow. The ApneaLink device is harmless and painless to wear. You will be wearing this device one night while you sleep only at the beginning of the study.

Heart rate variability (HRV): HRV will be utilized to assess autonomic function, which is another proposed mechanism linking obstructive sleep apnea and cardio vascular disease. You will be asked to complete a resting HRV and heart rate measurement using a monitor that is strapped

on your chest. You will be asked to lie flat on your back in a darkened room, while heart rate and HRV are measured over a 15 minute time period. You will be asked to breathe in rhythm with an instrument that is set at 12 beats per minute, thus representing 12 breaths per minute which is considered to be the average respiration rate for a healthy adult.

Health Status. Your health status will be determined via questionnaires and ACSM's Risk Stratification for Cardiovascular Disease Risk (ACSM, 2010). Assessment of your risk for cardiovascular disease will be made using the ACSM's Coronary Artery Disease Risk Factor Thresholds along with the ACSM Risk Stratification. Risk stratification is based upon age, family history, smoking habits, blood lipid levels, and fasted blood glucose values, resting blood pressure, body mass index and physical activity habits. We will also be asking about current and previous conditions, surgeries, and medications, so that we may ensure that you are healthy enough to participate in this study.

Lifestyle Behaviors

You will be asked to complete the following questionnaires: a. *Exercise Behavior* – The International Physical Activity Questionnaire (IPAQ) estimates how

much activity you have participated in over the previous seven days. It will ask about your physical activity as part of your daily life, including work, as well as leisure time activity.

b. *Perceived Enjoyment* – The Physical Activity Enjoyment Scale (PACES) asks you about your perceptions and feelings about physical activity.

c. *Dietary Behavior* –A 3-day dietary record, where you will record what you consumed for 3 nonconsecutive days.

d. Sleepiness- The Epworth Sleepiness Scale is a measure of a person's general level of daytime sleepiness, or their average sleep propensity in daily life.

f. *Health Related Quality of Life-* The Health Related Quality of Life Scale is a measure of a person's physical and mental health and function.

Time Required. If you are randomized to the training group then you will be asked to commit to up to three hours per week, for sixteen weeks for the training segment of this project. Additionally, you will be asked to commit to ten testing and informational sessions that will each last up to two hours. Testing and training will take place as follows:

• Familiarization Session (Pre): This is the familiarization session. During this session, all tests and procedures will be explained, after which we'll ask you to complete the appropriate health and medical status questionnaires and an Informed Consent Form. Additionally, participants will be asked to complete the questionnaires pertaining physical activity levels, health behavior, sleepiness, and perceived enjoyment. This session is estimated to last approximately 1 ½ -2 hours. You will also be given dietary record forms to be completed and returned to the researchers at the next meeting. After this session, future questionnaires will be completed during the clinical testing sessions.

• Clinical Testing (Pre, Mid, Post, 3M FU, 6M FU): In this session we measure your blood pressure and heart rate and complete a dual x-ray absorptiometry (DXA) scan for the assessment of body composition and bone mineral (hip) density. Diet records will also be collected. This session is estimated to last approximately 1 ½ -2 hours: 1 ½ hours for testing, 20 minutes for dietary records. All clinical testing will take place in the Kinesiology Human Performance Lab. For the mid-point, post-training, follow-up sessions, you will also be asked to complete the study questionnaires at this session. This is expected to add approximately 15 minutes to the session.

• Fitness Testing (Pre, Mid, Post, 3M FU, 6M FU): You will be asked to come to complete a maximal exercise test (VO_{2max} test) the same day as your clinical testing. Maximal testing will be completed in the Kinesiology Human Performance Lab.

• Blood Values (Pre, Mid, Post, 3M FU, 6M FU): In this session you will be asked to visit the Sentara RMH Outpatient Center located with the Sentara RMH Occupational Health Center at 1790-64B to have blood taken. Researchers will provide all documentation for you to take to each session. You will be required to fast for 8-10 hours. Please note that per SRMH protocol you will be required to provide a medical provider's information at each blood draw session. If blood values are outside normal/optimal ranges the blood values will be sent to your primary medical provider. This session should last 15 minutes.

• Training Protocol: As the main portion of the study, you will participate in a training session 3 days per week that will progress from 30 minutes per session, to 60 minutes per session for the next 16 weeks. Your group assignment will determine exactly what these exercise sessions will consist of. In brief, you will either be participating in moderate-intensity training, which consists of a continuous bout of exercise performed at a moderate intensity (moderate intensity is described as a 5 or 6 on a scale of 1 to 10); short high-intensity interval training, which consists of short bouts (30 seconds) of maximal effort exercise followed by longer recovery periods (4 minutes); or a combination of the two, which consists of one day of the continuous moderate intensity training session and two days of the high intensity interval training. You will be asked to come into the Marilyn Crawford Fitness Center (Godwin Hall) to complete all training sessions. Training groups are expected to see improvements in fitness.

