THESIS

EFFECTIVENESS OF A LOW DOSE BEHAVIOR CHANGE INTERVENTION ON PHYSICAL ACTIVITY MAINTENANCE FOLLOWING AN EXERCISE TRIAL IN PRE-TYPE II DIABETICS

Submitted by

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ABSTRACT

EFFECTIVENESS OF A LOW DOSE BEHAVIOR CHANGE INTERVENTION ON PHYSICAL ACTIVITY MAINTENANCE FOLLOWING AN EXERCISE TRIAL IN PRE-TYPE II DIABETICS

Pre-type II diabetes (PT2D) is emerging as one of the fastest growing chronic diseases among adults. Increasing physical activity (PA) levels is often a first line of defense for managing PT2D; however, PA levels in this population are below the national average. PA behavior change (PABC) interventions can be useful in assisting with the adoption and maintenance of regular PA, yet the feasibility and effectiveness of embedding a low dose PABC within an exercise efficacy trial for PT2D has not been examined. The main purpose of this study is to determine the effectiveness of one PABC counseling session on PA maintenance following a 12-week exercise efficacy trial. This study also aims to examine changes in self-efficacy following the PABC counseling session. Finally, this study aims to explore both social support and perceptions of neighborhood walkability as determinants of PA following an exercise trial. Participants were randomized to receive a one-hour PABC counseling session, or not (CON), held after completion of the 12-week exercise trial. The session was based on social-cognitive theory, and the primary goal was to increase post-intervention PA maintenance through discussion of PA benefits, PA goal setting, and identifying and overcoming PA barriers. Self-reported PA was measured using the International PA Questionnaire (IPAQ), pre, post and three-months after the exercise trial. Participants also completed questionnaires assessing self-efficacy, social support and neighborhood walkability. Baseline, post-intervention questionnaires, and the

PABC counseling session were done while participants were in the laboratory doing their oral glucose tolerance test, and the follow-up questionnaire was completed by mail or online. Participants (N=21, M Age = 62±5.8), were mostly female (86%), Caucasian (88%), and high socioeconomic status (70.6% completed at least 4 years of college, and 76.5% had an annual household income ≥ $50,000). Paired t-tests detected a significant difference in total PA between post-intervention to follow-up, $t(15) = 3.33$, $p = .005$, with total PA decreasing from post to follow-up for the entire sample. No significant within group changes (N=16; PABC N=8, CON N=8) were found between post and follow-up. Repeated measures analysis of variance (ANOVA) did not detect statistical significance between groups in total PA change from post-intervention to three-month follow-up, $F(1, 14) = 2.93$, $p = .109$. Barriers self-efficacy significantly improved from before to after the PABC, $t(12) = -2.63$, $p = .022$. Social support, neighborhood crime and neighborhood aesthetics were significantly associated with PA measures at three-month follow-up. Incorporating a single session PA behavior change intervention as part of an exercise efficacy trial is feasible. While the PABC counseling session did not result in a lower rate of total PA decline from post to follow-up, those who received the PABC did report higher levels of PA at follow-up. Self-efficacy, social support and perceptions of neighborhood walkability are important determinants of PA maintenance in adults at risk of developing type-II diabetes. Future studies should explore the dose response of PABC counseling sessions in this population to determine the lowest dose needed to enhance PA maintenance following an exercise trial.

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TABLE OF CONTENTS

I. INTRODUCTION

Pre-type II Diabetes and Physical Activity

Prevalence

Type-II diabetes is emerging as one of the fastest growing chronic diseases among adults in the United States. According to the American Diabetes Association, at least 86 million Americans are pre-type II diabetic, while an alarming 29.1 million Americans have diabetes (American Diabetes Association [ADA], 2015). In 2010, diabetes was listed as the seventh leading cause of death in the United States, with over 234,000 death certificates listing the disease as the underlying or contributing cause of death (ADA, 2015). Not only is the burden of this chronic disease significant for the individual and their families, but the healthcare costs associated with treating diabetes and pre-type II diabetes are staggering. The culmination of all costs related to diabetes and pre-type II diabetes in the United States, including productivity loss and treatment costs, surpassed 322 billion dollars in 2012 (Dall et al., 2014). This resulted in an economic burden of over $1000 for every American (Dall et al., 2014). This is significantly higher than the estimated cost in 2007 of 174 billion (Cowie et al., 2009).

Of the 30 million cases of diabetes, about 90-95% are cases of type-II (Centers for Disease Control and Prevention [CDC], 2016), and although both type I and type-II diabetes are problematic, much of the concern has shifted towards treating and preventing type-II diabetes. Type-II diabetes is a debilitating chronic condition leading to a variety of co-morbidities such as obesity, cardiovascular disease, hypertension and hyperlipidemia, but perhaps most importantly, type-II diabetes can be *preventable* with lifestyle changes. Prevention of type-II diabetes begins with identifying individuals at-risk for pre-type II diabetes and managing its progression.

The need to identify those most at-risk for developing type-II diabetes has led to the development of a set of criteria to define pre-type II diabetes (Abraham & Fox, 2013). The American Diabetes Association defines pre-type II diabetes using three different tests. The oral glucose tolerance test (OGTT) includes a fast of 8 to 12 hours, and the individual's blood glucose is measured before and 2 hours after drinking a glucose-containing solution. Impaired glucose tolerance is considered a blood glucose of 140-199 mg/dL after the 2-hour test. A second test includes a fasting sample of blood glucose. Impaired fasting glucose is defined as 100-125 mg/dL. The third test includes a non-fasted blood sample where the amount of glycated hemoglobin (HbA1c) is determined and an HbA1c value of 5.7% to 6.4% is considered impaired or pre-type II diabetic (Abraham & Fox, 2013; ADA, 2014). Individuals falling into the above ranges for any of the three measurements are considered pre-type II diabetic. Impaired fasting glucose, impaired glucose tolerance and HbA1c values are each highly predictive of developing type-II diabetes from pre-type II diabetes (Yokota et al., 2017).

The prevalence of individuals identified as pre-type II diabetic has increased rapidly over the past decade. In just two years, between 2010 and 2012, diagnosed cases of pre-type II diabetes have increased from 79 million to 86 million (ADA, 2015). An analysis of over 19,000 participants ages 12 and older revealed the age-adjusted prevalence of pre-type II diabetes has climbed from 27.4% between 1999-2002 to 34.1% between 2007-2010 (Abraham & Fox, 2013). When looking at HbA1c or fasting glucose levels, the 2014 National Diabetes Statistics Report found 37% of American adults over the age of 20 had pre-type II diabetes, with half of these adults ages 65 or older (CDC, 2014). While prevalence rates of pre-type II diabetes are increasing among all adults, the rates have trended higher in men compared to women (Cowie et al., 2009). In Colorado, the Colorado Diabetes Prevention Program estimates one third of adults

in the state have pre-type II diabetes, with the numbers increasing to 50% of adults ages 65 and older (ADA, 2017).

Risk factors for the development of pre-type II diabetes are often linked to aging, poor health behaviors and a history of type-II diabetes in the immediate family (National Institutes of Health [NIH], 2008). High blood pressure, HDL levels below 35mg/dL or triglyceride levels above 250 mg/dL are additional risk factors for pre-type II diabetes. Finally, any adults over the age of 45 or those who are overweight or obese are at a greater risk for pre-type II diabetes (NIH, 2008). A sample of overweight adults found close to 23% met the criteria for pre-type II diabetes (Khavandi, Amer, Ibrahim, & Brownrigg, 2013).

Over the course of a few decades, the prevalence of type-II diabetes and pre-type II diabetes has become widespread, and lifestyle modifications provide an important solution for decreasing this epidemic. Interventions targeting lifestyle changes such as a healthy diet and physical activity (PA) can be successful in managing several risk factors for pre-type II diabetes and decreasing the number of cases of pre-type II diabetes that progress into type-II diabetes.

Physical Activity to Prevent Type-II Diabetes

Pre-type II diabetes and the progression to type-II diabetes is often a product of poor lifestyle behaviors such as physical inactivity and a diet high in sugar and fat, which are also closely associated with increases in body max index (BMI) and obesity rates (Abraham & Fox, 2013). As a result, the first line of defense for managing pre-type II diabetes is behavior modification through interventions and programs designed to decrease BMI, such as healthy diet and increased PA (Cowie et al., 2009).

PA is commonly encouraged for the treatment and management of pre-type II diabetes (Cowie et al., 2009; Rossen et al., 2015; Penn et al., 2009). It is estimated that without increasing

PA levels and modifying dietary habits, pre-type II diabetics are likely to develop type-II diabetes in the next decade (Tuso, 2014). Interventions including a PA component have resulted in at least a 50% reduction in the risk of developing type-II diabetes (Penn et al., 2009; Colberg et al., 2010). Regular PA increases the body's metabolic control (Rossen et al., 2015), leading to management of blood glucose and ultimately the management of disease progression. PA increases energy expenditure, assisting with weight management, improves blood pressure and blood lipid control, leading to a decrease in cardiovascular events and mortality (Colberg et al., 2010).

PA recommendations for pre-type II diabetics mirror the public health recommendations for PA (Physical Activity Guidelines Advisory Committee, 2008). Pre-type II diabetic individuals are advised to participate in at least 150 minutes per week of moderate to vigorous aerobic PA as well as resistance training at least two days per week (Colberg et al., 2010).

Despite the benefits of regular PA, many pre-type II diabetics do not engage in recommended levels of PA (Colberg et al., 2010; Morrato, Hill, Wyatt, Ghushchyan, & Sullivan, 2007). In a study analyzing the prevalence of regular PA in adults with and at-risk for developing type-II diabetes, results indicate this population's PA levels are below the national average (Morrato et al., 2007). For adults with diabetes, 39% reported engaging in regular PA compared to 58% of adults without diabetes. For those without type-II diabetes, the proportion reporting regular PA decreased as the number of risk factors for type-II diabetes increased. This suggests pre-type II diabetics, who have many risk factors for and are on the verge of developing type-II diabetes, report lower PA levels than the general adult population. PA levels were also negatively correlated with BMI and cardiovascular risk factors. As BMI increased and an increase in cardiovascular risk factors were reported, PA levels decreased (Morrato et al., 2007).

A decade of research has indicated regular PA leads to management of pre-type II diabetes, yet many adults with pre-type-II diabetes struggle to engage in sufficient levels of PA. This suggests that modifying PA behavior in this population can be challenging, difficult to maintain, and that more research is needed to increase our understanding of how to best increase PA among pre-type II diabetics.

Increasing Physical Activity among Pre-type II Diabetics

As stated above, PA is integral in the treatment and management of pre-type II diabetes (Cowie et al., 2009; Rossen et al., 2015; Penn et al., 2009), yet many pre-type II diabetics do not get the recommended levels of PA (Morrato et al., 2007). Therefore, behavior change interventions, grounded in behavior change theories, can be useful to assist this population in adopting and maintaining PA. Below is a brief discussion of two behavior change theories, Social Cognitive Theory (Bandura, 1986) and Social Ecologic Models (Sallis et al., 2006; Sallis, Owen, & Fisher, 2008), that have been commonly used and shown to be successful for increasing and maintaining PA in several populations.

Social Cognitive Theory

Social Cognitive Theory (SCT) suggests that individuals can learn behaviors from others and their environment, with behavior being a continuous interactive cycle between the individual and their social environment (Bandura, 1986). SCT suggests behavioral factors, personal factors and environmental factors all interact to influence an individual's behavior, with self-efficacy, or the belief in one's ability to perform a certain behavior such as PA, being a primary component of this theory (Bandura, 1986).

SCT has been identified as a useful framework for analyzing important constructs related to long-term PA behavior (McAuley, Jerome, Elavsky, Marquez, & Ramsey, 2003), and PA

interventions that include SCT constructs have shown an advantage in increasing PA maintenance (Bock, Marcus, Pinto, & Forsyth, 2001).

Social Ecologic Models

Social Ecologic Models of health behavior posit that multiple levels of influence determine an individual's behavior, and have been frequently applied to PA behaviors (Spence & Lee, 2003). Social Ecologic models of health behavior suggest that PA is influenced by extra-individual factors such as the social and built environments (Sallis et al., 2006; Sallis et al., 2008).

Applying Theories of Behavior Change to Physical Activity in Pre-type II Diabetics

Currently one of the most successful theory driven interventions designed for managing pre-type II diabetes and preventing progression to type-II diabetes is the Diabetes Prevention Program (DPP), which is grounded in SCT (The Diabetes Prevention Program Research Group, 2002; Venditti & Kramer, 2013). This program began in 1996 and has been evaluated several times by randomized controlled trials (The Diabetes Prevention Program Research Group, 2002). Intervention goals include weight loss and participation in at least 150 minutes of moderate PA per week (i.e. lifestyle intervention) (Knowler et al., 2002). When compared to treatment with oral medications such as Metformin, the lifestyle intervention was found to be more effective in reducing the incidence of type-II diabetes among those at-risk (Knowler et al., 2002). Initial evaluations of the program found Metformin to reduce rates of type-II diabetes by 31% while weight loss and increased PA resulted in a reduction by 58% (Knowler et al., 2002). Specifically, the lifestyle modification had a greater influence on the HbA1c value, a marker of long-term glucose regulation, while the lifestyle intervention and Metformin had similar effects on fasting blood glucose (Knowler et al., 2002). Additional studies have found this program's lifestyle

intervention is also successful in reducing cardiovascular risk factors such as hypertension (The Diabetes Prevention Program Research Group, 2005).

The DPP can attribute its success to a well-designed, comprehensive behavior change intervention. The program promotes effective goal-setting, offers support through lifestyle coaches, tailors the program to individual participants and manages delivery of the program through extensive staff training, constant feedback and evaluation (The Diabetes Prevention Program Research Group, 2002). All participants completed an intensive 16-session behavior change curriculum within the first 24 weeks. After completion of the 16 sessions, participants continued to meet with a lifestyle coach once every two months until completion of the program several years later as well as received scheduled phone calls from the coaches in between in-person visits. Each session ran between 30-60 minutes with the curriculum covering goal setting, self-monitoring, basic information on proper diet and exercise, relapse prevention and overcoming barriers (The Diabetes Prevention Program Research Group, 1999). Translation of this program has been successful in a variety of settings including primary care (Whittemore et al., 2009).

The DPP has made an important impact on preventing type-II diabetes, however the program does have some limitations. The program is extremely time intensive for participants, involving at least 16 in-person sessions over the course of several months. Further, extensive training was offered for all lifestyle coaches, which many not be feasible in many settings. More research is needed to determine whether lower dose behavior change interventions similar to the highly successful DPP can effectively manage pre-type II diabetes and reduce risk for the development of type-II diabetes.

Physical Activity Maintenance

PA maintenance is difficult following the end of a structured intervention (Hall et al., 2010; Nigg, Borrelli, Maddock, & Dishman, 2008; Opdenacker, Delecluse, & Boen, 2011). Around 50% of people who begin an exercise program will drop out within the first six months (Nigg et al., 2008), with some clinical studies indicating this drop off can occur in just 3 months (Bock et al., 2001; King, Rejeski, & Buchner, 1998). This is a challenging obstacle for many researchers and health professionals who enroll participants in PA behavior change interventions or programs. *Healthy People 2010* recognized this challenge and suggested that interventions and programs be designed to lead to *both* adoption and maintenance of PA (Nigg et al., 2008).

PA maintenance can be defined as continuance of PA behavior between two designated time points (Kahlert, 2015). The distance between the two time points varies, stretching over the course of a couple weeks, month or year (Kahlert, 2015). For instance, PA maintenance can be considered an individual engaging in 150 minutes of PA per week at the beginning of the month and continuing to engage in this behavior until the end of the month. PA maintenance has also been defined as a statistical difference between two research groups, such as a control or usual care group and an intervention group (Kahlert, 2015; Fjeldsoe, Neuhaus, Winkler, & Eakin, 2011). This statistical difference is often quantifying the difference in at least one PA outcome between groups at post-intervention and follow-up visits (Fjeldsoe et al., 2011). PA maintenance can also be defined in terms of meeting specific PA recommendations post-intervention, such as Canada's Physical Activity Guide to Healthy Active Living (Irwin, 2007) or the American College of Sports Medicine (ACSM) guidelines for PA. Finally, PA maintenance has been defined as an individual participating in recommended levels of PA for a minimum of 6 months (Spencer, Adams, Malone, Roy, & Yost, 2006). The variety and scope of these definitions can

complicate comparing intervention or program results and translating these results to the general public.

