CHANGE IN PHYSICAL ACTIVITY LEVELS AND PREDICTORS OF SUCCESS IN DPP-BASED COMMUNITY LIFESTYLE INTERVENTION EFFORTS

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ABSTRACT

INTRODUCTION: Efficacy trials, including the U.S. Diabetes Prevention Program (DPP), demonstrated that lifestyle interventions focusing on increased physical activity (PA) and modest weight loss (WL) can prevent or delay the onset of type 2 diabetes and reduce cardiovascular disease risk. Based upon knowledge gained from these trials, the DPP lifestyle intervention has been modified for delivery in community settings using the DPP goals of 150 minutes moderate PA per week and 7% WL. Intervention impact on weight change has been frequently described, but reporting of program success related to PA is limited, creating gaps in knowledge regarding the effectiveness of intervention for increasing PA level and on the participant socio-demographic characteristics or external factors, such as season, associated with PA levels. **METHODS:** The first investigation identifies DPP-translation studies using PubMed and Ovid databases and determines the extent to which studies report PA assessment and outcomes. The second and third investigations report PA results from an NIH-funded study designed to test the feasibility and effectiveness of a DPP-based translation, Group Lifestyle Balance™, delivered in diverse community settings. The investigations utilize PA data collected via the Modifiable Activity Questionnaire and a brief lifestyle questionnaire from 223 participants enrolled in the study. These investigations examine how intervention and season independently impact PA level and the participant baseline characteristics and program adherence markers that predict success in meeting PA and WL goals. **RESULTS:** A review of the published DPP translation literature identified issues of inconsistent assessment and incomplete reporting of PA results. Examination of PA information from the lifestyle intervention translation study showed the significant independent effects of lifestyle intervention and season on increasing leisure PA and revealed baseline BMI, pre-diabetes status, session attendance, and self-monitoring of PA and diet as predictors of achieving both PA and WL success. **PUBLIC HEALTH SIGNIFICANCE**: The literature review exposed the need for standardized PA assessment and results reporting in translation research. The original investigations reported in this dissertation advance the understanding of lifestyle intervention effectiveness for increasing PA levels independent of season and provide insight as to the participant characteristics and adherence behaviors that enhance individual success.

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PREFACE

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Nomenclature:

AOR-Adjusted Odds Ratio

BRFSS- Behavioral Risk Factor Surveillance System

CDC- Centers for Disease Control and Prevention

CVD- Cardiovascular Disease

DPP- Diabetes Prevention Program

DPPOS- Diabetes Prevention Program Outcomes Study

DPRP- Diabetes Prevention Recognition Program

GLB- Group Lifestyle Balance

IFG- Impaired Fasting Glucose

IGT- Impaired Glucose Tolerance

ILI- Intensive Lifestyle Intervention

IQR-Interquartile Range

LPA- Leisure Physical Activity

LSQ-Lifestyle Questionnaire

MAQ-Modifiable Activity Questionnaire

MET-hour- Metabolic equivalent hour

MetS- Metabolic Syndrome

NHANES- National Health and Nutrition Examination Survey

NHIS- National Health Interview Survey

OGTT- Oral Glucose Tolerance Test

OR-Odds Ratio

PA- Physical Activity

p-change- p-value for test within one group

p-diff- p-value for test between two groups

PRISMA- Preferred Reporting Items for Systematic Reviews and Meta-Analysis

WL-Weight Loss

1.0 INTRODUCTION

The concerning global burdens of diabetes (1) and cardiovascular disease (CVD) (2-4) in the latter 20^{th} and early 21^{st} centuries created interest in developing programs to prevent these conditions. The association between physical activity (PA) and markers of improved insulin sensitivity and glucose metabolism as well as improved cardiovascular fitness in early clinical and observational studies (5-8) indicated PA as an important behavior to target in prevention efforts. Several randomized controlled trials of lifestyle intervention, which included increasing PA, were developed to test the efficacy of lifestyle changes for the prevention of diabetes. These trials have demonstrated that the combination of increased physical activity (PA) and modest weight loss can reduce subsequent risk for diabetes and CVD (9-11). Thus, PA has been included as one of two key lifestyle goals in translation of the behavioral interventions from efficacy to effectiveness. The success of these translation efforts for reducing weight and improving CVD risk factors has been extensively evaluated (12-14), but reporting on PA behaviors is limited. Thus, less is known about the role that PA plays in translation efforts or how social, demographic, or environmental factors influence PA success in community programs. This introduction provides a brief overview of physical activity patterns in the United States, the importance of diabetes as a public health issue, a description of existing efforts to reduce diabetes risk, and the role that physical activity plays in diabetes prevention efforts. The chapters of the dissertation will then provide more in-depth discussion of these topics in order to highlight why PA in an important lifestyle behavior to target in prevention and how understanding and influencing PA behaviors can lead to improved health.

1.1 PHYSICAL ACTIVITY DEFINITION AND TRENDS

Physical activity (PA) is broadly defined as any movement that increases energy expenditure (15, 16). PA can take many forms that are characterized within the subcomponents of frequency, intensity, and duration of the activity. The national guidelines for PA reflect decades of observational and experimental evidence determining the characteristics of the subcomponents of PA necessary to elicit health benefit (17). The current recommendation for adults is to perform 150 minutes per week of moderate intensity PA, collected in bouts of at least 10 minutes, for improved health (18). The latest data from national surveys reveal that approximately 50% of American adults are meeting these guidelines (19, 20), with demonstrated variation by age, education, gender, race/ethnicity (20, 21), and geographic region (22), which may be due to environmental and demographic differences.

Fluctuation in PA levels has been documented occurring with calendar seasons, resulting from environmental changes (23-25). The effect of season on PA levels is most notable when PA is measured frequently and over a relatively short time-frame, such as past week and past month. Thus, in addition to social and demographic factors, season and time-frame captured by the assessment instrument should be considered when determining the success of intervention programming for increasing PA (Paper 2).

In addition to only half of the U.S. population getting sufficient PA for their health, physical inactivity is a huge problem. It is estimated that approximately 25% of American adults report no PA in the previous month (20), with little decline in this estimate from 1997 to 2012 (21). Low levels of physical activity and increasing time spent sedentary has recently been linked to substantial increases in risk for diabetes and CVD (26), emphasizing the importance of developing effective strategies for increasing PA a key public health priority (27).

1.2 DIABETES DEFINITION AND TRENDS

Diabetes is a general term for metabolic disorders of glucose metabolism, resulting in high levels of circulating blood glucose (28). Through biologic mechanisms that affect insulin sensitivity and glucose uptake (29), high levels of physical activity have been shown to reduce risk for diabetes (30). If left untreated or poorly controlled, diabetes can cause many localized and systemic complications including heart disease, stroke, kidney disease, and blindness (31). Diabetes is a growing public health concern, affecting 29.1 million people in the United States, mostly in the form of type 2 diabetes (31). An additional 86 million adults are estimated to have the condition known as pre-diabetes, which is a state of elevated blood glucose that is predictive for developing type 2 diabetes. Additional risk factors for type 2 diabetes include excess weight, older age, race/ethnicity (non-white and ethnic minorities), and family history of diabetes (32). In 2012, managing and treating diagnosed diabetes and its complications cost the U.S. health care system approximately $245 billion in direct and indirect costs. Personal health care expenditures for persons with diabetes are an estimated to be 2.3 times higher than for persons without diabetes (31). Given the health and financial impact of diabetes, preventing type 2 diabetes and diabetes complications can have an enormous impact on the individual patient as well as the entire health care system.

1.3 DIABETES PREVENTION

With low levels of PA and weight being key modifiable risk factors for type 2 diabetes and pre-diabetes (32), changing these behaviors has been the focus of efficacy trials in diabetes prevention. As rates of type 2 diabetes began to increase globally, several randomized controlled trials were conducted in China, Japan, Finland, India, and the United States to evaluate the efficacy of lifestyle intervention which focused on increasing PA and achieving modest weight loss for the prevention of diabetes (9-11, 33). In the U.S., The National Institutes of Health (NIH) funded the Diabetes Prevention Program (DPP), a multi-center trial that tested the efficacy of a lifestyle intervention with the goals of losing 7% of initial body weight and increasing moderate physical activity (PA) to 150 minutes per week for reducing diabetes risk. The DPP lifestyle intervention resulted in significant increases in PA and weight loss and was efficacious for lowering the risk for diabetes (9).

1.4 PHYSICAL ACTIVITY IN DIABETES PREVENTION RESEARCH

The success of efficacy trials for preventing type 2 diabetes is due to improvements in lifestyle that include increased physical activity. In the DPP, the lifestyle participants increased leisure PA at one year and maintained this significant increase through 3 years of follow-up (9). In terms of meeting the PA goal, 74% met the 150 minute per week activity goal at the end of intervention (9) and 67% met the PA goal after an average 3.2 years of follow-up (34). In post-hoc analysis, meeting the physical activity goal was associated with a 44% reduction in diabetes incidence, independent of meeting the weight loss goal (35).

Similarly, efficacy trials in China, Japan, India, and Finland reported significantly higher PA levels at the end of intervention and increases in the proportion of participants meeting the PA goals (10, 11, 33, 36). In the Finnish Diabetes Prevention Study, meeting the PA goal was associated with decreased diabetes risk, independent of meeting other dietary and weight loss goals (10).

1.5 PHYSICAL ACTIVITY IN TRANSLATION RESEARCH

With the success of the DPP lifestyle intervention and other international trials, translation efforts have been implemented in diverse community settings utilizing various strategies for program delivery in order to minimize resources required to reach those most at-risk. Less dramatic results, but with similar trends, are expected in community translation due to altered intensity, resource availability, and other socio-demographic factors of participants in community programs compared to the DPP. Weight is the most frequently reported outcome in these translation efforts. Many individual studies and several review articles have reported on the effectiveness of translation efforts in achieving weight loss, with similar trends for weight loss as those seen in the DPP (12-14, 37, 38). Similarly, the success of translation programs for modifying diabetes and cardiovascular disease risk factors has been reported (12-14, 38, 39). However, reporting on the PA component of intervention and success of these programs for increasing PA is limited. For studies that do report PA outcomes, social, demographic, and environmental factors that may influence physical activity behaviors are seldom addressed.

1.6 PREDICTORS OF ACHIEVING PHYSICAL ACTIVITY GOALS

High achievements of PA and weight loss goals were markers of success in the DPP. Understanding the factors that predict this success are important for developing strategies to increase likelihood that participants will meet program goals in order to achieve health benefit. In the DPP, achievement of the PA goal was significantly associated with increased age, retirement, male sex, lower baseline BMI, self-monitoring of diet and PA, and non-White race/ethnicity. Meeting the PA goal was a predictor of meeting the weight loss goal, both short and long term. Self-monitoring of diet and PA also predicted successful weight loss. (34).

Although PA is an important study goal, little is known about the factors predicting successfully meeting the PA goal in community translation efforts. Only one study has examined the factors associated with meeting the PA goal (40), reporting that men and those self-monitoring dietary fat intake are more likely to meet the PA goal. Factors associated with achievement of the weight loss goal have been evaluated in a few DPP translation studies (40-44), showing that age, sex, BMI, self-monitoring of behaviors, and PA level are predictors of weight loss success. These few evaluations of factors related to weight loss and PA success have guided the selection of social and demographic factors that will be considered in the evaluation of predictors of PA and weight loss success in a community diabetes prevention effort (Paper 3).

1.7 STUDY GOALS

This dissertation addresses the gaps in knowledge regarding the role of physical activity in behavioral lifestyle programs designed to reduce diabetes and cardiovascular disease risk. This will be accomplished by reviewing and evaluating the literature to identify potential issues with PA assessment and reporting in translation efforts and by providing results from a randomized controlled trial testing the effectiveness of a DPP-based lifestyle intervention implemented in diverse settings. The foundation for this dissertation is the NIH-funded Healthy Lifestyle Project (PI: Dr. A. Kriska), an investigation of the translation potential of the DPP into diverse settings, including the worksite, community centers, and the military. The specific aims of this dissertation are:

1. *Describe reporting of PA assessment and related PA results in DPP translation efforts*. A systematic review of the translation literature will be conducted to identify PA assessment methods and PA outcomes reported in DPP-based intervention studies (Paper 1). Without reporting of physical activity assessment and related outcomes, program effectiveness for increasing PA cannot be evaluated and the role of PA in weight loss and improvement in cardio-metabolic health cannot be examined. With various curricula being used in diverse settings, reporting of PA assessment and outcomes is needed to answer questions about program effectiveness and to help fill the gaps in knowledge regarding the relationship between PA and diabetes risk factors. This evaluation will determine the types of assessment methods being used in translation and the frequency of reporting PA related outcomes. The goal of this paper is to identify issues in reporting PA assessment and results in translation efforts and to provide recommendations for reporting PA in future program evaluations.

2. *Determine the independent impact of a behavioral lifestyle intervention and season on increasing PA levels*. The second investigation will present key findings in regard to PA outcomes from a randomized delayed-control trial among adults at high-risk for diabetes and CVD (Paper 2). PA assessment in this study includes two questionnaires that capture leisure PA

in MET-hours and minutes per week and a pedometer that captures step counts. Multiple assessment methods allow for an in-depth summary of PA trends over the course of a one-year lifestyle intervention in terms of volume and frequency of PA, PA goal attainment, and variation in PA level due to season. This investigation will also provide a broad view of PA and its relation to weight loss and establish the importance of reporting PA outcomes and related seasonal impact on PA levels in community-based programs.

3. *Identify demographic, social, and behavioral factors that predict achieving physical activity and weight loss goals during a one-year lifestyle program and during follow-up*. A few translation studies have described the characteristics determining weight loss success, but were limited in assessment of physical activity. This investigation will examine factors associated with improving PA and decreasing weight during a lifestyle program (Paper 3). Potential predictors include demographic and social factors, such as age, sex, education level, and employment status; and behavioral factors such as self-weighing, recording of diet and PA, and baseline PA level. Factors associated with increasing PA, independent and in conjunction with achieving weight loss goals, will be evaluated to determine program behaviors that should be reinforced and emphasized to increase likelihood of participant success and to identify social or demographic groups that may need additional strategies and encouragement to achieve desired outcomes.

2.0 PHYSICAL ACTIVITY IN EPIDEMIOLOGIC RESEARCH

Physical activity (PA) is a critical component of a healthy lifestyle, as higher levels of PA have been shown to be protective for several chronic diseases, including diabetes and cardiovascular disease (5, 6, 45). The evidence for the health benefits of PA is so extensive that national guidelines for PA have been established (17) and increasing PA has been identified as a top public health priority (27).

In order to understand PA behaviors and examine the relationships between PA levels and health, researchers need to be aware of the many methods available to measure PA and what detail each assessment instrument can provide. First, this chapter defines the components of PA relevant to public health research. Next, the methods to assess PA that are commonly used in epidemiologic studies are described. Then, the evidence for some of the health benefits of PA, the U.S. public health recommendations for PA, and the current rates of meeting PA recommendations among U.S. adults by social, demographic, and geographic factors will be described. Finally, given the PA assessment options and observed PA trends by demographic, geographic, and seasonal factors, considerations for measuring PA in community translation studies of lifestyle intervention will be discussed.

2.1 DEFINITION AND DESCRIPTION OF PHYSICAL ACTIVITY

Physical activity (PA) is defined as any movement produced by skeletal muscle that results in energy expenditure (16). This definition encompasses movement within many domains, including activities necessary for daily living as well as activities required for sport, recreation and leisure, occupation, or transport (46). Although lifestyle interventions typically focus on improving leisure or recreational PA, activity within one or several domains can be targeted for intervention.

PA is further characterized in terms of frequency, intensity, duration, and type (15, 47). "Frequency" describes how often activities are performed within a given time period (i.e. days per week). The time period typically used for lifestyle interventions is a week, but can be longer depending on outcomes of interest (47). "Duration" describes the amount of time spent performing one bout of the activity (47). "Type" describes the mode of energy expenditure, often classified into the four health-related types of activities including 1) aerobic and cardiovascular fitness, 2) muscular strength and resistance, 3) range of motion and flexibility, and 4) weight-bearing and bone-loading (47). The current focus of intervention efforts is on increasing time spent in aerobic type activities, with resistance training as an added component (25). Aerobic activities are those that are continuous and involve large muscle groups such as walking, biking, and dancing (15). Finally, "intensity" describes the physiological demand required to perform the activity (25, 47) and is often expressed in metabolic equivalents (METs) (16, 46). A MET reflects a multiple of an individual's resting energy expenditure, with one MET representing the metabolic rate at rest (15, 48). PA intensity varies across a spectrum covering light, moderate, and vigorous activities. Light activities require energy expenditure of 1.6-2.9 METs (15, 46) and include things such as casual walking, cooking, and light cleaning. Moderate intensity activity is that which elicits an increase in respiration and heart rate but still allows for casual conversation and includes activities with a MET value of 3.0-5.9, such as brisk walking or dancing (15, 46). Vigorous intensity activities elicit an even greater increase in respiration and heart rate which may make it difficult to carry on a conversation and require $\geq$6 METs, such as jogging or bicycling across hilly terrain (15, 46, 49).

At the bottom end of the movement spectrum is the lack of movement or near lack of movement, i.e. “sedentary behavior” (50). Although there is still some debate as to the appropriate definition of “sedentary”, it is generally agreed that sedentary behaviors are those which require little to no additional energy expenditure beyond what is required at rest (50), within a MET range of 1.0-1.5 (15, 46). Sedentary behaviors include those similar to sitting or lying down (50), such as passive TV watching or reading. As with PA, sedentary behaviors can be classified into domains such as leisure, occupational, and transport.

Collectively, frequency, duration, type, and intensity information is used to calculate PA-related energy expenditure (48) within the PA domains. Precise estimates of energy expenditure from PA can be measured in a laboratory setting using specialized equipment or processes (25). More practical to population studies, energy expenditure from PA is estimated from data provided by individual-worn activity monitors or questionnaires (25) that use standardized MET values for light, moderate, and vigorous intensity activities (51). The methods often used in epidemiologic research will be discussed in more detail in the next section.

2.2 PHYSICAL ACTIVITY ASSESSMENT

Physical activity (PA) level is assessed in populations and individuals in order to estimate national trends in PA and to examine associations between PA levels and health status. In order to accomplish this, different assessment techniques are used to capture the important PA characteristics (frequency, intensity, duration, type) within the common domains (leisure, occupational, household, transport) of activity discussed. In experimental and translational research, individual PA levels are determined by many subjective and objective measures, including laboratory and field methods. The choice of assessment instrument will depend on the research question and PA outcomes of interest. Each PA assessment instrument has strengths and limitations within public health and epidemiologic research and can provide a different level of detail in regard to important PA characteristics. Thus, the strengths and limitations of each instrument should be considered as well as the appropriateness for the population being studied before selecting an assessment tool.

Subjective methods of PA assessment are often used in public health research (25, 48) in part due to ease of use in large populations, low cost, and adaptability to specific populations (25). Subjective measures of PA include population-based surveillance surveys/questionnaires and activity logs/diaries. Depending on the instrument selected, subjective measures can provide somewhat varied PA information on frequency, duration, certain levels of intensity, type, and domain (48).

Questionnaires are a common assessment instrument utilized to capture PA information at the population and individual levels. At the population level, PA is estimated in representative samples by surveillance systems including the National Health Interview System (NHIS), National Health and Nutritional Examination Survey (NHANES), and the Behavioral Risk

Factors Surveillance System (BRFSS). These population-based surveillance surveys originally included a few global PA questions, such as “Would you say that you are physically more active, less active, or about the same as other persons your age?” and have since evolved to include a few general recall questions about specific activities performed within a given time frame, such as “During the past 7 days, did you walk for at least 10 minutes for [fun, relaxation, exercise, or to walk the dog]?” (52). Recall questionnaires provide additional information on the types of activities performed, as well as the frequency, duration, and intensity of PA. The information obtained from these recall questionnaires are able to more accurately discriminate between individuals based on difference in PA levels (47).

Many questionnaires are designed to capture time spent in moderate and vigorous intensity activities common to adults and children. Some questionnaires have been designed to capture light intensity activity in addition to moderate-vigorous to use in populations that may acquire most of their PA in light intensity activities, such as the elderly or chronically ill (48). These questionnaires often focus on functional ability to perform activities that fall into the light intensity range (such as activities of daily living), rather than on specific time spent in light activities, as this is typically more difficult to recall (48, 53).

In line with the shifting focus to include assessment of sedentary behavior, several questionnaires that include questions about moderate-vigorous activity also include questions about time spent in sedentary behaviors, such as reading, TV viewing, or sitting (25). The inclusion of sedentary behavior assessment can range from a single question, such as “during a typical day, how much time do you spend watching television?”, to a series of questions about occupational, leisure, and transport time spent in sitting endeavors (54, 55).

In general, PA questionnaires have been shown to be reliable and valid for capturing moderate and vigorous activity across diverse populations (48). However, data from questionnaires regarding light activity and unstructured sedentary behavior are generally not as valid as estimates of time spent in moderate-vigorous activity or specific sedentary behaviors such as computer use and TV watching (25). Assessment of light PA and sedentary behavior may require objective measurements to supplement information collected for a more accurate estimate of PA levels (25, 56).

Diaries and logs can also provide detailed information on frequency, intensity, duration, and type of PA recorded over a given time frame. Both diaries and logs are prospective assessment tools that are sometimes used as an adjunct to objective monitoring (46). Diaries often ask participants to track activity as it occurs, marking the time the activity started and stopped and providing detail on type and intensity (46, 57). Due to the high participant burden for recording, standard diaries are typically used over shorter recording time frames, such as a single day or week, and not as a long-term intervention tool (46, 57). Modified, simple written diaries in which participants only record activity relevant to the program goal (i.e. moderate-vigorous activity) are commonly used in lifestyle interventions as a tool for participants to track progress (57). Logs typically contain less detail than diaries, having individuals either record individual activities performed or use a pre-populated checklist to mark activities performed. Common recording time frames for logs are either once per day or in discreet time intervals, such as every 15 or 30 minutes (57).

In general, subjective measurements are limited in the information they collect and can be affected by reporting bias. As most questionnaires are historical in nature, an important limitation of questionnaires is the potential for recall bias (48). Imprecise recall is more likely a concern when the questionnaire is capturing PA information over a longer time frame and requires participants to recall more distant information (e.g. past year or lifetime) (48). It can also be a concern in populations with lower cognition such as children or the elderly (48). Recall bias is also higher for unstructured lower intensity activities, such as cleaning or short distance walking, compared to planned moderate or vigorous intensity activities (25). The frequent recording of activities such as with a diary or log can minimize recall bias, as activities are to be recorded in real-time; however, the requirement of frequent recording can be quite burdensome to the participant and may result in reporting errors (25).

Objective methods of determining PA-related energy expenditure and PA level have been used to validate subjective methods (25, 48). These objective measurements include many laboratory and field based methods, such as direct observation, motion sensors, and oxygen consumption testing. More practical to population surveillance and individual research, motion sensors, primarily accelerometers and pedometers, are used to collect objective PA data (25, 46). Traditional waist worn monitors record real-time vertical accelerations of the hip as either counts (accelerometers) or steps (pedometers) during movements similar to walking (46). The many monitors available vary in the complexity of the instrument and the level of detail recorded (46, 58). Newer and more complex pedometers are becoming more like accelerometers and have the ability to store PA information and time-stamp the data, which can allow for more detailed analysis of PA level (46). In addition to recording PA levels, pedometers are often used as intervention tools to promote PA (25).

There are a few important limitations to using pedometers and accelerometers in epidemiologic research. The limitations of using a basic pedometer is that the devices do not distinguish the type, duration, or intensity of activity and rely on the participant to record or provide this information if needed as well as to reset the device between wear (25). In contrast, accelerometers can provide information on duration of intensity patterns (in counts) of PA and automatically reset each day, but also are unable to provide information on type of activities performed (25). Pedometers in general are also more sensitive to gait patterns than accelerometers, and have been shown to be less accurate among those who have shuffling or swaying gaits and reduced gait speeds, such as the elderly (25, 59). Furthermore, pedometers and accelerometers were designed to capture movement similar to walking and running, thus the less similar the activity is to walking and running the less accurate the device will be for recording that activity which can affect estimates of time spent active (47). Additionally, waist worn pedometers and accelerometers do not capture activities that do not involve trunk movement, such as bicycling and resistance exercises. Although some monitors worn on the arm or wrist can capture upper body movement, the results are less comparable to traditional step-based pedometers and waist worn devices for estimating total body energy expenditure (60, 61) and the evidence for the accuracy of wrist worn devices for capturing total PA is variable (62-65). Finally, many pedometers and accelerometers cannot be worn for water-related activities and there are currently no accepted methods for interpreting data on water activity from devices that can be worn in the water (66).

Time frame is an important consideration for both subjective and objective measurements. Compared to longer time frames (past year, lifetime), questionnaires with short time frames (3- or 7-day) are least affected by recall bias and most easily validated by objective measurements (which are typically worn for a period of one week or less). Conversely, using a questionnaire with a shorter time frame can be a limitation as past week or past month PA is less likely to reflect “usual” behavior (25, 47, 48). PA assessment over a short time frame can also be affected by season and weather patterns, illness, or temporary changes in participant time commitment (47). The strengths and limitations of using different time frames should be considered carefully when deciding the PA-related outcomes of interest.

Given that each assessment instrument has strengths and limitations in collecting complete information within the characteristics and domains of PA described, multiple assessment instruments could be used, if resources allow, in order provide a more complete understanding of participant PA levels.

2.3 EVIDENCE FOR THE HEALTH BENEFITS OF PHYSICAL ACTIVITY

Although assessment of PA has varied in detail and complexity over the years, decades of observational and experimental research have demonstrated the positive associations between higher levels of moderate-vigorous PA and improved health (17, 67, 68). The strongest evidence exists linking PA level to improved cardiovascular and metabolic outcomes, but evidence is building for the association between higher levels of PA and decreased risk for cancer, Alzheimer's disease, and chronic sleep disorders, among others. As these latter outcomes are still under investigation, the focus of this section will be on the strong and consistent evidence linking PA to improved cardiovascular and metabolic outcomes.

Clinical and laboratory studies have shown that adequate moderate-vigorous physical activity can have positive effects on cardiovascular and musculoskeletal performance, body composition, and metabolism (15, 67, 69), which together comprise physical fitness. Epidemiologic studies have demonstrated that higher volumes of moderate-vigorous intensity PA are closely linked to high cardiorespiratory fitness (5, 70-72), which predicts lower all-cause mortality (73). Additionally, some studies have reported that greater quantities of moderate-vigorous PA are related to increased longevity (5, 74). In line with these findings, analyses using global health data estimate physical inactivity (no regular moderate-vigorous PA) is directly responsible for 9% of premature mortality (75).

Low amounts of moderate-vigorous leisure PA have also been linked to risk for certain metabolic conditions. Physical inactivity is recognized as a risk factor for type 2 diabetes, estimated to account for 7% of the global burden of type 2 diabetes (75). In studies of populations at high-risk for developing type 2 diabetes, it has been established that higher leisure PA levels are associated with lower insulin and plasma glucose concentrations, independent of obesity status (6, 45, 76). In these epidemiologic studies, individuals with plasma glucose concentrations indicative of diabetes reported lower historic and lower current levels of leisure PA than their non-diabetic counterparts (6, 76). Most importantly, high-risk individuals with higher PA levels (leisure plus occupational) had a lower incidence of type 2 diabetes during longitudinal observation (30). The role of PA in the prevention of diabetes and the improvement of diabetes risk factors has been explained through acute effects on insulin production, insulin sensitivity, and glucose uptake observed in clinical and laboratory settings (77). The results from these early studies suggested the potential for PA interventions to be used to prevent type 2 diabetes.

Clinical observations have also shown that regular moderate-vigorous intensity PA can be used to manage type 2 diabetes by triggering acute changes in insulin sensitivity and glucose control (29) and stabilizing plasma glucose levels (78). For prolonged effects on insulin sensitivity and glucose regulation, it is recommended that PA bouts should be performed no more than 72 hours apart (77). The current recommendation for adults with pre-diabetes and diabetes is 150 minutes of moderate intensity aerobic activity per week spread over 3-7 days in order to control blood sugar levels and maintain health (15).

Epidemiologic evidence also indicates physical activity level as a predictor of coronary health (79, 80) and as a protective factor for developing cardiovascular disease (81, 82). Like with diabetes, physical inactivity is estimated to cause 6% of the global burden of coronary heart disease (75). This relationship can be explained by evidence from clinical and epidemiologic studies that demonstrate that moderate-vigorous PA is independently linked to increased HDL cholesterol, decreased LDL-cholesterol, decreased blood pressure, and decreased triglycerides (67, 71, 82, 83). Furthermore, in clinical settings, PA is recognized as an integral component to preventing and controlling hypertension, even in the absence of weight loss (84). Some of the relationship between higher levels of moderate-vigorous PA and improved coronary health is mediated through improvements in cardiorespiratory fitness as a result of exercise training (71) and some improvement in CVD risk factors is due to exercise-related weight loss (85). The amount of moderate-vigorous PA needed to elicit improvements in CVD risk factors may differ for each individual based on other personal and genetic factors (83), but the general guideline endorsed by the American Heart Association is 150 minutes per week of moderate aerobic PA (68).

As overweight and obesity is linked to increased morbidity (4), especially in terms of diabetes and cardiovascular disease, it is important to understand the role of PA in weight management. Evidence from clinical trials and observational studies supports the positive role of PA in achieving desirable weight loss and maintaining weight loss (34, 86-88). Although PA at the threshold of 150 minutes of moderate intensity per week results in only modest weight loss (85, 86) or no change in weight in the absence of decreased caloric intake (86), continued PA at this level has been shown to be important for weight loss maintenance (87, 89-91). Thus, weight loss programs should include modest diet restriction and adequate levels of physical activity at 150 minutes per week to achieve desirable weight loss that will benefit health (85), with maximum long-term benefit achieved with regular PA.

2.4 PHYSICAL ACTIVITY RECOMMENDATIONS

The conglomerate of evidence for the benefits of PA in relation to all-cause mortality and cardio-metabolic health led to national recommendations for PA within the four characteristics of PA (frequency, intensity, duration, and type). The first national public health recommendations for PA were released in the 1996 Surgeon General's Report (SGR) on Physical Activity and Health (17). Based on the existing evidence, a panel of experts concluded that 30 minutes of moderate intensity PA performed on most, if not all, days of the week would provide substantial health benefit. Since the 1996 SGR, several health organizations and government bodies have reinforced these recommendations and simplified the recommendation for aerobic activity to 150 minutes of moderate intensity PA per week for general health (18, 69). These more recent statements include further details regarding frequency and duration of activity, such as performing aerobic activities in bouts of at least 10 minutes spread over several days per week (18). Additionally, guidelines for strength and flexibility activities have been added. These include doing strengthening activities for all major muscle groups on 2 or more days per week and doing some type of balance and flexibility activity daily (18, 69). In 2010, the American College of Sports Medicine and the American Diabetes Association released a joint statement reiterating the national guidelines and emphasizing that aerobic activity should be performed on a minimum of 3 days per week to manage and prevent type 2 diabetes (29).

2.5 PHYSICAL ACTIVITY TRENDS IN THE UNITED STATES

Given the many health benefits of PA, it is important to identify how many adults are getting adequate PA and how these estimates vary by demographic, social, and geographic factors in order to determine in what populations, if any, interventions are needed to increase PA. The multiple national surveillance systems previously described estimate that 70-77% of American adults are performing any recreational PA within the past month and that approximately 50% of adults are meeting the guidelines for aerobic PA of 150 minutes of moderate intensity per week (19-21, 92). Estimates in meeting the guidelines, as measured by national surveys, vary by demographic subgroups as well as by geographic region and calendar season. The following sections describe this variation in order to determine potential factors to consider in relation to meeting PA goals in an intervention program.

2.5.1 Demographic Trends

Closely examining subjectively measured PA levels by demographic subgroups, meeting the PA recommendations varies by age, sex, race/ethnicity, and education. Data from 2010 and 2012 NHIS cycles indicate that rates of meeting PA guidelines are highest among young adults, aged 18-24 years, and decline steadily across age groups 25-44, 45-64, 65-74, and 75 and over (21, 92). The same data set shows that nationally a higher proportion of men appear to meet the PA guidelines than women (21, 92), though these differences may not be significant. Similar patterns of meeting PA guidelines by age and sex have been measured objectively by accelerometer in nationally representative samples from the NHANES 2003-2004 cycle (93). According to subjective 2012 NHIS data categorized by race/ethnicity, rates of meeting the recommendations are highest among Native Hawaiians or other Pacific Islanders, with non-Hispanics Whites, Asians, American Indians or Alaska Natives, Hispanics or Latinos, and non-Hispanic blacks decreasingly meeting PA recommendations (21). The 2012 NHIS data indicates that the proportion of adults meeting recommendations is highest among Americans with advanced college degrees, with trending declines across lower educational attainment categories (21).

Given the variability in meeting PA guidelines across social and demographic subgroups, these socio-demographic characteristics should be considered when predicting who will be successful in a community lifestyle program that promotes physical activity. As part of this dissertation, the characteristics of age, sex, and education will be considered in the evaluation of factors predicting individual success in a community diabetes prevention program (Paper 3). Due to a primarily non-Hispanic White population in the study region, race was not evaluated as a potential moderator of program success.

2.5.2 Geographic and Seasonal Trends

In addition to demographic differences in meeting PA recommendations, understanding how physical environment influences PA level is important when considering the impact interventions can have on PA behaviors. Physical activity levels vary greatly by geographic region and fluctuation in PA levels due to seasonal weather patterns has been well documented in various geographic areas (24). Variation in PA by geographic region is partially the result of the diversity in climates and landscapes in the U.S., but may also be attributed to socio-demographic differences. As an example of this geographic diversity, relative proportions of residents who report any past month PA and physical inactivity (no PA in the past 30 days) range from 68.5% active/31.5% inactive in Arkansas to 83.7% active/16.3% inactive in Oregon (20). Overall, residents in the Southern states are getting less PA than residents in the West, Midwest, and Northeast (22). This may be due in part to the different climates of the Northern and Midwestern states compared to those of the South and Southwest, but also due to demographic and social differences between the populations in these areas.

Seasonal variation in PA levels results from combinations of changes in temperature, precipitation, and number of daylight hours (25). In areas where there are four distinct seasons, such as the Northeastern U.S., physical activity levels tend to be higher in the mild summer months and lower in the cold winter months. This seasonal variation was documented by Newman et al. in 500 post-menopausal women over an 18-month enrollment period in Pittsburgh, Pennsylvania (23). In Canadian provinces where weather patterns are similar to the Northeastern U.S., PA levels have been shown to be lowest in winter months and higher in non-winter months in large population samples (94, 95). Although environmental changes cannot be controlled by researchers, the expected fluctuation in PA due to seasonal changes can be diminished with lifestyle intervention that promotes PA (23). Therefore, it is important to have an understanding of underlying seasonal variation in PA level when conducting and evaluating interventions that influence PA behaviors.

2.6 CONSIDERATIONS FOR PHYSICAL ACTIVITY ASSESSMENT IN COMMUNITY TRANSLATION STUDIES

In the assessment of PA levels in translational research, important factors to consider when selecting an assessment instrument include the demographic and social characteristics of the population, the characteristics of PA desired to be measured, and the characteristics of the assessment instrument itself. Given the evidence for higher levels of moderate-vigorous PA being linked to improved health outcomes in epidemiologic studies, existing translational studies primarily focus on increasing participants' moderate and vigorous PA, an intensity and volume of PA that is well-captured by questionnaires. First, the selected questionnaire should be appropriate for the population being studied. Many questionnaires exist that have been shown valid and reliable in different populations (48), including the Modifiable Activity Questionnaire (MAQ) (96-99) that is used in the Healthy Lifestyle Project. Next, the level of detail and discrimination of the PA assessment instrument should match that of the assessment instrument used to determine the health income of interest (48). Other important considerations are the time frame of assessment and the frequency in which information is being collected. As intervention is likely to have proximal changes in PA levels, frequent assessment of shorter time frames may be used to document the intervention effect on PA levels. As discussed earlier, this methodology will be sensitive to changes in environment and weather due to season (25) and may also be impacted by acute illness and changes in time commitment from the participants (47).

In lifestyle change programs, basic diaries are often provided for participants to record moderate and vigorous intensity PA within given time frames to track progress toward meeting program goals (57). In the Healthy Lifestyle Project, a simple diary was given to participants to record time spent in moderate and vigorous intensity PA each day, in addition to detailed food consumption, in order to monitor progress toward meeting weekly goals. Although often used as an intervention strategy, the frequent burden of recording can lead to low compliance to this assessment instrument. As such, caution should be taken when relying on diaries as the sole PA measurement in translation efforts, as those who are compliant with self-monitoring of PA have been shown to be more successful in increasing PA and meeting PA goals (40, 100).

