A Translational Study Determining the Impact of Timing and Duration of Aerobic Walking on Metabolic Control and Personal Preferences Among Adults Recently Diagnosed with Type 2 Diabetes

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To the Dean of the Graduate School:

We are submitting a thesis written by Cory Cox entitled A TRANSLATIONAL STUDY DETERMINING THE IMPACT OF TIMING AND DURATION OF AEROBIC WALKING ON METABOLIC CONTROL AND PERSONAL PREFERENCES AMONG ADULTS RECENTLY DIAGNOSED WITH TYPE 2 DIABETES.

We recommend acceptance in partial fulfillment of the requirements for the degree of Master of Science in Sport and Fitness Administration through the Richard W. Riley College of Education.
A TRANSLATIONAL STUDY DETERMINING THE IMPACT OF TIMING AND
DURATION OF AEROBIC WALKING ON METABOLIC CONTROL AND
PERSONAL PREFERENCES AMONG ADULTS RECENTLY DIAGNOSED WITH
TYPE 2 DIABETES

A Thesis
Presented to the Faculty
Of the
Richard W. Riley College of Education
In Partial Fulfillment
Of the
Requirements for the Degree
Of
Master of Science
In Sport and Fitness Administration
Winthrop University

May, 2015

By

Cory Cox
Abstract

Type 2 diabetes (T2D) is a potentially life threatening metabolic disease characterized by insulin resistance and inability to metabolize glucose (Meneilly & Elliott 1999). According to the American Diabetes Association (ADA, 2013), diabetes played a contributing role in 231,404 deaths in 2007 alone. Because of this, researchers strive to develop the best methods of managing diabetes. Physical activity has been shown to improve glucose control by reducing insulin resistance and reducing body fat (Bacchi et al., 2012). Recent data from DiPietro et al. (2013) indicated that multiple bouts of exercise may be favorable over one continuous bout in managing blood glucose. In this pilot study three adults recently diagnosed with T2D, were asked to perform three testing conditions in random order. The control condition consisted of the subjects remaining sedentary over the testing days. The 15-minute testing condition consisted of the subjects aerobically walking for a period of three 15-minute bouts 30 minutes after each meal. Finally, subjects also walked in one 45-minute continuous bout at least 2 hours after their most recent meal. The results of this pilot study indicated that three 15-minute bouts may be more favorable for blood glucose control and be a more acceptable walking protocol for all subjects. Benefits from increased physical activity were seen immediately and were shown to be cumulative in 66% of tests. Aerobic exercise was shown to reduce postprandial (post-meal) insulin levels in 100% of subjects; the effect was shown to be 66% more effective if done in three 15-minute bouts 30 minutes after each meal when compared to a single 45-minute bout of exercise.
Dedication

To my family and friends, especially my loving fiancée Emily:

You have always provided extraordinary guidance and encouragement during all my endeavors. I appreciate your love, support, and patience more than you will ever know.

Thank you.
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I would like to thank my graduate thesis committee, Dr. Janet Wojcik, Dr. Charles Bowers, and Dr. Joni Marr for dedicating their time and expertise to this thesis project. I am extremely grateful for the guidance and patience you all displayed.

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Chapter 1

Introduction

Type 2 diabetes (T2D) is a potentially life threatening metabolic disease characterized by insulin resistance (Meneilly & Elliott 1999). As a result, the body is unable to breakdown glucose, the main fuel source for the body. According to the American Diabetes Association (ADA, 2013), diabetes played a contributing role in 231,404 deaths in 2007 alone. Because of this, researchers strive to develop the best methods of managing diabetes. Aerobic and resistance training have been used to help manage T2D. Physical activity is extremely important in the prevention and treatment of T2D. Physical activity has been shown to improve glucose control by reducing insulin resistance and reducing body fat (Bacchi et al., 2012). Benefits from increased physical activity are seen immediately and are cumulative. Aerobic exercise can be used to reduce postprandial insulin levels, if done during a sustained bout of exercise or broken up into multiple bouts as demonstrated by DiPietro, Gribok, Stevens, Hamm, Rumpler (2013). Because the effect of exercise is cumulative, people who are obese and who cannot walk for 45 minutes at one time can take several small walks throughout the day to achieve the same or better results.

Aerobic exercise has two beneficial properties for people with T2D. The first benefit is that it temporarily reduces insulin resistance, and second it lowers blood glucose (BG) in the absence of effective insulin action. Therefore, aerobic exercise has the potential of being a powerful “medicine” in the self-treatment by those with T2D. The
biggest barrier to the use of aerobic exercise in the management of T2D is compliance. Consequently, it is important to be able to identify the minimal, most palatable and most effective “dose” of this intervention to optimize its routine use. The purpose of this study was to determine the best application of aerobic exercise for the treatment of T2D. The goal was to find out if prolonged exercise is just as effective as intermittent bouts and which is more enjoyable for the participant. Will one method be more likely to be conducted by the subject after the experiment is over?

**Statement of the Problem**

It is clear that aerobic exercise is essential for individuals with T2D. The World Health Organization (WHO, 2013) recommends that adults participate in 150 minutes of moderate intensity aerobic exercise a week. For people with T2D this can be very intimidating and may lead to anxiety and avoidance. It is important to determine the most effective method of means of implementing aerobic exercise into the lives of people dealing with T2D.

**Significance**

While it was presumed that aerobic walking was reduced BG, the magnitude of this effect among adults with recently diagnosed T2D is not known. To know this, if substantial, could be a significant “selling point” to promote its routine performance. Further, to know if its effected is similar or different when performed in a single block or post-prandially were important to guide clinicians in their recommendations to patients. If post-prandial exercise leads to significantly lower 2-hour post-prandial BG, then
theoretically this would have significant benefit in terms of lowering risk of future cardiovascular disease. However, knowing which format of physical activity led to lower BG is not the same as knowing which was more palatable to patients and which was more likely to be performed. Given that some routine aerobic walking is better than none, regardless of its different benefits, was important for clinicians to consider when prescribing a physical activity program. Being able to lower mean BG, and thus glycosylated hemoglobin in a sustained, safe and satisfying manner has the potential of preventing/diminishing the long-term complications of diabetes and improving the quality of life of these individuals.

**Hypotheses**

The following hypotheses were postulated:

1. Forty-five minutes of brisk walking in the living and working daily environment was more effective than no moderate physical activity in terms of lowering overall BG levels.
2. Compared to a 45-minute block of brisk walking, three 15-minutes of post-prandial brisk walking would result in lower post-prandial BG, a presumed risk factor for cardiovascular disease.
3. The effects of exercise were cumulative, that is there will be a greater BG lowering effect on the second consecutive day of exercise than on the first day.
4. Three 15-minute bouts of brisk walking would be likely to produce consistent adherence in adults with T2D than setting aside a 45-minute block of time for brisk walking.

5. At one-month follow up, participants would routinely perform more post-prandial aerobic walking following their experience in the study and learning how exercise impacts their BG.

Delimitations

Adults diagnosed with T2D within the past 5 years who are not taking medication for the management of their diabetes were recruited from the Charlotte, NC region.

Advertisements in local papers, billboards, websites, and diabetes clinics were invited interested individuals to contact the researcher. All participants tested BG levels with a LifeScan Verio IQ BG meter, and steps for all participants were measured with an Omron pedometer. The LifeScan Verio IQ BG meter was proven reliable is a study conducted by Bellary et al. (2012). Their diabetes physicians gave them medical clearance to participate in the study. Subjects were included in the study if they were:

- Between the ages of 25 and 75
- Diagnosed with T2D within the past five years of the study
- Not taking medication for their diabetes management
- Capable and willing to measure BG 8/day for six experimental days
- Not involved in regular physical activity (i.e., fewer than two 20-min bouts of exercise per week during the previous 6 months).
- Capable of walking 2.7 miles in 45 minutes, i.e.~3.5 miles/hour
• Given approval of their diabetes physician to participate.

Limitations

The study was limited by the following:

1) Researcher could not control for the honesty of the answers provided by participants during the 24-hour dietary recall.

2) Subjects likely walked different courses throughout the day.

3) Courses were not controlled in terms of level of difficulty.

4) Subjects occasionally had difficulty achieving the minimum walking speed needed for aerobic walking at the speed required for the entire 45 minutes.

Definition of Terms

For the purpose of this study, the following terms are operationally defined:

**Aerobic walking.** Walking at a speed of three mph for a period of no less than 10 minutes; as determined by the Centers for Disease Control and Prevention (CDC, 2011).

**Postprandial exercise.** For the purposes of this study, postprandial is operationally defined as exercise conducted after eating a meal (DiPietro, Gribok, Stevens, Hamm, & Rumpler, 2013).

**Palatability.** Palatability is operationally defined as the extent to which one program is preferred over another. Additionally, it alludes to the likelihood that the subject will continue with the program after the study.
Chapter 2

Review of the Related Literature

Introduction

According to TODAY Study Group (2007), T2D is a metabolic disease characterized by insulin resistance. As a result, the body is unable to breakdown glucose, the main fuel source for the body. Traditionally, there have been three methods of treatment for T2D including diet modification, increased physical activity, and insulin therapy. People with T2D should avoid foods that are high in fat and that consist of simple carbohydrates. They should choose foods that are high in fiber and complex carbohydrates such as whole grains, fruits, and vegetables suggests Bogardus et al. (1984). Physical activity has been shown by Boule, Haddad, Kenny, Wells, Sigal (2001) to help with blood glucose control by reducing insulin resistance. Insulin therapy is considered the final step in the treatment of T2D and is only recommended when lifestyle modifications are not adequate in the management of the disease states Swinnen, Hofkstra, & DeVries, (2009). Modest weight loss has also been shown to improve insulin resistance and therefore should be a goal in the management of T2D by Sigal, Kenny, Wasserman and Castaneda-Sceppa (2004).