In an effort to simplify the idea of PA maintenance the Health Maintenance Consortium (HMC) branch of the National Institutes of Health defines behavior maintenance as "a continued behavior shown during a given period and after an intervention complying with a threshold believed to improve well-being or health" (Kahlert, 2015). HMC further analyzed how maintenance was utilized across 16 HMC interventions for a variety of behaviors including PA (Seymour et al., 2010). Of the interventions studied, 75% included a specific plan for measuring maintenance of the behavior and measured it as a continuous variable (Seymour et al., 2010). Due to the complexity of defining PA maintenance, researchers and health professionals should clearly explain how maintenance is defined in their interventions and programs.

The literature is further complicated by research on PA maintenance achieving either statistical or clinical significance. Bock and colleagues found statistical significance 6 months after the start of the intervention, where those who received a motivation-matched, theory based intervention were more likely than those receiving a standard print intervention to achieve CDC or ACSM guidelines for PA, yet found only clinical significance between the two groups at month 12 (Bock et al., 2001). The literature on PA maintenance, with its many definitions and results, is complicated. However, understanding the determinants can help researchers and health professionals better assist different populations in achieving PA maintenance.

Determinants of Physical Activity Maintenance

The Physical Activity Maintenance (PAM) model provides a framework to understand the predictors of PA maintenance. The PAM suggests that individual factors (e.g. goal-setting, self-efficacy, motivation), social support and the environment influence PA maintenance (Nigg

et al., 2008). Of the broad individual factors thought to influence PA, self-efficacy has emerged as a critical determinant of PA maintenance (McAuley & Blissmer, 2000; Nigg et al., 2008). For example, in a study of sedentary adults enrolled in a home-based PA intervention, self-efficacy and perceived satisfaction were predictive of maintenance at the 12-month mark (Williams et al., 2008). Self-efficacy is defined as the belief in one's ability to successfully perform a task or behavior (Bandura, 1986). More specifically, exercise self-efficacy (EXSE) is the belief in one's ability to continue exercising on a weekly basis, while barriers self-efficacy (BARSE) is the belief in one's ability to exercise on a weekly basis when faced with commonly identified barriers to exercise participation. Both exercise self-efficacy and barriers self-efficacy have been identified as important predictors of PA maintenance (McAuley, 1992 & 1993).

Social support is also a strong predictor of PA maintenance, influencing what PA levels an individual returns to once completing an intervention (Nigg et al., 2008). In particular, social support can have an indirect influence on PA behaviors (McAuley et al., 2003; Resnick, Orwig, Magaziner, & Wynne, 2002), and a direct influence on self-efficacy (Resnick et al., 2002). McAuley and colleagues analyzed the predictors of PA maintenance after a 6-month exercise trial in older, sedentary adults, and found greater social support during the exercise trial was associated with higher self-efficacy at the end of the trial (McAuley et al., 2003). This higher self-efficacy was then predictive of PA at 18 month follow-up, indicating social support can indirectly impact PA maintenance (McAuley et al., 2003).

Finally, research has indicated built environment can also have a strong influence on PA behaviors such as PA maintenance (Nigg et al., 2008; Sallis, Floyd, Rodríguez, & Saelens, 2012). With respect to the built environment, neighborhood walkability has been identified as a reliable and valid measure of the built environment, and can be assessed subjectively with

questionnaires such as the NEWS or NEWS-A (Cerin, Saelens, Sallis, & Frank, 2006). Neighborhood walkability is defined as a collection of neighborhood characteristics including residential density, land-use mix diversity and access, street connectivity, walking and/or cycling facilities, aesthetics, pedestrian traffic safety and crime that are associated with PA levels, particularly walking and/or cycling trips (Cerin et al., 2006). Measuring neighborhood walkability with scales such as the NEWS or NEWS-A provides subjective data on an individual's built environment, which can be used to predict PA behaviors such as maintenance.

A review of PA maintenance among those diagnosed with type-II diabetes or pre-type II diabetes found self-efficacy influenced PA maintenance (Qiu, Sun, Cai, Liu, & Yang, 2012), and a lack of social support and lack of a supportive built environment were listed as important barriers. This indicates that in exploring determinants of PA maintenance for pre-type II diabetics and type-II diabetics self-efficacy and improving the social and built environments (i.e. neighborhood walkability) may be key factors (Qiu et al., 2012).

Intervention Dose Needed to Achieve Physical Activity Maintenance

PA maintenance is critical for improving the health of pre-type II diabetics and managing the disease progression to type-II diabetes, and while programs such as the DPP have successfully addressed PA maintenance in this population, the DPP is very time and resource intensive. Declines in PA following an intervention are expected (Hall et al., 2010) and health behavior changes often plateau or decrease one to five years after an intervention (Toobert, Strycker, Barrera, & Glasgow, 2010). A 2015 study of adults at-risk for developing or already diagnosed as type-II diabetic found a decrease in compliance with a strength training program 12 months after the start of the intervention (Teychenne et al., 2015).

Behavioral counseling sessions of varying length and dose have been found effective in the maintenance of a variety of behaviors, including PA (Di Loreto et al., 2003; Hall et al., 2010; Moore et al., 2006; Safren et al., 2001), and a variety of populations. Moore and colleagues found that five small group counseling sessions reduced the likelihood of participants decreasing regular PA in the year after a cardiac event and rehabilitation (Moore et al., 2006), while a year-long counseling program in older adults with multiple morbidities resulted in increased PA maintenance 12-months post-intervention compared to the usual care group (Hall et al., 2010). PA counseling (Di Loreto et al., 2003) and educational sessions (Yates, Davies, Gorely, Bull, & Khunti, 2008) are also effective in those with pre-type II diabetes or type-II diabetes. For those already diagnosed with type-II diabetes, Di Loreto and colleagues found a 30-minute counseling session, followed by a telephone call and in-office 15 minute consultations every 3 months, resulted in 69% from the intervention group verses 18% from the control group achieving the target metabolic equivalent (METs) hours per week two years post-intervention (DiLoreto et al., 2003). The intervention group also achieved statistically significant reductions in both BMI and HbA1c (Di Loreto et al., 2003).

While behavioral counseling sessions along with follow-up telephone calls and short visits successfully increase PA maintenance, little is known about the effectiveness of a single behavioral counseling session on PA maintenance. Due to the lack of literature on the effectiveness of this type of intervention, it is unclear what influence these interventions could have on PA maintenance in a pre-type II diabetic population. However, single behavioral counseling sessions have been effective in other populations with various targeted behaviors. A single counseling session has shown effectiveness in improving adherence to antiretroviral treatment in a sample of those with HIV. This counseling session utilized cognitive-behavioral

techniques from SCT as well as motivational interviewing in order to increase medication adherence (Safren et al., 2001). A single counseling session guided by similar SCT constructs may have similar effects on PA behavior, even in the absence of follow-up telephone calls and short visits.

Exercise Efficacy Trials and Physical Activity Behavior Change

Exercise efficacy trials are typically designed to examine the effects of exercise on a physiologic outcome, such as cardiorespiratory fitness or insulin sensitivity, while PA behavior change trials have a primary purpose of effects of the intervention on changes in PA (Courneya, 2010). Prior to the widespread acceptance of the Consolidated Standards of Reporting Trials (CONSORT), these two types of trials remained largely separated. However, once researchers were required to report and analyze data on all participants, regardless of adherence, behavior change interventions were viewed as important components of exercise efficacy trials. While recent exercise efficacy trials have been more likely to incorporate behavior change strategies, these interventions are often focused on increasing exercise adherence during the study, and not on using the intervention to maintain PA following the trial (Courneya, 2010).

Although the primary goal of exercise efficacy trials is not to induce PA behavior change, due to the intensive, often supervised design of these interventions, they can be very effective in increasing PA. However, once the exercise trial ends the participant is left to plan for and participate in PA on their own, often without the tools to maintain their increased levels of PA. Exercise efficacy trials may be missing an opportunity to influence PA behavior following cessation of the study, particularly in populations who can benefit immensely from long-term PA.

The effectiveness of incorporating a behavior change intervention as part of an exercise efficacy trial to focus on PA maintenance *following* the intervention rather than PA adherence *during* the trial is not well understood. Further, the feasibility of incorporating a single session PA behavior change intervention needs to be analyzed since a single session intervention has been successful in altering behaviors in the HIV population, and it is likely not feasible to add hundreds of behavior change contact hours on top of an already intensive exercise trial. Pre-type II diabetics are important subjects for this type of research as PA maintenance is critical for improving their health outcomes (Bock et al., 2001), and little is known about this population's PA maintenance following a 12-week exercise efficacy trial.

In order to successfully run these low-dose behavioral counseling sessions, it is important to understand what should be discussed with the participant during these sessions. Understanding these determinants of PA maintenance allows researchers and health professionals to better manage the complexities of this behavior.

II. STUDY PURPOSE

The overall purpose of this study is to examine the effectiveness of one behavior counseling session on PA maintenance following a 12-week exercise efficacy trial in a sample of pre-type II diabetics.

Specific Aims and Hypotheses

Aim 1: Determine if one PA behavior change counseling session (PABC) increases the likelihood of maintaining PA three-months following an exercise intervention.

Hypothesis: Participants randomized to PABC will report a lower rate of PA decline three-months post-intervention compared to the no counseling control (CON) group.

Aim 2: Examine changes in self-efficacy following a single PA behavior change counseling session.

Hypothesis: Exercise self-efficacy and barriers self-efficacy will increase from before, to after the PABC.

Aim 3: Explore social support and perceptions of neighborhood walkability as determinants of PA three-months following an exercise intervention.

Hypothesis: Greater social support and more positive perceptions of neighborhood walkability will be associated with PA levels three-months following the exercise intervention.

III. METHODS

Study Design

This study was a randomized controlled trial with a longitudinal follow-up, and conducted as part of an exercise efficacy trial, "Milk protein feeding after aerobic exercise in older adults with pre-diabetes taking the biguanide Metformin". The PA behavior change counseling session was guided by SCT (Bandura, 1986), and social ecologic models of health behavior (Sallis & Owen, 2015) were used as a framework to explore extra-individual factors associated with PA maintenance.

Milk Protein Feeding after Aerobic Exercise in Older Adults with Pre-Diabetes Taking the Biguanide Metformin

This study was a four arm randomized controlled exercise trial conducted in the Department of Health and Exercise Science at Colorado State University (Funded by the National Dairy Council, Miller BF & Hamilton KL Co-PIs). The purpose of this study was to examine interactions between Metformin, protein from a dairy product, and regular exercise on muscle mitochondrial protein synthesis, mitochondrial function, glucose tolerance and insulin sensitivity. Participants were randomized to one of four groups: 1) exercise, carbohydrate and placebo, 2) exercise, protein and placebo, 3) exercise, carbohydrate and Metformin, or 4) exercise, protein and Metformin. All groups completed a 12-week individually supervised exercise intervention. Exercise sessions were 45 minutes long, held three times per week. Participants completed aerobic exercise for the entire length of each session, at an intensity of 60% of maximal heart rate (determined by a VO_2 max test) for the first 15 minutes, followed by a progressive increase from 65%-85% of heart rate max in the remaining 30 minutes. Progression of intensity occurred on a weekly basis and was monitored by a trained lab

professional and heart rate monitor. Pre- and post-intervention oral glucose tolerance tests (OGTT) were used to analyze changes in glucose uptake.

Subject Selection

Participants for this study met the eligibility criteria for the "Milk protein feeding after aerobic exercise in older adults with pre-diabetes taking the biguanide Metformin" study.

Males and females over the age of 55 were eligible, and had to meet the following criteria: fasting glucose values ≥100 mg/dl, hemoglobin A1c ≥5.7 to <6.4%, impaired glucose tolerance (glucose 2 hours postprandial ≥140 to <200 mg/dl), *or* a family history of type-II diabetes. Participants were not excluded based on PA levels. Participants who completed the entire study received a $500 compensation.

Refer to Figure 2 for a detailed description of where subjects came from and how the final sample size was determined.

Procedures

Subjects enrolled in the "Milk protein feeding after aerobic exercise in older adults with pre-diabetes taking the biguanide Metformin" study had the option to participate in this study, and were provided information about the study in the informed consent document (See Appendix A).

After written informed consent was obtained, a baseline questionnaire packet was administered prior to beginning the 12-week exercise trial. The baseline questionnaire packet was completed during the two hour pre-intervention OGTT, and included measures of sociodemographics, PA, self-efficacy, social support and neighborhood walkability. After beginning the 12-week exercise trial, participants were randomized to one of two groups: 1) receive one session of physical activity behavior counseling (PABC), or 2) no counseling control

(CON). Randomization was stratified based on the exercise trial's intervention groups, and all study staff for the exercise trial were blinded to the counseling condition. The PABC was conducted during the participant's three hour post-intervention OGTT and muscle biopsy appointment.

Immediately following the 12-week exercise intervention, all participants completed the identical post-intervention questionnaires to measure changes in PA, self-efficacy and social support. Participants who were randomized to PABC, also completed questionnaires to measure changes in self-efficacy immediately following the counseling session. Three months following completion of the 12-week intervention, all participants completed a questionnaire to measure PA.

Baseline and post-intervention questionnaires were completed during the OGTTs, and per individual requests, three-month follow-up questionnaires were sent via email or standard mail. Those requesting email correspondence were sent a link to the follow-up questionnaire, administered through SurveyMonkey. Participants requesting a mailed copy of the survey were mailed the survey along with a stamped, return-addressed envelope.

Physical Activity Behavior Counseling (PABC)

The PABC session was administered immediately following the 12-week exercise intervention during the post-intervention OGTT. The PABC session was based on SCT and social ecologic models of health behavior, with the goal of increasing PA maintenance. Session topics and activities included:

1) Discuss the benefits of PA 2) Discuss the evidence based recommendations for frequency, intensity, time and type of PA for reducing the risk of type-II diabetes and associated co-morbidities 3) Set short and long-term PA goals 4) Identify and discuss barriers and

facilitators for PA and 5) Identify strategies to overcome barriers. All participants randomized to the PABC condition were provided with a copy of the discussion guide, *Physical Activity for the Prevention and Management of Type-II Diabetes* (See Appendix B). Participants were guided through the information and activities in the order indicated above. Participants were engaged in specific activities during the session, which included writing SMART goals for PA, identifying PA barriers, discussing the importance of social support, and identifying how rewards will be used when PA maintenance is achieved. A resource page was included at the back of the packet where participants could find further assistance with both PA and dietary behaviors. Participants were encouraged to keep the discussion guide and refer back to what was discussed when engaging in PA became challenging.

Measures

Physical Activity

PA was measured using the International Physical Activity Questionnaire-Short (IPAQ). The IPAQ has been shown to be a reliable and valid measure in a variety of populations (Craig et al., 2003). The IPAQ-short provides self-reported PA data regarding the frequency, duration and intensity of vigorous, moderate and walking PA in the previous seven days. The IPAQ-short also provides data regarding the average time spent sitting on a single week day in the previous seven days. PA was measured at three time points: pre-intervention, post-intervention and three-months post-intervention. PA was expressed in MET-minutes per week (Days * time * metabolic equivalent of task (MET)), and calculated according to IPAQ established scoring protocols. Vigorous PA MET-min/week was calculated as (Days * time * 8.0). Moderate PA MET-min/week was calculated as (Days * time * 4.0).

Walking PA MET-min/week was calculated as (Days * time * 3.3). Total PA MET-min/week was calculated as the (sum of Walking + Moderate + Vigorous MET-minutes/week scores).

Self-Efficacy

Self-efficacy was measured using the Barriers Specific Self-Efficacy Scale (BARSE) as well as the Exercise Self-Efficacy Scale (EXSE) (McAuley, 1992 & 1993). The BARSE was designed to determine an individual's perceived capability to exercise in the face of commonly identified barriers to participation. The BARSE is a 13-item questionnaire, and for each item, participants indicate their confidence to exercise on a 100-point percentage scale comprised of 10-point increments, ranging from 0% (not at all confident) to 100% (highly confident). Total score is calculated by summing the confidence ratings and dividing by the total number of items answered in the scale, resulting in a maximum possible self-efficacy score of 100 (McAuley, 1992 & 1993).

The EXSE was designed to determine an individual's perceived capability to exercise three times per week, at a moderate intensity for 40+ minutes per session, for the next 8 weeks. The EXSE is an 8-item questionnaire, and for each item, participants indicate their confidence to exercise on a 100-point percentage scale comprised of 10-point increments, ranging from 0% (not at all confident) to 100% (highly confident). Total score is calculated by summing the confidence ratings and dividing by the total number of items answered, resulting in a maximum possible self-efficacy score of 80 (McAuley, 1992 & 1993).