As evidence emerges that sedentary behavior is an important target for health improvement (26), instruments that capture total PA and movement, such as pedometers and accelerometers, have been included in community efforts. As with questionnaires, important considerations for selecting an activity monitor are the appropriateness of the instrument for the population being studied, the time frame of assessment, the frequency in which PA information will be collected, and the desired program outcomes. A simple spring-lever pedometer was selected as an intervention and assessment tool in the Healthy Lifestyle Project to capture total ambulatory movement across the complete spectrum of intensities, recorded as steps. The large display on the device allowed for immediate feedback to the participant and gave the participant the ability to monitor progress toward meeting daily step goals. An advantage of using this pedometer over other devices (46) is the relatively inexpensive cost and simple design which increases participant ease-of-use. In the context of examining PA behaviors in interventions, the pedometer does not provide information on the domain in which PA is performed and would require participant input (46). However, this is only a limitation when changing PA behaviors within a particular domain, such as occupational or leisure, is of importance to program evaluation.

A unique strength of the investigations within this dissertation is that PA information was collected via three subjective measures (two interviewer-administered questionnaires and a participant food diary which included daily recording of PA) and one objective measure (pedometer). This allows for an understanding of PA in multiple time frames and within the four characteristics of PA. The pedometer was used to assess past week total PA and change in total PA in the community center participants, allowing for insight as to the practicality of using a pedometer in an older adult population for intervention and assessment purposes. The use of one general and one detailed questionnaire allowed for determination of frequency, duration, and intensity of usual and past month leisure PA. Each questionnaire was used to evaluate program success for improving leisure PA levels (Paper 2) and to define individual participant success in meeting the PA goal (Paper 3). The use of a past month questionnaire permitted for the influence of season on PA level to be determined (Paper 2), which is rarely examined in intervention research. Finally, adherence to daily recording of PA in a basic diary during intervention was considered as a predictor of program success in terms of increasing PA and achieving weight loss (Paper 3).

3.0 DIABETES AND PRE-DIABETES

Physical inactivity has been identified as a modifiable risk factor for cardio-metabolic diseases, including diabetes and cardiovascular disease (5, 30, 75), as described in the previous chapter. The modest achievement of PA recommendations among American adults has contributed to the growing burden of these chronic diseases. Cardiovascular disease has long been a public health concern, leading the list of causes of death in the United States among both men and women (101). Diabetes Mellitus, or diabetes, is a growing public health concern, as the disease itself is a risk factor for cardiovascular disease. The high morbidity and mortality from diabetes in the United States and globally calls for efficacious and effective prevention programs to reduce diabetes burden and improve public health. In order to fully comprehend the potential impact of diabetes prevention on public health, it is important to understand the pathophysiology of diabetes and related complications as well as the risk factors for the disease.

3.1 DEFINITION AND DESCRIPTION OF DIABETES

Diabetes is a general term for metabolic disturbances that result in high levels of circulating blood glucose, or hyperglycemia (28, 102). Diabetes is classified based on the underlying cause of hyperglycemia, which may include decreased insulin secretion, insulin action, or both (28, 103). The mechanisms of diabetes vary and depend on the underlying cause. Persons with diabetes may have symptoms of increased thirst, increased urine production, or increased appetite (28). Life-threatening symptoms of diabetes include blood pH imbalances which present as blurred vision, confusion, dizziness, and in some cases coma (28, 102). The main types of diabetes include type 1, type 2, and gestational, which will be expanded on in the following sections.

3.1.1 Type 1 Diabetes

Type 1 diabetes, formerly called insulin-dependent diabetes mellitus (28), accounts for approximately 5% of diabetes cases (31). The condition is marked by decreased insulin produced due to pancreatic beta cell dysfunction (103). Type 1 diabetes onset usually occurs during childhood or adolescence, but sometimes remains latent until young adulthood (103). In some cases, beta-cell dysfunction occurs as a result of an autoimmune destruction of the pancreas (28). In other etiologies, the destruction of the pancreas is a result of other underlying genetic conditions, such as Cystic Fibrosis. The result is decreased secretion of insulin, the consequence of which is decreased circulating insulin and insulin action. The treatment for type 1 diabetes is insulin injections administered at the time of meals (28). There is no known intervention to prevent type 1 diabetes (31).

3.1.2 Type 2 Diabetes

Type 2 diabetes, formerly called non-insulin dependent diabetes mellitus (28), is the most prevalent form of diabetes, accounting for 90-95% of cases (31). Type 2 diabetes results from increased insulin resistance and subsequent reduced glucose transport from the blood to metabolically active tissues (103). Type 2 diabetes is usually adult onset, but with the increase in childhood obesity it has been seen increasingly in adolescents and young adults (31, 104). Due to the pathogenesis of type 2 diabetes, a prolonged state of hyperglycemia may be present before symptoms occur (28). This prolonged state can have negative pathologic changes to affected tissues, making early detection key to disease management and prevention of disease progression. The treatment for type 2 diabetes includes pharmacologic agents that decrease hepatic glucose production and increase insulin action and lifestyle modifications including low-carbohydrate diets and increased physical activity (28, 31). Without proper glycemic control, some individuals will progress to insulin-dependency during their lifetime (28).

3.1.3 Gestational Diabetes

Gestational diabetes is marked by increased circulating glucose and insulin resistance beginning during pregnancy (28, 103). The classification applies regardless if disease management requires insulin or lifestyle modification or if hyperglycemia persists after pregnancy. Diagnosis of gestational diabetes ensures proper medical and nutritional therapies are used to maintain the health of the mother and infant (28). Most women return to normoglycemic status after delivery, however 5-10% of cases persist (31). Having gestational diabetes increases the risk for type 2 diabetes later in life (28, 31).

3.1.4 Diagnosis of Diabetes

Several diagnostic tests are available for diabetes and each test follows standardized criteria from the World Health Organization (102, 103). The three tests used for diabetes diagnosis are the 2-

hour oral glucose tolerance test (OGTT) with a 75g glucose load, fasting (defined as greater than 8 hours) plasma glucose readings, or plasma hemoglobin A1c levels. A 2-hour OGTT of greater than or equal to 200 mg/dL, a fasting plasma blood glucose value greater than or equal to 126 mg/dL (28, 103) or a plasma hemoglobin A1c level greater than or equal to 6.5% (103) are all individually conclusive for diabetes diagnosis. Due to potential complications during pregnancy, gestational diabetes is conservatively classified as having a 2-hour OGTT of greater than or equal to 155 mg/dL (28). Each test should be repeated, or used in conjunction with a second test, to confirm the diagnosis. In the event of a hypo- or hyperglycemic crisis, only one glucose test in the elevated range is needed to make a diabetes diagnosis (28). In epidemiologic research, it is recommended that fasting glucose levels be used to classify diabetes status due to increased practicality over using a 2-h OGTT (28).

3.2 BURDEN OF DIABETES

Diabetes is the most common metabolic disease in the United States and thus has an enormous impact on public health. Estimates of diabetes prevalence rates are taken from national survey data. Similar to physical activity estimates, the prevalence rates of diabetes vary based on the survey sampling method and whether diabetes status is determined objectively via a diagnostic test or by participant self-report. In the past 30 years, the estimated U.S. prevalence rates of diabetes have increased 176%, from 2.5% to 6.9% (105), according to data collected by the Centers for Disease Control and Prevention (CDC). However, some of this increase may be attributed to changes in survey methodology and diagnostic criteria for diabetes. The latest CDC National Diabetes Statistics Report estimates that 9.3%, or 29.1 million, of people in the United

States presently have diabetes (types 1 and 2), with 8.1 million of those being undiagnosed (31). The number of new diagnosed cases among adults aged 20 years and older is approximately 1.7 million per year (31). Not only does diabetes affect a large number of people, but certain population subgroups have higher prevalence rates of diabetes than others. The prevalence of diabetes increases with age, with 11.2 million adults over age 65 living with diabetes. Racial and ethnic disparities exist, with the prevalence of diabetes highest among American Indians/Alaska natives and lowest among non-Hispanic Whites (31).

The cost of diagnosed diabetes to the health care system is approximately $245 billion in direct and indirect costs per year, with personal health care expenditures being 2.3 times higher for individuals with diabetes than for those without diabetes (31). Diabetes is currently the seventh leading cause of death, behind cardiovascular disease, cancer, respiratory infections, stroke, injury, and Alzheimer's disease, accounting for 2.8% of all U.S. deaths in 2010 (101). However, diabetes may be underreported as a cause of death with only about 35-40% of people with diabetes having it listed anywhere on the death certificate (31).

3.3 COMPLICATIONS OF DIABETES

Diabetes can affect many of the bodies' tissues and organ systems, causing localized and systemic effects (31). The long-term effects of hyperglycemia result in damage to the blood vessels and nerves which lead to dysfunction in the kidneys, eyes, and heart as well as other organs (28). Complications resulting from microvascular damage can be reduced with good blood glucose control (31). Early detection and treatment is vital to preventing the many complications than can arise from poor glucose control.

Microvascular damage to coronary blood vessels increases the risk for cardiovascular complications in those with diabetes (28). CVD deaths and rates of hospitalization from myocardial infarctions and stroke are higher among adults with diagnosed diabetes (31). The age-adjusted risk for each of these conditions is 1.7, 1.8, and 1.5 times higher, respectively for those with diabetes compared to those without (31).

More acute conditions related to diabetes include high blood pressure and high LDL-cholesterol, which is prevalent in 71% and 65% of people with diagnosed diabetes, respectively (31). Recent research has shown a higher frequency of arrhythmias among patients with type 2 diabetes that is related to cardiac neuropathy and nephropathy (106). Blood pressure and lipid management is important for individuals with diabetes in order to prevent these cardiovascular complications (31) and can be managed through a healthy lifestyle including PA and a balanced diet.

Through damage to vessels and nerves and other physiologic and systemic effects, diabetes can also cause kidney disease or renal failure, periodontal disease, non-alcoholic fatty liver disease, blindness, hearing loss, and depression (31, 107). Gestational diabetes can result in maternal complications including chronic hypertension, causing fetal distress that increases the likelihood of cesarean section (28). Maintaining regular medical exams and managing blood glucose levels can help identify and prevent progression of these complications.

3.4 RISK FACTORS FOR TYPE 2 DIABETES

Several modifiable and non-modifiable risk factors have been identified in relation to type 2 diabetes. These factors include age, family history, race/ethnicity, physical activity, and weight.

How each of these risk factors contributes to the risk of type 2 diabetes depends on the physical and social environment of the individual. Understanding each risk factor can help develop effective programs and target high-risk populations for delivery of prevention programming.

3.4.1 Non-modifiable Risk Factors

Diabetes rates are different across socio-demographic factors including age, sex, race/ethnicity, and education. Certain classifications of these factors in conjunction with a family and personal history can increase the risk for diabetes substantially. Although non-modifiable, being aware of these risk factors can help inform those who are at high-risk to continue to get screened for diabetes and follow healthy lifestyle practices in order to reduce future risk.

Increasing age is associated with increased risk for type 2 diabetes. The number of new cases of type 2 diabetes is estimated at 7.8 per 1,000 persons. This incidence is distributed unevenly across age groups, with 3.6, 12.0, and 11.5 new cases per 1,000 in adults ages 20-44, 45-64, and 65 and older, respectively (31). Prevalence rates of diabetes also appear to vary between men and women. The latest estimates from one national survey indicate that men have a higher prevalence of diabetes than women, at 6.9% and 5.9%, respectively (105). However, once adjusted for age, this relationship is no longer apparent, with 7.7% of men and 7.5% of women having diagnosed diabetes. Estimates from another survey are higher but similar, with 13% of men and 11% of women having diabetes (31).

Family and personal history affect risk for diabetes. Family history of diabetes among parents or siblings increases an individual's risk of developing type 2 diabetes (31). Family history as a risk factor is thought to indicate underlying genetic and environmental factors which contribute to risk. Additionally, having gestational diabetes or giving birth to a child weighing more than 9 pounds increases an individual's risk for developing diabetes in their lifetime (32). Hormonal imbalances in women, manifesting as polycystic ovary syndrome, also increases risk for diabetes (108).

Disparity in the burden of type 2 diabetes exists across racial and ethnic groups in the United States (105). Persons of Native American and Alaska Native descent have the highest estimated prevalence of type 2 diabetes at 15.9%. Non-Hispanic blacks, Hispanics, and Asian Americans also have elevated levels of diabetes compared to non-Hispanic Whites, with rates of 13.2%, 12.8%, and 9.0%, respectively, compared to 7.6% among non-Hispanic Whites (31). Even within racial and ethnic groups, there is disparity among sub-groups. For example, among Asian Americans, Chinese descendants have the lowest prevalence of diabetes at 4.4% compared to 13.0% for Asian Indians. Similarly, among Hispanics, Central and South Americans have the lowest prevalence at 8.5% and Puerto Ricans have the highest prevalence at 14.8% (31). The highest rates in the United States are among American Indiana in southern Arizona, at a startling 24.1% (31).

Rates of diabetes are associated with educational attainment and income. Data from the National Health Interview Survey between 1980 and 2011 indicates consistently higher prevalence among adults with less than high school education compared to adults with some post-secondary education (105). The latest reported rates of diabetes among those with post-secondary education, high school education, and less than high school education are 5.9%, 7.5%, and 8.6%, respectively. Similarly, a study in the Netherlands (109) found that women with the lowest education level had a three times greater likelihood for developing gestational diabetes compared to those with the highest educational attainment after adjusting for age, family history of diabetes, and parity. The risk was slightly attenuated when adjusting for BMI (109). Whether the relationship between diabetes risk and education level is moderated by income and access to health care services is unknown.

3.4.2 Modifiable Risk Factors

Since type 2 diabetes can be prevented by changing modifiable risk factors, it is important to understand the relationship between these factors. Several lifestyle factors, including physical activity, nutrition, and overweight/obesity are interconnected in their relationship to type 2 diabetes risk. Physical inactivity, poor diet, and overweight/obesity together contribute to a state of impaired fasting glucose or impaired glucose tolerance, which is collectively referred to as the condition pre-diabetes (28).

The observed relationships between PA level and diabetes status, discussed in the previous chapter, shows that physical activity is protective against diabetes development (30). The role of physical activity in the prevention of diabetes and the improvement of diabetes risk factors has been explained through acute effects on insulin production, insulin sensitivity, and glucose uptake (77). Physical inactivity and sedentary behavior is thus a risk factor for developing type 2 diabetes (26). National surveys estimate that 36% of adults diagnosed with diabetes report no physical activity in the past 30 days (105). This estimate has remained stable from 1994-2010.

Physical activity can also help manage some of the complications of diabetes, such as high blood pressure and CVD (7, 70, 84), and prevent further morbidity and mortality. Physical activity is closely related to other lifestyle factors, such as diet and overweight/obesity (85). A healthy diet can help prevent types 2 diabetes and further complications. Diets high in fat and calories have been linked to increased risk for type 2 diabetes (32). Conversely, eating meals that are modest in fat and include whole grains, a variety of fruits and vegetables, lean meats, and low-fat dairy can help maintain normal glucose levels (108). Additionally, a healthy diet in conjunction with physical activity can help individuals lose weight and maintain a healthy weight.

Overweight and obesity is generally classified by body mass index (BMI). The guideline for overweight for adults is a BMI $\geq$ 25 kg/m^2. For Asian-Americans, the at-risk cut-point is 23 kg/m^2 (108). Excess body weight causes insulin resistance (28) and contributes to high blood glucose (32). Overweight and obesity is also related to other health issues that increase diabetes risk, including high blood pressure and high cholesterol (32, 108). It is important to reiterate here that PA has been associated with lower plasma glucose and lower insulin resistance even after adjusting for BMI (45). Thus it is imperative to include PA as part of weight management strategies for reducing diabetes risk.

Cigarette smoking is another risk factor for both type 2 diabetes and cardiovascular disease (31). In a large cohort of European men and women (110), the increase in risk for type 2 diabetes was 43% and 13% among current smokers for men and women, respectively. In this same study, former smoking increased diabetes risk by 40% and 18% among men and women, respectively. This risk is independent of age, physical activity, education, and dietary components.

3.5 PRE-DIABETES

Individuals with pre-diabetes, previously referred to as impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) (28), are at high risk for developing type 2 diabetes. Thus, identifying individuals with pre-diabetes and offering effective prevention programs can greatly reduce the burden of type 2 diabetes in the U.S. Pre-diabetes is characterized by elevated glucose levels not yet at the stage of clinical disease. Even without having blood glucose levels in the diabetes range, negative health effects have been observed as a result of hyperglycemia, such as an increased risk of cardiovascular disease and stroke (31). Based on criteria of the American Diabetes Association, pre-diabetes is diagnosed by fasting blood glucose between 100-125 mg/dL, a 2-hour OGTT range of 140-199 mg/dL, or a plasma HbA1c of 5.7-6.3% (28, 103). The World Health Organization uses similar criteria for pre-diabetes (102).Without lifestyle modifications, the progression rate from pre-diabetes to type 2 diabetes is between 15-30% within 5 years (31).

In line with increasing prevalence rates of diabetes, the prevalence of pre-diabetes is estimated to be increasing. Data from NHANES indicates the prevalence of pre-diabetes has increased from 27.4% in 1999-2002 to 34.1% in 2007-2010 (111). The latest report from the CDC estimates that 86 million adults, or 37% of the adult population, in the United States have pre-diabetes (31). Similar to changes in diabetes estimates, the changes in pre-diabetes estimates have been affected by modifications of the diagnostic criteria, most notably to include HbA1c as a diagnostic test (111).

Pre-diabetes is largely asymptomatic (32), so knowing the risk factors can help people determine if they are at-risk and should consider routine testing. The risk factors for pre-diabetes are similar to those for type 2 diabetes and include non-modifiable risk factors such as age and family history of diabetes and CVD and modifiable risk factors such as physical inactivity, overweight/obesity, and smoking (108). Although diabetes and pre-diabetes share most risk factors, the level of risk associated with each can vary. For example, cigarette smoking contributes similar risk for pre-diabetes as it does diabetes (112). In contrast, the risk profile by race/ethnicity is quite different for pre-diabetes, with similar prevalence rates among non-Hispanic whites, non-Hispanic blacks, and Hispanics of 35%, 39%, and 38%, respectively (31).

3.6 THE METABOLIC SYNDROME

The metabolic syndrome (MetS) consists of a compilation of diabetes and cardiovascular disease risk factors and thus identifies another population to target for prevention efforts. MetS is classified by having three or more of the following: elevated fasting plasma glucose, below optimal HDL-cholesterol, increased waist circumference, elevated triglyercides, and elevated systolic and/or diastolic blood pressure (113). The National Cholesterol Education Program's Adult Treatment Panel III (NCEP ATP III) defines risk factors as waist circumference > 102 cm in men and >88 cm in women, triglycerides ≥ 150 mg/dL and/or on drug treatment for elevated triglycerides, HDL cholesterol <40 mg/dL in men and <50 mg/dL in women and/or on treatment for reduce HDL-C, blood pressure ≥130/≥85 mm Hg and/or on antihypertensive medication, and fasting glucose ≥ 100 mg/dL and/or treatment for elevated glucose (113, 114). The World Health Organization (WHO) criteria for MetS are similar, but include lower thresholds for HDL cholesterol of <35 mg/dL in men and <39 mg/dL in women as well as consideration of BMI and/or waist-to-hip ratio and urinary albumin excretion rate (102).

Recommended treatments for MetS include first-line therapy of weight loss and increased physical activity through lifestyle modifications and second-line therapy of pharmacological interventions (113). The population-attributable risk for diabetes is estimated to be 50% from MetS. Similarly, MetS predicts about 10-20% of new cases of CVD. For individuals with diabetes and MetS, the risk for CVD increases to 25% (113). Thus, targeting the individual components of MetS is important for both diabetes and CVD prevention.

4.0 RANDOMIZED CONTROLLED TRIALS TO PREVENT DIABETES

In response to the increasing incidence of type 2 diabetes in the latter twentieth century, several research groups around the world developed randomized controlled trials to test the efficacy of lifestyle intervention for the prevention and delay of onset of type 2 diabetes. All of these trials were able to demonstrate the benefit of lifestyle intervention for diabetes prevention among individuals with pre-diabetes [previously referred to as impaired glucose tolerance (IGT)]. Although all the trials focused on healthy lifestyle changes including increased physical activity in order to achieve weight reduction, the intervention goals varied among programs. A brief description of each trial follows, with a final focus on the Diabetes Prevention Program (DPP) in the United States.

4.1 INTERNATIONAL DIABETES PREVENTION PROGRAMS

Several international initiatives demonstrated the efficacy of lifestyle intervention for the prevention of type 2 diabetes. The studies confirmed the potential for lifestyle interventions to delay and prevent type 2 diabetes onset among diverse racial and ethnic populations.

4.1.1 The Da Qing and IGT Diabetes Study

The first randomized trial investigating the efficacy of lifestyle intervention for type 2 diabetes prevention was the Da Qing and IGT Diabetes Study in China (11). In 1986, men and women over age 25 were screened in 33 health clinics for the presence of IGT via plasma glucose concentrations and confirmed via 2h-OGTT. A total of 577 individuals who had IGT and agreed to participate were subsequently enrolled and randomized by clinic to one of four treatment groups: diet intervention, exercise intervention, diet and exercise intervention, and standard care control (11).

The diet only intervention focused on proportional consumption of carbohydrates, protein, and fat as well as increased intake of vegetables and reduced alcohol and sugar consumption. Participants with a BMI greater than 25 kg/m^2 were encouraged to reduce caloric intake in order to achieve a 0.5-1.0 kg weight loss per week to reach a BMI of 23 kg/m^2. All participants received individual physician counseling as well as opportunities for small group sessions, weekly then monthly initially, followed by every 3 months for the duration of the study (11).

The exercise only intervention encouraged participants to increase their physical activity above enrollment levels by adding 30 minutes of light, 20 minutes of moderate, or 10 minutes of vigorous activity per day. This equates to 140 minutes of additional moderate intensity PA per week, a goal similar to current public health recommendations. Physician counseling provided individual exercise goals based on age and presence of CVD risk factors or subclinical disease. Group sessions were offered with the same frequency as the diet only intervention (11).

Clinics in the diet plus exercise intervention provided counseling on both diet and exercise, as described above. The clinics in the control group provided basic information about IGT and diabetes along with general recommendations for diet and physical activity (11).

The primary outcome was diabetes incidence, assessed via 2h-OGTT at 2 year intervals during follow-up. At 6 years, all three intervention groups resulted in decreased diabetes incidence, with reductions of 31%, 46%, and 42% in the diet only, exercise only, and diet plus exercise arms, respectively (11), when compared to the control group.

Twenty years after enrollment in the Da Qing study, participants in any of the original lifestyle intervention arms (diet only, exercise only, diet plus exercise) had a combined 43% lower incidence of diabetes compared to the control group (115) as well as a reduction in retinopathy as a complication of diabetes (116). Rates of CVD events and deaths were similar among groups (115).

4.1.2 The Finnish Diabetes Prevention Study

The results from early randomized and non-randomized studies prompted the development of the Finnish Diabetes Prevention Study (DPS) to answer questions regarding the efficacy of lifestyle intervention for the prevention of type 2 diabetes in the absence of pharmacologic approaches (117). Conducted across five medical centers in Finland, the DPS randomized 522 participants between 1993-1998 into a behavioral lifestyle intervention (N=265) or to standard care control (N=257) (118). Eligible participants were overweight (BMI $\geq$ 25 kg/m^2), 40-64 years of age, and had IGT as assessed by 2h-OGTT at time of enrollment. Further, participants were randomized by center, sex, and mean 2h glucose concentration (117).

The lifestyle intervention was administered for 4 years, consisting of individual counseling and group sessions. The goals of the DPS lifestyle arm were a weight reduction of 5-10 kg and 30 minutes of moderate physical activity per day. Participants met with a nutritionist to establish dietary guidelines, centering around reduced fat and cholesterol intake and increased fiber intake. Lifestyle participants were individually counseled to increase physical activity, both aerobic and resistance training exercises. Each study center offered guided exercise classes when resources allowed, including supervised resistance training sessions (117).

The primary outcome of the DPS was incident cases of diabetes, detected annually by 2h-OGTT. After an average 3.2 years of follow-up, investigators reported a 58% reduction in the incidence of type 2 diabetes in the lifestyle arm (118). Secondary outcomes of the DPS included glucose tolerance, insulin, CVD risk factors, and quality of life (117). In addition to reduced diabetes incidence, the lifestyle intervention group achieved significantly greater reductions in weight and improvements in metabolic and CVD risk factors (117, 118). Continued follow-up of DPS lifestyle arm participants indicated an overall 43% reduction in relative risk for type 2 diabetes at 7 years (119) and continued reduced risk at 13 years (120).

The physical activity goal was the most often met goal in the DPS. At one year, 86% of DPS participants reported achieving 30 minutes of moderate PA per day based on a general questionnaire of lifestyle behaviors (10). Among participants who did not meet the 5% weight loss goal, meeting the PA goal resulted in 0.2 odds for developing diabetes compared to those who maintained a sedentary lifestyle (10). After 3 years, 82% of participants continued to meet the PA goal and experienced continued benefit for diabetes risk reduction (119). Physical activity level, captured by the Kuopio Ishaemic Heart Disease Risk Factor Study 12-month Leisure-Time Physical Activity questionnaire, increased from baseline to one and three years compared to the control group. Participants in the lifestyle intervention increased moderate-to-vigorous leisure activity by 49 and 61 minutes per week at years one and three, respectively (118). Total activity, assessed by the same questionnaire, did not increase significantly over the control group during this same period of follow-up.

4.1.3 The Indian Diabetes Prevention Programme

Following the Da Qing, Finnish DPS, and the U.S. DPP, the Indian Diabetes Prevention Programme (IDPP-1) demonstrated the efficacy of lifestyle intervention for type 2 diabetes prevention among Asian Indians (33). The IDDP-1 enrolled and randomized 531 participants working in service organizations into four groups: usual care control, lifestyle intervention, Metformin medication, and a combination of lifestyle intervention and Metformin. Eligible participants were non-diabetic adults aged 35-55 with IGT, confirmed by 2-h OGTT (33). In contrast to earlier trials, the IDDP-1 did not use BMI or weight as entry criteria, with the resulting cohort having a relatively low mean baseline BMI of 25.8 kg/m^2.

The IDPP-1 lifestyle intervention included dietary modifications to reduce total calories, refined carbohydrates/sugars, and fat and increase fiber as well as to achieve 30 minutes of moderate physical activity per day. Participants received individual sessions over 6 monthly visits as well as monthly telephone contacts for continued motivation to make lifestyle changes (33). The proportion of participants getting the recommended PA level increased from approximately 40% at baseline to approximately 70% at 36 months in the lifestyle and lifestyle plus Metformin groups (33). Similarly, 80% of participants in the lifestyle and lifestyle plus Metformin groups adhered to the dietary guidelines at 36 months (33).

As with the Da Qing and DPS, diabetes incidence was the primary outcome, diagnosed by either fasting glucose or 2-h plasma glucose concentration. The lifestyle intervention resulted in a 28.5% reduced risk for type 2 diabetes, as well as lifestyle plus Metformin showing a 28.2% reduced risk (33). Contrary to previous trials, weight loss was not observed in any intervention arm and significant weight gain was noted at 24 months in the lifestyle arm; however, this was not unexpected given the relatively low mean baseline BMI and recruitment of normal weight individuals into the trial. Prevalence of elevated CVD risk factors was investigated as a secondary outcome. It was found that prevalence of hypertension increased in all four intervention groups, there were no significant changes in total cholesterol, HDL-cholesterol, or triglycerides and there was a significant improvement in LDL-cholesterol observed for all intervention groups (121).

4.1.4 The Japan Diabetes Prevention Program

The unexpected rapid increases in type 2 diabetes incidence in Japan led to a diabetes prevention effort among adults in Japan (122). The study enrolled men who were mostly government employees. Participants were recruited from a health-screening program and had a fasting plasma glucose and two-hour plasma glucose corresponding to impaired glucose tolerance (IGT). Exclusion criteria included history of diagnosed diabetes, neoplasm, and kidney or cardiovascular diseases. Participants were randomized to a standard or intensive lifestyle intervention in a 4:1 ratio (N=356, N=102, respectively). The primary outcome was incidence of diabetes, determined by a 100g OGTT every 6 months.

All participants received information about diabetes risk factors and healthy lifestyle practices, including maintaining a BMI <22 kg/m^2 and increasing physical activity, at time of enrollment. The intensive lifestyle intervention was tailored to each participant, with focus on portion sizes, fat and alcohol consumption, increasing fruit and vegetable intake, and achieving desirable levels of physical activity. Participants were advised to perform 30-40 minutes a day of moderate exercise similar to walking and were coached on individual strategies to achieve this goal. Intensive lifestyle participants met every 3-4 months to review progress and adjust habits to achieve desirable weight loss of 0.5-1.0 kg/month. Participants in the standard group reported to the hospital once every 6 months for assessments and information on healthy lifestyle practices was re-emphasized (122).

Success similar to the previous trials was observed in the Japanese prevention effort. After 4 years of follow-up, the incidence of diabetes was 3.0% in the intensive intervention group and 9.3% in the standard intervention group, corresponding to a 64.7% reduction in diabetes incidence in the intensive lifestyle group compared to standard intervention controls. This was accompanied by a significantly greater weight loss of 2.18 kg in the intensive intervention group compared to a loss of 0.39 kg in the standard intervention group. Success of the PA portion of the lifestyle intervention was not reported. Additionally, 53.8% compared to 33.9% of participants improved from having IGT to non-IGT after 4 years in the intensive and standard groups, respectively (122).

The initial success in Japan sparked an investigation among overweight adults (BMI $\geq$ 24 kg/m^2) with impaired fasting glucose (36). This unmasked, multi-center, randomized controlled trial enrolled a more diverse sample of 641 Japanese adults, 72% of which were men. Participants were randomized to a frequent lifestyle intervention (9-11 individual sessions at 3-6 month intervals) or control group (4 sessions at 12 month intervals) over a 3 year period. The primary outcome was incidence of type 2 diabetes, determined by a 75g OGTT conducted annually.

All participants were advised to reduce energy intake and increase physical activity. Participants in the frequent intervention (N=311) were counseled on specific strategies to reduce fat and calorie intake and gradually increase physical activity to achieve daily expenditure of 200 kilocalories and a 5% weight loss. After 36 months of follow-up, the incidence of type 2 diabetes was 12.2% in the frequent intervention group and 16.6% in the control group, corresponding to a 44% reduction in risk for type 2 diabetes. The proportions of participants who met the 5% weight loss and 200 kcal/day physical activity goals were significantly higher in the frequent intervention group (36). Additionally, participants in the frequent intervention group significantly increased amount of time spent walking. All PA behaviors were self-reported on a general questionnaire that inquired about the frequency, duration, and type of leisure activities performed.

4.2 THE U.S. DIABETES PREVENTION PROGRAM

The U.S. Diabetes Prevention Program (DPP) tested the efficacy of an intensive lifestyle intervention compared to Metformin and placebo treatment for the prevention of type 2 diabetes. The DPP oversampled racial and ethnic minorities, women, and those over age 65 in order to better understand efficacy of prevention and reflect the disparities in diabetes prevalence among sub-populations as well as provide greater better generalizability than previous studies (123).

4.2.1 Methods and Description

The DPP enrolled 3,234 participants from 27 geographically diverse sites across the United States (9). Eligibility criteria included age $\geq$ 25 years and presence of IGT determined by fasting plasma glucose between 95-125 mg/dL or 2-h OGTT between 140-199 mg/dL (123). Participants were randomized to an intensive lifestyle intervention, treatment with Metformin, or to receive a placebo. The primary outcome was incidence of type 2 diabetes in each of the three intervention arms, determined by fasting plasma glucose or 2-h OGTT every 6 months. Secondary outcomes included rates of cardiovascular disease and changes in glycemia, beta-cell function, insulin sensitivity, obesity, physical activity, and health-related quality of life between the three intervention arms (123).

All participants received general lifestyle information at time of randomization. This included recommendations to lose 5-10% of body weight through healthy eating and increased physical activity. Participants receiving Metformin and placebo started with oral doses taken once daily and progressed to twice daily doses. These participants had annual sessions with a case manager who reviewed the general lifestyle practices initially recommended (123).

The intensive lifestyle intervention was individually administered by a case manager. The goals of the intervention were 7% weight loss through healthy eating and physical activity. The physical activity goal was 150 minutes of moderate intensity activity per week, which aligns with public health recommendations for PA and was based on the 1996 Surgeon General's Report. Participants received guidelines on reducing fat and calorie intake in addition to coaching on self-monitoring and goal setting. The intervention consisted on a 16-session core delivered by the case managers over 24 weeks, followed by monthly contacts. Additional supervised group exercise sessions were offered to interested participants twice per week during core intervention to help with increasing physical activity levels. Group courses were offered during the maintenance phase to assist participants with weight loss, exercise, and behavioral issues (123).

4.2.2 Results

The intensive lifestyle intervention was incredibly successful for improving behaviors and reducing the incidence of type 2 diabetes. Related to program goals, lifestyle participants achieved significant weight loss and increases in physical activity. The PA goal was achieved by74% of participants at 24 weeks and 58% maintained activity at the recommended level at the last follow-up. Similarly, the weight loss goal was achieved by 50% of lifestyle participants at the end of 24 weeks and 38% maintained the weight loss to end of follow-up (approx. 3 years). At 3 years, participants in the lifestyle arm increased physical activity by 6 MET-hours per week, as assessed by the past-year Modifiable Activity Questionnaire, and lost an average of 5.6 kg. These desirable changes were significantly greater than those observed in the Metformin and placebo groups (9).

As a result of changes in physical activity and weight, participants in the lifestyle arm had a 58% and 39% lower incidence of type 2 diabetes compared to the placebo and Metformin groups, respectively. This reduction in risk due to intervention held across social and demographic characteristics (9), a finding uniquely shown by the DPP due to the design and recruitment strategies used. The success of the DPP for modifying lifestyle behaviors led to further investigation between achieving each goal and diabetes risk reduction. In post-hoc analysis, meeting the PA goal was associated with a 44% reduction in diabetes incidence, independent of meeting the weight loss goal (35).

In regards to secondary outcomes, the DPP lifestyle intervention was found to be beneficial for cardiovascular disease risk reduction (124). Among participants who did not have the metabolic syndrome (MetS) at baseline, three-year incidence of MetS was 34%, 45%, and 51% in the lifestyle, Metformin, and placebo arms, respectively. This translates to a 41% reduction in incidence of MetS in the lifestyle arm compared to the placebo. Similarly, the lifestyle intervention demonstrated an effect on existing MetS, resulting in resolution of MetS components after 3 years (124).

Given the reduction in diabetes incidence that resulted from high achievement of PA and weight loss goals in the DPP, researchers investigated factors that predicted participant success in meeting these goals. Achievement of the PA goal was significantly associated with increased age, male gender, and lower BMI (34). Additionally, a higher proportion of participants who were retired met the PA goal than those who were employed full or part time. Long-term PA goal achievement was also predicted by race/ethnicity, with non-White participants more likely to meet the PA goal than White. In contrast, White participants were more likely to meet the weight loss goal at the end of core intervention. Meeting the PA goal was a predictor of meeting the weight loss goal, both short and long term. The number of self-monitoring records submitted predicted meeting both PA and weight loss goals, independently (34).

The success of the lifestyle intervention for reducing diabetes incidence led to early termination of the trial (9). Participants receiving Metformin and placebo then entered a wash-out period to remove lingering effects of the medication. All participants, regardless of randomization assignment, were then offered the lifestyle intervention (125). Sessions were conducted in group format and covered the 16-session core curriculum of the DPP. The participants were then invited to enroll in a follow-up study to monitor diabetes incidence and related cardiovascular outcomes.

4.2.3 Diabetes Prevention Program Outcomes Study

Of the original DPP cohort, 2,766 participants enrolled in the Diabetes Prevention Program Outcomes Study (DPPOS) (125). The DPPOS offered continued lifestyle support to all participants through two programs. Lifestyle sessions were offered every 3 months to review educational materials originally presented in the intervention and reinforce lifestyle goals. Group classes were offered as a sequence of 4 sessions to enhance self-management practices. Outcomes related to diabetes incidence and CVD were assessed every 6 months. The primary outcome, as with the DPP, was incidence of type 2 diabetes (125).