Effects of Diet on Type 2 Diabetes

Diet modification is the first step in the process of achieving healthy weight loss. Weight loss for persons with T2D is important because it improves insulin sensitivity and can help with glucose control inanition to reducing triglycerides, lower cholesterol and
blood pressure, but when it comes to diabetes the focus is not just on weight loss. A nutritionally balanced diet low in fatty foods and high in complex carbohydrates and fiber make a significant beneficial impact on a person suffering from T2D American Diabetes Association (ADA, 2008).

Weight reduction of 5-10% leads to improvements in serum glucose and insulin levels as well as reducing mortality rates of people with T2D according to Heymsfield et al. (2000). It is important to make sure that healthy diets are maintained. Extreme or crash diets tend to do more harm than good. An effort should be made to consult with a physician or registered dietitian to ensure patients are consuming sufficient calories and nutrients.

**Carbohydrates and Fiber**

Carbohydrates are utilized by the body as the primary fuel source and are essential in a healthy diet. The challenge comes from determining the difference between the healthy carbohydrates and the unhealthy. Simple carbohydrates are found in refined sugar and provide very little nutritional value. They are easily broken down by the body very quickly causing blood glucose levels to rise quickly. Complex carbohydrates are richer in fiber, vitamins and minerals; they are broken down much slower in the body producing a gradual rise in blood glucose (TODAY Study Group, 2007). Counting carbohydrates can be a key strategy in controlling blood glucose levels, 130 grams of carbohydrates are recommended for a typical person every day. No evidence has been shown that a person with diabetes needs to consume less than 130g/day. It is believed to
be beneficial for the carbohydrates ingested be complex in nature. Fiber is important for diabetics because it helps to delay glucose absorption, which helps to control blood sugar levels (Bogardus et al. 1984). A goal for people with T2D should be to ingest the intake goals for the general population of 14g/1000kcals (ADA, 2008).

**Dietary Fat and Cholesterol**

It is suggested by TODAY (2007) that avoiding high fat foods and limiting cholesterol are necessary for a healthy T2D diet. When it comes to dietary fat, it is important to make the distinction between the different types of fat. Delahanty et al. (2012) suggests that Tran’s fats and saturated fats should be avoided, should make up less than 7% of total calories. Dietary fats should consist of mono and polyunsaturated fats, but should not exceed 20-35% of caloric intake according to ADA (2008).

Atherosclerosis is defined by the National Heart Lung and Blood Institute (2011) as the buildup of plaque in the arteries that deliver oxygen rich blood to the heart and other parts of the body. The consumption of large amounts of dietary fats has been shown to increase the likelihood of atherosclerosis in the general population (Weintraub, 2002). In populations of type 2 diabetics there is an increased risk of developing atherosclerotic diseases, including coronary heart disease, peripheral arterial disease, and cerebrovascular disease according to Watson, Peters, and Matson (2003). The effect of exercise on diabetes and other related illnesses is extreme.

**Effect of Exercise on Diabetes**
Physical activity is extremely important in the prevention and treatment of T2D. Physical activity has been shown to improve glucose control by reducing insulin resistance and reducing body fat as is shown in Bacchi et al. (2012). Benefits from increased physical activity are seen immediately and are cumulative. Aerobic exercise can be used to reduce postprandial insulin levels, if done during a sustained bout of exercise or broken up into multiple bouts (DiPietro et al., 2013). Because the effect of exercise is cumulative people, who are extremely obese and could not walk for 45 minutes at one time can take several small walks throughout the day to achieve the same or better results. Physical activity plays an important role in weight management, which is particularly important for people with type 2 diabetes. Increased physical activity leads to greater caloric expenditure resulting in a decrease in body weight when the total caloric expenditure is greater than the caloric consumption (Harvard School of Public Health, 2013).

**Aerobic Exercise in Diabetes**

It is recommended that people with T2D participate in a minimum of 30 minutes of moderate to vigorous physical activity at least five days a week (Colgerg et al., 2010). Aerobic exercise including brisk walking, jogging, biking, and swimming have been shown by Niu, Yuan, and Fu (2010) to reduce insulin resistance and stimulate the breakdown of blood glucose. The benefit to the cumulative effect of aerobic exercise is twofold. It eliminates the excuses that are used to justify not exercising and has been shown to have a greater impact on 24-hour blood glucose concentrations (Hu et al., 1999). When broken up into multiple bouts per day, exercise has more opportunities to
keep up with carbohydrate consumption. Therefore, exercise is more effective when looked at over 24 hours. A onetime bout of prolonged aerobic exercise will result in a greater usage of calories and will increase glucose breakdown and not affect anything ingested after the workout (Maiorana et al., 2001). To get the greatest response from aerobic exercise it should be done at an absolute intensity of three METs according to DiPietro et al. (2013). Depending on how deconditioned the individual any increase in physical activity will be beneficial.

**Combined Resistance and Aerobic Exercise in Diabetes**

Enhanced glucose uptake has been shown in T2D populations after implementing a combined program consisting of aerobic and resistance training (Zacker, 2005). Higher physical activity levels seen in combination programs lead to a reduced risk of developing T2D as well as an increase beneficial response according to Eizadi, Bagheri, Kasparast, Zahedmanesh, and Afsharmand (2012). Resistance training has similar effects on populations with T2D in that it improves insulin sensitivity and reduces abdominal fat, which impairs glucose uptake (Bacchi et al. 2012). Resistance training is most effective when conducted three times a week on nonconsecutive days at an intensity of 75-80% of 1-RM according to Colgerg et al. (2010). Greater weight loss is seen with a combination of aerobic and resistance training than is seen with either mode individually; this is important because increased weight loss aids in glucose homeostasis likely do to improvement in adipocyte-secreted cytokines (Cuff et al., 2003).

**Conclusion**
The first two steps that should be taken in the treatment of T2D are improved diet and increased physical activity. Proper nutrition has been shown to aid in weight loss, which improves insulin sensitivity. In addition to weight loss, a proper diet means that people with diabetes are getting the right amount of complex carbs and high fiber foods while avoiding high fat foods (Delahaty et al., 2012), all of which will aid in blood glucose homeostasis. However, diet alone can only do so much. For the most effective and longest lasting results, diet needs to be paired with increased physical activity as shown by Bogardus et al. (1984). Exercise is known to reduce insulin resistance and aid in weight loss leading to countless benefits (Boule et al., 2001). It is important to note that the positive effects of diet and exercise only last as long as the modifications are maintained, and, so, the emphasis should be put on lifestyle modification rather than quick fixes.

Diet modifications should be considered a first step for the diabetic population. The interesting question is how does physical activity fits in to the treatment of T2D. Increased physical activity levels have been shown and are commonly known to be beneficial to all populations including and especially diabetic populations (Colgerg et al., 2010). Should persons “suffering” from T2D participate in aerobic exercise, resistance training or a combination of both? In a perfect world, every one with T2D would exercise at least 30 minutes at a moderate to vigorous intensity every day of the week and alternate between aerobic exercise and resistance training, but it is important to consider the population. Typically, individuals diagnosed with T2D are overweight, sedentary individuals with a very poor diet. As a result, the individual may be inclined to only
consider insulin therapy as a means of treating the T2D, because insulin therapy does not require an immediate and complete lifestyle change. Diet modification alone will be a huge transition for individuals initially, and the idea of that combined with suddenly jumping into a level of physical activity they have not experienced in years will seem like a daunting task.

Patients with T2D should be progressed gradually into lifestyle modifications, starting with improved diet. It is important to start physical activity as soon as possible, but it will be important to determine the most palatable approach to the individual. Aerobic exercise while intimidating to some is far less so than going into a gym and picking up a barbell. Aerobic exercise can be done anywhere at any time and has the added benefit of having cumulative effects in the body as is shown in the study conducted by DiPietro et al. (2013), because of this it should be the first form of activity added in the treatment of T2D.
Chapter 3

Methods and Procedures

Introduction

A recent hospital-based study DiPietro et al. (2013) demonstrated that 45 minutes of aerobic walking, whether done in three 15 minutes bouts after meals or in a single dose, similarly and significantly lowered 24-hour blood glucose (BG) among adults at-risk for developing type 2 diabetes (T2D). Exercise performed after meals, however, led to significantly lower post-prandial BG, a risk factor for cardiovascular disease. The reported pilot study replicated and extended this investigation to: 1) adults with T2D, 2) during their daily routine, 3) while documenting personal preference for and performance of the two types of physical activity. This involved a cross-over design where three subjects recently diagnosed with T2D collected 7-point self-monitoring of blood glucose (SMBG) readings during two consecutive days when engaging in no aerobic walking, 15 minutes of such walking after the three daily meals or a single 45 minute dose of walking after supper, in a randomized order while controlling for net carbohydrates consumed. Findings from this pilot study have the potential of immediately and significantly impacting the lives of those with T2D and those caring for patients with T2D.

Subjects

Three adults diagnosed with T2D within the past five years, who were not taking medication for the management of their diabetes, were recruited from the Charlotte NC region. Advertisements in local fitness centers, websites, and diabetes clinics invited
interested parties to contact the researcher. As an incentive for participation, all participants received a sophisticated pedometer (Omron Hj-323U), a LifeScan Verio IQ BG meter Milpitas, CA), and information about how brisk walking impacts their BG for completion of all data. Their diabetes physicians were required to give them medical clearance to participate in the study. Subjects were included in the study if they were (Appendix D):

- Between the ages of 25 and 75.
- Diagnosed with T2D within the past five years.
- Not currently taking medication for their diabetes management.
- Capable and willing to measure BG 8/day for six experimental days.
- Not involved in regular physical activity (i.e., fewer than two 20-min bouts of exercise per week during the previous 6 months).
- Capable of walking 2.7 miles in 45 minutes, i.e. ~3.5 miles/hour.
- Given approval of their diabetes physician to participate.