Self-efficacy was measured at three time points: pre-intervention, post-intervention and post-counseling session, if randomized to the PABC.

Social Support

Social support was measured at pre- and post-intervention using the Social Support and Exercise Survey (SSES). This questionnaire has been validated as an appropriate measurement of perceived social support for exercise behaviors (Sallis, Grossman, Pinski, Patterson, & Nader, 1987). The SSES determines how often family and friends participate in activities that either support or criticize someone who is trying to exercise regularly. The SSES is a 13-item questionnaire, where participants answer all 13-items for both family and friends, providing 26 total responses. For each item, participants indicate how often family and friends participate in these activities on a 6-point scale, ranging from 1 (None) to 5 (Very often) and 8 (Does not apply). The SSES will be scored by first recoding any "8" into a "1". The optional Family/Friends Rewards and Punishment scale will not be used for this analysis. Total scores for both Family and Friend Participation are calculated by summing the scores for questions 11-16 and 20-23, resulting in a maximum Family or Friend Participation score of 50. An overall total score is calculated by summing the total scores for both Family and Friend Participation, resulting in a maximum social support score of 100. For the SSES, higher scores indicate higher levels of social support (Sallis et al., 1987).

Neighborhood Walkability

Participants' perceptions of neighborhood walkability were measured using the Neighborhood Environment Walkability Scale – Abbreviated (NEWS-A) (Cerin et al., 2006). The NEWS is a 54-item questionnaire, which asks about neighborhood characteristics. The subscales assessed include: residential density (Subscale A), land use diversity (Subscale B), land-use access (Subscale C), street connectivity (Subscale D), infrastructure and safety for walking (Subscale E), neighborhood aesthetics (Subscale F), traffic hazards (Subscale G) and

crime (Subscale H). Subscale A was calculated as (the answer to A1 + (12*A2) + (10*A3) + (25*A4) + (50*A5) + (75*A6)). Subscale B was calculated by first reverse coding all answers and then tallying the number of stores or facilities within a 5, 10 or 20-minute walk. Subscales C through H were calculated by summing the answers and averaging over the number of questions in each section. Higher scores indicate higher walkability (Cerin et al., 2006)

While our intervention did not seek to change social support or neighborhood walkability, both were measured to explore their influence on PA maintenance.

Body Mass Index (BMI)

BMI was measured by dividing the weight in kilograms by the height in meters squared (kg/m^2). Height and weight were assessed by study staff of the exercise trial in the first visit following verification of participant eligibility.

Maximal Oxygen Uptake (VO_{2peak})

Maximal Oxygen Uptake or VO_{2peak} was directly measured through gases breathed during a graded exercise test. The graded exercise test was performed on a stationary bike. Study staff of the exercise trial assessed VO_{2peak} as part of several visits used to determine eligibility for the study.

Fasting Glucose and 2-hr Postprandial Glucose

Both fasting glucose and 2-hr postprandial glucose measurements were assessed by study staff of the exercise trial as part of an oral glucose tolerance test (OGTT). Participants fasted for the 12 hours prior to the OGTT. All OGTT appointments were scheduled in the morning on a weekday. Blood sampling via a venous catheter provided the information for fasting glucose and 2-hr postprandial glucose measurements. These measurements were conducted at baseline and post-intervention.

Hemoglobin A1c

Hemoglobin A1c was also assessed by study staff of the exercise trial as part of the oral glucose tolerance test (OGTT). Participants fasted for the 12 hours prior to the OGTT. Blood sampling via a venous catheter provided the information for the hemoglobin A1c measurement. This measurement was conducted at baseline and post-intervention.

Statistical Analysis

A power analysis was performed using *G*Power version 3.0.10*. The standard alpha and beta were set at $\alpha = 0.5$ and $\beta = 0.8$ and effect sizes were estimated between $d = 0.5$ and 0.7. This power calculation was based on detecting a significant difference in PA change between groups. Results of the power analysis indicated that a total sample size of approximately N=60 would be required for a two-tailed independent t-test to detect significance, while a total sample size of N=26 would be required for a repeated measures, between factors ANOVA to detect significance. Prior to analysis, all PA data was cleaned and converted to MET-minutes per week, according to the IPAQ-short scoring protocol (Craig et al., 2003). Cases were excluded from analysis if the sum total of vigorous, moderate and walking time variables exceeded 960 minutes (i.e. 16 hours). This is based on the assumption that an individual spends about 8 hours per day sleeping. Further, all cases where the vigorous, moderate or walking time variables exceeded 180 minutes or 3 hours were truncated to equal 180 minutes. This allows a maximum of 21 hours of activity per week to be reported for each intensity category (Craig et al., 2003).

Outliers and assumptions of normality were assessed using boxplots, histograms and residual plots. Any outlier at or exceeding three standard deviations from the mean was replaced with the next highest score that is not considered an outlier, using the winsorizing method (Field, 2013).

To verify effectiveness of the randomization procedure, descriptive statistics and independent t-tests were run between the intervention and control groups for all baseline characteristic variables. Baseline characteristics were also compared between those that did and did not complete the three-month follow-up questionnaire.

Descriptive statistics are presented as percentages or means and standard deviation. Means and standard deviations were calculated for social support, neighborhood walkability scores and PA at each time point.

Within-group differences in PA and PA differences within the entire sample between baseline, post-intervention and follow-up were assessed using paired t-tests. Independent t-tests assessed PA differences between groups at each time point.

For Aim 1, a repeated measures analysis of variance (ANOVA) compared the difference in PA change from post-intervention to three-month follow-up between groups. For Aim 2, paired t-tests assessed the difference in self-efficacy scores between post-intervention and post-counseling for both the EXSE and BARSE questionnaires.

For Aim 3, Pearson correlations examined univariate associations between three-month follow-up PA and continuous variables: self-efficacy, social support and neighborhood walkability scores, age, baseline BMI, baseline VO_2 and baseline PA data. Kendall's tau correlations examined univariate associations between three-month follow-up PA data and categorical variables: sex, education and income. Then, variables that were significantly associated ($p<.10$) with three-month follow-up PA were included in linear regression models. Separate models were run for Total PA, Walking PA, Moderate PA and Vigorous PA as the dependent variables. Each model included the baseline PA measure as well as any variables that were found to be significantly associated with the follow-up PA measure. For all analyses, with

the exception of the univariate associations, significance was set at $\alpha = 0.5$. All analyses were conducted using *IBM SPSS Statistics 24* software.

IV. RESULTS

Baseline demographic and PA characteristics were assessed for all participants who completed baseline questionnaires (*N*=45) and for participants who had data at all three time-points (*N*=21; PABC N=10, CON N=11) (See Table 1). There were no significant differences in baseline characteristics between the PABC and CON conditions. At baseline, participants who completed the three-month post PA questionnaire (*N*=21) reported more vigorous PA than those who did not complete the three-month post PA questionnaire (*N*=5) (*p*=0.015) (See Table 1). For all remaining analyses only those who completed measures at all three time-points were included (*N*=21).

Hypothesis 1: Participants randomized to PABC will report a lower rate of PA decline three-months post-intervention compared to the CON group.

Across the entire sample size (*N*=21), total PA increased from baseline to post-intervention, [$t(15) = -2.62$, $p = .019$], and decreased from post-intervention to three-month follow-up, [$t(15) = 3.33$, $p = .005$] (See Table 2). Vigorous PA also increased from baseline to post-intervention for the entire sample, [$t(16) = -3.52$, $p = .003$] (See Table 2). When separated by intervention group, there was an increase in total PA, [$t(8) = -2.49$, $p = .038$], and vigorous PA, [$t(8) = -4.41$, $p = .002$] from baseline to post for the CON group (See Table 3). No significant within group differences between baseline, post and follow-up were found for the PABC group (See Table 3).

Those randomized to PABC reported higher levels of moderate, walking and total PA compared to those in the CON group at each time point; however, none of these differences were statistically significant (See Table 3; Figures 1a-d).

The repeated measures analysis of variance (ANOVA) did not detect statistical significance between the CON and PABC groups in total PA [$F(1, 14) = 2.93$, $p = .109$], vigorous PA [$F(1, 16) = 0.21$, $p = .65$], moderate PA [$F(1, 18) = 1.99$, $p = .176$] or walking PA [$F(1, 17) = 1.45$, $p = .246$] changes from post-intervention to three-month follow-up.

Due to an inadequate sample size to detect statistical significance using the ANOVA, additional exploratory analyses were conducted. PA change scores were computed by subtracting post-intervention PA from three-month follow up PA. Next, independent t-tests examined the difference in PA change scores between groups. The independent t-tests did not detect statistical significance between groups in the PA change scores from post-intervention to follow-up for total [$t(14) = 0.57$, $p = .575$], vigorous [$t(16) = 0.07$, $p = .948$], moderate [$t(18) = -1.17$, $p = .259$] or walking [$t(17) = 0.44$, $p = .668$] PA.

Those who received the PABC had a greater decrease in total PA between post-intervention and three-month follow-up (PABC $M\Delta$ = -1432 ±1723 MET-min/week vs. CON $M\Delta$ = -1002 ±1232). However this difference was not statistically significant, [$t(14) = 0.57$, $p = .575$] (See Table 3).

Hypothesis 2: Self-efficacy for PA and barriers self-efficacy will increase from before, to after the PABC.

All participants randomized to the PABC condition were included in this analysis (N=13). EXSE scores were not significantly different from before to after the PABC [$t(12) = -1.76$, $p = .105$, $M\Delta = 0.5 \pm 1.1$]. BARSE scores increased from before to after the PABC [$t(12) = -2.63$, $p = .022$, $M\Delta = 0.4 \pm 0.6$].

Univariate analysis did not detect any significant associations between the change in barriers self-efficacy score from before to after the PABC and follow-up PA measures.

Hypothesis 3: Greater social support and more positive perceptions of neighborhood walkability will be associated with PA levels three-months following the exercise intervention.

There were no significant differences in social support or perceptions of neighborhood walkability between the PABC and CON groups at either baseline or post-intervention (See Table 4).

Univariate associations revealed that baseline VO_{2peak} (ml/kg/min) was associated with three-month follow-up vigorous PA (*N*=17; *p*=.045, R=.778). Baseline moderate PA was also associated with three-month follow-up vigorous PA (*N*=14; *p*=.002, R=.778).

Social support was associated with three-month follow-up moderate PA (*N*=19; *p*=.039, R= .647).

NEWS-A Subscale B (land use diversity) was associated with three-month follow-up walking PA (*N*=15; *p*=.097, R= .677). NEWS-A Subscale F (neighborhood aesthetics) was associated with three-month follow-up walking PA (*N*=15; *p*=.009, R= .677).

Finally, baseline VO_{2peak} (ml/kg/min) was associated with three-month follow-up total PA (*N*=15; *p*=.046, R=.710). Baseline vigorous PA was associated with three-month follow-up total PA (*N*=12; *p*=.093, R=.710). NEWS-A Subscale H (crime) was associated with three-month follow-up total PA (*N*=12; *p*=.067, R=.710) All other univariate associations were not significant (*p*>.10).

Linear regression models included the respective significant univariate predictors for each domain of three-month follow-up PA as well as baseline PA (See Tables 5-8). The following are the results of the F-statistics from the linear regression models: three-month follow-up vigorous PA [F(12) = 4.6, *p* = .033, with an R^2 = 0.605], moderate PA [*F*(13) = 4.0, *p*

= .051, with an R^2 of 0.419], walking PA [$F(14) = 3.1$, $p = .071$, with an R^2 of 0.458] and total PA [$F(10) = 1.5$, $p = .306$, with an R^2 of 0.505].

For three-month follow-up vigorous PA, a one-unit increase in baseline moderate PA resulted in a one MET-min/week increase in three-month follow-up vigorous PA. A one-unit increase in baseline VO_{2peak} (ml/kg/min) resulted in about a 16 MET-mins/week increase in three-month follow-up vigorous PA (See Table 5).

For three-month follow-up moderate PA, a one-unit increase in social support score resulted in about a 47 MET-mins/week increase in three-month follow-up moderate PA (See Table 6).

For three-month follow-up walking PA, a one-unit increase in land use diversity score resulted in about a 19 MET-mins/week decrease in three-month follow-up walking PA. On the other hand, a one-unit increase in neighborhood aesthetics score resulted in about a 410 MET-mins/week increase in three-month follow-up walking PA (See Table 7).

Finally, for three-month follow-up total PA, a one-unit increase in baseline VO_{2peak} (ml/kg/min) resulted in about a 48 MET-mins/week increase in three-month follow-up total PA. However, a one-unit increase in neighborhood crime score resulted in about a 1552 MET-mins/week decrease in three-month follow-up total PA (See Table 8).

V. DISCUSSION

The main findings of this study were (1) no differences between the PABC and CON groups in PA change from post-intervention to three-month follow-up, (2) BARSE scores improved from before to after the PABC and (3) social support, perceptions of neighborhood aesthetics and crime were significant predictors of three-month follow-up PA.

Across all domains, PA was not maintained following the cessation of a 12-week, supervised exercise trial, regardless of receiving one PABC session. This finding is consistent with the literature stating PA maintenance is difficult following the end of a structured intervention (Hall et al., 2010; Nigg et al., 2008).

In an effort to slow the rate of decline in PA from post-exercise trial to three-month follow-up, a single session, one-hour behavior change intervention, grounded in SCT, was tested. Single counseling sessions have been effective in other populations with different target behaviors (Safren et al., 2001), and SCT grounded interventions have long shown an advantage in improving PA maintenance (Bock et al., 2001). Unfortunately, the PABC did not result in a slower rate of total PA decline from post to three-month follow-up. It is possible the one-hour, single session behavior change intervention did not provide enough support to enhance PA maintenance. Similar studies targeting PA maintenance have found statistically significant differences between the control and intervention groups by adding follow-up check-ins either in person or over the phone between post-intervention and the follow-up time point (DiLoreto et al., 2003; Yates et al., 2008). Therefore, by adding these types of check-in measures between the end of the exercise trial and the three-month follow-up it is possible the results of this study would more closely mirror those of DiLoreto and Yates and colleagues.

Further, results of the power analysis suggested it would be difficult to detect statistical significance given the small sample size ($N = 21$), and data will need to be re-evaluated as the full sample completes the study. By including the full sample (N~50) it increases the likelihood that an ANOVA could detect statistical significance between the PABC and CON groups, indicated by the power analysis revealing a sample size of at least (N=26) is required. If the single session behavior change intervention does in fact provide enough support to enhance PA maintenance, the full sample size will have enough power to detect a statistical difference between groups.

The sharpest declines in PA from post-intervention to follow-up occurred in vigorous and walking PA for both groups (See Figures 1a-d). A sharp decline in moderate PA between post-intervention and follow-up was also seen in the control group, yet moderate PA only slightly declined between post and follow-up for those in the PABC group (PABC MΔ= -56 ±679.1 MET-mins/week vs CON MΔ= -502 ±1002.2 MET-mins/week). This suggests that the single session behavior change intervention may have specifically targeted moderate PA activities such as carrying light loads, bicycling at a regular pace or doubles tennis.

While statistical significance was not detected between the groups for any measure of PA at any time point, the study did find clinical significance. Clinical significance was defined as meeting the public health recommendations of 150 minutes (i.e. 600 MET-mins/week) of moderate PA per week at the three-month follow-up. Those in the control condition reported an average of 308 MET-mins/week of moderate PA at three-month follow-up, which is less than the 150 minutes per week (i.e. 600 MET-mins/week) recommended for pre type-II diabetics to maintain and improve their health (Colberg et al., 2010). On the other hand, those in the PABC condition reported an average of 1068 MET-mins/week of moderate PA at follow-up, which

greatly exceeds the weekly PA recommendations for the population. Three-months following the end of the exercise trial, those in in the CON group averaged only 77 minutes of moderate PA per week, while those in the PABC group averaged 267 minutes of moderate PA per week, at least a three-fold difference. It is this finding that brings into question if the PABC targeted moderate PA. If these results remain consistent once the full sample size is analyzed, then this type of PABC could be considered an effective tool for targeting maintenance of moderate PA in those at-risk of developing a chronic disease.

All time intensities (i.e. vigorous, moderate, walking and total) were higher at three-month follow-up for those who received the PABC verses those in the control. However, the PABC group also reported higher baseline PA for nearly all the categories. For this reason, it is difficult to determine the influence of the PABC in sustaining those higher than average PA levels throughout the intervention.