The cumulative incidence of diabetes was lowest in the original lifestyle arm from time of original randomization to follow-up in the DPPOS (125). During the mean 5.7 years in the DPPOS, progression to diabetes was similar between the three original DPP study arms. However, incidence rates in the Metformin and placebo arms were lower in the DPPOS than in the DPP, demonstrating the added benefit of lifestyle intervention. Additionally, 23%, 19%, and 19% of participants in the original lifestyle, Metformin, and placebo groups became normoglycemic during follow-up, respectively.

Change in weight during the DPPOS was similar among the three DPP arms (125). Lifestyle participants experienced a slight weight gain, while Metformin and placebo participants had a slight weight loss. Moderate-vigorous physical activity, assessed subjectively by the Modifiable Activity Questionnaire, remained significantly higher among lifestyle participants compared to placebo after 1 year in DPPOS and remained above DPP baseline by year 5 of

DPPOS, but this difference was not significant (126). After 10 years in the DPPOS, participants who originally started in the lifestyle arm reported more total PA than other DPP participants, as assessed objectively by accelerometer (127). Similarly, DPPOS participants had higher levels of objectively measured moderate-vigorous PA than a similar high-risk nationally representative sample (128). All participants reduced blood pressure, LDL cholesterol, triglycerides, and increased HDL cholesterol during the DPPOS, with no between arm differences (126). However, medication use was higher in the original Metformin and placebo arms (126). This demonstrates the added benefit of lifestyle intervention for managing CVD risk factors.

5.0 TRANSLATION OF THE DIABETES PREVENTION PROGRAM

The reduction in diabetes risk as a result of healthy lifestyle changes in the DPP and continued health benefit of lifestyle changes observed in the DPPOS exposed the tremendous potential for lifestyle intervention to be used to prevent or delay type 2 diabetes. The uniform benefit of lifestyle intervention compared to placebo and Metformin for diabetes prevention across socially and demographically diverse populations in the DPP indicated that translation to diverse community settings could be possible. As intervention studies moved from efficacy to effectiveness, the DPP lifestyle intervention materials were adapted for more cost-effective delivery in community settings using group-based approaches, existing health-care infrastructure, and multiple delivery methods to maximize reach. Although DPP-based interventions vary to some degree in content and structure, all programs utilize the behavioral approaches used in the DPP and focus on achieving 5-7% weight loss through healthy eating and increasing physical activity to at least 150 minutes per week. The 5% target has been used in translation as it is recommended by the CDC as the minimal weight loss required for substantial health benefits (129). Most studies have utilized a prospective observational design to evaluate intervention effectiveness for improving lifestyle behaviors and achieving weight loss, but a few have used randomized designs to test single or multiple intervention strategies (130-135).

5.1 SETTINGS

5.1.1 Primary care and health care facilities

Implementation of DPP-based intervention programs has been most extensively evaluated in primary care and health-care facilities. This is largely due to the ease of identifying at-risk individuals and the ability to integrate programming with medical care. More specifically, programs have been delivered in primary care offices (44, 130, 133, 135-139), out-patient facilities (40, 140-143), and an academic general internal practice (144-146). These programs typically test the effectiveness of a guided intervention program against standard or usual care. A few of the programs offered supervised exercise sessions in conjunction with the lifestyle intervention (41, 130, 141) and one program was in conjunction with a cardiac rehabilitation program (142).

Different methods of program delivery have been used, including in-person sessions and self-guided interventions. Lifestyle coaches in this setting are trained health professionals, often nurse practitioners or diabetes educators. These programs have been successful for improved behaviors and weight loss, whether participants are under direct supervision of their health care provider or the health care provider is receiving periodic feedback to then counsel the participant. As a whole, the structured interventions have been more successful for changing participant behaviors and achieving program goals than what is achieved with usual care.

5.1.2 Worksites

Little is known about translation of evidence-based programming into the worksite setting. Worksites offer a unique opportunity to provide health services, given a captive audience and general space availability (147). Several evaluations conducted in the worksite setting (147-151) have demonstrated success for achieving weight loss and increasing physical activity levels among employees. These programs were either self-directed (151) or administered by health professionals within the organization (147, 148). Two of these studies were able to offer employees resources for physical activity during the program (147, 148). The biggest concern for employers, outside of improving employee health, is cost of intervention delivery (147). Evaluating cost-effective and health-promoting programs in the worksite is increasingly an area of research interest.

5.1.3 Community Centers

Community and recreation centers have been frequently utilized to deliver diabetes prevention programming. This setting has been the most promising for reaching economically disadvantaged and medically underserved populations (42, 152-155). In this setting, trained health professionals, peer-educators, and community health workers have served as lifestyle coaches.

Several community-based programs, especially those delivered in centers such as the YMCA, have been able to offer participants access to exercise equipment and resources during the program (131, 154, 156-158). Additionally, a few programs offered supervised exercise sessions as part of intervention (159-162).

The success of community-based interventions for weight loss, improvement of diabetes and cardiovascular disease risk factors, and some physical activity outcomes has been consistently observed. The community setting shows the most promise for wide-spread dissemination of diabetes prevention programming, however many questions regarding feasibility and sustainability remain.

5.1.4 Churches

Several pilot studies (163-168) and one large cluster-randomized trial (134) have looked at delivering interventions through African American churches. These interventions attempt to draw on the sense of community within churches to provide social support for making healthy lifestyle changes. The results of these efforts indicate church-based programming is feasible and well-accepted (163, 165) and can achieve desirable improvements in weight and some diabetes and CVD risk factors (164, 167). Determining culturally appropriate and acceptable ways to increase moderate physical activity remains a challenge in this setting.

5.2 DELIVERY APPROACHES

5.2.1 Individual

A few translation studies have maintained the individual approach to intervention delivery (44, 133, 142, 161, 169), utilizing nurse practitioners and diabetes educators in addition to one-on-one physician counseling. Although the individual model has been successful for weight loss and modifying behaviors in translation, the long-term sustainability is questionable due to the resource-intensive nature of personalized intervention.

5.2.2 Face-to-Face Group

Group-based delivery is the most frequently used intervention format and has shown the most promise for a sustainable model for diabetes prevention program delivery. This strategy is particularly successful in community center and church settings. The elements of group-based delivery, including participant-coach interaction, peer-discussion and problem-solving, and sense of support, have enhanced the acceptability and satisfaction with these programs. Group sessions are highly attended (43, 137, 140, 166, 167, 170, 171) and attendance to these programs, as well as adherence to the behaviors, has been correlated with weight loss (41, 43, 152).

5.2.3 Interactive Technology

A handful of studies have investigated delivering intervention through technology-based mediums including DVD (130, 137, 172), video-on-demand (173), internet (144), and telephone calls (135, 174). A few programs used a combination of media sources to deliver the intervention and provide continued support (172, 173, 175). Most programs included contact with a lifestyle coach, either by phone or e-mail, in addition to media-based sessions.

DVD with coach support has been the most consistently successful technology-based intervention (130, 137, 176, 177). Results for internet and telephone delivered interventions have been promising, but mixed. McTigue et al. found that an intervention delivered through the internet with e-mail communication with participants resulted in significant weight loss and improved blood pressure (144). In contrast, another study found that an internet program did not enhance the success of an intervention delivered through a video-on-demand service (173). However, the authors did not evaluate the use of the internet as the sole form of intervention delivery. Likewise, individual and conference calls were found effective for weight loss in one setting (135) and only suggestive for improved weight and physical activity in another setting (174).

5.3 PRIMARY AND SECONDARY OUTCOMES

Most translation studies report weight change as the primary outcome (13, 37) in kilograms, percent change, percent achieving weight loss goal, or a combination. Weight loss has been consistently observed in most translation efforts, with some reflecting the weight loss seen in efficacy trials (13, 14, 37, 146, 178). Changes in diabetes and cardiovascular disease risk factors are less frequently reported in translation studies with inconsistent improvements found (12, 37, 179). Although one of two intervention goals, little is known about PA outcomes and the role of PA in translation efforts.. First, a comprehensive examination of the literature is needed to determine the types of assessment methods used to collect PA information and how frequently and to what degree the PA-related outcomes are reported (Paper 1). Results from this review will help guide future evaluations of lifestyle intervention programs by suggesting elements to include in order to fully address the PA component of intervention.

Factors associated with achievement of weight loss goals have been evaluated in a few DPP translation studies (40-44) to include age, sex, BMI, and self-monitoring of weight, diet, and PA level. Only one study examined the factors associated with meeting the physical activity goal (40), reporting that men and those who monitored dietary fat intake were more likely to meet the PA goal. In the other four studies, PA level or increased PA was positively associated with achieving successful weight loss. The assessment of PA was limited in these studies, with four using self-monitoring records to determine PA level (40-43), a behavior itself that is related to weight loss success (100). The fifth study used a questionnaire of exercise behaviors that included a question on approximate minutes per week of recreational activities (44).The inclusion of interviewer-administered questionnaires in addition to participant PA records as a means to assess PA in the Healthy Lifestyle Project (PI: Dr. A. Kriska) allows for "success" in PA to be considered independent of self-monitoring behavior This limits the information bias that can be inherent when using self-monitoring records to determine PA level since self-monitoring behavior has been shown to be associated with program success (100).

The findings from these translation studies support the evidence that high levels of PA are associated with achieving weight loss (86, 89, 90). Although PA is an important study goal, little is known about the factors predicting successfully meeting the PA goal and maintaining high PA levels. Although seasonal weather patterns have been shown to influence PA levels (23, 24), none of the evaluations of community interventions have looked at the impact of environment or season on PA levels. Further investigation of the individual impact of intervention and season (Paper 2) and the predictors of PA success (Paper 3) is warranted to help guide future prevention efforts and develop effective strategies for improving PA.

5.4 SUMMARY OF DPP TRANSLATION

Community diabetes prevention translation studies based on the DPP differ widely in their reach, depending on resources and dissemination patterns (community-based programming vs. state-wide prevention strategies) (13). Overall, these programs have been successful for weight loss, improvements in diabetes and CVD risk factors, and increases in physical activity. Continued evaluation of alternative delivery methods in a variety of settings will answer questions related to challenges of implementation and dissemination.

In an attempt to ensure consistency in delivery of evidence-based prevention programs, the CDC developed the National Diabetes Prevention Recognition Program (DPRP) to recognize organizations that are effectively delivering intervention programs to prevent diabetes (180). The DPRP provides guidelines for program content to insure fidelity to evidence-based programming. The standards and requirements for recognition provide guidelines for participant eligibility, safety of participants and data privacy, location, staffing, and curriculum content (181). In short, the DPRP requires a program to enroll at least 50% of participants based on presence of pre-diabetes, employ competent health professionals trained to deliver the specified intervention, and include sessions which cover the content of the 16 DPP core sessions. The National Registry of Recognized Diabetes Prevention Programs includes programs in all 50 states, the District of Columbia, and Guam (180).

6.0 GROUP LIFESTYLE BALANCE

Although many translation programs have been developed, those with the highest fidelity to the original DPP intervention are the most widely disseminated and evaluated. Some of these programs include adaptations at Indiana University for delivery in YMCAs (182) and adaptations at Wake Forest University for delivery by community health workers in Diabetes Care Centers (183). The program used for the investigations within this dissertation was adapted from the DPP by members of the DPP Lifestyle Resource Core who are now faculty at the University of Pittsburgh Diabetes Prevention Support Center (DPSC). The program, Group Lifestyle Balance (GLB), is an approved curriculum for application to the CDC's National Diabetes Prevention Recognition Program (180, 181) discussed in the previous section.

6.1 GROUP LIFESTYLE BALANCE CURRICULUM AND TRAINING

The GLB curriculum covers the content of the original DPP lifestyle intervention, with modifications that include condensing the 16 DPP sessions to 12 core sessions, and formatting for group delivery rather than individual (136). The core content focuses on increasing PA and reducing fat and calorie intake in order to achieve desired weight loss. The GLB also introduces a pedometer in session 10 as a tool to promote PA. After the 12 core sessions, ten additional sessions were added to assist individuals in maintenance of healthy lifestyle behaviors and further improve health. The post-core includes sessions focusing on strength and flexibility as well as reducing sedentary behavior and reflects the latest developments in the field. The GLB content is presented in a 12-month, 22-session format with 12 weekly, 4 bi-weekly, and 6 monthly sessions. The goals of the GLB are equivalent to the DPP lifestyle intervention and include 5-7% weight loss and 150 minutes of moderate intensity physical activity per week. The GLB is delivered by interventionists trained by the DPSC faculty.

The DPSC faculty provides training workshops for health professionals in order to ensure fidelity to the delivery of the GLB (136). The two-day workshop provides an overview of the DPP, including rationale, design, and results and the development of the GLB. The workshop prepares health professionals to act as lifestyle coaches delivering the GLB. This is accomplished by providing session-by-session tips for instruction and leading discussion about potential challenges and participant issues.

The GLB is delivered by trained lifestyle coaches over one year, including a 12-session "core" and a 10-session "post-core" (136, 158). Each session is delivered in approximately one hour. Materials for the first 12 sessions are available as handouts for face-to-face group meetings and in DVD-format. The GLB-DVD was developed with funding support from the Department of Defense in order to increase the utility of the intervention and provide a delivery option which expands the reach of the program (137). The DVD sessions are viewed on the participants' own time, with weekly follow-up provided by the lifestyle coach via e-mail or telephone contact.

6.2 GROUP LIFESTYLE BALANCE IMPLEMENTATION

The GLB program has been delivered in a variety of settings across the U.S. by DPSC trained lifestyle coaches. These settings include primary care (130, 137, 145, 184), outpatient diabetes education programs (140, 143), community settings (152, 154, 172, 185), and churches (186). These translation efforts include pilots to test implementation and dissemination procedures and program effectiveness (152, 186) as well as randomized trials to evaluate multiple delivery modalities (130, 172).

6.3 GROUP LIFESTYLE BALANCE EVALUATION

Evidence from GLB implementation indicates the translation potential into diverse community settings. Successful weight loss was achieved in all GLB evaluations, ranging from 3.5-6.6% (130, 136, 137, 140, 143, 152, 158). In one evaluation that did not report percent weight loss, a 12.2 and 14.0 pound weight loss was observed in intervention groups (172). The proportion of participants achieving the 5% weight loss goal in GLB evaluations ranged from 33% to 52.2% (130, 136, 140, 143, 152, 154). For the evaluations reporting on physical activity outcomes, the proportion of participants reporting regular PA of ≥ 3 days per week increased (137, 140) and recording PA behaviors increased (152). The proportion of participants meeting the PA goal in these studies was 41-52% (140, 143, 152). A few of the studies also measured and reported on diabetes and CVD risk factors, with varied improvement in fasting glucose, HbA1c, total and LDL-cholesterol, blood pressure, and waist circumference (136, 137, 140, 154, 172). The suggestive findings from these pilot and observational studies led to the development of The Healthy Lifestyle Project (PI: Dr. A. Kriska).

7.0 THE HEALTHY LIFESTYLE PROJECT

The Healthy Lifestyle Project (PI: Dr. A. Kriska) is supported by funding from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) grant number PRO10010131. The purpose of the project is to provide a thorough evaluation of the effectiveness of the DPP Group Lifestyle Balance (GLB) in diverse community settings, including a worksite, community centers, and a large military base. The focus was not only on changes in weight, physical activity, and diabetes and CVD risk factors, but on the unique challenges of implementing a community-based program in each of the three settings, with considerations for the sustainability of the program.

7.1 STUDY DESIGN

The study employed a randomized six-month delayed control design. Researchers used a stratified randomization scheme to assign participants by location to begin the DPP-GLB Program immediately (IMMEDIATE) or after a six month delay (DELAYED) in a 2:1 ratio. This design mimics the real-life circumstances surrounding community-based programs in that resources limit the frequency and capacity of programming, which may require potential participants to wait to begin a program.

7.1.1 The Worksite

The Healthy Lifestyle project investigators approached a large corporate employer with a campus in Allegheny County to implement the DPP-GLB. Principal and co-investigators established a relationship with the campus' medical director in order to create interest in the program and obtain support from the administration and management team. Employees and their family members were invited to participate in the study.

7.1.2 The Community

Project investigators partnered with three local community centers through the Area Agency on Aging in Allegheny County. The community centers were selected from diverse socio-economic neighborhoods, located in one urban and two sub-urban areas. Each center had membership opportunities, but was open to community members. The centers offered social activities and services, such as supervised exercise classes and a lunch program. One of the centers was also a fitness facility and day-care.

7.1.3 The Military

Researchers collaborated with a health-care provider at a large military hospital to provide the DPP-GLB. The military setting was chosen because very little evaluation has been done on the effectiveness of lifestyle programs for weight loss and risk modification in this population. The military setting offered a unique opportunity to explore approaches to implementation. The site principal investigator is a Certified Diabetes Educator and DPP-GLB trained lifestyle coach.

Additionally, support staff and interventionists had previously been trained to deliver the DPP-GLB. The investigation conducted at the military site is on-going, so the results of this phase of the project will not be included in this dissertation.

7.2 RECRUITMENT OF PARTICIPANTS

Multiple recruitment strategies unique to each setting were used. At the worksite, study staff held “lunch and learn” sessions in which employees were briefed on the study purpose and invited to speak with a staff member to determine potential eligibility. Additional strategies included staff attendance at health fairs, posters, and mailings to employees initiated from within the corporation. At the community centers, posters with dates and times of information sessions were placed on bulletin boards to create interest. The information sessions were held during the lunch hour at several sites and during times when community members were likely to frequent the centers. Additional posters advertised the dates and times for screening. Zip-code targeted mailings were also used to advertise and generate interest in the neighborhoods surrounding each community center. At the military hospital, posters advertised the program in high-traffic areas. Active-duty and retired service members and their dependents were encouraged to contact the site principal investigator if they were interested in screening for the program.

Interested individuals at the worksite and community center settings were assessed onsite or via telephone to determine eligibility for attending an on-site screening visit. In this initial step, volunteers who were less than 18 years old, had been diagnosed with diabetes, were planning to move away from the area, or had a self-reported BMI less than 24 kg/m^2 (<22 kg/m^2 for Asians) were deemed not eligible. Potentially eligible volunteers were invited to an on-site screening to determine eligibility for the study. Written, informed consent was provided by each participant prior to beginning the on-site screening. Participants provided demographic information, including date of birth, race/ethnicity, employment status, and highest education obtained in addition to information on family history of diabetes and CVD. On-site screening involved a finger stick with sterile lancet to obtain a blood sample. The sample was analyzed in a Cholestech LDX system for fasting plasma glucose and lipid measurements. Another sample taken from the same finger stick was evaluated in a Siemens/Bayer DCA 2000 for a measurement of hemoglobin A1c (HbA1c). Trained research staff also measured resting arterial blood pressure, height and weight to determine BMI, and waist circumference. Participants' medication history was reviewed for prescriptions affecting blood pressure, lipids, and glucose. Eligible adults had a BMI $\geq$ 24 kg/m^2 ($\geq$ 22 kg/m^2 for Asians) and pre-diabetes (fasting glucose of 100-125 mg/dL and/or HbA1c of 5.7-6.4%) and/or the metabolic syndrome (NCEP ATP III criteria), or hyperlipidemia and one additional component of the metabolic syndrome. Eligible and interested individuals provided written, informed consent before enrolling in the study.

7.3 INTERVENTION DELIVERY

The DPP-GLB was delivered within each setting by a DPSC trained health professional. The intervention followed a face-to-face group or individually-viewed DVD with coach support format. Each face-to-face group session was approximately one hour in length and covered designated DPP-GLB session materials. Prior to each session, participants were individually and privately weighed-in by the lifestyle coach, allowing for brief interaction and exchange of keeping track books. After the intervention session, the coach was available for questions and brief discussion of concerns. Each group was comprised of 8-15 individuals.

Participants viewing the DPP-GLB-DVD received a follow-up phone call or e-mail contact from their lifestyle coach each week during the first 12 weeks. The coach reviewed the prior week's session materials and provided feedback on participant progress. This presented participants an opportunity to ask questions and discuss concerns. The DPP-GLB-DVD participants met once per month in face-to-face groups during the first 12 weeks and then monthly during the remaining intervention.

Prior to intervention participation, participants were required to submit a physician approval form for physical activity equivalent to 150 minutes per week of moderate intensity, similar to brisk walking. This form was submitted prior to participants beginning physical activity or increasing the duration or intensity of their current physical activity.

7.4 EVALUATION

The primary end-point of this study is weight loss during the 6 month control period in the IMMEDIATE intervention arm compared to the DELAYED arm. Secondary outcomes of interest are change in physical activity, diabetes risk factors, and CVD risk factors in IMMEDIATE participants compared to the DELAYED participants during the control period. Tertiary outcomes are the changes in weight, physical activity, and cardio-metabolic parameters after 12 months of the DPP-GLB intervention, regardless of randomization assignment.

Participants were invited to attend assessment visits at randomization (baseline), and 6, and 12 months from start of intervention. Participants in the DELAYED arm attended one additional assessment visit at 6 months following randomization to capture clinical and PA measures at the end of the control period. At each of these assessment visits, participants were weighed in light clothing and without shoes. Participants were asked to provide a fasting (at least 8 hours) venous blood sample, drawn by a trained staff member. The sample was sent to a Quest Diagnostics® laboratory to be analyzed for plasma glucose, HbA1c, insulin, total cholesterol, HDL-cholesterol, LDL-cholesterol, and triglycerides. Prescription medication use and health history was reviewed with the participants and updated at each assessment visit. A trained staff member administered a brief lifestyle questionnaire to capture general behaviors and the Modifiable Activity Questionnaire (MAQ) in order to assess physical activity levels. Participants were asked to complete a questionnaire of willingness to engage in healthy lifestyle behaviors, the EuroQol Health Questionnaire (EQ-5D) to indicate quality of life, and an expenses survey to capture costs related to participating in intervention. At 6 and 12 months, a program satisfaction survey was completed by the participants. All participants were asked to attend a brief visit at 18 months from start of intervention to obtain weight and complete the Lifestyle Questionnaire.

7.5 COMPUTATION OF PHYSICAL ACTIVITY VARIABLES

The questionnaires used to assess physical activity are located in Appendix B. For the investigations in this dissertation, leisure PA measured by these questionnaires was used to determine success of the lifestyle intervention for increasing PA, since this is the domain most expected to be impacted by the intervention.

7.5.1 The Modifiable Activity Questionnaire (MAQ)

The MAQ was originally developed by Dr. Kriska to capture past year PA (96) and has been tested for reliability and validity in many diverse populations in past year, past month, and past week versions (48, 97-99, 187). The Healthy Lifestyle Project utilized a past month version of the MAQ to capture leisure, transportation, and occupational physical activity at baseline, 6, and 12 months. The use of the past month MAQ in this investigation enables changes in leisure PA to be determined at the mid-point and at the end of the 12-month intervention period, which occur in opposite calendar seasons.

The past month MAQ was used to assess leisure PA in MET-hours per week. Each participant was interviewed to determine the frequency and duration of participation in 41 pre-determined activities during leisure time over the past month. Each activity was assigned an intensity value, expressed in metabolic equivalents (METs). Light intensity activities, such as fishing and bowling, were assigned 1.5 METs. Moderate intensity activities, such as walking and dancing, were assigned 4 METs. Vigorous intensity activities, such as jogging, were assigned 7METs. These MET values represented the middle of a range of potential values for each intensity level (15). The intensity of each activity was multiplied by the average duration for that activity to determine the volume of physical activity performed, expressed in MET-hours. The MET-hours of all activities were totaled and then divided by 4 to determine total leisure PA per week. Calculations were completed using statistical analysis software and then a random sample of MAQs was calculated by hand to check accuracy.

Hours of leisure sitting per day was determined by the question "Excluding time at work, in general how many hours per day do you usually spend watching television or sitting at the computer?" Participant responses were given in 15 minute increments and converted to hours.

7.5.2 The Lifestyle Questionnaire (LSQ)

The LSQ collected participant information on family history of diabetes and CVD and smoking history, as well as frequency of performing healthy lifestyle behaviors such as self-monitoring of food and activity and self-weighing. This questionnaire was administered at baseline, 6, 12, and 18 months.

Minutes per week of leisure physical activity was determined by the LSQ by two subsequent questions. First, participants were asked “How often do you perform physical activity?” This was quantified in days per week. If the participant was active less than 1 day per week, the responses were “2-3 times per month” or “less than once per month or never”. If the participant responded “2-3 times per month” the number of times per week was determined by dividing the mid-range (2.5 times) by 4 weeks, equaling 0.625 times per week. If the participant responded “less than once per month or never” the number of times per week was zero.

Secondly, participants were asked “When you are active, how many minutes are you active on average?” This minute value was multiplied by the number of days per week the participant reported being active in the previous question to determine minutes of activity per week.

Regular physical activity was defined as being physically active on 3 or more days of the week. Participants were asked “Are you physically active on 3 or more days of the week?” To confirm this answer, the response was cross-checked with the participant response to “How often do you perform physical activity?” If this response was greater than or equal to 3 days per week, the person was considered to perform regular physical activity.

8.0 PAPER #1: EVALUATION OF THE REPORTING OF PHYSICAL ACTIVITY IN COMMUNITY LIFESTYLE INTERVENTIONS: A SYSTEMATIC REVIEW

8.1 INTRODUCTION TO PAPER #1

Lifestyle goals of DPP-based translation programs reflect the DPP goals of 7% weight loss and 150 minutes of moderate physical activity (PA) per week. Given that PA is one of two primary lifestyle goals and has been linked to both weight loss and improvements in metabolic health in the DPP, it is important to understand the role that PA plays in the success of translation efforts in the community setting. Without reporting of PA assessment and related outcomes, program effectiveness for increasing PA cannot be evaluated and the role of PA in weight loss and improvement in diabetes and CVD risk factors cannot be examined. The DPP-translation literature has been reviewed for the effectiveness of intervention for weight loss (12-14), but little is known about the impact of these translation efforts on PA levels.

8.1.1 Purpose

This systematic review will thoroughly evaluate the reporting of PA methodology and PA results in community translations of the DPP in order to guide future prevention efforts and program evaluations.

8.1.2 Methods

An article search was performed in PubMed and Ovid (MEDLINE and PsycINFO) databases on March 2, 2015 to identify publications detailing lifestyle interventions for the prevention of type 2 diabetes. The search was limited to abstracts and full-text articles published in English language, with human subjects, and a date range of January 2002-March 2015. The date range was selected to include articles published after the original publication of the Diabetes Prevention Program results.(Knowler et al., 2002) Keywords used include diabetes, pre-diabetes, metabolic syndrome, translation, lifestyle, intervention, prevention, adults, and diabetes prevention program, searched in article text and titles. Reference lists of published reviews and meta-analyses of DPP translation literature were searched for additional publications not identified in the online database search.

Inclusion criteria comprised peer-reviewed articles of original research conducted in the United States in adult populations at high-risk for type 2 diabetes and/or cardiovascular disease (CVD) that used an intervention design with a minimum of six sessions based on the DPP lifestyle intervention theory or curriculum. The literature search strategy is detailed in Figure C1 of Appendix C.

8.1.3 Information Extracted

Data extracted from each publication included the study design, participant demographics, location of the program (city/state), setting in which the intervention was delivered, format of intervention delivery, length of intervention and follow-up, PA goal, inclusion of PA sessions as part of intervention, PA measurement and assessment, PA results, and information related to primary and secondary study outcomes. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 27-item checklist was used to guide evidence acquisition and synthesis (Appendix A).

8.1.4 Key Findings

A total of 72 articles, representing 57 unique study populations, met the inclusion criteria for the evaluation of DPP-based intervention programs for reporting of PA goals, measurement, and outcomes. The focus of the evaluation is on the 44 unique study populations, with publications of the same study population being combined for the evaluation of inclusion of PA data collection and PA results reporting (Table C1 in Appendix C).

8.1.4.1 Reporting of PA Assessment Methods

Forty-seven of the 57 studies (82%) described the method used for collecting PA information during lifestyle intervention or at assessment visits, with some studies using multiple assessment tools. Of the studies collecting PA information, 46 used subjective measures. Questionnaires were the most frequently utilized assessment tool (59%) followed by daily activity logs (41%). The various questionnaires used are indicated in Table C2 in Appendix C.

8.1.4.2 Reporting of PA Results

Only 34 of the 57 translation studies (60%) reported PA results or PA related outcomes following intervention. Nineteen studies reported statistically significant results for improvements in PA measures (Table C3, Appendix C) derived from a variety of methodologies (i.e. intention to treat, last observation carried forward, and including those who complete a certain number of intervention sessions and/or assessment visits). The most frequent forms in which PA results were presented were the proportion who met the PA goal and/or the mean minutes of PA per week during intervention. Other outcomes reported included aerobic fitness, days per week of PA, MET-hours per week, self-efficacy related to PA, PA level, and proportion of participants reporting regular physical activity.

8.2 DISCUSSION OF KEY FINDINGS

Reporting of physical activity assessment and related outcomes in DPP-based translation efforts has been inconsistent. Although all 44 studies include a PA goal consistent with the DPP PA goal, only 82% assess PA and 60% report PA outcomes. A concern is that only 26% of the 57 studies report meeting the PA goal in the results, leaving incomplete information on the effectiveness of community-based lifestyle intervention for increasing PA levels among adults at-risk for diabetes and CVD.

For the studies (26%) reporting meeting the PA goal at the end of intervention, the proportion of participants meeting goal approached the DPP trial results of 74% and was similar to the 53.4% of adults estimated to meet the PA guidelines in the latest National Health and Nutrition Examination Survey (NHANES) (19). Not all studies that reported the proportion of participants meeting the PA goal as the outcome included pre-intervention values in the results, making it difficult to examine whether PA improved and how any change impacted on metabolic outcomes.

Variability in study design, program implementation, intervention length and participant follow-up time, PA assessment, data analysis methodology, and outcomes reported makes comparison of PA results between studies included in this review challenging. Although ranges for the proportion of participants achieving PA goals can be determined, success at achieving goals must be interpreted cautiously at established time points (i.e. 6 months) because participants may have been at different stages of a lifestyle change program and outcomes were analyzed in a variety of methods. Since several programs offered opportunities for PA (guided exercise sessions, free gym membership, etc.) as part of intervention, reaching PA goals must be carefully evaluated with consideration of exercise program sustainability.

8.3 PAPER #1 ABSTRACT

Background*:* Since the success of the Diabetes Prevention Program (DPP) lifestyle intervention for reducing type 2 diabetes and metabolic syndrome, researchers have modified the intervention for translation to community settings. Lifestyle goals of translation programs reflect the DPP goals of 7% weight loss and 150 minutes of moderate physical activity (PA) per week. Given that PA is one of two primary lifestyle goals and has been linked to both weight loss and improvements in metabolic health in the DPP, it is important to understand the role that PA plays in the success of translation efforts in the community setting.

Purpose: to thoroughly evaluate the reporting of PA methodology and PA results in DPP-based community translations in order to guide future prevention efforts.

Methods: PubMed and Ovid databases were searched to identify peer-reviewed original research articles on DPP-based translations for adults at-risk for developing diabetes or cardiovascular disease, limited to English language publications from January 2002-March 2015.

Results: 72 original research articles describing 57 translation studies met eligibility criteria. All 57 study interventions included a PA goal, 47 studies (82%) collected participant PA information, and 34 (60%) provided PA results.

Conclusions**:** Despite PA being a primary intervention goal, PA methodology and results are under-reported in published DPP translation studies. This absence and inconsistency in reporting PA needs addressed in order to fully understand translation efforts' impact on participant health.

The complete manuscript is available in Appendix C.

9.0 PAPER #2: IMPACT OF LIFESTYLE INTERVENTION AND SEASON ON PHYSICAL ACTIVITY LEVELS IN A COMMUNITY TRANSLATION PROGRAM TO REDUCE RISK FOR TYPE 2 DIABETES AND CARDIOVASCULAR DISEASE

9.1 INTRODUCTION TO PAPER #2

Translation of the DPP lifestyle intervention for delivery in community settings has shown promise for achieving clinically meaningful weight loss in high-risk individuals. However, as evidenced from the previous investigation (Paper 1), reporting of PA-related outcomes is limited. The Healthy Lifestyle Project (PI: Dr. A. Kriska) provides an opportunity to thoroughly examine changes in PA during a lifestyle intervention, assessed via subjective and objective methods. The unique randomized delayed-control design permits an investigation of the impact of season on PA levels, which is seldom addressed in evaluations of lifestyle intervention even though it has been shown to contribute to variation in PA level (23). As most intervention programs include shorter, intensive phases followed by longer maintenance phases (13), seasonal and environmental fluctuations affecting PA level should be considered when determining the effectiveness of intervention on meeting and maintaining PA goals long-term.

9.1.1 Purpose

The purpose of this project is to evaluate the effectiveness of the DPP-GLB for increasing and maintaining PA levels among individuals at risk for diabetes and cardiovascular disease (CVD). In the evaluation, influence of season on PA levels will be considered when assessing the impact of intervention on change in PA.

9.1.2 Setting

This evaluation included participants who enrolled in the DPP-GLB program at the worksite and three community centers.

9.1.3 Methods

The DPP-GLB program was delivered to participants in the IMMEDIATE arm beginning in the winter months (January-March) and to participants in the DELAYED arm beginning 6 months later in the summer months (July-September). This allowed for an evaluation of the impact of intervention separate from season on PA levels. The primary outcome is change in PA level at 6, 12, and 18 months after enrolling in the DPP-GLB program. The secondary outcomes are proportion meeting the PA goal and proportion reporting regular physical activity.

9.1.4 Measures

All outcome measures were collected by trained research staff following a standard protocol at randomization (baseline), and at 6 and 12 months from start of intervention. Participants in the DELAYED arm attended one additional assessment visit at 6 months following randomization to capture clinical and PA measures at the end of the control period. All participants were asked to attend a brief visit at 18 months from start of intervention to obtain weight and general PA information. For the purposes of this evaluation, all assessment points (6, 12, 18 months) will be in reference to start of intervention, regardless of randomization assignment.

9.1.4.1 Demographic

Participant demographic information collected during the on-site screening visit was used in this evaluation. Variables included sex, date of birth (to determine age), race/ethnicity, employment status, and educational attainment.

9.1.4.2 Anthropometric

Weight was assessed via digital scale (DETECTO® PD100) at baseline, 6, 12, and 18 months. Participants were weighed in light clothing and without shoes.

9.1.4.3 Physical Activity

Physical activity information was collected by two interviewer-administered questionnaires (Appendix B). At baseline, 6, 12, and 18 months the Lifestyle Questionnaire (LSQ) asked participants about the frequency (in days) and duration (average time active) of PA in a typical week, expressed as minutes per week. At baseline, 6, and 12 months the Modifiable Activity

Questionnaire (MAQ) captured specific estimates of past-month leisure PA, calculated from frequency and duration of common activities, expressed as MET-hours per week. As part of the MAQ, sedentary behavior during leisure time was determined by the question "Excluding time at work, in general how many hours per day do you usually spend watching television or sitting at the computer?"

9.1.5 Statistical Analysis

Descriptive statistics examined the distribution of population characteristics, clinical measures, and PA levels among participants enrolling in the study. Independent samples t-tests, Chi-Square tests, and Mann-Whitney U tests compared baseline demographic, biometric, and physical activity variables between randomization assignments and community settings. The Mann-Whitney U test was used to compare baseline PA variables between those that did/did not attend the assessment visits during follow-up.

Changes in weight and PA measures were calculated for 1. All participants using last observation carried forward for those with missing data; 2. Participants with complete assessment data at each assessment visit; and 3. Participants with complete assessment data for all assessment visits.

For the 6 month control period, the Mann-Whitney U test compared change in PA variables between IMMEDIATE and DELAYED intervention arms. Changes in weight and PA measures were tested for statistical significance at all assessment visits with the paired samples t-test and Wilcoxon Signed Rank test, respectively. Pre-post change in proportion of participants meeting the PA goal or reporting activity frequency $\geq$ 3 days per week was evaluated by

McNemar’s test between baseline and 6, 12, and 18 months of intervention. An alpha of 0.05 was used to determine significance for all statistical tests.