**Hypotheses.** This study investigated:

1. If 45 minutes of brisk walking in the natural environment was more effective than no moderate physical activity in terms of lowering 24 hour BG levels, a risk factor for diabetic complications.

2. Compared to a 45-minute block of brisk walking, three 15-minutes of post-prandial brisk walking resulted in lower post-prandial BG, a presumed risk factor for cardiovascular disease.
3. The effects of exercise was cumulative, in that is there was a greater BG lowering effect on the second consecutive day of exercise than on the first day.

4. Three 15-minute bouts of brisk walking are more palatable to adults with T2D than setting aside a 45-minute block of time for brisk walking.

5. At one-month follow up participants routinely performed more post-prandial aerobic walking, rather than blocks of 45 minutes of brisk walking, following their experience in the study and learning how exercise impacts their BG.

Overview

While wearing a sophisticated pedometer for 96 hours (Omron, HJ-323U) monitoring BG 8/day and performing a 48-hour recall of all foods eaten on test days for nutritional analyses. Three adults not taking medication in the management of their T2D were block randomized to perform no aerobic walking, 15 minutes of aerobic walking starting 30 minutes after completing all three meals, or 45 minutes of aerobic walking in a single block of time. Each condition was separated by one week. One month following completion of this study, participants were telephoned and queried as to which activity they prefer and how many times in the previous seven days, they either took a 45-minute aerobic walk or walked for 15 minutes post-prandial. While controlling for net carbohydrates consumed and aerobic steps taken, the three conditions were compared in terms of post-prandial BG spikes and overall BG.

Procedure
After the study received IRB approval (Appendix A), subject recruitment began. Interested parties were telephoned, informed of the study requirements, and were screened for inclusion criteria, Telephone Screening Interview. Qualified and interested individuals came to the convenient meeting place. At that consent session meeting, participants read, reviewed and signed an IRB-approved informed consent form (Appendix B). Participants were then taught how to accurately use the LifeScan Verio IQ BG meter, how to wear the Omron pedometer, and how to complete a data sheet which included BG levels and food and drink consumed as seen in appendix G. In addition, they were instructed on what constitutes a brisk/aerobic walk, walking 3.5 mph as determined by the Centers for Disease Control and prevention (CDC, 2011). This was reinforced in three ways. First, they walked on a Woodway Desmo-s treadmill (Waukesha, WI) at 3.5 miles/hour to give them the experience of what constitutes a “brisk walk”. Second, they walked a mile at this rate. If they were unable to walk a mile in 20 minutes, they were excluded from the study. Third, the pedometer provided a readout of number of aerobic steps and aerobic steps/minute. Finally, participants completed the “Typical” Test Day form, which allowed them to identify the optimal days to execute the study given their schedule. Participants left the Consent Session with all forms and equipment necessary to complete the study.
| Variable | Day 1 & 2 | | | | Day 3 | | | | Day 4 | | |
|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| CI       | Consistent | > 4.500 | Consistent | > 4.500 | Consistent | > 4.500 | Consistent | > 4.500 |
| AS       | < 100     | < 6,000  | < 100     | < 6,000  | < 100     | < 6,000  | < 100     | < 6,000  |
| TS       | Consistent | > 6,000  | Consistent | > 6,000  | Consistent | > 6,000  | Consistent | > 6,000  |

Note. CI = Carbohydrate Intake; AS = Aerobic Steps; TS = Total Steps.

Experimental Design

Table 1
**Testing Days.** Each condition spanned a 4-day period. The first two days only involved wearing the pedometer, to ensure that there was no significant physical activity, since aerobic activity can impact metabolism and insulin resistance for up to 48 hours (Zacker, 2005). If the pedometer readings exceeded the maximum of 6,000 steps or 100 aerobic steps, days one and two were repeated. Experimental data were collected during days three and four, allowing researchers to document whether there was a cumulative effect of physical activity (Hypothesis 3). Participants measured their BG twice on seven occasions: immediately before and two hours after three meals and again at bedtime. If the two BG readings were not within 10 points of one another, participants took a third reading, and the two closest readings were averaged. This addressed measurement error of the BG meter. Additionally, participants recorded all food and drinks consumed that day. Participants wore their pedometer from the time they woke up until they went to bed. At the end of each day they recorded total steps, aerobic steps and steps/minute in the data sheet provided (Appendix H).

**Testing conditions.** There were three test conditions during days three and four: Control, 15-minute Post-Prandial and 45-minute Block. In all three conditions, participants were asked to keep their diet consistent and keep a food diary (see Data Sheet, Appendix H). The only restriction was that no food or sugary drinks could be consumed after the meal and before the two-hour post-prandial BG recording. At the end of the study participants’ pedometers and BG meters were downloaded, and these data were used to validate/correct data recorded on the Data Sheets.
During the Control condition participants were asked to keep their number of steps < 6,000 a day and their aerobic steps to < 100 a day, as quantified by the Omron pedometer. BG data were collected starting pre-breakfast on day three and end at bedtime day four.

During the 15-minute Post-Prandial and the 45-minute Block conditions, participants were instructed to keep their steps to >9,000/day which includes >4,500 aerobic steps. This was achieved in the Post-Prandial condition by walking for a continuous 15 minutes briskly, starting 30 minutes after completing each meal, when absorption of glucose into the small intestine is anticipated to begin.

For the Block condition, participants began their aerobic steps > two hours after starting their evening meal of day two so this impacted BG readings during day three. The evening walk during day three should impact BG during day four. Thus, BG recordings began at bedtime on day two and conclude two hours post dinner on day four. See Figure 1. The Post-Prandial and the Block walking courses were not be the same, since the Block course was not available following each meal.

Participants wrote down all food and drinks consumed during day three and four (see Data Sheet). Within 24 hours following day three, the researcher called the participant and coded all food eaten and drinks consumed during day 3 and 4 for nutritional analysis using the ASA 24 Hour Dietary Recall (see Equipment below). The pedometer and BG meter was downloaded within 10 days, and these recorded readings
were compared to the diary entries for accuracy. Where there was a discrepancy, the downloaded data was presumed accurate and used for data analyses.

**Follow-up.** At the conclusion of the study, participants were asked which form of aerobic walking they preferred. At the one-month follow up, participants were asked how many times they performed 15 minutes of post prandial walking and how many times they performed a 45 minute block of aerobic walking within the last seven days.

**Equipment**

**LifeScan.** Verio IQ BG meter (LifeScan, 2014): LifeScan donated 12 meters and strips to this project. This meter is highly accurate and exceeds the International Organization for Standardization accuracy criterion of 95% of measurements being within \( \pm 0.85 \text{mmol/L} \) of reference values and is easy to use. Its memory stores 750 readings; date/time of entry and whether the user coded the reading as pre or post-prandial or other, which was critical for this study.

**Omron.** The Omron HJ-323U Multi-Function Downloadable Pedometer (Omron, 2012) accurately records total steps, aerobic steps, steps/minute during aerobic steps, distance traveled and calories expended. The pedometer was personalized, requiring the input of the user’s stride length, height and weight. It will be worn on a belt/waist band or kept in a pants pocket. It has a two-week downloadable memory. This allowed researchers to track total activity and aerobic steps taken during experimental days. Omron defines aerobic walking as; “walking more than 60 steps per minute for more than 10 minutes continuously. If a rest of less than 1 minute is taken after a continuous walk
for more than 10 minutes, this was regarded as part of a “continuous walk” (Omron, 2012, p.6)

**Automated Self-Administered 24-hour Dietary Recall (ASA24).** Extensive evidence has demonstrated that 24-hour dietary recalls provide the highest quality, least biased dietary data (Subar et al., 2012). Traditional 24-hour recalls, however, are expensive and impractical for large-scale research because they rely on trained interviewers and multiple administrations to estimate usual intakes. As a result, researchers often make use of food frequency questionnaires, which are less expensive but contain substantial error.

To address this challenge, investigators at National Cancer Institute (NCI) created the Automated Self-administered 24-hour Recall (ASA24) system, a web-based tool that enables multiple automated self-administered 24-hour recalls. ASA24 was developed under contract with Westat, a social science research firm located in Rockville, MD, and builds on the Food Intake Recording Software System (FIRSSSt) developed by Dr. Tom Baranowski of the Baylor College of Medicine. An External Working Group provided advice about the needs and interests of potential users (Subar et al., 2012).

ASA24 is based on research that has been found valid and has been shown to be accurate at determining total caloric intake and determining breakdown of macronutrients (Subar et al., 2012). It allows researchers and subjects to monitor 24-hour caloric intake for research or educational purposes. For reliability purposes, all dietary data entry into the ASA was performed by the Research Assistant. Researchers extracted total grams of
carbohydrates and fiber eaten each experimental day. Since fiber is a non-digestible carbohydrate, our primary variable was Net Grams of Carbohydrates (total grams of carbohydrates – total grams of fiber).

**Data Analysis**

**Manipulation checks.** While the primary variable for this study was the 7-point BG profiles, this study was premised on whether participants engaged in the appropriate amount (4,500 steps) and intensities (>108 steps/aerobic minute) of physical activity during the two experimental conditions and not during the control condition (see Table 1). Therefore, researchers compared aerobic steps and aerobic steps/minute taken during the Block and the Post-Prandial conditions. If the manipulation was successful, these should be statistically equivalent. However, these should be statistically significantly different from the Control condition. If a subject’s pedometer did not demonstrate such differences when turning in the pedometer, the subject would have to repeat the deviant condition. It was assumed that a similar amount of net carbohydrates was consumed during the six experimental days.

**Primary analyses.** Due to the limited number of subjects that participated in this pilot study, data were analyzed by descriptive statistics only.

To test Hypothesis 1, subjects were required to track BG levels eight separate times throughout the day on the data sheets provided for all testing conditions. Upon completion of the data collection, researchers looked at the Mean 24 BG levels for all subjects with respect to the Control testing days and the 45-minute block testing days.
To test Hypothesis 2, after data were submitted researchers compared the Mean post-prandial BG levels of all subjects with respect to the 45-minute continuous aerobic walking condition and the three bouts of 15 minutes of continuous aerobic walking for each meal.