An unexpected finding revealed those who received the PABC had a higher rate of decline in total PA between post-intervention and follow-up. This difference between groups was not statistically significant, yet does bring into question the effectiveness of the PABC. One potential reason for this larger decline in the intervention group could be due to the high levels of PA reported at baseline by those randomized to the PABC. A ceiling effect, where those in the PABC group were reporting higher baseline PA values than those randomized to the control, could have reduced our study's ability to detect significant effects at follow-up in addition to leading those in the PABC group to experience a larger decline in PA from post to follow-up. Beginning with a higher level of PA and then maintaining this higher level throughout the three-months post-intervention could result in a larger decline in PA post-exercise trial as it becomes difficult to sustain these higher levels (Chan, Ryan, & Tudor-Locke, 2004). Despite this larger

decline, it is possible the PABC group's PA plateau would remain higher than those in the control condition, when considering the PA graphs in the results section (See Figures 1a-d).

The single session PA behavior change intervention led to a significant improvement in the barriers self-efficacy score (BARSE) from before to after the one-hour PABC. This finding agrees with previous literature revealing a single session behavior change intervention can lead to higher exercise self-efficacy (EXSE) and barriers self-efficacy (BARSE) in a sample of pre-type II diabetics (Yates et al., 2008). Our study did not detect a significant change in EXSE as a result of the PABC. There are a few potential reasons for these findings. With respect to the BARSE scores, the PABC more clearly targeted these self-efficacy questions. The last section in the PABC extensively discussed barriers to PA maintenance and participants were led through exercises to identify their barriers to PA. Participants then identified and discussed specific solutions on how to overcome their barriers. For the EXSE scores, higher than average baseline scores could have hindered our ability to influence these scores in a single session behavior change intervention. Other studies in this population have shown that pre-type II diabetics who enroll in these types of interventions often enter with relatively high self-efficacy scores and motivation to change (Kolb, Kitos, Ramachandran, Lin, & Mann, 2014). Baseline EXSE scores for this study were similar to the baseline scores reported in the above mentioned study. The higher than average baseline EXSE scores as well as a PABC that heavily targets BARSE likely contributed to the different findings between the two types of self-efficacy as a result of the intervention.

Social support, neighborhood land-use diversity, neighborhood aesthetics and neighborhood crime were all associated with PA at three-month follow-up. This finding is consistent with research indicating social support and built environment, measured by

neighborhood walkability, are strong determinants of PA maintenance (Nigg et al., 2008). These findings add to the literature because they indicate these determinants are also important in those at risk of developing type-II diabetes following a 12-week exercise trial.

This exercise trial did not intentionally target social support in that participants often exercised in the presence of the trainer rather than other participants in the study. However, a few of the participants who had exercised in the same room as other participants, due simply to available space and scheduling, reported enjoying the social support and even exchanged numbers in an effort to exercise together at the end of the exercise trial. This anecdotal finding suggests important factors to consider for both exercise trials and behavior change interventions. For exercise trials, it might be beneficial to have participants exercise in the same room for the duration of the study. Even if study staff does not actively try to engage the group nor foster relationships between participants, these relationships could occur organically. Single session behavior change interventions could benefit from focusing more heavily on the importance of social support following a structured intervention. Future research should examine if this type of social support would translate to improved PA maintenance following an exercise trial.

Built environment was assessed subjectively by analyzing participants' perceptions of neighborhood walkability. In particular, neighborhood aesthetics and crime had the strongest influence on follow-up PA, with a one-unit increase in aesthetics resulting in a 410 MET-mins/week increase in walking PA. A one-unit increase in neighborhood crime resulted in a 1552 MET-mins/week decrease in total follow-up PA. Understanding participant perceptions of neighborhood aesthetics and discussing this in the PABC could lead to improved PA maintenance. Further, understanding perceptions of neighborhood crime and discussing this as a potential barrier in the PABC could also lead to improved PA maintenance. Understanding the

importance of these two aspects of the neighborhood or built environment is also critical for the dissemination of this type of intervention across the country, as the Fort Collins community is vastly different from many communities across the country.

Researchers and health professionals should consider interventions and programs that foster positive social support and find ways to overcome the barriers of neighborhood crime and unpleasant neighborhood aesthetics (such as a lack of trees and unattractive landscaping) to help foster long-term PA behavior change.

Implications for Exercise Efficacy Trials

The design of this study limited participants' and study staff's effort and time commitments, speaking to the feasibility of including a PABC in an exercise efficacy trial. All questionnaires and the PABC intervention were given to the participants during an already scheduled visit with the exercise trial. The only time needed to participate in this study outside of what was already required for the exercise trial was the completion of a three-month follow-up PA questionnaire, which took approximately 10-15 minutes. While behavior change interventions that include multiple sessions and follow-up reminders are more likely to result in maintenance outcomes (Fjelsoe et al., 2011), this type of low dose behavior change intervention resulted in positive clinical outcomes (i.e. meeting public health PA recommendations) and warrants further study with a larger sample size. Results from this study suggest exercise trials, particularly in research settings, could easily incorporate low dose behavior change interventions as part of their overall study design.

Adding behavior change interventions as part of an exercise trial to focus on PA maintenance following the intervention rather than exclusively PA adherence during the trial

would encourage study participants to maintain their newly adopted PA behavior, improving long-term health outcomes.

Study Limitations

This study was not without limitations. The first limitation is the lack of exclusion criteria for baseline PA. This resulted in relatively high baseline PA levels (M= 1940.6 ±1584.3), not often typical for those with a chronic disease such as type-II diabetes (Morrato et al., 2007). This could have impacted the study outcomes in that reporting higher baseline PA values than average could have reduced our study's ability to detect significant effects between the groups. Further, PA was measured via self-report, which by nature presents challenges. No objective PA data was collected as part of this study. Collecting both subjective and objective PA data would provide a clearer picture of PA in this population following an exercise trial.

In addition, this study only collected data on neighborhood walkability at baseline. Collecting this same information at post-intervention could reveal potential changes in participants' perceptions of their neighborhood as a result of participating in an exercise trial and behavior change intervention. Other research has shown PA interventions can lead to an improved perception of neighborhood walkability (Wallmann, Spittaels, De Bourdeaudhuij, & Froboese, 2012).This information would shed additional light on the influences of the built environment on PA maintenance for pre-type II diabetics.

Finally, in trying to collect as much data as possible on the determinants of PA maintenance in pre-type II diabetics entering an exercise trial, questionnaire-related fatigue was experienced by several participants.

In the future, minimizing the number of questionnaires participants are asked to fill out at each time point will be important for long-term sustainability of this type of study design.

VI. SUMMARY, CONCLUSIONS AND FUTURE RECOMMENDATIONS

Summary

Physical activity between post-intervention and three-month follow-up decreased in both the PABC and control groups, which is consistent with other findings regarding PA maintenance following a structured intervention (Hall et al., 2010; Nigg et al., 2008). While those randomized to receive the low dose PABC did report higher levels of PA three-months post-exercise trial, the PABC did not result in a lower rate of PA decline between post-intervention and three-month follow-up. The PABC did result in increased barriers self-efficacy scores, and this study revealed social support, neighborhood aesthetics and neighborhood crime were all predictors of follow-up PA.

Conclusions

Incorporating a single session PA behavior change intervention as part of an exercise efficacy trial is feasible and did result in higher PA at three-month follow up (although not statistically significant). Low dose PABC interventions have the advantage of a low economic and time burden to researchers and health professionals.

Future Recommendations

Future studies should examine the dose-response of PABC sessions to determine the lowest dose needed to effectively influence PA maintenance following a structured intervention as well as determine the most appropriate dose for such an intervention as part of an intensive exercise trial. Follow-up reminders, such as telephone calls once a month, in between post-intervention and follow-up should also be examined as ways to strengthen the effects of the PABC on PA maintenance.

Further, the PABC was administered by the same staff member for all participants. This brings to light a question of whether the procedure of administering the PABC or the social

aspect (i.e. personality) of the staff member was more influential on the self-efficacy changes and resulting PA maintenance. Personality as well as perceived credentials of the staff member administering the PABC could influence the overall effectiveness of the session. As it is not always feasible to have one staff member administer every behavior change session, it will be important in future research to tease apart whether the structure of the PABC or the personality of the staff member is more influential.

This study has started to shorten the gap between exercise efficacy trials and behavior change interventions by merging the two in a research setting. Further, this study revealed important determinants of PA maintenance for those at-risk of developing type-II diabetes, who are motivated to make lifestyle changes. Future research should continue examining the most effective way to merge exercise efficacy trials and behavior change interventions that target PA maintenance following these exercise trials, particularly to benefit those on the cusp of developing a chronic disease such as pre-type II diabetes or type-II diabetes.

VII. TABLES AND FIGURES

Table 1
Means and frequencies of baseline characteristics

Characteristics	Total sample (N = 45)	Completed follow-up (N = 21)
Women, %	77.8	85.7
Ethnicity, %		
Caucasian	86.7	88.2
Hispanic/Latino	11.1	11.8
Education, %	64.5, Completed ≥4 year college degree 35.6, Completed <4 year college degree	70.6, Completed ≥ 4 year college degree 29.4, Completed <4 year college degree
Income, %	22.3, Annual household income <$50K 53.3, Annual household income $50K-$150K 22.2, Annual household income >$150K	23.5, Annual household income <$50K 41.2, Annual household income $50K-$150K 35.3, Annual household income >$150K
Family history of T2D, %	80.8	NA
	M (SD)	M(SD)
Age, y	61.7 (4.95)	61.8 (5.77)
BMI, kg/m^2	31.4 (6.64)	30.3 (6.25)
VO_{2peak}, ml/kg/min	20.7 (6.18)	19.7 (5.52)
Fasting Glucose, mg/dL	100 (12)	NA
Hemoglobin, A1c, %	5.8 (0.3)	NA
2-hr postprandial glucose, mg/dL	111 (35)	NA
Vigorous PA, MET-minutes/week	397.9 (606.32)	498.8 (751.81)*
Moderate PA, MET-minutes/week	354.1 (495.37)	393.8 (518.44)
Walking PA, MET-minutes/week	1023.0 (998.34)	957.0 (1001.40)
Total PA, MET-minutes/week	1807.2 (1401.48)	1940.6 (1584.28)

BMI = body mass index; VO_{2peak} = peak oxygen consumption; PA = physical activity. Values are mean (SD) unless otherwise noted.
a. The sample size does not always equal either 45 or 21 due to missing data.
b. Fasting glucose, Hemoglobin A1c and two hour postprandial glucose data are only available for the full sample size.
*Vigorous PA was different between those that complied with the follow-up questionnaire (N = 21) and those that did not (N = 5) ($p<.05$).

Table 2
Physical activity data full sample size

Time point	Vigorous PA, MET-minutes/week	Moderate PA, MET-minutes/week	Walking PA, MET-minutes/week	Total PA, MET-minutes/ week
Baseline	498.8 (751.81)**	393.8 (518.44)	957 (1001.4)	1940.6 (1584.28)*
Post-intervention	1480 (1153.08)**	929.5 (966.22)	1138.5 (1386.44)	3257.3 (1970.15)*
Follow-up	937.8 (884.72)	688 (977.78)	567.9 (521.81)	2209.7 (1702.2)*

PA = physical activity. Values are mean (SD) unless otherwise noted.
a. The sample size does not always equal 21 due to missing data.
*Total PA was different between baseline and post-intervention and post-intervention and follow-up ($p<.05$).
**Vigorous PA was different between baseline and post-intervention ($p<.05$).

Table 3
Physical activity data by group

Time point	Vigorous PA, MET-minutes/week	Moderate PA, MET-minutes/week	Walking PA, MET-minutes/week	Total PA, MET-minutes/ week
CON				
Baseline	515.6 (852.4)**	260 (314.64)	810.3 (1025.27)	1585.9 (1689.5)*
Post-intervention	1483.6 (989.94)**	752.7 (851.65)	850.5 (1307.18)	2531.9 (1370.13)*
Follow-up	864 (921.87)	308 (518.48)	420.8 (476.52)	1601.2 (1624.31)
PABC				
Baseline	480 (678.82)	565.7 (691.83)	1122 (1015.87)	2396.6 (1427.47)
Post-intervention	1476 (1365.93)	1124 (1082.29)	1455.3 (1469.74)	4055 (2277.92)
Follow-up	1030 (889.24)	1068 (1195.26)	731.5 (547.74)	2818.2 (1650.5)

PA = physical activity. Values are mean (SD) unless otherwise noted.
a. The sample size does not always equal 21 due to missing data.
*Total PA was different between baseline and post-intervention for the control group.
**Vigorous PA was different between baseline and post-intervention for the control group.
***There were no differences within the PABC group. There were no differences in the change in PA between post and follow-up between the groups.

Table 4
Social support and neighborhood walkability scores

Measure	Baseline mean (SD)	Post-intervention mean (SD)
Total Participation Score (range 14-75)	35.6 (17.71)	39.8 (15.65)
NEWS Subscale A (range 176-297)	194.6 (29.84)	
NEWS Subscale B (range 1-22)	8.4 (6.03)	
NEWS Subscale C (range 1-4)	2.5 (0.86)	
NEWS Subscale D (range 1-4)	2.9 (0.93)	
NEWS Subscale E (range 1.3-3.8)	2.5 (0.85)	
NEWS Subscale F (range 1.5-4)	3.4 (0.68)	
NEWS Subscale G (range 1-3.7)	2.4 (0.59)	
NEWS Subscale H (range 1-1.7)	1.2 (0.27)*	

a. The sample size does not always equal 21 due to missing data.
b. NEWS was only collected at baseline.
c. Total Participation Score was calculated from the Social Support and Exercise Survey scoring protocol.
d. NEWS indicates Neighborhood Environment Walkability Scale-Abbreviated questionnaire.
* NEWS Subscale H was different between those that complied with the follow-up questionnaire (N = 21) and those that did not (N = 5) ($p<.05$).

Table 5
Linear regression for baseline moderate PA and baseline VO_2 as predictors of vigorous follow-up PA

	b	SE B	β	p
Step 1				
Constant	803.16	258		.01
Baseline vigorous PA (MET-mins/week)	.23	.32	.213	.485
Step 2				
Constant	129.76	616		.838
Baseline vigorous PA (MET-mins/week)	.17	.25	.161	.510
Baseline moderate PA (MET-mins/week)	1.00	.29	.728	.007
Baseline VO_2 (ml/kg/min)	16.37	33	.119	.627

Table 6
Linear regression for social support as a predictor of moderate follow-up PA

	b	SE B	β	p
Step 1				
Constant	676.33	378		.099
Baseline moderate PA (MET-mins/week)	.21	.59	.101	.731
Step 2				
Constant	-820.21	618		.211
Baseline moderate PA (MET-mins/week)	-.59	.55	-.288	.308
Social Support	46.84	17	.748	.018

Table 7
Linear regression for neighborhood aesthetics and land use diversity as predictors of walking follow-up PA

	b	SE B	β	p
Step 1				
Constant	417.24	173		.031
Baseline walking PA (MET-mins/week)	.18	.14	.339	.216
Step 2				
Constant	-680.54	756		.387
Baseline walking PA (MET-mins/week)	-.01	.15	-.026	.927
NEWS Subscale B	-19.09	21	-.220	.385
NEWS Subscale F	409.93	211	.572	.078

Table 8
Linear regression for predictors of total PA

	b	SE B	β	p
Step 1				
Constant	1155.88	621		.096
Baseline total PA (MET-mins/week)	.62	.27	.608	..047
Stetp 2				
Constant	2124.74	3498		.566
Baseline total PA (MET-mins/week)	.42	.35	.414	.280
Baseline vigorous PA (MET-mins/week)	.28	.73	.139	.718
Baseline VO_{2peak} (ml/kg/min)	48.45	85	.193	.589
NEWS Subscale H	-1552.12	2344	-.221	.532

Table 9
Timeline of questionnaire administration

Measure	Baseline – Week 0	Post-intervention – Week 12	Post-intervention – Week 12	Follow-up – Week 24
Socio-demographics	X			
Physical Activity	X	X		X
Self-efficacy	X	X	X	
Social Support	X	X		
Neighborhood Walkability	X			

