TRANSLATION OF THE DIABETES PREVENTION PROGRAM TO THE COMMUNITY: EVALUATION OF IMPLEMENTATION ISSUES

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ABSTRACT

INTRODUCTION: Clinical trials around the world have demonstrated that behavioral lifestyle interventions can prevent or delay the onset of type 2 diabetes. In the United States, the Diabetes Prevention Program (DPP) lifestyle intervention significantly reduced the incidence of diabetes by 58% compared to a control group and prompted the implementation of numerous community based translations. However, questions concerning intervention implementation in the community remain. The purpose of this dissertation is to evaluate some of these translation-related issues. Specifically, the ability of non-invasive screening methods to identify high-risk participants and the impact of pre-intervention delays and participant willingness to engage in healthy lifestyle practices on outcomes are examined.

METHODS: The foundation of this dissertation is data from an NIH-funded randomized delayed control group trial evaluating the feasibility and effectiveness of the DPP Group Lifestyle Balance (DPP-DPP-GLB) program, a direct adaptation of the DPP lifestyle intervention. A total of 223 participants were enrolled from a worksite and three community centers. Paper 1 describes the ability of non-invasive screening measures to identify participants with prediabetes and/or the metabolic syndrome. Paper 2 evaluates the impact of a pre-intervention delay and weight change during the lag time on participant success at 6 and 12 months. Paper 3 describes the association of

participants' willingness to engage in health lifestyle practices and other factors to achieving weight loss and physical activity goals.

RESULTS: Paper 1 demonstrated a lack of acceptable discrimination among all non-invasive methods in the identification of prediabetes and/or the metabolic syndrome. In paper 2, assignment to the delayed-control group and weight change during the pre-intervention delay did not affect weight loss, self-monitoring or attendance at 6 and 12 months. The results of paper 3 demonstrated the importance of willingness to engage in healthy lifestyle practices and self-monitoring and attendance for weight loss and physical activity (PA) goal achievement.

PUBLIC HEALTH SIGNIFICANCE: The results of this dissertation provide information regarding important issues in the implementation of community diabetes prevention programs. This knowledge will be extremely beneficial for organizations planning to implement a behavioral weight loss intervention in the community and will facilitate program delivery on a widespread basis.

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PREFACE

I would like to thank Dr. Kaye Kramer and Dr. Andrea Kriska for providing me with the opportunity to be a part of the HEALTHY Lifestyle Project and further develop my understanding of key issues in diabetes prevention translation. My committee members also deserve thanks for their guidance in putting this dissertation together and I would like to acknowledge Todd Harwell for his guidance early in my career.

1.0 INTRODUCTION

The Centers for Disease Control and Prevention (CDC) currently estimate that 25.8 million people in the United States (US) have diabetes, and an additional 79 million people are at high-risk for type 2 diabetes with prediabetes, a condition in which the glucose level is elevated but not yet in the diabetes range [1]. The prevalence of the metabolic syndrome, a constellation of risk factors that increase the risk for diabetes has also been increasing persistently during the past decade[2]. It is estimated that nearly one third of the US population will have diabetes by 2050 due to increases in type 2 diabetes incidence and low mortality rates[3].

1.1 DIABETES PREVENTION

In response to the steady increase in type 2 diabetes, several randomized controlled trials were conducted to evaluate the efficacy of lifestyle interventions to prevent type 2 diabetes [4-8]. In the US, the Diabetes Prevention Program (DPP) demonstrated that type 2 diabetes could be prevented or delayed through intensive lifestyle intervention, with achievement of moderate weight loss and increased physical activity levels [4]. The DPP lifestyle intervention was also successful in improving risk factors for cardiovascular disease [9] and reducing the incidence of the metabolic syndrome among lifestyle intervention participants [10]. The success of the DPP lifestyle intervention has led to a variety of community translations that have been conducted in

urban and rural areas, within the health care setting, through community groups, and at worksites and academic institutions across the US. Each has demonstrated some level of success in regard to reducing weight, increasing physical activity levels and improving risk factors for diabetes and cardiovascular disease [11-16]. However, many questions concerning intervention implementation in the community have yet to be addressed. One translation-related issue which requires further study relates to the effectiveness of non-invasive screening methods to identify high-risk participants. Identification of easy to implement non-invasive screening methods is desirable because of the time and cost involved with blood-based screening.

Another area of translation that has not been addressed is the impact of intervention delays on participant outcomes. A delay of weeks or months can occur due to the time it takes to identify those at risk and enroll them in the prevention program. Pre-intervention delays may also occur because organizations providing prevention programs have inadequate staffing levels and therefore can only offer a limited number of programs at one time [17].

Finally, it is well known that self-monitoring is important for success in behavioral lifestyle interventions [18, 19], but less is known regarding the importance of participant willingness to engage in self-monitoring and other healthy lifestyle practices. Additionally, individual participant characteristics such as age, gender and employment that may be related to weight loss and physical activity based on clinical trial data [20] are not often reported in community based translations of the DPP.

The NIH-funded Healthy LIFESTYLE Project (Dr. Kriska, PI) provides the foundation for this dissertation. The primary goal of the Healthy LIFESTYLE Project is to demonstrate that the Group Lifestyle Balance program derived from the DPP lifestyle intervention (DPP-GLB) can effectively reduce weight among participants at high-risk for diabetes in a worksite, community

and military setting. Secondary outcomes include changes in fasting glucose, insulin, blood pressure, waist circumference, lipids, physical activity and quality of life. The Healthy LIFESTYLE Project also provides the opportunity to answer important questions in diabetes translation regarding eligibility screening, the effect of intervention delays on participant outcomes and the importance of participant willingness to engage in prescribed behaviors in predicting weight loss and increases in physical activity.

1.2 SCREENING AND IDENTIFICATION OF ELIGIBLE PARTICIPANTS

When offering prevention programs in the community, individuals must first be identified as being at risk, and subsequently enrolled in such programs. However, methods for identification of eligible participants have not been well addressed in the literature regarding translation of the DPP to the community setting. In the DPP, participants completed several rounds of screening before final study eligibility was determined by a single 75-g oral glucose tolerance test (OGTT) to identify impaired glucose tolerance [21]. The methods used to identify high-risk participants and determine program eligibility among community based translations of the DPP have varied considerably [22]. The most commonly used eligibility criteria includes the identification of one or more diabetes risk factors such as overweight/obesity, gestational diabetes, polycystic ovary syndrome and delivery of baby >9 pounds [13, 15, 23, 24], random capillary blood glucose values[11], fasting blood glucose values[14, 25], diagnosed prediabetes and/or 3 of 5 metabolic syndrome components[16, 23, 26-28], physician referral[29] and scores from a diabetes risk test [11, 14, 30].

In addition, translation studies have reported using the 7 question American Diabetes Association (ADA) paper risk test developed by Herman et al. in 1995[11, 14, 30, 31]. The studies using the ADA risk test applied a score of ≥10 to indicate high-risk status and intervention eligibility [30] or eligibility to take part in further screening [11, 14]. The ADA risk test assesses 7 historical risk factors that increase an individuals' chance for having undiagnosed type 2 diabetes, but it was not developed as an independent screening tool to identify participants with prediabetes for diabetes prevention programs [32]. Although the ADA risk test was not originally developed as a prediabetes identification tool, it is included in the standards and operating procedures of the CDC National Diabetes Prevention Recognition Program (DPRP) for that purpose [33], likely due to a lack of superior, inexpensive alternatives. Some effort has also been made to investigate anthropometric measurements such as BMI [34-37], waist circumference [34, 35, 37], and waist to height ratio [34, 35, 37, 38] and future risk for type 2 diabetes, but none have been evaluated for their ability to identify participants at high-risk in the context of a community based diabetes prevention program.

Effective, non-invasive screening methods such as a paper risk test or anthropometric measurement are desirable in DPP translation to the community because they are easier, more convenient, and less costly to implement and are less burdensome to participants compared to blood based screening measures.

1.3 PRE-INTERVENTION DELAY

In translation of the DPP to the community, individuals at risk for diabetes and/or cardiovascular disease (CVD) may encounter a waiting period prior to receiving intervention. A

delay of weeks or months can occur due to the time it takes to identify those at risk and enroll them in prevention programs. Pre-intervention delays may also occur because organizations providing interventions have inadequate staffing levels and therefore a limited number of programs available [17].

In community based DPP translation studies very little is reported regarding the lag time from enrollment to the start of intervention. It is common for studies to provide figures detailing the steps involved in the screening and eligibility confirmation process, but the total time involved in this process is not reported [11, 15, 29, 39-41]. Others describe general information about the length of the total subject recruitment period with times ranging from nine months to a year [11, 27, 41] and as long as two years [39]. Yet, to the authors knowledge no DPP translation studies have reported mean or median wait times incurred by participants prior to intervention, or the impact of pre-intervention delays on participant outcomes.

One impact of lengthy pre-intervention time delays that appears particularly important to examine is the effect of any weight change that may occur during this time period. To date, one study has investigated pre-intervention weight change in the context of a behavioral lifestyle intervention categorizing participants as weight losers, weight maintainers and weight gainers based on weight change during the time from screening to the first intervention session [42]. The results of this study suggest that weigh losers lose significantly more weight after six months of intervention and also complete more self-monitoring records and attend more intervention sessions.

Given that there is a high probability of a waiting period occurring before enrollment in a community based diabetes prevention program with little known about the association between wait times and participant success validates the importance of this current investigation.

1.4 WILLINGNESS TO ENGAGE IN HEALTHY LIFESTYLE PRACTICES

In the Diabetes Prevention Program, 49% of participants achieved the 7% weight loss goal at the end of the 16-session core and 37% met the same goal at the end of the intervention. The ≥150 minutes/week PA goal was achieved by 74% and 67% of participants at the end of the core and the end of the intervention, respectively [4, 20]. Characteristics of participants more likely to meet the weight loss and PA goal included older age, lower BMI, male gender, certain ethnicities and those who were more frequent self-monitors [20].

Community based translations of the DPP continue to emphasize the importance of self-monitoring and the weight loss and PA goals of the DPP [19]. In translation, one study identified older age, male gender, lower BMI and more frequent self-monitoring as important factors for achieving 7% weight loss[43]; similar to the findings from the DPP [20, 44]. The association of more frequent self-monitoring (≥50% of the time) and achievement of the 7% weight loss is also supported by other community based translations [13, 45].

Although self-monitoring is a key component of community-based translation interventions, very little is known regarding other behavioral factors that may contribute to successful achievement of outcomes such as participants' willingness to engage in self-monitoring or other healthy lifestyle practices. One study suggested that obese and overweight patients are less willing to change their lifestyle practices than their normal weight counterparts [46], while investigators in another study evaluating motivators and barriers to exercise hypothesized that a lack of interest in exercise may be a surrogate for a lack of willingness to change exercise habits [47]. A study evaluating the feasibility of a PA intervention found that participants who were current smokers and who reported an insufficient amount of PA were more likely to enroll. These results may indicate that individuals who know they are at greater risk of future health issues are

more likely and willing to participate in healthy lifestyle interventions [48], but none of these studies provide specific information regarding willingness to make healthy behavior changes and success in meeting program goals. Other individual characteristics such as age, gender, and employment that were related to participant success in the DPP [20] have not been well examined in community based translations of the DPP.

Therefore, in an effort to learn more about the factors related to program success, the relationship between willingness to engage in healthy lifestyle practices, program engagement (i.e. self-monitoring and attendance) and individual characteristics and achievement of program goals will be evaluated.

1.5 STUDY GOALS

The purpose of this dissertation is to investigate three questions related to community based translation of the DPP lifestyle intervention; specifically: 1) Are non-invasive measures able to identify individuals who meet high-risk eligibility criteria for diabetes prevention interventions?, 2) How does a pre-intervention delay from screening to the start of intervention and weight changes during the delay impact participant outcomes?, and 3) Is willingness to engage in healthy lifestyle practices important for achieving weight loss and PA goals in community based DPP translation?.

The specific goals of this dissertation include:

1. To evaluate the ability of the ADA risk [31] test and other body composition measures to identify individuals with prediabetes. In addition the utility of these screening approaches to ascertain the presence of the metabolic syndrome will be assessed.

Paper 1 will provide a background regarding what measures have been utilized to screen and identify eligible participants in previous community based diabetes prevention translation efforts. This will be the first attempt to evaluate the performance of the ADA risk test in the identification of prediabetes in the context of a community based DPP translation. Body mass index, waist circumference and waist to height ratio will also be examined for their ability to identify participants with prediabetes. Sensitivity, specificity and results from receiver operating characteristic (ROC) curves will be presented for each screening method. Because the eligibility criteria of the Healthy LIFESTYLE project also includes the metabolic syndrome, these anthropometric measures and the ADA risk test will also be evaluated for their ability to identify participants with the metabolic syndrome. This investigation will provide recommendations regarding the effectiveness of selected non-invasive screening methods and their application to diabetes prevention programs in the community. Limitations of this study include the relatively small sample size that was screened compared to other studies evaluating diabetes screening methods and a lack of racial or ethnic diversity among screened participants.

2. To evaluate the impact of a pre-intervention time delay on participant weight loss and PA outcomes at two time points (6 and 12 months) during a one-year behavioral lifestyle intervention and to evaluate the effects of pre-intervention weight change during this delay on similar outcomes.

Participants may experience a waiting period prior to the start of intervention in community based DPP translations for a variety of reasons, including the screening and identification process, limited staffing and time needed to accumulate groups. Paper 2 will examine the effect of a pre-intervention time delay on weight change, physical activity levels, self-monitoring and intervention attendance during the one-year lifestyle intervention. Additionally, the impact of

weight change during the pre-intervention delay period on the same outcomes will be evaluated. To date, only one study has investigated the impact of pre-intervention weight change (defined as the delay from screening to the start of intervention) on participant outcomes in a behavioral lifestyle intervention. Findings from this study suggest that those who lose weight during the delay achieve significantly greater weight loss, attend more intervention sessions and self-monitor more frequently compared to those who gain or maintain their weight during the delay [42]. The current investigation is important because of the high likelihood that delays will occur prior to intervention in community based diabetes prevention efforts. Limitations include providing delayed-control group participants with monthly mailings that may not be generalizable to translation in the community and may have been an important component of keeping them engaged. Because individuals volunteered for participation, self-selection bias must be considered as another possible limitation in which the study results may not be representative of the general population. Also, over 90% of study participants were Caucasian, so the results of this study may not be generalizable. Physical activity data was also self-reported.

3. To investigate the relationship between participant willingness to engage in healthy lifestyle practices and achievement of the weight loss and PA goals of a community based adaptation of the DPP lifestyle intervention. In addition, other factors such as individual participant characteristics and program engagement (i.e. session attendance and self-monitoring) will be evaluated for their association with program success, defined as achievement of program goals.

The importance of self-monitoring for success in behavioral lifestyle interventions has been established, [18] but participants' willingness to engage in self-monitoring and other healthy lifestyle practices is not well understood. Paper 3 will evaluate participants' willingness to engage

in self-monitoring and other behaviors that are believed to be important for successful outcomes in behavioral lifestyle interventions. Willingness will be assessed by a 16-item questionnaire at baseline and at 6 and 12 months. The willingness questionnaire has not been formally validated, but due to the lack of literature regarding this topic this study will provide an important first look at this topic. Changes in participants' willingness to engage in healthy lifestyle practices will be described, and the association of willingness and other factors (self-monitoring and attendance) to achievement of weight loss and PA goals will be evaluated. This evaluation will provide the first assessment of the importance of participants' willingness to engage in healthy lifestyle practices compared to behaviors such as self-monitoring and attendance that are known to be related to weight loss and PA in translation of the DPP to the community. Limitations include the lack of previous validation of the willingness questionnaire, and the use of self-reported PA data. Also, participants volunteered to take part, and over 90% of the study population was Caucasian, thus the results may not be generalizable to other groups.

2.0 DIABETES AND PREDIABETES

2.1 DESCRIPTION OF DIABETES MELLITUS

Diabetes mellitus is a metabolic disorder characterized by hyperglycemia resulting from deficiencies in insulin secretion, insulin action or a combination of these two conditions [49, 50]. There are several pathways complicit in the development of diabetes that include autoimmune destruction of the beta cells of the pancreas leading to insulin deficiency and other metabolic abnormalities with the end result of insulin resistance [49, 50]. Abnormalities in metabolism of carbohydrate, fat and protein are due to insufficient insulin action on target tissues. Insufficient insulin action can result from deficient insulin secretion and/or deficient tissue response to insulin along the pathway of hormone action [49].

Persons with diabetes may demonstrate symptoms like thirst, polyuria, blurry vision and weight loss [49, 50]. In the short term, uncontrolled hyperglycemia can lead to ketoacidosis or non-ketotic hyperosmolar syndrome characterized by stupor, coma and if left untreated death. Chronic hyperglycemia can lead to retinopathy and blindness, neuropathy and amputation, nephropathy associated with renal failure, sexual dysfunction and cardiovascular disease [49, 50]. However, individuals may have some degree of hyperglycemia for many years before presenting with any symptoms of diabetes [49].

Diabetes cases are most frequently labeled by two, broad categories; type1 diabetes and type 2 diabetes. A third category, gestational diabetes mellitus (GDM) occurs in women during pregnancy, and may persist post-partum [49, 50]. Type 1 diabetes is caused by deficient insulin secretion, type 2 diabetes is caused by a combination of insulin resistance and deficiencies in

insulin secretion, and GDM is a result of carbohydrate intolerance during pregnancy [50]. Other specific types of diabetes that have been recognized, making up 1% to 5% of cases include genetic defects of the beta-cell, genetic defects in insulin action, diseases of the exocrine pancreas, endocrinopathies, drug or chemical induced diabetes, infections, uncommon forms of immune-mediated diabetes, and other genetic syndromes found to be associated with diabetes [49].

2.1.1 Type I Diabetes

Type 1 diabetes accounts for between 5% and 10% of the total population of persons with diabetes. In the past, type 1 diabetes was commonly referred to as insulin-dependent diabetes or juvenile onset diabetes and is a result of an autoimmune mediated attack on and destruction of the beta cells of the pancreas [49, 50]. The rate of beta cell destruction varies between cases, with more rapid progression mainly seen among children and adolescents and slower progression among adults. Patients can present with ketoacidosis as the first manifestation of disease, a slightly elevated fasting hyperglycemia that rapidly changes in the presence of infection or stress, while others may preserve function of beta cells for many years [49, 50]. Individuals with type 1 diabetes ultimately become dependent on insulin to survive in the long term [49, 50].

2.1.2 Type 2 Diabetes

Type 2 diabetes accounts for between 90% and 95% of the total population of persons with diabetes. Previous labels include non-insulin-dependent diabetes mellitus or adult onset diabetes and it is characterized by insulin resistance and some level of insulin deficiency. Individuals with type 2 diabetes may not need insulin initially and may never need it over their lifetime [49]. People

with type 2 diabetes are often obese, with obesity itself being responsible for some level of insulin resistance [49]. If individuals are not obese by standard criteria, they are often found to have excess body fat in the abdominal region [49]. Type 2 diabetes may go undiagnosed for many years because of the slow rate at which blood sugar becomes elevated and the lack of severity of classic diabetes symptoms [49].

2.1.3 Gestational Diabetes

Gestational diabetes is traditionally defined as hyperglycemia first recognized during pregnancy, not excluding the possibility that the glucose intolerance was present before the pregnancy [50, 51]. As increases in obesity and type 2 diabetes became commonplace among women in their child bearing years, the limitations of this definition of GDM were recognized. Deliberations among an international consensus group recommended that diabetes recognized at the first prenatal visit among high risk women be diagnosed as overt diabetes and not GDM [49]. Approximately 7% of all pregnancies in the United States (US) are affected by GDM, with the prevalence ranging from 1 to 14% depending on the population [49], with more frequent occurrences among African American, Hispanic/Latino American and American Indian women [52]. Ninety percent of pregnancies complicated by diabetes are due to GDM [49], and although most cases resolve post-partum, women who have had GDM are at a 35% to 60% increased risk of developing diabetes over the next 10-20 years [52].

2.1.4 Diagnosis of Diabetes

Generally in the US, the diagnostic criteria for diabetes established by the American Diabetes Association (ADA) are adhered to. The criteria for a diagnosis of diabetes includes hemoglobin A1c ≥6.5% using a certified and standardized method, fasting plasma glucose ≥126 mg/dL, a 2-hour plasma glucose ≥200mg/dL during an oral glucose tolerance test (OGTT) performed as described by the World Health Organization (WHO) or a random plasma glucose ≥200 mg/dL in a patient with classic hyperglycemia symptoms or hyperglycemic crisis. In the absence of hyperglycemic symptoms or hyperglycemic crisis a second, confirmatory test should be completed [49].

2.2 BURDEN OF TYPE 2 DIABETES

The Centers for Disease Control and Prevention (CDC) have been collecting surveillance data on diabetes cases in the United States since 1958, when an estimated 1.58 million (0.93%) people were diagnosed with diabetes (cite CDC long term trends). From that year forward, the prevalence of diabetes gradually increased over the next several decades until 1997 when the American Diabetes Association (ADA) amended the diagnostic criteria for diabetes, changing the level of fasting plasma glucose necessary for a diagnosis of diabetes from 140 to 126 mg/dL [53]. Following this change in diagnostic criteria the prevalence of diabetes began increasing at a rate greater than what had been seen in previous decades. In addition to changing diagnostic criteria, obesity has been identified as a key factor in the increase of diabetes, as well as reductions in physical activity, diet changes, environmental factors and increasing lifespan [54]. In 2010, the

CDC estimated that 25.8 million people or 8.3% of the US population were affected by diabetes; 7.0 million of estimated cases were undiagnosed [52].

The prevalence of type 2 diabetes varies by age, gender and racial or ethnic group [52]. An estimated 26.9% of people age ≥ 65 years have diabetes, compared to 13.7% and 3.7% among the 45-64 and 20-44 age groups, respectively. Men have a slightly higher prevalence of diabetes compared to women, 11.8% versus 10.8%. Population estimates of people aged 20 years or older suggest that non-Hispanic whites are least affected by diabetes (7.1%) followed by Asian Americans (8.4%), Hispanics (11.8%), non-Hispanic blacks (12.6%) and American Indians and Alaska Natives (14.2%) [52].

In 2012, the estimated cost associated with diabetes was $245 billion, $176 billion stemming from direct medical care and $69 billion as a result of lost productivity [55]. Fifty nine percent of direct medical care expenditures are attributed to the population aged 65 years and older, while nearly 88% of indirect costs are incurred by the population under 65 years [55]. Those with diabetes have annual health care expenditures 2.3 times greater than those without diabetes after adjusting for age and sex, and those with uncontrolled diabetes have costs 2 to 8 times greater than those with controlled diabetes [55]. Over one-fourth of the increase in health-care related spending from previous years' estimates is attributed to the increase in diabetes prevalence [55]. Overall hospital inpatient days have decreased by 10% nationally, but the reverse has been seen for those with diabetes, with a 6% increase in hospital inpatient days among those with diabetes and a 9% increase directly related to their diabetes [55].

CDC estimates indicate that diabetes is the seventh leading cause of death based on US death certificates [52]. Diabetes is perceived to be underreported on death certificates, with studies demonstrating that decedents with diabetes had the disease listed anywhere on the death certificate

only 35% to 40% of the time [52]. People with diabetes have almost a two times greater risk of death than similar aged diabetes free people [52]. In addition to an increased risk of death, diabetes has also been linked to heart disease and stroke, hypertension, retinopathy and blindness, nephropathy and kidney disease, neuropathy and amputation, periodontal disease and complications of pregnancy [52].

2.3 COMPLICATIONS OF DIABETES

The complications of diabetes are many. They include cardiovascular disease, retinopathy, nephropathy, neuropathy, periodontal disease, pregnancy related complications and others. Prevention of diabetes is paramount, as early onset of disease coupled with longer duration leads to more serious long-term complications.

2.3.1 Cardiovascular Disease (CVD)

Among people with diabetes, cardiovascular disease (CVD) is a leading cause of morbidity and mortality [56]. Of all CVD risk factors, hypertension and dyslipidemia are the most common, and studies have demonstrated that controlling these risk factors are important for prevention or delay of CVD. A recent analysis indicates that CVD mortality has improved among men with diabetes and is similar to their counterparts without diabetes, but the CVD mortality rate among women with diabetes is twice that of women without diabetes [57]. Hypertension is common among people with diabetes with prevalence dependent upon diabetes type, age, obesity and

ethnicity [56]. In addition to increasing risk of CVD, hypertension increases the risk of many microvascular complications, such as retinopathy, neuropathy and nephropathy [56].

2.3.2 Retinopathy

Retinopathy is a specific vascular condition characteristic of both type 1 and type 2 diabetes, and diabetes is the leading cause of blindness among adults age 20-74 years [52, 56]. From 2005 to 2008, over one quarter of people with diabetes over 40 years of age had diabetic retinopathy [52]. Other eye problems, such as glaucoma and cataracts, occur earlier and more frequently among those with diabetes [56]. Retinopathy is strongly related to duration of diabetes, as well as chronic hyperglycemia, nephropathy and hypertension [56].

2.3.3 Nephropathy

Nephropathy occurs in 20-40% of people with diabetes and is the leading cause of end stage renal disease (ESRD). It is also the complication associated with the greatest risk of mortality [56, 58]. Diabetes is the number one cause of kidney failure, making up nearly half of all cases in 2008 [52]. Albuminuria is not only a marker of nephropathy among persons with diabetes, but is also a well-established CVD risk factor [56]. If albuminuria is allowed to progress it can lead to ESRD [56]. Control of blood pressure is an important strategy in prevention of nephropathy and is often treated with angiotensin-converting-enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs) or a combination of these two drugs [56]. Unlike retinopathy, the risk for nephropathy is not contingent upon duration of disease, and in the absence of proteinuria for 25 to

30 years; risk begins to decrease [58]. If left uncontrolled, kidney disease can eventually lead to dialysis and death among patients [56].

2.3.4 Neuropathy

Neuropathy among people with diabetes can take on a variety of clinical manifestations, being either focal or diffuse, with the two most common varieties being chronic sensorimotor distal symmetric polyneuropathy (DPN) and autonomic neuropathy [56]. For several reasons, early detection and treatment is highly important among people with diabetes. First, non-diabetic neuropathies may be present and treatable, second a number of effective treatments exist, third as much as 50% of DPN may be asymptomatic and may lead to injury and fourth, autonomic neuropathy can lead to morbidity and even mortality [56]. Symptoms of diabetic autonomic manifestations may include resting tachycardia, exercise intolerance, constipation, erectile dysfunction, impaired neurovascular function and autonomic failure. Cardiovascular autonomic neuropathy (CAN) is a risk factor for CVD [56]. Gastrointestinal neuropathies are also common and may impact any portion of the gastrointestinal tract and most commonly lead to constipation that may alternate with episodic diarrhea [56]. Another common consequence of neuropathy is amputation and foot ulceration accounting for much of the morbidity and mortality attributed to diabetes [56]. Early recognition and treatment can mitigate adverse outcomes, and those with previous amputation, past foot ulcer history, peripheral neuropathy, foot deformity, peripheral vascular disease, visual impairment, diabetic nephropathy, poor glycemic control, and smokers are at increased risk [56]. Over 60% of all lower limb amputations occur in people with diabetes [52]. Typically, prevalence and severity increase with duration, although a severe form of early onset nephropathy has been described[58].

2.3.5 Periodontal Disease

Periodontal disease, although not more prevalent among those with diabetes, is more severe [56]. Among adults ≥45 years with poor glucose control, periodontitis is 2.9 times more likely to occur than among those without diabetes, and nearly a third of those with diabetes experience loss of attachment of the gums to the teeth [52].

2.3.6 Complications of Pregnancy

Type 1 diabetes, when poorly controlled prior to pregnancy and during the first trimester can lead to major birth defects and spontaneous abortions. These risks are minimized when glucose levels are controlled. If glucose levels remain uncontrolled in the second and third trimesters of pregnancy the result can be very large babies that increase risk for mothers and children [52].

2.3.7 Other Complications

Other comorbid conditions include hearing impairment, which is more common among people with diabetes possibly due to neuropathy or vascular disease [56]. Obstructive sleep apnea, a CVD risk factor, has been estimated to effect up to 23% of people with diabetes [56]. Diabetes has also been linked to fatty liver disease, lower testosterone in men, cancer, fractures, cognitive impairment and depression [56]. Poor diabetes control can also lead to birth defects, spontaneous abortions and delivery of marcosomic babies [52].

2.4 RISK FACTORS FOR TYPE 2 DIABETES

There are a number of risk factors for type 2 diabetes, of which some are modifiable and others are not. Non-modifiable risk factors include age, race/ethnicity, gender and family history. On the other hand, individuals can change dietary and activity behaviors to reduce their weight, improve glucose metabolism and other metabolic risk factors, and thus modify or reduce their risk for diabetes.

2.4.1 Non-modifiable Risk Factors

A positive family history of diabetes in a primary relative occurs in 30-60% of those with type 2 diabetes. Specific ethnic groups including African Americans, Hispanics, Asians and Native Americans are at increased risk of diabetes compared to their non-Hispanic white counterparts [59, 60]. The increase in diabetes risk associated with family history likely arises through several different mechanisms including similar genetic make-up, common environmental factors and other variables due to the ever-increasing number of people with diabetes in the population [60].

Age is also recognized as a non-modifiable risk factor for type 2 diabetes, with an increasing prevalence of disease seen with increasing age [60]. However, risk associated with age varies with respect to race/ethnicity, socioeconomic status (SES) and number of other risk factors and prevalence begins to decline after 75 years of age [60].

Other non-modifiable risk factors specific to women include polycystic ovary syndrome, giving birth to a baby > 9 lbs and previous diagnosis of gestational diabetes (GDM) [56]. Following a pregnancy affected by GDM, incidence of diabetes increases rapidly within the first 5 years and at a slower rate 10 years after the pregnancy [61]. Women who have had GDM are at a 35% to

60% increased risk of developing diabetes over the next 10-20 years compared to women without GDM [52].

2.4.2 Modifiable Risk Factors

Overweight and obesity, as a result of excessive caloric intake, sedentary lifestyle, genetics or a combination of these factors are major risk factors for type 2 diabetes [59, 62, 63]. Overweight and obesity are commonly quantified by Body Mass Index (BMI) or waist circumference and risk of diabetes increases with increased values on each of these measures [59, 64, 65]. In addition to current weight status, progressive weight gain over time increases an individual's risk for type 2 diabetes. The incidence of type 2 diabetes has mirrored that of obesity with 50% and 90% of those with type 2 diabetes being obese and overweight, respectively[66]. Among men, both total weight gain and recent weight gain are positively associated with increased diabetes risk [65, 67]. However, not all body weight in excess of a normal range constitutes an increase in risk for type 2 diabetes. Evidence suggests that abdominal obesity [60] and adipose tissue inflammation are of the most concern among the overweight and obese [64, 66].

Physical activity has long been associated with the improvement of risk factors for diabetes [68, 69]. Conversely, a mostly sedentary lifestyle and poor nutrition have been implicated as risk factors for type 2 diabetes, often through their relationship with obesity and overweight [60]. The negative effects of physical inactivity are more pronounced among those with additional risk factors for type 2 diabetes [60], but physical activity is important even in the absence of risk factors like obesity [62]. Recommendations suggest a minimum of 150 minutes of physical activity per week are necessary to prevent diabetes, however evidence indicates that any movement above a sedentary state is beneficial [62]. Complicit with physical inactivity in the current diabetes

epidemic is an unhealthy diet that is typically high in fat and coexists with excessive calorie intake [60]. Research has demonstrated that diet modifications consisting of a low fat diet made up of whole grains, and fruits and vegetables are associated with a lower risk of diabetes [70]. Environmental factors are also related to diet and physical activity, and those from the most resource poor environments as they relate to physical activity and nutrition tend be at the highest risk for diabetes [63, 71].

In addition to levels of physical activity and other lifestyle choices that lead to overweight and obesity, smoking has been implicated as an independent risk factor for diabetes. A prospective study among men demonstrated that smoking was significantly associated with diabetes risk after adjustment for confounders such as age and BMI [72]. The results of a larger cohort study provides further evidence of this association among men, reporting hazard ratios of 2.41 (95% CI:1.48-3.93) among those who smoke $\geq$ 20 cigarettes/day compared to never smokers [73]. The Women's Health Initiative study suggests that a similar relationship is seen among women who are smokers, with a hazard ratio of 1.28 (95% CI:1.20-1.36) for current smokers compared to their non-smoking counterparts [74].