Repeated measures analysis using Linear Mixed Models was used to evaluate the impact of participant characteristics (age, sex, education level, employment, BMI), intervention, setting, and season on change in PA during intervention. Variables with a univariate effect of $p<0.25$ were kept in the multivariate model. Assessment visit was included in each model as a time-dependent covariate in order to determine the independent effect of receiving intervention on change in PA levels. SAS 9.4 (SAS Institute, Inc.; Cary, NC) was used to conduct all statistical analysis

9.1.6 Results

9.1.6.1 Baseline Characteristics

The DPP-GLB enrolled 223 participants from a worksite and three community centers. Although the analysis for this investigation was not stratified by setting and included in the corresponding manuscript, baseline characteristics for the community centers and worksite were compared to determine any key differences between the settings (Table 1). As expected, the worksite participants were younger, attained a higher education level, were more likely to be employed at least part-time, and reported less leisure PA at baseline than community center participants. Examining the entire population combined by randomization assignment (see Table 1 in Appendix E), there were no differences in baseline demographics between the IMMEDIATE and DELAYED arms. The IMMEDIATE arm reported significantly more time spent sitting per day at baseline [3 (IQR 2, 4) vs. 2 (IQR 2, 3) hours per day (p-diff=0.001)].

Table 1. Baseline Characteristics for Participants Enrolling in the Healthy Lifestyle Project by Setting

Variable	Worksite (N=89)	Community Centers (N=134)	p-diff Between Group
Age (years); mean (sd)	52.3 (7.2)	62.5 (12.0)	**<0.0001**
Gender; % (n) Female	55 (49)	67 (90)	0.07
Education; % (n) H.S./Some College B.S. Degree Graduate Degree	 23 (25.8) 35 (39.3) 31 (34.8)	 59 (44.0) 33 (24.6) 42 (31.3)	**0.008**
Weight (lbs); mean (sd)	209.2 (39.3)	208.6 (43.5)	0.93
Waist (inches); mean (sd)	41.1 (5.0)	42.2 (5.4)	0.10
BMI (kg/m2); mean (sd)	33.0 (5.8)	34.4 (6.2)	0.10
MET•hr/wk LPA (Median, IQR); MAQ	4.67 (0.94, 13.0)	9.00 (3.0, 21.3)	**0.005**
Minutes/Week ; Median (IQR); LSQ	80 (15.63, 140)	150 (50, 240)	**0.0003**
Hours Leisure Sitting; Median (IQR); MAQ	2 (1.5, 3)	3 (2, 4)	**<0.0001**
Avg. Steps/Day; Median (IQR); Pedometer	-----	N=104 4850 (3470, 8162)	**-----**

9.1.6.2 Change in Leisure Physical Activity During Control Period

For participants attending assessment visits at both baseline and at the end of the 6 month control period, median leisure PA as determined by the MAQ increased in the IMMEDIATE (N=137) and DELAYED (N=71) arms by 14.31 (IQR 5.25, 30.92; p-change<0.0001) and 7.63 (IQR -0.77, 17.50; p-change<0.0001) MET-hours per week, respectively. Similarly, median leisure PA determined by the LSQ increased by 60 (IQR 0, 126; p-change<0.0001) and 7.5 (IQR -35, 75; p-change=0.14) minutes per week in the IMMEDIATE and DELAYED arms, respectively. The increases in leisure PA, measured by the MAQ and LSQ, were significantly greater in the IMMEDIATE arm than the DELAYED arm (p-diff=0.004 and p-diff=0.02, respectively). IMMEDIATE and DELAYED participants also reported decreases in median leisure sitting on the MAQ by 0.5 (IQR -1, 0; p-change<0.0001) and 0.0 (IQR -1, 0; p-change=0.01) hours per day (p-diff<0.0001), respectively.

9.1.6.3 Change in Leisure Physical Activity During Intervention

Both the IMMEDIATE and DELAYED arms significantly increased their PA levels after 6, 12, and 18 months from start of intervention. The magnitude of PA increases from baseline to each assessment visit differed between the two arms and reflected the season in which PA information was collected (discussed in section 9.1.6.4). Since both arms successfully increased PA, the results of both arms are combined in this evaluation.

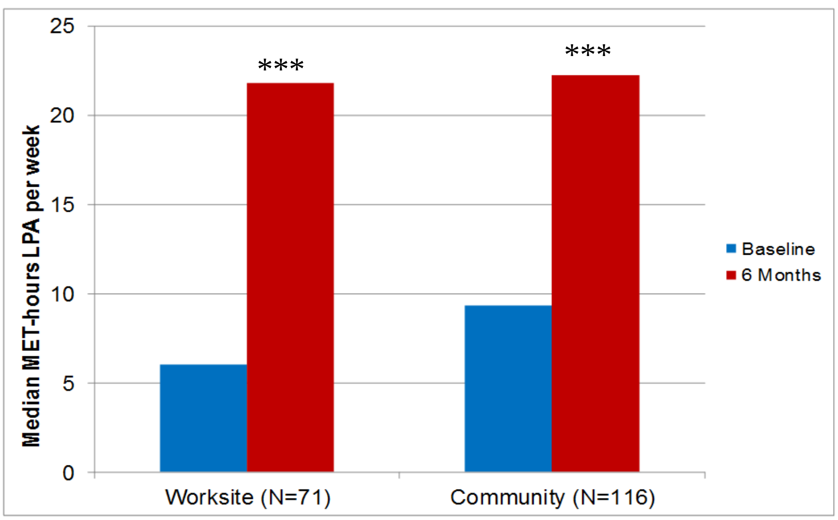
Leisure PA significantly increased and leisure sitting time significantly decreased during follow-up for the 184 and 163 participants with complete MAQ and LSQ PA information, respectively (see Figure E1 in Appendix E). Other than the fact that participants attending the 18 month visit reported a higher PA level at baseline than those who did not attend the 18 month visit ($p<0.05$), no other significant differences between baseline PA measures were observed between participants who did/did not attend individual assessment visits. For more conservative estimates of PA change not reported in the corresponding manuscript, the last observation carried forward method was used (Table 2), with similar to the changes in PA levels observed for those with complete PA data at all assessment visits (see Results in Appendix E).

For those with complete PA information at all assessment visits, participants increased median leisure PA in MET-hours per week as assessed by the MAQ and in minutes per week as assessed by the lifestyle questionnaire (see Results in Appendix E). Participants also reported a decrease in median hours of leisure sitting per day as assessed by the MAQ. Parallel to observed increases in PA level, the proportion of participants meeting the PA goal and the proportion of participants reporting regular PA increased at 6, 12, and 18 months, as determined by the lifestyle questionnaire (see Figure E2 in Appendix E).

Table 2. Change in Leisure PA Levels For All Participants With Last Observation Carried Forward

Variable	N	Baseline	6M Change	p-change	12 M change	p-change
MET-hours per week Leisure PA (M, IQR; MAQ)	223	7.88 (2.19, 16.69)	9.58 (0, 21.47)	**<0.0001**	6.42 (0, 15.70)	**<0.0001**
Minutes/week PA (M, IQR; LSQ)	223	120 (30, 210)	40 (0, 120)	**<0.0001**	30 (-30, 105)	**<0.0001**

After stratifying analysis by community setting and delivery mode, similar improvements in PA measures were observed for the worksite and community centers (Figure 1) and for group and DVD delivery formats (Figure 2) for those who attended assessment visits.



***p-change <0.0001

Figure 1. Physical Activity Level (MET-hours per week; MAQ) at Baseline and 6 Months by Setting

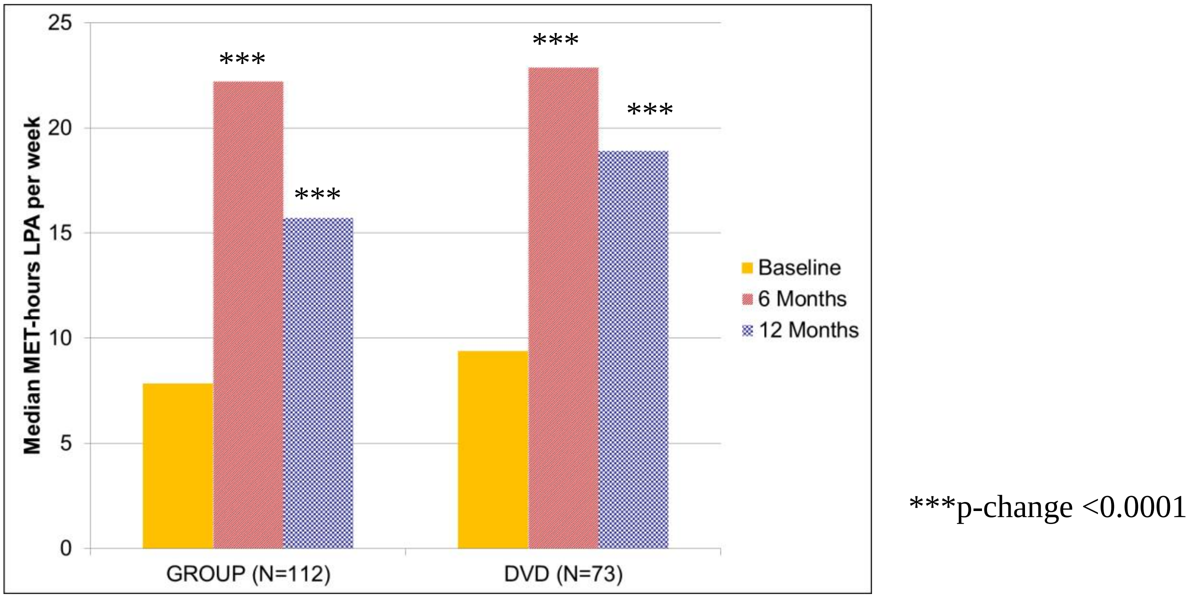


Figure 2. Physical Activity Level (MET-hours per week; MAQ) at Baseline, 6, and 12 Months by Delivery Mode

Considering other baseline characteristics, such as age, sex, education level, employment, and BMI, univariate analysis using linear mixed models showed similar changes in PA during intervention among all population subgroups (see Table E2 in Appendix E). These similar changes in leisure PA were observed even though men and individuals with at least a bachelor's degree reported a higher baseline PA level than their counterparts (Table 3).

Table 3. Differences in Baseline PA Level (MAQ) by Sex and Educational Attainment

Baseline Characteristic	Comparison of Baseline PA Level	p-diff
Sex (Men vs. Women)	10.23 (2.95-23.06) vs. 6.31 (1.75-13.96)	0.008
Educational Attainment ($\geq$Bachelor's Degree vs. $<$Bachelor's Degree)	9.28 (2.92-20.06) vs. 5.31 (0.58-12.50)	0.002

9.1.6.4 Impact of Season on Physical Activity Level

The past-month MAQ provided the most precise estimate of leisure PA in terms of frequency, intensity, duration, and type and could capture patterns of PA relative to the season the questionnaire was administered. Thus, the PA level determined by the MAQ was used to examine trends in PA over intervention. Notable fluctuation in MET-hours of leisure PA was observed prior to initiating intervention due to season with peaks in PA level during the summer months (Figure 3). This variation was also detected in comparing the change in leisure PA between the IMMEDIATE and the DELAYED groups during the 6-month wait control period (Section 9.6.1.2).

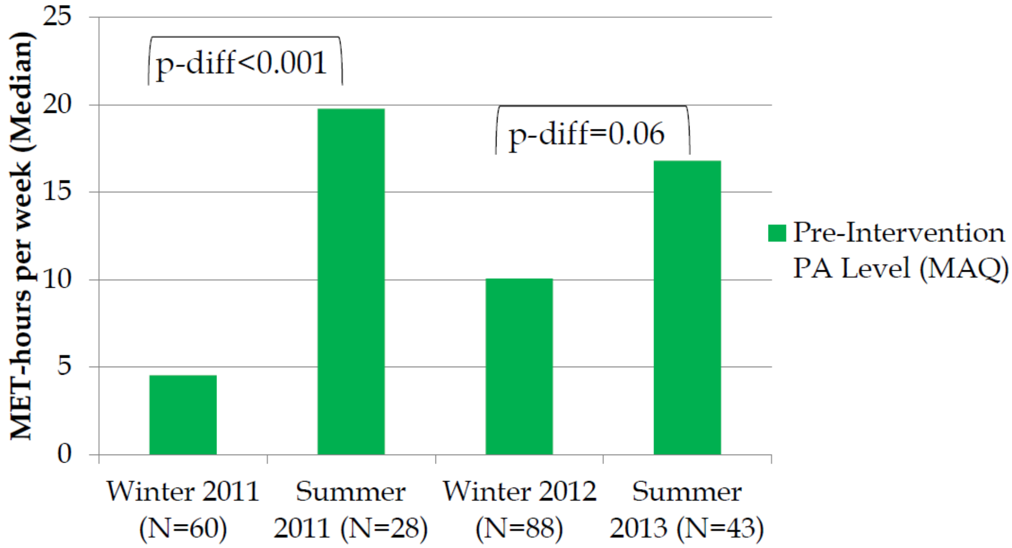
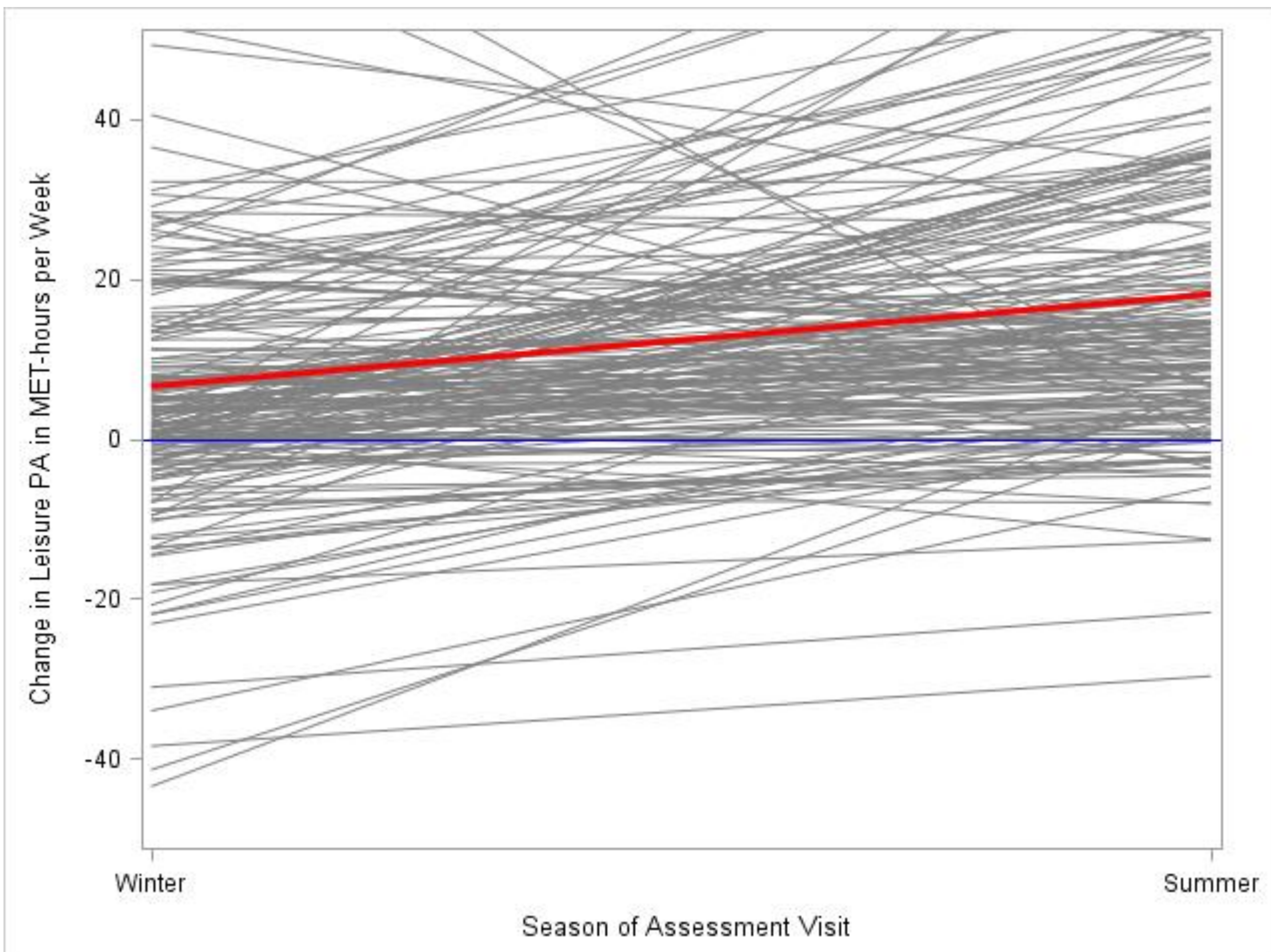


Figure 3. Seasonal Variation in MET-hours per week (MAQ) of Leisure PA Prior to Intervention

Linear mixed models with an unstructured covariance matrix were used to determine the underlying impact of intervention independent of seasonal variation. Examining change in MET-hours per week of leisure PA, the univariate effect of intervention on PA level was a 14.69 MET-hour per week mean increase from baseline at 6 months ($p<0.0001$) and a significant decline in change of 5.19 MET-hours per week between 6 and 12 months (see Table 2 in Appendix E). The univariate effect of season on PA level was an 11.40 MET-hour per week mean increase during the summer months compared to winter months (p<0.0001). In order to show individual and aggregate effects of season on PA and the degree of variation in PA changes, spaghetti line plots were used, though not included in the corresponding manuscript. Spaghetti line plots (Figure 4), which calculate a regression line for each participant (thin scattered gray lines) and an overall spline (thick red line trending upward), demonstrate the univariate effect of season on change in PA level. Regardless of the season, the overall change in PA is greater than zero (thick horizontal blue line), demonstrating the effect of intervention for increasing PA.



Blue horizontal line=zero reference; Red line trending upward=intervention effect on PA

Figure 4. Spaghetti Plot: Individual and Aggregate Regression Lines for Change in PA During Seasons

In multivariate linear mixed models, the independent effect of season was an 11.49 MET-hr/week greater mean increase in leisure PA during the summer months compared to the winter months ($p<0.0001$). Adjusting for seasonal variation, the impact of intervention on PA level was a 7.51 MET-hour per week mean increase at 6 months ($p=0.007$) with no significant difference in change in PA level from 6 to 12 months ($p=0.62$) (see Table E2 in Appendix E).

9.1.6.5 Correlation of Changes in PA level and Changes in Weight

Examining the relationship between PA and weight changes, weight loss was moderately correlated with an increase in leisure physical activity at 6, 12, and 18 months and decrease in leisure sitting time at 12 months, with similar trends at 6 months (Table 4). These relationships did not change when limiting the analysis to only those participants who had complete follow-up data (Table 5).

Table 4. Spearman Correlation of PA Change and Weight Change at each Assessment Visit

Time	N Spearmans' rho p-value	Change in Minutes per Week (LSQ)	Change in MET-hours per week (MAQ)	Change in Hours per day Leisure Sitting (MAQ)
6 Months	Change in Weight (lbs)	202 -0.30 **<0.0001**	203 -0.12 0.09	203 0.10 0.17
12 Months		186 -0.15 **0.05**	186 -0.26 **0.0004**	189 0.17 **0.02**
18 Months		169 -0.22 **0.004**	-----	------

Table 5. Spearman Correlation of PA Change and Weight Change for Participants Who Attended All Assessment Visits

Time	N Spearman's rho p-value	Change in Minutes per Week (LSQ)	Change in MET-hours per week (MAQ)	Change in Hours per day Leisure Sitting (MAQ)
6 Months	Change in Weight (lbs)	159 -0.28 **0.0004**	183 -0.08 0.29	183 0.14 0.06
12 Months		159 -0.25 **0.0013**	183 -0.21 **0.0039**	183 0.16 **0.03**
18 Months		159 -0.26 **0.0009**	-----	-----

9.2 DISCUSSION OF KEY FINDINGS

This project demonstrates the effectiveness of a DPP-based community program for increasing PA levels and decreasing leisure sitting time across diverse settings. Expected variation in PA level was observed between winter and summer seasons during follow-up. The lifestyle intervention independently increased PA levels above the anticipated fluctuations in physical activity due to seasonal changes.

The study design and use of the past month Modifiable Activity Questionnaire (MAQ allowed for a thorough examination of the impact of season on PA levels during lifestyle intervention. The MAQ, which is able to distinguish among the four dimensions of PA (frequency, intensity, duration, and type) within the domain of leisure PA, provided strong evidence for the effectiveness of lifestyle intervention for increasing PA levels. This investigation showed seasonal variation in PA levels with a steady upward trend of increased PA from the time of enrollment through end of follow-up at 18 months. Once adjusted for season, the mean increase in leisure PA at one year was similar to the results of the DPP, in which the past-year MAQ was used to assess leisure PA. As the past-year MAQ is not sensitive to season, this finding reveals the importance of considering the assessment instrument and time-frame when determining intervention impact on PA levels.

Similar to the current study, Newman et al. showed fluctuations in PA level among post-menopausal women over an 18-month enrollment period, with peak PA during the summer months (23). After participation in a lifestyle intervention, a higher PA level with reduced variation was observed over the course of a year. In this study, the greater increases in PA level for the IMMEDIATE arm compared to the DELAYED arm during the control period confirm the effectiveness of intervention for increasing PA beyond the expected increase in PA due to seasonal changes. Thus, season of intervention delivery should not be overlooked when evaluating the potential of interventions for improving PA behaviors. The decline in PA during the winter months exposes a need to research strategies for sustaining the initial improvement in PA achieved in successful lifestyle programs during times of extreme weather and environmental circumstances.

In the current study, the proportion of participants meeting the national guidelines of 150 minutes of PA per week (the DPP PA goal) increased at 6, 12, and 18 months. The proportion of participants able to meet the PA goal was lower than that observed in the DPP, but aligned with the 41-78% of participants reported to have met the PA goal in other translation efforts (40, 43, 44, 140, 141, 152, 159, 160, 162). As translation efforts have different resources and varied intensity compared to efficacy trials, it is expected that the improvements in PA and meeting PA goals are not as drastic.

The current evidence shows that physical activity plays an important role in weight loss and a greater role in weight maintenance (85, 87). The results of this evaluation support that evidence and emphasize the importance of reporting PA alongside weight loss and examining the relationship between the two. Future evaluation of the relationship between PA changes and weight loss, weight maintenance, and changes in diabetes and CVD risk factors is needed to further understand the role of PA in prevention efforts and to evaluate the impact PA has on participant health.

9.3 PAPER #2 ABSTRACT

Background: The Diabetes Prevention Program (DPP) lifestyle intervention was successful for increasing physical activity (PA) and subsequently reducing risk for diabetes and cardiovascular disease (CVD). The DPP lifestyle intervention has been translated to a variety of community settings promoting the same goals of modest weight loss and increasing physical activity to 150 minutes per week. Little is known about PA compliance, or the impact of season on PA compliance, and related outcomes in these programs.

Purpose: To evaluate the effectiveness of an evidence-based lifestyle intervention for improving PA levels, separate from seasonal variation.

Methods: The program enrolled 223 adults at-risk for diabetes and CVD. The Modifiable Activity Questionnaire (MAQ) assessed leisure PA, expressed as MET-hrs per week, and leisure hours of sitting per day at baseline, 6, and 12 months.

Results: Participants who completed follow-up (N=184) increased leisure PA by 10.99 and 6.44 MET-hrs/wk (both; $p<0.01$) at 6 and 12 months, respectively and decreased leisure sitting time

by 0.47 and 0.28 hours per day (both; $p<0.05$) at 6 and 12 months, respectively. A seasonal effect on PA levels was observed beyond the effect of intervention. Adjusting for seasonal variation, overall PA increase due to intervention was 7.51 and 6.7 MET-hrs/wk at 6 and 12 months, respectively ($p<0.01$).

Conclusions: This DPP-based translation effort demonstrated the feasibility of measuring PA in community settings and the effectiveness of lifestyle intervention for increasing PA levels. Results emphasize the importance of considering seasonal influences when examining intervention impact on PA.

The complete manuscript is available in Appendix E.

10.0 PAPER #3: ACHIEVING PHYSICAL ACTIVITY AND WEIGHT LOSS GOALS IN COMMUNITY SETTINGS: PREDICTORS OF SUCCESS USING THE DIABETES PREVENTION PROGRAM'S GROUP LIFESTYLE BALANCE™ INTERVENTION

10.1 INTRODUCTION TO PAPER #3

Both efficacy trials and effectiveness studies have shown that behavioral lifestyle interventions are successful for increasing physical activity (PA) levels and achieving weight loss (WL) to improve health, as discussed in chapters 4 and 5 and evidenced in chapter 9. As successful lifestyle interventions are translated for delivery in community settings, aspects of intervention that differ, such as setting, delivery format and structure, and resources available, may alter the level of success achieved by individuals in these programs. Differences in recruitment strategies and eligibility criteria between clinical trials and community-based translation studies can also result in differences in characteristics of participants who volunteer (188). Thus, further investigation of the factors that predict participant success within efficacy and effectiveness research constructs is needed.

Factors that predicted PA and WL success in the intensive, individual approaches to behavioral therapy utilized in the U.S. DPP and Finnish DPS efficacy trials included baseline age, sex, BMI, employment status, race/ethnicity, and adherence to self-monitoring behaviors during the program (34, 118). More specifically, in the DPP, older age and self-monitoring behaviors were independently related to meeting both goals. Men and those with lower baseline BMI were more likely to meet the PA goal than women and those who were heavier (34). Racial and ethnic minorities were more likely to meet the long-term activity goals than Whites. White compared to non-White participants were more likely to meet the 7% WL goal initially, but this trend did not persist long-term. Importantly, meeting the PA goal was a predictor of meeting the WL goal, both at the end of the core curriculum and after an average 3.2 years of follow-up (34).

Factors associated with achievement of the WL goal (5-7%) have been reported in several DPP translation studies (40-44) and include baseline age, sex, BMI, self-monitoring of weight, calories, fat, and PA; and PA level. In the DPP translation studies that documented predictors of achieving weight goals, PA level or increased PA was positively associated with achieving the WL goal. Common predictors of WL success in other observational studies include performing high amounts of moderate PA, self-weighing, and self-monitoring of diet and activity (87, 89, 90, 100).

Although PA is an important lifestyle intervention goal, and has been shown to be a predictor of WL success in clinical trials, little is known about the factors predicting increasing PA levels in community interventions. Only one DPP-translation, the Montana Cardiovascular Disease and Diabetes Prevention Program (40), has reported factors related to meeting the PA goal. Participants that were more likely to meet the PA goal, determined from self-monitoring records, were men and those who self-monitored dietary fat. Currently, there are no known community translation investigations that have examined the baseline social, demographic, and clinical characteristics and program adherence behaviors of participants that are related to achievement of both WL and PA goals (i.e. what features distinguish those who meet both program goals from those who do not achieve either goal). Investigation of factors related to program success in community interventions is warranted to help guide future prevention efforts and to develop effective strategies for improving PA levels and achieving PA goals.

10.1.1 Purpose

The repeated success of the DPP-GLB lifestyle intervention for improving weight and PA levels in multiple community settings (see section 6.3 on page 63) leads to the need to investigate the factors predicting this success. This investigation aims to identify the baseline demographic, social, and clinical characteristics and intervention adherence practices that predict meeting both program goals of 150 minutes per week PA and 7% WL in the one-year DPP-GLB program.

10.1.2 Setting

This evaluation includes participants in the DPP-GLB at the worksite and three community centers. Participants within each setting had different levels of social support and opportunities for participation in other programs, so delivery setting will be included as a potential predictor of program success.

10.1.3 Measures

Information pertaining to participants' social and demographic characteristics and engagement in the DPP-GLB program was collected and is summarized in Table 6. Participant demographic information was recorded by research staff during the on-site screening visit and included sex, date of birth (to determine age), race/ethnicity, smoking status, employment status, and educational attainment. Session attendance and/or telephone contact with the lifestyle coach and adherence to healthy lifestyle behaviors introduced during the DPP-GLB intervention, specifically self-monitoring of diet and PA and self-weighing, were considered as markers of adherence to the lifestyle program.

Table 6. Baseline Participant Characteristics and Adherence to Program Features Examined in the Healthy Lifestyle Project

Characteristic/Feature	Assessment Method	Time Collected
Age (Date of Birth)	Self-report	On-site screening
Sex	Self-report	On-site screening
Race/Ethnicity	Self-report	On-site screening
Educational Attainment	Self-report	On-site screening
Smoking Status	Self-report	On-site screening
Pre-diabetes Status	Objective	Baseline visit
PA Level	Self-report	Baseline, 6, 12, and 18 months
Weight	Objective	Baseline, 6, 12, and 18 months
Self-weighing (days per week)	Self-report	Baseline, 6, 12, and 18 months
Keeping Track (diet and PA)	Lifestyle Coach reported	Each session
Attendance	Lifestyle Coach reported	Each session
Meeting Fat and Calorie Goals	Self-report	Baseline, 6, 12, and 18 months

10.1.3.1 Adherence: Session Attendance and Self-Monitoring of Diet and PA

Participant attendance at each session and submission of self-monitoring records was noted by the lifestyle coach in a log. There were 16 possible sessions/coach telephone contacts in the core and 6 possible sessions/coach telephone contacts in the post-core. A participant was considered to “attend” a session if they were present at the face-to-face group session or contacted the lifestyle coach to discuss the session content. Self-monitoring was completed in a Keeping Track book, which provided space for participants to record daily calories, fat, minutes of PA, and pedometer steps. Participants were asked to record calories and fat starting in session 2, PA minutes in session 4, and pedometer steps in session 10. Participants could submit self-monitoring records at the group sessions or send them via postal mail in provided envelopes. During the core, there were 23 possible diet records and 20 possible PA records that a participant was instructed to complete. During the post-core, there were 24 possible records for both behaviors.

10.1.3.2 Goal Achievement

Achievement of the PA and WL goals was determined at the 6, 12, and 18 month assessment visits. The program goals examined were 7% WL and 150 minutes of at least moderate PA, which reflect the goals of the DPP lifestyle intervention. Minutes per week of PA was estimated using a general Lifestyle Questionnaire (LSQ) from a calculation of self-reported frequency and duration of usual weekly PA. Because the Modifiable Activity Questionnaire (MAQ) is a validated questionnaire (98, 99), PA data from the MAQ was used to determine PA goal achievement at 6 and 12 months. A PA level of 10 MET-hours per week was selected to approximate the 150 minute per week goal because this volume of PA is equivalent in duration and intensity to 150 minutes (2.5 hours) of brisk walking (MET-equivalent=4.0) per week. The MAQ was not administered at 18 months, so the LSQ was used to determine PA goal achievement at this specific time point.

10.1.3.3 Self-Weighing and Meeting Fat and Calorie Goals

Participant self-weighing and meeting fat and calorie goals was self-reported on the Lifestyle Questionnaire at baseline, 6, 12, and 18 months. Two questions asked participants "How often [do you] weigh [yourself]?" and "How often [do you] meet fat and calorie goals?" Responses were recorded in days per week. If participants reported achieving these behaviors less than one day per week, responses included either "2-3 times per month" or "less than once per month or never". For participants who indicated they did not track food intake on the LSQ, a response of "not applicable" could be indicated for meeting fat and calorie goals.

10.1.4 Statistical Analysis

Frequency statistics were used to describe the distribution of baseline characteristics in the participant sample that have been shown in the literature to predict PA level and weight loss success. For variables with low frequency in some categories, levels of each variable were collapsed to create binary variables. This was done for age (<60 or ≥60 years), educational attainment (<Bachelor’s degree or ≥Bachelor’s degree), employment status (full/part-time or not employed outside the home), and smoking status (never or current/former smoker). Descriptive statistics were used to examine session attendance and changes in weight and PA during the intervention and at follow-up.

Univariate logistic regression models were used to determine the odds of success for meeting the 7% WL goal and the 10 MET-hour per week PA goal for each of the specified demographic, social, and behavioral characteristics. From these models, predictors with a univariate $p \leq 0.25$ were considered in multivariate logistic regression models to determine the combination of baseline descriptive characteristics and adherence behaviors most related to program success. Chi-square tests were used to detect associations between dichotomous predictors and Spearman rank order correlations were used to detect relationships between continuous predictors before inclusion in multivariate models. Predictors that were significantly associated were fit individually into multivariate models.

Separate multivariate models were built to examine two specific groups of predictors that have been shown by previous research to be associated with achieving WL and PA goals: 1. Baseline social, demographic, and clinical characteristics; and 2. Program adherence behaviors. Backwards stepwise logistic regression with probability of remaining in the model set at 0.10 [pr(stay)=0.10] was used to determine the significant predictors in each respective model. A final multivariate model, combining both baseline characteristics and program adherence factors, included only those predictors with a $p \leq 0.10$ in the separate multivariate models (1. and 2. above). Each final model was evaluated with Hosmer-Lemeshow Chi-Square Goodness-of-Fit test to determine the appropriateness of the model. Similarly, logistic regression models were used to determine the odds of success for achieving each program goal separately.

As a sensitivity analysis, participant sex and educational attainment were forced into the final combined multivariate models due to baseline PA level being significantly higher among men and those with at least a college degree (see Table 3, page 87). Sub-analysis of factors predicting program success for achieving 7% weight loss and 10 MET-hours per week among participants with self-reported baseline PA less than 10 MET-hours per week was conducted as a sensitivity analysis for potential measurement error in the baseline PA assessment.

In addition, to determine if predictors of success varied across WL thresholds (5% and 7%) or PA volumes (150 min and 10 MET-hours per week), sensitivity analyses were conducted to examine predictors of achieving program goals using multiple definitions of PA and WL. The factors predicting achieving the combination of 5% weight loss, recognized as the minimum weight loss to elicit substantial health benefits (129, 189), and 10 MET-hours leisure PA per week at 6 months were investigated. Separate logistic regression models were used to examine the factors predicting achieving individual program goals (5% and 7% weight loss and 150 minutes and 10 MET-hours leisure PA per week) at 6 months. To determine whether there was variation in predictors of success at more distal time points from initial engagement in an intervention, factors predicting success for achieving both goals at 12 and 18 months were explored.

10.1.5 Results

10.1.5.1 Baseline Social, Demographic, and Biometric Characteristics

The Healthy Lifestyle Project enrolled 223 overweight or obese adults [mean weight=208.8 (sd 41.8) lbs.; mean BMI=33.8 kg/m^2 (sd=6.0); mean age=58.4 years (sd 11.5)] with pre-diabetes and/or the metabolic syndrome. The participants were fairly inactive, self-reporting medians of 120 (20-210) minutes and 7.88 (2.19-16.69) MET-hours of leisure physical activity per week, with approximately 60% of participants reporting baseline activity below desired program levels.

Baseline frequencies of characteristics potentially related to PA levels and achievement of program goals are presented in Table 7. The factors of interest were selected based on the characteristics related to PA level discussed in Section 2.5 and the factors related to achievement of PA and weight goals reported in efficacy and effectiveness trials. There was enough variation in age, sex, education, employment, and BMI within the study cohort to include these factors as potential predictors of program success. Given the minimal racial/ethnic diversity of the study population, which is reflective of the communities surrounding the study sites, race was eliminated as a predictor of program success in the current analysis.

Table 7. Baseline Demographic and Biometric Factors for Participants Enrolling in the Healthy Lifestyle Project (Total N=223)

Variable	Frequency: % (N)
Age (years)	
<60	58.7 (131)
60+	41.3 (92)
Sex	
Men	37.7 (84)
Women	62.3 (139)
Race/Ethnicity	
Non-Hispanic White	91.9 (205)
Hispanic	2.2 (5)
Black	1.8 (4)
Asian	3.1 (7)
Other	0.9 (2)
Educational Attainment	
High school diploma/Some college	36.8 (82)
College or Graduate Degree	63.2 (141)
Employment Status	
Full-time/Part-time	65.9 (147)
Not Employed Outside Home (Unemployed/Homemaker/Disabled/Retired)	34.1 (76)
BMI (kg/m^2)	
24-29.99	27.8 (62)
30-34.99	36.8 (82)
35-39.99	19.3 (43)
40+	16.1 (36)
Pre-Diabetes Status[a]	
Yes	64.6 (144)
No	35.4 (79)
Smoking Status	
Never	60.1 (134)
Ever (Former/Current)	39.5 (88)
Missing	0.4 (1)

[a]Defined as fasting plasma glucose 100-125 mg/dL and/or Hemoglobin A1c 5.7-6.4%

Sample retention was 91% (6 months), 85% (12 months), and 77% (18 months) at the respective assessment visits. Compared to those lost to follow-up, participants attending visits at 12 and 18 months, respectively, were more likely to be 60+ years (43.9% vs. 26.5%; p=0.06 and 45.6% vs. 26.9%; p=0.02) and not employed outside the home (37.0% vs. 17.7%;p=0.03 and 37.4% vs 23.1%; p=0.06).