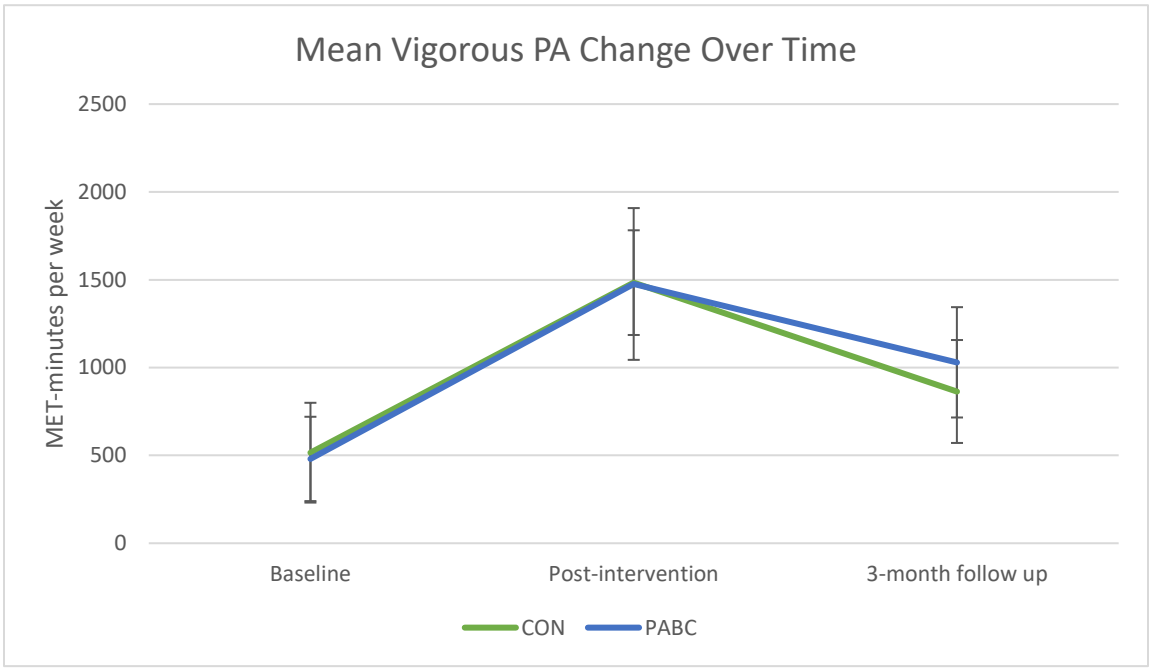

Figure 1a

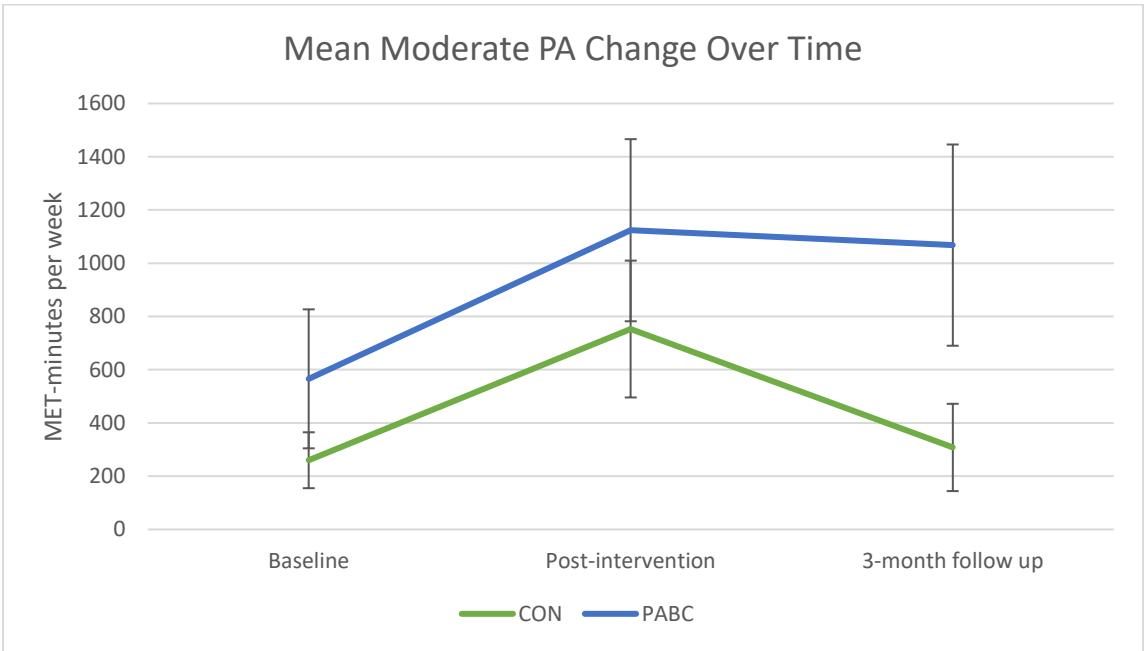

Figure 1b

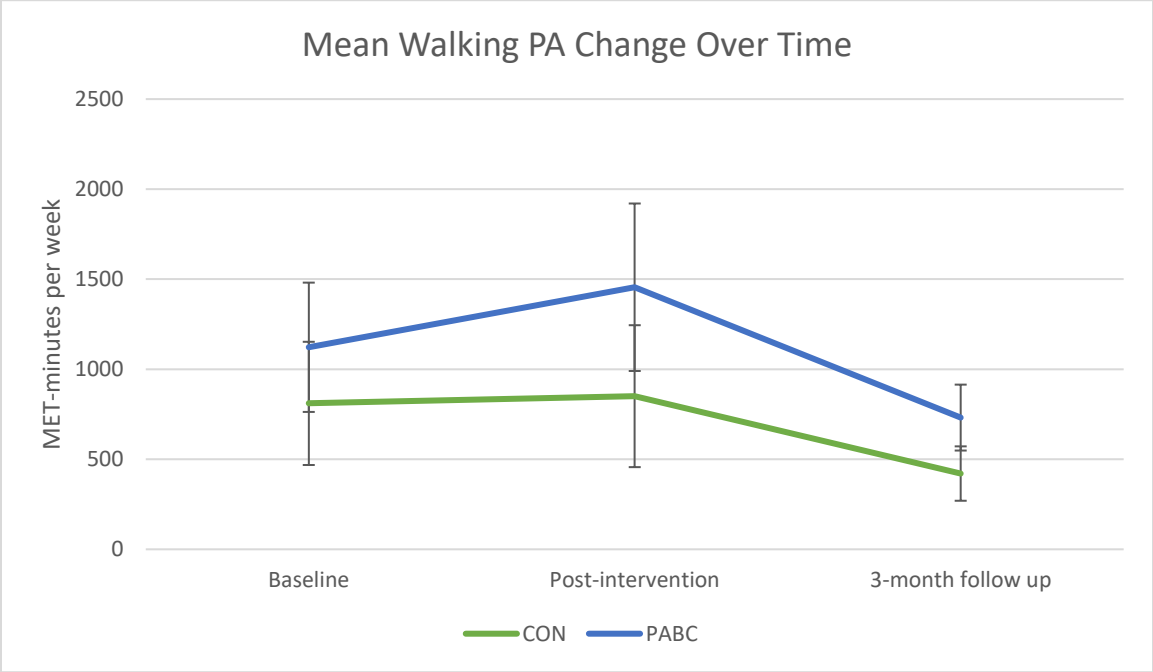

Figure 1c

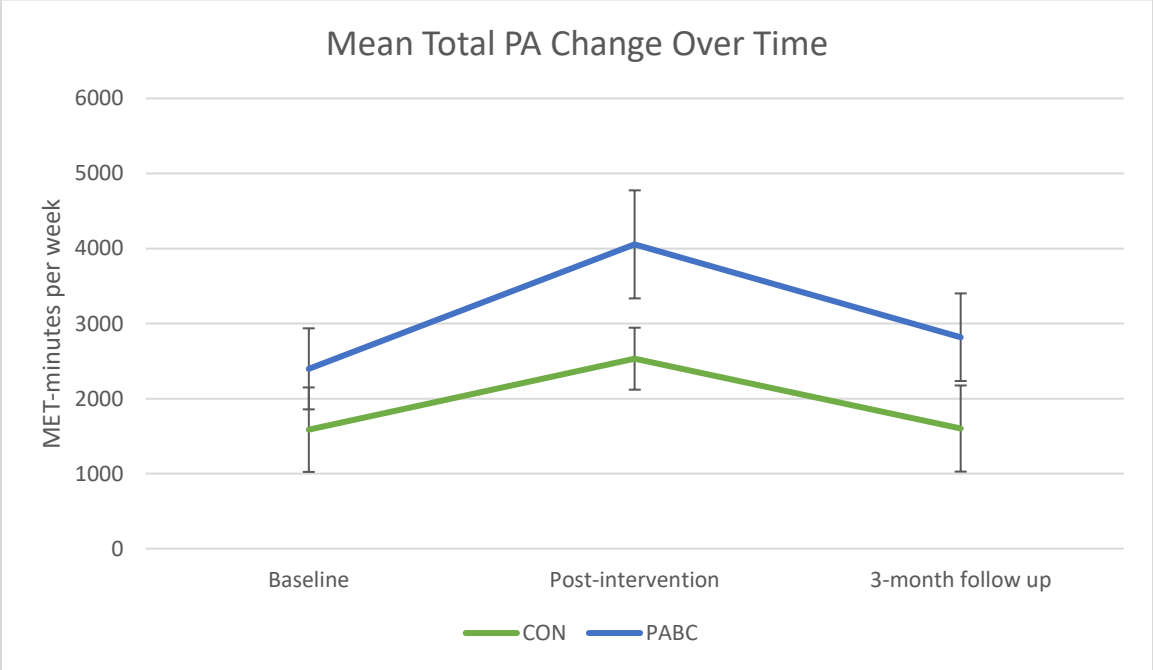

Figure 1d

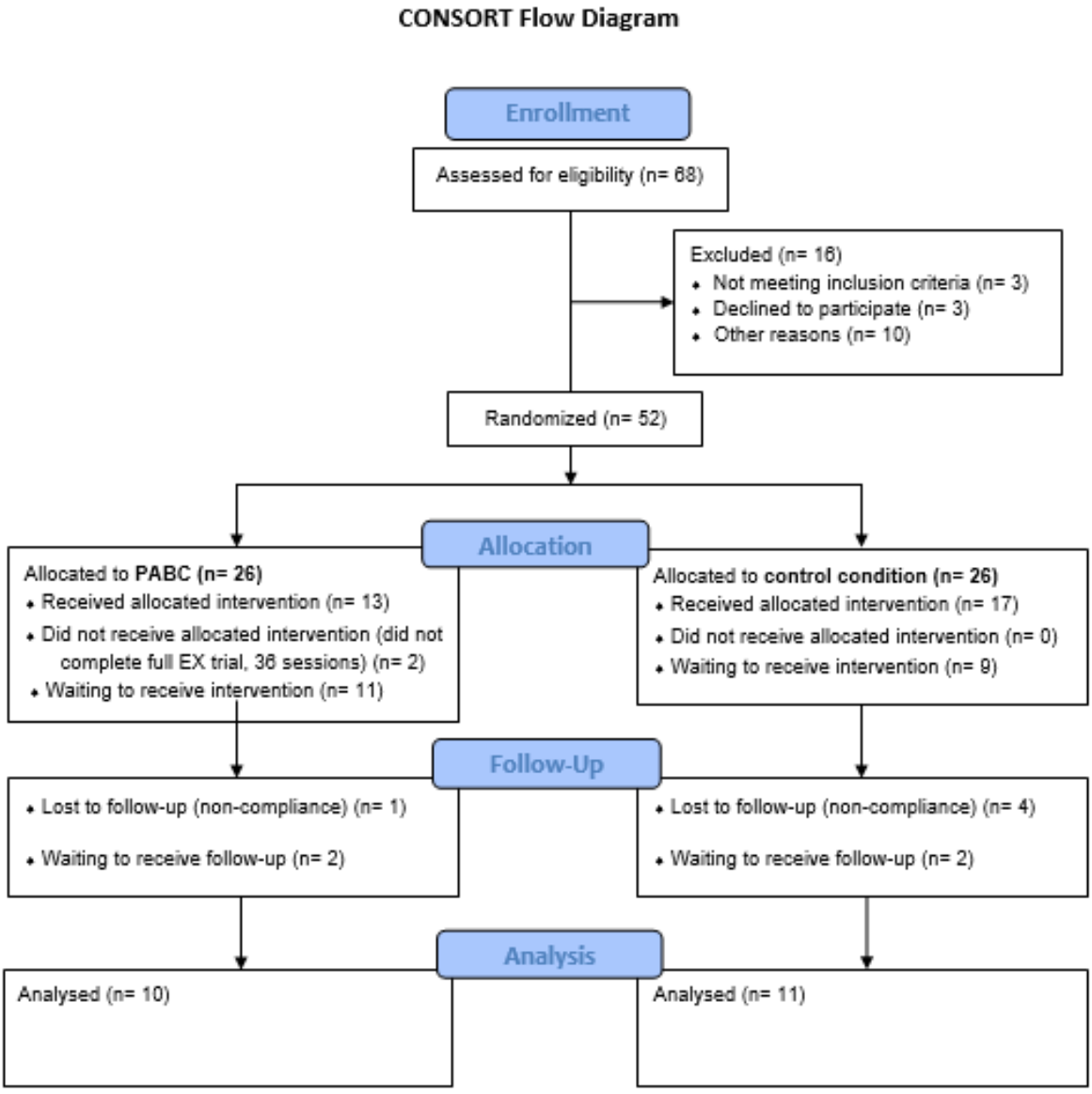
CONSORT Flow Diagram
Enrollment
Assessed for eligibility (n= 68)
Excluded (n= 16)
Not meeting inclusion criteria (n= 3)
Declined to participate (n= 3)
Other reasons (n= 10)
Randomized (n= 52)
Allocation
Allocated to PABC (n= 26)
Received allocated intervention (n= 13)
Did not receive allocated intervention (did not complete full EX trial, 36 sessions) (n= 2)
Waiting to receive intervention (n= 11)
Allocated to control condition (n= 26)
Received allocated intervention (n= 17)
Did not receive allocated intervention (n= 0)
Waiting to receive intervention (n= 9)
Follow-Up
Lost to follow-up (non-compliance) (n= 1)
Waiting to receive follow-up (n= 2)
Lost to follow-up (non-compliance) (n= 4)
Waiting to receive follow-up (n= 2)
Analysis
Analysed (n= 10)
Analysed (n= 11)

Figure 2

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APPENDICES

INFORMED CONSENT

Consent to Participate in a Research Study
Colorado State University

TITLE OF STUDY: Milk protein feeding after aerobic exercise in older adults with pre-diabetes taking the biguanide Metformin

PRINCIPAL INVESTIGATOR: Benjamin F. Miller PhD, Associate Professor, Department of Health and Exercise Science, Colorado State University. Benjamin.f.miller@colostate.edu, (970) 491-3291, and Karyn Hamilton, Associate Professor, Department of Health and Exercise Science, Colorado State University, Karyn.Hamilton@colostate.edu.

WHY AM I BEING INVITED TO TAKE PART IN THIS RESEARCH?
If you are over the age of 55 and have fasting glucose values ≥100 mg/dl, hemoglobin A1c ≥5.7 to <6.4%, impaired glucose tolerance (glucose 2 hours postprandial ≥140 to <200 mg/dl), or a family history of type 2 diabetes then we are interested in you taking part in this study. Males and females are invited to participate. Sixty participants will be selected to participate in this study.

WHO IS DOING THE STUDY? Drs. Miller and Hamilton are Associate Professors in the Department of Health and Exercise Science at CSU and are interested in using exercise and nutrition to combat the risk of developing Type 2 Diabetes with increasing age. Drs. Miller and Hamilton will be assisted by Post-doctoral researcher Dr. Adam Konopka and graduate students of the laboratory.

WHAT IS THE PURPOSE OF THIS STUDY?
As people age, they are at an increased risk of developing Type 2 Diabetes. The anti-diabetic drug Metformin and exercise are the standard treatments to prevent Type 2 Diabetes although there is evidence that Metformin may inhibit some of the positive effects of exercise. We are interested in testing how protein from dairy products could help restore the beneficial effect of exercise when taking Metformin.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?
The study will take place in the Department of Health and Exercise Science at Colorado State University and will last three years. Total time demand for each subject is estimated at 15 weeks that includes a 12-week, supervised exercise program and dietary intervention.

WHAT WILL I BE ASKED TO DO?
The time commitment in full is explained below for each group followed by detailed procedures.