Several metabolic conditions are known risk factors for diabetes. One of these is insulin resistance, which leads to an increase in blood glucose as a result of reduced tissue sensitivity [59]. There is evidence indicating that by the time fasting glucose levels are within the prediabetes range, significant beta-cell destruction has likely occurred; emphasizing the importance and early recognition of insulin resistance as a risk factor [60]. Due to the invasive nature of the euglycemic clamp, the gold standard test for insulin resistance, calculations such as the Homeostasis Model Assessment-Insulin Resistance Index (HOMA IR) and the Quantitative Insulin Sensitivity Check

Index (QUIKI) or assessment of fasting insulin are commonly used as surrogate measures to detect insulin resistance [59].

Impaired glucose tolerance (IGT) and impaired fasting glucose (IFG) are two additional metabolic risk factors for type 2 diabetes, and are commonly referred to as prediabetes [64, 75]. The presence of these two hyperglycemic conditions vary between ethnicities, are more frequently seen in those over 40 years of age, and IGT is also more common among men than women [75]. Compared to those with normal glycemic levels, those with IGT or IFG are 6 times more likely to develop diabetes and those with both conditions are 12 times more likely to develop diabetes [66].

The metabolic syndrome, a combination of abdominal obesity, dyslipidemia, hypertension and insulin resistance, is a risk factor for type 2 diabetes [59, 60]. Its individual parts are also known risk factors for diabetes. A condition referred to as dyslipidemia characterized by high triglyceride levels and/or low HDL cholesterol is a known risk factor for CVD and component of the metabolic syndrome, also increases risk for type 2 diabetes [59]. Hypertension, another component of the metabolic syndrome, is associated with insulin resistance and impaired glucose tolerance. It is also considered a risk factor for type 2 diabetes [59, 60].

2.4.3 PREDIABETES

2.4.3.1 Diagnosis of Prediabetes

An intermediate group, with glucose levels not meeting diagnostic criteria for diabetes but in excess of normal glucose levels is identified as having “prediabetes”. The ADA defines prediabetes as having impaired fasting glucose (IFG) levels of 100 mg/dL to 125 mg/dL, impaired glucose tolerance (IGT), with 2-hour oral glucose tolerance test (OGTT) readings of 140 mg/dL to 199 mg/dL, or an A1C of 5.7-6.4% [49]. Individuals meeting this criteria are at increased risk

for future development of diabetes and cardiovascular disease [49]. Hyperglycemia reflective of prediabetes is known to be associated with obesity, dyslipidemia, high triglycerides, low HDL cholesterol and hypertension. Lifestyle interventions targeting modest weight losses of 5-10% as well as some pharmacological agents have demonstrated the ability to prevent or delay progression to overt diabetes [49].

2.4.3.2 Risk Factors for Prediabetes

The risk factors for prediabetes are the same as those for type 2 diabetes [56, 76]. They include the modifiable risk factors of BMI $\geq$ 25kg/m^2, physical inactivity, hypertension, low HDL cholesterol, insulin resistance and hyperglycemia in the prediabetes range. Similar non-modifiable risk factors include a history of a first degree relative with diabetes or CVD, high risk race/ethnicity, history of delivering a macrosomic baby, history of GDM, age greater than or equal to 45 years and women with polycystic ovary syndrome [56, 76]. Other factors that should be considered when addressing increasing risk for prediabetes include economic and social conditions, the environment and access to health care [63].

2.4.3.3 PREVALENCE AND BURDEN OF PREDIABETES

Prediabetes is most prevalent among those who are overweight and obese and increases across all BMI categories [77, 78]. Estimates vary based on the type of glycemic testing; however from 2007 to 2010 prediabetes increased from 29.2% to 36.2% among NHANES participants 18 years of age or older [78]. Additionally, among this cohort investigators found a 21% increase in the prevalence of prediabetes from 1999-2010. They found the greatest increases in prevalence among non-Hispanic blacks and those who live below the federal poverty level [78]. Interestingly,

even with increasing rates across BMI categories, those in the normal BMI ranges had the highest relative increase in the prevalence of prediabetes [78].

A barrier to treatment of many metabolic disorders like hypertension, dyslipidemia and prediabetes are their lack of symptomology early on, when prevention is key. Diagnosis and treatment typically do not occur until many years of elevated blood pressure, lipids or glucose. In the case of prediabetes, although estimates indicate that approximately one-third of the population is affected by prediabetes, only one-tenth report that they have been told by a doctor that they have prediabetes [79]. Awareness of prediabetes status was low regardless of income, education and health insurance status [79]. Thus, a key step in future diabetes prevention efforts is improved identification of individuals with prediabetes and implementation of proven diabetes prevention interventions [77, 79].

3.0 RANDOMIZED CONTROLLED TRIALS TO PREVENT DIABETES

Several randomized controlled trials evaluating the efficacy of lifestyle interventions to prevent diabetes have been implemented among a variety of populations around the globe in response to the epidemic levels of type 2 diabetes. All of these clinical trials focused on high-risk participants with IGT, identified by a 2-hr 75g OGTT[4-8]. Although each trial was designed to evaluate the efficacy of a lifestyle intervention to prevent incident type 2 diabetes, intervention intensity varied from low intensity infrequent education regarding diet and exercise in the Indian [7] and Japanese [5] trials, to the very intensive individualized lifestyle change programs in the Finnish Diabetes Prevention Study [8] and the US Diabetes Prevention Program (DPP) [4]. The discussion to follow will introduce each of the international trials and highlight outcomes related to diabetes prevention before focusing on a detailed discussion of the US DPP.

3.1 CLINICAL TRIAL EVIDENCE FROM AROUND THE GLOBE

3.1.1 The Da Qing IGT and Diabetes Study

The Da Qing study was the first of a series of large-scale clinical trials to demonstrate the success of lifestyle interventions in the prevention of diabetes. Beginning in 1986, 577 residents of Da Qing, China with impaired glucose tolerance (IGT) were enrolled in a randomized controlled trial examining the effects of diet and/or exercise on the progression of IGT to diabetes.

Participants with IGT in the diet and/or exercise groups experienced a significant decrease in diabetes incidence over six years [6].

Health care clinics within the city were randomized to provide a dietary intervention, exercise intervention, a diet plus exercise intervention or a general information control group. The dietary intervention provided was composed of specific proportions of carbohydrates, protein and fat based on the participant's baseline body weight. In addition to individual counseling sessions with study physicians, participants met in small groups weekly for 1 month, monthly for 3 months and 1 meeting every three months for the remainder of the study [6].

The exercise intervention instructed participants to increase leisure time physical activity by a minimum of 1 unit per day, or 2 units per day for those $<$50 years of age with no contraindications [6]. Units of exercise were defined as 30 minutes of mild activity, 20 minutes of moderate activity, 10 minutes of strenuous activity or 5 minutes of very strenuous activity. Similar to the diet intervention group, they met in small groups weekly for 1 month, monthly for 3 months and 1 meeting every three months for the rest of the study. Intensity and volume of exercise depended upon age, past exercise history and other contraindications. The diet plus exercise intervention received the combination of the diet and exercise interventions. Control group participants received materials discussing IGT and diabetes, as well as general information regarding diet and leisure time physical activity [6].

The primary outcome of this study was incidence of diabetes and participants were evaluated at 2-year intervals for 6 years. All intervention groups had a significantly reduced incidence of diabetes compared to the control group ($p<0.05$), but between group diabetes incidence rates did not differ significantly ($p>0.05$) [6].

In addition to the original report following 6 years of intervention, the long-term effects of the Da Qing study have also been reported. Changes in body weight did not differ significantly between groups over the entire follow-up period (20 years). Intervention participants experienced an average of 3.6 more diabetes free years, and had a diabetes incidence hazard rate ratio of 0.57 (0.41-0.81) when compared to controls 20 years after baseline [80].

3.1.2 The Finnish Diabetes Prevention Study

The Finnish Diabetes Prevention Study (DPS) was the second of the large-scale diabetes prevention studies to demonstrate that lifestyle intervention could effectively prevent diabetes among high-risk participants [8]. Participants who were overweight (BMI$\geq$25kg/m^2), and between the ages of 40 and 65 years with IGT were eligible to participate. Upon enrollment, participants were randomized to the intervention or control group and were stratified by center, sex and mean plasma glucose concentration. Random assignment to intervention or control was done for 522 participants at 5 centers [8].

The intervention group was provided with detailed information regarding diet and exercise to help them achieve the study goals of 5% weight loss and 30 minutes/day of moderate exercise. Dietary advice was provided on an individual basis from information collected from dietary records. Participants had seven meetings with a nutritionist in year one, followed by one every three months for the remainder of the study. They also received individualized exercise advice including information about a variety of exercise options, as well as supervised progressive, resistance training. The control group was provided general information about diet and exercise at baseline and all annual visits [8].

Similar to the Da Qing study, the primary outcome in the Finnish study was incidence of diabetes [6, 8]. After a mean duration of 3.2 years of follow-up, the diabetes incidence rate was 58% lower among participants in the intervention group compared to participants in the control group ($p<0.001$). The intervention group also lost significantly more weight during year one and had significant improvements in waist circumference, fasting plasma glucose concentration, plasma glucose concentration two hours after oral glucose challenge, and serum insulin concentration two hours after oral glucose challenge when compared to the control group [8]. Change in weight, fasting plasma glucose, and plasma glucose concentration measured after two-hour oral glucose challenge remained significantly lower among intervention participants than control participants at two years. Intervention participants also saw significant improvement compared to controls in serum insulin concentration two hours after oral glucose challenge, triglyceride concentration and blood pressure at two years [8].

After 13 years of follow-up, the Finnish DPS demonstrated a significant, 32% relative risk reduction of diabetes among intervention participants when compared to controls. The amount of physical activity performed between groups was not significantly different, however, intervention participants made more significant improvements among dietary parameters collected than controls. Reduction in body weight also remained significant at year 10 between the two groups, while significant differences in fasting and two-hour glucose concentrations were attenuated over time [81].

3.1.3 The Indian Diabetes Prevention Program

The Indian diabetes prevention program was designed to test the efficacy of lifestyle modification among a young, relatively lean, native Asian population. Participants were middle-

class, working men and women with IGT. Eligible participants were randomized to one of four groups: control, lifestyle modification (LSM), metformin (MET) or lifestyle plus metformin (LSM+MET). They were recruited via workplace announcements and those without diabetes, between the ages of 35 and 55 years were eligible for screening. A total of 531 subjects were randomized (412 men, 110 women) [7].

The control group received standard health care advice while those in the MET and MET+LSM groups received similar doses of metformin that stabilized over time at a dose of 250mg twice per day and told to keep a diary to record daily consumption of tablets. In addition the LSM and MET+LSM also received information regarding diet and activity. Individual dietary advice was provided to subjects and they were generally told to reduce caloric intake, avoid refined carbohydrates and fats and increase fiber intake [7]. Participants received intervention information at the time of randomization, followed by a phone call or letter 2 weeks later. They were contacted monthly by phone following the initial contact and had personal meetings every 6 months [7].

The cumulative incidence of diabetes was significantly lower in all intervention groups compared to the control (LSM =28.5%, LSM+MET=28.2%, MET=26.4%). The control group demonstrated significant weight gain from baseline to the annual follow-up, as did the LSM group at 24 months. There were no significant changes in waist circumference compared to baseline among any of the groups [7].

3.1.4 The Japan Diabetes Prevention Program

Another large-scale diabetes prevention program was conducted in Japan among male participants with impaired glucose tolerance [5]. Participants were randomized to either standard intervention group (control) or an intensive intervention group. Participants were mostly

government employees participating in regular health screenings at a local medical center. A total of 458 were enrolled, 356 in the intensive intervention group and 102 in the standard intervention group. The primary outcome of this study was development of diabetes [5].

Prior to randomization, all participants were provided with information regarding risk factors for type 2 diabetes and the progression of the disease. They also received minimal education regarding the role of a healthy lifestyle in the prevention of type 2 diabetes. One in five subjects was randomized to take part in the intensive intervention group, with the remainder assigned to standard intervention (control). Participants with a BMI in excess of 24kg/m^2 in the standard intervention group were told to eat meals that were 5-10% smaller, increase physical activity and lose weight. Those with BMI<24kg/m^2 were advised against weight gain and to eat a healthy diet and be active. This information was reiterated every 6 months [5].

Participants in the intensive intervention group with a BMI ≥22kg/m^2 were give their ideal body weight, instructed to weigh themselves once/week at home and to reduce their weight by 0.5-1.0 kg/month [5]. Those with a BMI ˂22kg/m^2 were told to maintain their current weight. To accomplish body weight goals participants visited the hospital every 3 to 4 months, where they were queried about their diet and told to reduce consumption by 10%, unless special instruction was needed because of inadequate dietary habits. They were also instructed to consume less fat, less alcohol, eat out no more than once/day and told to participate in moderate physical activity of 30-40 minutes/day [5].

The development of diabetes was 67.4% less in the intensive intervention group compared to the standard intervention group following 4 years of study. The intensive intervention group lost a mean of 2.5 kg after 1 year, and maintained a significant weight loss to year 4. The control group also achieved significant weight loss from baseline; however it was significantly less than the

intensive intervention group. Additionally, the intervention group had significantly greater improvements in glucose tolerance from IGT to non-IGT than the control group [5].

3.2 THE DIABETES PREVENTION PROGRAM

The US Diabetes Prevention Program (DPP) was the largest of the previously discussed clinical trials, enrolling 3,234 participants in 27 centers across the country. The DPP also evaluated the most intensive, individual lifestyle intervention as well as a medication treatment arm (metformin). Due to the number of participants enrolled, and the diversity of the sample population it was powered to determine if intervention efficacy (lifestyle vs. metformin vs. placebo) was affected by age, gender, race or ethnicity [4]. The following discussion will provide a detailed description of the DPP methods and results, as well as results from the long-term follow-up of the DPP population in the Diabetes Prevention Program Outcomes Study.

3.2.1 Methods and Description

The primary goal of the DPP was comparing the efficacy of three interventions in the prevention or delay of type 2 diabetes development. Secondarily, the DPP aimed to assess the differences between the three groups in the development of CVD and its risk factors, glycemic changes, beta cell function, insulin sensitivity, obesity, physical activity, dietary intake, health related quality of life and the occurrence of adverse events [21].

Participant recruitment was carried out by the use of mass media, mail, telephone contacts and recruitment within employment and social groups as well as health care systems. Recruitment

was designed such that half of the study population would be women, one-fifth ≥ 65 years of age and 50% high-risk minorities including African Americans, Hispanics, American Indians, Asian Americans and Pacific Islanders. The primary study entry criterion was IGT based on one 75-g OGTT. Additionally, participants were required to be free of prior diabetes diagnosis and age 25 years or older. Based on type 2 diabetes risk BMI criteria were set at BMI≥ 24kg/m^2 and BMI ≥ 22kg/m^2 for Asian Americans. Exclusion criteria were chosen based on their risk for adverse effects related to the interventions under study. For example, those with ischemic heart disease, aortic stenosis or uncontrolled hypertension were excluded because of the physical activity requirement. Also, women who were pregnant or planning to become pregnant were excluded because use of metformin has been shown to be unsafe while pregnant or nursing. Those using medications known to cause IGT, such as thiazide diuretics and beta-blockers, were also excluded [21].

A four-step process was employed to identify eligible participants. Each step in the process included descriptions of relevant information for the participant to consider prior to making the decision to proceed to the next step. The first step was an initial eligibility assessment conducted via telephone followed by a single, fasting or casual glucose measurement taken in the clinic or field. In step two, participants were interviewed and had physical measurements, OGTT and other laboratory analysis conducted to assess clinical eligibility criteria. Step three for those with an OGTT result of 140-199mg/dl was a three-week run-in period evaluating individuals' medication adherence and compliance with self-monitoring of diet, physical activity and weight. The fourth and final step was done to rule out pregnancy and review eligibility criteria prior to randomization [21].

Following randomization, regardless of their intervention assignment, all participants attended an individual information session with a case manager. At this visit, participants received written information and education concerning healthy lifestyle as it pertains to type 2 diabetes prevention. They were provided information about the USDA food pyramid [82], told to lose 5-10% of their body weight and to engage in a minimum of 150 minutes of activity per week. They were also instructed to refrain from excessive alcohol use and to quit smoking if they were current smokers [21].

The intensive lifestyle intervention was based on previous studies suggesting that obesity and a sedentary lifestyle may increase the risk for type 2 diabetes. The goals of the intervention were to lose 7% of initial body weight within the first 24 weeks of intervention and engage in a minimum of 150 minutes of physical activity per week. The lifestyle intervention was conducted by case managers who met with participants individually for 16 sessions in the initial 24 weeks, followed by monthly contacts with at least every other month being an in-person contact for the duration of the program [21, 83]. During the initial 16 sessions participants learned to self-monitor weight, diet and physical activity, set goals, problem solve and prevent relapse. Individual dietary goals were established for participants, starting out with a fat gram goal that was less than 25% of total calories and, if necessary to achieve weight loss, a calorie goal was added. The activity portion of the intervention was moderate intensity physical activity similar to brisk walking, and participants were given the opportunity to attend 2 supervised group exercise sessions per week. Individuals who struggled to meet the weight and/or activity goals were provided with additional support in the form of a “tool box” that consisted of items like exercise videos, gym memberships, eating plans etc. They also had the opportunity to attend quarterly group sessions that lasted 4-6 weeks and covered topics related to the intervention [21].

Assignment to the metformin or placebo groups was double-blinded and participants were initially given an 850mg dose to be taken once daily before being increased to 850mg twice daily. Dosages were adjusted individually if participants were having gastrointestinal (GI) symptoms. Adherence to the pharmacological interventions was assessed by pill counts and interviews. Case managers were also provided with a tool box to enhance medication adherence [21].

Resources to maximize retention in response to barriers such as dissatisfaction of treatment assignment, masking of results, time commitments, transportation, parking and child and elder care were provided to research staff. Newsletters were sent to participants to foster a sense of community, and a computer-based system was developed to identify participants with adherence problems that would initiate recovery efforts to prevent dropout. Because retention was critical for statistical power, those participants considered inactive were continuously contacted regarding reentry into the DPP. Participants were assessed for primary and secondary outcomes at 6-month intervals [21].

3.2.2 Results

A total of 3234 participants were randomized (1082 to placebo, 1073 to metformin and 1079 to intensive lifestyle intervention). Average length of follow-up was 2.8 years and 92.5% of participants had attended an assessment visit in the past 5 months. Half of the lifestyle intervention participants met the 7% weight loss goal at 24 weeks, and 38% maintained that weight loss at the most recent visit [4]. The physical activity goal was met by 74% of participants at 24 weeks and maintained by 58% at the most recent visit. Medication adherence was greater in the placebo group compared to the metformin group. Lifestyle intervention participants had significantly greater

weight loss (5.6kg) and greater increase in activity than the metformin (2.1kg) and placebo (0.1kg) groups [4].

Cumulative incidence of diabetes was 58% and 31% lower in the lifestyle intervention and metformin groups, respectively, compared to the placebo group. In the lifestyle group, diabetes incidence was 39% lower than the metformin group. The lifestyle intervention was effective among all subgroups (age, race/ethnicity, age, BMI). It was significantly more effective among those with lower OGTT at baseline than those with higher OGTT values [4]. Metformin was less effective among those with lower BMI and lower FPG than those with higher values at baseline. The efficacy of lifestyle intervention compared to metformin was greatest among older participants and those with lower BMI compared to younger participants and those with higher BMI. More GI symptoms were reported among metformin group participants and musculoskeletal symptoms were reported most frequently among lifestyle participants; no deaths were attributed to the study interventions [4].

In addition to significant weight loss and reduction in the incidence of diabetes, the interventions were also evaluated for their effects on the metabolic syndrome and cardiovascular risk factors. The metabolic syndrome was present in 53% of participants at baseline and the severity (number of components) did not differ by treatment group, sex or age. Among those with the metabolic syndrome at baseline, a significantly reduced incidence of 41% was seem among lifestyle participants compared to placebo, and a significant reduction of 17% among metformin participants compared to placebo [10]. Among those without metabolic syndrome at baseline, lifestyle intervention reduced the incidence of specific metabolic syndrome components compared to placebo, with the exception of HDL. Metformin was only effective at reducing the incidence of waist circumference criteria and fasting glucose level compared to placebo [10].

Resolution of the metabolic syndrome among those meeting criteria at baseline differed significantly ($p<0.001$) by group at 3 years, with 18% of the placebo group, 23% of the metformin group and 38% of the lifestyle group no longer meeting criteria. Both interventions decreased the prevalence of low HDL cholesterol, increased waist circumference and fasting glucose but lifestyle intervention also reduced the prevalence of high blood pressure and triglyceride levels among those meeting criteria at baseline [10].

3.2.3 "Bridge" and the Diabetes Prevention Program Outcomes Study

Following the initial success of the DPP lifestyle intervention all three intervention groups were provided the opportunity to participate in a group-implemented version of the lifestyle intervention. A 13-month span, termed the bridge period, separated the DPP from the Diabetes Prevention Program Outcomes Study (DPPOS). During the bridge period 57% of placebo, 58% of metformin and 40% of lifestyle participants attended at least some of the 16-session lifestyle curriculum. Enrollment in the lifestyle intervention during the bridge period did not differ by sex or treatment group, but was lower among women with GDM and greater among those with diabetes compared to those without diabetes. Enrollment was also associated with increased age, HbA1c, cholesterol and among women specifically those with lower weight and BMI [84, 85].

The DPPOS officially began in September 2002, with the primary objectives of evaluating the effects of the DPP interventions on incident diabetes and its associated complications in the long-term. Lifestyle (HELP) sessions were provided to all participants every 3 months, while participants in the original lifestyle intervention were offered two group (BOOST) sessions each year. Each BOOST was four sessions designed to stimulate weight loss and encourage continued participation in self-management behaviors for weight loss. The metformin group continued taking

their tolerated dose of metformin and the placebo was discontinued. Assessment visits continued at the same schedule as in the DPP and the primary outcome continued to be incident diabetes [84].

The DPPOS was first evaluated at 10 years after baseline randomization. At 10 years, diabetes incidence rate was reduced by 34% and 18% in the lifestyle and metformin groups, respectively, compared to placebo. Lifestyle participants had a 2kg weight reduction; metformin participants had a 2.5kg weight reduction, while the placebo group lost less than 1kg. Lifestyle and metformin participants had lower HbA1c and fasting glucose values than the placebo group, and all groups experienced improvements in cardiovascular disease risk factors at 10 years. [84]. More recently, DPPOS results were published indicating that lifestyle participants achieved similar CVD risk factor improvement, with less medication, than the other groups [86].

4.0 TRANSLATION OF THE DIABETES PREVENTION PROGRAM

The continued increase in the prevalence of diabetes and prediabetes necessitates the implementation of successful diabetes prevention interventions, like the DPP, to as many high-risk individuals as are reachable [52]. Theoretical models have demonstrated that providing everyone at highest risk for type 2 diabetes (i.e. with IGT) with a proven lifestyle intervention could reduce the annual incidence of diabetes by 25% [3]. Following publication of the DPP, translation efforts to provide the successful lifestyle intervention were initiated in a variety of settings. Programs were offered at community locations like churches [14, 87, 88] and the YMCA [11], within worksites [12, 30, 89] and in healthcare settings [13, 15, 16, 29, 40, 90]. Although these interventions are all considered DPP translations, a great deal of variation exists between them. These variations including study design, setting, delivery mode, eligibility criteria, intervention providers and others to be discussed in the following sections. The studies will be described based on the general venue of the intervention and focus on those implemented in the community, worksite and healthcare settings.

Moving forward from an individualized intensive lifestyle intervention delivered in a clinical trial has required adaptations of the DPP intervention in order to facilitate success in a variety of settings. The most typical modification among translations of the DPP has been to shift from an individual-based lifestyle intervention to a group-based approach. Other changes include the number of core intervention sessions offered, and how much, if any, post-core follow-up is provided. Some studies have chosen to utilize lay health workers as lifestyle coaches [11, 39], rather than health professionals as in the original DPP [21], while others have continued to use trained health professionals to implement diabetes prevention [13, 26, 40]. Increasingly advances

in technology are being incorporated, such as the use of DVD-based [26] internet [91], and remotely broadcast telehealth [92] interventions to increase the reach of diabetes prevention.

Another important factor to consider in translation is selection of a study design that is the most appropriate to evaluate the effectiveness of group-adapted DPP lifestyle interventions, which should be determined by the research question(s) [93]. The highly controlled nature of the DPP randomized-controlled efficacy trial is not likely the way forward if the aim is widespread application of diabetes prevention interventions. [4]. Past translations of the DPP have been implemented using a variety of designs, and will be discussed further in relation to each translation setting. Translation science is defined as being composed of two separate but sequential phases. In phase one translation studies, basic science is applied to participants in highly controlled settings (clinical research), while phase two translation studies attempt to adapt efficacious interventions from phase one studies and implement them in community based settings in much less controlled environments [93]. The perspective provided by an NIH review committee assembled to generate recommendations for diabetes translation research suggested that when utilizing a randomized design with a control group that it not be devoid of contact or attention. However, this committee also suggested that designs like cluster randomized trials or other non-randomized studies may be the most appropriate but the limitations of these designs must be understood [93].

4.1 COMMUNITY INTERVENTIONS

Many interventions are self-described as “community-based” and have elements in common with those implemented in other settings, however all interventions in this group (the majority being face-to-face) take place in a setting other than a worksite or healthcare facility. A

total of 14 DPP translations have occurred in community settings at locations such as churches [14, 87, 94, 95], YMCA's [11, 96, 97], schools and universities [23, 98], and senior and cultural centers [23, 39, 41, 45, 98-101]. Although all are community-based, a considerable amount of variation exists among these evaluations including study design, eligibility criteria, lifestyle coach vocation and training, specific adaptations made to the DPP lifestyle intervention and outcomes measurement and reporting.

Translation of the DPP in the community has taken place using several different study designs. The majority of studies followed some variation of a pre-post, non-randomized group design [14, 23, 28, 41, 87, 88, 98-101] with one example of a matched-pair, group randomized trial [11], a cluster randomized trial [45] and a randomized controlled trial [39]. Participant eligibility criteria have also differed across community interventions. Nearly all community-based studies required participants to have a minimum BMI ranging from $\geq$24 kg/m^2 [11] to $\geq$30 kg/m^2 [45] or in the case of high risk ethnic groups a lower BMI criteria was used [100]. Studies not reporting minimum BMI criteria all reported mean baseline BMIs $\geq$30 kg/m^2 [14, 45, 87]. The two studies using higher BMI criteria took place in specific population groups, Arab Americans [99] and senior citizens [45]. In addition to BMI criteria, age was addressed in all studies. Most required participants to be adults, $\geq$ 18 years of age [11, 14, 28, 41, 87, 88, 96, 100, 101], but one study aimed at older adults required participants to be $\geq$60 years of age [45], and a few set an age maximum [23, 88, 98].

Another area of eligibility that varied considerably among all studies was defining "high-risk" for diabetes. Determination of high-risk differed substantially across community-based interventions from a conservative, glucose based definition [11, 14, 39, 87] to a very lenient BMI only definition [45, 88, 98-100]. The remaining studies lie somewhere between these extremes,

focusing on the metabolic syndrome or its components [28, 41, 101] or a BMI cut-point and at least one additional risk factor for diabetes such as a history of gestational diabetes (GDM) [23, 102]

In the original DPP, health professionals trained by the DPP Lifestyle Resource Core provided the lifestyle intervention [21]. In translation, the lifestyle coaches providing the intervention and the training they receive vary considerably. Among community-based interventions lifestyle coaches came from diverse backgrounds including YMCA staff members [11], other lay volunteers or peer educators [45, 100], community health workers [39, 98], graduate students [23] and health professionals [14, 28, 41, 88, 99, 101, 102]. Training of lifestyle coaches ranged from multi-day workshops [11, 28, 39, 41, 45, 88, 98, 99, 101, 102] to a brief session with study investigators [14, 23, 100] or no mention of lifestyle coach training at all [87].

All community-based interventions implemented a version of the DPP lifestyle intervention modified for group delivery, rather than the individual intervention provided in the original study [21]. The number of intervention sessions typically ranged from 6 [87] to 16 [11, 14, 23, 98] core sessions followed by anywhere from zero [11, 14, 23, 28, 41, 45, 87, 88, 100, 101] to six post-core sessions [102] and one example similar to the DPP bridge period [84] followed by 12 maintenance sessions [96]. One DPP-based clinical translation trial implemented an intervention featuring weekly meetings for the first six months of the intervention with special consultation with a registered dietician at 3 time points, followed by 2 contacts per month for the remaining 6 months [39].

In general, the success of community-based interventions is reported in terms of weight loss from baseline, either as percent weight loss, total pounds/kilograms lost, percent of participants meeting 5% or 7% weight loss or some combination of all of these. The heterogeneity

in reporting makes it difficult, if not impossible, to compare across studies and examine which approaches may be more successful than others. Generally speaking, most community-based interventions have demonstrated some level of success, reporting weight losses ranging from 1.5% immediately following intervention [100] to 7.5% at approximately 6 months after baseline [39]. Weight loss among studies reporting at 12 months varies from 0.5% [14] to 7.2% [39]. Sample size is an important factor to consider when evaluating the success and potential scalability of these studies as some have enrolled as few as 26 [14] and up to as many as 434 [41].

Another, less frequently documented metric of success among community based interventions is attendance. Attendance is typically reported either as a percentage or mean/median number of sessions [11, 14, 15, 45]. Due to the variability in the number of sessions offered by community-based interventions percentages are likely a more valuable representation of attendance; however, similar to weight loss outcomes, these percentages are often quite different. Some are reported as the mean percent of participants attending all core sessions [11, 103] or the percent of core sessions attended [11, 12, 39, 40] while others offer the percentage of participants meeting study specific definitions of completers [102].

In addition to weight loss and attendance, some community-based interventions have reported improvement of risk factors for diabetes and CVD. Significant improvements were noted in total cholesterol [11, 96], fasting blood glucose [14, 39, 87, 102], insulin [39], blood pressure [14, 23, 96, 102] and waist circumference [23, 98, 99]. Physical activity is the most sparsely reported outcome in all community-based studies and is collected with entirely subjective measures. Typically reported as a mean number of minutes at the end of the intervention [23, 98, 99, 102], percent of participants meeting the 150 minute/week goal [23, 99, 102] or as a positive change from baseline [98, 100].

4.2 WORKSITE INTERVENTIONS

Much less evidence exists regarding the effectiveness of worksite DPP translations, in comparison to both the community and healthcare settings. However, the first published example of a DPP translation occurred at a worksite and a few others have since followed[12, 30, 89, 104]. The four worksite interventions were implemented in very different settings including several, large organizations in one community [104], within a maintenance facility where employees worked 3 distinct shifts, a county government worksite [30] and at a medical and technology supply company [12]. Similar to the community efforts discussed previously, worksite interventions had different approaches to study design, eligibility criteria, lifestyle coach vocation and training, adaptations to the DPP lifestyle intervention, and outcome measurement and reporting.

Study designs were similar to those in community-based interventions. A version of the non-randomized pre-post design [12, 89] was implemented in 3 out of 4 studies, with one study evaluating three different delivery methods [104]. The fourth study was a randomized trial with a 3-month delayed control group [30]. Overall, the eligibility criteria among worksite implementations of the DPP were more open than those in both the community-based and healthcare settings. BMI was used to identify level of risk for diabetes in two studies [12, 30], but none of the worksite studies reported minimum BMI criteria. One worksite included all employees regardless of weight status [89], and only two studies reported that participants must be adults [12, 30].

In addition to more liberal BMI and age criteria, determining which participants were high-risk at the worksite was much more inclusive. Two of the four worksites enrolled all employees who were interested in participation [30, 89], one allowing those with newly diagnosed diabetes

to participate [30] and the other making no mention of diabetes status [89]. A more calculated approach to identify those at high-risk was carried out by Aldana and colleagues, requiring participants to have blood glucose in the prediabetes range following a 2-hr OGTT or be newly diagnosed with diabetes [12]. The fourth study provided no details regarding intervention eligibility criteria [104].