10.1.5.2 Improvement in Physical Activity and Weight During Intervention and Follow-up

The DPP-GLB lifestyle program resulted in significant improvements in PA and weight at 6, 12, and 18 months (Figure 5) with the greatest improvements observed at 6 months. The results were similar when using last observation carried forward for missing data (Table 2 on page 86) or using data from only those participants who completed follow-up (Figure E1, Appendix E). Both the LSQ and MAQ showed similar increases in PA and responses to the questionnaires were significantly correlated at the 6 and 12 month time points (Spearman's rho=0.57 and 0.59; both p<0.0001).

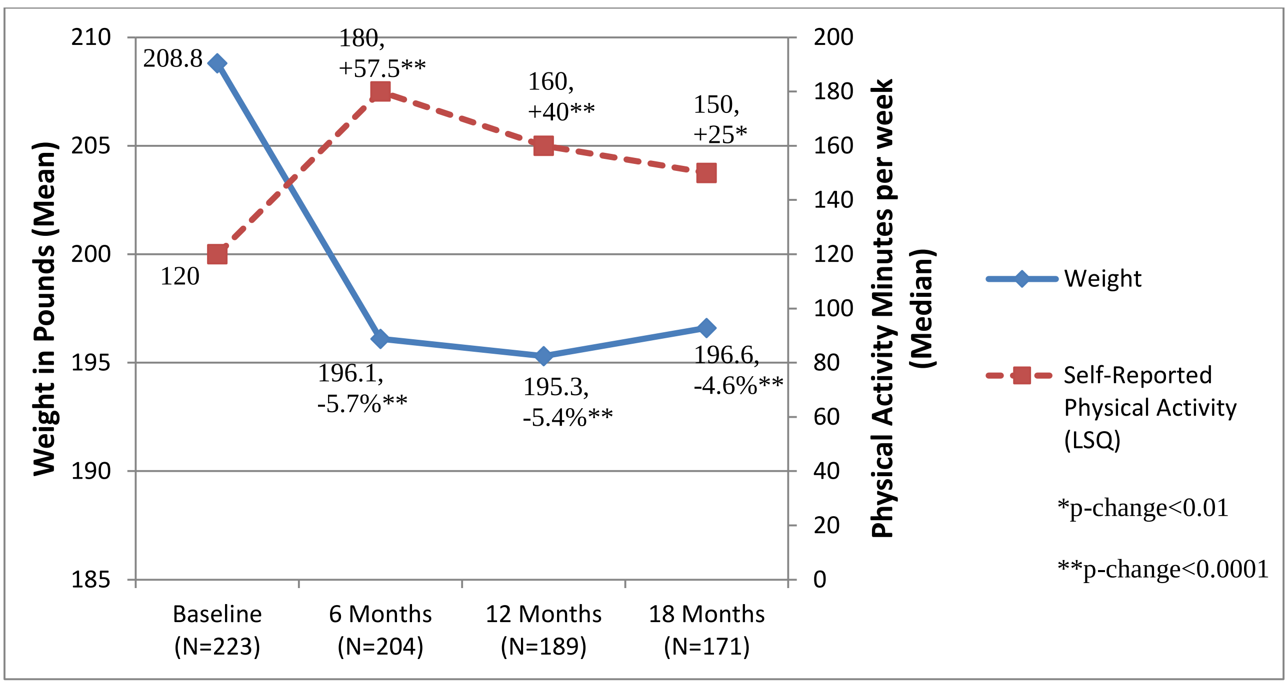
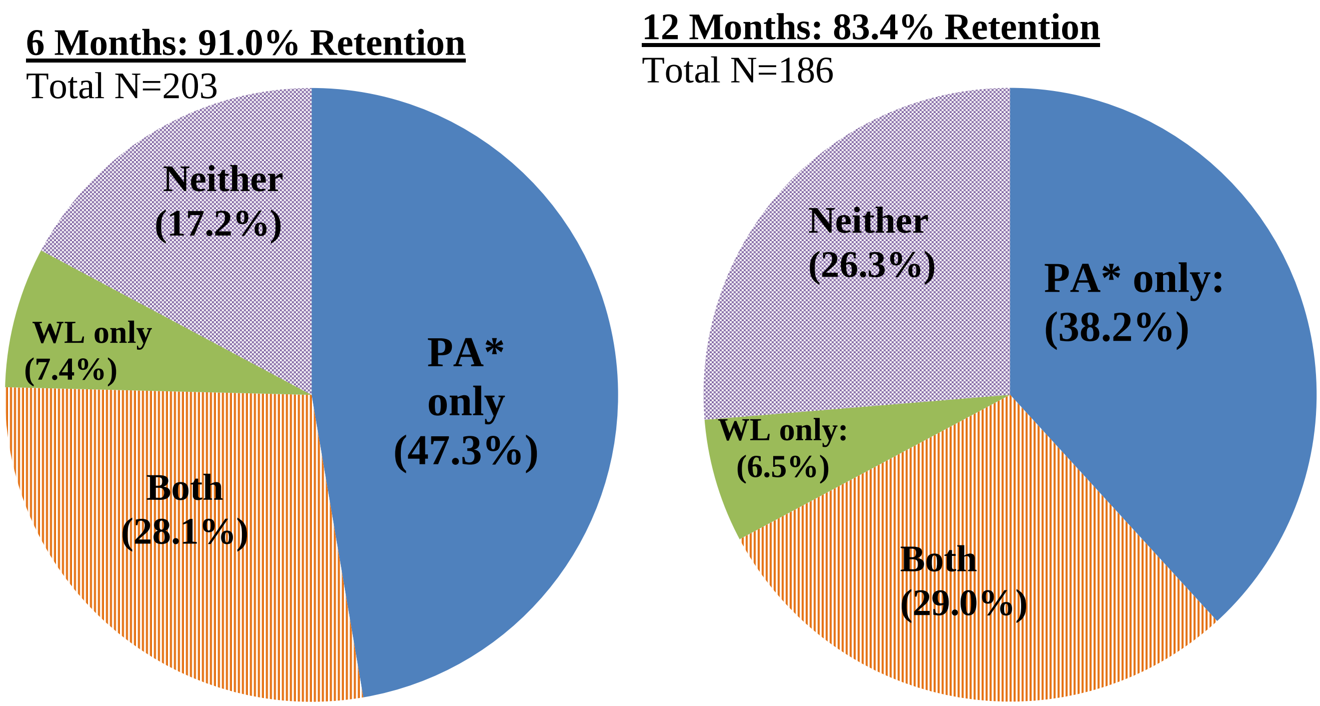


Figure 5. Weight and Physical Activity Level (Lifestyle Questionnaire) During Intervention and Follow-up

10.1.5.3 Achievement of Physical Activity and Weight Loss Goals

Given the overall improvement in PA and weight, the number of participants who met the PA and WL goals at each time point was examined. The proportions of participants meeting the 10

MET-hour per week PA and 7% WL goals during the program are summarized in Figure 6. At 6 months, 82.8% of participants with who attended the assessment visit achieved at least one program goal and 28.1% met both program goals. At 12 months, goal achievement was similar, with 74.7% of assessment visit completers achieving at least one goal and 29% achieving both goals.



*****Note: 150 minute per week PA goal approximated as 10 MET-hours per week at 6 and 12 months

Figure 6. Frequency of Achieving Weight Loss and Physical Activity (Modifiable Activity Questionnaire) Goals at 6 and 12 Months

A total of 171 participants completed the 18 month assessment visit (76.7% retention). PA information was collected at this visit by the LSQ in minutes per week. At 18 months, 15.4% achieved both goals of 150 minutes per week PA and 7% weight loss, 37.3% achieved only the

150 minute per week PA goal, 12.4% achieved the 7% weight loss goal, and 34.9% did not achieve either program goal.

10.1.5.4 Adherence to the Lifestyle Intervention: Attendance and Behaviors

High attendance to the program sessions and adherence to behaviors, especially during the core, support the idea that successful PA and weight changes were a result of intervention and not a result of other external factors.

Table 8. Adherence to DPP-GLB Program and Recommended Behaviors

Adherence Measure	Maximum Possible	Mean (sd)	Median (IQR)	Median % of Possible
Attendance/Contact with Coach during Core	16	12.6 (4.0)	14 (11-16)	87.5
Attendance/Contact with Coach during Post-core	6	3.3 (2.4)	4 (1-6)	66.7
Self-Monitoring Diet during Core	23	10.6 (6.9)	10 (4-17)	43.5
Self-Monitoring Diet during Post-core	24	3.3 (6.6)	0 (0-3)	0
Self-Monitoring PA during Core	20	7.0 (6.2)	6 (1-12)	30
Self-Monitoring PA during Post-core	24	3.0 (6.4)	0 (0-2)	0

10.1.5.5 Selecting Predictors to Include in Logistic Regression Modeling: Associations Between Proposed Variables

Before building multivariate models, Chi-Square analysis was used to reveal potential collinearity between binary predictors (Table 9). From the previous investigations describing PA levels in the entire study population (Paper 2) and by setting (Chapter 10), it is known that community center participants were older and reported higher levels of physical activity at baseline (see Table 1 on page 84). This analysis confirms that participants who were employed full- or part-time were younger and more likely to have enrolled from the worksite setting, as previously discussed. Participants with pre-diabetes were more likely to be older than 60 years and have an educational attainment less than a bachelor's degree. In cases where both predictors in a variable pair fit the criteria for inclusion in a multivariate model (univariate $p<0.25$), individual multivariate models were built to test the significance of each variable in the pair, keeping the remaining variables in the model the same. Additionally, cigarette smoking is identified as a risk factor for pre-diabetes and diabetes (112), so smoking status and baseline pre-diabetes status were fit independently into multivariate models.

Table 9. Chi-Square Association Between Binary Predictor Variables

Variable Pair	Chi-Square Value; p-association
Education <Bachelor's Degree-Pre-diabetes	4.2; 0.04
Age ≥60-Pre-diabetes	9.1; 0.003
Age≥60-Education <Bachelor's Degree	11.8; 0.0006
Age ≥60-Employment	82.5; <0.0001
Age ≥60-Intervention Setting	39.8; <0.0001
Intervention Setting-Employment Status	49.3; <0.0001
Baseline PA Level-Baseline PA Frequency	61.2; <0.0001
Baseline PA Level-6 Month PA Frequency	10.4; 0.001
Sex-Lifetime Participation in Competitive Sports	17.4; <0.0001

Spearman rank order correlation coefficients were used to detect collinearity between continuous predictors. Attendance or contact with the lifestyle coach was significantly correlated with keeping track of diet ($r=0.80$, $p<0.0001$) and keeping track of PA ($r=0.73$, $p<0.0001$). Keeping track of diet was also significantly correlated with keeping track of PA ($r=0.93$, p<0.0001). Thus, each of these adherence behaviors were tested individually in multivariate models, keeping the remaining predictors in the model the same.

10.1.5.6 Modeling Factors Predicting Achievement of Weight Loss and Physical Activity Goals using Logistic Regression

In univariate analysis, factors emerging as potential predictors (unadjusted $p \leq 0.25$) of achieving both program goals included baseline BMI, baseline pre-diabetes status, sex, smoking status, self-reported physical activity on $\geq$ 3 days per week, being physically active at baseline, lifetime participation in sports, calendar season, session attendance and contact with the lifestyle coach, adherence to self-monitoring of diet and PA, and self-reported self-weighing behavior (Table 10).

In backwards stepwise multivariate logistic regression analysis (Table 10), baseline social and demographic characteristics that predicted achieving both goals (7% weight loss and 10 MET-hours per week leisure PA, n=57) compared to achieving neither goal (n=35) at 6 months included pre-diabetes status, BMI, sex, and season. Program adherence behaviors that predicted being the most successful compared to the least successful included self-reported self-weighing, attendance to sessions or contact with the lifestyle coach, and keeping track of PA and diet.

Combining the baseline and program adherence characteristics into one multivariate model (Table 10), having pre-diabetes at baseline resulted in a lower odds (AOR=0.20, p=0.02) of achieving both goals compared to those who had metabolic syndrome with normal glucose indicators. Each unit increase in baseline BMI also resulted in lower odds (AOR=0.87, p=0.0006) of meeting both program goals. Conversely, enrolling in the program during the winter months (and subsequently attending intervention during the transition to summer), resulted in a significantly greater likelihood of meeting both goals (AOR=12.76, p=0.0005). Adherence behaviors including session attendance (AOR=1.71, p=0.001), each additional day per week that participants' reported self-weighing (AOR=1.42, p=0.006), each weekly PA record submitted (AOR=1.25, p<0.0001), and each weekly dietary monitoring record submitted (AOR=1.20, p=0.0006) enhanced probability of success. The final model had a Hosmer-Lemeshow goodness-of-fit χ^2=11.79 (p=0.16) indicating an acceptable fit.

In sensitivity analysis, forcing sex and educational attainment into the final model did not change the AOR estimates. In the sub-analysis of participants who reported baseline PA level less than 10 MET-hours per week, similar factors predicted their achievement of both 7% weight loss and 10 MET-hours per week at 6 months (Table 11) compared to the entire group that included participants with self-reported baseline PA level greater or equal to 10 MET-hours per week (Table 10). Differences from the full-group analysis were that pre-diabetes was no longer significant and the effects of baseline PA level remained significant even after adjusting for program adherence behaviors.

Table 10. Predicting meeting both program goals of 7% weight loss and 10 MET-hours/week PA (N=57) compared to meeting neither goal (N=35) at 6 Months using logistic regression models

Predictor Variable[a]	OR (95% CI); Univariate Model	AOR (95% CI); Separate[b] Multivariate Model	AOR (95% CI); Combined[c] Multivariate Model	AOR (95% CI); Forced[d] Multivariate Model
Age (≥60 years)	0.85 (0.37-1.97)	----	-----	-----
Sex (Female)	0.44 (0.18-1.11)**	0.25 (0.07-0.82)***	----	0.36 (0.09-1.48)*
Educational Attainment (≥ Bachelor's Degree)	1.14 (0.48-2.71)	----	----	1.31 (0.37-4.66)
Employment Outside the Home (Full- or Part-time)	0.92 (0.39-2.16)	----	-----	-----
Intervention Setting (Worksite)	1.12 (0.46-2.70)	----	----	----
Smoking (Never)	2.04 (0.87-4.79)**	----	-----	-----
Pre-diabetes	0.44 (0.18-1.11)**	0.21 (0.06-0.68)***	0.20 (0.05-0.76)***	0.16 (0.04-0.67)***
Baseline BMI (kg/m^2)	0.93 (0.88-0.99)***	0.87 (0.80-0.96)***	0.87 (0.79-0.96)***	0.87 (0.78-0.97)***
Baseline Self-reported Self-Weighing (days per week)	1.14 (0.97-1.33)*	---	----	----
Active at Baseline ≥10 MET-hours per week	3.77 (1.27-11.18)***	----	----	----
Lifetime Participation in Competitive Sports (Yes)	2.29 (0.96-5.46)	-----	----	----
^Core Attendance/Coach Contact (maximum=16)	1.38 (1.15-1.67)***	1.49 (1.16-1.91)***	1.71 (1.24-2.36)***	1.72 (1.24-2.38)***
6 Month Self-reported Self-weighing (days per week)	1.35 (1.14-1.61)***	1.39 (1.12-1.71)***	1.42 (1.11-1.81)***	1.36 (1.05-1.75)***
^Keeping Track PA (max= 20)	1.19 (1.09-1.28)***	1.23 (1.11-1.36)***	1.25 (1.12-1.40)***	1.25 (1.11-1.40)***
^Keeping Track Diet (max= 23)	1.14 (1.06-1.22)***	1.17 (1.07-1.27)***	1.20 (1.08-1.32)***	1.20 (1.08-1.34)***
Meeting Fat and Calorie Goals >=4 days per week	1.02 (0.31-3.21)	----	-----	-----
Season (Summer)	4.43 (1.74-11.27)***	7.04 (2.08-24.08)***	12.76 (3.01-54.07)***	15.34 (3.31-71.15)***

[a]Category modeled in parentheses; [b]Separate models built for baseline and program adherence factors, with univariate $p \leq 0.25$ tested in multivariate model; [c]Baseline and adherence factors with multivariate $p \leq 0.10$ tested in final combined model; [d]Sex and educational attainment forced into combined model; ^Individually fit into multivariate models, keeping remaining predictor variables the same: AOR estimates for other predictors shown for model with KT diet; *$p \leq 0.25$, **$p \leq 0.10$, ***$p \leq 0.05$

Table 11. Predicting 7% Weight Loss AND 10 MET-hour/week PA Goal at 6 Months (N=35) compared to meeting neither goal (N=30) using Logistic Regression Models Limiting to those with Baseline Below 10 Met-Hours per Week

Predictor Variable[a]	OR (95% CI); Univariate Model	AOR (95% CI); Separate[b] Multivariate Model	AOR (95% CI); Combined[c] Multivariate Model	AOR (95% CI); Forced[d] Multivariate Model
Age (≥60)	0.74 (0.28-1.96)	----	----	----
Sex (Female)	0.58 (0.20-1.75)	---	----	0.72 (0.13-4.01)
Educational Attainment (≥Bachelor's Degree)	0.69 (0.25-1.86)	---	----	0.51 (0.11-2.42)
Employment Outside the Home	0.89 (0.33-2.39)	---	----	----
Setting (Worksite)	1.04 (0.37-2.93)	----	----	----
Smoking (Never)	1.92 (0.71-5.21)*	----	----	----
Pre-diabetes	0.43 (0.15-1.23)*	0.32 (0.09-1.06)**	0.30 (0.07-1.32)*	0.31 (0.07-1.43)*
Baseline BMI (kg/m2)	0.91 (0.84-0.99)***	0.92 (0.84-1.01)**	0.87 (0.77-0.98)***	0.85 (0.75-0.97)***
Baseline Self-reported Self-Weighing (days per week)	1.10 (0.92-1.32)	----	----	----
Baseline MET-hours per week (MAQ)	1.17 (1.00-1.38)**	1.19 (0.99-1.43)**	1.17 (0.94-1.47)*	1.19 (0.95-1.50)*
Lifetime Participation in Competitive Sports (Yes)	2.85 (1.03-7.88)***	2.37 (0.78-7.22)	----	----
^Core Attendance/Coach Contact (maximum=16)	1.54 (1.19-2.01)***	1.62 (1.19-2.22)***	1.87 (1.21-2.88)***	1.88 (1.22-2.89)***
6 Month Self-reported Self-weighing (days per week)	1.33 (1.09-1.63)***	1.32 (1.04-1.67)***	1.38 (1.02-1.87)***	1.38 (1.01-1.88)***
^Keeping Track PA (max=20)	1.19 (1.09-1.30)***	1.20 (1.08-1.33)***	1.24 (1.10-1.40)***	1.23 (1.08-1.39)***
^Keeping Track Diet (max=23)	1.16 (1.07-1.26)***	1.16 (1.05-1.27)***	1.19 (1.06-1.34)***	1.19 (1.06-1.34)***
Meeting Fat and Calorie Goals >=4 days per week at 6months	0.92 (0.22-3.80)	---	----	----
Season (Summer)	2.89 (1.02-8.19)***	4.09 (1.09-15.43)***	8.54 (1.59-45.84)***	8.97 (1.62-49.81)***

[a]Category modeled in parentheses; [b]Separate models built for baseline and program adherence factors, with univariate $p \leq 0.25$ tested in multivariate model; [c]Baseline and adherence factors with multivariate $p \leq 0.10$ tested in final combined model; [d]Sex and educational attainment forced into combined model; ^ Individually fit into multivariate models, keeping remaining predictor variables the same: AOR estimates for other predictors shown for model with KT diet; *$p \leq 0.25$, **$p \leq 0.10$, ***$p \leq 0.05$

10.1.5.7 Modeling Factors Predicting Achievement of Either the Weight Loss or Physical Activity Goals in Separate Logistic Regression Models

Univariate and Multivariate Modeling for Achievement of the Weight Loss Goal

Baseline demographic and social factors, clinical characteristics, and program adherence behaviors that have been hypothesized to be related to program success were examined in association with meeting either 7% WL or 10 MET-hour per week PA goals at 6 months. Factors that emerged as potential predictors of 7% weight loss at 6 months (Table 12) included employment status, baseline physical activity level (both; $p<0.25$), self-reported meeting fat and calorie goals $\geq$ 4 days per week, self-monitoring of diet and physical activity, self-reported self-weighing, attendance to sessions or contact with coach, self-reported physical activity on $\geq$ 3 days per week (all; $p<0.05$).

In multivariate modeling, the factors that significantly predicted achieving 7% weight loss at 6 months of intervention (Table 12) included attendance (AOR=1.39 per session, p=0.0001), self-reported self-weighing (AOR=1.20 per each day per week, p=0.0005), self-monitoring of diet (AOR=1.17 per record submitted, p=<0.0001), and self-monitoring of PA (AOR=1.16 per record submitted, $p<0.0001$). The estimates were similar when sex and educational attainment were forced into the model.

Table 12. Logistic Regression Models Predicting Success at Achieving 7% WL (N=72) compared to not achieving 7% WL (N=132) at 6 months

Predictor Variable[a]	OR (95% CI); Univariate Model	AOR (95% CI); Separate[b] Multivariate Model	AOR (95% CI); Forced[c] Multivariate Model
Age (>60)	1.30 (0.73-2.33)	---	---
Sex (Female)	0.88 (0.49-1.58)	---	0.68 (0.33-1.38)
Educational Attainment (> Bachelor's Degree)	0.77 (0.43-1.43)	---	0.86 (0.43-1.75)
Employed Outside the Home (Full- or Part-time)	0.63 (0.35-1.15)*	----	-----
Setting (Worksite)	0.74 (0.41-1.34)	----	----
Smoking (Never)	1.07 (0.59-1.92)	---	---
Pre-diabetes	0.73 (0.40-1.34)	-----	----
Baseline BMI (kg/m^2)	0.99 (0.95-1.04)	---	---
Self-weighing at baseline (days per week)	1.05 (0.95-1.16)	-----	**-----**
+Achieve 10 MET-hours per week (MAQ) Baseline 6 Months	 0.64 (0.35-1.16)* 1.49 (0.71-3.12)*	 ------ ---	 **-----**
+PA Level (MET-hours/week)	1.00 (0.99-1.02)	---	**---**
Self-Report PA >3 days/week Baseline 6 Months	 0.81 (0.45-1.45) 2.04 (0.88-4.78)*	 ---- ----	 ---- ----
Core Attendance/Coach Contact (maximum=16)	1.42 (1.22-1.66)**	1.39 (1.18-1.65)***	1.43 (1.21-1.69)***
Self-reported Self-weighing at 6 months (days per week)	1.22 (1.09-1.36)*	1.20 (1.06-1.37)***	1.18 (1.04-1.34)***
^Keeping Track Diet (max=23)	1.18 (1.12-1.25)***	1.17 (1.10-1.23)***	1.18 (1.11-1.25)***
^Keeping Track PA (max=20)	1.17 (1.11-1.24)***	1.16 (1.09-1.22)***	1.16 (1.10-1.23)***
Achieve Fat and Calorie Goals >4 days/week (self-reported)	3.04 (1.38-6.71)*	----	**----**
Season (Summer)	0.93 (0.51-1.72)	----	---

[a]Category modeled in parentheses; [b]Separate models built for baseline and program adherence factors, with univariate p<0.25 tested in multivariate model; [c]Sex and educational attainment forced into combined model; ^Individually fit into multivariate models, keeping remaining predictor variables the same: AOR estimates for other predictors shown for model with KT diet; +Individually tested in multivariate models; *p<0.25, **p<0.10, ***p<0.05

Univariate and Multivariate Modeling for Achievement of the Physical Activity Goal

Factors that emerged as potential predictors of achieving 10 MET-hours of leisure PA at 6 months in univariate modeling (Table 13) included educational attainment, lifetime participation in competitive sports, self-weighing, baseline pre-diabetes status (all; $p<0.25$), baseline BMI, sex, smoking status, baseline physical activity level, self-reported physical activity on $\geq$ 3 days per week, self-reported self-weighing, and calendar season (all; $p<0.05$).

In multivariate modeling, the factors that significantly predicted achieving 10 MET-hours per week leisure PA at 6 months of intervention (Table 13) included activity on at least 3 days per week at 6 months (AOR=10.27, $p<0.0001$) and baseline (AOR=2.84, $p=0.007$), summer season (AOR=7.74, $p<0.0001$), being active at least 10 MET-hours per week at baseline (AOR=4.83, $p=0.0006$), and never smoking (AOR=3.37, $p=0.004$). Conversely, factors predicting a lower odds of achieving 10 MET-hours of PA per week at 6 months included having pre-diabetes at baseline (AOR=0.40, $p=0.04$) and having a higher baseline BMI (AOR=0.89 per one unit increase in BMI, $p=0.0006$). The estimates were similar when sex and gender were forced into the model.

Table 13. Predicting meeting the 10 MET-hour per week PA goal (N=153) at 6 months compared to not meeting the PA goal (N=50) using Logistic Regression Models

Predictor Variable[a]	OR (95% CI); Univariate Model	AOR (95% CI); Separate[b] Multivariate Model	AOR (95% CI); Combined[c] Multivariate Model	AOR (95% CI); Forced[d] Multivariate Model
Age (≥60)	0.72 (0.38-1.37)	----	----	----
Sex (Female)	0.48 (0.23-0.97)***	-----	----	0.54 (0.23-1.30)*
Educational Attainment (≥ Bachelor's Degree	1.49 (0.78-2.86)*	------	----	1.19 (0.53-2.67)
Employed Outside the Home (Full- or Part-time)	1.33 (0.69- 2.58)	-----	----	----
Setting (Worksite)	1.43 (0.74-2.79)	-----	----	----
+Smoking (Never)	1.91 (1.00-3.65)***	2.31 (1.14-4.68)***	3.37 (1.49-7.64)***	3.40 (1.48-7.79)***
+Pre-diabetes	0.52 (0.25-1.07)**	0.46 (0.21-1.00)**	0.40 (0.17-0.94)***	0.38 (0.16-0.91)***
Baseline BMI (kg/m^2)	0.92 (0.88-0.97)**	0.92 (0.87-0.97)***	0.89 (0.83-0.95)***	0.89 (0.84-0.96)***
Self-weighing Baseline (days per week)	1.09 (0.96-1.23)*	---	---	---
^Active at Baseline ≥10 Leisure MET-hours/week	5.32 (2.34-12.08)***	5.19 (2.25-12.00)***	4.83 (1.97-11.82)***	4.65 (1.88-11.55)***
Lifetime Participation in Competitive Sports (Yes)	1.83 (0.96-3.50)	-----	----	----
^PA Frequency ≥3 days/week				
Baseline	2.53 (1.32-4.86)***	2.53 (1.29-4.98)***	2.86 (1.34-6.10)***	2.91 (1.35-6.25)***
6 Months	7.32 (3.25-15.66)***	8.63 (3.57-20.85)***	10.27 (3.83-27.52)***	11.61 (4.20-32.07)***
Core Attendance/Coach Contact (maximum=16)	1.05 (0.96-1.14)	---	----	----

Table 13. Con't

Predictor Variable[a]	OR (95% CI); Univariate Model	AOR (95% CI); Separate[b] Multivariate Model	AOR (95% CI); Combined[c] Multivariate Model	AOR (95% CI); Forced[d] Multivariate Model
Self-reported Self-weighing at 6 Months (days per week)	1.12 (0.99-1.27)**	1.15 (1.01-1.32)**	----	----
Keeping Track PA (max= 20)	1.04 (0.99-1.10)*	----	---	---
Keeping Track Diet (max= 24)	1.00 (0.95-1.05)	----	---	---
Meeting Fat and Calorie Goals >=4 days per week (self-reported)	0.93 (0.78-1.08)	-----	----	----
Season (Summer)	5.50 (2.77-10.91)***	5.87 (2.91-11.85)***	7.74 (3.46-17.33)***	8.30 (3.64-18.93)***

[a]Category modeled in parentheses; [b]Separate models built for baseline and program adherence factors, with univariate $p \leq 0.25$ tested in multivariate model; [c]Baseline and adherence factors with multivariate $p \leq 0.10$ tested in final combined model; [d]Sex and educational attainment forced into combined model; ^Individually fit into multivariate models, keeping remaining predictor variables the same: AOR estimates for other predictors shown for model with baseline PA level; [+]Individually fit into multivariate models, keeping remaining predictor variables the same; AOR estimates for other predictors shown for model with pre-diabetes; *$p \leq 0.25$, **$p \leq 0.10$, ***$p \leq 0.05$

10.1.5.8 Sensitivity Analysis

Analysis was conducted to determine if predictors of long-term success were different than those that predict initial success in a lifestyle program. In examining the predictors of success at 12 months for achieving both 7% weight loss and 10 MET-hours per week leisure PA (Table 14), 7% weight loss at 6 months (AOR=41.65, p<0.0001), baseline PA level greater than or equal to 10 MET-hours per week (AOR=10.10, p=0.007), self-weighing at 12 months (AOR=1.37 per additional day per week, p=0.02), total attendance (AOR=1.22 per session, p=0.03), keeping track of diet (AOR=1.09 per record submitted, p=0.004), and keeping track of PA (AOR=1.09 per record submitted, p=0.005) were significant. At 18 months, the only significant predictors of achieving both 7% weight loss and 150 minutes per week PA in multivariate models were 7% weight loss at 6 months (AOR=8.33, p=0.0006) and PA level greater or equal to 150 minutes per week at 6 months (AOR=7.17, p=0.003). Summer season was marginally significant (AOR=3.31, p=0.07).

Table 14. Predicting 7% Weight Loss AND 10 MET-hour/week PA Goal at 12 Months (N=54) compared to meeting neither goal (N=49) using Logistic Regression Models

Predictor Variable[a]	OR (95% CI); Univariate Model	AOR (95% CI); Separate[b] Multivariate Model	AOR (95% CI); Combined[c] Multivariate Model	AOR (95% CI); Forced[d] Multivariate Model
Age >=60	1.13 (0.52-2.45)	----	----	----
Sex (Female)	0.90 (0.40-2.02)	----	-----	2.09 (0.44-9.91)
Educational Attainment (>=Bachelor's Degree)	0.78 (0.35-1.73)	-----	-----	0.55 (0.14-2.21)
^Employment Outside the Home	0.50 (0.22-1.14)**	---	---	---
^Setting (Worksite)	0.48 (0.22-1.06)**	0.47 (0.21-1.06)**	----	----
Smoking (Never)	0.79 (0.36-1.74)	----	-----	-----
Pre-diabetes	0.74 (0.32-1.70)	---	---	---
Baseline BMI (kg/m2)	0.98 (0.92-1.04)	---	---	---
Self-weighing baseline	1.06 (0.93-1.21)	---	----	----
Active >=10 MET-hours per week				
Baseline	3.30 (1.34-8.13)***	3.30 (1.34-8.13)***	10.10 (1.87-54.66)***	11.47 (2.04-64.55)***
6 Months (Adjusted for Season)	6.04 (1.81-20.14)***	-----	----	----
Lifetime Participation in Competitive Sports (Yes)	1.38 (0.62-3.06)	----	----	----
7% Weight Loss at 6 Months	27.36 (9.28-80.72)***	28.12 (7.45-106.18)***	41.65 (8.73-198.73)***	49.88 (9.89-251.46)***
Self-weighing (days per week) at 12 months (self-reported)	1.38 (1.18-1.61)***	1.35 (1.06-1.71)***	1.37 (1.06-1.78)***	1.36 (1.05-1.76)***
^Total Attendance/Contact (max 22)	1.40 (1.21-1.61)***	1.28 (1.06-1.54)***	1.22 (1.02-1.47)***	1.22 (1.00-1.48)***
^Total Keeping Track Diet (Max 47)	1.12 (1.06-1.18)***	1.10 (1.04-1.16)***	1.09 (1.03-1.16)***	1.09 (1.03-1.16)***
^Total Keeping Track PA (Max 44)	1.11 (1.06-1.17)***	1.09 (1.03-1.16)***	1.09 (1.03-1.15)***	1.09 (1.02-1.15)***
Meeting Fat and Calorie Goals $\geq$4 days per week at 12 months (self-reported)	0.98 (0.82-1.16)	----	-----	-----
Season (Summer)	3.00 (1.13-7.99)***	----	---	---

[a]Category modeled in parentheses; [b]Separate models built for baseline and program adherence factors, with univariate p$\leq$0.25 tested in multivariate model; [c]Baseline and adherence factors with multivariate p$\leq$0.10 tested in final combined model; [d]Sex and educational attainment forced into combined model; ^Individually fit into multivariate models, keeping remaining predictor variables the same: AOR estimates for other predictors shown for model with KT diet; *p$\leq$0.25, **p$\leq$0.10, ***p$\leq$0.05

To determine if characteristics predicting two thresholds of weight loss success differed, logistic regression models that predicted success for 5% and 7% reduction of initial body weight were built. Both univariate and multivariate modeling revealed similar odds ratio estimates for predictors of 5% (Table 15) and 7% weight loss (Table 12). In multivariate logistic regression modeling, monitoring diet and PA, attendance, and self-weighing behavior were the significant predictors for achievement of either 5% or 7% weight loss.

In evaluating the long-term success of meeting the 7% weight loss goal, the overwhelming predictor of achieving 7% weight loss at 12 months was achieving the goal at 6 months (AOR=16.74, $p<0.0001$). Other significant predictors of 7% weight loss at 12 months included self-reported PA on at least 3 days per week (AOR=5.68, $p=0.008$), being active at least 10 MET-hours per week (AOR=2.78, $p=0.06$), total attendance (AOR=1.28, $p=0.002$), self-reported self-weighing (AOR=1.24 per day per week, $p=0.01$), total diet records submitted (AOR=1.07, $p=0.0004$), and total PA records submitted (AOR=1.07, $p=0.0009$). Educational attainment greater or equal to a bachelor's degree was significantly inversely related to achieving 7% weight loss (AOR=0.36, $p=0.04$). At 18 months, 7% weight loss was positively associated with achieving 7% weight loss at 12 months (AOR=39.76, $p<0.0001$) or at 6 months (AOR=11.81, $p<0.0001$), and inversely associated with educational attainment greater or equal to a bachelor's degree (AOR=0.24, $p=0.004$).

Table 15. Logistic Regression Models Predicting Success at Achieving 5% WL (N=105) compared to not achieving 5% WL (N=99) at 6 months

Predictor Variable[a]	OR (95% CI); Univariate Model	AOR (95% CI); Separate[b] Multivariate Model	AOR (95% CI); Combined[c] Multivariate Model	AOR (95% CI); Forced[d] Multivariate Model
Age (>=60)	1.30 (0.74-2.27)	---	---	---
Sex (Female)	0.86 (0.49-1.51)	---	----	0.67 (0.33-1.33)
Educational Attainment (≥ Bachelor's Degree)	1.01 (0.57-1.79)	---	----	1.15 (0.57-2.33)
Employed Outside the Home (Full- or Part-time)	0.58 (0.38-1.02)**	0.53 (0.29-0.95)***	----	----
Setting (Worksite)	0.80 (0.46-1.40)	----	----	----
Smoking (Never)	0.91 (0.52-1.60)	---	----	----
Pre-diabetes	0.59 (0.33-1.06)**	0.54 (0.30-0.99)***	0.57 (0.28-1.12)**	0.59 (0.29-1.18)*
Baseline BMI (kg/m^2)	1.00 (0.96-1.05)	---	---	---
Self- reported Self-weighing at baseline (days per week)	1.00 (0.91-1.10)	-----	----	----
Achieve 10 MET-hours per week (MAQ)				
Baseline	0.94 (0.54-1.64)	----	----	----
6 Months	1.67 (0.83-3.33)	----	----	---
^ Core Attendance/Coach Contact (max = 16)	1.34 (0.19-1.51)***	1.33 (1.16-1.52)***	1.35 (1.19-1.53)***	1.36 (1.20-1.55)***
^Keeping Track Diet (max = 23)	1.19 (1.13-1.25)***	1.18 (1.11-1.24)***	1.18 (1.18-1.25)***	1.19 (1.12-1.26)***
^Keeping Track PA (max = 20)	1.19 (1.13-1.26)***	1.18 (1.11-1.25)***	1.19 (1.12-1.26)***	1.19 (1.12-1.26)***

Table 15. Con't

Predictor Variable[a]	OR (95% CI); Univariate Model	AOR (95% CI); Separate[b] Multivariate Model	AOR (95% CI); Combined[c] Multivariate Model	AOR (95% CI); Forced[d] Multivariate Model
Self-weighing 6 months (days per week)	1.19 (1.07-1.32)***	1.16 (1.02-1.31)***	1.15 (1.02-1.30)***	1.15 (1.02-1.30)***
Meeting Fat and Calorie Goals $\geq$4 days/week (self-reported)	2.20 (1.14-4.27)***	----	----	----
Season (Summer)	0.91 (0.51-1.64)	----	---	---

[a]Category modeled in parentheses; [b]Separate models built for baseline and program adherence factors, with univariate $p \leq 0.25$ tested in multivariate model; [c]Baseline and adherence factors with multivariate $p \leq 0.10$ tested in final combined model; [d]Sex and educational attainment forced into combined model; ^Individually fit into multivariate models, keeping remaining predictor variables the same: AOR estimates for other predictors shown for model with KT diet; *$p \leq 0.25$, **$p \leq 0.10$, ***$p \leq 0.05$

Univariate logistic regression analysis examining the factors related to program success for PA at 6 months quantified as 150 minutes per week (Table 16) or 10-MET hours per week (Table 13) produced similar results. In multivariate analysis, both models demonstrated that baseline PA level, defined in minutes or MET-hours per week, respectively, was the strongest predictor of meeting the respective goal. Key differences in the final models are that season, pre-diabetes status, and baseline BMI were predictors of achieving 10 MET-hours per week, but not of achieving 150 minutes per week. Conversely, keeping track of diet and PA was associated with achieving 150 minutes per week, but not 10 MET-hours.