Risks. There is minimal risk associated with submaximal exercise testing in individuals who are "low" or "moderate" risk according to guidelines established by the American College of Sports Medicine. There is a minimal level of discomfort that may be experienced during the exercise testing, which includes muscle soreness and fatigue. Muscle soreness may be felt 24-48 hours following the testing.

The risks of venipuncture blood sampling include possible mild bruising and the risk of transfer of blood-borne pathogens. This risk is considered to be minimal and all safety precautions for handing blood samples will be followed according to OSHA protocols and SRMH.

According to the manufacture's specifications (i.e., GE Healthcare), whole body DXA analysis exposes participants to 1.5 mrem of radiation. The exposure to radiation during a single chest x-ray (i.e., 5 mrem) is more than 3 times greater than radiation from DXA. Also, background

radiation from DXA is about equal to the amount of radiation one experiences during a flight from New York to London. Please note that the effects of the DXA scan are cumulative depending on your prior exposure to radiation. If you have questions regarding your risk from the scan please consult with the researchers.

Benefits. Potential benefits from participation in this study include free testing of cardiorespiratory fitness, body composition, lipid profile, and bone mineral density. You will receive the results from your individual tests, including a rating of how you compare to individuals within your age category. Along with these results, you'll receive information regarding the importance and meaning of measure, as well as what steps you could take to improve these measures if you would like to. You will also have the opportunity to learn about habitual dietary intake and your percentages of energy nutrients and total caloric intake. Participation in this study will also help researchers understand metabolic responses and adherence to long-term exercise. Finally, if you complete the study, you'll receive a free dietary consultation.

If you are randomized to the two training groups you will also receive free monitored workout sessions and motivation from the researchers. The researchers expect to see positive metabolic changes for participants in all training protocols that may result in improved health and general well-being.

Confidentiality. All data and results will be kept confidential. You will be assigned an identification code. All of your questionnaires and other results will be filed only according to your identification code, with your full name not located in that file. For the duration of the study, your first name will be stored with this data, so that research staff may address you, but this will be removed at the completion of the study. These results will be stored in a locked cabinet in a locked office. Electronic copies of the data will be password protected and kept only on secure servers. Only research personnel, who may include students, will have access to this data in either hard or electronic format. Any forms that link your name with your identification number, including this form, will be kept in a different file, which will be located in the office of one of the head researchers on this study. Additionally, any electronic formats of this information will be kept by one of the head researchers and will be password protected with a different password than the data. None of your test results or data will be located in this file. Access to these files will be limited to the head researchers on this staff and will only be used for the purposes of matching up your data to previous results and to contact you for the follow-up measures. After the second follow-up measure, any form that links your name to your identification number will be destroyed. The data collected will be analyzed and used to complete three graduate student research theses, a national presentation, and submission for publication in a professional journal.

Participation and Withdrawal. Your participation is entirely voluntary. You are free to choose not to participate. Should you choose to participate, you can withdraw at any time without consequences of any kind. If at any time you choose to withdraw from the study, any identifying information that links your name to your data will be destroyed at that time.

Reporting Procedures. You will be provided health and fitness tests data at the completion of each test and will receive the results of your blood tests after they have been processed. The

findings of the study will be presented at regional and national organizations conferences and submitted for publication in professional journals.

Questions about the Study. If you have questions or concerns during the time of your participation in this study, or after its completion or you would like to receive a copy of the final aggregate results of this study, please contact:

Dr. Elizabeth Skidmore Edwards Department of Kinesiology James Madison University <u>edwardes@jmu.edu</u> <u>mailto:edwardes@jmu.edu</u> 540-568-5220 Dr. Jeremy D. Akers, PhD Department of health Sciences James Madison University <u>akersid@jmu.edu</u>

540-568-8974

Questions about Your Rights as a Research Subject

Dr. David Cockley Chair, Institutional Review Board James Madison University (540) 568-2834 <u>cocklede@jmu.edumailto:cocklede@jmu.edu</u> mailto:cocklede@jmu.edu

Giving of Consent

I have read this consent form and I understand what is being requested of me as a participant in this study. I freely consent to participate. I have been given satisfactory answers to my questions. The investigator provided me with a copy of this form. I certify that I am at least 18 years of age.

Name of Participant (Printed)	
Name of Participant (Signed)	Date
Name of Researcher (Printed)	
Name of Researcher (Signed)	Date
Demographic Information	
Full Name:	Nickname:
ID# (Research personnel	use)
Address:	
Preferred phone:Is this your: \Box W	/ork 🗆 Home 🗆 Cell 🗆 Other:
Email address: (Month/ Day/ Year)	Date of Birth:

Optional Additional Consent

I understand that new risk factors are constantly emerging and that further analysis of my blood samples, beyond those tests outlined in this consent form may provide valuable information. I consent to having my blood samples stored indefinitely, so that they may be used in future analyses. If my blood is used in these tests and yields information that would be pertinent to my health, the research team will attempt to contact me to give me these results.

Name of Participant (Printed)

Name of Participant (Signed)

Date

Name of Researcher (Printed)

Name of Researcher (Signed)

Date

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