All but one of the worksite translations used health professionals (nurse, dietitian, health educator, etc.) in some capacity as lifestyle coaches [12, 30, 89]. The study that did not use health professionals instead used employees who received training in health promotion [104]. Only one study described the lifestyle coach training used; a 1-hour meeting with the research team [89]. Interventions ranged from a passive intervention delivered via email, mail and telephone [104] to 26 weekly one-to-one sessions with a lifestyle coach [104]. Only one of the worksite studies reported providing a post-core intervention consisting of six monthly sessions [12].

Following the intervention, weight loss reported at six months ranged from <1% [89, 104] to 3.3% [12] of baseline weight. Twelve-month weight loss was only reported by two of the worksite translations; both indicating an increase in the percent of weight loss compared to six months. The study by Aldana and colleagues reported 5.5% weight loss at 12 months while Dejoy and colleagues reported 1.4% weight loss at 12 months compared to baseline. Three out of four studies reported significant decreases in BMI at 6 months [12, 89, 104] and those significant decreases were maintained at 12 months in two of them [12, 89]. Two studies also reported significant decreases in waist circumference at six months [12, 30]. Other risk factor improvements at 6 months included blood pressure [104], fasting blood glucose [12], total cholesterol [12], LDL-cholesterol [12] and triglycerides [12]. At twelve months, one study reported improvements in fasting blood glucose and waist circumference [12].

All four worksite studies reported outcomes related to physical activity, however they were not assessed similarly across studies. Aldana and colleagues reported significant increases in aerobic fitness as measured by a submaximal aerobic fitness test following the intervention [12]. Physical activity was assessed using the International Physical Activity Questionnaire (IPAQ) in one study that reported significant increases in MET-hours of physical activity at 3 months [30]. A self-report measure that was not well explained indicated that approximately 50% of participants participated in regular exercise at both 6 and 12 months at the maintenance facility [89]. Lastly, the Baecke Questionnaire of Habitual Physical Activity was used to capture self-reported physical activity among participants in the study at multiple large employers where participants demonstrated a significant increase in physical activity following the intervention [104].

4.3 HEALTH CARE INTERVENTIONS

Labeled as healthcare-based translations, many of these interventions take place in outpatient medical clinics [27], ADA recognized diabetes education programs [13, 92, 105, 106] with strong community ties, primary care practices [15, 16, 26, 40], and academic hospital-based programs [29, 90]. A total of 10 different translations of the DPP have been implemented within the healthcare setting. The majority of studies were a pre-post non-randomized design [13, 15, 16, 26, 27, 90, 92, 103, 105-107], one was a controlled cohort [29] and one was a randomized controlled trial [40]. Translations in the healthcare setting have more similarities to those in the community than the worksite, and feature more precisely defined eligibility criteria. However, there is still a great deal of variety among them including lifestyle coach training, specific

adaptations to the DPP lifestyle intervention, reporting of weight change and other outcome data which makes it difficult to compare across studies.

Within the health care setting three of the studies did not specify a minimum BMI criteria [90, 103, 107], while all of the remaining studies required participants to have a BMI≥25kg/m^2 [13, 16, 26, 27, 29, 40, 92, 105, 106]. All studies only enrolled adults ≥ 18 years of age, with the exception of one requiring participants to be ≥ 25 years [27], another ≥21 years [15] and one that did not report an age criteria [90]. The study by McBride and colleagues also limited the age for eligibility at 75 years [90].

Identification of participants who were at high-risk varied between healthcare based studies, but featured a more rigorous definition than the worksite and closely mirrored the variability within the community. In addition to meeting BMI and age criteria, some studies required participants to possess one or more additional risk factor for diabetes [13, 15, 92, 105, 106], others required participants to have prediabetes [16, 26, 27, 40, 103] and/or the metabolic syndrome [16, 26, 27, 40, 107] and two studies only required physician referral indicating that weight loss was appropriate for the participant [29, 90]. One of the healthcare based translations allowed those with diabetes duration <6 months to participate [107].

The most consistent component across healthcare-based translations of the DPP was that they all reported using lifestyle coaches who were health professionals, something that was not consistent among the other translation settings. In addition to the consistency among lifestyle coaches, the studies that provided information regarding lifestyle coach training typically reported a two-day training led by a member of the DPP study staff [13, 16, 26, 27, 92, 105, 106], while only one reported generically that lifestyle coaches received training from study staff [15].

The length of the group adapted DPP interventions was most commonly 12 [15, 16, 26, 27, 29, 107] or 16[13, 90, 92, 103, 105, 106] core sessions followed by anywhere from 6 [13, 29, 92, 105, 106] to 9 [16, 26, 97] monthly follow-up contacts. Translations within the healthcare setting also provided unique examples of utilizing technology to expand the reach of diabetes prevention, including a DVD application [26, 40], a remotely broadcast telehealth intervention [92] and the use of the internet [91].

Like the other settings, weight loss was the primary outcome of the healthcare-based translations of the DPP, and was reported in a variety ways. Among studies reporting percent weight loss at the end of the core intervention, six reported a mean weight loss of at least 5% [13, 26, 27, 40, 105, 106]. The interventions that were implemented using DVD [26, 40] and telehealth [92] demonstrated similar levels of success regarding weight loss as the traditional face-to-face groups, with DVD studies reporting 4.9% [26, 40] to 5.6% weight loss and the telehealth study reporting weight loss of 7.7kg [92] following the core intervention. At the conclusion of the core intervention healthcare based studies reported significant reductions in FBG [26, 40, 103, 106], systolic [16, 26, 27, 103, 106, 107] and diastolic blood pressure [16, 27, 40, 103, 106, 107], triglycerides [27, 40, 103] and other risk factors. Outcomes related to physical activity were more frequently reported among healthcare based translations, typically in terms of the percent of participants meeting the 150-minute/week intervention goal [13, 15, 27, 92, 103, 105, 106]. The percentage of participants meeting to the 150-minute/week goal at the conclusion of the intervention ranged from 46% [15] to 70% [13] and all physical activity data was collected using subjective measures.

4.4 SUMMARY OF DPP TRANSLATION

In summary, a great deal of work has been done in the decade following the publication of the DPP to provide diabetes prevention services to those at high-risk with a high rate of success. However, with the degree of variability that exists among published translation studies it is difficult, if not impossible to come to any definitive conclusions about what the best approach may be, and the idea of a best approach may be different in different settings. In addition to the differences discussed previously, reporting of outcomes can be done following an intention to treat protocol [16] or completers analysis [13], and in some cases both are reported [16]. By definition, intention to treat means that all participants are included in the analysis regardless of their performance during intervention or at follow-up [108]. In contrast, "completers" analysis is at the discretion of the study author and has been reported in a variety of forms. For example, Amundson and colleagues defined completers as participants not missing more than three consecutive sessions or formally dropping out [13], while Kramer and colleagues defined completers as participants attending≥ 50% of sessions and the follow-up assessments [16].

A recent meta-analysis of DPP-based behavioral lifestyle interventions investigated effectiveness across categories grouped by delivery personnel that included health professionals, lay community members and electronic media assisted [109]. The authors provided conflicting conclusions regarding the findings of their study, at one point stating that interventions provided by lay community members may be associated with greater weight loss. However, there was no significant relationship between weight loss and any provider category, and although not significant, point estimates from the meta-analysis are in direct conflict of this assertion. The results suggest that interventions provided by health professionals achieve greater weight loss, 4.27% in comparison to 3.15% among interventions delivered by lay community members [109].

As described previously, a major limitation when making comparisons between DPP translations, and more specifically comparisons by delivery personnel, is the high degree of variability among many aspects of current translations.

In response to the diabetes epidemic and the necessity to provide high quality, standardized lifestyle interventions based on the DPP, the CDC has developed the Diabetes Prevention Recognition Program standards and operating procedures [33]. The aims of the DPRP standards are to ensure diabetes prevention interventions are evidence based, to develop and maintain a registry of approved programs and to provide technical assistance to diabetes prevention programs [33]. In addition, the DPRP standards require programs to provide standardized reports of participant outcomes to both qualify for and maintain their recognition. The standards suggest calculating attendance as an average number of core sessions attended by those who were present for a minimum four core sessions. Mean percentage of weight loss from baseline is the required reporting method for weight loss outcomes. Post-core attendance will similarly be calculated as an average number of sessions attended for participants who were present for a minimum four core sessions and weight loss is to be reported as a mean percentage from baseline for participants attending at least one post-core session. In light of evidence that demonstrates very little similarity in outcomes reporting among translations of the DPP, standardization may provide future translation efforts with a model to follow when publishing results and help facilitate comparison across intervention setting or delivery methods [33].

5.0 GROUP LIFESTYLE BALANCE

5.1.1 Group Lifestyle Balance Curriculum and Training

The DPP Group Lifestyle Balance (DPP-GLB) program is a modified version of the DPP lifestyle intervention that was completed by members of the DPP Lifestyle Resource Core who make up the Diabetes Prevention Support Center faculty at the University of Pittsburgh [16, 83]. Modifications made to the DPP that are included as part of the DPP-GLB were compacting the core curriculum from 16 to 12 sessions and providing the sessions to groups rather than individuals, a focus on healthy food choices rather than the food pyramid [82], an emphasis on both fat and calories from session 1, and including the pedometer in the core rather than the post-core. The majority of the fundamental aspects of the DPP behavioral lifestyle intervention were left unchanged in the adaptation of the DPP-GLB. These include the 7% weight loss and 150 minute/week of physical activity goals, delivery of the intervention by trained group leaders, strong emphasis on self-monitoring, the use of problem solving techniques to overcome barriers to healthy eating and physical activity, and adherence to a safe and effective intervention incorporating nutrition, physical activity and behavior change [16].

The DPSC is responsible for updating the DPP-GLB and functions in a similar capacity to the Lifestyle Resource Core of the DPP [83]. DPSC faculty members offer a 2-day workshop to health professionals providing them an overview of the DPP-GLB as well as instructions for implementation [16]. At the workshop, participants receive a review of the DPP background and results, the evidence supporting the weight loss and physical activity goals of the DPP-GLB, and instructions and tips for delivering all 22 DPP-GLB sessions. Additional instruction includes a

discussion regarding how to lead effective groups and planning for implementation in their setting. Attendees are provided with a complete manual of operations that includes a leaders guide and complete set of participant handouts. Following training, health professionals are also provided with ongoing implementation support from DPSC [16].

The 22-session DPP-GLB program, consisting of 12 core and 10 post-core sessions, is designed for implementation in traditional face-to-face groups or via a DPP-GLB-DVD. The face-to-face groups are typically 1-hour sessions, delivered by a DPSC trained lifestyle coach over the course of 1 year following a pattern of weekly, bi-weekly and monthly meetings. The DPP-GLB-DVD was developed in partnership with the US Air Force Center of Excellence for Medical Multimedia and is a series of 12 staged group sessions following a script based on the DPP-GLB participant handouts [26]. The DPP-GLB-DVD is not available for post-core sessions. Participants are asked to view the DVD on their own time and receive a 5-10 minute follow-up phone session with a DPSC trained lifestyle coach following each DVD where the main objectives of each session is discussed and any participant questions are addressed [26].

5.1.2 Group Lifestyle Balance Implementation

The DPP-GLB face-to-face group intervention has been implemented by DPSC trained lifestyle coaches and DPSC faculty in a variety of settings across the US, including primary care practices [16, 26, 40], outpatient diabetes education programs [27], community settings [28, 41, 101], and African American Churches [88]. The DPP-GLB-DVD has also been evaluated in primary care [26, 40] and in the community [41]. Additionally, the internet has served as a platform for DPP-GLB evaluation in a community setting [110]. Aside from one randomized controlled trial [40] most DPP-GLB implementations featured a pre-post non-randomized design to evaluate

the effectiveness of different DPP-GLB modalities [16, 26-28, 88, 101]. The widespread implementation of the DPP-GLB has set the stage for a larger, more robust evaluation of a DPP-GLB translation effort implemented in different settings where questions of effectiveness still remain.

5.2 THE HEALTHY LIFESTYLE PROJECT

The Healthy LIFESTYLE Project is a National Institute of Health funded effort to evaluate the delivery of the DPP-GLB in three settings including a worksite, community centers and the military. Although the DPP-GLB has been shown to be effective in reducing weight and improving risk factors for diabetes and CVD, a more robust evaluation with a larger sample size was needed to examine intervention effectiveness, but more importantly to gather information regarding how best to make community translation work in these three diverse settings. Each setting was chosen with sustainability and novelty in mind. The primary outcome of the study is significant weight change and secondary outcomes include fasting glucose, insulin, blood pressure, waist circumference lipids, physical activity and quality of life.

5.2.1 Study Design

The study is a randomized-controlled trial featuring a six month delayed control group. At baseline, two-thirds of eligible participants were randomized to receive the intervention immediately (IMMEDIATE group) and the other one-third was assigned to a delayed-control group (LATER group). Participants randomized to the immediate group were given the choice to

attend face-to-face meetings in their setting or to watch the 12 core sessions using the DPP-GLB-DVD. Following an approximately six-month delay, the control participants were given the same intervention choice, face-to-face group or DPP-GLB-DVD, as the immediate group. All participants attended assessment visits at baseline, and six, twelve and eighteen months after baseline. The University of Pittsburgh Institutional Review Board approved this project and all participants signed informed consent.

5.2.2 The Worksite

The worksite setting that was selected for implementation of the DPP-GLB in this study was a large, international corporate employer, in Allegheny County, Pennsylvania. Healthy LIFSTYLE Project investigators met with the worksite medical director to establish interest in program delivery at the site, and then proceeded to elicit support from the executive management team. Approximately 1,800 individuals are employed at the worksite's Allegheny County campus, and they along with their family members were recruited to take part in the worksite-based intervention. The worksite is a very important component to the study as very little evidence has been published regarding the effectiveness of lifestyle interventions to prevent diabetes in this setting.

5.2.3 The Community

Three community sites were selected for implementation through a partnership with Allegheny County Health Department Area Agency on Aging program officials and Healthy

LIFESTYLE Project investigators. The three sites represented varying levels of socioeconomic status across the county. Two of the sites are located in surrounding suburbs and one is located in a neighborhood within the city of Pittsburgh, Pennsylvania. The two suburban sites serve primarily as gathering places for area senior citizens to socialize, play games, attend educational programs and participate in formal and informal physical activity. One of the suburban sites serves lunch Monday through Friday. The community site within the city primarily functions as a recreational facility, but also offers classes to community members and houses a school. Participants were not required to have any affiliation with the community centers and all who were able to attend assessment visits and intervention sessions were able to participate pending confirmation of eligibility criteria and physician referral.

5.2.4 The Military

The Healthy LIFETYLE Project staff collaborated with a Certified Diabetes Educator and DPP-GLB trained lifestyle coach at the Wright-Patterson Air Force Base in Dayton, OH. The DPP-GLB program has been provided previously at Wright Patterson Medical Center (WPMC), and there are several DPP-GLB trained lifestyle coaches on staff. However, the success of the DPP-GLB has never been formally evaluated in the military and this partnership will be valuable for both parties. The investigation at the military site has just been recently initiated and implementation of the DPP-GLB program at the military site will not be discussed in this dissertation.

5.2.5 Recruitment of Participants

At the worksite, information was provided to potential participants through email, print advertisements, health fairs and information session. Posters were displayed in high-traffic areas on the worksite campus along with table tents in a popular dining facility. Study staff members were also present to discuss the upcoming screening and intervention with employees at health fairs. In the community, study investigators conducted information sessions regarding screening and the upcoming intervention at several community centers that were open to anyone to attend. A targeted mass mailing to residents within one mile of two of the three community centers was also distributed.

5.2.6 Screening and Eligibility Criteria

Eligibility screening followed a multi-tiered approach. Initial eligibility criteria were first assessed over the phone or in-person at health fairs and were followed by an in-person screening at each site. The initial screening insured participants were adults ≥18 years of age, without diagnosed diabetes, with a BMI ≥24kg/m^2 (≥22 kg/m^2 for Asians), were not pregnant or breastfeeding, and were not planning to move away from the area during the projected study time period. Participants who answered "no" to all of these questions and were interested in taking part in the intervention were scheduled to attend an onsite in-person screening. At the onsite screening participants completed assessments of blood pressure, height, weight and waist circumference following standard protocol. The Cholestech LDX system was used to measure total cholesterol, High-density lipoprotein cholesterol (HDL-C), Low-density lipoprotein cholesterol (LDL-C), triglycerides and glucose after a minimum 8-hour fast, and hemoglobin A1c was measured using

a Siemens/Bayer DCA 2000 by a certified research assistant. Additional information collected for each participant included date of birth, gender, family history of diabetes and heart disease, smoking status, race/ethnicity, employment status, physical activity level, education level, prescription medication use for blood pressure, dyslipidemia and dysglycemia and other female risk factors for diabetes including history of giving birth to an infant >9 lbs., history of gestational diabetes (GDM) and polycystic ovary syndrome (PCOS). Participants also completed the 7 question ADA risk test [31, 33]. Intervention eligibility criteria included: BMI $\geq$24kg/m^2 or $\geq$22 kg/m^2 for Asians, prediabetes (fasting glucose of 100-125mg/dl and/or HbA1C of 5.7%-6.4%), and/or the metabolic syndrome (National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) criteria or hyperlipidemia and 1 additional component of the metabolic syndrome) [111, 112].

After eligibility was determined and before the baseline randomization visit was completed, participants meeting criteria were required to attend an in-person or telephone information session. At the information session participants were provided with background about the DPP lifestyle intervention and its success, details regarding their participation in the DPP-GLB program and their option to choose a face-to-face group and DVD intervention. They were also informed the two-thirds of participants would be randomized to begin the intervention of their choice immediately following the baseline visit and one-third would be randomized to a six-month delayed intervention control group.

5.2.7 Assessment Visits

Complete assessment visits were conducted at baseline (pre-intervention), and at two times during the one-year intervention (6 and 12 months). A trained research assistant following

standard protocol measured blood pressure, pulse, height, weight, and waist circumference. A venous blood draw was taken to assess total cholesterol, High-density lipoprotein cholesterol (HDL-C), Low-density lipoprotein cholesterol (LDL-C), triglycerides, glucose, hemoglobin A1C and insulin following a minimum 8-hour fast and analyzed at local laboratories. Prescription medication use, health history and the Modifiable Activity Questionnaire (MAQ), and a Lifestyle Questionnaire were completed via participant interview. Participants were also asked to complete the EQ-5D quality of life measure, a cost survey, a willingness questionnaire, a 7-day log of steps using a study issued pedometer and to collect 14 days of food receipts.

A less detailed assessment visit which was completed 6 months after the conclusion of the intervention (18 months) and included assessment of weight and waist circumference, the Lifestyle Questionnaire, and the 7-day log of steps using a study issued pedometer. For the delayed control group, this assessment was completed at 24 months following baseline.

5.2.8 Intervention Delivery

The DPP-GLB program is a one-year 22-session behavioral lifestyle intervention based on the DPP [16, 83]. Following randomization to IMMEDIATE or LATER intervention, participants had the choice to enroll in a face-to-face group or DVD based intervention [26]. Face-to-face groups met weekly for the first 12 sessions with a DPP-GLB trained lifestyle coach. At each in-person session participants were weighed, turned in self-monitoring records, received new session materials and took part in a 1-hour lesson covering the day's topic(s). Participants who missed a face-to-face session were provided with the DVD and instructed to view it as a make-up session.

Participants who chose the DVD intervention watched the first 12 sessions on their own and also attended three scheduled in-person group meetings with a lifestyle coach at sessions one,

five, and nine during the core intervention. At these meetings DVD participants had an opportunity to discuss any issues encountered in the previous sessions, be weighed, receive session handouts for future sessions and turn in their self-monitoring records. During weeks when a group meeting did not occur, DVD participants received weekly phone or email support from their lifestyle coach, including feedback on their self-monitoring records. Following the initial 12-sessions face-to-face and DVD participants were invited to attend 1-hour group sessions, which transitioned to bi-weekly and then monthly sessions over the course of one year.

During the six-month delay, LATER group participants received handouts that were mailed to them approximately every six weeks to help promote engagement and retention. The handouts covered topics such as the importance of staying hydrated during physical activity, selecting a good pair of shoes and tips for being active outdoors.

5.2.9 Self-Monitoring

During the initial DPP-GLB intervention sessions, participants were instructed to begin daily self-monitoring of diet and weight following session 1, daily physical activity minutes following session 4 and daily steps following session 10. They were encouraged to continue self-monitoring throughout the program. Methods of self-monitoring included paper keeping track books or other readily available online tracking programs that could be printed out or submitted via email or postal mail to their lifestyle coach.

During the intervention, both face-to-face and DVD participants submitted their self-monitoring information to their lifestyle coach either in-person or via email or postal mail. Coaches documented diet and physical activity monitoring frequency on a scale of 0-7, based on the number

of days per week the participant monitored each behavior. Coaches also documented the total number of activity minutes and steps.

5.2.10 Evaluation

The primary outcome of this study is weight loss evaluated at six months post-intervention for the intervention group compared to the delayed control group. Secondary outcomes include change in physical activity, fasting glucose, insulin, blood pressure, waist circumference, lipids and quality of life.

6.0 PAPER #1: EVALUATION OF NON-INVASIVE SCREENING MEASURES TO IDENTIFY INDIVIDUALS WITH PREDIABETES

The following chapter will provide an overview of the background, methods and findings of Paper 1 which is attached as APPENDIX A.

6.1 OVERVIEW OF PAPER # 1

Development of a simple, inexpensive method, such as a paper risk test or application of an anthropometric measurement, to identify high-risk individuals who could benefit from lifestyle intervention is desirable due to the large number who are at risk for type 2 diabetes. In translation of the DPP, several studies have reported use of the 7 question American Diabetes Association (ADA) paper risk assessment developed by Herman et al. in 1995[11, 14, 30, 31]. The ADA risk test assesses 7 historical risk factors for diabetes that increase an individuals' risk for having undiagnosed type 2 diabetes as determined by the tests final score [31]. However, it was not developed to identify participants with prediabetes for diabetes prevention programs [32]. Lifestyle interventions using the ADA risk test determined intervention eligibility [30] or eligibility to take part in further screening [11, 14] by a score of $\geq$10.

Although the ADA risk test was not originally developed as a prediabetes identification tool, it is included in the standards and operating procedures of the CDC National Diabetes Prevention Recognition Program (DPRP) for that purpose, likely due to a lack of viable, cost-efficient, non-invasive screening methods [33]. The cut point for program inclusion set by the

CDC DPRP is a score ≥9 on the ADA risk test. In addition to paper risk tests, others have evaluated anthropometric measurements such as BMI[34-37], waist circumference[34, 35, 37], and waist to height ratio[34, 35, 37, 38] for their ability to provide details about an individual's future risk for type 2 diabetes. However, to the author's knowledge, no translations of the DPP lifestyle intervention have evaluated anthropometric measurements for their ability to identify high-risk participants.

Therefore, the aims of this paper are to evaluate the ability of the ADA risk test in as well as other non-invasive body composition measures to identify individuals with prediabetes as measured by fasting blood glucose or hemoglobin A1c. In addition the utility of these alternate screening methods to ascertain the presence of the metabolic syndrome is assessed.

6.1.1 Setting

This evaluation included all participants who were screened at the worksite and all three community intervention sites and is a secondary analysis of the randomized trial evaluating the effectiveness of the DPP-GLB with the primary study outcome of weight loss.

6.1.2 Measures

6.1.2.1 Demographics

Demographic data were collected at the onsite screening visit and included date of birth, gender, family history of diabetes and heart disease, smoking status, race/ethnicity, employment status, and education level.

6.1.2.2 ADA Risk Test

Participants were asked to complete the ADA risk test that assesses 7 historical risk factors for diabetes. The CDC DPRP suggests using a score of ≥9 to identify eligible participants. This is the cut-point that was used for identification of prediabetes and other eligibility criteria in this paper [33]. The ADA risk test was originally developed by Herman et al. in 1995[11, 14, 30, 31].

6.1.2.3 Anthropometric Tests

Anthropometric measures (BMI, waist circumference and waist to height ratio) were evaluated singularly and in combination with other diabetes risk factors (e.g. family history, physical inactivity) for their ability to identify eligible participants with prediabetes, and/or the metabolic syndrome. A BMI cut-point of ≥27kg/m^2 was selected for evaluation because it is the point at which an individual is considered to be at increased risk according to the BMI question on the ADA risk test [33, 113]. Waist circumferences of >102 centimeters (40 inches) for men and > 88centimeters (35 inches) for women, based on the NCEP ATPIII guidelines for metabolic syndrome [111] and waist to height ratios of ≥0.5 and ≥0.6, selected based on previous investigations, were also evaluated [37, 114, 115]. Each measure was examined individually and combined with other easily acquired information (i.e. family history and physical activity habits) to examine any improvements in sensitivity and specificity that these combinations might provide.

6.1.2.4 Laboratory and Anthropometric Data

At the onsite screening the Cholestech LDX system was used to measure total cholesterol, High-density lipoprotein cholesterol (HDL-C), Low-density lipoprotein cholesterol (LDL-C), triglycerides and glucose after a minimum 8-hour fast, and a certified research assistant measured

hemoglobin A1c using a Siemens/Bayer DCA 2000. Trained research staff completed assessments of participant blood pressure, height, weight and waist circumference following standard protocol.

6.1.3 Statistical Analysis

Differences among baseline characteristics between sites were evaluated using two sample independent t-tests for normally distributed variables and the Wilcoxon-Mann-Whitney test for variables not normally distributed. The Chi-square test was used to test for differences in proportions or Fisher's exact test when groups had less than five participants. Sensitivity and specificity were calculated for the ADA risk test scores of 9 through 13, BMI≥27kg/m^2, BMI≥30kg/m2, BMI≥27kg/m^2 plus family history of diabetes, BMI≥27kg/m^2 plus self-report of physical activity <30 minutes per week, BMI≥27kg/m^2 plus self-report of physical activity <3 days per week, waist to height ratio ≥0.5, waist to height ratio ≥0.5 plus family history of diabetes, waist to height ratio ≥0.6, waist to height ratio ≥0.6 plus family history of diabetes, waist circumference >40 inches for men and >35 inches for women and waist circumference >40 inches for men and >35 inches for women plus family history of diabetes in relation to prediabetes, the metabolic syndrome and both eligibility combined using the PROC FREQ procedure. Receiver operating characteristic (ROC) curves were calculated for the ADA risk test score of ≥9, BMI≥27kg/m^2, BMI≥27kg/m^2 plus family history of diabetes, BMI≥27kg/m^2 plus self-report of physical activity <30 minutes per week, BMI≥27kg/m^2 plus self-report of physical activity <3 days per week, waist to height ratio ≥0.5, waist to height ratio ≥0.6 and waist circumference >40 inches for men and >35 inches for women using the PROC LOGISTIC procedure.

Data analyses were conducted using Statistical Analysis Software Version 9.3 (Cary, NC).

6.1.4 Baseline Demographic and Anthropometric Characteristics

A total of 364 participants were screened onsite, 64% (233) were female, mean age was 55.8 ±12.5 years, mean BMI was 33.4±6.2 kg/m^2 and mean weight was 93.3±20.1 kg. Forty-seven percent of participants reported a family history of diabetes, 45% reported a family history of heart disease, and 22% reported both a family history of diabetes and heart disease (Table 2). Participants were predominately white (92.5%), 89% had at least some college or technical school at screening and 93% were either never or former smokers (Table 2).

Because of the diversity of the study sites, demographic characteristics are presented by screening site. Those screened at the worksite (n=160) were significantly younger, had a significantly lower BMI, waist circumference and hemoglobin HbA1c than those screened at the community sites. Community site screening participants (n=204) had significantly lower total cholesterol, LDL cholesterol and diastolic blood pressure than those screened at the worksite. Other significant differences between the sites included the percent of female participants, level of education and smoking status.

6.2 PAPER #1 SUMMARY

Purpose: Because blood-based screening to identify those with prediabetes to take part in Diabetes Prevention Program (DPP) translation efforts can be costly and time-consuming, non-invasive methods are needed. The aims of this paper are to evaluate the ability of the American Diabetes Association (ADA) risk test in identifying individuals with prediabetes, as well as the

use of body composition measures for this purpose. In addition the utility of these alternate methods to ascertain the presence of the metabolic syndrome will be assessed.

Methods: Potential participants were recruited from a worksite and three community centers as part of a DPP translation study. Participants completed onsite screening where anthropometric measures, fasting lipids and glucose, and hemoglobin A1c were assessed. The ADA risk test and other body composition measures were evaluated for their ability to identify those with prediabetes based on clinically measured values. These methods were also assessed for their usefulness in detecting those with the metabolic syndrome.

Results: All non-invasive methods were highly sensitive (68.9% to 98.5%) in the detection of prediabetes, but specificity was low (6.7% to 44.5%). None of the alternatives evaluated achieved acceptable discrimination levels in ROC analysis. Similar results were noted in identifying the metabolic syndrome.

Conclusions: The non-invasive methods evaluated in this study effectively identified participants with prediabetes, but would have allowed for enrollment of a large number of individuals without prediabetes. Deciding whether to use these alternatives, blood-based measures, or a combination of both will ultimately depend on the purpose of the program and the level of flexibility regarding participant eligibility related to prediabetes status or the use of other risk factors.

7.0 PAPER #2: EVALUATING THE IMPACT OF A PRE-INTERVENTION DELAY ON PARTICIPANTS SUCCESS IN A COMMUNITY DIABETES PREVENTION EFFORT

The following chapter will provide an overview of the background, methods and findings of Paper 2, which is attached as APPENDIX B.

7.1 OVERVIEW OF PAPER # 2

In translation of the DPP into the community, individuals at risk for diabetes and/or cardiovascular disease (CVD) may encounter a waiting period prior to receiving intervention. A delay of weeks or months can occur due to the time it takes to identify those at risk and enroll them in the prevention program. Pre-intervention delays may also occur because organizations providing prevention programs have inadequate staffing levels and therefore can only offer a limited number of programs at one time [17].

In community based DPP translation studies, little is reported regarding the impact of lag time from enrollment to the start of intervention. It is common for studies to provide descriptions of the screening and eligibility confirmation process, but the time from the initiation of these processes to start of intervention is typically not reported [11, 15, 29, 39-41]. Some studies have also described the length of the screening and recruitment process itself, with time periods ranging from nine months to a year [11, 27, 41] or two years [39], but to the authors' knowledge, no DPP

translation studies have reported on wait times incurred by participants prior to intervention, or the impact of these pre-intervention delays on participant outcomes.

One impact of lengthy pre-intervention time delays that appears particularly important to examine is the effect of any weight change that may occur during this time period. To date, one study has investigated pre-intervention weight change in the context of a behavioral lifestyle intervention (categorizing participants as weight losers, weight maintainers and weight gainers based on weight change during the time from screening to the first intervention session) [42]. The results of this study indicated that weight losers achieved significantly greater weight loss, attended more intervention sessions and completed more self-monitoring records overall than either their weight gaining or weight maintaining counterparts at 6 months [42].

The purpose of this paper is to evaluate the impact of a pre-intervention time delay on participant weight loss and PA outcomes at two time points (6 and 12 months) during a one-year behavioral lifestyle intervention and to evaluate the effects of pre-intervention weight change during this delay on similar outcomes. The high probability of a waiting period occurring before enrollment in a community based DPP translation combined with the lack of knowledge about the association between wait times and participant success validates the importance of this current investigation.

7.1.1 Setting

This evaluation included all participants who met study eligibility criteria at the worksite and the three community centers and is a secondary analysis of a randomized trial evaluating the effectiveness of the DPP-GLB with the primary study outcome of weight loss.

7.1.2 Delayed Intervention Control Group

During the six-month delay, control group participants received approximately monthly mailings to keep them engaged in the study. The mailings covered topics such as the importance of staying hydrated during physical activity, selecting a good pair of shoes and tips for being active outdoors.

7.1.3 Measures

7.1.3.1 Demographics

Demographic data were collected at the onsite screening visit and included date of birth, gender, family history of diabetes and heart disease, smoking status, race/ethnicity, employment status, and education level.

7.1.3.2 Self-monitoring and Attendance

Self-monitoring of diet was calculated as the number of weeks a participants recorded dietary intake ≥4 days per week during the core, post-core and as a total. Self-monitoring of physical activity was calculated in a similar DPP-GLB. Attendance was also documented at each session and recorded as an in-person, telephone, email or other contact.