In analysis of factors predicting the PA goal long-term, being at a PA level greater or equal to the goal at 6 months was a strong predictor of achieving the PA goal at 12 (AOR=10.63, $p<0.0001$) and 18 months (AOR=11.54, $p<0.0001$). Summer season at time of assessment also predicted being at the PA goal (AOR=8.50, $p=0.0002$ at 6 months; AOR=4.71, $p=0.0002$ at 18 months). At 12 months, participants at the work site were less likely to meet the goal than those at the community centers (AOR=0.29, $p=0.0006$), a potential artifact of work site participants having a lower baseline PA level (Chapter 9, Table 1). At 18 months, participants with at least a bachelor's degree were more likely to meet the goal than those with educational attainment less than a bachelor's degree (AOR=2.68, $p=0.01$), as was demonstrated at baseline (Chapter 9, Table 3).

Table 16. Logistic Regression Models Predicting Success at Achieving 150 min/week PA (N=119) compared to not Achieving 150 min/week (N=83) at 6 months

Predictor Variable[a]	OR (95% CI); Univariate Model	AOR (95% CI); Separate[b] Multivariate Model	AOR (95% CI); Combined[c] Multivariate Model	AOR (95% CI); Forced[d] Multivariate Model
Age (>=60)	1.39 (0.79-2.47)	---	----	----
Sex (Female)	0.95 (0.53-1.69)	---	---	1.21 (0.60-2.45)
Educational Attainment (≥ Bachelor's Degree)	0.99 (0.55-1.77)	---	---	1.17 (0.58-2.36)
Employed Outside the Home (Full- or Part-time)	0.68 (0.38-1.24)*	----	----	----
Setting (Worksite)	0.45 (0.26-0.81)***	---	---	---
Smoking (Never)	0.74 (0.42-1.32)	---	---	---
Pre-diabetes	0.67 (0.37-1.22)*	0.52 (0.27-1.00)**	----	----
Baseline BMI (kg/m^2)	0.98 (0.93-1.02)	---	---	---
Self-reported Self-weighing at baseline (days per week)	1.04 (0.94-1.15)	-----	----	----
Achieve 150 Min/week Baseline	6.57 (3.33-12.97)***	7.19 (3.59-14.41)***	6.39 (3.13-13.05)***	6.53 (3.17-13.43)***
Lifetime Participation in Competitive Sports (Yes)	1.48 (0.83-2.61)*	---	----	----
Achieve Fat and Calorie Goals ≥4 days/week (self-reported)	1.90 (0.98-3.67)**	1.23 (1.06-1.42)***	1.23 (1.05-1.45)***	1.24 (1.05-1.46)***
Self- reported Self-weighing 6 months (days per week)	1.15 (1.04-1.28)***	1.15 (1.02-1.29)***	1.14 (1.01-1.29)***	1.15 (1.01-1.30)***

Table 16. Con't

Predictor Variable[a]	**OR (95% CI); Univariate Model**	**AOR (95% CI); Separate[b] Multivariate Model**	**AOR (95% CI); Combined[c] Multivariate Model**	**AOR (95% CI); Forced[d] Multivariate Model**
^Core Attendance/Coach Contact (max = 16)	1.10 (1.01-1.20)***	1.14 (1.03-1.25)***	1.13 (1.02-1.26)***	1.13 (1.01-1.26)***
^Keeping Track PA (max=20)	1.09 (1.04-1.15)***	1.10 (1.04-1.16)***	1.10 (1.04-1.16)***	1.10 (1.04-1.16)***
^Keeping Track Diet (max = 23)	1.05 (1.00-1.09)***	1.06 (1.01-1.11)***	1.05 (1.00-1.10)**	1.05 (1.00-1.10)**
Season (Summer)	1.31 (0.72-2.37)	----	---	---

[a]Category modeled in parentheses; [b]Separate models built for baseline and program adherence factors, with univariate $p \leq 0.25$ tested in multivariate model; [c]Baseline and adherence factors with multivariate $p \leq 0.10$ tested in final combined model; [d]Sex and educational attainment forced into combined model; ^Individually fit into multivariate models, keeping remaining predictor variables the same: AOR estimates for other predictors shown for model with KT diet; *$p \leq 0.25$, **$p \leq 0.10$, ***$p \leq 0.05$

10.2 DISCUSSION OF KEY FINDINGS

The community DPP-GLB program participants were successful in achieving the 7% weight loss and 150 minute (or 10 MET-hour) per week PA goals during intervention. The greatest improvements in weight and PA were observed within 6 months of starting the lifestyle intervention, although significant changes were maintained at 12 and 18 months. This pattern has been observed in efficacy trials and other community-based translation programs (13, 34). The strongest predictor of weight loss and physical activity success at 12 and 18 months was achieving those same goals independently at 6 months, demonstrating the importance of engaging participants in a lifestyle program early on in the process.

Examination of factors associated with program success was possible in this large community sample due to information collection on multiple social, demographic, and clinical characteristics prior to engaging in the intervention. The DPP-GLB participants were successful in achieving weight loss and PA goals at 6 months regardless of age, educational attainment, or employment status, as these did not emerge as potential predictors of success. Achieving both program goals at 6 months had a weak association with sex, though this relationship did not reach statistical significance once adjusting for program adherence behaviors. Higher baseline BMI was significantly associated with lower odds of success of meeting both goals and of meeting the PA goal. This finding is similar to the DPP, in which lower BMI was related to increased likelihood for achieving the weight and PA goals and remained significant in predicting the PA goal once adjusting for other factors (34).

Efficacy trials, including the DPP, enrolled only those with impaired glucose tolerance or impaired fasting glucose, limiting the ability to investigate pre-diabetes as a predictor of program success. The broader eligibility criteria in this investigation allowed for the comparison between those with pre-diabetes and those with normal glucose and hemoglobin A1c values within this study cohort. Although successful for weight loss and increasing PA, participants in this evaluation with pre-diabetes at baseline had lower odds of achieving both goals compared to participants who had the metabolic syndrome but normal glucose and hemoglobin A1c values at baseline. Demographic characteristics that are known risk factors for pre-diabetes, such as age and education (105), that were related to baseline pre-diabetes status and baseline PA level (education only) in this sample may contribute to the apparent relationship between pre-diabetes status and goal achievement. Further exploration of these potential interactions, other risk factors for pre-diabetes, and duration of pre-diabetes is needed to understand how pre-diabetes status affects goal achievement in a lifestyle program.

Markers of intervention adherence were significantly associated with achievement of both program goals. Participants who were able to achieve both program goals at 6 months were more likely to attend sessions, monitor diet and PA, and self-weigh. This finding reinforces earlier clinical and observational studies that have shown adherence to program behaviors are important to program success and maintenance of weight loss and PA (34, 87, 100). Incorporating new strategies into lifestyle programs that encourage diet and PA self-monitoring, such as mobile applications and activity monitors, can provide additional options for participants and have potential to enhance participant success in achieving goals.

The significance of calendar season (measurement during summer compared to winter months) as a predictor of meeting both goals was driven by the underlying influence of calendar season on PA level, demonstrated in the second investigation of this dissertation (Chapter 9, Appendix E) and in analysis of factors predicting the PA goal (Table 13). The finding that calendar season is significantly associated with goal achievement demonstrates the need to add strategies to assist participants in maintaining or increasing PA during the winter season (as is here in Pittsburgh) or during inclement weather and the importance of considering calendar season in program evaluation.

Two predictors of success in the DPP that were not significant predictors of PA and weight loss in this community sample are age and employment status (retired vs. full/part-time). Among the DPP lifestyle participants, older adults were more likely to complete self-monitoring records and to report adherence to the calorie goals (34). It is possible that some of the effects of age and the associated employment status in this sample may have been overshadowed by the markers of program adherence (self-monitoring, self-weighing, and attendance) that predicted meeting goals at 6 and 12 months. Completion of assessment visits at 12 and 18 months, also a marker of adherence, was more likely among those who were older and not employed outside the home and may have affected the ability to detect differences in long-term goal achievement by age and employment status.

The racial and ethnic make-up of the sample was representative of the communities surrounding the intervention sites (190); which, unfortunately is quite small thereby not providing a large enough sample size of diverse individuals to explore differences in goal achievement among ethnic/racial sub-groups. This is a limitation to this study as race/ethnicity was related to achieving the short-term weight loss and long-term PA goals in the DPP (34). Other community DPP-translation programs among populations of at least 50% racial/ethnic minority (42, 44, 152, 153, 155, 159, 160, 167, 170) have reported weight loss success of 1.3-

5.7% and PA goal achievement of 41.2-78% (44, 152, 159, 160). One of these efforts examined factors associated with weight loss achievement and found that attendance, PA level, and family support were associated with success (42). Community efforts among racially and ethnically diverse populations should further evaluate factors that predict success to help guide program development.

Subjective PA measures, such as the MAQ, are quite reliable for ranking individuals based on relative PA level, but are less accurate for estimating absolute PA level compared to objective measures (25, 48). Thus, another limitation to this study is that self-reported data was used to classify participants as meeting goal based on an absolute rather than relative PA level. This could have led to a misclassification of being "at goal" at baseline that potentially attenuated the relationship between baseline PA level and goal achievement at time points during intervention. A sub-analysis was conducted to examine factors predicting success among participants who reported baseline PA <10 MET-hours per week to determine if the use of an absolute PA measure affected the results. In the sub-analysis, baseline leisure MET-hours per week marginally predicted meeting both goals at 6 months. Other factors predicting success in this sub-group were similar to the entire cohort, indicating that misclassification of goal achievement at baseline had minimal effects on the results. Efforts that include objective PA measures will help minimize the error in classifying participant success.

Although the Healthy Lifestyle Project enrolled a large sample from the work site and community center settings, the high proportion of participants who met at least one program goal left a relatively small sample that did not achieve either program goal. This relatively small sample may have affected the reliability of odds ratio estimates in multivariate analysis, reflected in the 95% confidence limits, and the overall model fit. Since the overarching goal of lifestyle intervention programs is to help participants achieve both substantial weight loss and adequate PA, having a small sample that does not meet either goal is a positive thing from the evaluator's perspective. This analysis helps provide insight as to the strategies that may be needed to assist the small sample of participants who are not meeting either program goal in being more successful.

10.3 PAPER #3 ABSTRACT

Background: The Diabetes Prevention Program (DPP) and subsequently adapted community lifestyle interventions have been successful for improving physical activity (PA) and weight. In the DPP, age, sex, BMI, employment status, race, ethnicity, and adherence to program behaviors were associated with goal achievement. DPP lifestyle participants who achieved the 150 minute per week PA goal were more likely to achieve the 7% weight loss goal both short- and long-term. Participant characteristics and adherence behaviors that enhance success for achieving both of these program goals have not yet been reported in translation.

Purpose: To evaluate factors that predict success for achieving both 7% weight loss and 150 minute per week PA goals in a one-year community DPP-lifestyle intervention.

Methods: 223 adults at-risk for diabetes and CVD enrolled and completed an assessment at 6 (N=203) and 12 (N=186) months. Demographic, social, and clinical measures were collected at baseline and objective weight and self-reported PA (Modifiable Activity Questionnaire) were ascertained at baseline, 6, and 12 months.

Results: Participants who achieved both goals at 6 months (N=57) were more likely to attend sessions (AOR=1.71, $p<0.01$), self-weigh (AOR=1.42, $p<0.01$), self-monitor PA (AOR=1.25,

$p<0.01$) and diet (AOR=1.20, $p<0.01$), complete the assessment in the summer months (AOR=12.76, $p<0.01$) than those who met neither goal (N=35). Baseline BMI (AOR=0.87, $p<0.01$) and pre-diabetes status (AOR=0.20, $p<0.05$) were inversely related to program success. Meeting goals in the first 6 months was the strongest predictor of meeting goals long-term.

Conclusions: This evaluation supports the importance of engaging participants early in a lifestyle program and reinforcing self-monitoring and self-weighing behaviors. Strategies should be added to assist participants in increasing and maintaining PA, particularly during winter months and inclement weather, and to make tracking diet and PA more user-friendly.

11.0 DISSERTATION FINAL CONSIDERATIONS

11.1 SUMMARY AND CONCLUSIONS

This dissertation identified and addressed key issues related to physical activity (PA) assessment and intervention in translational research. The first investigation (Paper 1) demonstrated that, although efficacy trials have shown substantial increases in PA due to intervention and PA is included as one of two key intervention goals in community translation programs, PA assessment and outcomes reporting in translation studies is lacking and inconsistent. Through the efforts of the Healthy Lifestyle Project, significant increases in PA levels during intervention were able to be described (Paper 2) using a detailed, validated, interviewer-administered questionnaire [Modifiable Activity Questionnaire (MAQ)]. In addition, the frequency of MAQ administration and the short time-frame (past month) captured by the MAQ allowed for a thorough examination of the impact of calendar season on PA levels during intervention (Paper 2). Finally, the success of the Healthy Lifestyle Project, which utilized the Group Lifestyle Balance lifestyle intervention program, for improving PA levels and achieving significant weight loss allowed for the investigation of baseline characteristics and markers of program adherence common among participants who achieved both weight and PA goals compared to those who did not achieve program goals. This third investigation identified baseline pre-diabetes status and baseline BMI as the demographic and clinical characteristics associated with achieving both weight loss and

PA goals (Paper 3). The interpretation of the observed associations between clinical characteristics and goal achievement are limited by the use of subjective, self-report PA data. Program adherence behaviors including attendance to sessions or contact with the lifestyle coach, self-monitoring of diet and physical activity, and self-weighing also enhanced odds for success. In line with the findings from the second investigation, season at the time of assessment was a strong predictor of achieving both program goals and especially the PA goal.

11.2 PUBLIC HEALTH SIGNIFICANCE

The ever-present burden of diabetes and CVD in the United States can be attributed to unhealthy lifestyle behaviors such as physical inactivity and poor diet (4). Physical activity has been shown repeatedly through experimental and observational research to be a protective factor for many chronic illnesses, including diabetes and CVD (6, 30, 71, 82). Efficacy trials have demonstrated that increasing PA and achieving modest weight loss can successfully prevent or delay onset of these chronic conditions (9-11). Even with the health benefits of PA widely publicized, many Americans are not meeting the recommendations of 150 minutes of moderate intensity aerobic PA per week for general health (20, 22). Thus, developing and disseminating effective community-based programs for increasing PA is recognized by the CDC as an important public health priority in order to reduce chronic disease burden (27).

The translation of efficacious interventions to community-based programs has been promising in regards to diabetes and CVD prevention. The existing literature provides extensive evaluation of the effectiveness of these programs for achieving weight loss (13, 14, 37, 179) at a magnitude that is beneficial for health (189). Less is known about the success of these programs for increasing PA and improving PA behaviors. The first investigation in this dissertation exposed the void in reporting PA assessment and related-outcomes in translation studies. As PA has been shown to reduce risk for diabetes even in the absence of weight loss (35), it is important to evaluate the PA component of these interventions.

The results of this dissertation are important for guiding the development and dissemination of community intervention programs aimed at increasing PA for improved health. The second investigation within this dissertation showed that delivery of an evidence-based lifestyle intervention resulted in improved PA levels and that PA was associated with the accompanying weight loss. Additionally, it was shown that the lifestyle intervention was effective for improving PA level independent of the observed fluctuations in PA level due to seasonal changes. The increases in PA level occurred across multiple community settings and across socio-demographic characteristics, showing the potential for dissemination of this effective program in diverse populations in order to improve individual health.

The third investigation identified baseline characteristics that predict program success for weight loss and physical activity during a lifestyle intervention. The results confirmed that the first 6 months is a critical time frame to engage participants to maximize likelihood of success, given that success at 6 months was the overwhelming predictor of success at 12 and 18 months. The characteristics identified to predict program success can be used by health practitioners and providers to identify persons who may need extra tools or enhanced strategies to achieve desired weight loss and PA levels.

11.3 FUTURE DIRECTIONS

This dissertation exposed inconsistent PA assessment and outcomes reporting in diabetes prevention translation research. It is imperative that PA assessment improves in community translation programs and that PA-related outcomes are reported in order to guide future programming. This dissertation provided evidence for the effectiveness of a community diabetes prevention translation program for increasing physical activity. The addition of objective PA measurements, i.e. wearable monitors, in future efforts will provide more information on total PA and changes in light and moderate-vigorous intensity PA during interventions. The impact of season on PA levels during an intervention program was demonstrated, as well as season being a predictor of program success related to PA. As a result, it is recommended that evaluators consider the frequency and time frame of assessment and how the results with be impacted by environmental changes related to calendar season. Moving forward, community intervention programs can be adapted to enhance the probability of program success by including strategies specific to those with higher baseline BMI, as well as focusing on ways to maintain or increase PA level during the winter season and inclement weather. Future efforts that include monitor-based measures of PA in diverse populations will provide more insight as to how various intensity PA levels and total PA levels change during a lifestyle intervention. Larger, more diverse cohorts will provide a better picture of what factors predict program success in specific population subgroups.

APPENDIX A: PREFERRED REPORTING ITEMS CHECKLIST FOR SYSTEMATIC REVIEWS AND META-ANALYSIS

(PRISMA)

PRISMA 2009 Checklist (191)

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	

Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	

DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	

APPENDIX B: PHYSICAL ACTIVITY QUESTIONNAIRES

B.1 LIFESTYLE QUESTIONNAIRE

The Lifestyle Questionnaire (LSQ) assessed family history and smoking status in addition to key lifestyle behaviors including self-weighing, self-monitoring food and physical activity, and frequency and duration of physical activity.

LIFESTYLE INFORMATION DATA FORM

1. **Family history of diabetes? (Type 1 or Type 2: Parents, siblings or children)** YES=1 NO=0	
2. **Family history of heart disease? (Parents, siblings, or children, age <55 male, <65 female)** YES=1 NO=0	
3. **Smoking status:** • Never Used (<100 over lifetime) =1 • Former Use ($\geq$ 100 but no use within past 6mo) =2 • Current Use (any use at all within past 6mo) =3	
4. **Physically active on 3 or more days/week?** YES=1 NO=0	
5. **How often does the participant weigh his/her self?** • Daily= 7 • 6/week=6 • 5/week=5 • 4/week=4 • 3/week=3 • 2/week=2 • Once per week=1 • 2-3 times/month=0 • Less than 1/month or never=9	
6. **Lifestyle Practices: How often does the participant keep track of food intake?** • Daily= 7 • 6/week=6 • 5/week=5 • 4/week=4 • 3/week=3 • 2/week=2 • Once per week=1 • 2-3 times/month=0 • Less than 1/month or never=9	
7. **How often does the participant meet fat and calorie goals?** • Daily= 7 • 6/week=6 • 5/week=5 • 4/week=4 • 3/week=3 • 2/week=2 • Once per week=1 • 2-3 times/month=0 • Less than 1/month or never=9 • Not applicable=8	
8. **How often does the participant perform physical activity?** • Daily= 7 • 6/week=6 • 5/week=5	

• 4/week=4 • 3/week=3 • 2/week=2 • Once per week=1 • 2-3 times/month=0 • Less than 1/month or never=9	
9. **How often does the participant keep track of physical activity?** • Daily= 7 • 6/week=6 • 5/week=5 • 4/week=4 • 3/week=3 • 2/week=2 • Once per week=1 • 2-3 times/month=0 • Less than 1/month or never=9 • Not applicable=8	
10. When the participant is active, how many minutes is he/she active on average?	
11. Has the participant taken part in any weight loss programs within the past year (other than GLB)? YES=1 NO=0 If yes, please describe: ____ Dates of participation: __________ to ____________	

B.2 MODIFIABLE ACTIVITY QUESITONNAIRE

The Modifiable Activity Questionnaire (MAQ) was used to assess past month leisure and occupational physical activity at baseline, 6, and 12 months.

MODIFIABLE ACTIVITY QUESTIONNAIRE

Please check the box of all activities that you have done during the past month (4 weeks) and then determine the average frequency and duration of each activity.

Activity	Frequency	Duration
	Average number of times per month	Average # of minutes each time
☐ Aerobic Dance/Step Aerobics		
☐ Badminton		
☐ Baseball		
☐ Basketball		
☐ Bicycling (indoor, outdoor)		
☐ Bowling		
☐ Calisthenics/Toning Exercises		
☐ Canoeing/Rowing/Kayaking		
☐ Dancing (square, line, ballroom)		
☐ Elliptical Trainer		
☐ Fencing		
☐ Fishing		
☐ Football		
☐ Gardening or Yardwork		
☐ Golf		
☐ Hiking		
☐ Horseback Riding		
☐ Hunting		
☐ Jogging (outdoor, indoor)		
☐ Jumping Rope		
☐ Martial Arts (karate, judo)		
☐ Racquetball/Handball/Squash		
☐ Rock Climbing		
☐ Scuba Diving		
☐ Skating (roller, ice, blading)		
☐ Snow Shoeing		
☐ Snow Skiing (downhill)		
☐ Snow Skiing (x-country, Nordic Track)		
☐ Soccer		
☐ Softball		
☐ Stairmaster		
☐ Strength/Weight Training		
☐ Swimming (laps, snorkeling)		
☐ Tai Chi		
☐ Tennis		
☐ Volleyball		
☐ Walking for Exercise (outdoor, indoor, treadmill)		
☐ Water Aerobics		
☐ Water Skiing		
☐ Yoga		
☐ Other ____________________		

☐ I did none of these activities over the past month (4 weeks).

BAS 6MO 12MO ID#: LIF______ Date: _________

Rev. 1-2011

1. Was this month reflective of your usual activity levels? ☐ YES ☐ NO

2. Excluding time at work, in general how many HOURS per DAY do you usually spend watching television or sitting at the computer? ______ hours.

3. Over the past month (4 weeks) have you spent more than one week confined to a bed or chair as a result of an injury, illness, or surgery? ☐ YES ☐ NO

If yes, how many weeks over the past month were you confined to a bed or chair? _____weeks.

4. Do you have difficulty doing any of the following activities?

a. getting in or out of a bed or chair? ☐ YES ☐ NO
b. walking across a small room without resting? ☐ YES ☐ NO
c. walking for 10 minutes without resting? ☐ YES ☐ NO

5. Did you ever compete in an individual or team sport (not including any time spent in sports performed during school physical education classes)? ☐ YES ☐ NO

If yes, how many total years did you participate in competitive sports? _____ years.

6. Have you had a job for more than two weeks over the past month?

If Yes, list all JOBS that the individual held over the past month for more than two weeks. If unemployed/disabled/retired/homemaker/student during all or part of the past month, list as such and probe for job activities of a normal 8 hour day, 5 day week.

			Average Job Schedule over past month		Out of the total # of "hrs/Day" the individual reported working at this "job", how much of this time was usually spent sitting? Enter this # in "Hrs Sitting " column, then place a check "✓" in the category which best describes their job activities when they were not sitting.			
		Walk or bicycle to/from work			Hrs. spent sitting at work	Check the category that best describes job activities when not sitting		
Job Name	Job Code		Days/Wk	Hrs/Day	Hrs Sitting	A	B	C

<u>Category A</u>
(includes all sitting activities)
Sitting
Standing still w/o heavy lifting
Cleaning – ironing, cooking, washing, dusting
Driving a bus, taxi, tractor
Jewelry making, weaving
General office work
Occasional/short distance walking

<u>Category B</u>
(includes most indoor activities)
Carrying light loads
Continuous walking
Heavy cleaning – mopping, sweeping, scrubbing, vacuuming
Gardening- planting, weeding
Painting/Plastering
Plumbing/Welding
Electrical Work
Sheep Herding

<u>Category C</u>
(heavy industrial work, outdoor construction, farming)
Carrying moderate to heavy loads
Heavy construction
Farming – hoeing, digging, mowing, raking
Digging ditches, shoveling
Chopping (ax), sawing wood
Tree/pole climbing
Water/coal/wood hauling

JOB CODES

<u>Not employed outside of the home</u>:
1. Student
2. Home Maker
3. Retired
4. Disabled
5. Unemployed

<u>Employed (or volunteer):</u>
6. Armed Services
7. Office Worker
8. Non-Office Worker

APPENDIX C: PAPER #1

EVALUATION OF THE REPORTING OF PHYSICAL ACTIVITY IN COMMUNITY LIFESTYLE INTERVENTIONS: A SYSTEMATIC REVIEW

Introduction

The Diabetes Prevention Program (DPP) was one of the first randomized clinical trials to demonstrate that a chronic disease could be prevented by adopting lifestyle changes. The DPP enrolled 3,234 overweight adults with impaired glucose tolerance from across 27 diverse U.S. sites (Diabetes Prevention Program Research Group, 1999). Participants were randomized to an intensive lifestyle intervention with a weight loss goal of 7% and a physical activity (PA) goal of 150 minutes per week of moderate intensity PA or to receive Metformin or placebo. The lifestyle arm had a 58% lower incidence of diabetes and 41% lower incidence of the metabolic syndrome (NCEP-ATP III criteria) after 3 years compared to the placebo arm (Knowler et al., 2002, Orchard et al., 2005).

The DPP lifestyle intervention participants reported 15.5 MET-hours leisure PA at baseline and significantly increased PA by 6 MET-hours per week at the end of the trial, an equivalent in duration and intensity to 1.5 hours of brisk walking (MET-equivalent 4.0), both assessed by the past-year Modifiable Activity Questionnaire (Knowler et al., 2002, Hamman et al., 2006). In terms of meeting the PA goal, 74% and 67% of participants met the PA goal at the end of the 16-session core and at the final intervention visit, respectively (Wing et al., 2004). PA was shown to be a strong predictor of both weight loss and maintenance of weight loss among DPP lifestyle participants. In post-hoc analysis, incident diabetes was 44% lower among participants in the lifestyle intervention that met the PA goal compared to those not meeting either weight loss or PA goals (Hamman et al., 2006). It is clear that PA played a significant role in the success of the DPP at achieving long-term weight loss and directly or indirectly reducing diabetes incidence.

Since the success of the DPP, the lifestyle intervention curriculum has been modified and implemented in diverse community settings. As the DPP lifestyle intervention is translated to community settings, several implementation aspects may differ including delivery method and program structure. The delivery models and program structures have been previously reviewed and summarized (Jackson, 2009, Johnson et al., 2013, Ackermann, 2013, Whittemore, 2011). The effectiveness of translation efforts for achieving substantial weight loss, reported between 3-7%, and modification of diabetes and cardiovascular disease (CVD) risk factors have been evaluated (Ali et al., 2012, Cardona-Morrell et al., 2010, Whittemore, 2011). What is much less clear is the success of these community translation programs in achieving the PA goals and the impact of any PA change on various metabolic risk factors.

In translation, as with clinical research, PA information can be collected objectively (such as with activity monitors) or subjectively (logs, diaries, and questionnaires) with each assessment method varying in the components of PA that they can measure accurately (Bassett et al., 2000, Bassett, 2009, van Poppel et al., 2010). Since different PA assessment methods capture different aspects of PA, the results of translation efforts may not be directly comparable (Pettee et al., 2009, Kriska and Caspersen, 1997). Further, different characteristics of physical activity (intensity, duration, frequency) may impact different aspects of health, so understanding PA in the context of these characteristics is important for evaluation. These differences can be addressed when reporting PA methodology and results by providing an appropriate explanation of the measurement tool used, including administration of the instrument, so that the results can be interpreted in the context of the measurement instrument.

Given that PA is one of two primary goals of the DPP lifestyle intervention and subsequent translation efforts, and that PA has been linked to both weight loss and improvements in metabolic health in the DPP, it is important to understand the role that PA plays in the success of translation efforts. Since the translation of DPP-based lifestyle interventions to community settings and weight loss achieved in these programs have been evaluated, the focus of this review will be on the PA components of these programs. The purpose of this review is to thoroughly evaluate the reporting of PA methodology and results in DPP-based community translation studies in order to guide future prevention efforts and program evaluations.

Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 27-item checklist was used to guide evidence acquisition and synthesis (Moher et al., 2009).

Data Sources

An article search was performed in PubMed and Ovid (MEDLINE and PsycINFO) databases on March 2, 2015 to identify publications detailing lifestyle interventions for the prevention of type 2 diabetes. The search was limited to abstracts and full-text articles published in English language, with human subjects, and a date range of January 2002-March 2015. The date range was selected to include articles published after the original publication of the Diabetes Prevention Program results.(Knowler et al., 2002) Keywords used include *diabetes*, *pre-diabetes, metabolic syndrome, translation, lifestyle, intervention, prevention, adults,* and *diabetes prevention program,* searched in article text and titles. Reference lists of published reviews and meta-analyses of DPP translation literature were searched for additional publications not identified in the online database search.

Article Eligibility Criteria

After the keyword search, each title and abstract was screened by the primary author for potential inclusion in the review. Inclusion criteria comprised peer-reviewed articles of original research in adult populations at high-risk for type 2 diabetes and/or cardiovascular disease (CVD) (i.e. having pre-diabetes, the metabolic syndrome, or risk factors for type 2 diabetes such as age and overweight/obesity) (American Diabetes Association, 2014) and that used an intervention design with a minimum of six sessions based on the DPP lifestyle intervention theory or curriculum.

Abstracts that indicated the content was a systematic review, method and/or implementation article (and thus would not include intervention outcomes), or author commentary were excluded. Interventions listed in published study protocols and methods articles were searched to determine if results from these studies had been published as a separate manuscript. Lifestyle interventions that enrolled primarily diabetic participants or those with CVD were excluded. In addition, studies that investigated the utility of lifestyle intervention for alternative outcomes, such as gestational diabetes or chronic kidney disease, were excluded.

Data Extraction

The primary author extracted data from each publication to include the design of the study, participant demographics (age, sex, race/ethnicity), the location of the program (city/state or country), the setting in which the intervention was delivered, the intervention delivery format, length of intervention and follow-up, PA goal, inclusion of PA sessions as part of intervention, PA measurement, and PA results. The secondary author (BRW) reviewed this information for correctness and completeness. Discrepancies were discussed with and resolved by the remaining authors. The extracted information was used to summarize the design and implementation of translation efforts, with a focus on descriptions of PA assessment and PA-related outcomes.

Results

The literature search strategy is detailed in Figure 1. The PubMed and Ovid keyword and title search yielded 1,824 publications and after careful review of article title for relevance, 441 abstracts were identified for possible inclusion. Duplicates were removed and publications identified from review article reference lists were added. After screening abstracts, 162 publications met eligibility criteria for full-text review. After reading full-text articles, 90 additional articles were excluded (Figure 1) because they did not meet eligibility criteria. The most common reason for exclusion was that the intervention was not based on the DPP curriculum.

A total of 72 articles, representing 57 unique study populations, met the inclusion criteria for the evaluation of DPP-based intervention programs for reporting of PA goals, measurement, and outcomes (Table 1). The focus of this paper will be on the 57 unique study populations, with publications of the same study population being combined for the evaluation of inclusion of PA data collection and PA results reporting. A brief summary of participant demographics, program setting and delivery, and study design will be provided before detailing PA goals, PA assessment methods, and PA results.

Study Design and Participant Characteristics

The majority (59.6%) of DPP-based translation efforts included in this review utilized a prospective, non-randomized design with pre-post analysis methods to evaluate the effect of intervention on study outcomes. Other study designs included randomized controlled, cluster-randomized, and quasi-experimental trials. The different study designs utilized in these translation programs resulted in varied analysis methods including intention-to-treat, last observation carried forward, and including those who completed a certain number of intervention sessions and/or assessment visits.

A variety of study designs including pilot and state-wide prevention programs resulted in a range of participant enrollment from 10 to 2,553. The small sample sizes, primarily in pilot studies, may affect the ability to detect changes in PA as a result of intervention. The range of mean age participant age was 32.2 to 62 years. The studies enrolled between 47-93% females, with the exception of two studies recruiting specifically women with a history of gestational diabetes (Ferrara et al., 2011, Nicklas et al., 2014) and two studies enrolling predominantly men (95% and 97%) (DeJoy et al., 2013, Wilson et al., 2015). Racial and ethnic diversity of participants varied from studies of only minority populations (African American, Hispanic/Latino, Asian/Pacific Islander) to studies of 19-100% White, non-Hispanic participants.

Program Setting and Delivery

Fifty-six of the DPP-translation efforts reviewed were delivered within the United States in multiple community settings. These included churches, community centers or community service providers, Diabetes Education Programs, health-care facilities, primary care practices, universities, worksites, and YMCAs. One DPP-translation effort was delivered internationally in the primary care setting (Endevelt et al., 2015).

Translation of the DPP into community-based lifestyle programs has taken on a multitude of delivery methods including group-based, individual counseling, remote technologies (phone, DVD, internet), or multiple components. Programs were offered with varying session frequency, to include more frequent contact during the initial phase of the program and transitioning to less frequent contact (Barham et al., 2011, Guyse et al., 2011, Kramer et al., 2009, Ma et al., 2013, Matvienko and Hoehns, 2009, McTigue et al., 2009b, Weinstock et al., 2013) or a consistent weekly or monthly approach for the time frame of the intervention being reported (Dodani and Fields, 2010, Estabrooks and Smith-Ray, 2008, Islam et al., 2013, Jaber et al., 2011, Kramer et al., 2010, Kramer et al., 2011, Kramer et al., 2013, Piatt et al., 2012, Piatt et al., 2013, Seidel et al., 2008, West et al., 2011, Whittemore et al., 2009, Yeary et al., 2011).

Lifestyle Intervention: Physical Activity Goals and Content

All 57 studies identified PA as a key component of lifestyle interventions and provided a goal for PA. The DPP goal of 150 minutes of moderate PA was utilized by 54 studies and three studies established alternative goals including one with 180 minutes of moderate PA per week (Katula et al., 2011), one with 200 minutes of moderate PA per week (Cox et al., 2012), and one with 4,000 steps per day above baseline PA level (Ockene et al., 2012).

Session content related to physical activity varied, but included the key principles of the DPP such as ways to safely increase PA, addressing barriers to PA, and changing environmental and social cues relating to PA. Thirteen studies included PA sessions or supervised exercise as an option for participants (Amundson et al., 2009, Guyse et al., 2011, Harwell et al., 2011, Islam et al., 2013, Jaber et al., 2011, Ma et al., 2013, Matvienko and Hoehns, 2009, McBride et al., 2008, Vadheim et al., 2010a, Vadheim et al., 2010b, Endevelt et al., 2015, Kutob et al., 2014, Swanson et al., 2012), three studies offered free fitness center membership (Aldana et al., 2005, Seidel et al., 2008, Nicklas et al., 2014), and two studies offered participants access to onsite resources for PA (Ackermann et al., 2008, Barham et al., 2011).

Reporting of Physical Activity Assessment Methods

Forty-seven of the 57 studies (82%) described the method used for collecting PA information during lifestyle intervention or at assessment visits (Table 2), with four studies using multiple assessment tools. Of the studies collecting PA information, 46 used subjective measures and one study used an objective laboratory assessment (Aldana et al., 2005). Questionnaires were the most frequently used PA measurement tool (59%), followed by daily activity logs or diaries (41%). The various questionnaires used are indicated in Table 1. In addition to questionnaire, one study used an accelerometer to measure PA level (Estabrooks and Smith-Ray, 2008) and one study evaluated physical function via the 6-minute walk test (Mau et al., 2010). Ten studies did not mention a PA measurement in the methods.