You will be expected to:
Participate in an initial screening procedure that includes detailed review of the informed consent, physical activity and medical history questionnaire (approximately 45 min).
Complete an oral glucose tolerance test (approximately 2 hrs).
Perform an ECG during resting and exercise conditions (approximately 1 hr).
Measure body weight and composition via a dual x-ray absorptiometry (DEXA) scan, followed by providing a muscle sample (once before and once after the intervention) for a total of two muscle samples for the entire study (approximately 1 hr).
Consume labeled water during the last 4 weeks of the study (1 minute daily).
Participate in a 12-week exercise intervention (approximately 45 min/day, 3 days/week).
Consume a nutritional beverage (i.e, a smoothie) immediately after each exercise bout (<15 minutes).

Optionally complete questionnaires to measure sociodemographic information, physical activity, self-efficacy, planning, self-regulation and outcome expectancy of exercise, and perceptions of neighborhood support for physical activity and participate in physical activity behavior counseling (<1 hour)
After the 12-week exercise intervention, repeat the oral glucose tolerance test (2 hrs), DEXA scan, body weight measurement and an exercise ECG (approximately 1 hour) as well as complete the questionnaires and physical activity behavior counseling, if applicable.

Before undergoing the sampling procedures, you will be asked a few questions related to your past and present state of health, current medication and past medical history. This is to exclude the presence of any condition or medication that might prolong your bleeding time, make blood sampling unsafe for you or be contraindicated with exercise or the drug Metformin. Following this examination, we will place a hollow plastic tube (a venous catheter) into a vein in your arm or hand. The tube will remain in your vein for over 2 hours. In total, we will sample a small amount of blood (~ 100 ml or 7 tablespoons per test). The first sample will be used to inform us if your liver and kidneys are healthy. In addition, the first and subsequent samples will be used to determine how your body regulates blood glucose after an overnight fast and after consuming a sugary drink. This test is called an oral glucose tolerance test and is commonly done in research and medical settings. A small blood sample will also be taken after week 6 to monitor liver and kidney enzymes after six weeks of metformin and/or exercise.

If you meet the study criteria, you will also undergo cardiac screening in the presence of qualified personnel. This will involve the placement of 12 electrodes on your chest, which will be connected to an electrocardiogram (ECG). This will be done at rest and during a graded exercise test (stress test) performed on a stationary bicycle. A mouthpiece will also be used to collect the gas you are breathing during exercise. This test will measure your fitness levels and indicate whether you can safely perform the exercise intervention.

If anything adverse is found in any of the medical screening, you will be notified. A copy of your results will be available for you. You may wish to speak with your primary care physician to have the results explained to you. We will not share any information that may be used to identify you.

In the next visit, we will measure your body weight, height, and body composition by DEXA. Subsequently, a small (100-200mg, about the size of a pea) sample of muscle will be taken from one of your thighs. This will be done under a local anesthetic. A small (6-8mm or approximately 1/3 of an inch) cut will be made in your skin and another cut of the same size in your muscle. The muscle sample will be taken under sterile conditions and will be carried out by an experienced investigator (Dr. Benjamin Miller PhD, Dr. Matthew Hickey PhD, or Dr. Adam Konopka PhD) with medical oversight. Following this, pressure and ice will be applied, the incision will be secured by band-aids, then firmly bandaged with gauze. The biopsy procedure will not prevent you from performing any of your normal daily activities afterwards. After 12 hours you can remove the gauze, by three or four days the steri-strips will fall off, and the incision will heal normally like a cut. The resultant scar will gradually fade and be hardly noticeable. This visit will last about an hour.

You will be randomized to participate in 1 of 4 groups outlined in table 1 below. All groups will perform a 12-week exercise intervention. The exercise will be performed on a treadmill, stationary bicycle or elliptical for 45 minutes, 3 days per week. For the first 15 minutes, the desired exercise intensity will be 60% of your heart rate max and the next 30 minutes will progressively increase from 65 to 85% of heart rate max on a weekly basis. A trained member of the investigative team will supervise all exercise sessions by watching a heart rate monitor that you will wear during the exercise session. Immediately following each exercise bout, you will be asked to consume a ~300 calorie smoothie beverage that contains either 20 grams of protein plus carbohydrate (yogurt and fruit) or carbohydrate (fruit) only, although you will be blinded to which treatment you are assigned to.

In addition, you will be asked to consume capsule(s) consisting of either Metformin or placebo. During the first 4 weeks, the pill consumption is increased each week by 500 mg/day until a maximum dose of 2000 mg/day is reached, which is the standard therapeutic dose (see table 2). For participants with a body weight of ≤75kg, the maximum dose will be 1500 mg/day to decrease the risk of side effects. Increasing the dose slowly and consuming Metformin with food helps avoid gastrointestinal side effects.

Table 1. Outline of the four groups within this study.

Group	Exercise	Nutrition	Drug
Group 1	12-wks Exercise	Carbohydrate	Placebo
Group 2	12-wks Exercise	Protein	Placebo
Group 3	12-wks Exercise	Carbohydrate	Metformin
Group 4	12-wks Exercise	Protein	Metformin

Table 2. Dosing scheme for both metformin and placebo

Week	Daily Dose (mg)	Number of Pills With Meal
Week 1	500	1 pill with dinner
Week 2	1000	1 pill with breakfast and 1 pill with dinner
Week 3	1500	1 pill with breakfast and 2 pills with dinner
Week 4-12	2000	2 pills with breakfast and 2 pills with dinner

During the last 4 weeks of this 12-week exercise and nutritional intervention you will be asked to drink a small volume of labeled water daily. During study week 9, you will consume a small cup of water (50 ml) three times a week, and during weeks 10-12 you will consume a small cup of water (50 ml) twice a day. The glass of water you will consume contains what is called an isotope of water. The water we provide you has a label that makes the water heavier, but imperceptible to you. This label is present naturally, but we add it in a higher concentration in order to follow metabolic reactions in the body. You will not notice this label, nor will it change anything in your body. We can only locate it by special analysis procedures after sample collection.

You will be asked to recall and record your food intake from the day before your first glucose tolerance test and then repeat the same food intake the day before your second glucose tolerance test.

A second graded exercise test as well as a DEXA scan will be completed to measure any change in fitness and body composition, respectively.

Two to three days after the last exercise session, you will repeat the muscle biopsy procedure in which a small piece of muscle will be obtained from one of your thighs.

Participants will be given the option to participate in an additional study component to determine the impact of physical activity behavior counseling following exercise training on levels of physical activity 12 weeks after the intervention ends as well as identifying individual, socio-cultural and environmental determinants of physical activity three months after the end of the exercise intervention.

If subjects decide to participate, after completion of the 12-week exercise intervention, participants will be randomized to 1) receive one session of physical activity behavior counseling (PABC), or 2) no counseling control (CON). The counseling session will consist of strategies based on social-cognitive theory. Session activities will include 1) discussion of the benefits of physical activity, 2) discussion of evidence based recommendations for frequency, intensity, time and type of physical activity for reducing the risk of type 2 diabetes and associated co-morbidities, 3) setting individual physical activity goals, 4) identifying and discussing barriers and facilitators for physical activity, and 5) identifying strategies to overcome barriers.

Table 3 Timeline of Questionnaires and Counseling Session

	Baseline	Post Intervention	Post Behavior Counseling Session	3 Month Follow-Up
Sociodemographics	X			
Physical Activity (IPAQ)	X	X		X
Self-Efficacy (EXSE & BARSE)	X	X	X	X

Planning, Self-Regulation, and Expectancy	X	X	X	X
Neighborhood Support (NEWS)	X			

ARE THERE REASONS WHY I SHOULD NOT TAKE PART IN THIS STUDY?

You should not participate if you have or have had any problems with bleeding, lung, kidney or liver dysfunction, heart failure, Type 1 or overt Type 2 diabetes, be on medication that prolongs bleeding time, or medications known to alter metabolism.

You should not participate if you have had or are planning to have imaging that requires intravenous contrast dye (within 6 weeks) or are on any of the following medications since they are contraindicated with the use of Metformin: Dofetilide, Lamotrigine, Pegvisomant, Somatropin, Trimethoprim, Trospium, Gatifloxacin, Cephalexin, Cimetidine, Dalfampridine.

You should not participate if you have cancer or are in remission for < 5 years.

Because tobacco is known to affect the factors being investigated, you cannot participate if you use tobacco.

If you are allergic to dairy products (lactose intolerant), lidocaine, or Metformin you should not participate because these items will be administered during this study.

Any change in medication (prescription or over the counter) during the study needs to be immediately reported to the study team to ensure your safety.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

These procedures are all low risk in a healthy population.

There is a very small chance of an irregular heartbeat during exercise (< 1% of all subjects). Other rare risks of a stress test are heart attack (< 5 in 10,000) and death (<2 in 10,000). Wearing a mouthpiece and nose-clip during the graded exercise test can sometimes cause dryness in the mouth and mild discomfort.

You are likely to experience temporary physical discomfort during the blood sampling procedure, the possibility of bruising or fainting, and an extremely slight risk of infection. Discomfort during the blood sampling is minor and brief (<30s) and bruising will not last more than one week.

There is a small risk of infection at the site of the incision for the muscle biopsy, and a small risk of the biopsy incision reopening or bleeding after you leave the lab. The risk of allergic reaction to lidocaine (the anaesthetic used for the biopsy incision) is extremely low. There is also a risk of fainting or muscle cramp during the procedure, loss of feeling in the leg, damage to the skin (cutaneous) nerve and a risk of bruising around the biopsy site. You will have a small scar at the incision site. The rate and degree of healing varies considerably, but it is expected that scars will be difficult to see within 6-12 months after the procedure.

The risks associated with the DEXA are very low. The maximum radiation dose you will receive in this study is less than 1/1000th of the federal and state occupational whole body dose limit allowed to radiation workers (5,000 mrem). Put another way, the maximum dose from any scan we utilize with this DEXA ranges from 1.2 mrem (Whole body scan) to 12.2 mrem (for several of the regional scans, such as lumbar, femur, and forearm scans). The average annual background radiation you already receive is at least 620 mrem/year. The more radiation you receive over the course of your life, the more the risk increases of developing a fatal cancer or inducing changes in genes. The radiation in this scan is not expected to significantly increase these risks, but the exact increase in such risks is not known. There are no discomforts associated with this procedure.

In a small number of cases, transient dizziness may result from the initial consumption of the heavy water.

Metformin has the risk of causing several side effects, however, there are nearly 50 Million people in the US who use metformin on a daily basis to treat their diabetes and do not experience any side effects from Metformin use. You should be aware that metformin may cause lactic acidosis (a build-up of lactic acid in the body, that may be fatal). Lactic acidosis can start slowly and get worse over time and is more prevalent in those with liver or kidney disease or heart failure. Contact the study team and/or seek medical attention immediately if you have even mild symptoms of lactic acidosis, such as: muscle pain or weakness; numb or cold feeling in your arms and legs; trouble breathing; feeling dizzy, light-headed, tired, or very weak; stomach pain, nausea with vomiting; or slow or uneven heart rate. Call 911 or your doctor at once if you have any other serious side effects such as: feeling short of breath, even with mild exertion; swelling or rapid weight gain; or fever, chills, body aches, flu symptoms. Less serious side effects of metformin may include: headache or muscle pain; weakness; or mild nausea, vomiting, diarrhea, gas, stomach pain. It is

important to stay hydrated (drink lots of water) while taking metformin. This is not a complete list of side effects and others may occur. Although very rare metformin may cause low blood sugar which could be masked if you are taking beta-blockers to control blood pressure. Call your doctor or ask the researchers for advice about side effects. In the US, Metformin is also known as Fortamet / Glucophage / Glucophage XR / Glumetza / and, Riomet.

- Here is a list of possible side effects of Metformin collated into most likely, less likely, rarely, and rare but serious.

- Most Likely (greater than 20%): These symptoms are generally temporary, occur during the start of treatment, and disappear without stopping the drug.

•Diarrhea
•Nausea
•Vomiting
•Abdominal bloating
•Flatulence (gas)
•Anorexia (loss of appetite)

- Less likely [Occasional] (5 to 20%):
  - Loss of taste or metallic taste (during start of therapy)
  - Minor weight loss (less than 1 kilogram or 2 pounds)
  - Reduced appetite

- Rarely (1 to 4%): These effects will disappear when Metformin is stopped.
  - Rash, redness or itchiness
  - Decrease in the level of a vitamin in the blood (called B12) that does not cause symptoms
  - Decrease in the red blood cell count
- Liver function test abnormalities as seen by blood tests or hepatitis (inflammation of the liver)
- Anxiety and nervousness
- Depression

- Rare but Serious (less than 1%):

Lactic acidosis (a high acid level in the blood) occurs rarely (3 cases per 100,000 years of use) and can cause death. Individuals at risk of this complication include persons with diabetes who have kidney, liver or heart abnormalities. Symptoms of lactic acidosis may include tiredness, muscle aches, difficulty breathing, vomiting or severe abdominal pain.

- There are reproductive risks, as well, so women of child bearing potential should not become pregnant and men should not father a child.

- There are alcohol consumption risks: Participants should not drink excessive alcohol while taking the drug. There is a limit of less than 3 alcoholic beverages/day.

- It is not possible to identify all potential risks in research procedures, but the researcher(s) have taken reasonable safeguards to minimize any known and potential, but unknown, risks.

You may contact the investigators before and after working hours if you have medical concerns pertaining to study participation. Please first contact Adam Konopka at 507-602-2322 then if unable to reach Adam, please contact Benjamin Miller at 970-217-7906.

ARE THERE ANY BENEFITS FROM TAKING PART IN THIS STUDY?
Although there are no guaranteed benefits from participating in this study. Current clinical practice includes lifestyle modifications with or without the use of Metformin as the first line of care for preventing the progression to overt Type 2 Diabetes.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation in this research is voluntary. If you decide to participate in the study, you may withdraw your consent and stop participating at any time without penalty or loss of benefits to which you are otherwise entitled.

WHAT WILL IT COST ME TO PARTICIPATE?
It will not cost you any money to participate in the study. Any treatment or medical costs that arise as a result of your participation in this study are your responsibility.

WHO WILL SEE THE INFORMATION THAT I GIVE?
We will keep private all research records that identify you, to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

In the researchers' records you will be identified by a number. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. For example, your name will be kept separate from your research records and these two things will be stored in different places under lock and key. Your identity/record of receiving compensation (NOT your data) may be made available to CSU officials for financial audits. We may be asked to share the research files for audit purposes with the CSU Institutional Review Board ethics committee, if necessary, and the Food and Drug Administration (FDA). In addition, for funded studies, the CSU financial management team may also request an audit of research expenditures. For financial audits, only the fact that you participated would be shared, not any research data.
A description of this clinical trial will be available on http://www.ClincialTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

CAN MY TAKING PART IN THE STUDY END EARLY?
If you are not compliant with any aspect of the intervention, including the exercise training, or if you miss too many appointments, you will be removed from the study.

WILL I RECEIVE ANY COMPENSATION FOR TAKING PART IN THIS STUDY?
You will receive free heart screening, stress test, comprehensive blood panel, oral glucose tolerance test and DEXA scan. At the completion of the study you will receive $500 for your participation. If you do not complete the study, you will be compensated $20 for each oral glucose tolerance test completed and $50 for each muscle sample obtained.

WHAT HAPPENS IF I AM INJURED BECAUSE OF THE RESEARCH?
We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care. The Colorado Governmental Immunity Act determines and may limit Colorado State University's legal responsibility if an injury happens because of this study. Claims against the University must be filed within 180 days of the injury.

WHAT IF I HAVE QUESTIONS?
Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions about the study, you can contact our laboratory at 970-491-7913, Dr. Adam Konopka at 970-491-7193 or Dr. Benjamin Miller at 970-491-3291. If you have any questions about your rights as a volunteer in this research, contact the CSU IRB at: RICRO_IRB@mail.colostate.edu; 970-491-1553. We will give you a copy of this consent form.

If you are interested in participating in the additional study component please check the box below. You may still participate in this study if you do not wish to complete this additional study component.

☐ Wear a continuous glucose monitor (CGM) for 10 consecutive days at three different time points (before, during, and after intervention for a total of 30 days) to measure and record your glucose values every 5 minutes during those 10 day blocks of time.

☐ Complete questionnaires to measure sociodemographic information, physical activity, self-efficacy, planning, self-regulation and outcome expectancy of exercise, and perceptions of neighborhood support for physical activity and participate in physical activity behavior counseling.

Your signature acknowledges that you have read the information stated and willingly sign this consent form. Your signature also acknowledges that you have received, on the date signed, a copy of this document containing 7 pages.