7.1.3.3 Laboratory Data and Anthropometrics

At the onsite screening the Cholestech LDX system was used to measure total cholesterol, High-density lipoprotein cholesterol (HDL-C), Low-density lipoprotein cholesterol (LDL-C),

triglycerides and glucose after a minimum 8-hour fast, and a certified research assistant measured hemoglobin A1c using a Siemens/Bayer DCA 2000. Trained research staff completed assessments of participant blood pressure, height, weight and waist circumference following standard protocol.

At the baseline assessment visit and at 6 and 12 months a trained research assistant following standard protocol measured blood pressure, pulse, height, weight and waist circumference. A venous blood draw was taken to assess total cholesterol, High-density lipoprotein cholesterol (HDL-C), Low-density lipoprotein cholesterol (LDL-C), triglycerides, glucose, hemoglobin A1C and insulin following a minimum 8-hour fast and analyzed at a local laboratory. Prescription medication use, health history and the Modifiable Activity Questionnaire (MAQ) were completed via participant interview and participants were asked to complete the EQ-5D quality of life measure, a willingness questionnaire and a cost survey. Participants were also interviewed regarding their current lifestyle habits using a Lifestyle Questionnaire that assessed current diet and activity monitoring frequencies, the number of days they engaged in physical activity, average minutes of activity per session and how frequently they achieved fat, calorie and physical activity goals.

7.1.3.4 Pre-Intervention Delay and Weight Change Categories

As a result of the randomized-delayed control group design the current study had the unique ability to evaluate the impact of a pre-intervention delay on participant success. The pre-intervention delay was calculated as the length of time from screening to the first intervention session. During the pre-intervention delay participants were also classified into three weight change categories. Weight gainers were defined as gained ≥3 pounds, weight losers were defined as lost ≥3 pounds and weight maintainers were defined as gained <3 pounds and lost <3 pounds.

Support for the 3 pound threshold comes from evidence that < 3 pounds of weight fluctuation could occur due to normal changes in fluid balance [116], and is in line with what other investigations have used[42] [117].

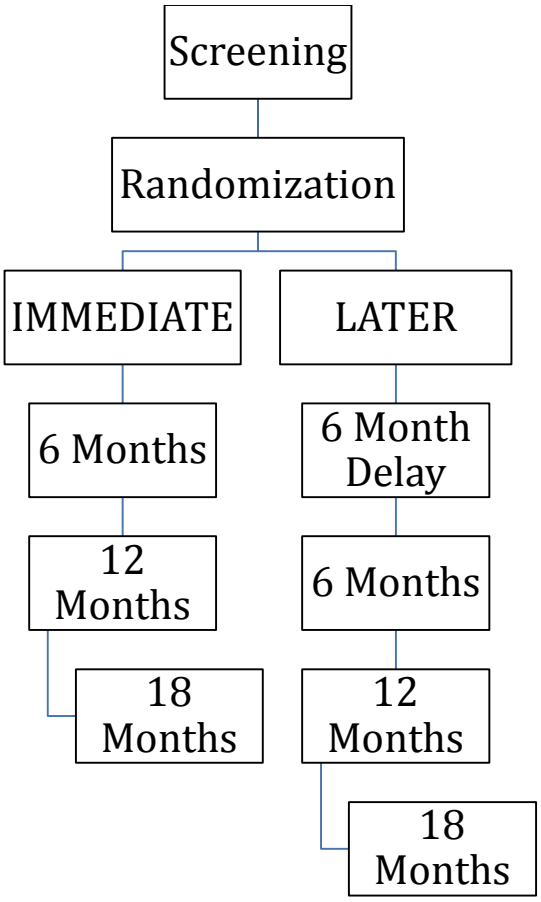

Figure 7-1: Randomized-delayed control group study design.

7.1.4 Statistical Analyses

Screening characteristics among those who attended all assessment visits, i.e., baseline, 6 and 12 months, and had complete data were compared to those with missing data using two sample independent t-tests for normally distributed variables and the Wilcoxon-Mann-Whitney test for variables not normally distributed. The Chi-square or Fisher's exact test was used to test for differences in proportions.

To examine differences in weight loss at 6 and 12 months between the IMMEDIATE and LATER groups, two sample independent t-tests were used. Differences between the two groups for intervention attendance, self-monitoring and MET hours of leisure PA were compared using the Wilcoxon-Mann-Whitney test. This evaluation was conducted for all participants combined and stratified by site, age (age<55 and age≥55), gender and education (education < bachelors degree, education ≥ bachelors degree).

Weight change at 6 and 12 months among the three pre-intervention weight change categories was evaluated using one-way ANOVAs. Intervention attendance, self-monitoring and MET hours of self-reported leisure PA were evaluated among the three weight change categories using the Kruskal-Wallis test because outcomes were not normally distributed. This evaluation was also completed for all participants combined and stratified by site, random assignment, age, gender and education.

Comparisons between IMMEDIATE and LATER groups and across the three pre-intervention weight change groups were conducted for participants with complete data from each time point and utilizing the last observation carried forward method for those with missing data. Outcomes are reported for those with complete data from each time point unless otherwise noted. Data analyses were completed using Statistical Analysis Software Version 9.3 (Cary, NC).

7.1.5 Baseline Demographic and Anthropometric Characteristics

A total of 223 participants attended the baseline randomization visit; of that number 174 (78%) attended the baseline, 6 and 12 month assessments and had complete data at all time points for these current analyses (worksite N=69, community center N=105). The 49 participants without complete data had significantly greater mean weight (p=0.02), BMI (p=0.002) and waist circumference (p=0.02) (data not shown) at screening compared to those with complete data. However, random assignment to either the IMMEDIATE (n=28) or LATER (n=21) group (p=0.1) was not significantly different among those without complete data. Participants with complete data had a mean age of 59±11.1 years, mean BMI of 33.1±5.5 m/kg^2, and mean weight of 205±41.5 lbs at screening. Sixty percent of these participants were female, the majority possessed a bachelors or graduate degree, and 56% were employed full time (>35 hours per week) (Table 7-1).

Table 7-1: Characteristics at the time of screening among participants who attend the randomization visit at the worksite and three community centers (N=174).

	Combined (N=174)
	Mean (SD) **Median (IQR)**
Age (n=174)	59 (11.1) 58.7 (51.8-67)
Body mass index, kg/m^2 (n=174)	33.1 (5.5) 32.1 (29.5-36.6)
Weight, lbs (n=174)	205 (41.5) 196.4 (176.6-223)
Waist circumference, in (n=174)	41.8 (5.1) 41.2 (39-44)
Total Cholesterol (n=174)	192.2 (36.9) 192.5 (167-217)
LDL Cholesterol (n=164)	109.9 (32.1) 109 (87.5-133)
HDL Cholesterol (n=169)	49.5 (14) 48 (39-58)
Triglycerides (n=171)	163 (81.1) 143 (111-199)
Glucose (n=174)	98.2 (9.7) 98 (92-104)
Hemoglobin A1c (n=174)	5.7 (0.3) 5.7 (5.5-5.9)
Systolic Blood Pressure (n=174)	120.1 (12.1) 119 (111-128)
Diastolic Blood Pressure (n=174)	76.1 (10.4) 77 (68-84)
Gender	**% (n)**
Male	40 (70)
Female	60 (104)
Education	
Some High School	0.5 (1)
High School Graduate/GED	9.5 (17)
Some College or technical school	23 (40)
College graduate (bachelor's)	33 (58)
Graduate degree	33 (58)
Employed	
Full time (≥35hrs/week)	56 (98)
Part-time (<35hrs/week)	14 (8)
Unemployed/laid off & looking	2 (4)
Homemaker	3 (6)
Retired	28 (49)
Disable/unable to work	3 (6)
Smoke	
Never	61 (106)
Former	32 (55)
Current	7 (13)

7.1.6 Weight loss and adherence at 6 and 12 months among pre-intervention weight change groups

Among all participants combined, there was a significant difference in the pre-intervention delay length from screening to the time first intervention session between the three pre-intervention weight change groups (F=8.7, p=0.01). During the pre-intervention delay 35% (61) participants were categorized as weight gainers, 42% (73) as weight maintainers and 23% (40) as weight losers among those with complete data (Table 7-2). Percent weight loss at 6 (p=0.1) and 12 (p=0.1) months did not significantly differ among the three pre-intervention weight change categories groups nor did intervention attendance, frequency of self-monitoring of diet and PA and MET hours of leisure PA (Table 7-2). When stratified by random assignment the same relationships were documented except the difference in pre-intervention delay length was no longer significant (Table 7-3). Similar results were seen when applying the last observation carried forward method of analysis.

Further stratification of comparisons across the three weight change groups by intervention site, gender, age (age<55, age ≥55), and education (education < bachelors degree, education ≥ bachelors degree) yielded similar results as the combined analysis for weight and PA outcomes. The pre-intervention delay was not significantly different among women, but was significantly different among men (p=0.04). Among those age<55 significant differences were present for pre-intervention delay length (p=0.003) and among those age ≥ significant differences were present in the number of core contacts (p=0.04). Finally, pre-intervention delay length among those with education < bachelors degree was significantly different (p=0.02) across the three weight change groups.

Table 7-2: Weight loss, attendance, self-monitoring and self-reported leisure time PA levels following 6 and 12 months stratified by pre-intervention weight change group based on the delay from screening to first intervention visit among all participants combined

	Gainer N=61	**Maintainer N=73**	**Loser N=40**
Outcome Variable	Mean (SD) Median (IQR)	Mean (SD) Median (IQR)	Mean (SD) Median (IQR)
Percent weight loss at 6 months	4.9 (4.0) 4.4 (2.2-7.4)	6.0 (5.5) 6.0 (2.6-9.3)	6.9 (4.0) 6.4 (4.2-9.2)
Percent weight loss at 12 months	4.0 (5.3) 3.5 (1.1-7.1)	5.6 (6.6) 5.4 (0.6-10.4)	6.2 (6.2) 5.4 (2.3-9.4)
Length of Intervention Delay*	166.7 (89) 123 (105-259)	142.7 (80.7) 118 (96-175)	189.9 (90.7) 149.5 (118-278.5)
Total number of sessions attended	17 (4.7) 18 (14-21)	17.3 (5.1) 19 (15-21)	19 (3) 20 (17.5-22)
Number of core sessions attended	13.4 (2.9) 14 (12-16)	13.6 (3.3) 15 (13-16)	14.7 (1.5) 15.5 (13.5)
Number of post-core sessions attended	3.6 (2.2) 4 (2-6)	3.9 (2.2) 5 (2-6)	4.4 (1.9) 5 (4-6)
Total number of diet records submitted	15.6 (12.1) 12 (7-23)	16 (12.4) 13 (7-23)	17.5 (12.3) 12.5 (9-22.5)
Number of core diet records submitted	11.9 (6.6) 12 (7-18)	12.1 (6.7) 12 (7-18)	13.1 (5.7) 12 (9-18.5)
Number of post-core diet records submitted	3.7 (6.7) 0 (0-5)	4.1 (7.1) 0 (0-6)	4.5 (8.2) 0 (0-5)
Total number of activity records submitted	11 (11.9) 7 (2-15)	11.7 (11.8) 7 (2-18)	13.7 (12.3) 9.5 (5-18.5)
Number of core activity records submitted	7.6 (6.3) 7 (2-12)	8.2 (6.3) 6 (2-14)	9.4 (5.8) 9 (4.5-14)
Number of post-core activity records submitted	3.3 (6.6) 0 (0-2)	3.7 (6.7) 0 (0-4)	4.4 (8.2) 0 (0-4)
Self-reported leisure PA at 6 months (MET hrs)	30.6 (28.6) 22.6 (13-40.6)	26.7 (22.3) 21.8 (9.6-32.4)	30.5 (23.6) 25.6 (14.9-41.1)
Self-reported leisure PA at 12 months (MET hrs)	22.4 (23.1) 12 (8.2-30.3)	21.0 (16.8) 17.9 (8.9-29.3)	29.2 (22.5) 22.4 (9.0-45.1)

Table 7-3: Reporting of outcome variables for all participants combined among pre-intervention weight change categories based on the delay from screening to first intervention visit and stratified by random assignment (N=174).

	IMMEDIATE			**LATER**		
	GAINER (N=41)	**MAINTAINER (N=56)**	**LOSER (N=23)**	**GAINER (N=20)**	**MAINTAINER (N=17)**	**LOSER (N=17)**
Outcome Variable	Mean (SD) Median (IQR)	Mean (SD) Median (IQR)	Mean (SD) Median (IQR)	Mean (SD) Median (IQR)	Mean (SD) Median (IQR)	Mean (SD) Median (IQR)
Percent weight loss at 6 months	4.3 (3.6) 4.1 (2.3-6.7)	6.1 (5.7) 6.2 (2.6-9.6)	7.5 (3.4) 7.3 (4.6-9.6)	6.0 (4.7) 4.8 (1.5-9.3)	6.0 (4.8) 5.7 (2.9-9.0)	6.0 (4.7) 5.3 (3.6-6.8)
Percent weight loss at 12 months	3.2 (5.2) 3.4 (0.7-5.8)	5.8 (6.8) 6.4 (0.5-10.7)	5.3 (4.9) 3.9 (1.7-9.6)	5.5 (5.4) 4.7 (1.7-8.1)	5.1 (6.0) 3.9 (0.9-8.0)	7.4 (7.6) 5.5 (2.9-8.7)
Length of Intervention Delay*	107.4 (21.5) 111 (96-123)	104.3 (43.1) 102.5 (82.5-124.5)	116.9 (26.5) 120 (102-128)	288.1 (31.3) 290.5 (262-304)	269.2 (27.9) 266 (247-293)	288.6 (33.2) 285 (263-304)
Total number of sessions attended	16.7 (5) 18 (14-21)	17 (5.2) 19 (14.5-21)	18.8 (3.1) 20 (18-21)	17.7 (4.1) 19 (16-21)	18.1 (4.7) 20 (17-21)	19.1 (3.0) 20 (17-22)
Number of core sessions attended	13.2 (3.1) 14 (12-16)	13.4 (3.3) 14.5 (12-16)	14.8 (1.6) 16 (14-16)	13.9 (2.5) 15 (12-15.5)	14.2 (3.3) 16 (14-16)	14.6 (1.5) 15 (13-16)
Number of post-core sessions attended	3.5 (2.3) 4 (1-6)	3.8 (2.3) 5 (2-6)	4.2 (1.9) 5 (4-6)	3.9 (2.1) 4 (2.5-6)	3.9 (1.9) 4 (4-5)	4.5 (2) 5 (4-6)
Total number of diet records submitted	13.9 (10.9) 11 (6-19)	16.3 (13.2) 13 (5-25)	15.2 (10.4) 11(8-21)	19.1 (13.9) 15 (8.5-27)	15.2 (9.4) 12 (9-20)	20.7 (14.3) 15 (11-33)
Number of core diet records submitted	10.9 (6.2) 11 (6-16)	11.6 (6.7) 11.5 (5-17.5)	12.4 (5.8) 11(8-18)	13.9 (7.1) 15 (8.5-21)	13.6 (6.7) 12 (9-20)	14.1 (5.7) 12 (9-20)
Number of post-core diet records submitted	3 (5.9) 0 (0-3)	4.9 (7.7) 0 (0-8)	2.9 (6) 0 (0-3)	5.2 (8.2) 0 (0-6)	1.6 (3.8) 0 (0-1)	6.6 (10.34) 0 (0-10)
Total number of activity records submitted	10 (11) 7 (2-15)	12.2 (12.5) 7 (1.5-20)	11.2 (10.6) 8 (3-18)	12.9 (13.7) 8.5 (2.5-19)	10.1 (9.2) 6 (3-14)	16.9 (14) 10 (6-29)
Number of core activity records submitted	7.1 (6.1) 6 (2-12)	8.1 (6.4) 6.5 (1.5-14)	8.6 (6.1) 8 (3-14)	8.7 (6.8) 8 (2.5-15)	8.5 (6.3) 6 (3-14)	10.4 (5.5) 10 (5-14)
Number of post-core activity records submitted	2.9 (5.9) 0 (0-2)	4.3 (7.3) 0 (0-6)	2.8 (6) 0 (0-2)	4.3 (8) 0 (0-5)	1.5 (3.7) 0 (0-1)	6.5 (10.3) 0 (0-9)
Self-reported leisure PA at 6 months (MET hrs)	36.5 (30.8) 26.2 (16.6-50.6)	31.7 (23.1) 27.6 (15.2-39.2)	36.9 (24.6) 31.5 (20.8-43)	18.4 (19.1) 11.6 (3.1-32.8)	10.1 (5.7) 8.84 (5.9-13.3)	21.8 (19.6) 13.8 (8.1-28)
Self-reported leisure PA at 12 months (MET hrs)	20.6 (24.1) 11.3 (8-23)	20.1 (18.2) 14.1 (8.3-28.7)	24 (22.1) 17 (7-35.9)	26.4 (20.8) 18.4 (8.6-42.0)	23.9 (10.8) 25.7 (16.9-30.5)	36.7 (21.5) 39.9 (18.7-48.4)

7.1.7 Distribution of weight change groups

The distribution of pre-intervention weight change categories was evaluated in the same way described above based on weight change that occurred from the time of screening to the time of first intervention visit (Table 7-4). The distribution of weight gainers, weight maintainers and weight losers was not significantly different when stratified by site (p=0.9) or when stratified by site and random assignment (IMMEDIATE p=0.3, LATER p=0.1). In addition, the proportion of participants selecting DVD or group intervention was not significantly different across the three weight change groups (p=0.1).

Table 7-4: Percent and frequency of participants categorized as pre-intervention weight gainers, weight maintainers and weight losers combined across sites, by site and by random assignment.

	ALL (N=174)	**WORKSITE (N=69)**	**COMMUNITY (N=105)**
Weight Change Category from Screening to first intervention visit	**% (n)**	**% (n)**	**% (n)**
Weight gainers	35 (61)	42 (29)	30 (32)
Weight maintainers	42 (73)	42 (29)	42 (44)
Weight losers	23 (40)	16 (11)	28 (29)
	IMMEDIATE (n=120)	IMMEDIATE (n=49)	IMMEDIATE (n=71)
Now Weight gainers	34 (41)	43 (21)	28 (20)
Now Weight maintainers	47 (56)	45 (22)	48 (34)
Now Weight losers	19 (23)	12 (6)	24 (17)
	LATER (n=54)	LATER (n=20)	LATER (n=34)
Later Weight gainers	37 (20)	40 (8)	35 (12)
Later Weight maintainers	32 (17)	35 (7)	30 (10)
Later Weight losers	31 (17)	25 (5)	35 (12)

7.1.8 Comparison of IMMEDIATE and LATER groups

To evaluate the effect of a pre-intervention delay on weight change, self-monitoring, session attendance and PA levels at 6 and 12 months, these outcomes were compared among IMMEDIATE and LATER groups. The mean pre-intervention delay was 107.8±34.1 days (about 3.5 months) among IMMEDIATE participants and 282.3±31.6 days (about 9.5 months) among LATER participants ($p<0.0001$). Among all participants combined there were no statistically significant differences noted for percent weight loss at 6 ($p=0.8$) or 12 ($p=0.3$) months, total session attendance ($p=0.03$), total diet self-monitoring ($p=0.1$) or total PA self-monitoring ($p=0.2$) (Table 7-5). Applying the last observation carried forward method of analysis yielded similar results to the analysis among those with complete data.

Among all participants combined, both the IMMEDIATE and LATER groups achieved significant percent weight loss at 6 and 12 months. Among IMMEDIATE participants mean percent weight loss at 6 months was 5.8±4.8 % ($p<0.0001$) and 4.8±6.0 % ($p<0.0001$) at 12 months. LATER participants achieved mean weight loss of 6.0±4.6 % ($p<0.0001$) and 6.0±6.3 % ($p<0.0001$) at 6 and 12 months, respectively (Table 7-5).

Self- reported leisure PA was significantly greater among IMMEDIATE participants compared to LATER participants at six months ($p<0.0001$) (Table 7-5) among all participants combined. At 12 months, LATER participants reported significantly greater leisure PA compared to IMMEDIATE participants among all participants combined ($p=0.002$). Overall, when compared to self-reported levels of leisure PA at randomization all participants achieved significant increases at 6 months and maintained those significant increases at 12 months.

The comparison among IMMEDIATE and LATER groups was also stratified by intervention site, gender, age (age<55, age ≥55) and education (education < bachelors degree,

education ≥ bachelors degree) and yielded similar results as the combined analysis for weight change outcomes as the combined analysis. When stratified by age and education significant differences in self-monitoring and intervention attendance among the IMMEDIATE and LATER groups were detected in favor of the LATER group, but did not impact weight loss outcomes. Comparisons of leisure time PA between IMMEDIATE and LATER groups yielded slightly different results than the combined analysis when stratified by gender, age and education, but did not affect the overall message of maintaining significant increases in leisure PA at 6 and 12 months compared to levels of leisure time PA at randomization.

Table 7-5: Weight loss, attendance, self-monitoring and self-reported leisure time PA levels at 6 and 12 months among IMMEDIATE and LATER groups at both sites combined.

	Combined site comparison	
	IMMEDIATE N=120	LATER N=54
Outcome Variable	Mean(SD) Median (IQR)	Mean(SD) Median (IQR)
Percent weight loss at 6 months	5.8 (4.8) 5.6 (2.8-8.6)	6.0 (4.6) 5.3 (2.3-9.2)
Percent weight loss at 12 months	4.8 (6.0) 4.5 (0.7-9.3)	6.0 (6.3) 4.8 (2.2-8.2)
Length of Intervention Delay*	107.8 (34.1) 109 (95-126)	282.3 (31.6) 282.5 (263-302)
Total number of sessions attended	17.2 (4.8) 19 (14-21)	18.3 (4.0) 19.5 (16-21)
Number of core sessions attended (Sessions 1-16)	13.6 (3.0) 14.5 (12-16)	14.2 (2.5) 15 (13-16)
Number of post-core sessions attended (Sessions 17-22)	3.8 (2.3) 5 (2-6)	4.1 (2) 4 (3-6)
Total number of diet records submitted	15.3 (11.9) 11.5 (6-22.5)	18.4 (12.8) 14.5 (9-24)
Number of core diet records submitted	11.5 (6.4) 11 (6-17)	13.9 (6.4) 12.5 (9-21)
Number of post-core diet records submitted	3.9 (6.8) 0 (0-5)	4.5 (8.0) 0 (0-5)
Total number of activity records submitted	11.3 (11.6) 7 (2-17)	13.3 (12.7) 9 (5-18)
Number of core activity records submitted	7.9 (6.2) 7 (2-13.5)	9.2 (6.2) 8 (4-14)
Number of post-core activity records submitted	3.5 (6.6) 0 (0-4)	4.1 (7.9) 0 (0-5)
Self-reported leisure PA at 6 months* (MET hrs)	34.3 (26.1) 27.5 (16.7-44.3)	16.8 (16.7) 11.5 (5.3-21.5)
Self-reported leisure PA at 12 months** (MET hrs)	21 (21) 12.2 (7.9-29.8)	28.8 (18.9) 25.5 (13-41.3)

*$p<0.0001$, **$p=0.002$

7.2 PAPER # 2 SUMMARY

Objective: Participants in community based diabetes prevention programs are likely to experience a time delay prior to the start of intervention; however little is known regarding the impact of this delay on participant outcomes. The primary objectives of this manuscript are to evaluate the impact of a pre-intervention time delay and weight change during this delay on participant outcomes during a one-year adaptation of the Diabetes Prevention Program (DPP) lifestyle intervention.

Design and Methods: Participants were recruited at a worksite and three community centers to take part in this randomized delayed-control trial with two-thirds randomized to start the intervention immediately (IMMEDIATE) and one-third assigned to a six-month delayed control group (LATER). The pre-intervention delay was calculated as the number of days from screening to the first intervention session, and participants were categorized as weight gainers, weight maintainers and weight losers during this delay.

Results: A total of 174 overweight or obese adults with prediabetes and/or metabolic syndrome attended baseline, 6 and 12 month assessments. Both IMMEDIATE and LATER participants achieved significant mean percent weight loss at 6 and 12 months, with no significant difference in mean percent weight loss found between the two groups at either time point. Across the three pre-intervention weight change groups no significant differences in percent weight loss, physical activity levels, attendance, and self-monitoring were noted at 6 or 12 months.

Conclusions:

The results of paper 2 suggest that a mean pre-intervention delay of 6 months among LATER participants did not adversely affect weight loss, intervention attendance, and self-monitoring when compared to IMMEDIATE participants. In addition, weight change, as

categorized in this paper, occurring during the pre-intervention delay did not impact weight loss and PA levels at 6 and 12 months. These results suggest that a pre-intervention delay should not be viewed as a barrier to implementation among organizations with an interest in providing community based diabetes prevention programs.

8.0 PAPER #3: THE IMPACT OF PARTICIPANT CHARACTERISTIS, COGNITIVE FACTORS AND PRESCRIBED LIFESTYLE BEHAVIORS ON ACHIEVING THE GOALS OF A COMMUNITY BASED DIABETES TRANSLATION

8.1 OVERVIEW OF PAPER # 3

Participants in the US Diabetes Prevention Program (DPP) lifestyle intervention achieved a significant, 58% reduction in type 2 diabetes incidence compared to control group participants after an average of approximately 3 years of follow up [4]. At the conclusion of the 16-session core, 49% of DPP participants achieved the 7% weight loss goal and 37% met the weight loss goal at the end of the intervention. The ≥150 minutes/week PA goal was achieved by 74% and 67% of participants at the end of the core and the end of the intervention, respectively [4, 20]. An investigation into factors (demographic, psychosocial, behavioral) related to achieving the weight loss and PA goals among DPP participants by Wing et al. suggests that older age, lower BMI, male gender, certain ethnicities and an increased frequency of self-monitoring are important for goal achievement [20].

The success of the DPP lifestyle intervention prompted implementation of community based translations across the US in health care settings, community centers, rural and urban communities and among a variety of racial and ethnic groups[14, 98, 99, 105, 118]. These translation efforts continued to emphasize the importance of self-monitoring and the weight loss and PA goals of the DPP [19]. In translation, one study identified older age, male gender, lower BMI and more frequent self-monitoring as important factors for achieving 7% weight loss; similar to the findings from the DPP [20, 44]. The association of more frequent self-monitoring (≥50% of

the time) and achievement of the 7% weight loss is also supported by other community based translations [13, 45].

Although self-monitoring is a key component of community based diabetes translation interventions, very little is known regarding participants' willingness to engage in self-monitoring or other healthy lifestyle practices. Previous research suggests that obese and overweight patients are less willing to change their lifestyle than their normal weight counterparts [46], and in an evaluation of motivators and barriers to exercise, investigators hypothesize that a lack of interest in exercise may be a surrogate to a lack of willingness to change exercise habits [47]. A study evaluating the feasibility of a PA intervention found that increasing age was associated with an individual's willingness to participate [48], but did not address the impact of age on study outcomes [119]. In the same study, participants who were current smokers and who reported an insufficient amount of PA were more likely to enroll. This is contrary to the DPP where participants who enrolled were more physically active when compared to a national sample [120]. These results may indicate that individuals who know they are at greater risk of future health issues are more likely and willing to participate in healthy lifestyle interventions [48], but none of these studies provide specific information regarding willingness to make healthy behavior changes and future success in meeting program goals.

The purpose of this manuscript is to investigate the relationship between participant willingness to engage in healthy lifestyle practices and achievement of the weight loss and PA goals of a community based adaptation of the DPP intervention. In addition, other factors such as individual participant characteristics and program engagement (i.e. session attendance and self-monitoring) will be evaluated for their association with program success, defined as achievement of program goals.

8.1.1 Measures

8.1.1.1 Demographics

Demographic data were collected at the onsite screening visit and included date of birth, gender, family history of diabetes and heart disease, smoking status, race/ethnicity, employment status, and education level. Education was collapsed into two categories; education < bachelor's degree and education ≥ bachelor's degree. Similarly, employment was collapsed into two categories; those working full or part-time and all other employment classifications.

8.1.1.2 Self-monitoring and Attendance

Self-monitoring of diet was calculated as the number of weeks a participants recorded dietary intake ≥4 days per week during the core, post-core and as a total. Self-monitoring of physical activity was calculated as the number of weeks a participant recorded PA on ≥3 days per week during the core, post-core and as a total. Attendance was also documented at each session and recorded as an in-person, telephone, email or other contact.

8.1.1.3 Willingness

At baseline, 6 and 12 months participants completed a Willingness Questionnaire consisting of 16 questions to assess willingness to engage in healthy lifestyle practices emphasized in the DPP-GLB program (APPENDIX D). The Willingness Questionnaire was adapted from the Weight Loss Behavior Questionnaire and has not been previously validated, however no other measure evaluating participant willingness could be found in the literature. Questions addressed

willingness to self-monitoring fat, calories and activity, engage in physical activity, measure portions, make healthy substitutions or modifications and change attitudes about healthy eating and PA. Participants were instructed to read each statement and rate their level of willingness to participate in the behavior by circling the number of days per week they were willing to participate in the behavior, ranging from 0 to 7.

8.1.1.4 Laboratory Data and Anthropometrics

Assessment visits were completed at baseline (randomization) and at three other time points: one during the one-year intervention (6 months), one at the conclusion of the intervention (12 months) and one 6 months after the conclusion of the intervention (18 months). At the 6 and 12 months assessments a trained research assistant following standard protocol measured blood pressure, pulse, height, weight and waist circumference. A venous blood draw was taken to assess total cholesterol, High-density lipoprotein cholesterol (HDL-C), Low-density lipoprotein cholesterol (LDL-C), triglycerides, glucose, hemoglobin A1C and insulin following a minimum 8-hour fast and analyzed at a local laboratory. Prescription medication use, health history and the Modifiable Activity Questionnaire (MAQ) were completed via participant interview and participants were asked to complete the EQ-5D quality of life measure, a willingness questionnaire and a cost survey. Participants were also interviewed regarding their current lifestyle habits using a Lifestyle Questionnaire that assessed current diet and activity monitoring frequencies, the number of days they engaged in physical activity, average minutes of activity per session and how frequently they achieved fat, calorie and physical activity goals. At the 18 month assessment, weight and waist circumference were measured by a trained research assistant and participants were interviewed regarding their current self-monitoring and PA habits.

8.1.2 Statistical Analyses

This evaluation is a secondary analysis of a randomized trial evaluating the effectiveness of the DPP-GLB with the primary study outcome of weight loss.

Participants who completed an in-person meeting, phone call or email interaction with discussion including that week's session were considered to have attended the session. During the core and post-core intervention participants who self-monitored PA on ≥3 days/week and diet ≥4 days/week were considered self-monitors of that specific behavior for the week, while those who monitored less frequently were not considered self-monitors for that week.

Differences in baseline characteristics among those who attended all assessment visits (completers), i.e., baseline, 6 and 12 months were compared to those who did not attend the 6 and 12 month visits using two sample independent t-tests for normally distributed variables and the Wilcoxon-Mann-Whitney test for variables not normally distributed. The Chi-square or Fisher's exact test was used to test for differences among categorical variables.

Willingness to engage in each healthy lifestyle practice was dichotomized into two categories: participants who were willing (≥4 days/week) and participants who were not willing (<4 days/week). To evaluate changes in willingness, the proportion of participants willing to engage in health lifestyle practices and 6 and 12 months were compared to the proportions of participants willing to engage in healthy lifestyle practices at baseline using the McNemar's test.

To examine the effects of willingness to engage in specific healthy lifestyle practices (use a keeping track book, record calories, record fat, measure food portions and record PA) at 6 months and adherence to dietary and PA self-monitoring during the core intervention on weight loss and PA outcomes at 12 months participants were placed into four categories: (1) Willing and adhering, (2) willing and NOT adhering, (3) NOT willing and adhering, and (4) NOT willing and NOT

adhering. For this analysis adhering to dietary self-monitoring was completing ≥9 records and adhering to PA self-monitoring was completing ≥ 6 PA records.

Simple logistic regression was used to identify willingness to engage in specific healthy lifestyle practices at 6 months that were associated with achieving 5% or 7% weight loss and ≥150 minutes/week of PA at 12 and 18 months. The same analysis was carried out for willingness to engage in specific healthy lifestyle practices at 12 months and achievement of 5% or 7% weight loss and ≥150 minutes/week of PA at 18 months.