**Secondary analyses.** To test Hypothesis 3, because subjects were required to perform the tests on two consecutive days, researchers were able to compare the Mean 24 hour BG levels from day one to day two for both the 45-minute continuous aerobic walking condition and the three bouts of 15 minutes of continuous aerobic walking condition.

To test Hypothesis 4, subjects were required to report their preference after the study. All subjects indicated a preference for 15-minute post-prandial exercise bouts over the single 45-minute block of walking. No analysis was performed.

To test Hypothesis 5, Subjects were required to report the number of times they performed either 15 minutes of post-prandial continuous aerobic walking or 45 minutes of continuous aerobic walking over the most recent seven-day period. No analysis was performed.
Chapter 4

Results

Aerobic exercise has two beneficial properties for people with T2D: 1) temporarily reduces insulin resistance (Niu, Yuan & Fu 2010) and 2) lowers blood glucose in the absence of effective insulin action (Eizadi et al., 2013). Therefore, aerobic exercise has the potential of being a powerful “medicine” in the self-treatment of those with T2D.

The biggest barrier to the use of aerobic exercise in the management of T2D is compliance, for a variety of reasons. Consequently, it is important to be able to identify the minimal, most palatable and most effective “dose” of this intervention to optimize its routine use.

A recent, innovative, and exquisitely controlled study (Dipietro et al., 2013) investigated timing and “dose” of aerobic exercise with seniors at-risk for developing T2D. They evaluated the metabolic benefits of 45 minutes of brisk walking when performed in one block of time or when divided into three 15-minute “bouts.” Using a within subject design, their 10 subjects wore continuous BG monitors for three 48 hour periods spent in a whole-room calorimeter. The first 24 hours of each trial was a control period with no moderate physical activity, while during the second 24 hours the experimental periods where participants walked on a treadmill, set at an absolute intensity of three METs. At 10:30h, 16:30h or 30 minutes after each meal. Standardized meals (32 kcal/kg/day: 53% carbohydrate, 31% fat) were provided for subjects by a
metabolic kitchen. They found that: 1) aerobic exercise led to lower BG than no exercise, 2) the BG lowering effects of a 45-minute bout of aerobic exercise was equivalent when done mid-morning or mid-afternoon, 3) there was a greater post-prandial BG lowering effects when the 45 minutes of exercise was divided into three 15 minute dose done 30 minutes after meals.

The proposed study added to DiPierto et al., (2013)’s findings by investigating the effects of timing and duration of aerobic exercise in the natural environment, with adults on no medication in the management of T2D, assessing both palatability and impact on BG control.

Results by Hypotheses

**Hypothesis 1** stated that 45 minutes of brisk walking in the living and working daily environment was more effective than no moderate physical activity in terms of lowering average 24 BG levels.

As illustrated by Figure 1, 45 minutes of physical activity performed once a day, lowered 24-hour average blood glucose levels for two out of the three subjects tested. For all three subjects, the mean BG for the no exercise and exercise days was 119.7 and 114.5 mg/dl, respectively.

Since BG is a function of energy input (net carbohydrates eaten) and energy expenditure (physical exertion), hypothesis 1 can also be assessed when controlling for energy input by dividing BG by total net carbohydrates. Figure 2 compares the two conditions when controlling for net carbohydrates by dividing average blood glucose by
average net carbohydrates. Figure 2 is controlling for net carbohydrates did not change the result. Again, subjects 1 and 2 showed the benefits of aerobic walking for 45 minutes. Because of this, the remaining result will not control for net carbohydrates.

\[\text{Figure 1. 45-min Block vs. Control 24 Hour BG Averages} \]

Average 24 hour blood glucose levels during control and 45 minute testing conditions. Control = no aerobic walking, 45 min = a single block of continuous aerobic walking for 45 minutes no sooner than two hours after the subjects last meal.
**Hypothesis 2** stated that compared to a 45-minute block of brisk walking, three fifteen minute bouts of post-prandial brisk walking would result in lower post-prandial BG, a presumed risk factor for cardiovascular disease.

As illustrated by Figure 3 the hypothesis was supported in six of the nine meals—not true after two lunches and one dinner.
Figure 3. Post-Prandial BG levels 45-min. Block vs 15-min Bout BG levels following each meal when comparing the three 15 minute bouts of aerobic walking to a single bout of aerobic walking lasting 45 minutes. Post-P15= BG levels after a given meal when performing the three bouts of 15 minutes of continuous aerobic walking, Post-P 45= BG levels after a given meal when performing the 45 minutes of continuous aerobic walking. B= breakfast, L= lunch, D= dinner

**Hypothesis 3** stated that the effects of exercise will be cumulative, that is there will be a greater BG lowering effect on the second consecutive day of exercise than on the first day.

As hypothesized, a “carry over” effect for exercise seems to be evident. That is, to say the effects of exercise seem to be cumulative, with lower BGs on day two compared to day one. As illustrated in Figure 4, for four out of the six days this was true. For one day the opposite was observed (subject 101, 45min condition), and for another day there was no change (subject 102, 15 minute condition).
Figure 4. Carry over Effect the cumulative effect of exercise on BG levels, when exercise is performed on two consecutive days. 45 min-1= the first of the two consecutive days of performing a single block of 45 minutes of continuous aerobic walking, 45 min-2= the second of the two consecutive days of performing a single block of 45 minutes of continuous aerobic walking, 15 min-1= the first of two consecutive days of performing 15 minutes of continuous aerobic walking after each meal, 15 min-2= the second of two consecutive days of performing 15 minutes of continuous aerobic walking after each meal.

Hypothesis 4 stated, three 15-minute bouts of brisk walking are more likely to produce consistent adherence in adults with T2D than setting aside a 45-minute block of time for brisk walking. Subjects were contacted one month following the completion of the study, and asked which duration of exercise they preferred and how many times in the last seven days, they had performed either form of exercise. All three subjects reported a preference toward the three 15 minute post-prandial exercise bouts over the single 45-minute bout of walking. Subject 103 stated that the 45 minute block was pushing the threshold of what he could comfortable do at the required speed.
Hypothesis 5 state that at one month follow up, participants would routinely perform more post-prandial aerobic walking following their experience in the study and learning how exercise impacts their BG.

As illustrated in Figure 5, one month after the study was completed all subjects were walking more often after meals than in a larger block of time at some point in the day. On the assumption that individuals walk exactly 15 minutes after meals and 45 minutes during block sessions, the data suggests that the group accumulated 495 minutes of block walking and 555 minutes of post meal waling.

![Figure 5](image_url)

*Figure 5. Post-Study Retention Number of times a subject performed either the single block of 45 minutes of continuous aerobic walking or 15 minutes of continuous walking after meals. 45 min. Block= performing a single block of 45 minutes of continuous aerobic walking, 15 min. Bout= 15 minutes of continuous aerobic walking.*
Chapter 5

Discussion

This thesis was a feasibility study, successfully demonstrating the possibility of systematically evaluating the relative potential benefits of 45 minutes/day of aerobic walking, whether it was done in three 15-minute periods after meals when blood glucose of adults with T2D should be rising or in a single block at least two hours after any meal. Because only three subjects from the same community participated in this study, these findings do not have external validity, which they cannot be comfortably generalized to other adults with T2D. The limited number of subjects also means that this pilot study lacks significant internal validity.

It is important to note that once subjects completed the consent process, they were all very cooperative in complying to the study protocol, promptly and thoroughly executing the study. There were no gaps in data. This was impressive since each subject was asked to measure BG levels a minimum of 16 times a day, and on 25% of these measurements the subjects measured their blood glucose a third time, as prescribed by the protocol, because their initial blood glucose readings were more than 10 mg/dl apart. This finding is important, and talks to the unreliability of self-blood glucose monitoring which directs millions of individuals to manage their diabetes, frequently used to adjust insulin levels.

Hypothesis 1 predicted whether a 45-minute block of aerobic walking would lower the subsequent 24-hour mean blood glucose levels. This was confirmed by subject 101 and 102, and the effects were even more evident when controlling for the grams of
net carbohydrates eaten that day. Interestingly, the only subject who did not demonstrate this effect was, subject 103. What makes subject 103 different is that he was taking the blood glucose medication Metformin. Braun et al. (2008) reported that Metformin alone may decrease functional performance, with reductions evidenced in peak ventilation, exercise duration, peak heart rate, and peak VO2. While accounting for net carbohydrates consumed illustrated the effect of exercise on 24 hour BG levels it did not impact the results of the data and therefore was not tracked on any further figures.

Hypothesis 2 predicted whether walking aerobically for 15 minutes after each meal was more effective at lowering post prandial BG levels than walking once a day for 45 minutes. This hypothesis was confirmed in six of the nine meals eaten. When reviewing the diet analysis, it was seen that the meals where the 15-minute post-prandial condition was less effective than the 45-minute condition coincided with the largest meal that the subject ate that day. The average caloric intake across all subjects on control days was 1357.50 kcals, whereas the average caloric intake on test days that included aerobic walking was 1442.46 kcals.

After speaking with the subjects following the study and reviewing their dietary data it was apparent that their dietary habits differed with the testing condition they were performed. When the subjects performed the control condition, with no aerobic walking, they unconsciously kept their consumption lower with regard to carbohydrate and total caloric intake. The lower carbohydrate and caloric intake during the control condition was in direct contrast to the testing conditions that required aerobic walking. When asked about the increased intake levels each subject stated they had not intentionally consumed
more. This tendency played a direct role in the daily BG control of diabetics and merits its own research, i.e. during periods of increased exercise to individuals consume more carbohydrates. While this may have real survival benefits, it counter-acts the potential benefits of exercise for those managing diabetes.