Reporting of Physical Activity Results

Thirty-four of the 57 translation studies (60%) reported PA results or PA-related outcomes following intervention, with 12 studies reporting two PA-related outcomes. Nineteen studies reported statistically significant results for improvements in PA measures (Table 3) derived from a variety of methodologies (i.e. intention-to-treat, last observation carried forward, and including those who complete a certain number of intervention sessions and/or assessment visits). Nineteen studies report on the proportion of participants who met the PA goal and/or the mean minutes of PA per week during intervention. Other methods of reporting included aerobic fitness, days per week of moderate and/or vigorous PA, MET-hours per week, self-efficacy, kilocalories energy expenditure per week, PA level, proportion of participants reporting regular activity (>=3 days per week), and/or proportion reporting any PA. In addition to primary PA outcomes, five studies report on the significant positive relationship between achieving PA goals and/or high PA level and achievement of weight loss goals (Amundson et al., 2009, Harwell et al., 2011, Pinelli et al., 2011, Vanderwood et al., 2011, Whittemore et al., 2009). Four studies included the proportion of participants submitting PA diaries/logs during intervention, but did not report any information on PA level or frequency (Cox et al., 2012, McTigue et al., 2009b, West et al., 2011, Trief et al., 2014). Two studies reported baseline PA levels, but did not provide any follow-up information (Dodani and Fields, 2010) (Yank et al., 2014).

Achievement of Physical Activity Goals

The DPP goal of 150 minutes of moderate PA per week or an equivalent was implemented in all 57 DPP translation studies. Only 15 (26%) studies reported results for the proportion of participants meeting the PA goal, with a follow-up period ranging from 12 weeks to 12 months. The proportion of participants meeting goal prior to intervention ranged from 19.6-53.6% (Islam et al., 2013, Jaber et al., 2011, Matvienko and Hoehns, 2009, Whittemore et al., 2009, Jiang et al., 2013). After the initial phase of intervention, or at the first follow-up assessment, the range was 41.2-75% (Amundson et al., 2009, Guyse et al., 2011, Islam et al., 2013, Jaber et al., 2011, Kramer et al., 2011, Kramer et al., 2013, Vadheim et al., 2010a, Vanderwood et al., 2010, Whittemore et al., 2009, Jiang et al., 2013). After intervention completion, or at the final assessment, the range was 61.5-78% (Jaber et al., 2011, Matvienko and Hoehns, 2009, Vadheim et al., 2010a, Vanderwood et al., 2010). Eight studies included mean minutes of PA per week at the end of core, ranging from 181-251 minutes (Amundson et al., 2009, Guyse et al., 2011, Matvienko and Hoehns, 2009, Ockene et al., 2012, Vadheim et al., 2010a, Vadheim et al., 2010b, Jiang et al., 2013). Two studies reported a mean of 250 and 258 minutes per week of PA at the end of post-core (Matvienko and Hoehns, 2009, Vadheim et al., 2010a).

Discussion

The DPP-based translation efforts included in this review demonstrated the feasibility of collecting physical activity data across a broad spectrum of settings and populations. Despite the fact that PA is an important intervention goal in DPP-translation efforts, PA methodology and PA results are under- and inconsistently reported. Although all of the DPP-based translation studies included a PA goal as part of the intervention and 82% collected PA information using a variety of assessment tools, only 60% of translation studies reported any PA results. In addition, only 26% provided the proportion of those meeting the PA goal during intervention. Thus, there is incomplete PA information from DPP translation studies to be used for evaluating the effectiveness of lifestyle interventions for increasing PA to meet recommended guidelines. The relative difficulty of properly assessing PA compared to weight and other clinical outcomes may be contributing to less frequent assessment and reporting of PA outcomes.

Assessment of PA was described in 82% of the studies, primarily by subjective methods. Subjective measurements continue to be the most feasible PA collection method in community-based lifestyle programs due to low cost and ease of data collection. Although questionnaires may be more practical in community-based practice, activity monitors (i.e. accelerometers) can provide additional information on time spent in different PA intensities and highlight patterns of PA, so they should be considered where resources allow. The use of daily PA logs to measure PA by a majority of the translation efforts raises concerns about selection bias, as those who comply with recording PA behaviors are more likely to meet program goals (Wing et al., 2004) which may inflate the estimate of success of the PA portion of the program. As new technology emerges, more convenient and user-friendly objective options to assess daily PA may increase compliance to self-monitoring and minimize these concerns.

For the 15 studies that report meeting the PA goal at the end of intervention as an outcome, the proportion of participants meeting the goal approached the DPP trial results of 74% (Knowler et al., 2002). This demonstrates the potential of community-based programs to achieve the success observed in the DPP, but due to the methodological inconsistencies, this data must be interpreted carefully. Not all studies that reported the proportion of participants meeting the PA goal as the outcome included pre-intervention values in the results, making it difficult to examine whether PA improved and how any change impacted on metabolic outcomes. Although ranges for the proportion of participants achieving PA goals can be determined, success at achieving goals must be interpreted cautiously at established time points (i.e. 6 months) because participants may have been at different stages of a lifestyle change program and outcomes were analyzed in a variety of methods. Since several programs offered opportunities for PA (guided exercise sessions, free gym membership, etc.) as part of intervention, reaching PA goals must be carefully evaluated with consideration of exercise program durability, as pointed out by Koller et al.(2013).

Variability in study design, program implementation, intervention length and participant follow-up time, PA assessment, data analysis methodology, and outcomes reported makes comparison of PA results between studies included in this review challenging. Studies with non-randomized designs, smaller sample size, and/or shorter follow-up time may be limited in their ability to detect significant changes in PA level or to draw definitive conclusions regarding program effectiveness for increasing PA levels. Further, it is uncertain how data collection and analysis methodology in each study affected reliability of estimates of change, given the incomplete reporting discussed in this review. Regardless of design and numbers enrolled, part of the evaluation of community programs should be participant adherence to the program and success for achieving desired PA and weight goals in order to inform future programming.

As the definition of “translational research” is not clearly defined (Rubio et al., 2010), it is difficult to establish criteria in which to critically evaluate individual translation studies. This is in part due to the heterogeneity of translation studies (and relatively recent shift from efficacy to effectiveness). It is important to understand that the focus of many translation efforts is feasibility of program delivery and process evaluation in addition to the effectiveness of the program for achieving desired behavioral and clinical outcomes. One process goal of translation efforts is to provide evidence-based interventions to as many at-risk individuals as possible given the available resources, which may limit the capacity to enroll large numbers of individuals. In addition, while the randomized controlled trial design is appropriate for clinical research trials evaluating the efficacy of an intervention and may offer a higher level of confidence in study results, this study design may be less applicable in real-world effectiveness/translational research efforts (National Institutes of Health, 2004). Thus, traditional factors used to rate quality in efficacy studies may not be appropriate, as efficacy trials are generally designed to evaluate clinical outcomes and not the process variables that are an important component of translational research. Although this review provides information on study design, sample size, and length of follow-up for each translation study, these features should be carefully considered when evaluating the scientific contribution of individual studies in the context of this review.

This review shows that community DPP-based lifestyle interventions have been successful at increasing PA levels when reported. However, little is known about the long-term effect of these interventions for maintaining increased PA levels. Without consistency in reporting PA assessment and outcomes, it is difficult to make appropriate estimates of the effect of PA in lifestyle interventions and to investigate the complex relationship between PA and weight loss, weight maintenance, and change in metabolic profile. Recently, the CDC National Diabetes Prevention Recognition Program (DPRP) established standard guidelines for program implementation and evaluation (Centers for Disease Control and Prevention, 2014). It is anticipated that use of the CDC DPRP guidelines may help facilitate a more systematic approach to PA evaluation in DPP translation efforts.

Review Strengths and Limitations

This review is the first attempt to examine the inclusion of PA methodology and subsequent reporting of PA findings among community-based translations of the DPP. The broad search terms used to identify articles for this review ensured that relevant DPP translations were included. However, the initial review of titles and abstracts for inclusion in the review was conducted by one researcher and this potentially contributed to incomplete retrieval of relevant research. In addition, behavioral weight-loss and lifestyle modification programs that were not based on the DPP-curriculum, and therefore did not use the same weight loss and PA goals, were excluded in order to increase comparability across eligible studies. Conclusions drawn from this review may not be applicable to all lifestyle intervention studies.

Conclusion

The significant role of PA in the success of the DPP emphasizes the need for measuring and reporting PA outcomes in community lifestyle programs translated from the DPP. This review identified two main concerns with PA measurement and reporting in translation efforts: 1) The absence of PA assessment standards or guidelines for use in community-based translation programs and 2) the under- and inconsistent reporting of PA results in lifestyle change programs. Decades of research have demonstrated the positive health benefits of PA (Warburton et al., 2006); however, uncertainty exists as to the volume and frequency of PA that is required to elicit substantial health benefits among high-risk populations. Thus, the true effect of PA on the prevention and/or delay of diabetes development independent of dietary change is unclear. Improvement in PA assessment techniques and complete reporting of information on PA assessment methods, including administration of and compliance to assessment tools, and in reporting outcomes related to achieving the PA goal including PA level at baseline, end of intervention, and end of follow-up will increase the ability to examine the relationships between different levels of PA and clinical outcomes. Without consistent reporting of PA results in these community based translation programs as identified in this review, researchers will be unable to come to a consensus on the importance of increasing PA for weight loss and the improvement of diabetes and CVD risk factors among populations at high risk.

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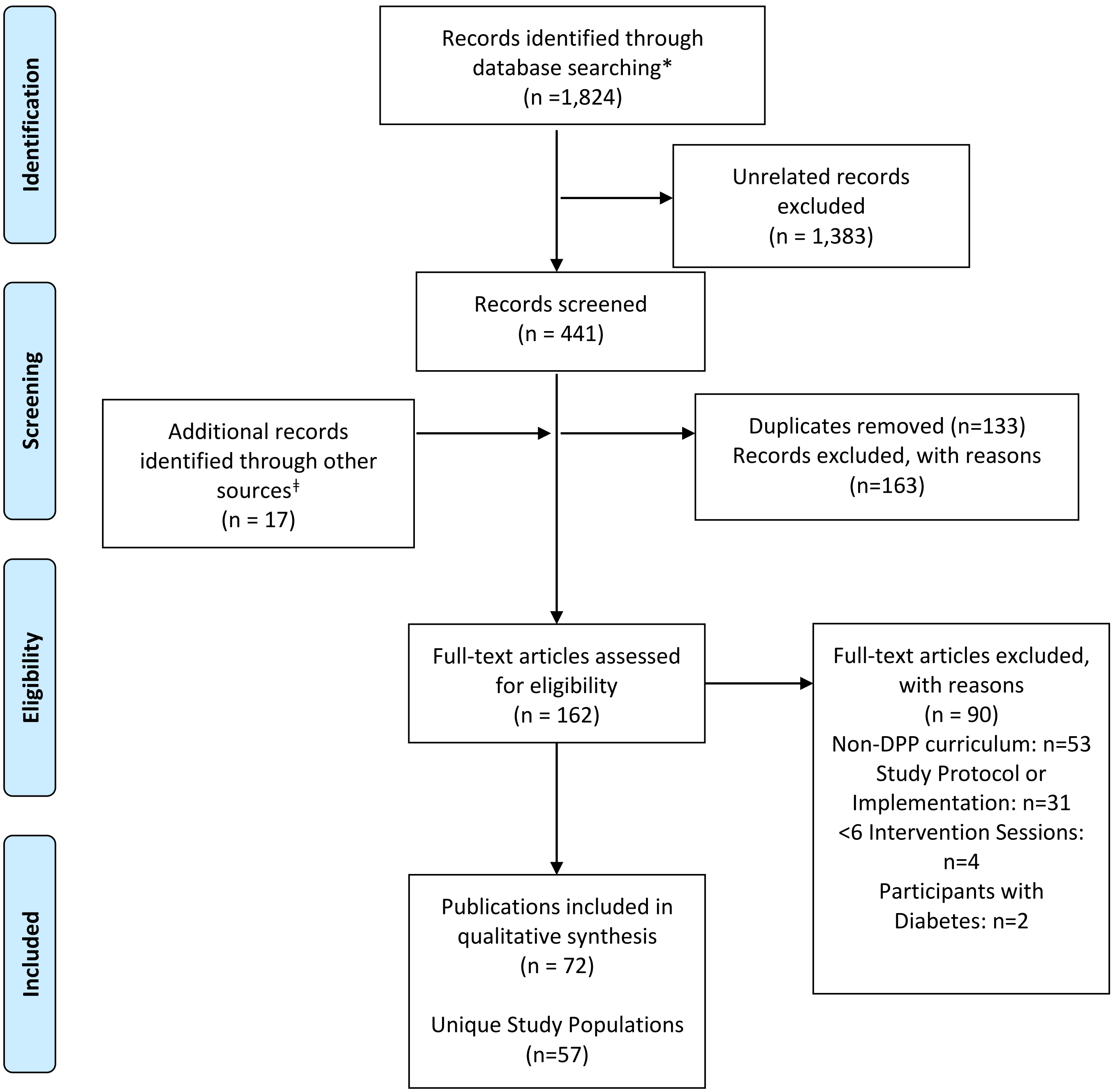

*Databases used include: PubMed and Ovid (MEDLINE/PsycINFO)
ǂAdditional sources included: reference lists of review articles and search from published protocols

Figure C1. PRISMA Four-Phase Flow Diagram: Literature Search Strategy

Table C1. Summary of DPP-Translation Efforts Among Adults at High-Risk for Diabetes and Cardiovascular Disease

First Author (Surname)	Year	Setting	Delivery	Study Design & Enrollment	PA Goal	PA Measurement	Follow-up time	PA Results
Ackermann Lipscomb Ackermann	2008 2009 2011	YMCA	Group	Cluster-RCT N=92 Prospective, Pre-Post N=66	150 minutes per week	None	4-6 months and 12-14 months from enrollment 28 months	None
Ackermann	2014	In-home	Television/ Video-on-Demand Service	RCT N=314	150 minutes per week	None	5 and 12 months	None
Aldana	2005 2006	Worksite	Group	Prospective, Pre-Post N=37	150 minutes per week	Aerobic fitness; submaximal treadmill test Bruce Protocol	12 and 24 months	Aerobic fitness[a]
Amundson Vanderwood	2009 2011	Health-care facilities	Group	Prospective, Pre-Post N=355 N=188	150 minutes per week	Self-monitoring records	4 and 10 months 12-24 months post-intervention	% Meeting goal and Minutes per week[a]

CHAMPS, Community Healthy Activities Model Program for Seniors; DPP, Diabetes Prevention Program; DVD, digital versatile disc; IPAQ, International Physical Activity Questionnaire; MAQ, Modifiable Activity Questionnaire; PA, physical activity; PAQ, Physical Activity Questionnaire; PAR, Physical Activity Recall; RAPA, Rapid Assessment of Physical Activity; RCT, randomized controlled trial; WIC, Women, Infants, and Children; YMCA, Young Men's Christian Association

[a] PA results statistically significant in positive direction ($p<0.05$)

Table C1. Cont.

First Author (Surname)	Year	Setting	Delivery	Study Design & Enrollment	PA Goal	PA Measurement	Follow-up time	PA Results
Azar Ma Xiao Yank	2013 2014	Primary Care	Group and Internet/ DVD	RCT N=241	150 minutes per week	Self-monitoring records (online); Questionnaire (Stanford 7-Day Recall)	15 months 3, 6, and 15 months 24 months	No PA outcomes; Baseline PA Level
Barham	2011	Worksite	Group	RCT N=45	150 minutes per week	Questionnaire (IPAQ)	3,6,12 months (baseline, 3, and 9 months for control group)	PA Level[a]
Bersoux Swanson	2010 2012	Primary Care	Group and Individual	Prospective, Pre-Post N=92	150 minutes per week	Questionnaire (general survey)	12 months	No PA outcomes; Participant opinion
Boltri	2008	Churches	Group	Prospective, Pre-Post N=34	150 minutes per week	None	16 weeks, 6 months, 12 months	None
Boltri	2011	Churches	Group	Prospective, Pre-Post N=37	150 minutes per week	None	6 and 12 months	None

[a]PA results statistically significant in positive direction (p<0.05)

Table C1. Cont.

First Author (Surname)	Year	Setting	Delivery	Study Design & Enrollment	PA Goal	PA Measurement	Follow-up time	PA Results
Bozack	2014	YMCA	Group	Prospective, Pre-Post N=254	150 minutes per week	Self-reported PA recorded by lifestyle coach	10 months	None
Cene	2013	Churches, Community	Group	Prospective, Pre-Post N=104	150 minutes per week	Questionnaire (researcher developed)	7.5 months	Days per week
Cox	2012	Community	Group	RCT N=44	200 minutes per week	Self-monitoring records	12 weeks	No PA results; Self-monitoring frequency of PA
Dallam	2012	Worksite	Multi-component/ arm	Quasi-experimental N=264	150 minutes per week	Questionnaire (Baecke Questionnaire of Habitual PA)	26 weeks	PA Level[a]
Davis-Smith	2007	Churches	Group	Prospective, Pre-Post N=10	150 minutes per week	Self-monitoring records	6 weeks, 6 and 12 months	None

Table C1. Cont.

First Author (Surname)	Year	Setting	Delivery	Study Design & Enrollment	PA Goal	PA Measurement	Follow-up time	PA Results
DeJoy	2013	Worksite	Multi-component/ arm	Prospective, Pre-Post N=67	150 minutes per week	Questionnaire (stage of behavioral change single-item measures; self-efficacy 12-item scales)	6 and 12 months	% Regular PA[a]; Stage of Change; Self-efficacy
Dodani	2010	Churches	Group	Prospective, Pre-Post N=40	150 minutes per week	Questionnaire (MAQ)	12 weeks	None; Baseline % inactive
Endevelt	2015	Primary Care	Individual or Group	Cluster RCT N=223	150 minutes per week	None	6 and 18 months	None
Estabrooks	2008	Health-care facilities	Interactive voice response calls	RCT N=77	150 minutes per week	Accelerometer and Questionnaire (RAPA)	3 months	% Meeting Goal and Minutes per Week
Ferrara	2011	Health-care facilities	In-person/ Telephone	Pilot RCT N=197	150 minutes per week	Questionnaire (5 City Project)	12 months	Minutes per Week

[a] PA results statistically significant in positive direction ($p<0.05$)

Table C1. Cont.

First Author (Surname)	Year	Setting	Delivery	Study Design & Enrollment	PA Goal	PA Measurement	Follow-up time	PA Results
Faridi	2010	Churches	Group/ Individual	Prospective, Pre-Post N=246	150 minutes per week	Questionnaire (7-Day PAR)	12 months	Energy Expenditure
Guyse	2011	YMCA	Group	Prospective, Pre-Post N=265	150 minutes per week	Self-monitoring records	16 weeks and 10 months	% Meeting Goal and Minutes per Week
Harwell	2011	Health-care facilities	Group	Prospective, Pre-Post N=989	150 minutes per week	Self-monitoring records	4 (end of core) and 10 (end of post-core) months	% Meeting goal
Islam	2013	Community	Group	RCT N=48	150 minutes per week	Questionnaire (Bandura Self-Efficacy Scale)	6 months	% Meeting Goal; Proportion Inactive
Islam	2014	Community	Group and Telephone	Quasi-Experimental N=126	150 minutes per week	Questionnaire (Bandura Self-Efficacy Scale)	3 and 6 months	% Reporting Any PA[a]; Self-efficacy[a]

Table C1. Cont.

First Author (Surname)	Year	Setting	Delivery	Study Design & Enrollment	PA Goal	PA Measurement	Follow-up time	PA Results
Jaber Pinelli	2011 2011	Community	Group	Prospective, Pre-Post N=71	150 minutes per week	Self-monitoring records	12 and 24 weeks	% Meeting goal[a]; Weight loss correlated with PA minutes[a]
Jiang	2013	Health-care Facilities	Group	Prospective, Pre-Post N=2,553	150 minutes per week	Questionnaire (researcher developed)	24 weeks, 12, 24, and 36 months	% Meeting Goal and Minutes per week[a]
Katula Lawlor	2011 2013	Diabetes Education Program	Group	RCT N=301	$\geq$180 minutes per week	Questionnaire (IPAQ)	12 & 24 months	Hours PA per capita[a]
Kramer	2009	Primary Care	Group	Prospective, Pre-Post N=93	150 minutes per week	None	Baseline, post-intervention; 6 and 12 months	None
Kramer	2010	Primary Care	Technology	Prospective, Pre-Post N=48	150 minutes per week	Self-monitoring records	3 months	% >= 3 days/week[a]

[a] PA results statistically significant in positive direction ($p<0.05$)

Table C1. Cont.

First Author (Surname)	Year	Setting	Delivery	Study Design & Enrollment	PA Goal	PA Measurement	Follow-up time	PA Results
Kramer Kramer	2011 2014	Health-care facilities	Group	Prospective, Pre-Post N=81	150 minutes per week	Self-monitoring records	3-4 months, and 12 months	% Meeting goal and % >= 3 days/week[a]
Kramer	2012	University/YMCA	Group	RCT N=60	150 minutes per week	None	4,8, and 12 months	None
Kramer	2013	Community (WIC)	Group	Prospective, Pre-Post N=27	150 minutes per week	Questionnaire (unspecified); questions about PA monitoring and barriers	12 -15 weeks (end of core)	% Meeting Goal
Kumanyika	2011	Primary Care	Individual	RCT N=261	150 minutes per week	Questionnaire (Paffenbarger)	12 months	None
Kutob	2014	Primary Care	Group	Prospective, Pre-Post N=58	150 minutes per week	Questionnaire (Arizona Activity Frequency)	6, 12, and 18 months	% Meeting goal and Minutes per week

[a] PA results statistically significant in positive direction ($p<0.05$)

Table C1. Cont.

First Author (Surname)	Year	Setting	Delivery	Study Design & Enrollment	PA Goal	PA Measurement	Follow-up time	PA Results
Matvienko	2009	University	Individual	Prospective, Pre-Post N=31	150 minutes per week	Self-monitoring records	6 and 12 months	% Meeting goal and Minutes per week
Mau Kaholokula	2010 2014	Community	Group	Prospective, Pre-Post N=239	150 minutes per week	Questionnaire (PAQ 3-item); 6 Minute Walk	12 weeks 6 Months	Physical function[a]; Frequency of PA[a]
McBride	2008	Health-care facilities	Individual	Prospective, Pre-post N=37	150 minutes per week	Questionnaire (IPAQ)	12 weeks and 12 months	MET scores[a]
McTigue	2009	Health-care facilities	Group	Prospective, Pre-Post N=155	150 minutes	None	10-14 months	None
McTigue	2009	Health-care facilities	Internet	Prospective, Pre-Post N=50	150 minutes per week	Self-monitoring records (online); pedometer daily records	12 months	No PA results; Self-monitoring frequency of PA

[a] PA results statistically significant in positive direction ($p<0.05$)

Table C1. Cont.

First Author (Surname)	Year	Setting	Delivery	Study Design & Enrollment	PA Goal	PA Measurement	Follow-up time	PA Results
Nicklas	2014	In-home	Internet	RCT N=75	150 minutes per week	Questionnaire (IPAQ)	12 months	No outcome data; % using pedometers
Ockene	2012	Community	Group	RCT N=312	Increase walking 4,000 steps per day above baseline	Questionnaire (24-hour dietary recall); Intervention tools Pedometer, self-monitoring	12 months	Minutes per week
Pagoto	2008	Primary Care	Group	Prospective, Pre-Post N=118	150 minutes per week	Self-report with physician; patient satisfaction survey (Likert scale)	16 weeks	Self-efficacy
Piatt	2012	Community	Group	Prospective, Pre-Post N=105	150 minutes per week	None	24 months	None
Piatt	2013	Community	Multi-component/ arm	Quasi-experimental N=434	150 minutes per week	Self-monitoring records; Physical Functioning via Medical Outcomes Study Short Form 12	3 and 6 months	None

Table C1. Cont.

First Author (Surname)	Year	Setting	Delivery	Study Design & Enrollment	PA Goal	PA Measurement	Follow-up time	PA Results
Ruggiero	2011	Community	Group	Prospective, Pre-Post N=69	Walk 150 minutes per week	Questionnaire (7-Day short version of IPAQ)	6 and 12 months	Minutes per week[a]
Seidel	2008	Community	Group	Prospective, Pre-Post N=88	150 minutes per week	None	3 and 6 months	None
Tang	2014	Churches	Group	Prospective, Pre-Post N=13	150 minutes per week	Questionnaire (CHAMPS)	8 and 20 weeks	Kilocalories per week[a]
Vadheim	2010	Health-care facilities	Group	Prospective, Pre-Post N=101	150 minutes per week	Self-monitoring records	16 weeks and post-core (~10 months)	% Meeting goal and Minutes per week
Vadheim	2010	Health-care facilities	Multi-component/ arm	Quasi-experimental N=29	150 minutes per week	Self-monitoring records	16 weeks	Minutes per week

[a] PA results statistically significant in positive direction ($p<0.05$).

Table C1. Cont.

First Author (Surname)	Year	Setting	Delivery	Study Design & Enrollment	PA Goal	PA Measurement	Follow-up time	PA Results
Vanderwood	2010	Health-care facilities	Group	Prospective, Pre-Post N=1,003	150 minutes per week	Self-monitoring records	16 weeks and post-core (~10 months)	% Meeting goal
Vincent	2014	Churches	Group	Cluster RCT N=58	150 minutes per week	Questionnaire (Self-efficacy scale)	2 and 5 months	Self-efficacy[a]
Weinstock Trief	2013 2014	Primary Care	Technology	RCT N=257	DPP goals	Self-monitoring records	6, 12, and 24 months	No PA results; % self-monitoring diet and PA
West	2011	Community	Group	Cluster-RCT N=228	150 minutes per week	Intervention tools pedometers and self-monitoring diaries	4 months	No PA results; Self-monitoring frequency of PA

Table C1. Cont.

First Author (Surname)	Year	Setting	Delivery	Study Design & Enrollment	PA Goal	PA Measurement	Follow-up time	PA Results
Whittemore	2009	Primary Care	Individual	Cluster-RCT N=58	Exercise 30 min 5 days per week (150 min)	Questionnaire (Health Promoting Lifestyle Profile II)	3 and 6 months	% Meeting goal[a]
Williams	2013	Churches	Group	Cluster-RCT N=604	150 minutes per week	Questionnaire (IPAQ-Long Form)	12-14 weeks (3 months) and 12 months	None
Wilson	2015	Work site	Individual and Print Materials	Cluster RCT N=362	150 minutes per week	Questionnaire (IPAQ-short form)	6 and 12 months	Minutes and MET-minutes per week[a]
Yeary	2011	Churches	Group	Prospective, Pre-Post N=26	150 minutes per week	Questionnaire	16 week	MET-h per week[a]

[a] PA results statistically significant in positive direction ($p<0.05$)

Table C2. Summary of Physical Activity Assessment in Diabetes Prevention Translation Studies

PA Assessment Method	Number (%) of total studies using assessment method[b]	Number (%) of studies reporting results for given assessment method[b]
Questionnaire	29 (50.8)	23 (79.3)
Diaries/logs	19 (33.3)	10 (52.6)
Objective Testing	1 (1.8)	1 (100)
Monitor (Accelerometer/Pedometer)	2 (3.5)	1 (50)
TOTAL (All Assessment Methods)	47 (82.5)	34 (72.3)
None	10 (17.5)	0 (0)

[b]Percent does not add to 100; Multiple studies reported two PA assessment methods and are included in two categories

Table C3. Summary of Physical Activity Outcomes in Diabetes Prevention Translation Studies

PA Outcome	Number (%) of studies reporting outcome[c]	Number (%) of studies reporting significant improvement for measured outcome[c]
Proportion Meeting PA Goal	15 (26.3)	5 (38.5)
Minutes per week	11 (40.7)	3 (37.5)
Self-efficacy	4 (7.0)	3 (75.0)
Regular Activity (>=3 d/wk)	3 (5.3)	3 (100)
MET-hours per week	3 (5.3)	2 (66.7)
Aerobic Fitness/Function	2 (3.5)	2 (100)
Kilocalories expenditure per week	2 (3.5)	1 (50)
PA level	2 (3.5)	2 (100)
Days per week/Frequency	2 (3.5)	2 (66.7)
Any PA	1 (1.8)	1 (100)
Hours per capita	1 (1.8)	1 (1)
TOTAL (Any PA outcome)	34 (59.6)	19 (55.9)

[c]Percent does not add to 100; Several studies reported multiple outcomes and are included in multiple categories
D, days; MET, Metabolic Equivalent; PA, physical activity; WK, week

APPENDIX D: POSTER PRESENTATIONS

POSTER PRESENTATION: CAN A LIFESTYLE PROGRAM AIMED AT REDUCING RISK FOR TYPE 2 DIABETES AND CARDIOVASCULAR DISEASE INCREASE PHYSICAL ACTIVITY ACROSS DIVERSE SETTINGS?

Can a Lifestyle Program Aimed at Reducing Risk for Type 2 Diabetes and Cardiovascular Disease Increase Physical Activity Levels in Diverse Settings?

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GROUP LIFESTYLE BALANCE

BACKGROUND

The Diabetes Prevention Program, or DPP, demonstrated the effectiveness of lifestyle intervention comprised of weight loss and increasing physical activity for the reduction of diabetes development and cardiovascular disease (CVD) risk.

Translation efforts developed from the DPP lifestyle intervention have successfully achieved weight reduction and improved diabetes and CVD risk factors in a multitude of settings.

Although these translation efforts also encouraged increasing physical activity as well as weight loss, the success of the PA portion of the program is typically not reported.

STUDY PURPOSE

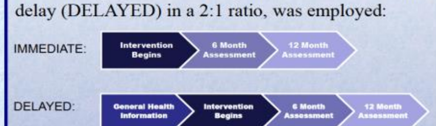
Members of the original DPP Lifestyle Resource Core from the University of Pittsburgh translated the DPP materials into the DPP Group Lifestyle Balance™ (DPP-GLB).

The DPP-GLB has been shown to be effective for weight loss in a variety of settings, however the PA results are not frequently reported.

The purpose of this project is to address the gap in PA reporting in translation efforts by determining the changes in PA levels reported during the DPP-GLB, delivered at a worksite and three community centers of varying socioeconomic status (determined by education level).

STUDY DESIGN & ELIGIBILITY

A randomized delayed control design, in which participants were randomized to begin DPP-GLB immediately (IMMEDIATE) or after a six month delay (DELAYED) in a 2:1 ratio, was employed:



Eligibility criteria included:

- ≥18 years of age
- No previous history of diagnosis of diabetes
- BMI ≥24kg/m² (≥22kg/m² for Asians)
- Pre-diabetes and/or the metabolic syndrome

INTERVENTION

The goals of the DPP-GLB include:

- 5-7% weight loss
- 150 min/week moderate intensity PA

The one-year, 22 session DPP-GLB focuses on:

- healthy eating behaviors
- safely increasing PA to ≥150 minutes/ week
- self-monitoring of behaviors

Program participants had the option of completing the program by attending face-to-face group sessions or via individually-viewed DVD with coach support (*see Kriska, et al., abstract E-18: 2247/2*).

OUTCOMES ASSESSMENT

Data collection at baseline, 6, and 12 months:

1) Weight, waist, blood pressure, lipids, and glucose

2) Physical Activity Measures:

- **Lifestyle questionnaire** including frequency and duration of PA in a typical week, summarized as minutes per week, to determine meeting the PA goal
- **Modifiable Activity Questionnaire (MAQ)** assessed past-month leisure PA (LPA) expressed as MET-hours per week (MET•hr/wk)

BASELINE RESULTS

223 individuals enrolled in the study. At baseline there were no significant differences noted between the IMMEDIATE (N=148) and DELAYED (N=75) groups for any of the risk factors for type 2 diabetes or CVD. **(Table 1)**

Table 1. Baseline Characteristics

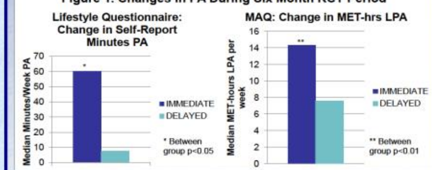
	IMMEDIATE (N=148)	DELAYED (N=75)
Variable	Mean (sd)	Mean (sd)
Age (years)	59.0 (11.4)	57.2 (11.6)
Gender; n (% Female)	92 (62.6)	47 (62.7)
Education:	n (%)	n (%)
H.S./Some College	57 (38.5)	25 (33.3)
B.S. Degree	45 (30.4)	23 (30.7)
Graduate Degree	46 (31.1)	27 (36.0)
Weight (lbs)	209.2 (43.9)	208.1 (37.6)
Waist (inches)	41.8 (5.6)	41.6 (4.6)
BMI (kg/m2)	34.0 (6.5)	33.5 (5.0)
MET•hr/wk LPA (Median, IQR)	8.69 (2.19-19.57)	6.31 (2.38-12.66)

Comparing baseline characteristics between settings, worksite participants were significantly younger and less active than community participants (p <0.01; data not shown).

RANDOMIZED CONTROL RESULTS

At 6 months, IMMEDIATE participants (N=137) demonstrated significantly greater increase in LPA compared to the DELAYED group (N=71) as assessed by both PA measures (**Figure 1**).

Figure 1. Changes in PA During Six Month RCT Period

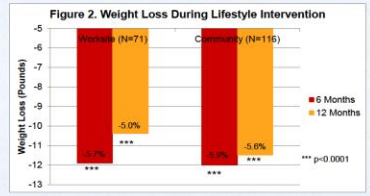


Results were similar between the worksite and community centers.

PRE-POST INTERVENTION RESULTS

In both settings, significant weight loss was observed at 6 and 12 months (**Figure 2**).

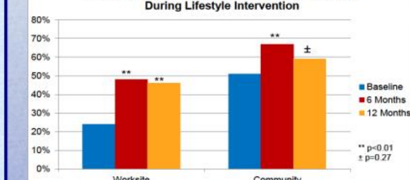
Figure 2. Weight Loss During Lifestyle Intervention



Significant improvements in diabetes and CVD risk factors were observed in both settings at 6 and 12 months (data not shown).

The proportion of participants meeting the PA goal, determined by the lifestyle questionnaire, increased in both settings at 6 and 12 months (**Figure 3**).

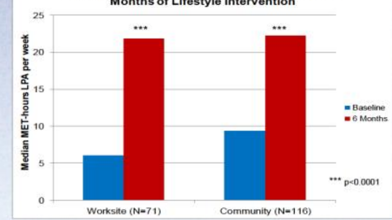
Figure 3. Proportion Self-Reporting Meeting PA Goal During Lifestyle Intervention



PRE-POST INTERVENTION RESULTS

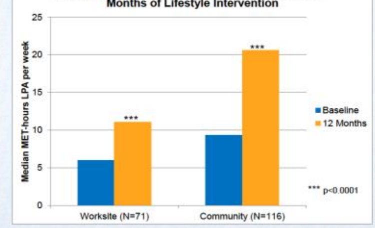
For participants with assessment data at 6 and 12 months, a greater than two-fold increase in MET•hr/wk of LPA was reported in both settings at 6 months (**Figure 4**).

Figure 4. MAQ: MET-hours LPA Per Week After 6 Months of Lifestyle Intervention



Participants maintained a two-fold increase in LPA in both settings at 12 months (**Figure 5**).

Figure 5. MAQ: MET-hours LPA per week After 12 Months of Lifestyle Intervention



CONCLUSION

- A community-based lifestyle intervention (DPP-GLB) program not only demonstrated a significant weight loss, but showed a significant increase in PA levels in high-risk individuals.
- The weight and PA changes are consistent across the worksite and community center settings.
- The relatively smaller improvement in PA at 12 months compared to 6 months emphasizes the importance of researching strategies for sustaining initial improvements in PA level.
- The current effort supports the need for community behavioral lifestyle intervention programs to address PA changes as well as weight loss when reporting results.

The authors would like to thank the DPP-GLB participants, community partners, and staff for their time and continued commitment to this project. Funding provided by the NIH through the NIDDK Project Title: The Healthy Lifestyle Project ClinicalTrials.gov Identifier: NCT01050205 Principal Investigator: Andrea Kriska, PhD

POSTER PRESENTATION: EVALUATION OF A FLEXIBLY-DELIVERED LIFESTYLE PROGRAM DESIGNED TO REDUCE RISK FOR TYPE 2 DIABETES AND CARDIOVASCULAR DISEASE PROVIDED VIA DVD

Evaluation of a Flexibly-delivered Lifestyle Program Designed to Reduce Risk for Type 2 Diabetes and Cardiovascular Disease Provided via DVD

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GROUP LIFESTYLE BALANCE

BACKGROUND

The current prevalence of diabetes, cardiovascular disease (CVD), and obesity is alarming and identifies the immediate need for primary prevention efforts.

The individually-administered lifestyle intervention used in the Diabetes Prevention Program (DPP) resulted in a 58% reduction in type 2 diabetes incidence[1] and an improvement in CVD risk factors.