The Lifestyle Questionnaire assessed self-reported frequencies of self-monitoring of weight, diet and activity as well as the number of days of physical activity per week and average number of minutes per activity session. Comparisons among frequency of self-monitoring, days of activity and minutes of activity among all participants combined and stratified by intervention site were conducted using the Wilcoxon-Signed Rank test.

The relationship between core and post-core self-monitoring of diet and PA and attendance was evaluated using non-parametric spearman correlations. Self-monitoring in the core and attendance in both the core and post-core were categorized into roughly the lowest 25%, 25%-75% and the upper 25% of adherence. Due to the low frequency of self-monitoring in the post-core self-monitoring was categorized as monitored or did not monitor. The difference in the frequency of participants achieving 5% and 7% weight loss and ≥150 minutes/week of PA at 6, 12 and 18 by category of self-monitoring and attendance was evaluated using the Chi-square test. Simple logistic regression was used to evaluate the association of attendance and self-monitoring of diet and PA during the core to achieving 5% or 7% weight loss and ≥150 minutes/week of PA at 6, 12 and 18 months. Similarly, simple logistic regression was used to evaluate the association of

attendance and self-monitoring of diet and PA during the post-core to achieving 5% or 7% weight loss and ≥150 minutes/week of PA at 12 and 18 months.

To identify individual characteristics (i.e. age, education, employment) unique to participants achieving 5% and 7% weight loss and ≥150 minutes/week of PA at 6, 12 and 18 months a two sample independent t-test, Wilcoxon-Mann-Whitney test, Chi-square or Fisher's exact test were used.

In multivariate analyses, willingness behaviors that were significantly associated with weight loss and PA outcomes using simple logistic regression were further adjusted by age, gender, education, employment and documented self-monitoring from keeping track books. The relationship of documented self-monitoring and attendance to weight loss and activity outcomes was similarly adjusted by age, gender, education and employment.

8.1.3 Baseline Demographic and Anthropometric Characteristics

Of the 223 participants enrolled at baseline, 187 (84%) completed the 6 and 12 month follow-up visits and are included in this analysis (completers). Among completers, mean age at baseline was 58.4±11.5 years, mean BMI was 33.8±6 m/kg^2, and mean weight was 208.8±38.6 lbs. The 36 participants not included in the analysis were significantly younger (54.1±11.2 years; p=0.01), and had significantly greater mean BMI (36.4±7 m/kg^2; p=0.006), weight (222.1±38.6 lbs; p=0.04) and diastolic blood pressure (79.6±10.6;p=0.02) at baseline compared to completers (Table 8-1).

Table 8-1: Baseline characteristics of completers (N=187).

	Combined (N=187)
	Mean (SD) **Median (IQR)**
Age (n=187)	58.4 (11.5) 57.5 (50.4-66.4)
Body mass index, kg/m^2 (n=187)	33.8 (6) 32.8 (29.6-37)
Weight, lbs (n=187)	208.8 (41.8) 200 (179.4-232.2)
Waist circumference, in (n=187)	41.8 (5.3) 41.3 (38.3-44.5)
Total Cholesterol (n=186)	194.4 (38.7) 188 (166-217)
LDL Cholesterol (n=183)	114.5 (34.2) 113 (90-135)
HDL Cholesterol (n=186)	50.8 (13.9) 49 (41-58)
Triglycerides (n=186)	147.1 (69.4) 129 (100-172)
Glucose (n=186)	94.4 (11.1) 93 (87-100)
Hemoglobin A1c (n=186)	5.7 (0.3) 5.7 (5.5-5.9)
Systolic Blood Pressure (n=187)	119.4 (11.9) 118 (111-126)
Diastolic Blood Pressure (n=187)	75.9 (10.1) 77 (69-82)
Gender	**% (n)**
Male	40 (74)
Female	60 (113)
Education	
Some High School	0.5 (1)
High School Graduate/GED	10 (19)
Some College or technical school	23.5 (44)
College graduate (bachelor's)	33 (61)
Graduate degree	33 (62)
Employed	
Full time (≥35hrs/week)	56 (111)
Part-time (<35hrs/week)	7 (14)
Unemployed/laid off & looking	2 (4)
Homemaker	3 (6)
Retired	30 (55)
Disable/unable to work	2 (4)
Family History of Diabetes	49 (91)
Family History of Heart Disease	49 (92)

8.1.4 Willingness to engage in healthy lifestyle practices among all participants

Among all participants combined at baseline over 80% of participants were willing to engage in all healthy lifestyle practices on the majority of days per week except recording fat grams, measuring food portions and eating out at restaurants less often. At six months, significant decreases in willingness to use a keeping track book ($p<0.0001$), record calories ($p<0.0001$), record fat ($p=0.01$), measure portions ($p=0.02$), record physical activity ($p<0.0001$), be active for 30 minutes ($p=0.03$), try a different physical activity ($p<0.0001$), eat out less often ($p=0.04$) and be active even when I don't feel like it ($p=0.006$) were noted (Table 8-2). Willingness to engage in all of these healthy lifestyle practices remained significantly lower at 12 months. Additionally, willingness to modify food preparation ($p=0.02$), make physical activity a priority ($p=0.001$), change thoughts about eating and activity ($p=0.02$) and to self-weigh ($p=0.006$) were significantly lower than baseline at 12 months.

Table 8-2: Percent of completers willing to engage in healthy lifestyle practices on the majority of days per week (≥4 days) at baseline and at 6 and 12 months (N=187).

	Baseline	**At 6 Months**	**Baseline vs Six month**	**At 12 Months**	**Baseline vs Twelve month**
Willingness Survey Question	**% ≥ 4/week**	**% ≥ 4/week**	**p-value**	**% ≥ 4/week**	**p-value**
To use a Keeping Track book to write down everything I eat & drink.	91	73	<.0001	60	<.0001
To record the number of calories that I eat.	83	67	<.0001	61	<.0001
To record the amount of fat grams that I eat.	78	66	0.01	58	<.0001
To measure my food portions using scales, spoons, cups, etc.	74	64	0.02	50	<.0001
To purposely eat smaller portion sizes of food.	96	93	0.1	94	0.5
To substitute water for high calorie/sugar-filled beverages	96	94	0.5	92	0.2
To record the physical activity that I do (in minutes or steps).	97	79	<.0001	75	<.0001
To exercise at least 30 minutes at a moderate intensity.	89	81	0.03	83	0.02
To take time to plan out my meals.	83	79	0.5	76	0.1
To try a different physical activity than I usually do or increase the intensity of the activity.	81	66	<.0001	62	<.0001
To modify the way I cook & prepare food (use low-fat substitutes, limit high calorie ingredients, use less salt/sodium, etc.	93	92	1.0	87	0.02
To eat out at restaurants less often than I currently do.	75	66	0.04	64	0.01
To make physical activity a priority as much as possible.	94	89	0.05	85	0.001
To be physically active even when I don't feel like it.	90	80	0.006	76	<.0001
To change my thoughts related to eating and physical activity.	96	92	0.2	90	0.02
To weigh myself.	86	81	0.2	74	0.006

8.1.4.1 Willingness to engage in healthy lifestyle practices at the worksite

Among worksite participants three-fourths were willing to engage in all healthy lifestyle practices on the majority of days per week except for measuring food portions at baseline. At six months, willingness to record fat grams, measure food portions, substitute water for high-calorie/sugar sweetened beverages, exercise for 30 minutes, plan meals, modify food preparation, eat out less often, make physical activity a priority, change thoughts about eating and activity, and self-weigh remained similar to baseline willingness (Table 8-3). At 12 months willingness to eat smaller portions, substitute water for other beverages, exercise for 30 minutes, plan meals, modify food preparation, eat out less often, and change thoughts about eating and activity remained similar to willingness at baseline (Table 8-3).

Table 8-3: Percent of worksite completers willing to engage in healthy lifestyle practices on the majority of days per week (≥4 days) at baseline and at 6 and 12 months (N=71).

	Baseline	**At 6 months**	**Baseline vs Six month**	**At 12 Months**	**Baseline vs Twelve month**
Willingness Survey Question	**% ≥ 4/week**	**% ≥ 4/week**	**p-value**	**% ≥ 4/week**	**p-value**
To use a Keeping Track book to write down everything I eat & drink.	89	64	0.0005	54	<.0001
To record the number of calories that I eat.	80	59	0.006	56	0.003
To record the amount of fat grams that I eat.	75	59	0.06	54	0.02
To measure my food portions using scales, spoons, cups, etc.	66	61	0.5	37	0.0005
To purposely eat smaller portion sizes of food.	97	89	0.03	94	0.5
To substitute water for high calorie/sugar-filled beverages	96	94	1.0	91	0.5
To record the physical activity that I do (in minutes or steps).	96	68	<.0001	71	0.0002
To exercise at least 30 minutes at a moderate intensity.	89	80	0.2	80	0.2
To take time to plan out my meals.	80	78	1.0	73	0.4
To try a different physical activity than I usually do or increase the intensity of the activity.	83	58	0.0009	64	0.01
To modify the way I cook & prepare food (use low-fat substitutes, limit high calorie ingredients, use less salt/sodium, etc.	92	86	0.3	81	0.07
To eat out at restaurants less often than I currently do.	75	61	0.06	61	0.08
To make physical activity a priority as much as possible.	93	83	0.07	79	0.02
To be physically active even when I don't feel like it.	89	75	0.03	68	0.004
To change my thoughts related to eating and physical activity.	96	87	0.1	87	0.1
To weigh myself.	89	79	0.09	67	0.002

8.1.4.2 Willingness to engage in healthy lifestyle practices in the community

Among community participants, three-fourths were willing to engage in all healthy lifestyle practices on the majority of days per week at baseline. At six months, a significant decrease in willingness was noted in only four behaviors; willingness to use a keeping track book (p=0.0009), record calories (p=0.01), measure portions (p=0.02) and record physical activity (p=0.003) (Table 8-4). All of the significant decreases in the willingness at 6 months were present at 12 months, and willingness to record fat grams (p=0.0008), try a different activity or intensity (p=0.0006) and be active even when I don't feel like it (p=0.02) all significantly decreased compared to proportions at baseline.

Although willingness to engage in some healthy lifestyle practices did not decrease significantly in the community as they did at the worksite at 6 and 12 months, they did trend in the direction of a decrease in willingness to engage in these healthy lifestyle practices similar to what was shown at the worksite. Therefore, the remainder of the analysis regarding willingness to engage in healthy lifestyle practices will be shownwith all participants combined.

Table 8-4: Percent of community completers willing to engage in healthy lifestyle practices on the majority of days per week (≥4 days) at baseline and at 6 and 12 months (N=116).

	Baseline	**At 6 months**	**Baseline vs Six month**	**At 12 Months**	**Baseline vs Twelve month**
Willingness Survey Question	**% ≥ 4/week**	**% ≥ 4/week**	**p-value**	**% ≥ 4/week**	**p-value**
To use a Keeping Track book to write down everything I eat & drink.	93	78	0.0009	63	<.0001
To record the number of calories that I eat.	84	72	0.01	64	<.0001
To record the amount of fat grams that I eat.	80	71	0.1	60	0.0008
To measure my food portions using scales, spoons, cups, etc.	79	66	0.02	58	<.0001
To purposely eat smaller portion sizes of food.	96	96	1.0	94	1.0
To substitute water for high calorie/sugar-filled beverages	97	94	0.5	93	0.4
To record the physical activity that I do (in minutes or steps).	97	85	0.003	77	<.0001
To exercise at least 30 minutes at a moderate intensity.	89	82	0.1	83	0.1
To take time to plan out my meals.	84	80	0.5	78	0.2
To try a different physical activity than I usually do or increase the intensity of the activity.	80	72	0.1	60	0.0006
To modify the way I cook & prepare food (use low-fat substitutes, limit high calorie ingredients, use less salt/sodium, etc.	93	96	0.5	90	0.3
To eat out at restaurants less often than I currently do.	75	69	0.3	65	0.09
To make physical activity a priority as much as possible.	95	93	0.5	89	0.06
To be physically active even when I don't feel like it.	91	84	0.1	81	0.02
To change my thoughts related to eating and physical activity.	96	95	1.0	91	0.1
To weigh myself.	84	82	0.9	79	0.4

8.1.5 Self-monitoring and self-reported activity

Participants, responses to questions from the lifestyle questionnaire are summarized in Table 8-5. Following six months of intervention participants reported significant median increases in the number of days keeping track of weight, days of activity per week and total number of activity minutes. These significant increases were maintained following 12 months of intervention. Similar trends were noted when participants were stratified by intervention site.

Table 8-5: Summary of lifestyle questionnaire responses at baseline, 6 and 12 months among completers.

	Baseline	**At 6 Months**	**Baseline vs. 6 month**	**At 12 months**	**Baseline vs.12 month**
Lifestyle Questionnaires	**Mean (SD) Median (IQR)**	**Mean (SD) Median (IQR)**	**p-value**	**Mean (SD) Median (IQR)**	**p-value**
Keeping track of weight (days/week)	3.8 (2.9) 2 (1-7)	4.1 (2.6) 4 (1-7)	<.0001	3.7 (2.7) 3 (1-7)	0.001
Keeping track of diet (days/week)	4.9 (2.7) 7 (3-7)	6.0 (1.8) 7 (5-7)	0.02	5.0 (1.9) 7 (3-7)	0.4
Days of activity/week	3.6 (2) 3 (2-5)	4.6 (1.8) 5 (3-6)	<.0001	4.3 (1.9) 3.0 (3-5)	<.0001
Keeping track of activity (days/week)	4.4 (2) 4 (3-7)	5 (2) 5 (3-7)	0.7	4.9 (2.3) 5 (3-7)	0.5
Average minutes per activity session	50.4 (34.8) 45 (30-60)	47.3 (28.2) 45 (30-60)	0.7	47.7 (28.2) 45 (30-60)	0.9
Total activity minutes/week	195.2 (224) 137.5 (90-240)	220.8 (171.1) 180 (105-300)	<.0001	213.6 (192.9) 180 (90-280)	0.0007

Self-monitoring data collected from keeping track records submitted by participants during the core and post-core, and session attendance during these two phases of the intervention are summarized in Table 8-6.

Table 8-6: Dietary and PA self-monitoring and intervention attendance during the core and post-core among completers.

	Core **Mean (SD)** **Median (IQR)**	**Post-Core** **Mean (SD)** **Median (IQR)**	**Total** **Mean (SD)** **Median (IQR)**
Number of weekly records submitted tracking diet (max 23 core, max 24 post-core)	11.7 (6.7) 11 (7-18)	3.8 (7.0) 0 (0-5)	15.4 (12.2) 12 (7-22)
Number of weekly records submitted tracking PA (max 20 core, max 24 post-core)	7.9 (6.2) 7 (2-13)	3.5 (6.8) 0 (0-4)	11.3 (11.8) 7 (2-16)
Sessions Attended (max 16 core, max 6 post-core)	13.4 (3.3) 15 (12-16)	3.8 (2.2) 4 (2-6)	17.1 (5) 19 (14-21)

Self-monitoring in the core and post-core were highly correlated and are presented in Table 8-7. Specifically, correlations between diet and PA self-monitoring in the core (rho=0.92, $p<0.0001$) and post-core (rho=0.93, $p<0.0001$) were very high.

Table 8-7: Spearman correlation coefficients among self-monitoring and attendance in the core and post-core.

	Self-monitoring diet (core)	**Self-monitoring Activity (core)**	**Self-monitoring diet (post-core)**	**Self-monitoring Activity (post core)**	**Core attendance**	**Post-Core attendance**
	rho p	rho p	rho p	rho p	rho p	rho p
Self-monitoring diet (core)	1.0	0.92 <.0001	0.73 <.0001	0.68 <.0001	0.74 <.0001	0.61 <.0001
Self-monitoring Activity (core)	0.92 <.0001	1.0	0.69 <.0001	0.71 <.0001	0.68 <.0001	0.58 <.0001
Self-monitoring diet (post-core)	0.73 <.0001	0.69 <.0001	1.0	0.93 <.0001	0.45 <.0001	0.56 <.0001
Self-monitoring Activity (post core)	0.68 <.0001	0.71 <.0001	0.93 <.0001	1.0	0.44 <.0001	0.53 <.0001
Core attendance	0.74 <.0001	0.68 <.0001	0.45 <.0001	0.44 <.0001	1.0	0.59 <.0001
Post-Core attendance	0.61 <.0001	0.58 <.0001	0.56 <.0001	0.53 <.0001	0.59 <.0001	1.0

8.1.6 The association between willingness to engage in healthy lifestyle practices at 6 months and weight loss and PA outcomes at 12 months

At six months, participants willing to use a keeping track book (OR=2.2, 95% CI 1.1,4.3), record calories (OR=2.2, 95% CI 1.4,4.2), record fat grams (OR=2.6, 95% CI 1.3,3.4), be physically active even when not feeling like it (OR=2.6, 95% CI 1.2,5.8) and change thoughts related to eating and physical activity (OR=5.9, 95% CI 1.3,27.0) were all significantly more likely to achieve 5% weight loss at 12 months (Table 8-8). With the exception of willingness to change thoughts related to eating and PA, participants willing to engage in behaviors mentioned above at 6 months were also significantly more likely to achieve 7% weight loss at 12 months. Willingness to record PA (OR=2.4, 95% CI 1.1,8.8) and exercise at least 30 minutes at moderate intensity (OR=3.2, 95% CI 1.4,6.9) at 6 months were both significantly associated with achieving ≥150 minutes of PA/week at 12 months (Table 8-8). Willingness to use a keeping track book and to be physically active even when not feeling like it at 6 months were both significant predictors of achieving 5% and 7% weight loss and ≥150 minutes of PA/week at 12 months.

The association between willingness to use a keeping track book, record calories, record fat, measure portions, and to be active even when not feeling like it at 6 months and achieving 5% and 7% weight loss at 12 months remained significant after adjusting for age, gender, education and employment. However, after further adjustment for core and post-core diet and PA self-monitoring no willingness behaviors were associated with 5% weight loss at 12 months, and only willingness to be active even when not feeling like it (OR=4.1 95% CI 1.2-13.9) remained significantly associated with 7% weight loss at 12 months. Similarly, the relationship between willingness to use a keeping track book, record

PA, be active for ≥30 minutes and be active even when not feeling like it at 6 months and achieving ≥150 minutes/week of PA at 12 months remained significant after adjusting for age, gender, education and employment. After adjusting for core and post-core diet and PA self-monitoring willingness to record PA, be active for ≥30 minutes and be active even when not feeling like it at 6 months remained significantly associated with achieving ≥150 minutes/week of PA at 12 months.

Willingness to be physically active even when not feeling like it at 6 months was significantly associated with achieving 5% and 7% weight loss at 18 months (Table 8-8). Additionally, participants willing to use a keeping track book, record fat and record calories at 6 months had a significantly greater likelihood of achieving 7% weight loss at 18 months than participants not willing to engage in these practices at 6 months (Table 8-8).

Willingness to be active even when not feeling like it at 6 months remained significantly associated with 5% weight loss at 18 months after adjusting for age, gender, education and employment, but not after further adjustment for core and post-core dietary and PA self-monitoring. After adjusting for age, gender, education and employment the significant association between willingness to record fat and record calories at 6 months and 7% weight loss at 18 months remained but willingness to use a keeping track book and to be active even when not feeling like it were no longer significant. Adjustment for documented self-monitoring of diet and activity during the core and post-core attenuated the relationship between willingness to record fat and calories at 6 months and 7% weight loss at 18 months. Willingness to measure portions and be active for ≥30 minutes at 6 months remained significantly associated with achieving ≥150 minutes/week of PA at 18

months after adjusting for age, gender, education, employment and self-monitoring of diet and PA during the core and post-core.

Table 8-8: Odds ratios and 95% CI's for the association of willingness at 6 months to weight loss and PA at 12 and 18 months among completers.

	Weight Loss and Activity Goals											
	At 12 months						At 18 months					
	5% weight loss		7% weight loss		150 minutes		5% weight loss		7% weight loss		150 minutes	
Willingness Question	OR	CI	OR	CI	OR	CI	OR	CI	OR	CI	OR	CI
To use a Keeping Track book to write down everything I eat & drink.	2.2	1.1, 4.3	3.0	1.4,6.7	2.0	1.0, 3.9	1.6	0.7,3.8	3.1	1.0,9.7	1.3	0.6,2.9
To record the number of calories that I eat.	2.2	1.2, 4.2	3.3	1.6,6.9	1.7	0.9, 3.1	1.9	0.9,4.2	3.5	1.2,9.8	1.6	0.8,3.4
To record the amount of fat grams that I eat.	2.6	1.3, 4.9	4.0	1.8,8.5	1.2	0.7, 2.2	1.9	0.9,4.2	3.5	1.2,9.7	1.4	0.7,2.4
To measure my food portions using scales, spoons, cups, etc.	1.8	1.0, 3.4	2.4	1.2,4.7	0.8	0.4, 1.5	1.6	0.7,3.3	1.7	0.7,4.1	1.3	0.7,2.8
To purposely eat smaller portion sizes of food.	2.9	0.8, 11.0	3.0	0.6,14.0	1.9	0.6, 6.2	4.9	0.6,40.7	2.6	0.3,21.9	10.4	1.2,87.4
To substitute water for high calorie/sugar-filled beverages	4.0	0.8, 18.9	2.4	0.5,11.4	2.1	0.6, 7.5	1.7	0.3,9.1	0.9	0.2,4.9	1.8	0.4,8.5
To record the physical activity that I do (in minutes or steps).	1.4	0.7, 3.0	2.0	0.9,4.5	2.4	1.1, 4.8	1.3	0.5,3.1	1.6	0.6,4.7	0.8	0.3,1.9
To exercise at least 30 minutes at a moderate intensity.	0.9	0.5, 2.0	1.6	0.7, 3.6	3.2	1.4, 6.9	1.2	0.4,3.0	4.2	0.9,19.1	4.5	1.6,12.5
To take time to plan out my meals.	1.5	0.7, 3.1	2.1	0.9,5.0	1.6	0.8, 3.2	1.4	0.6,3.7	1.5	0.5,4.4	1.5	0.6,3.5
To try a different physical activity than I usually do or increase the intensity of the activity.	1.1	0.6, 2.1	1.2	0.7,2.4	1.8	0.97, 3.3	1.6	0.7,3.3	1.7	0.7,4.1	2.0	0.98,4.2
To modify the way I cook & prepare food (use low-fat substitutes, limit high calorie ingredients, use less salt/sodium, etc.	3.6	0.97, 13.1	3.6	0.8,16.3	1.4	0.5, 4.0	--	--	--	--	1.3	0.3,5.6
To eat out at restaurants less often than I currently do.	1.0	0.5, 1.8	0.9	0.5,1.6	0.9	0.5, 1.6	1.1	0.5,2.4	0.8	0.4,1.8	1.7	0.8,3.6
To make physical activity a priority as much as possible.	1.6	0.6, 4.1	3.1	0.9,11.1	2.4	0.9, 6.2	1.7	0.5,5.8	5.2	0.7,41.6	1.9	0.6,5.9
To be physically active even when I don't feel like it.	2.6	1.2, 5.8	5.3	1.8,15.9	3.0	1.4, 6.5	2.9	1.1,7.7	3.6	1.0,12.9	1.4	0.6,3.3
To change my thoughts related to eating and physical activity.	5.9	1.3, 27.0			1.9	0.6, 5.4	7.2	0.9,58.4	--	--	1.1	0.3,3.8
To weigh myself.	1.2	0.6, 2.5	1.2	0.6,2.6	1.1	0.5, 2.2	0.9	0.4,2.1	1.0	0.4,2.5	2.1	0.9,5.1

8.1.7 The association between willingness to engage in healthy lifestyle practices at 12 months and weight loss and PA outcomes at 18 months

There were no significant associations present between willingness to engage in any healthy lifestyle practices at 12 months and weight loss outcomes at 18 months (Table 8-9). However, willingness to engage in several healthy lifestyle practices at 12 months were significantly associated with achieving ≥150 minutes of PA/week at 18 months. Notably, participants willing to record PA (OR=3.9, 95% CI 1.7, 9.3), exercise for at least 30 minutes (OR=4.1, 95% CI 1.5, 11.5) and to make physical activity a priority (OR=5.8, 95% CI 1.8, 18.9) were significantly more likely to achieve ≥150 minutes of PA/week at 18 months than participants not willing to engage in these practices (Table 8-9).

After adjusting for age, gender, education and employment the relationship between willingness to engage in healthy lifestyle practices at 12 months and achieving ≥150 minutes/week of PA at 18 months remained similar to the results of simple logistic regression shown in table 8-9. Adjusting for core dietary self-monitoring attenuated the relationship between willingness to use a keeping track book and willingness to plan meals at 12 months and achieving ≥150 minutes/week of PA at 18 months. Willingness to record calories, eat smaller portions, substitute water for high-calorie/sugar sweetened beverages, record PA, be active for ≥30 minutes, make physical activity a priority and change thoughts related to diet and PA were significantly associated with ≥150 minutes/week of PA 18 months after further adjusting for core PA and post-core dietary and PA self-monitoring.

Table 8-9: Odds ratios and 95% CI's for the association of willingness at 12 months to weight loss and PA at 18 months among completers.

	Weight Loss and Activity Goals					
	At 18 months					
	5% weight loss		7% weight loss		150 minutes	
Willingness Question	OR	OR	OR	OR	OR	OR
To use a Keeping Track book to write down everything I eat & drink.	0.8	0.4,1.7	1.2	0.5,2.7	2.1	1.0,4.2
To record the number of calories that I eat.	0.9	0.5,2.0	1.4	0.6,3.3	2.4	1.1,4.9
To record the amount of fat grams that I eat.	1.1	0.5,2.2	1.4	0.6,3.1	1.8	0.9,3.6
To measure my food portions using scales, spoons, cups, etc.	1.2	0.6,2.4	1.3	0.6,2.8	1.2	0.6,2.3
To purposely eat smaller portion sizes of food.	1.3	0.3,5.5	3.0	0.4,24.9	5.1	1.0,25.8
To substitute water for high calorie/sugar-filled beverages	2.8	0.6,13.8	--	--	5.9	1.2,29.1
To record the physical activity that I do (in minutes or steps).	1.0	0.5,2.4	1.7	0.6,4.5	3.9	1.7,9.3
To exercise at least 30 minutes at a moderate intensity.	1.8	0.6,4.9	3.9	0.9,17.9	4.1	1.5,11.5
To take time to plan out my meals.	0.7	0.3,1.6	0.8	0.3,2.1	2.3	1.0,5.2
To try a different physical activity than I usually do or increase the intensity of the activity.	0.6	0.3,1.3	0.9	0.4,2.1	1.6	0.8,3.3
To modify the way I cook & prepare food (use low-fat substitutes, limit high calorie ingredients, use less salt/sodium, etc.	1.3	0.5,3.8	3.2	0.7,14.9	1.8	0.6,4.8
To eat out at restaurants less often than I currently do.	1.0	0.5,2.1	0.8	0.4,1.9	1.5	0.7,3.2
To make physical activity a priority as much as possible.	1.3	0.5,3.8	1.9	0.5,7.1	5.8	1.8,18.9
To be physically active even when I don't feel like it.	1.6	0.7,3.9	1.5	0.5,4.0	2.3	0.99,5.4
To change my thoughts related to eating and physical activity.	1.0	0.3,2.9	1.5	0.4,5.6	4.3	1.3,14.3
To weigh myself.	1.0	0.5,2.3	1.6	0.6,3.8	1.9	0.9,4.0

8.1.8 The association of willingness to engage in self-monitoring and documented self-monitoring to weight loss and PA outcomes at 12 and 18 months

A greater percentage of participants who self-monitored diet during the core and were willing to use a keeping track book at 6 months (57%) achieved 5% weight loss at 12 months compared those who were willing and not self-monitoring diet (21%), not willing and self-monitoring diet (42%), and not willing and not self-monitoring diet (25%) (Table 8-10). However, as shown in figure 8-1, a greater percentage of participants who indicated they were not willing to use a keeping track book at 6 months, but did self-monitor diet during the core achieved 5% weight loss at 12 months compared to participants in the two categories that did not self-monitor diet during the core (Table 8-10).

This relationship was also evaluated for willingness to record calories and self-monitoring diet, willingness to record fat and self-monitoring diet, willingness to measure portions and self-monitoring diet and willingness to record PA and self-monitoring PA in relation to weight loss and PA outcomes at 12 months. All of these combinations are reported in Table 8-10 and generally follow the pattern of those who are willing at 6 months and self-monitor during the core achieve the highest rates of weight loss and PA success at 12 months. Followed by those who were not willing but did self-monitor during the core and the two groups who did not self-monitor during the core achieve the lowest rate of success.

The relationship between these combinations of willingness at 6 months and self-monitoring during the core and achievement of 5% and 7% weight loss ≥150 minutes of PA/week at 18 months were also evaluated (8-11). Similarly, participants willing to engage

in the monitoring behavior with documented self-monitoring achieve the highest rates of success, followed by those who were not willing but did self-monitor. Finally, achievement of ≥150 minutes of PA/week at 18 months appears to be less influence by the combination of willingness and self-monitoring. Interpretation of willingness to self-monitor PA and documented self-monitoring of PA should be done cautiously due to small sample sizes among some of the groups.

Table 8-10. Willingness to engage in self-monitoring specific behaviors at 6 months, dietary and PA self-monitoring adherence during the core and the frequency of achieving 5% and 7% weight loss and ≥150 minutes of PA at 12 months.

	Outcomes at 12 Months					
	5% Weight Loss		7% Weight loss		150 minutes	
Willingness at 6 months and Core self-monitoring	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)
Willing to use keeping track book and recording diet	57 (61)	43 (46)	48 (51)	52 (56)	62 (66)	38 (41)
Willing to use keeping track book and NOT recording diet	21 (6)	79 (22)	7 (2)	93 (26)	46 (13)	54 (15)
Not Willing to use keeping track book and recording diet	42 (8)	58 (11)	26 (5)	74 (14)	58 (11)	42 (8)
Not Willing to use keeping track book and NOT recording diet	25 (8)	75 (24)	33 (14)	67 (28)	31 (10)	69 (22)
Willing to record calories and recording diet	60 (59)	40 (40)	51 (50)	49 (49)	63 (62)	37 (37)
Willing to record calories and NOT recording diet	19 (5)	81 (21)	8 (2)	92 (24)	42 (11)	58 (15)
Not Willing to record calories and recording diet	39 (11)	61 (17)	25 (7)	75 (21)	57 (16)	43 (12)
Not Willing to record calories and NOT recording diet	26 (9)	74 (25)	12 (4)	88 (30)	35 (12)	65 (22)
Willing to record fat and recording diet	60 (60)	40 (40)	51 (51)	49 (49)	61 (61)	39 (39)
Willing to record fat and NOT recording diet	21 (5)	79 (19)	8 (2)	92 (22)	33 (8)	67 (16)
Not Willing to record fat and recording diet	37 (10)	63 (17)	22 (6)	78 (21)	63 (17)	37 (10)
Not Willing to record fat and NOT recording diet	25 (9)	75 (27)	11 (4)	89 (32)	42 (15)	58 (21)
Willing to measure portions and recording diet	60 (52)	40 (35)	51 (44)	49 (43)	57 (50)	43 (37)
Willing to measure portions and NOT recording diet	25 (8)	75 (24)	13 (4)	88 (28)	38 (12)	63 (20)
Not Willing to measure portions and recording diet	45 (18)	55 (22)	33 (13)	68 (27)	70 (28)	30 (12)
Not Willing to measure portions and NOT recording diet	21 (6)	79 (22)	7 (2)	93 (26)	39 (11)	61 (17)
Willing to record PA and recording PA	56 (55)	44 (43)	48 (47)	52 (51)	63 (62)	37 (36)
Willing to record PA and NOT recording PA	29 (14)	71 (35)	14 (7)	86 (42)	49 (24)	51 (25)
NOT Willing to record PA and recording PA	55 (6)	45 (5)	36 (4)	64 (7)	64 (7)	36 (4)
NOT Willing to record PA and NOT recording PA	31 (9)	69 (20)	17 (5)	83 (24)	28 (8)	72 (21)

Table 8-11: Willingness to engage in self-monitoring specific behaviors at 6 months, dietary and PA self-monitoring adherence during the core and the frequency of achieving 5% and 7% weight loss and ≥150 minutes of PA at 18 months.