Hypothesis 3 predicted the cumulative effect of exercise between two consecutive days. It states that the observable effect was greater on the second day of exercise than was witnessed on the first day. It was shown that there was a consistent cumulative effect to consecutive days of exercise. A strong majority of testing day suggested improvement from one day to the next. This is a strong link between frequent and consistent exercise and lowered average BG levels in diabetics. As can be seen in Figure 4 four out of the six days a cumulative effect was witnessed by the subjects.

For subject 101 during the 45-minute single dose testing condition the opposite effect was witnessed. The increase in BG on the second day of 45 minute testing could be due to a total caloric intake content of 1080.64 on the first day of testing and a total caloric content of 1146 on the second day of testing. Subject 102 showed an elevated BG on the second day of testing for the 15-minute post-prandial testing condition. This is interesting because this subject reported being sick that day and so the total caloric intake for the second day was 693.57 as compared to 1384.94 on the first day of testing. Looking at the caloric content the result was not what would be expected; however considering, that an error rate of 25% of BG readings the glucometer during this study. The issue could potentially be attributed to errors in technology; however, without further research this claim cannot be substantiated.
Hypothesis 4 predicted the palatability of 15 minutes of post-prandial aerobic walking over a single 45-minute bout of aerobic walking once a day. All subjects indicated a preference towards the repeated 15-minute post-prandial condition. This showed that if rather than being told to get out and exercise, people with diabetes were specifically told to aerobically walk for 15 minutes after each meal; the compliance rate of exercise may be much higher.

Subject 101 indicated an appreciation for both exercise conditions. When asked to select a condition that was most favorable. The 15-minute testing condition was decided to be the most favorable method of aerobic walking for the subjects. The reasoning for this was because subject 101 noticed lower BG levels and wanted to take an initiative over his diabetes. Subject 103 stated that the 45-minute block of exercise pushed the limits of what they could comfortably complete under the restrictions and requirements provided for this study.

Hypothesis 5 predicted the performance of physical activity after the study was completed. It was hypothesized that subjects would be more likely to continue with the 15-minute post-prandial approach for controlling 24-hour BG levels rather than the 45-minute block of aerobic walking. It was believed that this would be because the shorter duration of the exercise would make it far more palatable to the subjects over a longer bout of exercise.

As can be seen from Figure 5 the subjects overwhelmingly reported performing the 15-minute post-prandial aerobic walking over the 45-minute block. Each subject
reported performing both 15-minute post-prandial aerobic walking and single blocks of aerobic walking within the last seven days one month after the study was concluded. This was a very impressive result because it means that the previously sedentary subjects not only gained appreciation for a single exercise modality but for increased exercise in general. This suggests that if doctors can get patients to begin an exercise routine and be committed to it for at least two weeks while receiving feedback that the exercise is working, i.e. reducing blood glucose, they will be far more likely to retain the lifestyle change.

**Conclusion**

These results of this study demonstrate the procedures are feasible to employ in a larger randomized clinical trial, which the control procedures of multiple blood glucose measurements at a single event are essential and the use of a 24-hour food recall is necessary for accurate and understandable results. It also indicates that such a larger study is likely to find significant results. It further suggests that such studies might want to control for the different medications for T2D during testing. If such studies can replicate that individuals with T2D are more likely to prefer and engage in brief post-prandial aerobic walking and if this brief exercise lowers post-prandial blood glucose and lower glycosylated hemoglobin, the standard measure of diabetic metabolic control, then such findings could have major implications for the management of type 2 diabetes. The reduction of diabetes complications and the saving of billions of health-care dollars would have major impacts on the United States healthcare system.
Appendix A
Winthrop University

REQUEST FOR REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS
Institutional Review Board

INSTRUCTIONS

1. Always secure the most recent version of this form from the website. Failure to use the most recent version could result in the protocol being returned to you.

2. The form may be completed on-line and then printed out in order to obtain necessary signatures.

3. Ensure that all items are completed on the Request for Review form.

4. You must attach to the Request for Review form all related materials such as:
   - Informed Consent, Parental Permission and/or Subject Assent forms
   - Copies of recruitment materials, including emails, flyers, letters, etc
   - Copies of surveys to be used in the study
   - Copies of interview questions to be used in the study
   - Debriefing Form
   - Copies of all other materials to be used in the study, such as pictures, videos, website URL’s, etc

SUBMISSION

You may submit this Request for Review either electronically or in paper copy form, but you do not have to submit both electronically and on paper.

1. Electronic Submission – You will need to print out the form in order to obtain all appropriate signatures. Then prepare an electronic file, combining a scanned copy of the Signed Request for Review and all related materials into one .pdf file. Arrange this file in the order shown in the checklist above. Do not include this instruction page in your .pdf file. Electronic files not arranged in accordance with the check list above will be returned to you for correction. Send the electronic copy to Teresa Justice, Director of SPAR at justiceet@winthrop.edu

OR

2. Paper Copy – Submit a paper copy of the Signed Request for Review form and attachments to the SPAR Office at Rm 142 or Rm. 149 McLaurin Bldg
Winthrop University
REQUEST FOR REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS
Institutional Review Board

RESEARCHER OF RECORD: Cory Cox
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ADVISOR PHONE: HOME: WORK: 803/323-4687 EMAIL: jwojciek@winthrop.edu CELL PHONE: 704-926-6854
ADDRESS: 216G West Center

TITLE OF RESEARCH: A translational study determining the impact of timing and duration of aerobic walking on metabolic control and personal preferences among adults recently diagnosed with Type 2 Diabetes

DATES OF THE RESEARCH PROJECT:
Approval Requested for Start Date: 8/20/2014 (The requested start date should be at least 2 weeks after the next scheduled meeting of the IRB)
End Date: 7/31/2015 (Maximum of one year; must be renewed annually)

IS THIS RESEARCH BEING FUNDED BY RESEARCH GRANT?
[ ] Yes [ ] No
Funding Applied for: [ ] Sponsor: [ ] No

[ ] Yes [ ] No Is this activity being carried out by student as a classroom assignment to be reviewed by the faculty member.

[ ] Yes [ ] No Will the information gathered or developed in this activity be used in a presentation or publication outside of the classroom?
If you checked yes to both questions above, please explain how the information will be used outside of the classroom: Presented at conference or for publication

INDICATE THE TYPES OF MEMBERS OF THE RESEARCH TEAM WHO WILL HAVE DIRECT CONTACT WITH HUMAN SUBJECTS:

1. [ ] Faculty Member [ ] Staff Member [ ] Undergraduate Student [ ] Graduate Student [ ] Other: Specify: 
A. BRIEFLY DESCRIBE THE PURPOSE OF THE RESEARCH IN NON-TECHNICAL LANGUAGE: The purpose of this study is to determine the most effective amount of aerobic exercise to both reduce 24 hour blood glucose levels and encourage continued implementation.

B. DESCRIBE RESEARCH PROTOCOL OR METHODOLOGY TO BE USED: Over the course of three weeks the subjects will participate in three separate 4 day long testing conditions. I will have 30 subjects with Type 2 Diabetes walk for 15 minutes, thirty minutes after completing each of the days three meals, all subjects will also walk for 45 minutes at some point during the day for an alternative test. The effects these different amounts of walking have on blood glucose control will be compared to a control day with no aerobic walking. One month following the study we will contact the subjects to determine which of the testing protocols they enjoyed more and are more likely to implement on a permanent basis.