Community translation efforts emerging from the DPP are exploring a variety of delivery approaches including group-based, online, telephone, and DVD to maximize community reach and increase feasibility.

A key DPP goal was to achieve and maintain 150 minutes of moderate physical activity (PA) per week, which is now echoed in all DPP-based translations. Yet, only half of all DPP translation efforts report change in PA in their results and even less often in those with unique delivery approaches.

1. Knowler, W.C., et al., N Engl J Med, 2002

STUDY PURPOSE

Investigators at the University of Pittsburgh, who were members of the original national DPP Lifestyle Resource Core, translated the DPP into the Group Lifestyle Balance™ (DPP-GLB) Program.

This effort evaluated whether PA significantly increased in the DPP-GLB delivered in diverse community settings for both delivery approaches, i.e., face-to-face groups or the individually-viewed DVD with coach support.

RECRUITMENT AND ELIGBILITY

Individuals were recruited from a local worksite and three community centers of variable SES (determined by education level) to participate in the DPP-GLB Program.

Eligibility criteria included:
- ≥18 years of age
- no previous history of diagnosis of diabetes
- not pregnant or planning to become pregnant
- BMI ≥24kg/m² (≥22kg/m² for Asians)
- Pre-diabetes and/or the metabolic syndrome

OUTCOMES ASSESSMENT

Data collection at baseline, 6, and 12 months:
1) Weight, waist, blood pressure, lipids, and glucose
2) Physical Activity Measures:
- **Lifestyle questionnaire** including frequency and duration of PA in a typical week, summarized as minutes per week, to determine meeting the PA goal
- **Modifiable Activity Questionnaire (MAQ)** assessed past-month leisure PA (LPA) expressed as MET-hours per week (MET•hr/wk)

INTERVENTION

The goals of the one-year, 22 session DPP-GLB include:
- 5-7% weight loss
- 150 min/week of moderate intensity PA

Participants chose their preferred delivery mode of either ***Group*** or ***DVD***:

DPP-GLB **GROUP**:
- Face-to-face groups led by lifestyle coach
- 12-weekly sessions transitioning to monthly meetings

DPP-GLB **DVD**:
- DVD for first 12 weekly sessions portrayed as "real-life" scenarios
- Weekly coach support provided via telephone or e-mail to collect self-reported weight/PA and provide feedback
- Participants were invited to attend monthly group meetings in addition to viewing DVD

BASELINE RESULTS

A total of 185 individuals completed baseline, 6, and 12 month assessments:
- 73 selected *DVD* (N=36 worksite; N= 37 community)
- 112 selected *group* (N=35 worksite; N= 77 community)

DVD participants were younger, were more likely to be male, and more likely to have a higher education level at baseline (**Table 1**).

Table 1. Baseline Characteristics

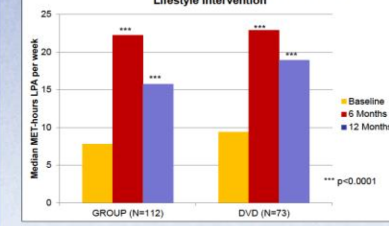
	Group (N=112)	DVD (N=73)	
Variable	Mean (sd)	Mean (sd)	p
Age	61.9 (11.6)	55.0 (9.3)	**<0.0001**
Gender; n (% Female)	79 (70.5)	35 (47.9)	**0.002**
Education: H.S./Some College B.S. Degree Graduate Degree	n (%) 48 (42.9) 32 (28.6) 32 (28.6)	n (%) 16 (21.9) 29 (39.7) 28 (38.4)	**0.01**
Weight (lbs)	205.1 (44.1)	209.2 (39.6)	0.52
Waist (inches)	41.9 (6.2)	41.1 (5.1)	0.37
Fasting Glucose (mg/dL)	95.5 (10.7)	93.2 (11.9)	0.18
Hemoglobin A1c (%)	5.78 (0.34)	5.70 (0.28)	0.08
Systolic BP (mm/Hg)	120.2 (11.9)	118.9 (11.8)	0.49
Diastolic BP (mm/Hg)	74.7 (10.1)	76.4 (9.4)	0.26
Total Cholesterol (mg/dL)	195.6 (41.9)	190.9 (33.4)	0.42
HDL Cholesterol (mg/dL)	52.2 (14.8)	48.8 (13.7)	0.12
MET•hr/wk LPA (M, IQR)	7.83 (1.97-15.92)	9.38 (3.00-19.90)	0.28

For more information on outcomes by setting, see Eaglehouse, et al., abstract A-46: 413/251.

GROUP & DVD: 6 and 12 MONTH RESULTS

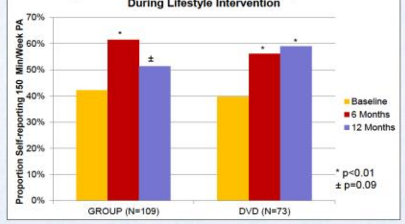
- LPA significantly increased for both *group* and *DVD* participants from baseline to 6 and 12 months (**Fig. 1**).

Figure 1. MAQ: LPA in MET-hours per Week During Lifestyle Intervention



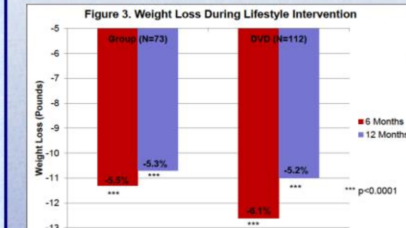
- Likewise, the proportion of participants meeting the PA goal in both *group* and *DVD* increased from baseline to 6 and 12 months (**Figure 2**).

Figure 2. Proportion Self-Reporting Meeting PA Goal During Lifestyle Intervention



- Both *Group* and *DVD* delivery resulted in significant weight loss at 6 months and 12 months (**Figure 3**).

Figure 3. Weight Loss During Lifestyle Intervention



6 and 12 MONTH RESULTS (cont.)

- Finally, improvements in several diabetes and CVD risk factors were also observed for both *group* and *DVD* participants at 6 and 12 months **(Table 2).**

Table 2. Change in Diabetes & CVD Risk Factors

Delivery Mode	Risk Factor	6 Month Change (mean, sd)	p	12 Month Change (mean, sd)	p
Group (N=112*)	Waist (inches)	**-2.1 (4.2)**	**<0.0001**	**-1.7 (2.7)**	**<0.0001**
	Fasting Glucose (mg/dL)	**-1.7 (9.2)**	**0.05**	-1.4 (10.9)	0.17
	Hemoglobin A1c (%)	**-0.11 (0.18)**	**<0.0001**	**-0.09 (0.21)**	**<0.0001**
	Systolic BP (mm/Hg)	-1.4 (11.9)	0.23	**-3.4 (11.0)**	**0.003**
	Diastolic BP (mm/Hg)	**-2.0 (8.9)**	**0.02**	**-3.0 (8.6)**	**0.001**
	Total Cholesterol (mg/dL)	-2.3 (24.5)	0.36	-0.19 (23.8)	0.94
	HDL-C (mg/dL)	0.0 (7.6)	0.96	**+1.7 (6.2)**	**0.01**
DVD (N=73*)	Waist (inches)	**-1.9 (2.2)**	**<0.0001**	**-1.9 (2.1)**	**<0.0001**
	Fasting Glucose (mg/dL)	**-2.4 (6.7)**	**0.004**	**-2.2 (7.8)**	**0.02**
	Hemoglobin A1c (%)	**-0.12 (0.16)**	**<0.0001**	**-0.11 (0.17)**	**<0.0001**
	Systolic BP (mm/Hg)	**-5.4 (10.3)**	**<0.0001**	**-4.8 (11.3)**	**0.0008**
	Diastolic BP (mm/Hg)	**-2.9 (9.6)**	**0.01**	-2.0 (9.9)	0.10
	Total Cholesterol (mg/dL)	**-8.0 (21.8)**	**0.003**	+1.2 (21.2)	0.64
	HDL-C (mg/dL)	+0.1 (7.7)	0.89	**+2.3 (8.2)**	**0.02**

* Participants with medication changes for individual risk factor removed from analysis for given risk factor

- Results were similar across the worksite and three community centers.

CONCLUSIONS

- DVD with coach support, as well as face-to-face group, was found to be successful in increasing PA levels, achieving weight loss, and improving diabetes and CVD risk factors among high-risk individuals.
- The availability of a flexible and effective intervention tool such as the DVD expands the reach of the intervention to include those who are unable or choose not to participate via group setting for their lifestyle "dose".
- This DPP-based translation effort demonstrates the feasibility of measuring PA in diverse community settings and addresses the gap in reporting PA results in translation efforts.

ACKNOWLEDGEMENTS

The authors would like to thank the DPP-GLB participants, community partners, and GLB staff for their time and continued commitment to this project.

Funding provided by the NIH through the NIDDK   Project Title: The Healthy Lifestyle Project   ClinicalTrials.gov Identifier: NCT01050205   Principal Investigator: Andrea Kriska, PhD

APPENDIX E: PAPER #2

IMPACT OF INTERVENTION AND SEASON ON PHYSICAL ACTIVITY IN A COMMUNITY TRANSLATION PROGRAM TO REDUCE RISK FOR DIABETES AND CARDIOVASCULAR DISEASE

Introduction

Physical inactivity is a known risk factor for obesity and cardio-metabolic diseases such as diabetes and cardiovascular disease (CVD) (1). Evidence from the U.S. Diabetes Prevention Program (DPP) and other clinical trials suggest that lifestyle interventions with goals of increasing physical activity (PA) and achieving modest weight loss can reduce the risk for these diseases (2-6). Although the DPP was not designed to look at PA and weight loss goals separately, in post-hoc analysis achievement of the PA goal was associated with a 44% reduction in diabetes incidence independent of meeting the weight loss goal (7).

The successful DPP lifestyle intervention has been translated for delivery in a variety of community settings (8-13), focusing on weight loss and improving PA levels. Translation efforts have been evaluated for weight loss effectiveness, with success demonstrated in diverse community settings (14-17). In contrast, much less is known about PA as the other primary intervention goal, as only about half of DPP translation efforts report the results of the PA component of intervention (unpublished review).

Variation in PA levels has been well documented in geographic regions with distinct seasonal shifts in temperature and weather patterns, with reported PA levels generally higher in milder months and lower in months with more extreme temperatures (18, 19). However, to the authors' knowledge, seasonal variation in PA has never been considered in evaluations of the effectiveness of community translation programs for increasing PA levels. As most intervention programs include shorter, intensive phases followed by variable-length maintenance phases (17), seasonal and environmental fluctuations could likely be impacting on participants' PA levels above and beyond the influence of the intervention program itself.

Given the rising concern of physical inactivity and its effect on public health and given the importance of PA as one of the two key lifestyle goals in diabetes prevention (as demonstrated in the DPP), the role of PA in resulting community prevention translation efforts needs to be thoroughly understood. Therefore, the purpose of this project is to determine the impact of a DPP-based behavioral lifestyle intervention translated to community settings on change in PA levels among adults at risk for diabetes and CVD. This investigation will include a necessary thorough examination of the influence of season on PA levels in order to better understand how PA and the assessment of PA within a lifestyle intervention can be impacted by season.

Methods

This investigation is part of a larger on-going NIH funded randomized intervention trial, the Healthy Lifestyle Project (PI: Dr. A. Kriska; clinicaltrials.gov identifier NCT01050205), evaluating the effectiveness of a DPP-based lifestyle intervention implemented in diverse community settings. The study intervention program, Group Lifestyle Balance ™ (GLB), is a 12-month, 22-session adaptation of the DPP that was developed by members of the original DPP Lifestyle Resource Core who are now faculty members of the University of Pittsburgh Diabetes Prevention Support Center (DPSC). The DPSC study investigators partnered with a worksite and three community centers to implement the DPP-GLB Program. The study protocol was approved by the University of Pittsburgh Institutional Review Board.

The Healthy Lifestyle Project employed a randomized six-month delayed control design. This design mimics the real-life circumstances facing community-based providers in that resources may limit the frequency and capacity of programming, requiring interested participants to wait to begin a program. Researchers used a stratified randomization scheme to assign participants by location to begin the DPP-GLB Program immediately (IMMEDIATE) or after a six month delay (DELAYED) in a 2:1 ratio. The randomization allocation was generated for each location using SAS 9.3 (SAS Institute, Inc.; Cary, NC) simple random sampling procedure by K.V. and randomization assignment was distributed to each participant in a sealed envelope at the end of their baseline assessment visit.

Study population

Recruitment was conducted at a worksite and three community centers in the Pittsburgh, Pennsylvania metropolitan area during September 2010-December 2010 at the worksite and September 2011-December 2011 at the community centers. Site-specific strategies were used to generate interest, including program flyers, 'lunch and learn' sessions, e-mail blasts, and mailings. Interested individuals were interviewed in-person or via telephone to determine eligibility for attending an on-site screening visit. On-site screening involved a finger stick for fasting plasma glucose, HbA1c, and lipid measurements as well as assessment of blood pressure, height and weight to determine BMI, and waist circumference. Eligible adults had a BMI $\geq$ 24 kg/m^2 ($\geq$ 22 kg/m^2 for Asians) and pre-diabetes (20) and/or the metabolic syndrome (21), or hyperlipidemia and one additional component of the metabolic syndrome. Eligible and interested individuals provided written, informed consent before enrolling in the study. Enrolled participants were required to obtain physician approval for physical activity prior to engaging in the intervention.

Intervention

The DPP-GLB curriculum has been described elsewhere (22-24) and program materials are available online (www.diabetesprevention.pitt.edu). In brief, the one-year, 22-session program focuses on healthy eating behaviors and increasing PA to at least 150 minutes of moderate intensity per week in order to achieve a 5-7% weight loss goal. At time of randomization, participants were given the option of completing the first 12 weekly DPP-GLB sessions in face-to-face groups or to participate via individually-viewed DVD. The remaining 10 bi-weekly and monthly sessions were delivered as face-to-face groups. During the program, participants were presented with information regarding safely increasing PA, self-monitoring PA behaviors, and setting PA goals. A pedometer was distributed to participants as a tool for monitoring PA and setting daily and weekly step goals. Information related to safely incorporating a resistance training and flexibility routine and reducing sedentary behavior was provided in latter sessions.

General health information was mailed to DELAYED participants periodically during the six month control period. This included hand-outs on wearing proper shoes during exercise, staying hydrated, and reducing salt in the diet.

Outcomes Assessment

All measures were collected by trained research staff following a standard protocol at randomization (baseline), and at 6 and 12 months from start of intervention. Due to the study design, participants in the DELAYED arm attended one additional assessment visit. All participants were asked to attend a brief visit at 18 months from start of intervention to obtain weight and general PA information. For the purposes of this evaluation, all assessment points (6, 12, 18 months) will be in reference to start of intervention, regardless of randomization assignment.

Physical Activity Measures. Research staff assessed PA behaviors via two interviewer-administered questionnaires. At baseline, 6, 12, and 18 months a general lifestyle questionnaire (LSQ) asked participants about the frequency (in days) and duration (average each day) of PA in a typical week, expressed as minutes per week. At baseline, 6, and 12 months the Modifiable Activity Questionnaire (MAQ) captured specific estimates of past month leisure PA, calculated from frequency and duration of common activities, expressed as MET-hours per week. As part of the MAQ, sedentary behavior during leisure time was determined by the question "Excluding time at work, in general how many hours per day do you usually spend watching television or sitting at the computer?" and recorded in 15 minute increments.

Clinical Measures. Weight was assessed via digital scale (DETECTO® PD100) at baseline, 6, 12, and 18 months. Participants were weighed in light clothing and without shoes. Trained research staff measured resting arterial blood pressure and collected a fasting venous blood sample to assess lipids, plasma glucose, insulin, and HbA1c at baseline, 6, and 12 months.

Statistical Analysis

SAS 9.4 (SAS Institute, Inc.; Cary, NC) was used to conduct all statistical analysis. Independent samples t-tests, Chi-square tests, and Mann-Whitney U tests were used to compare baseline differences in demographic, biometric, and PA variables across randomization assignments and community settings. The Mann-Whitney U test was used to compare baseline PA variables between those that did/did not attend the assessment visits during follow-up.

Changes in weight and PA measures were calculated for each assessment visit using three methods: 1. Last observation carried forward for participants with missing data; 2. Assessment visit completers for participants that attended the respective visit; and 3. Assessment visit completers for participants who attended all visits. For the 6 month control period, the Mann-Whitney U test and independent samples t-test compared changes in PA variables and weight, respectively, between IMMEDIATE and DELAYED intervention arms. Pre-post intervention changes in PA and weight were evaluated with the Wilcoxon Signed Rank test and the paired samples t-test, respectively. Pre-post intervention changes in proportion of participants meeting the PA goal or reporting PA frequency $\geq$ 3 days per week was evaluated by McNemar's test between baseline and 6, 12, and 18 months. An alpha of 0.05 was used to determine significance for all statistical tests.

Repeated measures analysis using linear mixed models was used to evaluate the impact of participant characteristics, intervention setting and delivery mode (face-to-face group or DVD), and season on change in PA during intervention. All participant data points were used in this analysis, with a maximum of four observations per person. Variables with a univariate effect of $p<0.25$ were kept in the multivariate model. Assessment visit was included in each model as a time-dependent covariate in order to determine the independent effect of receiving intervention on change in PA levels.

Results

The study enrolled 223 participants at a worksite and three community centers. Worksite participants were significantly younger, attained a higher education level, were more likely to be employed at least part-time, and reported less leisure PA at baseline than community center participants (p <0.01). Since results were similar across settings (25-27), worksite and community center participants were combined for this current evaluation.

Baseline characteristics for the entire study population and by randomization assignment are presented in Table 1. Overall, participants reported medians of 7.88 (IQR 2.19, 16.69) MET-hours and 120 (IQR 30, 210) minutes of leisure PA per week and a median of 2.5 (IQR 2, 4) hours of leisure sitting per day at baseline.

After enrollment, participants in the IMMEDIATE arm began the DPP-GLB program, which happened to be during the winter months (January-March). Using a six-month delay control design, participants in the DELAYED arm then began intervention 6 months later, during the summer months (July-September). The six-month delayed control design, meant to emulate a potential wait period before starting a community program due to limited resources, created a 6 month time period in which comparisons could be made between those who received the intervention and those who were waiting to begin. This design also provided the opportunity to investigate the impact of season on attempts to increase PA as some of the participants were asked to increase PA as the season transitioned from winter to summer while the rest were to do so in reverse order, summer to winter.

For participants attending assessment visits at both baseline and at the end of the 6 month control period, median leisure PA as determined by the MAQ increased in the IMMEDIATE (N=137) and DELAYED (N=71) arms by 14.31 (IQR 5.25, 30.92; p<0.0001) and 7.63 (IQR -0.77, 17.50; p<0.0001) MET-hours per week (p-diff=0.004), respectively. Similarly, median leisure PA determined by the LSQ increased by 60 (IQR 0, 126; p<0.0001) and 7.5 (IQR -35, 75;

p=0.14) minutes per week (p-diff=0.02) in the IMMEDIATE and DELAYED arms, respectively. IMMEDIATE and DELAYED participants also reported decreases in median leisure sitting on the MAQ by 0.5 (IQR -1, 0; p<0.0001) and 0.0 (IQR -1, 0; p=0.01) hours per day (p-diff<0.0001), respectively. Likewise, participants in the IMMEDIATE arm lost significantly more weight than the DELAYED arm during the control period [11.2 (sd 10.1) lbs. vs. 1.9 (sd 8.0) lbs.; p-diff<0.0001].

Since the intervention was successful for increasing PA in both randomized arms (data not shown), IMMEDIATE and DELAYED arms were combined to evaluate pre-post changes in PA during intervention and follow-up. Similar changes in PA were observed whether using last observation carried forward for participants with missing data, only data from participants who attended each respective visit, or only data from participants with complete follow-up. The results presented are for the 184 and 163 participants with complete MAQ and LSQ PA information, respectively, during 18 months of follow-up. Other than the fact that participants attending the 18 month visit reported a higher PA level on the LSQ at baseline than those who did not attend the 18 month visit (p<0.05), no other significant differences between baseline PA measures or weight were observed between participants who did/did not attend individual assessment visits.

Leisure PA significantly increased during follow-up (Figure 1). At 6 months, participants increased median leisure PA by 10.99 (IQR 1.02, 23.45) MET-hours and 60 (IQR 0, 120) minutes per week (both; p<0.0001). At 12 months, participants' PA levels dropped but remained at 6.44 (IQR 0, 19.05; p<0.0001) MET-hours and 40 (IQR -30, 105; p=0.0001) minutes per week above baseline. At 18 months, participants reported a median PA level of 30 (IQR -45, 120) minutes per week above baseline (p=0.0006). Although the median change in hours of sitting per day did not suggest changes in leisure sitting behavior, the interquartile range and associated p-value indicated decreases in hours of sitting time at 6 months (Median=0; IQR -1, 0; p<0.0001), with similar results at 12 months (Median=0, IQR -1, 0.5; p=0.04).

Parallel to observed increases in PA level as assessed by the MAQ and LSQ, the proportion of participants meeting the PA goal, determined by the LSQ, increased from 44.2% at baseline to 62.0% (p<0.0001), 57.1% (p<0.01), and 52.2% (p=0.09) at 6, 12, and 18 months, respectively. Concordantly, the proportion of participants reporting regular PA, defined as ≥ 3 days per week, significantly increased from 63.8% at baseline to 86.5%, 80.4%, and 80.4% at 6, 12, and 18 months (all; p<0.0001), respectively.

In addition to significant increases in PA level, significant weight loss and improvements in diabetes and CVD risk factors were observed at 6, 12, and 18 months (25, 27). Examining the relationship between PA and weight changes, weight loss was moderately correlated with an increase in leisure PA as measured by the LSQ at all assessment visits (Spearman's r= 0.15-0.30; all p<0.05) and as measured by the MAQ at 12 months (Spearman's r=0.26; p<0.01). Likewise, weight loss was correlated with a decrease in leisure sitting time at 12 months (Spearman's r=0.17; p=0.02), with similar trends at 6 months.

Notable fluctuation in PA level among participants with complete PA information was observed due to season (Figure 2), with PA levels higher in the summer months and declining in the winter months with an overall increasing trend over time. Due to the clear impact of seasonal changes on PA level, linear mixed models were used to determine the independent contribution of intervention and season along with other potentially influencing factors on observed improvements in PA. Considering baseline characteristics such as age, sex, education level, employment, and BMI, univariate analysis showed similar changes in PA during intervention among all population subgroups (Table 2). This was despite the fact that men reported significantly higher levels of leisure PA at baseline and consistently higher PA during follow-up (data not shown). The final multivariate model revealed the effect of season was an 11.49 MET-hour per week greater mean increase in leisure PA during the summer months compared to the winter months ($p<0.0001$). Once adjusting for seasonal variation, the impact of intervention on PA level was a 7.51 MET-hour per week mean increase at 6 months ($p=0.007$) with no decline in change in PA level from 6 to 12 months (Table 2).

Discussion

This is one of few DPP-based translation efforts to report on PA-related outcomes in a large sample and the only investigation to examine the role of season and its impact on PA and PA change. This project demonstrated the effectiveness of a DPP-based community program for increasing PA levels and, to a lesser degree, decreasing leisure sitting time across diverse settings. Expected variation in PA levels due to season above and beyond the independent effect of intervention itself on PA level was also demonstrated in this effort.

Although efficacy trials have shown the benefit of increased PA for improved health (2, 3, 6, 28, 29), estimates from national surveys indicate that only 50% of American adults are meeting the guidelines of 150 minutes of moderate intensity PA per week (30-32). In the current community effort, 44% of the participants reported at baseline that they engaged in at least 150 minutes of PA per week, which is similar if not a little less than the general adult population. In the DPP itself, the lifestyle intervention resulted in 74% of participants meeting the PA goal at the end of the intensive intervention which occurred by approximately 6 months (33) compared to the current community study which found that 62 % of the participants reported achieving the PA goal at 6 months based upon two very crude lifestyle questions about PA. This is further compared to results showing 41-78% of participants reporting to have met the PA goal in other translation programs of similar length (10, 11, 13, 34-39). As translation efforts have diminished resources and compared to efficacy trials, it is encouraging to see that these translation studies are, in most cases, achieving reasonable improvements in increasing participant's PA levels.

In addition to increases in the proportion of participants in this study meeting national PA guidelines (32), the proportion of participants reporting regular PA defined as $\geq$ 3 days per week significantly increased from 64% to over 80% during intervention. This finding is consistent with other translation studies that reported an absolute increase of 18-42% in the proportion of participants engaging in regular PA as a result of the intervention (10, 40, 41). Given that acute bouts of PA beneficially impact glucose uptake and insulin sensitivity (42), regular PA spread out over the week is important for improving diabetes risk factors. This highlights the value of considering overall PA patterns and not just absolute volume of PA in evaluating risk reduction potential of translation programs.

The observed association between increased PA level and weight loss in this study supports recommendations to include PA interventions as a strategy for weight loss (43). In DPP translation, one other study showed that weight loss was significantly associated with PA level (44) and three additional studies have shown that PA level is related to meeting weight loss goals during the lifestyle program (35, 45, 46). As PA levels have been shown to be a strong predictor of meeting the weight loss goal and of long-term weight loss maintenance in the DPP (33), the finding from this study reaffirms the importance of examining the relationship between PA and weight changes to further understand the role of PA in prevention efforts.

Utilizing a past month version of the Modifiable Activity Questionnaire (in contrast to the past year version of the MAQ used in the DPP) allowed for a thorough examination of the impact of season on PA levels during lifestyle intervention performed in a region that has distinct seasons. This seasonal fluctuation in PA level (past week) was documented in 500 post-menopausal women over an 18-month enrollment period in Pittsburgh, Pennsylvania by Newman et al. with peak PA found in the milder months and the lowest PA levels identified during winter months (18). The current translation study observed a significant influence of season during the intervention period on PA levels that remained in multivariate modeling and is the first community translation effort of lifestyle intervention to do so.

Independent of this seasonal variation, the intervention was shown to be effective for increasing PA in multivariate models. In comparisons between IMMEDIATE and DELAYED arms at 6 months after intervention in the former, and also in pre-post comparisons of the entire cohort at 6 and 12 months, the lifestyle intervention was found to successfully increase PA levels. The greater increases in PA level for the IMMEDIATE arm compared to the DELAYED arm during the 6 month control period that occurred from winter to summer exhibit the effectiveness of intervention for increasing PA level beyond the expected increase due to seasonal changes. Looking at pre-post changes in PA levels for both randomized arms combined, after six months of intervention, participants reported a greater than two-fold increase in MET-hours per week of leisure PA, comparable to two additional hours of brisk walking in duration and intensity. Although change in PA level appeared to decrease by about 5 MET-hours per week from 6 to 12 months, after adjusting for season, the mean increase in PA at 6 and 12 months was stable at approximately 7 MET-hours per week, similar to the results of the DPP at 1 year (3). This finding reveals the importance of considering the assessment instrument and time-frame when determining intervention impact on PA levels.

As a limitation to this current study, not all samples were independent, though the independence assumption was maintained for statistical analysis. Although a small portion of the total enrollment, significant others, spouses, and family members were able and encouraged to enroll in the program in order to provide support throughout a lifestyle change program as this support has been linked to improved outcomes (44). The second limitation of this investigation is the low enrollment of racial and ethnic minorities (6% non-Caucasian). Only one other study that utilized and evaluated the DPP-GLB and also reported PA levels had a more diverse population at 100% non-Caucasian (11), similarly showing an increase in PA.

Conclusions

This investigation provides evidence that DPP translations, such as the DPP-GLB, delivered in community settings not only results in successful weight loss among individuals at-risk for diabetes and CVD but significantly improves PA levels. This evaluation allowed for the impact of intervention on increasing PA levels to be considered independently from the changes in PA level likely due to seasonal influence. Future evaluations should include a thorough assessment of PA levels and special consideration to the calendar season in which PA is measured in order to fully understand the impact of intervention on improving PA behaviors and related health outcomes.

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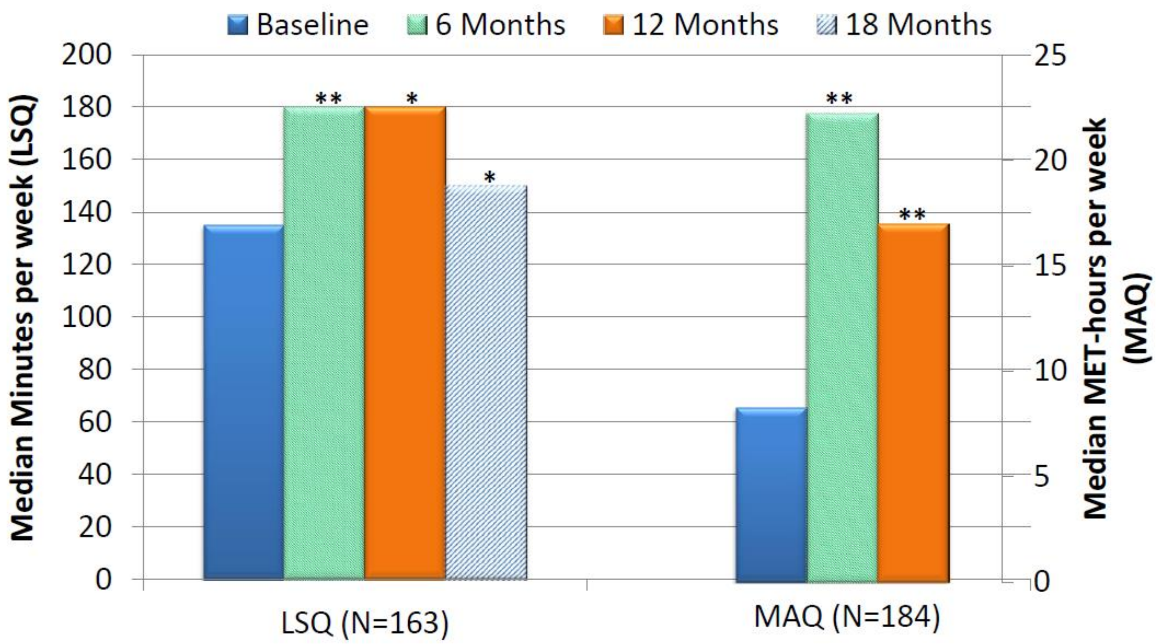
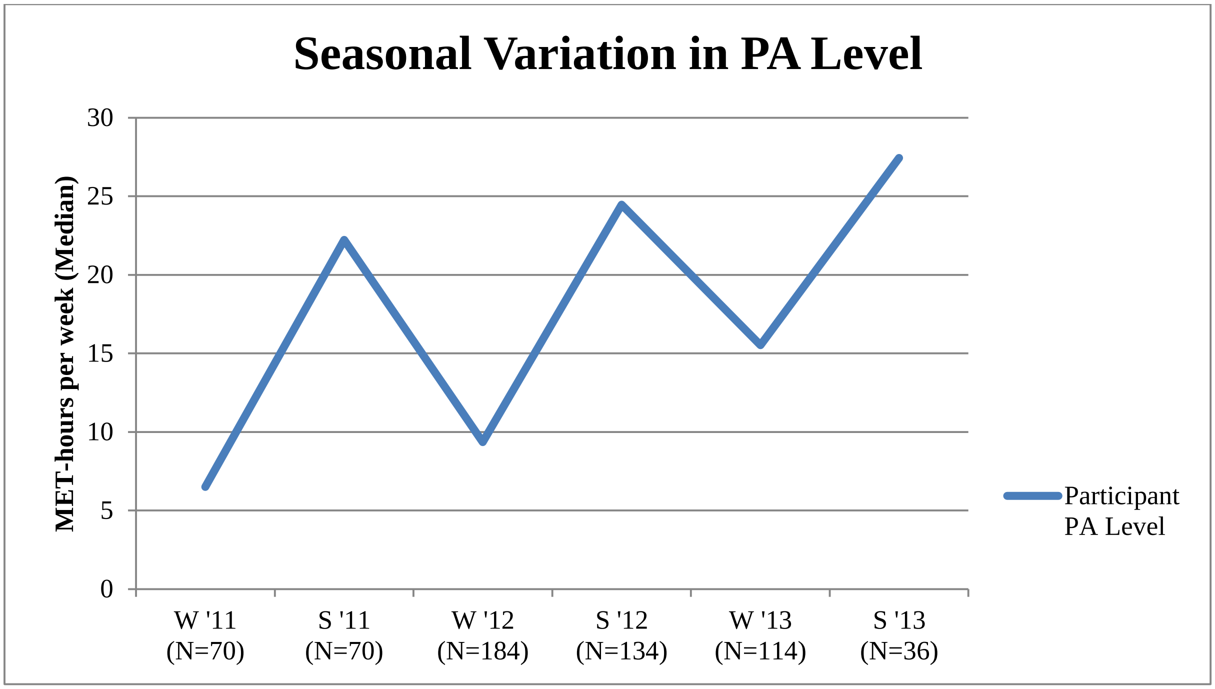
Table E1. Baseline Characteristics for Participants Enrolling in DPP-GLB Program

Randomization Assignment:	Total (N=223)	IMMEDIATE (N=148)	DELAYED (N=75)	Between Group p
Variable	Mean (sd)	Mean (sd)	Mean (sd)	
Age (years)	58.4 (11.5)	59.0 (11.4)	57.2 (11.6)	0.28
Sex; n (%) Female	139 (62.3)	92 (62.6)	47 (62.7)	0.94
Ethnicity; n (%) Non-Caucasian	14 (6.3)	10 (6.8)	4 (5.3)	0.78
Education:		n (%)	n (%)	0.73
H.S./Some College	82 (36.8)	57 (38.5)	25 (33.3)	
B.S. Degree	68 (30.5)	45 (30.4)	23 (30.7)	
Graduate Degree	73 (32.8)	46 (31.1)	27 (36.0)	
Employment:				0.90
Full-time/Part-time	147 (65.9)	98 (66.2)	49 (65.3)	
Retired/Disabled/Unemployed	76 (34.1)	50 (33.8)	26 (34.7)	
Weight (lbs)	208.8 (41.8)	209.2 (43.9)	208.1 (37.6)	0.85
BMI (kg/m2)	33.8 (6.0)	34.0 (6.5)	33.5 (5.0)	0.50
MET•hr/wk LPA (Median, IQR; MAQ)	7.88 (2.19, 16.69)	8.69 (2.19-19.57)	6.31 (2.38-12.66)	0.20
Minutes/Week (M, IQR; LSQ)	120 (30, 210)	120 (30, 240)	120 (20, 180)	0.13
Hours Leisure Sitting per day (M, IQR; MAQ)	3.01 (1.9), 2.5 (2, 4)	3.22 (2.1), 3 (2, 4)	2.61 (1.5), 2 (2, 3)	**0.0011**



**p-change<0.0001; *p-change<0.01; all comparisons to baseline

Figure E1. Reported physical activity level from the Modifiable Activity Questionnaire (MAQ) and Lifestyle Questionnaire (LSQ) for participants who attended all assessment visits



MAQ, Modifiable Activity Questionnaire; W, Winter (January-March); S, Summer (July-September) with two digit year indicator (‘11=2011)

Figure E2. Seasonal variation of physical activity in MET-hours per week (MAQ) over enrollment and follow-up (January 2011-August 2013) for participants with data at 6- and 12-month assessment visits (Total N=184)

Table E2. Change in MET-hours leisure PA per week (MAQ) over intervention estimated from Linear Mixed Models

Effect (Category Modeled)	Univariate Model[a] Estimate (MET-hours per week)	p-value	Mulitvariate Model[b]Estimate (MET-hours per week)	p-value
Change in PA	**14.69**	**<0.0001**	**7.51**	**0.007**
Sex (Female)	-3.90	0.10	-3.37	0.17
Age (>= 60)	-1.93	0.40	----	----
Baseline BMI (continuous value)	-0.13	0.51	----	----
Education (>=BS Degree)	-2.45	0.31	----	----
Setting (Worksite vs. Community Centers)	3.01	0.20	2.45	0.31
Delivery Mode (DVD vs. Group)	3.27	0.16	1.65	0.50
Employed (Full/Part-time)[c]	0.69	0.77	----	----
Season (Summer vs. Winter)	**11.40**	**<0.0001**	**11.49**	**<0.0001**
Visit 6 Month 12 Month	 **---** **-5.19**	 **---** **0.002**	 --- -0.81	 --- 0.62

PA, physical activity; MAQ, Modifiable Activity Questionnaire
[a] all univariate models include visit as time-dependent covariate
[b] all variables with univariate p<0.25 included in multivariate model
[c] comparison group is retired/disabled/unemployed

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