	Outcomes at 18 Months					
	5% Weight Loss		7% Weight loss		150 minutes	
Willingness at 6 months and Core self-monitoring	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)
Willing to use keeping track book and recording diet	47 (35)	53 (40)	33 (25)	67 (50)	55 (41)	45 (34)
Willing to use keeping track book and NOT recording diet	24(5)	76 (16)	19 (4)	81 (17)	57 (12)	43 (9)
Not Willing to use keeping track book and recording diet	36 (4)	64 (7)	9 (1)	91 (10)	64 (7)	36 (4)
Not Willing to use keeping track book and NOT recording diet	27 (6)	73 (16)	14 (3)	86 (19)	36 (8)	64 (14)
Willing to record calories and recording diet	49 (35)	51 (36)	36 (26)	64 (45)	58 (41)	42 (30)
Willing to record calories and NOT recording diet	22 (4)	78 (14)	17 (3)	83 (15)	56 (10)	44 (8)
Not Willing to record calories and recording diet	31 (5)	69 (11)	6 (1)	94 (15)	50 (8)	50 (8)
Not Willing to record calories and NOT recording diet	28 (7)	72 (18)	16 (4)	84 (21)	40 (10)	60 (15)
Willing to record fat and recording diet	49 (35)	51 (36)	36 (26)	64 (45)	58 (41)	42 (30)
Willing to record fat and NOT recording diet	22 (4)	78 (14)	17 (3)	83 (15)	50 (9)	50 (9)
Not Willing to record fat and recording diet	31 (5)	69 (11)	6 (1)	94 (15)	50 (8)	50 (8)
Not Willing to record fat and NOT recording diet	28 (7)	72 (18)	16 (4)	84 (21)	44 (11)	56 (14)
Willing to measure portions and recording diet	49 (30)	51 (31)	34 (21)	66 (40)	54 (33)	46 (28)
Willing to measure portions and NOT recording diet	26 (6)	74 (17)	17 (4)	83 (19)	57 (13)	43 (10)
Not Willing to measure portions and recording diet	38 (10)	61 (16)	23 (6)	77 (20)	62 (16)	38 (10)
Not Willing to measure portions and NOT recording diet	25 (5)	75 (15)	15 (3)	85 (17)	35 (7)	65 (13)
Willing to record PA and recording PA	46 (33)	54 (38)	35 (25)	65 (46)	55 (39)	45 (32)
Willing to record PA and NOT recording PA	27 (9)	73 (24)	12 (4)	88 (29)	48 (16)	52 (17)
NOT Willing to record PA and recording PA	50 (3)	50 (3)	17 (1)	83 (5)	67 (4)	33 (2)
NOT Willing to record PA and NOT recording PA	30 (6)	70 (14)	20 (4)	80 (16)	50 (10)	50 (10)

Further evaluation of the combinations of willingness to self-monitor and actual self-monitoring were completed for: (1) self-monitoring during the core, willingness at 12 months and outcomes at 18 months (Table 8-12), (2) willingness at 6 months, self-monitoring during the post-core, and outcomes at 18 months (Table 8-13), and (3) self-monitoring during the post-core, willingness at 12 months and outcomes at 18 months (Table 8-14).

In general, the relationship between self-monitoring during the core and willingness at 12 months to 18 month outcomes is similar to what was shown regarding core self-monitoring and willingness at 6 months and weight loss and PA outcomes (Table 8.-12). The two groups with documented self-monitoring achieve the highest frequency of success, but there appears to be less of difference between the groups. However, participants who indicated they are willing to use a keeping track book, record calories and record fat at 12 months, but do not self-monitor diet during the core appear to have the most limited success achieving 5% and 7% weight loss at 18 months. Interestingly, those who are willing to record PA at 12 months, regardless of their adherence to self-monitoring have the greatest success achieving the ≥150 minutes of PA/week at 18 months compared to those not willing to record PA (Table 8-12).

Willingness at 6 months, self-monitoring during the post-core and 18 months outcomes are presented in table 8-13and are similar to what was shown for self-monitoring during the core, willingness at 6 months and 12 month weight loss outcomes. It should be noted that the not willing and self-monitoring category contains a very small number of participants. Also, there does not appear to be a clear relationship between willingness, self-monitoring and the PA goal. Perhaps the most important finding is participants who indicate that they are not willing to self-monitor at 6 months, do not in fact monitor following this declaration.

Finally, the relationship between self-monitoring during the post-core, willingness at 12 months and 18 month outcomes is presented in Table 8-14. Again, the theme appears to be that participants who self-monitor achieve the highest rates of weight loss success, and among participants with documented self-monitoring those who are willing to self-monitor achieve a slightly higher level of success compared to those who are not willing. Participants willing to record PA at 12 months regardless of their post-core PA self-monitoring adherence have the highest rates of achieving ≥150 minutes of PA/week at 18 months. Interestingly, for all behaviors assessed, those who are willing at 12 months but do not self-monitor diet or PA in the post-core achieve ≥150 minutes of PA/week at 18 months at higher rates than participants who are not willing at 12 months but do self-monitor diet or PA in the post-core.

Table 8-12: Willingness to engage in self-monitoring specific behaviors at 12 months, dietary and PA self-monitoring adherence during the core and the frequency of achieving 5% and 7% weight loss and ≥150 minutes of PA at 18 months.

	Outcomes at 18 Months					
	5% Weight Loss		7% Weight loss		150 minutes	
Willingness at 12 months and core self-monitoring	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)
Willing to use keeping track book and recording diet	47 (28)	53 (32)	33 (20)	67 (40)	63 (38)	37 (22)
Willing to use keeping track book and NOT recording diet	10 (2)	90 (18)	10 (2)	90 (18)	50 (10)	50 (10)
Not Willing to use keeping track book and recording diet	44 (12)	56 (15)	26 (7)	74 (20)	41 (11)	59 (16)
Not Willing to use keeping track book and NOT recording diet	39 (9)	61 (14)	22 (5)	78 (18)	43 (10)	57 (13)
Willing to record calories and recording diet	46 (29)	54 (34)	33 (21)	67 (42)	63 (40)	37 (23)
Willing to record calories and NOT recording diet	12 (2)	88 (15)	12 (2)	88 (15)	53 (9)	47 (8)
Not Willing to record calories and recording diet	46 (11)	54 (13)	25 (6)	75 (18)	38 (9)	62 (15)
Not Willing to record calories and NOT recording diet	35 (9)	65 (17)	19 (5)	81 (21)	42 (11)	58 (15)
Willing to record fat and recording diet	47 (23)	53 (32)	33 (20)	67 (40)	62 (37)	38 (23)
Willing to record fat and NOT recording diet	13 (2)	88 (14)	13 (2)	87 (14)	50 (8)	50 (8)
Not Willing to record fat and recording diet	44 (12)	56 (15)	26 (7)	74 (20)	44 (12)	56 (15)
Not Willing to record fat and NOT recording diet	31 (8)	69 (18)	19 (5)	81 (21)	46 (12)	54 (14)
Willing to measure portions and recording diet	45 (22)	55 (27)	31 (15)	69 (34)	61 (30)	39 (19)
Willing to measure portions and NOT recording diet	29 (4)	71 (10)	21 (3)	79 (11)	43 (6)	57 (8)
Not Willing to measure portions and recording diet	47 (18)	53 (20)	32 (12)	68 (26)	50 (19)	50 (19)
Not Willing to measure portions and NOT recording diet	24 (7)	76 (22)	14 (4)	86 (25)	48 (14)	52 (15)
Willing to record PA and recording PA	47 (30)	53 (34)	34 (22)	66 (42)	64 (41)	36 (23)
Willing to record PA and NOT recording PA	26 (9)	74 (25)	18 (6)	82 (28)	59 (20)	41 (14)
NOT Willing to record PA and recording PA	46 (6)	54 (7)	31 (4)	69 (9)	15 (2)	85 (11)
NOT Willing to record PA and NOT recording PA	33 (6)	67 (12)	11 (2)	89 (16)	33 (6)	67 (12)

Table 8-13: Willingness to engage in self-monitoring specific behaviors at 6 months, dietary and PA self-monitoring adherence during the post-core and the frequency of achieving 5% and 7% weight loss and ≥150 minutes of PA at 18 months.

	Outcomes at 18 Months					
	5% Weight Loss		7% Weight loss		150 minutes	
Willingness at 6 months and Post-Core self-monitoring	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)
Willing to use keeping track book and recording diet	59 (27)	41 (19)	43 (20)	57 (26)	46 (21)	54 (25)
Willing to use keeping track book and NOT recording diet	28 (13)	72 (34)	19 (9)	81 (38)	64 (30)	36 (17)
Not Willing to use keeping track book and recording diet	50 (1)	50 (1)	0 (0)	100 (2)	0 (0)	100 (2)
Not Willing to use keeping track book and NOT recording diet	27 (8)	73 (22)	13 (4)	87 (26)	50 (15)	50 (15)
Willing to record calories and recording diet	61 (28)	39 (18)	46 (21)	54 (25)	48 (22)	52 (24)
Willing to record calories and NOT recording diet	27 (11)	73 (30)	20 (8)	80 (33)	68 (28)	32 (13)
Not Willing to record calories and recording diet	33 (1)	67 (2)	0 (0)	100 (3)	0 (0)	100 (3)
Not Willing to record calories and NOT recording diet	28 (10)	72 (26)	14 (5)	86 (31)	47 (17)	53 (19)
Willing to record fat and recording diet	61 (28)	39 (18)	46 (21)	54 (25)	48 (22)	52 (24)
Willing to record fat and NOT recording diet	27 (11)	73 (30)	20 (8)	80 (33)	66 (27)	34 (14)
Not Willing to record fat and recording diet	33 (1)	67 (2)	0 (0)	100 (3)	0 (0)	100 (3)
Not Willing to record fat and NOT recording diet	28 (10)	34 (26)	14 (5)	86 (31)	50 (18)	50 (18)
Willing to measure portions and recording diet	62 (24)	38 (15)	46 (18)	54 (21)	41 (16)	59 (23)
Willing to measure portions and NOT recording diet	26 (11)	74 (31)	17 (7)	83 (35)	69 (29)	31 (13)
Not Willing to measure portions and recording diet	50 (5)	50 (5)	30 (3)	70 (7)	60 (6)	40 (4)
Not Willing to measure portions and NOT recording diet	29 (10)	71 (25)	17 (6)	83 (29)	46 (16)	54 (19)
Willing to record PA and recording PA	60 (26)	40 (17)	44 (19)	56 (24)	53 (23)	47 (20)
Willing to record PA and NOT recording PA	26 (15)	74 (42)	18 (10)	82 (47)	53 (30)	47 (27)
NOT Willing to record PA and recording PA	50 (1)	50 (1)	0 (0)	100 (2)	0 (0)	100 (2)
NOT Willing to record PA and NOT recording PA	33 (18)	67 (16)	21 (5)	79 (19)	58 (14)	42 (10)

Table 8-14: Willingness to engage in self-monitoring specific behaviors at 12 months, dietary and PA self-monitoring adherence during the post-core and the frequency of achieving 5% and 7% weight loss and ≥150 minutes of PA at 18 months.

	Outcomes at 18 Months					
	5% Weight Loss		7% Weight loss		150 minutes	
Willingness at 12 months and Post-Core self-monitoring	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)
Willing to use keeping track book and recording diet	62 (23)	38 (14)	46 (17)	54 (20)	51 (19)	49 (18)
Willing to use keeping track book and NOT recording diet	18 (7)	82 (33)	13 (5)	87 (35)	68 (27)	32 (13)
Not Willing to use keeping track book and recording diet	50 (6)	50 (6)	33 (4)	67 (8)	25 (3)	75 (9)
Not Willing to use keeping track book and NOT recording diet	38 (14)	62 (23)	22 (8)	78 (29)	49 (18)	51 (19)
Willing to record calories and recording diet	63 (24)	37 (14)	47 (18)	53 (20)	50 (19)	50 (19)
Willing to record calories and NOT recording diet	18 (7)	85 (32)	13 (5)	87 (34)	72 (28)	28 (11)
Not Willing to record calories and recording diet	45 (5)	55 (6)	27 (3)	73 (8)	27 (3)	73 (8)
Not Willing to record calories and NOT recording diet	37 (14)	63 (24)	21 (8)	79 (30)	45 (17)	55 (21)
Willing to record fat and recording diet	62 (23)	38 (14)	46 (17)	54 (20)	49 (18)	51 (19)
Willing to record fat and NOT recording diet	19 (7)	81 (29)	14 (5)	86 (31)	69 (25)	31 (11)
Not Willing to record fat and recording diet	50 (6)	50 (6)	33 (4)	67 (8)	33 (4)	67 (8)
Not Willing to record fat and NOT recording diet	34 (14)	66 (27)	20 (8)	80 (33)	49 (20)	51 (21)
Willing to measure portions and recording diet	57 (17)	43 (13)	43 (13)	57 (17)	50 (15)	50 (15)
Willing to measure portions and NOT recording diet	26 (8)	74 (23)	16 (5)	84 (26)	65 (20)	35 (11)
Not Willing to measure portions and recording diet	63 (12)	37 (7)	42 (8)	58 (11)	37 (7)	63 (12)
Not Willing to measure portions and NOT recording diet	28 (13)	72 (33)	17 (8)	83 (38)	54 (25)	46 (21)
Willing to record PA and recording PA	61 (25)	39 (16)	44 (18)	56 (23)	54 (22)	46 (19)
Willing to record PA and NOT recording PA	25 (14)	75 (41)	18 (10)	82 (45)	67 (37)	33 18()
NOT Willing to record PA and recording PA	50 (2)	50 (2)	25 (1)	75 (3)	25 (1)	75 (3)
NOT Willing to record PA and NOT recording PA	36 (9)	64 (16)	20 (5)	80 (20)	28 (7)	72 (18)

8.1.9 The relationship between self-monitoring and attendance on weight loss and PA outcomes at 6, 12 and 18 months

The relationships of core and post-core dietary and PA self-monitoring and attendance to weight loss and PA outcomes at 6, 12 and 18 months are reported in Tables 8-15 and 8-16. Generally, as participants engage in higher frequencies of self-monitoring and attendance the frequency of achieving 5% and 7% weight loss and ≥150 minutes of PA/week at 6, 12 and 18 months increases compared to those who are the least frequent self-monitors and attenders (Table 8-15). Interestingly, no participants who attend <2 post-core sessions achieve 7% weight loss at 12 months, while 59% participants who attend all 6 post-core sessions achieve to 7% weight loss ($p<0.0001$). Seventy-eight percent of participants who submitted >13 core activity self-monitoring records achieve 5% weight loss at 12 months, compared to 35% and 33% among participants completing 2-13 and <2 core activity self-monitoring records, respectively (Figure 8-2) . Weight loss and PA goal achievement at 18 months also appear to be related to self-monitoring and attendance during the core and post-core.

Table 8-15: Frequency and percent of participants in each self-monitoring and attendance category during the core and post-core achieving 5% and 7% weight loss and ≥150 minutes of PA/week at 6 and 12 months.

	Weight Loss and Activity Goals											
	At 6 months						At 12 months					
	5% weight loss		7% weight loss		150 minutes		5% weight loss		7% weight loss		150 minutes	
Predictors	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)
Core Diet	p<0.0001		p<0.0001		p<0.05		p<0.0001		p<0.0001		P=0.01	
<7	20 (9)	80 (37)	15 (7)	85 (39)	43 (20)	57 (26)	22 (10)	78 (36)	9 (4)	91 (42)	35 (16)	65 (30)
7-18	54 (54)	46 (46)	31 (31)	69 (69)	63 (63)	37 (37)	43 (43)	57 (57)	34 (34)	66 (66)	60 (60)	40 (40)
>19	83 (34)	17 (7)	61 (25)	39 (16)	66 (27)	34 (14)	76 (31)	24 (10)	61 (25)	39 (16)	61 (25)	39 (16)
Core Activity	p<0.0001		p<0.0001		p=0.007		p<0.0001		p<0.0001		p=0.003	
<2	31 (13)	69 (29)	21 (9)	79 (33)	40 (17)	60 (25)	33 (14)	67 (28)	14 (6)	86 (36)	33 (14)	67 (28)
2-13	47 (47)	53 (53)	25 (25)	75 (75)	60 (60)	40 (40)	35 (35)	65 (65)	28 (28)	72 (72)	56 (56)	44 (44)
>13	82 (37)	18 (8)	64 (29)	36 (16)	73 (33)	27 (12)	78 (35)	22 (10)	64 (29)	36 (16)	69 (31)	31 (14)
Core Attendance	p=0.0002		p=0.0001		p=0.1		p=0.01		p=0.0008		p=0.03	
>12	23 (8)	77 (27)	11 (4)	89 (31)	43 (15)	57 (20)	26 (9)	74 (26)	9 (3)	91 (32)	40 (14)	60 (21)
12-15	53 (47)	47 (42)	29 (26)	71 (63)	62 (55)	38 (34)	44 (39)	56 (50)	35 (31)	65 (58)	51 (45)	49 (44)
16	67 (42)	33 (21)	52 (33)	48 (30)	63 (40)	37 (23)	57 (36)	43 (27)	46 (29)	54 (34)	67 (42)	33 (21)
Post-Core Diet							p<0.0001		p<0.0001		p=0.006	
0							31 (38)	69 (84)	20 (25)	80 (97)	47 (57)	53 (65)
>=1							71 (46)	29 (19)	58 (38)	42 (27)	68 (44)	32 (21)
Post-Core Activity							p<0.0001		p<0.0001		p=0.0003	
0							33 (42)	67 (85)	23 (29)	77 (98)	45 (57)	55 (70)
>=1							70 (42)	30 (18)	57 (34)	43 (26)	73 (44)	27 (16)
Post-Core Attendance							p<0.0001		p<0.0001		p=0.02	
<2							15 (7)	85 (39)	0 (0)	100 (46)	37 (17)	63 (29)
2-5							43 (35)	57 (47)	34 (28)	66 (54)	56 (46)	44 (36)
6							71 (42)	29 (17)	59 (35)	41 (24)	64 (38)	36 (21)
Total Diet							p<0.0001		p<0.0001		p=0.01	
<7							22 (10)	78 (36)	9 (4)	91 (42)	35 (16)	65 (30)
7-22							40 (38)	60 (57)	32 (30)	68 (65)	59 (56)	41 (39)
>22							78 (36)	22 (10)	63 (29)	37 (17)	63 (29)	37 (17)
Total Activity							p<0.0001		p<0.0001		p=0.0007	
<2							33 (14)	67 (28)	14 (6)	86 (36)	33 (14)	67 (28)
2-16							33 (33)	67 (66)	28 (28)	72 (71)	54 (53)	46 (46)
>16							80 (37)	20 (9)	63 (29)	37 (17)	74 (34)	26 (12)
Total Attendance							p<0.0001		p<0.0001		p=0.02	
<14							15 (6)	85 (33)	0 (0)	100 (39)	36 (14)	64 (25)
14-21							46 (52)	54 (61)	37 (42)	71 (71)	56 (63)	44 (50)
22							76 (29)	24 (9)	60 (21)	14 (14)	69 (24)	31 (11)

Table 8-16: Percent and frequency of participants in each self-monitoring and attendance category during the core and post-core achieving 5% and 7% weight loss and ≥150 minutes of PA/week at 18 months.

	At 18 months					
	5% weight loss		7% weight loss		150 minutes	
Predictors	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)	Met %(n)	Not Met %(n)
Core Diet	P=0.004		P=0.009		P=0.2	
<7	27 (9)	73 (24)	18 (6)	82 (27)	45 (15)	55 (18)
7-18	34 (23)	66 (45)	21 (14)	79 (54)	63 (43)	37 (25)
>18	66 (19)	34 (10)	48 (14)	52 (15)	55 (16)	45 (13)
Core Activity	P=0.001		P=0.005		P=0.7	
<2	38 (11)	62 (18)	21 (6)	79 (23)	52 (15)	48 (14)
2-13	27 (18)	73 (49)	18 (12)	82 (55)	57 (38)	43 (29)
>13	65 (22)	35 (12)	47 (16)	53 (18)	62 (21)	38 (13)
Core Attendance	P=0.04		P=0.02		P=0.4	
>12	22 (5)	78 (18)	1 (4)	96 (22)	52 (12)	48 (11)
12-15	36 (21)	64 (38)	27 (16)	73 (43)	53 (31)	47 (28)
16	52 (25)	48 (23)	35 (17)	65 (31)	65 (31)	35 (17)
Post-Core Diet	P=0.0003		P=0.0008		P=0.3	
0	27 (22)	73 (59)	16 (13)	84 (68)	60 (49)	40 (32)
>=1	59 (29)	41 (20)	43 (21)	57 (28)	51 (25)	49 (24)
Post-Core Activity	Pp=0.0004		P=0.002		P=0.9	
0	28 (24)	72 (61)	18 (15)	82 (70)	56 (48)	44 (37)
>=1	60 (27)	40 (18)	42 (19)	58 (26)	58 (26)	42 (19)
Post-Core Attendance	P<0.0001		P<0.0001		P=0.2	
<2	10 (3)	90 (26)	7 (2)	93 (27)	45 (13)	55 (16)
2-5	35 (19)	65 (36)	18 (10)	82 (45)	56 (31)	44 (24)
6	63 (29)	37 (17)	48 (22)	52 (24)	65 (35)	(16)
Total Diet	P=0.0008		P=0.002		P=0.02	
<7	27 (9)	73 (24)	18 (6)	82 (27)	45 (15)	55 (18)
7-22	31 (19)	69 (43)	18 (11)	82 (51)	69 (43)	31 (19)
>22	66 (23)	34 (12)	49 (17)	51 (18)	46 (16)	54 (19)
Total Activity	P=0.001		P=0.0006		P=0.7	
<2	38 (11)	62 (18)	21 (6)	79 (23)	52 (15)	48 (14)
2-16	26 (17)	74 (48)	15 (10)	85 (55)	57 (37)	43 (28)
>16	64 (23)	36 (13)	50 (18)	50 (18)	61 (22)	39 (14)
Total Attendance	P=0.0003		P=0.003		P=0.06	
>14	12 (3)	88 (22)	8 (2)	92 (23)	48 (12)	52 (13)
14-21	38 (29)	62 (47)	24 (18)	76 (58)	53 (40)	47 (36)
22	66 (19)	34 (10)	48 (14)	52 (15)	76 (22)	24 (7)

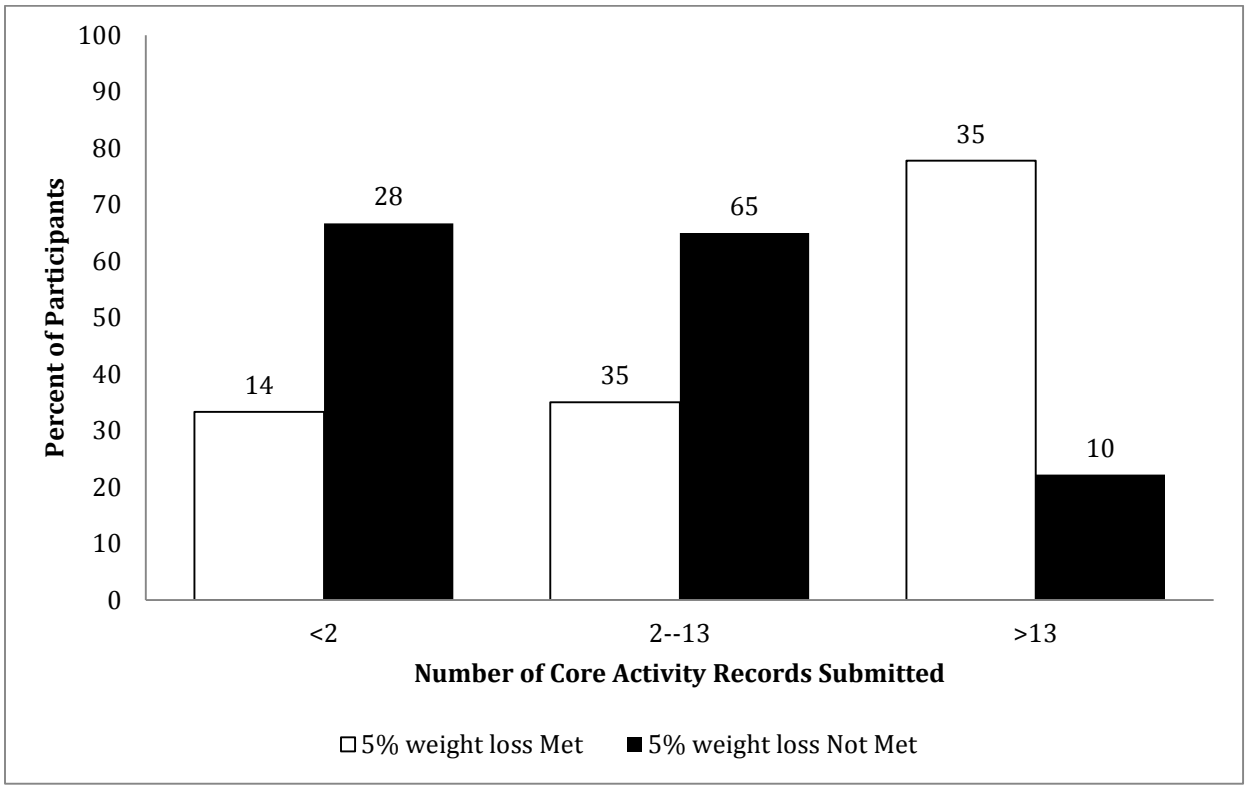

Figure 8-1: Percentage of participants who achieved 5% weight loss at 12 months categorized by the number of core activity records submitted (Number per category on top of bar).

The results of simple logistic regression evaluating the relationship of self-monitoring and attendance during the core and post-core to weight loss and PA at 6 and 12 months are presented in Table 8-17. Not surprisingly, participants who submit >18 core dietary self-monitoring records are 20.0 (95% CI 6.7-59.5) times more likely to achieve 5% weight loss at 6 months compared to participants who submit <7 core dietary self-monitoring records (Table 8-17). Participants submitting >13 PA self-monitoring records during the core are 7 (95% CI 2.7-18.1) times more likely to achieve 5% weight loss at 12 months than participants who submitted <2 PA self-monitoring records during the core (Table 8-17).

In addition, participants who self-monitor and attend in the highest frequency category during the core are significantly more likely to achieve 5% and 7% weight loss at 18 months compared to participants in the least frequent monitoring and attendance categories. Post core attendance and dietary and PA self-monitoring are also significantly related to 18 month weight loss outcomes (Table 8-18).

The relationships between core self-monitoring and core attendance and achieving 5% and 7% weight loss and ≥150 minutes of PA/week at 6 months remained similar to the results of simple logistic regression (Table 8-17) after adjusting for age, gender, education and employment, with the exception of the relationship between core-dietary self-monitoring and achievement of ≥150 minutes/week of PA at 6 months, which was no longer significant. Similarly, after adjusting for age, gender, education and employment the relationships between core and post-core self-monitoring and core and post-core attendance and 12 month outcomes were similar to the results of simple logistic regression (Table 8-17). At 18 months, the relationship between core activity monitoring >13 times and achieving 7% weight loss were and the relationship between attending 12-15 core sessions and achieving 7% weight loss were attenuated by adjusting for age, gender,

education and employment. All remaining relationships between self-monitoring and attendance during the core and post-core and 18 month outcomes were similar to the results of simple logistic regression (Table 8-18).

Table 8-17: Odds Ratios and 95% CIs for self-monitoring and attendance during the core and post-core and achievement of 5% and 7% weight loss and ≥150 minutes of PA/week at 6 and 12 months.

	Weight Loss and Activity Goals											
	At 6 months						At 12 months					
	5% weight loss		7% weight loss		150 minutes		5% weight loss		7% weight loss		150 minutes	
Predictors	OR	CI	OR	CI	OR	CI	OR	CI	OR	CI	OR	CI
Core Diet												
<7	1.0	--	1.0	--	1.0	--	1.0	--	1.0	--	1.0	--
7-18	4.8	2.1,11.0	2.5	1.0,6.2	2.2	1.1,4.5	2.7	1.2,6.1	5.4	1.8,16.3	2.8	1.4,5.8
>18	20.0	6.7,59.5	8.7	3.1,24.1	2.5	1.1,6.0	11.2	4.1,30.3	16.4	4.9,54.6	2.9	1.2,7.0
Core Activity												
<2	1.0	--	1.0	--	1.0	--	1.0	--	1.0	--	1.0	--
2-13	2.0	0.9,4.2	1.2	0.5,2.9	2.2	1.1,4.6	1.1	0.5,2.3	2.3	0.9,6.1	2.5	1.2,5.4
>13	10.3	3.8,28.2	6.6	2.6,17.3	4.0	1.6,10.0	7.0	2.7,18.1	10.9	3.8,31.3	4.4	1.8,10.9
Core Attendance												
>12	1.0	--	1.0	--	1.0	--	1.0	--	1.0	--	1.0	--
12-15	3.8	1.5,9.2	3.2	1.0,10.0	2.2	0.9,4.8	2.3	0.9,5.4	5.7	1.6,20.1	1.5	0.7,3.4
16	6.8	2.6,17.4	8.5	2.7,27.0	2.3	0.9,5.4	3.9	1.6,9.5	9.1	2.5,32.8	3.0	1.3,7.1
Post-Core Diet												
0							1.0	--	1.0	--	1.0	--
>=1							5.3	2.8,10.3	5.4	2.8,10.6	2.3	1.3,4.5
Post-Core Activity												
0							1.0	--	1.0	--	1.0	--
>=1							4.7	2.4,9.2	4.4	2.3,8.5	3.4	1.7,6.6
Post-Core Attendance												
<2							1.0	--	1.0	--	1.0	--
2-5							4.1	1.6,10.3	--	--	2.2	1.0,4.6
6							13.8	5.2,36.7	--	--	3.1	1.4,6.9
Total Diet												
<7							1.0	--	1.0	--	1.0	--
7-22							2.4	1.1,5.4	4.8	1.6,14.8	2.7	1.3,5.6
>22							13.0	4.8,34.9	17.9	5.5,58.7	3.2	1.4,7.5
Total Activity												
<2							1.0	--	1.0	--	1.0	--
2-16							1.0	0.5,2.2	2.4	0.9,6.2	2.3	1.1,4.9
>16							8.2	3.1,21.7	10.2	3.6,29.3	5.7	2.3,14.2
Total Attendance												
>14							1.0	--	1.0	--	1.0	--
14-21							4.7	1.8,12.1	--	--	2.3	1.1,4.7
22							15.9	5.0,50.4	--	--	3.9	1.5,10.3

Table 8-18: Odds Ratios and 95% CIs for self-monitoring and attendance during the core and post-core and achievement of 5% and 7% weight loss and ≥150 minutes of PA/week at 18 months.