_____ _____

Signature of person agreeing to take part in the study Date

_____

Printed name of person agreeing to take part in the study

_____ _____

Name of person providing information to participant Date

_____

Signature of Research Staff

EDUCATION PACKET

Physical Activity Information for Individuals with or at Risk of Developing Type II Diabetes

Contents:

Physical Activity and Exercise Principles

Goal Setting

Social Support

Barriers and Relapse Prevention

BENEFITS OF PHYSICAL ACTIVITY

Meet new friends
Improve self-esteem
Improved psychological well-being
Achieve a healthy body weight
Build strong bones and muscles
Maintain flexibility
Promote good posture and balance
Improve fitness and health
Strengthen the heart
Relaxation and reduce stress
Promote healthy growth and development

What is the most important benefit to you?

_____

BENEFITS OF PHYSICAL ACTIVITY FOR INDIVIDUALS WITH TYPE II DIABETES

Psychological and Emotional Benefits
Improved mood
Improved self-esteem
General satisfaction with life
Increased ability to manage stress

Physical Benefits
Improved glucose and A1C control
Weight management
Improved circulation for neuropathy
Lowers risk of developing heart disease
Increased insulin sensitivity

What is the most important benefit to you?

_____

The importance of physical activity in preventing and managing Type 2 Diabetes

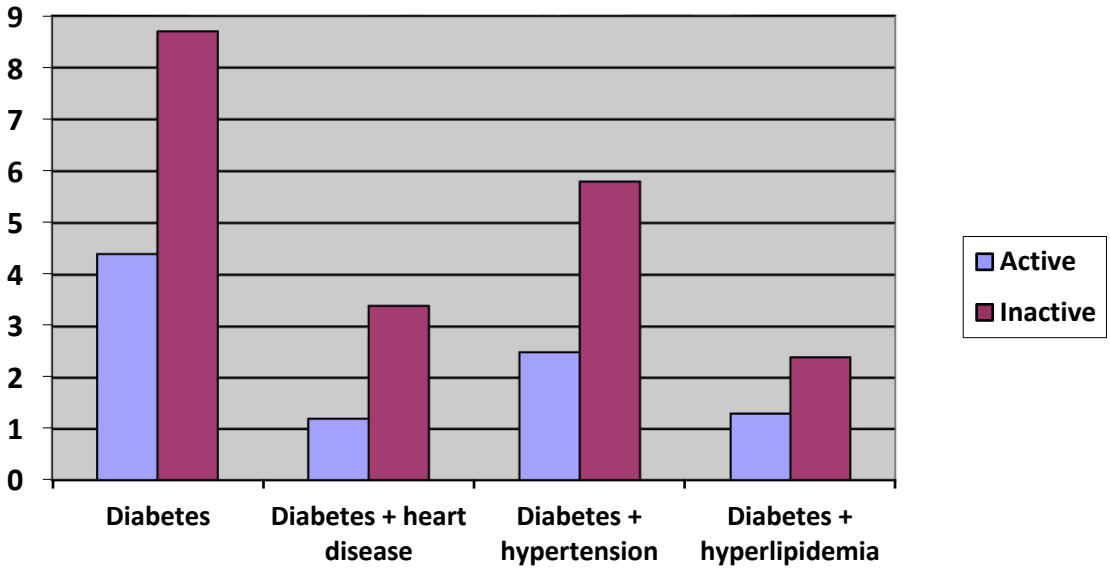
Regular physical activity and a healthy diet are used as primary prevention for those at risk of developing diabetes (Gulve, 2008).

Physical activity can aid in weight loss maintenance as well as improved glucose tolerance, increased insulin sensitivity and decreased HbA1C (ACSM, 2010).

Aerobic exercise helps lower the risk of developing cardiovascular disease, a significant common danger for those with Type II Diabetes (Gulve, 2008).

Performing aerobic exercise in water provides an excellent alternative for individuals with neuropathy where high impact exercise such as running is difficult (Delevatti et al 2015).

The prevalence of comorbidities in individuals with Type 2 Diabetes is higher among those who are inactive



***Adapted from Sullivan et al., 2005**

Education Session: Physical Activity and Exercise Principles

Physical Activity: Activity that is part of daily living. Examples include: workplace, household and lifestyle physical activity.

Exercise: Planned and structured physical activity that is done to improve at least one aspect of physical fitness.

HEALTH-RELATED PHYSICAL FITNESS

The components of health-related physical fitness include:

Cardiorespiratory Fitness

- Ability to perform activities for extended periods of time
- Ability of the heart, lungs and circulatory system to deliver oxygen to the working tissues
- Cardiorespiratory fitness is associated with reduced risk of high blood pressure, obesity and coronary heart disease

Muscular Strength

- Ability to exert force for a brief period of time

Muscular Endurance

- Ability to perform repetitive muscular contractions against some resistance

Flexibility

- Ability to move the joint and use your muscles throughout their full range of motion

Body Composition

- Lean mass, bone mass, organ mass and fat mass
- Obesity (Body Mass Index > 30.0) is a major risk factor for
    - diabetes
    - high blood pressure
    - some forms of cancer
    - gall bladder disease
    - musculoskeletal problems
    - atherosclerosis (fatty deposits in your arteries)

Notes:

The FITT Principle

- **Frequency:** How often you exercise
  Example: 3 times / week

- **Intensity:** How hard you work during exercise
  Example: 4/10 on the Rating of Perceived Exertion Scale

- **Time:** How long you exercise
  Example: I exercised for 30 minutes

- **Type:** What type of activity
  Example: Cycling

Other Exercise Principles:

- **Overload:** A greater than normal stress on the body is required for physical adaptation to take place.

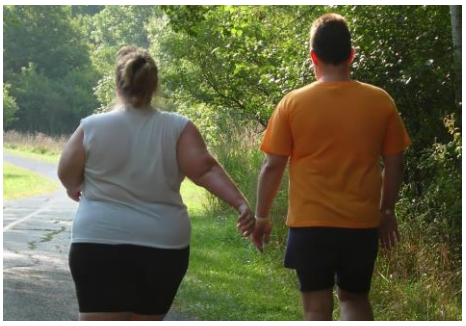
- **Progression:** Overload needs to be progressively increased, and there is an optimal level of overload that should be applied

- **Specificity:** Training to match your goals. To become better at a certain skill, you must practice that skill.
- **Adaptation:** The body's ability to adapt to the increase or decrease in physical demands.

- **Reversibility: '**Use it or Lose it'. Muscles increase in size and strength with use, and decrease in size and strength with disuse.

- **Rest and Recovery:** To properly adapt, your body must rest and recover.

Exercise helps prevent the development of Type II Diabetes



Notes:

Education Session: Goal Setting

Goal setting is an excellent first step toward improving your health and staying motivated to be physically active. Setting goals will help you track your progress. First set a long-term goal. This is the big goal you want to achieve by the end of the 12 week exercise program. Then set short-term goals; those that you want to achieve in several weeks that will help you reach your long-term goal. Below is a helpful guideline for setting SMART Goals:

Specific

Measurable

Attainable

Realistic and Relevant

Time-Oriented

Below is space for you to record three goals for the next 3 months.

Goal #1:

_____
_____
_____
_____

Goal #2:

_____
_____
_____
_____

Goal #3:

_____
_____
_____
_____

Below is space for you to record your physical activity plan based on the FITT Principle.

FITT Goal # 1 (Short-term) **FITT Goal # 2 (Long-term)**

How I Will Reward Myself for Achieving My Goals:

Signature: **Date:**

S.M.A.R.T. Goals to Make a Change:

A goal should provide guidance and direction. Goals like 'lose weight', 'eat better', or 'have less stress' are far too vague and unspecific to help much in making change. Use the S.M.A.R.T. criteria to help put more detail into your goal. Spending some time creating effective goals will be a huge help later on.

S - Specific:

- You must state your goal as specifically as possible.
- Try to put as much decision work into your goal now.
- Set the goal "lose 20 pounds" instead of "lose weight".
- But you can do even better. Try "Lose 20 pounds by increasing my exercise to 4 times a week and reducing sugar and portion size".
- Have your goal be like an instruction telling you what to do.

M - Measurable:

- You need to have a way to measure progress.
- Progress will feel good and measuring will keep you from cheating. The goal "lose 20 pounds" can be measured by a scale.
- Produce evidence for your progress. If your goal is to "reduce stress" create a stress measure for yourself like the number of times you get upset every day.
- Keep a log and record each stressful reaction.

A - Attainable:

- Your goal should be meaningful to you. It should be set by you, not someone else.
- The goal should be inspiring enough that it motivates you to success. If you are not determined to meet your goal, obstacles will be very difficult to overcome.
- If your doctor says, "lose weight" and your wife says, "lose weight" but you are not inspired by this, find another goal that also improves your health while you try to find a way to become inspired about weight loss.

R - Realistic:

- Goals should be ambitious, but not impossible.
- Do not set yourself up for failure.
- Choose a goal that you are confident you can reach, but that will stretch yourself also.
- Break large goals into smaller goals.
- Create a plan to do all the steps you need.

T – Time Based:

- When will you finish your goal?
- You need to choose a time, the sooner the better.
- Saying "I will lose 20 pounds in 3 months" is good, but saying "I will lose an average of 2 pounds every week for 10 weeks" is better.

Write your goal:

Now really think about your goal. Finish the following sentence, write it down and put it somewhere you can see it. I will [your goal here] by [how you will do the goal]. I will know I am making progress because [how you will measure the goal] [time goes here].

For example: I will lose 20 pounds by increasing my exercise to 4 times a week and cutting back on sugar and portion size. I will know I am making progress because I will lose 2 pounds a week for ten weeks.

Now evaluate your goal – is it **Specific, Measurable, Attainable, Realistic, and Time-Based**? Good. Now go do it!

TOP 10 STRATEGIES FOR SUCCESS

Use These Ideas to Meet Your Goals

1. Start Small

Quite possibly the biggest mistake people make is pushing the accelerator too soon. You can't lose 20 pounds in a week. But you can lose one. Taking small bites and chewing slowly have as much to do with goal achievement as they do with your mom's dinner table scolding.

2. Get It On Paper

Whether setting your first goals, tracking daily progress, or sharing your deepest thoughts with a journal, writing things down crystallizes your ideas, exposes underlying fears, and paints an accurate picture of real life.

3. Focus On Everyday Habits

The building blocks of a healthy lifestyle are forged in the smallest of actions you take every day and every week. Healthy choices can become as natural as brushing your teeth or locking the front door. Build one habit, one action at a time.

4. Always See Your Goal

Goals need attention. They need to be seen and heard and thought of often if they ever hope to come true. So surround yourself with as many reminders as possible.

5. Be Consistent

Imagine a plane taking off. In the beginning, a lot of energy is spent to simply get moving down the runway. But as speed and momentum take over, the plane is pulled forward and up into the sky, faster and further by the second. Consistent action, no matter how small, has more power than you ever imagined.

6. Never Stop Learning

A healthy lifestyle is a process—a journey more than a destination. You can always learn more about nutrition, fitness, and even yourself that can help you be just a little bit better tomorrow.

7. Come Out of Seclusion

Has anyone ever achieved anything of real value all alone? Probably not many. Most receive some form of help from other people. Support, information, a sense of shared experience, encouragement, advice, and a well-timed pep talk are all invaluable as you set off on your adventure.

8. Allow For Setbacks

Accept the fact right now that you will make mistakes, *and* that it can be a positive thing. We are usually harder on ourselves that we are on anyone else we know. Be your own #1 fan. That means being supportive (instead of critical) when you stumble, and enjoying your wins (rather than ignoring your accomplishments) when you succeed.

9. Trust Your Plan

You'll have up weeks and down weeks, and frustrating weeks that make no sense at all. The tools and strategies you're learning will help you build a plan that makes a healthier lifestyle almost inevitable. If you consistently make the right choices and build healthy habits, weight loss is literally just a matter of time.

10. Have Fun!!!

Who says getting healthy has to be a chore, a burden to be endured or suffered through? Probably a very unhappy person, that's who. This is an exciting adventure of self-discovery and building a meaningful life. Enjoy the ride!

Information taken from www.sparkpeople.com

Education Session: Social Support and Relapse Prevention

SOCIAL SUPPORT

Social support is an important ingredient in the behavioral change process. You are more likely to be successful if your friends, family, and co-workers are supportive than if they are indifferent to or actively oppose your efforts towards change.

Think about the following questions:

- ***Who do you feel is providing you with social support?***

- ***What "kinds" of social support do they provide?***

- ***How do your supporters help/support you?***

- ***Who are your exercise/physical activity role models?***

- ***How could you improve your support system?***

BARRIERS AND PHYSICAL ACTIVITY RELAPSE PREVENTION

Lapsing is something all of us have to deal with:
Other demands (family/work), illness, vacation can result in "missed" exercise sessions.
Acknowledging it will happen is important.
It allows you to devise strategies to then deal with it and avoid full-blown relapses!

However, there are also all kinds of reasons why we're less active than we should be.
These 'reasons' or 'barriers' can also be called ***excuses***
but real or imagined, they may serve as obstacles to a more active lifestyle.

Identify some potential barriers to your goals:

Potential Barriers:

1.

2.

3.

Complete the following exercise to identify more possible barriers:

Potential Barriers	NO Barrier									Major Barrier	
Previous negative experience with physical activity	1	2	3	4	5	6	7	8	9	10	N/A
Lack of time	1	2	3	4	5	6	7	8	9	10	N/A
Cost of activity	1	2	3	4	5	6	7	8	9	10	N/A
Lack of energy	1	2	3	4	5	6	7	8	9	10	N/A
Lack of knowledge	1	2	3	4	5	6	7	8	9	10	N/A
Lack of skills	1	2	3	4	5	6	7	8	9	10	N/A
I feel uncomfortable or intimidated when exercising	1	2	3	4	5	6	7	8	9	10	N/A
I can't reach my exercise goals, so why bother	1	2	3	4	5	6	7	8	9	10	N/A
I wasn't successful in previous attempts to be active	1	2	3	4	5	6	7	8	9	10	N/A
Fear of injury	1	2	3	4	5	6	7	8	9	10	N/A
Breathlessness	1	2	3	4	5	6	7	8	9	10	N/A
Fear of making an existing injury worse	1	2	3	4	5	6	7	8	9	10	N/A
How I see my body	1	2	3	4	5	6	7	8	9	10	N/A
Lack of safe places	1	2	3	4	5	6	7	8	9	10	N/A
Lack of child care	1	2	3	4	5	6	7	8	9	10	N/A
Lack of ability (to make it worthwhile)	1	2	3	4	5	6	7	8	9	10	N/A
Lack of exercise partner	1	2	3	4	5	6	7	8	9	10	N/A
Lack of available/suitable programs at my level	1	2	3	4	5	6	7	8	9	10	N/A
Lack of support from others	1	2	3	4	5	6	7	8	9	10	N/A
Lack of transportation	1	2	3	4	5	6	7	8	9	10	N/A
Other areas of my life take priority	1	2	3	4	5	6	7	8	9	10	N/A

The excuses people most often name are as follows:

- ☒ **Lack of time**
- ☒ **Lack of self-confidence**
- ☒ **Lack of a partner**
- ☒ **Lack of ability**

Were any of these on your list???

- ***What are your thoughts and beliefs about your top three?***

- ***How you would prevent each of the barriers you identified, OR the ones you listed as a '7' or higher, from becoming an obstacle for you? How will you overcome these barrier and prevent relapse?***

1.

2.

3.

Other strategies:

- ***In the past, what has helped you get back on track?***

Additional Resources

Making a lifestyle change can be difficult and we are here to help! If you want additional information on local programs that can assist you in making this change please take a look at these resources.

Fitness Programs:

Adult Fitness Program, CSU:

http://www.hes.chhs.colostate.edu/outreach/adultfitness/
(970) 491-0928

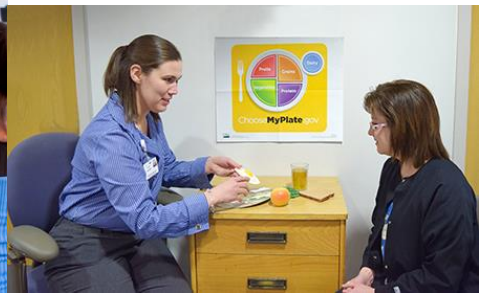
Group Fitness Classes, Miramont Lifestyle Fitness:

http://miramontlifestyle.com/group-fitness/
(970) 225-2233 (Central Location)

Dietary Assistance:

Kendall Anderson Nutrition Center, CSU:

http://www.nutritioncenter.chhs.colostate.edu/programs-services/diabetes.aspx
(970) 491-8615



References

Thompson, W. R., Gordon, N. F., & Pescatello, L. S. (2010). *ACSM's guidelines for exercise testing and prescription* (8th ed.). Philadelphia, PA: Lippincott Williams & Wilkins.