| EXPLAIN BRIEFLY BUT COMPLETELY WHAT TASKS OR ACTIVITIES THE SUBJECTS IN THIS RESEARCH WILL BE DOING | [IF A SURVEY/QAUTIONNAIRE IS TO BE USED, STATE HOW MANY QUESTIONS WILL BE ASKED AND THE EXPECTED TIME TO COMPLETE THE SURVEY]; SUBJECTS PARTICIPATION WILL BE DETERMINED BY A 10 MINUTE PHONE INTERVIEW IN WHICH I WILL BRIEFLY DESCRIBE THE STUDY. SUBJECTS WILL BE REQUIRED TO OBTAIN WRITTEN CONSENT FROM THEIR PRIMARY CARE PHYSICIAN STATING THAT THEY ARE HEALTHY ENOUGH TO PARTICIPATE IN THIS STUDY. SUBJECTS WILL BE ASKED TO COME INTO THE WINTHROP UNIVERSITY COLISEUM IN ORDER FOR A MEETING THAT WILL LAST NO LONGER THAN TWO HOURS, AT THIS POINT I WILL EXTENSIVELY EXPLAIN THE STUDY AND THE EXPECTATIONS PLACED UPON THEM AS WELL AS PROVIDE THEM WITH ALL MATERIALS NEEDED FOR THIS STUDY. THROUGHOUT THE STUDY SUBJECTS WILL BE ASKED TO WEAR A PROVIDED Pedometer DURING EACH OF THE FOUR EXPERIMENTAL DAYS, AS WELL AS TEST THEIR BLOOD SUGAR EIGHT TIMES A DAY (WHEN THEY FIRST WAKE UP, BEFORE AND AFTER EACH MEAL, AND BEFORE BED) USING THE PROVIDE BLOOD GLUCOSE METER AND TESTING STRIPS. WHILE SUBJECTS WILL BE INSTRUCTED TO TAKE NOTE OF THESE READINGS FOR THEIR OWN KNOWLEDGE THEY WILL NOT NEED TO KEEP TRACK OF THEM FOR THE STUDY. BOTH THE PedomETER AND BLOOD GLUCOSE METER HAVE INTERNAL MEMORIES OF AT LEAST 14 DAYS. I WILL MEET WITH EACH SUBJECT ONCE A WEEK TO RETRIEVE THE DATA. SUBJECTS WILL BE ASKED TO PARTICIPATE IN THREE SEPARATE TESTING SESSIONS. IN A RANDOMIZED ORDER THEY WILL BE ASKED TO PERFORM A CONTROL WEEK WHERE THE SUBJECTS WILL BE ASKED TO KEEP THEIR TOTAL DAILY STEPS AND TOTAL AEROBIC STEPS UNDER 6000 AND 100 RESPECTIVELY OVER THE FOUR DAY PERIOD. DURING THE 15 MINUTE BLOCK TEST WEEKS SUBJECTS ARE INSTRUCTED TO HAVE TWO CONTROL DAYS IN WHICH THEIR TOTAL DAILY STEPS AND TOTAL AEROBIC STEPS UNDER 6000 AND 100 RESPECTIVELY. FOLLOWING THE CONTROL DAY’S SUBJECTS WILL BE REQUIRED TO BRISKLY WALK CONTINUOUSLY FOR 15 MINUTES AT A SPEED OF 3.5 MPH STARTING 30 MINUTES AFTER COMPLETING EACH DAILY MEAL. DURING THE 45 MINUTE BLOCK TEST SUBJECTS WILL AGAIN BE ASKED TO PARTICIPATE IN TWO CONTROL DAYS BEFORE THE TWO TESTING DAYS, THE GUIDELINES FOR THE CONTROL DAYS AS THE SAME AS BEFORE. DURING THE TESTING DAYS SUBJECTS ARE ASKED TO BRISKLY WALK CONTINUOUSLY FOR A PERIOD OF 45 MINUTES AT A SPEED OF 3.5 MPH WITHIN 2 HOURS OF STARTING THEIR EVENING MEAL. DURING THE THREE SETS OF TWO TESTING DAYS SUBJECTS WILL BE ASKED TO WEAR A FOOD LOG FOR 48 HOURS INCLUDING ALL FOOD AND DRINK CONSUMED INCLUDING WATER. THEY WILL BE ASKED TO KEEP THEIR DIET AS CONSISTENT AS POSSIBLE. I WILL CONTACT THE SUBJECTS VIA PHONE FOLLOWING THE TESTING DAYS TO TRACK THEIR PROGRESS AND ANSWER ANY ADDITIONAL QUESTIONS THEY MAY HAVE, DURING THIS 30-45 MINUTE LONG PHONE CALL THE SUBJECTS WILL USE THEIR FOOD LOGS AS A PROMPT FOR THEIR MEMORY AS I FILL OUT A 48 HOUR DIETARY RECALL USING ASA24. THE PURPOSE OF THE FOOD LOGS IS TO QUANTIFY THEIR NET CARBOHYDRATES CONSUMED BY EACH SUBJECT IN ORDER TO DETERMINE THE FULL EFFECT OF THE INTERVENTION. THE REASON FOR HAVING TWO TESTING DAYS FOR EACH CONDITION IS BECAUSE I BELIEVE THE EFFECTS OF EXERCISE TO BE ACCUMULATIVE AND I WANT TO ILLUSTRATE THIS WITH THE DATA. THE REASON FOR THE TWO CONTROL DAYS BEFORE THE TESTING CONDITIONS IS BECAUSE I WANT THE SUBJECTS TO RETURN TO BASE LEVEL AND TO START FROM THE SAME DETERMINATION; THIS WILL HELP TO REDUCE OUTLIERS. A SPEED OF 3.5 MPH EQUATES TO A PACE OF 17.1428 MINUTES PER MILE. SUBJECTS WILL BE INSTRUCTED TO WALK AT A PACE OF 17 MINUTES PER MILE. THE SPEED OF 3.5 MPH WAS CHOSEN BECAUSE THAT IS THE SPEED THAT THE CENTERS FOR DISEASE CONTROL DEFINES AS A BRISK AEROBIC WALK. |
|---|
| 3. |
| 4. |
DESCRIBE SUBJECTS FOR THIS RESEARCH, INCLUDING A STATEMENT OF WHO WILL BE RECRUITED AND THE ANTICIPATED POPULATION SIZE: 30 subjects will be recruited and inclusion criteria will include:

- Subjects will be between the ages of 25 and 75
- Diagnosed with T2D within the past 5 years
- Not currently taking medication for their diabetes management, or taking only Metformin
- Capable and willing to measure BG 3/day for six experimental days
- No regular physical activity or occasional exercise within the past three months (i.e., fewer than two 20-min bouts of exercise per week during the previous 6 months)
- Capable of walking 2.7 miles in 45 minutes, i.e., ~3.5 miles/hour
- Approval of their diabetes physician to participate.

5.

DO YOUR SUBJECTS INCLUDE ANY OF THE FOLLOWING:

- Yes ☐ No ☑ Infants and children younger than 7 years?
- Yes ☑ No ☐ Institutionalized mentally impaired people?
- Yes ☐ No ☑ Students enrolled in your own classes?
- Yes ☐ No ☑ Students enrolled at Winthrop University?
- Yes ☐ No ☑ Prisoners?
- Yes ☑ No ☑ Other special populations? Specify - people with Type 2 Diabetes

6.

DESCRIBE HOW SUBJECTS WILL BE RECRUITED FOR THIS RESEARCH: Subjects will be recruited using flyers, ads in newspapers, and from word of mouth of their doctors.

7.

HOW WILL YOU ASSURE THAT PARTICIPATION OF THE SUBJECTS IS VOLUNTARY? Subjects will be informed that they are free to drop out of the study at any point without penalty on the informed consent form.

CAN THE HUMAN SUBJECT BE DIRECTLY IDENTIFIED BY: (For any responses of "yes" indicate in the space provided how the subject's privacy will be protected.)

- Yes ☑ No ☐ Name on Response form: The forms will be kept in a sealed cabinet. All data will be reported using a subject ID.
- Yes ☑ No ☐ Photograph:
- Yes ☑ No ☐ Television/VCR/DVD tapes:
- Yes ☑ No ☐ Audiotape:
- Yes ☑ No ☐ Coded Research Forms:
- Yes ☑ No ☐ Detailed Biographical Data:
- Yes ☑ No ☐ Informed Consent, Assent or Parental Permission forms: Doctor and consent forms will be kept in a locked cabinet.
- Yes ☑ No ☐ Other:

8a.

If you checked yes to any item in 8a; then:

- Yes ☑ No ☐ Will personally identifiable data be shared with others outside of this research team? If you checked yes, please explain.

9.

THE RESEARCHER SHALL MAKE EVERY POSSIBLE ATTEMPT TO MAINTAIN CONFIDENTIALITY OF THE RESEARCH AND THE HUMAN SUBJECTS. IF FOR SOME REASON, THE RESPONSES, INFORMATION, OR OBSERVATIONS OF THE SUBJECT BECAME KNOWN TO PERSONS OTHER THAN THE RESEARCHERS, COULD THIS INFORMATION POTENTIALLY PLACE THE SUBJECT AT RISK OF:

- Yes ☑ No ☐ DAMAGE TO HIS/HER FINANCIAL STANDING?
- Yes ☑ No ☐ DAMAGE TO HIS/HER PRESENT OR FUTURE EMPLOYABILITY?
- Yes ☑ No ☐ CRIMINAL OR CIVIL LIABILITY?
41

10. Explain any "yes" answers and steps that have been taken to minimize risk:

- Invasive medical procedures?
- Non-invasive medical procedures?
- Strenuous exercises?
- Other physical testing?

Explain any "yes" answers and steps that have been taken to minimize risk: Subjects will be required to test their blood sugar which involves a finger prick and a small amount of blood. Walking, even brisk walking, is considered a moderate-intensity exercise by the American College of Sports Medicine.

11a Describe how legally effective informed consent will be obtained and attach a copy of the consent form. If minors are to be used as research subjects, describe procedures used to gain consent of their parent(s), guardian(s), or legal representative(s). Subjects will be required to get written consent from their doctor by whom they will again be informed of all health risks. HIPAA Subjects will be asked to sign a consent form when they arrive for the in person introduction. Additionally subjects will be informed to contact their physician if they should experience any unusual symptoms such as extreme blood glucose levels high or low while participating in this project.

11b Waiver of signed informed consent requirement

To request a waiver of a signed informed consent, complete the following:

- The only record linking the subject and the research would be the consent document, and the principal risk will be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern. Section 46.117(c)(1)

- The research presents no more than minimal risk of harm to the subjects, and involves no procedures, for which written consent is normally required outside of the research context. Section 46.117(c)(2)

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine (i)public benefit or service programs; (ii)procedures for obtaining benefits or services under these programs; (iii)possible changes in or alternatives to those programs or procedures; or (iv)possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practically be carried out without the waiver or alteration. Section 46.116(c)

- The research involves no more than minimal risk to the subjects, the waiver will not adversely affect the rights and welfare of the subjects, the research could not practically be carried out without the waiver, and whenever appropriate, the subjects will be provided with additional pertinent information after participation. Section 46.116(d)

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

12. Storage and disposal of data and other research materials:

A. How and where will the data and other research material be stored until no longer
42

Revised 07/05/2013

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☐ Yes  ☐ No | PSYCHOLOGICAL/EMOTIONAL PROBLEMS?

EXPLAIN ANY "YES" ANSWERS AND STEPS THAT HAVE BEEN TAKEN TO MINIMIZE RISE:

☐ Yes  ☐ No | INVASIVE MEDICAL PROCEDURES?

☐ Yes  ☐ No | NON-INVASIVE MEDICAL PROCEDURES?

☐ Yes  ☐ No | STRENUEOUS EXERCISE?

☐ Yes  ☐ No | OTHER PHYSICAL TESTING

EXPLAIN ANY "YES" ANSWERS AND STEPS THAT HAVE BEEN TAKEN TO MINIMIZE RIS:

Subjects will be required to test their blood sugar which involves a finger prick and a small amount of blood. Walking, even brisk walking, is considered a moderate-intensity exercise by the American College of Sports Medicine.