	At 18 months					
	5% weight loss		7% weight loss		150 minutes	
Predictors	OR	CI	OR	CI	OR	CI
Core Diet						
<7	1.0	--	1.0	--	1.0	--
7-18	1.4	0.5,3.4	1.2	0.4,3.4	2.1	0.9,4.8
>18	5.1	1.7,15.0	4.2	1.3,13.2	1.5	0.5,4.0
Core Activity						
<2	1.0	--	1.0	--	1.0	--
2-13	0.6	0.2,1.5	0.8	0.3,2.5	1.2	0.5,2.9
>13	3.0	1.1,8.4	3.4	1.1,10.5	1.5	0.6,4.1
Core Attendance						
>12	1.0	--	1.0	--	1.0	--
12-15	2.0	0.6,6.1	8.2	1.0,65.8	1.0	0.4,2.7
16	3.9	1.3,12.3	12.1	1.5,97.4	1.7	0.6,4.6
Post-Core Diet						
0	1.0	--	1.0	--	1.0	--
>=1	3.9	1.8,8.2	3.9	1.7,8.9	0.6	0.3,1.2
Post-Core Activity						
0	1.0	--	1.0	--	1.0	--
>=1	3.8	1.8,8.2	3.4	1.5,7.7	1.1	0.5,2.2
Post-Core Attendance						
<2	1.0	--	1.0	--	1.0	--
2-5	4.6	1.2,17.1	3.0	0.6,14.7	1.5	0.6,3.9
6	14.8	3.9,56.3	12.4	2.6,58.2	2.3	0.9,6.0
Total Diet						
<7	1.0	--	1.0	--	1.0	--
7-22	1.2	0.5,3.0	1.0	0.3,2.9	2.7	1.1,6.5
>22	5.1	1.8,14.4	4.3	1.4,12.8	1.0	0.4,2.6
Total Activity						
<2	1.0	--	1.0	--	1.0	--
2-16	0.6	0.2,1.4	0.7	0.2,2.1	1.2	0.5,3.0
>16	2.9	1.1,8.0	3.8	1.3,11.6	1.5	0.5,3.9
Total Attendance						
>14	1.0	--	1.0	--	1.0	--
14-21	4.5	1.2,16.5	3.6	0.8,16.6	1.2	0.5,3.0
22	13.9	3.3,58.2	10.7	2.1,54.1	3.4	1.1,10.8

8.1.10 Individual characteristics related to weight loss and PA outcomes at 6, 12 and 18 months

The evaluation of individual characteristics among participants achieving/not achieving 5% or 7% weight loss and ≥150 minutes/week of PA at 6, 12 or 18 months identified significant

differences in age, education and employment. Participants achieving 5% weight loss at 12 or 18 months and participants achieving 5% weight loss at 6, 12 and 18 months were significantly older than those not achieving 5% weight loss at these time points. Also, participants achieving 5% weight loss at 6, 12 and 18 months had significantly different employment status (employment =part-time/full-time, employment=all others) ($p=0.02$) than those not achieving 5% weight loss at these time points, with a greater frequency of those employed less than full or part-time achieving the 5% weight loss goal compared to those employed full or part-time. However there were no significant differences noted in achievement of the 5% weight goal at any time point when stratified by age (age<55 and age≥55). At 18 months, employment ($p=0.007$) and education ($p=0.003$) (education < bachelor's degree, education ≥ bachelor's degree) were significantly different among participants who achieved 5% weight loss compared to those who did not achieve 5% weight loss, with a greater frequency of those employed less than full or part-time and those with less than a bachelor's degree achieving the 5% weight loss goal compared to those employed full or part-time or with a bachelor's degree or higher. However, when stratified by age these relationships were no longer significant. Additionally, education was significantly different ($p=0.02$) among participants who did and did not achieve 7% weight loss at 18 months, with a greater frequency of those with less than a bachelor's degree achieving the 7% weight loss goal compared to those with more education. Again, this relationship was no longer significant when stratified by age.

8.2 SUMMARY OF FINDINGS

In the current study, willingness to engage in healthy lifestyle practices was high at baseline for almost all reported behaviors. However, at 6 months the proportion of participants willing to engage in healthy lifestyle practices decreased significantly for approximately half of the behaviors and at 12 months willingness to engage in all behaviors except to purposely eat smaller portions, substitute water for calorie/sugar-filled beverages and plan meals decreased significantly. During the core and post-core intervention session attendance was high, while the high levels of dietary and activity self-monitoring observed during the 6 month core were not sustained during the 6 month post-core. Not surprisingly, participants who attended more sessions and self-monitored diet and PA more frequently met weight loss and PA goals at a higher rate.

Individuals who participate in lifestyle intervention studies are often already committed to making healthy lifestyle changes or identify more positive results associated with a healthy lifestyle than those who do not volunteer[121, 122]. This mindset is likely related to their willingness to engage in healthy lifestyle practices, so it is not surprising that the overwhelming majority of participants in the current study were willing to engage in healthy lifestyle practices at baseline. Although there is a large literature base regarding readiness to change or the stages of change in weight loss and other health behaviors [123, 124], there is little specifically related to participant willingness to participate in the healthy lifestyle practices before and during the program.

In the current study, a significant proportion of these same highly willing participants reported a reduction in willingness to engage in healthy lifestyle practices at 6 and 12 months. Specifically, the healthy lifestyle practices believed to be important for success in behavioral lifestyle interventions [18], such as using a keeping track book, recording calories, fat and PA and

measuring portions, all declined significantly at the conclusion of the intervention. If the goal is to identify participants who will engage in these important behaviors, perhaps requiring a run-in period similar to that of the DPP [21] should be utilized, but the question of feasibility in community based DPP translation remains to be answered.

Evaluation of the association between willingness to engage in healthy lifestyle practices at 6 months and achieving 5% and 7% weight loss and ≥150 minutes/week of PA at 12 and 18 months suggests that willingness to self-monitor diet and participate in PA is important for achieving weight loss and PA goals. These results are similar to what has been found in other weight loss and weight maintenance studies regarding the importance of self-monitoring and being physically active. Successful participants in the National Weight Control Registry, a cohort that has maintained significant weight loss over a long period of time, report engaging in high levels of physical activity and maintaining a low-fat, low-calorie diet [125]. Similarly, a DPP translation investigating achievement and long-term maintenance of the 7% weight loss goal demonstrated that successful participants engaged in high-levels of PA and identified and corrected poor dietary choices before they led to weight gain [126]. The results of the current investigation suggesting participants who are willing to be active even when not feeling like and to use a keeping track book further demonstrate the importance of these behaviors for weight maintenance.

During the 6 month core intervention participants completed a mean of 11.7 and 7.9 dietary and activity records, respectively. This was similar to the mean of 10.1 and 9.2 dietary records reported in two other diabetes prevention translation studies [13, 105]. As shown in table 8-15, the association between greater frequencies of self-monitoring and weight loss and PA outcomes is consistent with what has been reported in other diabetes prevention translation studies [13, 44, 45]. Session attendance is a frequently reported outcome among diabetes prevention translation efforts,

but the association between attendance and future weight loss and PA outcomes is not often explored in diabetes prevention translation. In the current study, attending all 16 core intervention sessions was significantly associated with achieving 5% and 7% weight loss at 6, 12 and 18 months. Additionally, attending all 6 post-core intervention sessions was significantly associated with achieving the same weight loss outcomes at 12 and 18 months. Although it is difficult to discern whether attendance at the intervention sessions promotes weight loss or those who are doing well are attending the sessions, while those who are not doing well do not attend, the results of this study suggest that encouraging higher levels of session attendance will aid in weight loss success.

In the DPP, other factors that were significantly related to achieving 7% weight loss included older age, lower BMI at baseline and male gender [20]. In a DPP translation study evaluating other characteristics associated with meeting the 7% weight loss goal the findings were similar to that of the DPP, suggesting that older participants and men were more likely to meet the weight loss goal than participants without these characteristics [44]. In the current study, participants achieving 5% weight loss at 12 or 18 months and participants who achieved 5% weight loss at 6, 12 and 18 months were significantly older compared to participants not achieving 5% weight loss at these time points. Interestingly, the current study did not find a significant difference in gender among those achieving and not achieving weight loss or PA goals.

Adjusting for documented self-monitoring of diet and PA during the core and post-core attenuated the relationship between willingness to engage in behaviors related to self-monitoring at 6 months and weight loss outcomes at 12 and 18 months. However, the relationship between willingness to be active even when not feeling like it at 6 months and 7% weight loss at 12 months remained significant. Additionally, willingness to engage in ≥ 30 minutes of PA and to be active

even when not feeling like it at 6 months continued to be significantly associated with achieving ≥150 minutes/week of PA at 12 months after adjusting for core and post-core diet and activity self-monitoring. Willingness to engage in ≥ 30 minutes of PA at 6 months was also significantly associated with achieving ≥150 minutes/week of PA at 18 months after adjusting for core and post-core diet and activity self-monitoring. These results suggest that willingness to engage in practices related to PA may be important for participants following through and being more physically active.

There are limitations to the current study that should be addressed. The Willingness Questionnaire that was used has not been validated, however very little exists in the literature regarding assessment of participants' willingness to engage in important healthy lifestyle practices. Additionally, participants attended an information session prior to enrolling in the study which may have helped to identify and deter from enrollment those who were not willing to engage in healthy lifestyle practices. The measure of physical activity reported in this study was collected via a subjective, self-report survey. Also, the study population was composed of over 90% Caucasians and may not be generalizable to other groups or settings.

Although baseline willingness, as assessed in the current study, was of limited value as a predictor for future achievement of weight loss and PA goals, the notion that willingness to participate in these important healthy lifestyle practices decreases over time in a behavioral lifestyle intervention is a novel finding. Also, the high levels of willingness at baseline may lend support to the assertion that participants who volunteer for intervention studies are more motivated than those who do not. Results related to the importance of self-monitoring and attendance for success with weight loss and PA goal achievement in the current study reinforced what has been demonstrated previously in the relatively few studies that reported on this outcome in diabetes

prevention translation. The significance of willingness to be active even when not feeling like it after adjustment for self-monitoring, age, education, employment and gender suggests that willingness to be active is important for achieving weight loss and PA goals, independent of documented self-monitoring. Moving forward in diabetes prevention translation self-monitoring of diet and activity should remain integral parts of lifestyle interventions, but encouraging participants to be willing to incorporate PA into their routine as often as possible (even when they don't feel like doing so) may enhance success related to weight loss and PA outcomes.

8.3 PAPER #3 SUMMARY

Objective: Self-monitoring of diet and PA are key components in community based translations of the Diabetes Prevention Program, but little is known about participants' willingness to engage in these and other healthy lifestyle practices. The purpose of this manuscript is to investigate the relationship between participant willingness to engage in healthy lifestyle practices and achievement of the weight loss and PA goals of a community based adaptation of the DPP intervention. In addition, other factors such as individual participant characteristics and program engagement (i.e. session attendance and self-monitoring) will be evaluated for their association with program success, defined as achievement of program goals.

Design and Methods: Participants were recruited at a worksite and three community centers to take part in a randomized delayed-control trial evaluating the effectiveness of the DPP-GLB program with the primary outcome of weight loss. Participants completed the willingness questionnaire at baseline, 6 and 12 months and dietary and PA self-monitoring record keeping and attendance were documented over the course of the one-year intervention.

Results: A total of 187 out of 223 overweight or obese adults with prediabetes and/or metabolic syndrome attended baseline, 6 and 12 month assessments. Participants were very willing to engage in healthy lifestyle practices at baseline, and willingness to engage practices related to self-monitoring at 6 months were significantly related to achieving 5% and 7% weight loss at 12 months. However, in multivariate regression only willingness to be active even when not feeling like it remained significantly associated with 7% weight loss at 12 months.

Conclusions: In general, documented self-monitoring of diet and PA accounted for the achievement of 5% and 7% weight loss when compared to willingness to engage in health lifestyle practices with the exception of willingness to be active even when not feeling like it. Community

based translations of the DPP should continue to promote the importance of self-monitoring for the benefit of the participant, but at the same time encourage participants to be willing to adopt a more active lifestyle (even when they don't feel like it) as this may improve their chances of meeting weight loss and PA goals.

9.0 DISSERTATION FINAL CONSIDERATIONS

9.1 SUMMARY CONCLUSIONS

The level of concern presented by the projected increases in type 2 diabetes over the next several decades coupled with the already high prevalence of prediabetes and the metabolic syndrome highlight the importance of a public health level approach to this crisis [3, 52]. The HEALTHY Lifestyle study is a direct response to this call to action and as a whole will provide invaluable information regarding implementation of community based DPP translations in a worksite, at community centers and among both retired and activity duty military personnel and their spouses and dependents. Specifically, the results of this dissertation provide a more in depth investigation into questions regarding screening and identification of high-risk participants, the impact of a pre-intervention delay on participant weight loss and physical activity increases, and identification of important behavioral and personal elements unique to successful participants in a community based translation of the Diabetes Prevention Program (DPP) lifestyle intervention.

Paper 1 demonstrated that the ADA risk test, body mass index (BMI), waist circumference and waist to height ratio do not adequately discriminate between participants with prediabetes and/or metabolic syndrome and participants free of these conditions. Each measure identified the majority of participants with prediabetes and/or metabolic syndrome, but also had very low sensitivity. If used singularly, these measures would allow for the enrollment of a substantial number of participants who do not meet a definition of high risk that includes prediabetes and/or the metabolic syndrome. At the current time, there does not appear to be an adequate substitute for blood based measures to identify high risk participants. However, implementing a stepped

screening process in which participants are initially assessed using a non-invasive measure and following up with those meeting a high risk cut point using blood based measures may hold promise, as has been demonstrated previously [32]. Further study is needed to determine the most efficient, cost effective method to identify individuals who have prediabetes or meet additional program specific eligibility criteria like the metabolic syndrome and may include recent advances in technology such as skin fluorescence spectroscopy [127].

The results of paper 2 suggest that a mean pre-intervention delay of approximately 9 months among LATER participants did not adversely affect weight loss, intervention attendance, and self-monitoring when compared to IMMEDIATE participants. In addition, weight change, as categorized in this paper, occurring during the pre-intervention delay did not impact weight loss and PA levels at 6 and 12 months. These findings are important in community based translation due to the high likelihood that a delay will occur from the time a participant is screened and identified as high risk for diabetes and when they are enrolled in a community based DPP translation. Providers of community based DPP translations should not view delays resulting from the screening and enrollment process or due to lack of staffing as a barrier to providing prevention services.

Finally, the results of paper 3 confirm the widely held assumption that participants who volunteer for behavioral lifestyle interventions are willing to engage in healthy lifestyle practices at baseline. However, there was a general downward trend in willingness to engage in most practices over the course of the one-year intervention. In univariate analysis, willingness to use a keeping track book, record calories, record PA and be active when not feeling like it were associated with weight loss and PA outcomes. However, when evaluated in combination with self-monitoring and attendance, known predictors of success in behavioral weight loss interventions

[20, 44], the importance of willingness was attenuated, with the exception of willingness to be active even when not feeling like it. Community based translations of the DPP should continue to promote the importance of self-monitoring for the benefit of the participant, but at the same time encourage participants to be willing to adopt a more active lifestyle (even when they don't feel like it) as this may improve their chances of meeting weight loss and PA goals.

9.2 PUBLIC HEALTH SIGNIFICANCE

The results of this dissertation are very relevant for organizations planning to implement a community based translation of the DPP and will facilitate program delivery on a wider scale. Specifically, the results of the screening process evaluated in this dissertation provide key information regarding possible methods for identifying eligible individuals for community based DPP translations. This information will allow organizations to make decisions about this matter based on the purpose of their effort and/or the requirements of outside funding or recognizing agencies. Given that there are an estimated 79 million adults in the United States (US) with prediabetes, it is highly likely that many who enroll in community based diabetes prevention programs will be required to wait to start a program following the notification that they are at high-risk for diabetes. The results of this dissertation suggest that this waiting period should not hinder their participation and success related to weight loss and physical activity once the intervention begins. The importance of self-monitoring and attendance should continue to be a focal point of the lifestyle coaches message while delivering community based diabetes prevention programs. In addition, encouraging participants to be willing to adopt a more active lifestyle (even when they don't feel like it) may provide additional benefits in terms of meeting weight loss and PA goals.

The evaluation of non-invasive screening methods used in the context of a community based translation of the DPP lifestyle intervention demonstrated that none of the non-invasive screening methods achieved an acceptable level of discrimination in the identification of prediabetes and/or the metabolic syndrome; although each measure did have very high sensitivity (APPENDIX A). This finding is important because it identifies the shortcomings of these methods if the goal of implementation is to only enroll high-risk participants with prediabetes. However, if eligibility criteria are more flexible, the high levels of specificity shown by these non-invasive measures suggest that if used, they will identify most individuals screened who have prediabetes and/or the metabolic syndrome. This is an important consideration when planning a large scale, public health approach to diabetes prevention. The first step in a move towards a more inclusive eligibility criteria has been approved by the Centers for Disease Control and Prevention (CDC) Diabetes Prevention Recognition Program standards which allow approved programs to enroll up to 50% of participants based on the results of the ADA risk test in the absence of blood based confirmation of prediabetes [33].

As mentioned, the overwhelming number of adults in the US with prediabetes means it is likely that a delay from the time individuals are informed of their prediabetes status prior to enrollment in a diabetes prevention program will occur. This assertion is supported by a survey of diabetes education programs that indicate limited staff to provide interventions is a main concern when deciding to offer diabetes prevention services [17]. The non-significant finding of the comparison of weight loss among the IMMEDIATE and LATER groups in this dissertation is a key finding moving forward in community based translation of the DPP (APPENDIX B). From a participant's perspective, knowing that others have been successful in similar programs following a time lag prior to intervention should provide them with reassurance. From the perspective of the

organization offering the community based program, staff should not feel discouraged when putting participants on a waiting list for subsequent rounds of intervention. Finally, a physician should not be dissuaded from continuing to refer participants to community based DPP translations even when they are aware that patients may experience a waiting period. Prevention of diabetes is going to take a cooperative effort from many different groups; including patients and providers, and knowledge that something that was once thought of as a barrier should help to facilitate the level of cooperation that is needed.

The decision to provide community-based translations of the DPP lifestyle intervention is going to be influenced by the availability of resources. Therefore, identification of participants who are most likely to succeed is important. In this dissertation, participants were very willing to engage in healthy lifestyle practices at baseline, and willingness at 6 and 12 months were associated with future weight loss and PA outcomes. However, when evaluated in the presence of documented self-monitoring the relationship between willingness to engage in most health lifestyle practices and weight loss was attenuated, once again confirming the importance of self-monitoring of diet and PA. This study also suggests that those who volunteer to take part in a community based research trial are very willing to engage in healthy lifestyle practices. In community based DPP translations, the opportunity for a run-in period similar to that of the original DPP to identify those who adhere to the intervention protocol [21] is not available, so a measure that could identify those who are more likely to adhere and achieve success is desirable. The results of this dissertation do not support the use of the willingness questionnaire for this purpose, but these findings may lead to the development of another tool that can identify not only those who are willing but those who will follow through and engage in healthy lifestyle practices. In addition, the findings

regarding willingness to engage in healthy lifestyle practices may be valuable in the development of programs to promote weight loss maintenance.

Taken together the results of this dissertation provide insight into the screening and enrollment process that were not previously known in community based translation of the DPP. These findings provide critical information that future community based DPP translations can utilize to support decisions regarding what screening methods are most appropriate, how to balance staff time for prevention services through the possible use of a waiting list, and which factors are important to focus on for participant success.

9.3 FUTURE DIRECTIONS

Future community based translations will benefit in several ways from the results of this dissertation. In environments where less restrictive eligibility criteria can be used to enroll participants, organizations can select from a variety of non-invasive methods evaluated in paper 1 and be confident they will identify nearly all of the participants they screen with prediabetes and/or the metabolic syndrome. Additionally, when faced with a high volume of participants, utilizing a waiting list should not discourage participants, prevention delivery staff or referring physicians from continuing to offer and refer to diabetes prevention programs. Lastly, reinforcement of the importance of self-monitoring and attendance, as well as a willingness to adopt a more active lifestyle, should be emphasized during the intervention.

There are also several questions that remain to be answered that were brought to light during this investigation. In future community based DPP translations is a stepped screening process, pairing non-invasive methods with blood based measures the best approach? Or should

community based DPP translations place more energy in developing a physician referral base and eliminate the need for a formal screening process altogether? Alternatively, is more research needed on other kinds of tools that can efficiently identify high-risk participants? The likely answer is going to be a combination of these strategies that will be influenced by the organization leading the community based DPP translation or research effort.

Despite the results of this study demonstrating that a pre-intervention delay did not hinder participants' weight loss or increases in PA levels, the similarities of a delay resulting from study design and a delay resulting from limited community resources is unknown. Future community based translations should be aware of this issue and document delays prior to intervention so they can be evaluated in their individual settings.

Finally, determining that willingness to engage in most healthy lifestyle practices addressed by the Willingness Questionnaire are of limited importance for achievement of weight loss and PA goals should preclude its assessment in future diabetes prevention efforts. However, the results of this dissertation do raise an important question regarding the importance of participant's willingness to be active even when not feeling like it and meeting weight loss and PA goals. Further evaluation of this relationship is necessary to confirm the findings of this dissertation, but encouraging participants to engage in PA even when they are not be feeling like it may increase their chance of achieving program goals. In addition, the knowledge that willingness to engage in some of these important healthy lifestyle practices decreases overtime may influence the development of future weight maintenance interventions. On the other hand, reinforcement of the importance of known behavioral strategies like self-monitoring and attendance in future efforts to prevent diabetes should continue.

Appendix A : Paper 1

Title: Evaluation of non-invasive screening measures to identify individuals with prediabetes

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ABSTRACT:

Aims: Because blood-based screening to identify those with prediabetes to take part in Diabetes Prevention Program (DPP) translation efforts can be costly and time-consuming, non-invasive methods are needed. The aims of this paper are to evaluate the ability of the American Diabetes Association (ADA) risk test in identifying individuals with prediabetes, as well as the use of body composition measures for this purpose. In addition the utility of these alternate methods to ascertain the presence of the metabolic syndrome was assessed.

Methods: Potential participants were recruited from a worksite and three community centers to take part in a DPP translation study. Participants completed onsite screening where anthropometric measures, fasting lipids and glucose, and hemoglobin A1c were assessed. Those with a BMI ≥24kg/m^2 and prediabetes and/or the metabolic syndrome were eligible to participate. Non-invasive screening methods were evaluated for their ability to identify those with prediabetes based on clinically measured values.

Results: All non-invasive methods were highly sensitive (68.9% to 98.5%) in the detection of prediabetes, but specificity was low (6.7% to 44.5%). None of the alternatives evaluated achieved acceptable discrimination levels in ROC analysis. Similar results were noted in identifying the metabolic syndrome.

Conclusions: The non-invasive methods evaluated in this study effectively identified participants with prediabetes, but would have allowed for enrollment of a large number of individuals without prediabetes. Deciding whether to use these alternatives, blood-based measures, or a combination of both will ultimately depend on the purpose of the program and the level of flexibility regarding participant eligibility.

Key Words: screening, prediabetes, lifestyle intervention

1. Introduction

The Centers for Disease Control and Prevention (CDC) currently estimate that 25.8 million people in the United States (US) have diabetes, and an additional 79 million people are at high-risk with prediabetes, identified by impaired fasting glucose, impaired glucose tolerance or hemoglobin A1c[1]. The prevalence of the metabolic syndrome, a constellation of risk factors that increase the risk for diabetes has also been increasing persistently during the past decade[2]. It is estimated that nearly one third of the US population will have diabetes by 2050 due to increases in diabetes incidence and low mortality rates[3].

The US Diabetes Prevention Program (DPP) demonstrated that type 2 diabetes could be prevented or delayed through intensive lifestyle intervention, with the goals of moderate weight loss and increased physical activity levels [4]. The success of the DPP lifestyle intervention has led to a variety of translation efforts conducted in urban and rural areas, within the health care setting, through community groups, and at worksites and academic institutions across the US. Each has demonstrated some level of success in regard to reducing weight, increasing physical activity levels and even improving risk factors for diabetes and cardiovascular disease [5-10].

Accurate identification of high-risk individuals who will benefit the most from taking part in these diabetes prevention translation efforts is essential. In the DPP, eligibility criteria included age ≥25 years, Body Mass Index (BMI) ≥24 kg/m^2 or ≥22 kg/m^2 for Asian Americans, and impaired glucose tolerance diagnosed by a single 75-g oral glucose tolerance test (OGTT) [11]. However, the criteria used to identify high-risk participants who meet program eligibility among community translations of the DPP lifestyle intervention has varied considerably (Table 1). A common theme among them was use of a BMI cut-point (≥24 kg/m^2 or ≥25 kg/m^2), combined with at least one measure of diabetes risk listed in Table 1, including having the metabolic syndrome to determine eligibility [5-10, 12-19].

Given the high numbers of people at risk for diabetes, a simple, inexpensive method, such as a paper risk test or anthropometric measurement, is needed to facilitate the identification of individuals with prediabetes who could subsequently benefit from lifestyle intervention. Published DPP translation efforts that employed a paper risk test to identify high risk individuals to take part in their programs have reported using the 7 question American Diabetes Association (ADA) paper risk assessment developed by Herman et al. in 1995[5, 8, 20]; however the ADA paper risk assessment was created to identify individuals at risk for undiagnosed diabetes, not those with prediabetes. The CDC National Diabetes Prevention Recognition Program (DPRP) guidelines focus on blood-based screening for identification of those with prediabetes for inclusion in diabetes prevention programs. However, while the DPRP standards and operating procedures require that at least half of those enrolled in diabetes prevention programs have documented prediabetes, the guidelines also include use of the ADA paper risk test [21] as an alternative screening method for up to half of enrolled individuals, likely due to a lack of viable, non-invasive screening methods [22]. To date, the ADA risk test has not been evaluated for its ability to identify those with prediabetes in the context of a diabetes prevention translation study.

In other efforts, anthropometric measurements such as BMI[23-26], waist circumference[23, 24, 26], and waist to height ratio[23, 24, 26, 27] have been investigated for their ability to provide details about an individuals' future risk for type 2 diabetes. However, to the authors' knowledge, none of these anthropometric measurements have been evaluated for their ability to identify participants with prediabetes.

Therefore, the aims of this paper are to evaluate the ability of the ADA paper risk assessment test incorporated by the CDC DPRP as well as other non-invasive body composition measures to identify individuals with prediabetes. In addition the utility of these alternate screening methods to ascertain the presence of the metabolic syndrome is assessed. It is anticipated that the availability of alternative

accurate non-invasive methods to identify those at high risk for diabetes will facilitate enrollment of these individuals in community diabetes prevention efforts.

2. Methods

The current evaluation is a secondary analysis of a randomized delayed-control trial evaluating the effectiveness of a DPP based lifestyle intervention with the primary study outcome of weight loss.

2.1. Participant Recruitment and Eligibility

Participants were recruited from a local worksite and three community centers in Allegheny County, Pennsylvania to take part in a National Institutes of Health funded effort evaluating delivery of a DPP based lifestyle intervention translation, the Group Lifestyle Balance (DPP-GLB) program, in a variety of community settings. In the DPP-GLB program, which retains the same weight loss and physical activity goals as the DPP, participants are encouraged to self-monitor diet, physical activity and weight, as well as focus on healthy food choices and increasing physical activity levels [10]. Notification of the upcoming intervention was disseminated via email, print advertisements, mass mailing, health fairs and information sessions at each of the four sites. Interested participants were first screened over the phone or in person at health fairs and information sessions to determine initial eligibility criteria.

The initial screening ensured participants were adults ≥18 years of age, without diagnosed diabetes, with a BMI ≥24kg/m^2 (≥22 kg/m^2 for Asians), were not pregnant or breastfeeding, and were not planning to move away from the area during the projected study time period. Participants who answered "no" to all of these questions and were interested in taking part in the intervention were scheduled to attend an onsite in-person screening.

At the onsite screening, assessment of participants' blood pressure, height, weight and waist circumference were completed following standard protocol. The Cholestech LDX system was used to measure total cholesterol, High-density lipoprotein cholesterol (HDL-C), Low-density lipoprotein cholesterol (LDL-C), triglycerides and glucose after a minimum 8-hour fast, and hemoglobin A1c was

measured using a Siemens/Bayer DCA 2000 by a certified research assistant. Additional information collected for each participant included date of birth, gender, family history of diabetes and heart disease, smoking status, race/ethnicity, employment status, physical activity level, education level, prescription medication use for blood pressure, dyslipidemia and dysglycemia and other female risk factors for diabetes including history of giving birth to an infant >9 lbs. (4.1kg), history of gestational diabetes (GDM) and polycystic 0vary syndrome (PCOS). Participants also completed the 7 question ADA test [20, 22].

Intervention eligibility criteria included: BMI ≥24kg/m^2 or ≥22 kg/m^2 for Asians, prediabetes (fasting glucose of 100-125mg/dl and/or HbA1C of 5.7%-6.4%), and/or the metabolic syndrome (National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) criteria or hyperlipidemia and 1 additional component of the metabolic syndrome) [28, 29].

This project was approved by the University of Pittsburgh Institutional Review Board.

2.2. Non-Invasive Screening Measures Evaluated

The DPRP guidelines suggest using a score of ≥9 on the ADA risk test for participant inclusion criteria, [22] therefore this cut-point was evaluated for its ability to identify participants with prediabetes. Anthropometric measures (BMI, waist circumference and waist to height ratio) were evaluated singularly and in combination with other diabetes risk factors (e.g. family history, physical inactivity) for their ability to identify eligible participants with prediabetes. In addition, all methods were examined for their ability to identify those with the metabolic syndrome. A BMI cut-point of ≥27kg/m^2 is reported on because it is the point at which an individual is considered to be at increased risk according to the BMI question on the ADA risk test [22, 30]. Waist circumferences of >102 centimeters (40 inches) for men and > 88centimeters (35 inches) for women, based on the NCEP ATPIII guidelines for metabolic syndrome [28] and waist to height ratios of ≥0.5 and ≥0.6, selected based on previous investigations, were evaluated [26, 31, 32].

2.3. Data Analysis

Differences among screening characteristics between sites were evaluated using two sample independent t-tests for normally distributed variables and Wilcoxon-Mann-Whitney test for variables not normally distributed. The Chi-square or Fisher's exact tests were used to test for differences in proportions. Sensitivity and specificity were calculated for the non-invasive screening measures in relation to 3 diagnostic criteria using the PROC FREQ procedure to generate 2x2 tables and receiver operating characteristic (ROC) curves were calculated for all 5 screening tests using the PROC LOGISTIC procedure.

Data analyses were conducted using Statistical Analysis Software Version 9.3 (Cary, NC).

3. Results

A total of 364 participants were screened onsite, 64% (233) were female, mean age was 55.8 ±12.5 years, mean BMI was 33.4±6.2 kg/m^2 and mean weight was 93.3±20.1 kg (Table 2). Forty-seven percent of participants reported a family history of diabetes, 45% reported a family history of heart disease, and 22% reported both a family history of diabetes and heart disease (Table 2). Participants were predominately white (92.5%), 89% had at least some college or technical school at screening and 93% were either never or former smokers (Table 2).

Because of the diversity of the study sites, demographic characteristics are presented by screening site. Those screened at the worksite were significantly younger, had a significantly lower BMI, waist circumference and hemoglobin HbA1c than those screened at the community sites (Table 2). Community site screening participants had significantly lower total cholesterol, LDL cholesterol and diastolic blood pressure than those screened at the worksite. Other significant differences between the sites included the percent of female participants, level of education and smoking status (Table 2).

Of the 364 screened participants 72% (261) met DPP-GLB study eligibility criteria with 55% (200) determined to have prediabetes (criteria: fasting glucose of 100-125mg/dl and/or HbA1C of 5.7%-6.4%) (Table 3). A score of ≥9 on the ADA risk test identified 89% (323) of screening participants as eligible, and a BMI cut-point of ≥27kg/m^2 identified 86% (313) of screening participants as eligible. Further, the

selected waist circumference criteria identified 78% (285) of screening participants as eligible, a waist to height ratio of ≥0.5 identified 96% (350) screening participants as eligible and a waist to height ratio of ≥0.6 identified 62% (227) screening participants as eligible. The frequency of those meeting eligibility criteria and screening positive for the non-invasive methods are also presented stratified by intervention site to display similarities.

Table 4 provides the sensitivity and specificity results for the ADA risk test and the other methods in identifying those with prediabetes. The ADA risk test score of ≥9 was highly sensitive (93.5%) in the identification of participants with prediabetes, but specificity was also very low (17.1%). Subsequently higher scores on the ADA risk test decreased sensitivity and increased specificity with the greatest balance occurring at a score of ≥12 in the identification of prediabetes (sensitivity=64.5%, specificity=48.8%).

The BMI cut-point of ≥27kg/m^2 was also highly sensitive (89.0%) in the identification of participants with prediabetes, but also had very low specificity (17.7%). The BMI cut-point of ≥27kg/m^2 in combination with a family history of diabetes had a sensitivity of 47.6% for the identification of participants with prediabetes, but demonstrated better specificity than any of the other screening methods (62.8%). A BMI cut-point of ≥30kg/m^2 reduced sensitivity (68.5%) and increased specificity (37.2), but specificity still remained quite low and progressively higher BMI values did not improve the measure further.

A waist to height ratio ≥0.5 had similar issues to the BMI cut-point of ≥27kg/m^2 and the ADA risk test score ≥9 in the identification of participants with prediabetes (sensitivity=98.5% and specificity=6.7%); however, a waist to height ratio of ≥0.6 was moderately sensitive (68.0%) and moderately specific (44.5%). The waist circumference criteria performed similarly to the waist to height ratio of ≥0.6 in identification of prediabetes (sensitivity 82.0% and specificity 26.2%). Non-invasive methods performed similarly across intervention sites. The addition of family history of diabetes to waist circumference reduced sensitivity to 47.0% or less, with increases in specificity (data not shown).

Excluding A1c criteria from the category of prediabetes and using only IFG did not have a remarkable influence on sensitivity and specificity (data not shown).