Delevatti, R. S., Kanitz, A. C., Alberton, C. L., Marson, E. C., Lisboa, S. C., Pinho, C. D., . . . Kruel, L. F. (2015). Glucose control can be similarly improved after aquatic or dry-land aerobic training in patients with type 2 diabetes: A randomized clinical trial. *Journal of Science and Medicine in Sport, 15*.

Gulve, E. A. (2008). Exercise and Glycemic Control in Diabetes: Benefits, Challenges, and Adjustments to Pharmacotherapy. *Physical Therapy, 88*(11), 1297-1321.

Sullivan, P. W., Morrato, E. H., Ghushchyan, V., Wyatt, H. R., & Hill, J. O. (2005). Obesity, Inactivity, and the Prevalence of Diabetes and Diabetes-Related Cardiovascular Comorbidities in the U.S., 2000-2002. *Diabetes Care, 28*(7), 1599-1603.

ID:_____
DATE:_____

SOCIODEMOGRAPHIC QUESTIONNAIRE

ETHNICITY ORGIN (OR RACE)

1. Please specify your ethnicity *(Check one box)*

   a. White ..... 1☐
   b. Hispanic or Latino ..... 2☐
   c. Black or African American ..... 3☐
   d. Native American or American Indian..... 4☐
   e. Asian/Pacific Islander..... 5☐
   f. Other..... 6☐

EDUCATION

2. What is the highest level of education you have completed? *(Check one box)*

   a. 12th grade or less ..... 1☐
   b. High school graduate or GED ..... 2☐
   c. Some college/AA degree/Technical school training ..... 3☐
   d. College graduate (BA or BS) ..... 4☐
   e. Graduate school degree: Master's or Doctorate degree (MD, PhD, JD) ..... 5☐

WORK STATUS

3. Check the box that best corresponds to your current work situation.
   (Check "Yes" or "No" for each question.)

	Yes	No
a. Working full time	1☐	2☐
b. Working part time	1☐	2☐
c. Not working and not looking for work	1☐	2☐
d. Unemployed and looking for work	1☐	2☐
e. Disabled or retired and not looking for work	1☐	2☐
f. Currently in school	1☐	2☐

INCOME

4. What is your total combined family income for the past 12 months, before taxes, from all sources, wages, public assistance/benefits, help from relatives, alimony, and so on?

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE (August 2002)

SHORT LAST 7 DAYS SELF-ADMINISTERED FORMAT

FOR USE WITH YOUNG AND MIDDLE-AGED ADULTS (15-69 years)

The International Physical Activity Questionnaires (IPAQ) comprises a set of 4 questionnaires. Long (5 activity domains asked independently) and short (4 generic items) versions for use by either telephone or self-administered methods are available. The purpose of the questionnaires is to provide common instruments that can be used to obtain internationally comparable data on health–related physical activity.

Background on IPAQ

The development of an international measure for physical activity commenced in Geneva in 1998 and was followed by extensive reliability and validity testing undertaken across 12 countries (14 sites) during 2000. The final results suggest that these measures have acceptable measurement properties for use in many settings and in different languages, and are suitable for national population-based prevalence studies of participation in physical activity.

Using IPAQ

Use of the IPAQ instruments for monitoring and research purposes is encouraged. It is recommended that no changes be made to the order or wording of the questions as this will affect the psychometric properties of the instruments.

Translation from English and Cultural Adaptation

Translation from English is supported to facilitate worldwide use of IPAQ. Information on the availability of IPAQ in different languages can be obtained at www.ipaq.ki.se. If a new translation is undertaken we highly recommend using the prescribed back translation methods available on the IPAQ website. If possible please consider making your translated version of IPAQ available to others by contributing it to the IPAQ website. Further details on translation and cultural adaptation can be downloaded from the website.

Further Developments of IPAQ

International collaboration on IPAQ is on-going and an ***International Physical Activity Prevalence Study*** is in progress. For further information see the IPAQ website.

More Information

More detailed information on the IPAQ process and the research methods used in the development of IPAQ instruments is available at www.ipaq.ki.se and Booth, M.L. (2000). *Assessment of Physical Activity: An International Perspective*. Research Quarterly for Exercise and Sport, 71 (2): s114-20. Other scientific publications and presentations on the use of IPAQ are summarized on the website.

ID:_____
DATE:_____
TIMPOINT:_____

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

   _____ **days per week**

   ☐ No vigorous physical activities → ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

   _____ **hours per day**

   _____ **minutes per day**

   ☐ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

   _____ **days per week**

   ☐ No moderate physical activities → ***Skip to question 5***

SHORT LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised August 2002.

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

☐ No walking → ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

This is the end of the questionnaire, thank you for participating.

SHORT LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised August 2002.

EXSE QUESTIONNAIRE

ID:_____
DATE:_____
TIMEPOINT: BASELINE

Exercise Self-efficacy

The items listed below are designed to assess your beliefs in your ability to exercise on a three time per week basis at moderate intensities (upper end of your perceived exertion range), for 40+ minutes per session in the future. Using the scales listed below please indicate how confident you are that you will be able to exercise.

For example, if you have complete confidence that you could exercise three times per week at moderate intensity for 40+ minutes for the next four weeks without quitting, you would **circle 100%**. However, if you had no confidence at all that you could exercise at your exercise prescription for the next four weeks without quitting, (that is, confident you would not exercise), you would **circle 0%**.

Please remember to answer honestly and accurately. There are no right or wrong answers.
Mark your answer by circling a %:

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — HIGHLY CONFIDENT

---

1. I am able to exercise three times per week at moderate intensity, for 40+ minutes without quitting for the NEXT WEEK

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

2. I am able to exercise three times per week at moderate intensity, for 40+ minutes without quitting for the NEXT TWO WEEKS

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

3. I am able to exercise three times per week at moderate intensity, for 40+ minutes without quitting for the NEXT THREE WEEKS

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

4. I am able to exercise three times per week at moderate intensity, for 40+ minutes without quitting for the NEXT FOUR WEEKS

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Please remember to answer honestly and accurately. There are no right or wrong answers.
Mark your answer by circling a %:

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

NOT AT ALL CONFIDENT — MODERATELY CONFIDENT — HIGHLY CONFIDENT

---

5. I am able to exercise three times per week at moderate intensity, for 40+ minutes without quitting for the NEXT FIVE WEEKS

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

6. I am able to exercise three times per week at moderate intensity, for 40+ minutes without quitting for the NEXT SIX WEEKS

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Mark your answer by circling a %:

7. I am able to exercise three times per week at moderate intensity, for 40+ minutes without quitting for the NEXT SEVEN WEEKS

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

8. I am able to exercise three times per week at moderate intensity, for 40+ minutes without quitting for the NEXT EIGHT WEEKS

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

****

"Self-efficacy Scale for 40 minutes" : Sum all items and divide by 8

McAuley, E. (1993). Self-efficacy and the maintenance of exercise participation in older adults. *Journal of Behavioral Medicine, 16*, 103-113.

BARSE QUESTIONNAIRE

BARRIERS SELF-EFFICACY

ID:_____
DATE:_____
TIMEPOINT:_____

The following items reflect situations that are listed as common reasons for preventing individuals from participating in exercise sessions or, in some cases, dropping out. Using the scales below please indicate how confident you are that you could exercise in the event that any of the following circumstances were to occur.

Please indicate the degree to which you are confident that you could exercise in the event that any of the following circumstances were to occur by circling the appropriate %. Select the response that most closely matches your own, remembering that there are no right or wrong answers.

FOR EXAMPLE:

In question #1 if you have complete confidence that you could exercise even if "the weather was very bad," you would circle 100%. If however, you had no confidence at all that you could exercise (that is, confidence you would not exercise), you would circle 0%.

0	10	20	30	40	50	60	70	80	90	100
Not at all Confident					Moderately Confident					Highly Confident

I believe that I could exercise 3 times per week for the next 3 months if:

1. The weather was very bad (hot, humid, rainy, cold).

0	10	20	30	40	50	60	70	80	90	100
Not at all Confident					Moderately Confident					Highly Confident

2. I was bored by the program or activity.

0	10	20	30	40	50	60	70	80	90	100
Not at all Confident					Moderately Confident					Highly Confident

3. I was on vacation.

0	10	20	30	40	50	60	70	80	90	100
Not at all Confident					Moderately Confident					Highly Confident

4. I was not interested in the activity.

0	10	20	30	40	50	60	70	80	90	100
Not at all Confident					Moderately Confident					Highly Confident

5. I felt pain or discomfort when exercising.

0	10	20	30	40	50	60	70	80	90	100
Not at all Confident					Moderately Confident					Highly Confident

I believe that I could exercise 3 times per week for the next 3 months if:

6.	I had to exercise alone.										
	0	10	20	30	40	50	60	70	80	90	100
	Not at all Confident					Moderately Confident					Highly Confident
7.	It was not fun or enjoyable.										
	0	10	20	30	40	50	60	70	80	90	100
	Not at all Confident					Moderately Confident					Highly Confident
8.	It became difficult to get to the exercise location.										
	0	10	20	30	40	50	60	70	80	90	100
	Not at all Confident					Moderately Confident					Highly Confident
9.	I didn't like the particular activity program that I was involved in.										
	0	10	20	30	40	50	60	70	80	90	100
	Not at all Confident					Moderately Confident					Highly Confident
10.	My schedule conflicted with my exercise session.										
	0	10	20	30	40	50	60	70	80	90	100
	Not at all Confident					Moderately Confident					Highly Confident
11.	I felt self-conscious about my appearance when I exercised.										
	0	10	20	30	40	50	60	70	80	90	100
	Not at all Confident					Moderately Confident					Highly Confident
12.	An instructor does not offer me any encouragement.										
	0	10	20	30	40	50	60	70	80	90	100
	Not at all Confident					Moderately Confident					Highly Confident
13.	I was under personal stress of some kind.										
	0	10	20	30	40	50	60	70	80	90	100
	Not at all Confident					Moderately Confident					Highly Confident

SOCIAL SUPPORT AND EXERCISE SURVEY

Below is a list of things people might do or say to someone who is trying to exercise regularly. If you are not trying to exercise, then some of the questions may not apply to you, but please read and give an answer to every question.

Please rate each question *twice*. Under *family*, rate how often anyone living in your household has said or done what is described during the last three months. Under *friends*, rate how often your friends, acquaintances, or coworkers have said or done what is described during the last three months.

Please write *one* number from the following rating scale in each space:

none	rarely	a few times	often	very often	does not apply
1	2	3	4	5	8

During the past three months, my family (or members of my household) or friends:

	Family	Friends
11. Exercised with me.	11.	11.
12. Offered to exercise with me.	12.	12.
13. Gave me helpful reminders to exercise ("Are you going to exercise tonight?").	13.	13.
14. Gave me encouragement. to stick with my exercise program.	14.	14.
15. Changed their schedule so we could exercise together.	15.	15.
16. Discussed exercise with me.	16.	16.
17. Complained about the time I spend exercising.	17.	17.
18. Criticized me or made fun of me for exercising.	18.	18.
19. Gave me rewards for exercising (bought me something or gave me something I like).	19.	19.
20. Planned for exercise on recreational outings.	20.	20.
21. Helped plan activities around my exercise.	21.	21.
22. Asked me for ideas on how *they* can get more exercise.	22.	22.
23. Talked about how much they like to exercise.	23.	23.

Office Use Only

☐1. English ☐ 2. Spanish Date: Entered ☐☐/☐☐/☐☐ Coder: ☐☐

September 26, 1986

ID #_____
DATE:_____

Neighborhood Environment Walkability Scale (NEWS) - Abbreviated

We would like to find out more information about the way that you perceive or think about your neighborhood. Please answer the following questions about your neighborhood and yourself.

A. Types of residences in your neighborhood

Please circle the answer that best applies to you and your neighborhood.

1. How common are detached single-family residences in your immediate neighborhood?

1	2	3	4	5
None	A few	Some	Most	All

2. How common are townhouses or row houses of 1-3 stories in your immediate neighborhood?

1	2	3	4	5
None	A few	Some	Most	All

3. How common are apartments or condos 1-3 stories in your immediate neighborhood?

1	2	3	4	5
None	A few	Some	Most	All

4. How common are apartments or condos 4-6 stories in your immediate neighborhood?

1	2	3	4	5
None	A few	Some	Most	All

5. How common are apartments or condos 7-12 stories in your immediate neighborhood?

1	2	3	4	5
None	A few	Some	Most	All

6. How common are apartments or condos more than 13 stories in your immediate neighborhood?

1	2	3	4	5
None	A few	Some	Most	All

1

B. Stores, facilities, and other things in your neighborhood

About how long would it take to get from your home to the nearest businesses or facilities listed below if you walked to them? Please put only one check mark (√) for each business or facility.

	1-5 min	6-10 min	11-20 min	20-30 min	30+ min	don't know
example: gas station	1. ____	2. ____	3. √	4. ____	5. ____	8. ____
1. convenience/small grocery store	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
2. supermarket	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
3. hardware store	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
4. fruit/vegetable market	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
5. laundry/dry cleaners	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
6. clothing store	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
7. post office	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
8. library	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
9. elementary school	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
10. other schools	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
11. book store	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
12. fast food restaurant	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
13. coffee place	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
14. bank/credit union	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
15. non-fast food restaurant	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
16. video store	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
17. pharmacy/drug store	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
18. salon/barber shop	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
19. your job or school	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____

[check here _____ if not applicable]

	1-5 min	6-10 min	11-20 min	20-30 min	30+ min	don't know
20. bus or train stop	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
21. park	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
22. recreation center	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____
23. gym or fitness facility	1. ____	2. ____	3. ____	4. ____	5. ____	8. ____

C. Access to services

Please circle the answer that best applies to you and your neighborhood. Both local and within walking distance mean within a 10-15 minute walk from your home.

1. Stores are within easy walking distance of my home.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

2. There are many places to go within easy walking distance of my home.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

3. It is easy to walk to a transit stop (bus, train) from my home.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

D. Streets in my neighborhood

Please circle the answer that best applies to you and your neighborhood.

1. The distance between intersections in my neighborhood is usually short (100 yards or less; the length of a football field or less).

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

2. There are many alternative routes for getting from place to place in my neighborhood. (I don't have to go the same way every time.)

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

You're making great progress……keep it up!

E. Places for walking and cycling

Please circle the answer that best applies to you and your neighborhood.

1. There are sidewalks on most of the streets in my neighborhood.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

2. Sidewalks are separated from the road/traffic in my neighborhood by parked cars.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

3. There is a grass/dirt strip that separates the streets from the sidewalks in my neighborhood.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

4. My neighborhood streets are well lit at night.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

5. Walkers and bikers on the streets in my neighborhood can be easily seen by people in their homes.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

6. There are crosswalks and pedestrian signals to help walkers cross busy streets in my neighborhood.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

F. Neighborhood surroundings/aesthetics

Please circle the answer that best applies to you and your neighborhood.

1. There are trees along the streets in my neighborhood.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

2. There are many interesting things to look at while walking in my neighborhood.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

3. There are many attractive natural sights in my neighborhood (such as landscaping, views).

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

4. There are attractive buildings/homes in my neighborhood.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

G. Traffic hazards

Please circle the answer that best applies to you and your neighborhood.

1. There is so much traffic along nearby streets that it makes it difficult or unpleasant to walk in my neighborhood.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

2. The speed of traffic on most nearby streets is usually slow (30 mph or less).

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

3. Most drivers exceed the posted speed limits while driving in my neighborhood.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

H. Crime

1. There is a high crime rate in my neighborhood.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

2. The crime rate in my neighborhood makes it unsafe to go on walks during the day.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

3. The crime rate in my neighborhood makes it unsafe to go on walks at night.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

Single items that did not load on other factors

Parking is difficult in local shopping areas.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

The streets in my neighborhood do not have many cul-de-sacs (dead-end streets).

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

The streets in my neighborhood are hilly, making my neighborhood difficult to walk in.

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree

There are major barriers to walking in my local area that make it hard to get from place to place (for example, freeways, railway lines, rivers).

1	2	3	4
strongly disagree	somewhat disagree	somewhat agree	strongly agree