11a

DESCRIBE HOW LEGALLY EFFECTIVE INFORMED CONSENT WILL BE OBTAINED AND ATTACH A COPY OF THE CONSENT FORM. IF MINORS ARE TO BE USED AS RESEARCH SUBJECTS, DESCRIBE PROCEDURES USED TO OBTAIN CONSENT OF THEIR PARENT(S), GUARDIAN(S), OR LEGAL REPRESENTATIVE(S). Subjects will be required to get written consent from their doctor by whom they will again be informed of all health risks. HIPAA Subjects will be asked to sign a consent form when they arrive for the in person introduction. Additionally subjects will be informed to contact their physician if they should experience any unusual symptoms such as extreme blood glucose levels high or low while participating in this project.

11b

WAFER OF SIGNED INFORMED CONSENT REQUIREMENT

TO REQUEST A WAIVER OF A SIGNED INFORMED CONSENT, COMPLETE THE FOLLOWING:

☐ The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. Section 46.117(c)(1)

☐ The research presents no more than minimal risk of harm to the subjects, and involves no procedures, for which written consent is normally required outside of the research context. Section 46.117(c)(2)

☐ the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under these programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practically be carried out without the waiver or alteration. Section 46.116(e)

☐ The research involves no more than minimal risk to the subjects, the waiver will not adversely affect the rights and welfare of the subjects, the research could not practically be carried out without the waiver, and whenever appropriate, the subjects will be provided with additional pertinent information after participation. Section 46.116(d)

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

12.

STORAGE AND DISPOSAL OF DATA AND OTHER RESEARCH MATERIALS:

A. How and where will the data and other research material be stored until no longer
needed. Forms will be stored in a locked filing cabinet in my office at the coliseum.

B. When will the disposal of data and research materials take place? Three years after the study has concluded

At a minimum, investigators must maintain research records for at least three (3) years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of the IRB, any federal department or agency supporting the research, and sponsor, if any. (Source: 45CFR46.115) If the Principal Investigator is a student, then the faculty advisor will be responsible for the record retention. If you are a member of a professional association or society, you may be required by their practices to keep records longer than 3 years.

C. How will data and research materials be disposed of? They will be shredded.

### 13. Indicate on the Check List below, any documents that apply to your research and attach to this protocol a copy of the applicable document.

- [x] Survey instrument and/or interview questionnaires
- [ ] Informed consent agreement
- [ ] Parental or guardian permission for a minor child to participate in a research study
- [ ] Assent to participate in a research study (ages 7–14 years)
- [ ] Assent to participate in a research study (ages 15 – 17 years)
- [ ] Copies of any other mail to be delivered to respondents or subjects (e.g. cover letters, scripts of verbal instructions, etc.)

### 14. Yes [ ] No

**Do you consider this research exempt from review by the human subjects committee?** If yes, please check the reason for exemption from the list below:

- [ ] Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies; or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods [45CFR46.401(k)]

- [ ] Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures or observation of public behavior, unless (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects’ responses outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability or reputation. [45CFR46.401(k)(2)]

  - Research involving children (subjects that have not attained the age of 18 years) is not exempt under this category unless the research involves only the observation of public behavior and the researchers do not participate or impact the activities being observed. [45CFR46.401(k)(2)]

- [ ] Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior if (a) the human subjects are elected or appointed public officials or candidates for public office, or (b) federal statute(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. [45CFR46.406(b)(3)]

- [ ] Research involving the collection study of existing data, documents, records, pathological specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. [45CFR46(b)(4)]

- [ ] Research and demonstration projects which are conducted by or subject to the approval of a Federal department or agency, and which are designed to study, evaluate, or otherwise examine; (a) public benefit or service programs of Federal programs; (b) procedures for obtaining benefits or services under those Federal programs; (c) possible changes in methods or alternatives to those Federal programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those Federal programs. [45CFR46(b)(5)]

- [ ] Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed; or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. [45CFR46(b)(6)]
Certifications

By my signature below, I certify that each of the named co-researchers has accepted his/her role in this study. I agree to not begin any research activity on this study until written approval by the IRB has been received. I agree to a continuing exchange of information with the Institutional Review Board (IRB). I agree to obtain IRB approval before making any changes or additions to the project. I will provide progress reports at least annually, or as requested. I agree to report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. A copy of the informed consent will be given to each subject and the signed original will be retained in my files, unless a waiver of a signed informed consent has been granted.

I further certify that I have successfully completed the following Human Subjects Training Course:
- CITI – Biomedical Research Investigator
- CITI – Social and Behavioral Research Investigator
- CITI – Undergraduate Researcher
- CITI – IRB Member

Signature of Researcher: ___________________________ Date: ____________

I further certify that I have reviewed this research study and agree to counsel the student researcher in all aspects of the research study.

I further certify that I have successfully completed the following Human Subjects Training Course:
- CITI – Biomedical Research Investigator
- CITI – Social and Behavioral Research Investigator
- CITI – IRB Member

If Student Researcher: ___________________________ Signature of Faculty Advisor: ____________ Date: ____________

Approval by Department Chair of Researcher of Record

(Date if Chair is the Researcher or if Chair is otherwise unable to review)

I have reviewed this research study. I believe the research is sound, that the study design and methods are adequate to achieve the study goals, and that there are appropriate resources (financial and otherwise) available to the researcher. I support the study, and hereby submit it for further review by the IRB.

Signature of Department Head or Dean: ___________________________ Date: ____________

Note: Do not use personal home addresses and phone numbers on Informed Consent, Assent, Parental Permission or Debriefing statements.
Appendix B
Winthrop University
Informed Consent Agreement

Researcher: Cory Cox  ☒Graduate Student  ☐Undergraduate Student

Faculty Advisor: Dr. Wojcik  Faculty Advisor’s Position: Associate Professor, Exercise Science

Title of Study: A translational study determining the impact of timing and duration of aerobic walking on metabolic control and personal preferences among adults recently diagnosed with Type 2 Diabetes

You are invited to take part in a research study. Before you decide to be a part of this study, you need to understand the risks and benefits. This consent form provides information about the research study. I will be available to answer your questions and provide further explanations. If you take part in this research study, you will be asked to sign this consent form. Your decision to take part in this study is voluntary. You are free to choose whether or not you will take part in the study. If you should decide to participate, you may withdraw from the study at any time.

Purpose of the research study:
The purpose of this study is to determine the most effective amount and type of aerobic walking to both reduce 24 hour blood glucose levels and encourage continued exercise in persons with Type 2 diabetes.

Procedures or methods to be used in the study:
You must have been diagnosed with Type 2 diabetes within the past 5 years. You must be on no medications or only taking Metformin (brand names: Glucophage, Riomet, Glumetza, Fortamet). Before you will be invited to participate in this study you will be asked to have your primary care physician sign a consent waiver stating that you are healthy enough to participate in this study. Once this has been complete you will be required to meet with me at the Winthrop University Coliseum. When we meet I will clearly explain the study and what will be required from you and me throughout the study. I will also answer any questions you may have. During this time you will be provided with all equipment needed for this study, a pedometer and a blood glucose meter. I will also help you to gain a better understanding for what a speed of 3.5 miles per hour feels like. You will be asked to walk on a treadmill at a speed of 3.5 miles per hour for 15 minutes. Following the treadmill walk if you still believe you are physical able we will walk continuously at pace for 45 minutes around the Winthrop lake giving you the experience of walking in a natural setting. If at any point during this first meeting you feel you will not be able to complete the study you are free to back out with no penalty. You will participate in a three-week long study consisting of three separate four day long testing periods, in which you will be asked to complete two control days where you total daily step count does not exceed 6000 and your total aerobic step count does not exceed 100. If either step count exceeds these numbers you will be asked to return to your normal routine and try again the next week. Following the control days you will be asked to perform two days consisting of a testing intervention, this will be different each week. In a randomized order you will be asked to perform one of three testing interventions including: control, 15 minute block walking, and 45 minute block walking. The control testing days will be identical to the previous two control days in which your total daily step count does not exceed 6000 and your total daily aerobic step count does not exceed 100. The 15 minute block testing days will require you to briskly walk for 15 minutes starting 30 minutes after completing each daily meal. The 45 minute block testing days will require you to briskly walk continuously for 45 minutes two hours of eating your evening meal. You
will be required to maintain a pace of 3.5 miles per hour during your testing walks. A speed of 3.5 miles per hour equates to a pace of about 17 minutes per mile. If the limited number of steps allowed during the control days too greatly interferes with your daily life you are free to withdraw from the study at any point with no penalty. If you are unable to maintain a speed of 3.5 miles per hour for the required time you are free to withdraw from the study at any point with no penalty. Throughout the course of the study you will be asked to wear a pedometer that will be provided to you, this will help you to keep track of your total and aerobic steps during the control periods and testing periods. Additionally during the testing days you will be asked to check your blood glucose levels eight times a day (when you first wake up, before and after each meal, and before you go to bed) on a blood glucose meter that you will be provided with, and to keep a food journal keeping track of all food and drink consumed including water.

I will meet with you on a weekly basis to collect the data from the pedometer and blood glucose meter and discuss your progress in the study; at this time I will also use your food journal to complete a 48 hour dietary recall. It is suggested that you keep your diet at similar as possible across all testing days; however you do not need to change your diet unless otherwise instructed by your primary care physician. One month following completion of the study I will contact you and ask you two questions: 1) which method of aerobic walking did you most prefer? And 2) in the past seven days how many times have you participated in that method of aerobic walking?

Possible Risks/Benefits Associated with Participating in Study:
You do have risk of injuries associated with walking such as strains, sprains, trips and falls. Any injuries should be reported to the researcher and followed up by your health care provider. From this study, you can learn how your body adapts to exercise to manage your blood glucose levels to potentially better manage your diabetes. If something feels wrong contact your primary care physician or seek emergency medical help as soon as possible. Your results will be monitored weekly by the project team. If at any time during the study your blood glucose readings are below 70mg/dl or above 250mg/dl, you will be encouraged to contact your primary care physician as soon as possible. If at any time during the study your blood glucose readings are below 60mg/dl or above 350mg/dl you will be withdrawn from the study with no penalty and instructed to contact your primary care physician or seek emergency medical help as soon as possible. You will be required to have your primary care physician sign and return a letter stating that you are medically able to participate in this study.

Possible Costs/Compensation Associated with Participating in Study:
All equipment needed for this study will be provided to you. You will receive 1 OneTouch VerioIQ blood glucose monitoring system valued at: $43.13, 1 Omron Alvita USB pedometer with four activity modes and web solutions valued at: $39.99, and 1 box of 100 OneTouch Ultra blood glucose test strips valued at: $188.22 for a total of $271.34. All items received by participation in this study are considered taxable income and should be reported. Any injury or medical expense that should arise during the course of the study will be paid by you.

Number of questions in the survey/questionnaire and anticipated time to complete the survey/questionnaire: N/A

Right to withdraw from the study:
You are free to withdraw from the study at any time without penalty.

Privacy of records or other data collected in the study:
All identifiable records will be stored in a locked filing cabinet and shredded three years after completion of the study.

Questions – contact information:
If you have any questions about this study, you may contact me using my Winthrop email account: coxe17@winthrop.edu

Or through my faculty advisor:
Address: 216G West Center, Rock Hill, South Carolina 29733
Work Phone: 803-323-4687 Email: wojcikj@winthrop.edu

You may also contact:
Teresa Justice, Director
803-323-2460 justicet@winthrop.edu
Sponsored Programs and Research
Winthrop University
Rock Hill, SC 29733

Signatures:
By signing this consent agreement, you agree that you have read this informed consent agreement, you understand what is involved, and you agree to take part in this study. You will receive a copy of this consent form.

_________________________________________  ______________________________
Signature of Participant                        Date

_________________________________________  ______________________________
Signature of Researcher                          Date
Appendix C
Researchers at Winthrop University are conducting a 3-week long experiment, investigating the effects of brisk walking on blood sugar, when done for 15-minute blocks after breakfast, lunch and dinner or one 45-minute block not done right after a meal. You will

- Learn whether and how much brisk walking lowers your blood sugar
- Learn the best time to do brisk walking
- Contribute to a better understanding of blood sugar control and type 2 diabetes

1. Study involvement
Participants will wear a pedometer and measure their blood sugar under three conditions:

- Two days when they do not do brisk walking
- Two days when they do 15 minutes of brisk walking 30 minutes after breakfast, lunch and dinner
- Two days when they do 45 minutes of brisk walking once 2-hours after a meal

2. To participate, you should:

- Have been diagnosed with type 2 diabetes in the past 5 years
- Be between the ages of 24 and 75 years
- Not taking medication or only taking Metformin
- Be able to do brisk walking, that is walking 3 miles an hour, for 45 minutes

3. All participants will receive:

- A free blood glucose meter
- A free sophisticated pedometer

If interested,
Please call Cory Cox at 434-465-0157 OR email coxc17@winthrop.edu

Type 2 diabetes study
Appendix D
Telephone Screening Interview

Date: ________________ Subject No __________

Explain purpose of the study and what is involved if one chooses to participate.

If the individual is interested in proceeding, confirm inclusion/exclusion criteria

1. Date of Type 2 Diabetes diagnosis: ______
2. Current treatment regimen: ___ Lifestyle, ____ Oral Medication, ___ Insulin
3. Ability to walk 2.6 miles in 45 minutes ___ Yes, ___ No
4. Willingness to measure BG 8 times/day on six days ___ Yes, ___ No
5. Willingness to record food/drink intake for three test days: ___Yes, ___ No
6. Willingness to walk 2.6 miles in 45 minutes ___ Yes, ___ No
7. Willingness to wear a pedometer all day on nine days ___ Yes, ___ No
8. Willingness to secure PCP approval ___ Yes, ___ No
9. In the past two weeks, how many times have you taken a:
   a. Brisk/fast walk for 45 minutes or longer? ___
   b. Brisk/fast, walk for 15 minutes or longer 30-60 minutes after eating? ___
10. If you knew that walking briskly for 15 minutes after breakfast, lunch and dinner improves your blood glucose control as much as walking 45 minutes all at one time. Considering your preference, schedule and physical fitness level which would you be most likely to do:
   a. ___ Walking 15 minutes after meals.
   b. ___ Walking for 45 minutes all at once.

If “yes” to all but number nine, of the above question then collect contact information:

Name ____________________________

Best telephone number: _______________________________________________________

Alternate telephone number: ___________________________________________________

E-mail address: ________________________________________________________________

Best form of communication: ___________________________________________________

Diabetes physician name and address:
____________________________________________________________________________

Personal address: ______________________________________________________________
Schedule Consenting visit

1. Give location/mail map

2. Bring comfortable closes and shoe to practice “brisk” walking on treadmill

3. Date of apt. __________ Time of apt. ______
Appendix E
Physician’s Approval Letter

Dear Dr___:

Your patient _______ is interested in participating in a study on the effects of aerobic walking on BG control among adults with type 2 diabetes. Your patient will record their blood glucose and diet for six days. Two days while walking briskly for 15 minutes 30 minutes after each meal and two days while walking briskly for 45 minutes two hours post-prandial, each group of test days will be preceded by a control day in which BG levels will need to be recorded in the same fashion. You will continue to be responsible for your patient’s medical care. If your patient is assigned to the routine care group, then you will direct his/her diabetes care. We need your approval and affirmation documented as indicated by your signature below that Mr/s. ___

- Has type 2 diabetes, diagnosed within the past 24 months,
- Is not currently taking any medication for the management of diabetes,
- Is sufficiently fit, as determined by an EKG or your clinical judgment, to participate in moderate (walking 0.9 miles in 15 minutes) physical activity.

If you approve the patient’s participation in this study please sign the statement below and return this signed document to the study team by faxing it to 434-465-0157?

Sincerely,

Cory Cox, BS

I approve Mr. /s. ______________ participation in this study—IRB-HSR#:16293.

Print Name: ________________ Signature: ________________
Date __________

Read on for more information about the study

While wearing a sophisticated pedometer for 72 hours, monitoring BG 8/day and performing a 48 hour recall of all foods eaten on test days for nutritional analyses, 12 adults not taking medication in the management of their T2D will be block randomized to perform no aerobic walking, 15 minutes of aerobic walking starting 30 minutes after completing all three meals, or 45 minutes of aerobic walking in a single block of time. Each condition will be separated by one week. One month following completion of this study, participants will be telephoned and queried as to which activity they prefer and how many times in the previous 7 days they either took a 45 minute aerobic walk or walked for 15 minutes post-prandial. While controlling for net carbohydrates consumed and aerobic steps taken, the three conditions will be compared in terms of post prandial BG spikes and overall BG.
Appendix F
Consenting Visit

Date____, Time: ____ Subject No ______

1. Review, read and sign consent form
2. Complete demographic questionnaire
3. Personalize and demonstrate/instruct how to use pedometer
4. Demonstrate/instruct how to use BG meter
5. Complete “Typical” Test Day sheet
6. Instruct how to complete Data sheet
7. Explain what constitutes “brisk walking”, i.e. 2.6 miles in 45 minutes
   a. Demonstrate brisk walking on treadmill
   b. Do 1 mile brisk walk with pedometer
8. Schedule dates for data collection and return visit
Appendix G
“Typical” Test Day

Subject No._________ Date: ___/___/___

Select three consecutive days of the week when you’re eating and level of physical activity are consistent, that would be good days to do your three trials.

<table>
<thead>
<tr>
<th>Sunday</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
</tr>
</thead>
</table>

When would you prefer to do your 45-minute walk?

10:30 AM ___  4:30 PM ___

Where and when could you do your 15-minute walks 30 minutes after Breakfast, lunch and dinner on two consecutive days?

What and how much do you typically eat on that day for your:

Breakfast

Lunch

Dinner
Appendix H
Data Sheet

Subject No: ________

Condition: __ No brisk walking, __15 min. brisk walking beginning 30 minutes after each meal, __45 min brisk walk 2 hours after evening meal.

Remember:

1. Keep your test days as similar as possible
2. Keep your pedometer and BG meter someplace where you will see it the first thing in the morning
3. Put your pedometer on when you get dressed in the morning
4. Fill out completely the data sheet
5. Wash your hands/fingers before each BG measurement
6. Use a timer (smart phone) to make sure your after-meal BG occurs 2 hours after you started eating
7. No snacks/eating after each meal until after your 2hr BG measurement
8. Keep your BG meter with you.
9. Call me if you have any questions (434) 465-0157

<table>
<thead>
<tr>
<th>Event</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
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<tbody>
<tr>
<td>BG Pre Breakfast</td>
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<tr>
<td>Breakfast foods</td>
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<td>BG 2hr post BKF</td>
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<td>Snack</td>
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<td>BG pre Lunch</td>
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<td>Lunch foods</td>
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<td>BG 2hr post Lunch</td>
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<td>BG pre Dinner</td>
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<td>Dinner foods</td>
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<td>BG 2hr post Dinner</td>
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<td>Steps</td>
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<td>Aerobic Steps</td>
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<td>Aerobic Step/min</td>
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<td>Net Carbs</td>
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Appendix I
One-Month Follow Up Telephone Interview

Subject #: __________     Date: ________

Which physical activity program did you find most appealing?
__ Brisk walking for 15 minutes after meals
__ Brisk walking for 45 minutes at a single time

In the past 7 days, how many times did you do the following?
__ Walk briskly for at least 15 minutes after a meal
__ Walk briskly for at least 45 minutes sometime during the day?
References


cancer institute. *Journal of the Academy of Nutrition and Dietetics, 112*(8), 1134-1137


*Journal of Clinical Epidemiology, 55*, 1064-1072