Receiver operating characteristic (ROC) curve results demonstrated that a waist to height ratio of ≥0.6 was the most effective in the identification of prediabetes, but was not significantly different from either a BMI cut-point, waist circumference criteria or the ADA risk test (data not shown). None of the area under the curve (AUC) values for any screening criteria evaluated were within the acceptable discrimination range (i.e. a score of >0.70) described by Hosmer and Lemeshow.[33] Results were not different when stratified by site.

4. Discussion

This is the first study to report on the sensitivity and specificity of the ADA risk test and other non-invasive measures in the identification of prediabetes confirmed by fasting blood glucose or hemoglobin A1c in diabetes prevention translation. The ADA risk test score of≥9, BMI cut-point of ≥27kg/m^2 and waist to height ratio of ≥0.5 all effectively identified participants who had prediabetes, but they all suffered from low specificity. In the current study, if any non-invasive method were used exclusively to identify eligible participants without confirmatory blood-based screening methods, the result would have been enrollment of a large number of participants without prediabetes. Similar results were true in the identification of the metabolic syndrome by the non-invasive methods evaluated.

Although the ADA risk test has not been evaluated for identification of prediabetes, it has been assessed for its ability to identify undiagnosed diabetes and dysglycemia by Rolka and colleagues who noted a score ≥10 to be highly sensitive (69%), but limited by low specificity (54%) [21]. Sensitivity (93.5%) was higher in the current study, but specificity (17.1%) was markedly lower using the CDC DPRP recommended score of ≥9. The study by Rolka and colleagues occurred before prediabetes criteria changed from IFG = FPG 110-125mg/dL to IFG= FPG 100-125mg/dL, and the differences in sensitivity and specificity from our study may partially reflect this change [34]. The same study also found the risk score

to perform better, with increased specificity, when associated with a casual capillary blood glucose (CCBG). However, this combination method was contrary to the recommendations at the time, stating that the ADA risk score be employed prior to any glycemic tests [35]. Subsequent evaluation of the ADA risk test also reported that when combined with a logistic regression equation including blood glucose concentration the specificity of the measure improved [30].

The DEPLOY study used the combined method (ADA risk test + CCBG) discussed by Rolka and colleagues to identify eligible participants, but did not report sensitivity or specificity[5, 21]. A more recent translation of the DPP lifestyle intervention by Barham et al. used the current ADA risk score to identify high-risk employees, but they too did not report on sensitivity and specificity [14]. Although the discriminative ability of the ADA risk test is improved in combination with measures of blood glucose, this detracts from its application as a simple, paper and pencil risk assessment for the identification of people with prediabetes. In the identification of the metabolic syndrome, the ADA risk test results were similar to those for prediabetes.

The appeal of the ADA risk test is that it does not require clinical measurements or prior knowledge of clinical risk factors, making it easy for those implementing prevention programs to use for screening and for those being screened to complete [20, 21]. For a similar reason, the use of a BMI cut-point to identify participants with prediabetes was evaluated. Assessment of BMI only requires the measurement of height and weight and a standard calculation. Our results indicate that the BMI cut-point of ≥27kg/m^2 is highly sensitive, but suffers from low specificity in the identification of prediabetes. Similar results were noted in the identification of the metabolic syndrome. Other investigations suggest BMI is associated with future type 2 diabetes risk, but measures of central adiposity have a more robust association [26, 27, 36].

In the current study, waist circumference and waist to height ratio ≥0.6 demonstrated the best balance between sensitivity and specificity in identification of prediabetes, but were not significantly

different from a BMI cut-point ≥27kg/m^2 or the ADA risk test in ROC analysis. Considering metabolic risk, a study evaluating different waist circumference cut-points (WC>90cm for men, 80cm for women) found the measures to have low sensitivity (57% men, 31.9% women) and high specificity (74.9% men, 96.4% women) in identification of individuals at high metabolic risk (3 to 8 metabolic risk factors) [24]. In contrast, among participants in the current study, sensitivity was much higher for our selected waist circumference criteria, but specificity was reduced in identification of the metabolic syndrome. Unlike the ADA risk test and self-reported BMI, measures of central adiposity would require clinical measurement of height and waist circumference, but they cost less and are easier to assess than blood-based screening methods.

Limitations of this study include the relatively small sample size that was screened compared to other studies evaluating diabetes screening methods and a lack of racial or ethnic diversity among screened participants, with 92.5% of individuals being Caucasian.

The current study demonstrates that while non-invasive alternatives to blood-based testing exist, they may not be appropriate in all settings. According to the CDC DPRP standards, a program applying for recognition may enroll up to 50% of its participants based on a score of ≥9 on the ADA risk test without confirmatory blood-based testing or history of gestational diabetes [22]. In our study, all evaluated alternatives identified more than 50% (range 57-60%) of participants as having a confirmatory blood-based test indicating prediabetes, thus meeting the 50% standard set by the DPRP. However, if identification of the most high-risk participants (i.e. with prediabetes) is the primary goal then none of the measures evaluated, including the ADA risk test, are satisfactory and blood-based testing is the only reliable option.

Due to the lack of acceptable discriminative ability associated with all measures evaluated in this study, it may be more appropriate to use these screening tools initially as part of a sequential screening format, followed by confirmatory blood glucose and lipid values to verify eligibility. This has been

suggested in previous guidelines for diabetes screening [35] and at the present time may also be the best approach for translation to the community. Confirmatory values could come from a variety of sources depending on the nature of the intervention, including physician referrals, participant medical records, and worksite, community or practice-based screenings. Further study is needed to determine the most efficient, cost effective method to identify individuals who have prediabetes or meet additional program specific eligibility criteria like the metabolic syndrome and may include recent advances in technology such as skin fluorescence spectroscopy[37].

In conclusion, the alternative screening methods evaluated here effectively identify participants with prediabetes, but would also allow for enrollment of a large number of individuals who do not have prediabetes. Deciding whether to use these alternatives, blood-based measures, or a combination of both will ultimately depend on the purpose of the program and level of flexibility regarding participant eligibility.

Conflict of Interest

The authors declare that they have no conflict of interest.

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Table 1. Methods used to identify eligible participants and the order in which they were used if a stepped approach was employed.

	Methods to identify prediabetes					Methods to identify other high-risk categories		
	Blood-based screening							
Study Author	Random capillary glucose	Fasting Finger Stick	Fasting blood glucose	Diabetes risk test	Physician documentation	Blood based screening	Documentation of ≥ 1 diabetes risk factor	Physician documentation
Ackermann[5]	X(2)			X(1)				
Amundson[7]								X
Boltri[8]		X(2)	X(3)	X(1)				
Whittemore[9]							X	
Kramer[10]					X	X		X
Matvienko[13]					X			X
Merriam[18]					X		X	X
Katula[15]			X					
Kramer[16]					X			X
Kramer[17]					X			X
Seidel[19]						X		
McTigue[12]								X
Barham[14]				X				

*numbers indicate order in which screening methods were used

Table 2. Characteristics of participants taking part in the on-site screening overall and by site (N=364).

	Mean (SD)	**Mean (SD)**	
N=364 unless otherwise noted	Total (N=364)	Worksite (n=160)	Community (n=204)
Age (years)	55.8 (12.5)	49.6 (9.0)	60.7 (12.7)*
Body mass index (kg/m^2)	33.4 (6.2)	32.4 (6.2)	34.1 (6.1)*
Weight (kg)	93.3 (20.1)	93.0 (19.1)	93.6 (20.9)
Waist circumference (cm)	105.4 (14.0)	102.9 (13.5)	107.4 (14.2)*
Total Cholesterol (mg/dl)	193.7 (36.3)	200.9 (39.2)	188.1 (32.9)*
LDL Cholesterol (mg/dl) (n=341)	111.0 (32.2)	116.5 (33.6)	106.9 (30.5)*
HDL Cholesterol (mg/dl) (n=354)	52.8 (15.6)	53.0(16.3)	52.6 (15.0)
**Triglycerides (mg/dl) (n=354)	133 (100.0, 184.0)	138.5 (103.0,199.5)	129.0 (96.0,172.0)
Fasting glucose (mg/dl)	97.8 (15.8)	96.4 (14.7)	99.0 (16.6)
Hemoglobin A1c (%)	5.6 (0.5)	5.6 (0.4)	5.7 (0.5)*
Systolic Blood Pressure (mmHg)	119.7 (13.4)	121.1 (13.0)	118.5 (13.6)
Diastolic Blood Pressure (mmHg)	77.0 (10.3)	81.5 (9.9)	73.4 (9.2)*
	% (n)	**% (n)**	
Gender*			
Male	36 (131)	42.5 (68)	31 (63)
Female	64 (233)	57.5 (92)	69 (141)
Education*			
Some High School	1 (3)	0 (0)	1 (3)
High School Graduate/GED	10 (36)	3 (5)	15 (31)
Some College or technical school	24 (88)	21 (34)	27 (54)
College graduate (bachelor's)	34 (124)	41 (66)	28 (58)
Graduate degree	31 (113)	35 (55)	28 (58)
Family History of Diabetes	47 (170)	48 (77)	46 (93)
Family History of Heart Disease	45 (162)	43 (68)	46 (94)
Family History of both Diabetes and Heart Disease	22 (81)	21 (34)	23 (47)
History of Gestational Diabetes	4 (9)	3.2 (3)	4.3 (6)
History of baby > 9 lbs (4.1kg)	16 (37)	12 (11)	18.4 (26)
Polycystic Ovary Syndrome	2 (5)	3.3 (3)	1.4 (2)

*indicates p<0.05, **reported as medians, not normally distributed

Table 3. Frequency of participants meeting study eligibility criteria and screening positive based on the screening methods evaluated for those who took part in the on-site screening overall and by site (N=364).

	% (n)		
	Total (N=364)	Worksite (n=160)	Community (n=204)
Study Eligibility Criteria			
Eligible based on study criteria	72 (261)	67 (107)	75 (154)
Prediabetes*	35 (128)	31 (49)	39 (79)
Prediabetes**	40 (145)	31 (50)	47 (95)
Prediabetes***	55 (200)	48 (77)	60 (123)
Metabolic syndrome****	49 (180)	49 (79)	50 (101)
Screening Procedure			
Risk Score ≥9	89 (323)	84 (135)	92 (188)
BMI≥27kg/m^2	86 (313)	81 (130)	90 (183)
BMI + Family History of Diabetes	43 (145)	44 (63)	42 (82)
Waist to height ratio ≥0.5	96 (350)	93(148)	99(202)
Waist to height ratio ≥0.6	62 (227)	51(81)	72(146)
Waist circumference (>102 cm men, >88 cm women)	78 (285)	68(108)	87(177)

*prediabetes defined by impaired fasting glucose 100-125 mg/dl, **prediabetes defined by hemoglobin A1C 5.7-6.4%, ***prediabetes including both fasting glucose 100-125 mg/dl and hemoglobin A1C 5.7-6.4%, ****metabolic syndrome defined by NCEP ATPIII criteria

Table 4. Sensitivity, specificity and positive predictive value for evaluated screening methods in the identification of prediabetes (fasting glucose of 100-125mg/dl and/or A1C of 5.7%-6.4%) and the metabolic syndrome (NCEP ATPIII criteria or hyperlipidemia and 1 component of the metabolic syndrome).

	All Eligibility			Prediabetes			Metabolic Syndrome		
Screening Test	**Sensitivity (%)**	**Specificity (%)**	**Positive Predictive Value**	**Sensitivity (%)**	**Specificity (%)**	**Positive Predictive Value**	**Sensitivity (%)**	**Specificity (%)**	**Positive Predictive Value**
ADA risk test ≥9	92.3	20.4	74.6	93.5	17.1	57.9	92.2	14.7	51.4
BMI≥27kg/m^2	89.7	23.3	74.8	89.0	17.7	56.9	95.6	23.4	55.0
BMI + Family History of Diabetes	45.9	64.9	77.2	47.6	62.8	60.7	48.3	62.8	57.9
Waist to height ratio ≥0.5	98.5	9.7	73.4	98.5	6.7	56.3	98.3	6.0	50.6
Waist to height ratio≥0.6	69.0	54.4	79.3	68.0	44.5	59.9	79.4	54.3	63.0
Waist Circumference (>102 cm men, >88 cm women)	83.9	35.9	76.8	82.0	26.2	57.5	93.9	37.0	59.3
Worksite									
ADA risk test ≥9	89.7	26.4	71.1	89.6	20.5	51.1	91.1	22.2	53.3
BMI≥27kg/m^2	86.0	28.3	70.8	83.1	20.5	49.2	93.7	30.9	56.9
BMI + Family History of Diabetes	48.5	66.0	74.6	48.5	60.5	52.4	52.0	65.2	61.9
Waist to height ratio ≥0.5	96.3	15.1	69.6	96.1	10.8	50.0	96.2	11.1	51.4
Waist to height ratio≥0.6	57.0	62.3	75.3	53.3	51.8	50.6	70.9	69.1	69.1
Waist Circumference (>102 cm men, >88 cm women)	73.8	45.3	73.2	68.8	33.7	49.1	88.6	53.1	64.8
Community									
ADA risk test ≥9	94.2	14.0	77.1	95.9	13.6	62.8	93.1	8.7	50.0
BMI≥27kg/m^2	92.2	18.0	77.6	92.7	14.8	62.3	97.0	17.5	53.5
BMI + Family History of Diabetes	44.2	63.8	79.3	47.0	64.9	67.1	45.5	61.1	54.9
Waist to height ratio ≥0.5	100	4.0	76.2	100	2.5	60.9	100	1.9	50.0
Waist to height ratio≥0.6	77.3	46.0	81.5	77.2	37.0	65.1	86.1	42.7	59.6
Waist Circumference (>102 cm men, >88 cm women)	90.9	26.0	79.1	90.2	18.5	62.7	98.0	24.3	55.9

Appendix B : PAPER 2

Title: Evaluating the impact of a pre-intervention delay on participant's success in a community diabetes prevention effort

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Key Words: intervention delay, diabetes prevention, translation

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‘What is already known about this subject’

- Pre-intervention delays are likely to occur in community based translations of the Diabetes Prevention Program due to the screening and enrollment process, limited staffing and a limited number of programs available.
- Community based translation efforts have never reported the effects of pre-intervention delays on participant weight loss.
- A weight loss study demonstrated that weight losers during a pre-intervention delay are more successful than weight gainers or weight maintainers.

‘What this study adds’

- This current study clearly demonstrates that a pre-intervention delay does not negatively affect participant weight loss, attendance, self-monitoring or physical activity levels.
- Contrary to a previously published weight loss study, these results suggest that weight change during a pre-intervention delay does not impact weight loss, self-monitoring, intervention attendance or PA levels.
- Organizations looking to offer prevention services should not be deterred by the occurrence of a delay prior to the start of intervention.

ABSTRACT:

Objective: The primary objectives are to evaluate the impact of a pre-intervention time delay and weight change during this delay on participant outcomes during a one-year adapted Diabetes Prevention Program (DPP) lifestyle intervention.

Design and Methods: Participants were recruited at a worksite and three community centers to take part in this randomized delayed-control trial with two-thirds randomized to start the intervention immediately (IMMEDIATE) and one-third assigned to a six-month delayed control group (LATER). Pre-intervention delay was the number of days from screening to first intervention session, and participants were categorized as weight gainers, weight maintainers and weight losers during this delay.

Results: 174 overweight or obese adults with prediabetes and/or metabolic syndrome attended baseline, 6 and 12 month assessments. Both IMMEDIATE and LATER participants achieved significant weight loss at 6 and 12 months, with no significant difference in mean weight loss found between the two groups at either time point. Across the three pre-intervention weight change groups, no significant differences in weight loss, physical activity levels, attendance, and self-monitoring were noted at 6 or 12 months.

Conclusions: A delay in the start of intervention and pre-intervention weight change did not affect participant outcomes in this community DPP program.

Evaluating the impact of a pre-intervention delay on participants' success in a community diabetes prevention effort

Introduction

Diabetes currently affects 8.3% of the population in the United States (US), and it has been estimated that this will increase to 33% by 2050[1]. Additionally, more than two-thirds of US adults are overweight or obese, fewer than 10% achieve recommended levels of physical activity (PA), and an estimated 79 million have prediabetes, all of which are risk factors for future diabetes development [2-4]. Widespread implementation of interventions designed to address these issues are currently a top public health priority.

Research has demonstrated that behavioral lifestyle interventions can successfully prevent or delay type 2 diabetes among high-risk participants [5-9]. The US Diabetes Prevention Program (DPP), through promotion of a healthy, low-fat diet and increased physical activity (PA), achieved a 58% reduction in the incidence of diabetes among lifestyle intervention participants compared to those in a placebo control group [7]. The success of the DPP has led to widespread translation of the lifestyle intervention to a variety of community settings [10].

In translation of the DPP into the community, individuals at risk for diabetes and/or cardiovascular disease (CVD) may encounter a waiting period prior to receiving intervention. A delay of weeks or months can occur due to the time it takes to identify those at risk and enroll them in the prevention program. Pre-intervention delays may also occur because organizations providing prevention programs have inadequate staffing levels and therefore can only offer a limited number of programs at one time[11].

In community based DPP translation studies, little is reported regarding the impact of the lag time from enrollment to the start of intervention. It is common for studies to provide descriptions of the screening and eligibility confirmation process, but the time from the initiation of these processes to start of intervention is typically not reported [12-17]. Some studies have also described the length of the screening and recruitment process itself, with time periods ranging from nine months to a year [12,16,18] or two years [13], but to the authors' knowledge, no DPP translation studies have reported on wait times incurred by participants prior to intervention, or the impact of these pre-intervention delays on participant outcomes.

One impact of lengthy pre-intervention time delays that appears particularly important to examine is the effect of any weight change that may occur during this time period. To date, one study has investigated pre-intervention weight change in the context of a behavioral lifestyle intervention (categorizing participants as weight losers, weight maintainers and weight gainers based on weight change during the time from screening to the first intervention session) [19]. The results of this study indicated that pre-intervention weight losers achieved significantly greater weight loss, attended more intervention sessions and completed more self-monitoring records overall than either their weight gaining or weight maintaining counterparts at 6 months [19].

The purpose of this paper is to evaluate the impact of a pre-intervention time delay on participant weight loss and PA outcomes at two time points (6 and 12 months) during a one-year community based DPP translation and to evaluate the effects of pre-intervention weight change during this delay on similar outcomes. Given that there is a high probability of a waiting period occurring before enrollment in a community based diabetes prevention program with little known

about the association between wait times and participant success validates the importance of this current investigation.

Methods and Procedures

Study Design:

Participants were recruited at a large, local corporate worksite campus and three community centers sponsored by the Area Agency on Aging in Allegheny County, Pennsylvania to take part in a National Institutes of Health funded trial evaluating the effectiveness of the DPP Group Lifestyle Balance (DPP-GLB) program. The DPP-GLB is a direct adaptation of the DPP lifestyle intervention for group delivery that encourages participants to self-monitor diet, PA and weight, and make a commitment to choosing healthy foods and increasing PA levels. Investigators who developed the lifestyle intervention for the DPP also developed the DPP-GLB. Participant goals are to lose 7% of baseline weight and achieve a minimum of 150 minutes or more of moderate intensity PA per week [20].

A randomized delayed-control study design was utilized (Figure 1). Two-thirds of eligible participants were randomly assigned to take part in the intervention immediately following the baseline randomization assessment (IMMEDIATE group). The remaining one-third was assigned to begin intervention following a six-month delay (LATER group).

Recruitment, Screening and Eligibility:

Notification of the upcoming intervention was disseminated via email, posters, health fairs, information sessions and targeted mailings. Interested participants were first screened over the phone or in person to confirm that they were non-diabetic adults with a BMI $\geq$24kg/m^2 ($\geq$22 kg/m^2 for Asians), who were not planning to move away from the area during the projected study time

period. Women who were pregnant or breastfeeding were excluded from participation. Participants meeting initial eligibility criteria were scheduled to attend an onsite in-person screening that included collection of blood pressure, height, weight and waist circumference following a standard protocol. The Cholestech LDX system was used to measure total cholesterol, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), triglycerides and glucose after a minimum 8-hour fast, and a trained research assistant measured hemoglobin A1c (HbA1c) using a Siemens/Bayer DCA 2000. Additional demographic and risk factor data were collected including the 7 question American Diabetes Association (ADA) risk test promoted by the CDC Diabetes Prevention Recognition Program Standards (DPRP)[2,21]. Eligible participants had a BMI $\geq$24kg/m^2 or $\geq$22 kg/m^2 for Asians, prediabetes (fasting glucose of 100-125mg/dl and/or HbA1c of 38.8-46.4mmol/mol), and/or the metabolic syndrome (National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III)) and/or hyperlipidemia and one additional component of the metabolic syndrome [22,23]. In addition to the exclusion criteria addressed in the first step of the screening process, participants with blood glucose values in the diabetes range and those unable to provide physician approval to participate in moderate levels of PA were excluded. Considerable effort was made to ensure that those without a primary care physician had access to a local clinic to receive free or reduced fee care. This project was approved by the University of Pittsburgh Institutional Review Board and all participants provided informed consent.

Assessment Visits:

Assessment visits were completed at baseline (pre-intervention), and at two time points, one during the one-year intervention (6 months) and one at the conclusion of the intervention (12

months). Anthropometric measures were collected by a trained research assistant following standard protocol. A venous blood draw was collected to assess total cholesterol, HDL-C, LDL-C, triglycerides, glucose, hemoglobin HbA1c and insulin following a minimum 8-hour fast and analyzed at a local laboratory. Prescription medication use, health history, the Modifiable Activity Questionnaire (MAQ)[24], and self-monitoring and PA habits were assessed via participant interview. Participants were also asked to complete the EQ-5D quality of life measure[25], a willingness questionnaire and a cost survey developed specifically for this study.

Intervention:

The DPP-GLB program is a one-year 22-session behavioral lifestyle intervention based on the DPP [20,26]. Following randomization to IMMEDIATE or LATER intervention, participants had the choice to enroll in a face-to-face group or DVD based intervention [27]. Face-to-face groups met weekly for the first 12 sessions with a DPP-GLB trained lifestyle coach. At each in-person session participants were weighed, turned in self-monitoring records, received new session materials and took part in a 1-hour lesson covering the day's topic(s). Participants who missed a face-to-face session were provided with the DVD and instructed to view it as a make-up session.

Participants who chose the DVD intervention watched the first 12 sessions on their own and also attended three scheduled in-person group meetings with a lifestyle coach at sessions one, five, and nine during the core intervention. At these meetings DVD participants had an opportunity to discuss any issues encountered in the previous sessions, be weighed, receive session handouts for future sessions and turn in their self-monitoring records. During weeks when a group meeting did not occur, DVD participants received weekly phone or email support from their lifestyle coach, including feedback on their self-monitoring records. Following the initial 12-sessions face-to-face

and DVD participants were invited to attend 1-hour group sessions, which transitioned to bi-weekly and then monthly sessions over the course of one year.

During the six-month delay, LATER group participants received handouts that were mailed to them approximately every six weeks to help promote engagement and retention. The handouts covered topics such as the importance of staying hydrated during physical activity, selecting a good pair of shoes and tips for being active outdoors.

Self-Monitoring:

During the initial DPP-GLB intervention sessions, participants were instructed to begin daily self-monitoring of diet and weight following session 1, daily physical activity minutes following session 4 and daily steps following session 10. They were encouraged to continue self-monitoring throughout the program. Methods of self-monitoring included paper keeping track books or other readily available online tracking programs that could be printed out or submitted via email or postal mail to their lifestyle coach.

During the intervention, both face-to-face and DVD participants submitted their self-monitoring information to their lifestyle coach either in-person or via email or postal mail. Coaches documented diet and physical activity monitoring frequency on a scale of 0-7, based on the number of days per week the participant monitored each behavior. Coaches also documented the total number of activity minutes and steps.

Pre-intervention delay and weight change categories:

As a result of the randomized-delayed control group design, the current study had the unique ability to evaluate the impact of a pre-intervention delay on participant success at six months and one year. The pre-intervention delay was calculated as the length of time (days) from

screening to the first intervention session. During the pre-intervention delay participants were classified into three weight change categories. Weight gainers gained ≥1.36 kilograms, weight losers lost ≥1.36 kilograms and weight maintainers gained or lost <1.36 kilograms. Support for the 1.36 kilogram threshold comes from evidence that <1.36 kilograms of weight fluctuation could occur due to normal changes in fluid balance [28],and is in line with what other investigations have used[19 29].

Statistical analysis:

The current evaluation is a secondary analysis of a randomized delayed-control trial evaluating the effectiveness of a DPP based lifestyle intervention with the primary study outcome of weight loss.

Screening characteristics among those who attended all assessment visits, i.e., baseline, 6 and 12 months, and had complete data were compared to those with missing data using two sample independent t-tests for normally distributed variables and the Wilcoxon-Mann-Whitney test for variables not normally distributed. The Chi-square or Fisher's exact test was used to test for differences in proportions.

To examine differences in weight loss at 6 and 12 months between the IMMEDIATE and LATER groups, two sample independent t-tests were used. Differences between the two groups for intervention attendance, self-monitoring and MET hours of leisure PA were compared using the Wilcoxon-Mann-Whitney test. This evaluation was conducted for all participants combined and stratified by site, age (age<55 and age≥55), gender and education (education < bachelors degree, education ≥ bachelors degree).

Weight change at 6 and 12 months among the three pre-intervention weight change categories was evaluated using one-way ANOVAs. Intervention attendance, self-monitoring and MET hours of self-reported leisure PA were evaluated among the three weight change categories using the Kruskal-Wallis test because outcomes were not normally distributed. This evaluation was also completed for all participants combined and stratified by site, random assignment, age, gender and education.

Comparisons between IMMEDIATE and LATER groups and across the three pre-intervention weight change groups were conducted for participants with complete data from each time point and utilizing the last observation carried forward method for those with missing data. Outcomes are reported for those with complete data from each time point unless otherwise noted. Data analyses were completed using Statistical Analysis Software Version 9.3 (Cary, NC).

Results

A total of 223 participants attended the baseline randomization visit; of that number 174 (78%) attended the baseline, 6 and 12 month assessments and had complete data at all time points for these current analyses (worksite N=69, community center N=105). The 49 participants without complete data had significantly greater mean weight (p=0.02), BMI (p=0.002) and waist circumference (p=0.02) (data not shown) at screening compared to those with complete data. However, random assignment to either the IMMEDIATE (N=28) or LATER (N=21) group (p=0.1) was not significantly different among those without complete data. Participants with complete data had a mean age of 59±11.1 years, mean BMI of 33.1±5.5 m/kg^2, and mean weight of 92.9±18.8kgs at screening. Sixty percent of these participants were female, the majority possessed a bachelors or graduate degree, and 56% were employed full time (>35 hours per week) (Table 1).

Mean pre-intervention delay length for IMMEDIATE participants was 107.8±34.1 days (about 3.5 months) compared to 282.3±31.6 days (about 9.5 months) for LATER participants ($p<0.0001$). Participants in both the IMMEDIATE and LATER group achieved significant mean percent weight loss at 6 and 12 months ($p<0.0001$; 6 and 12 months) and mean percent weight loss was not significantly different at 6 ($p=0.8$) and 12 ($p=0.3$) months between participants from the two groups. Additionally, as seen in Table 2, there were no significant differences in total attendance ($p=0.3$), total diet self-monitoring records ($p=0.1$) and total PA self-monitoring records ($p=0.2$) between IMMEDIATE and LATER participants. Applying the last observation carried forward method of analysis yielded similar results to analysis using only participants with complete data. Further stratification by age and education yielded significant differences in self-monitoring and intervention attendance among IMMEDIATE and LATER in favor of the LATER group, but did not impact mean percent weight loss (data not shown).

Overall, when compared to self-reported levels of leisure PA at baseline, all participants achieved significant increases at 6 months and maintained those significant increases at 12 months (data not shown). Comparing self- reported leisure PA between the IMMEDIATE and LATER groups, there was variation in regards to which group reported greater physical activity change, likely due to seasonal variation[30]; i.e., the IMMEDIATE group was higher at 6 ($p<0.0001$) months whereas the LATER group was higher at 12 months ($p=0.002$) (Table 2).

During the pre-intervention delay 35% (61) participants were categorized as weight gainers, 42% (73) as weight maintainers and 23% (40) as weight losers among those with complete data (Table 3). Although pre-intervention delay length was significantly different among the three pre-intervention weight change groups ($p=0.01$), percent weight change at 6 ($p=0.1$) and 12

(p=0.1) months was not significantly different. In addition, attendance, self-monitoring and self-reported leisure PA were not significantly different across the three pre-intervention weight change groups for these same time points. These results were consistent with those from the last observation carried forward method of analysis (data not shown). Further stratification by gender, age and education resulted in subtle differences across the three pre-intervention weight change groups in regard to pre-intervention delay length and number of core contacts, but percent weight change and PA levels at 6 and 12 months were not significantly different.

The distribution of weight gainers, maintainers and losers was not significantly different when stratified by site (p=0.9) or when stratified by site and random assignment (IMMEDIATE p=0.3, LATER p=0.1). In addition, the proportion of participants selecting DVD or group intervention was not significantly different across the three weight change groups (p=0.1)(data not shown).

Discussion

This study provides unique information regarding the impact of a pre-intervention delay on participant outcomes at 6 and 12 months of a DPP translation effort in the community. The results of this study suggest that random assignment to a six month delay (with the average delay difference being 6 months) prior to receiving intervention does not hinder success in achieving the goals of weight loss and/or PA increases in work-site or community center based diabetes prevention programs. Further, weight change during the pre-intervention period, as categorized in the current study, does not significantly impact weight loss and/or PA levels at 6 and 12 months.

In the DPP, the delay from screening to the start of the individually administered intervention was limited to 3 to 13 weeks to maintain participant attention and minimize changes

in diabetes status [31]. Limiting the pre-intervention delay was feasible in the DPP because the intervention was implemented one-on-one. In contrast, community translations of the DPP are mostly group based and enroll participants over time from a variety of sources that face variable wait times due to available resources. In the current effort, the first DPP translation study to report on pre-intervention delay, participants experienced mean delays of 15 to 40 weeks, much longer than the 3 to 13 week window targeted in the DPP[31].

Several publications of group-based DPP translations provide information regarding the general length of time involved in the screening or recruitment process, but lack specific details regarding the impact of pre-intervention delays[12-18]. Additionally, the study designs used in DPP and some DPP translations would not have allowed for the evaluation of the impact of a pre-intervention delay [12-18,31]. Notably, the current results suggest that the pre-intervention delay did not hinder participants who waited an average of about 9 months to start their program. Following the significantly longer pre-intervention delay this group achieved comparable weight losses, at 6 and 12 months, compared to their counterparts who waited about 3 months to begin.

The information obtained from the current study is important as we move forward in translation of the DPP to the community, where delays prior to intervention are likely to occur for many reasons. A recent publication investigating implementation of diabetes prevention services cites lack of staffing as a common barrier to offering diabetes prevention in the community[11], which could in turn lead to a pre-intervention delay while participants wait for future groups to become available. It is unknown, but not likely that delays due to staffing and a limited number of groups offered would have a different impact on outcomes than those resulting from study design.

The results of this study support the use of a participant waiting list for future diabetes prevention groups that may be taking place several months later at resource limited organizations.

The current study also evaluated the effect of weight change during the pre-intervention delay on participant outcomes. In a similar analysis by West and colleagues, weight losers during the pre-intervention period achieved significantly greater weight loss and also completed more self-monitoring records and attended more intervention sessions compared to weight gainers and weight maintainers following six months of intervention[19]. These findings are contrary to those of the current study and may be explained by several differences between the studies. First, the mean pre-intervention period was much longer in the current study, 107.8±34.1 days and 282.3±31.6 among IMMEDIATE and LATER participants respectively, compared to 50±30 days in the West study. It is possible that this difference may have allowed for more weight stabilization prior to the start of intervention in the current study. Second, participants in the West study were required to complete self-monitoring records as part of an eligibility run-in period, which may have led to earlier adoption of important lifestyle change behaviors among pre-intervention weight losers who were more ready to make changes. Third, a significantly greater portion of pre-intervention weight losers in the West study were randomized to the more effective in-person intervention compared to the other intervention modalities under study. There were no differences in the proportion of group and DVD participants across the three weight change groups in the current study. In relation to community based translation of the DPP, the run-in period in the West study may not reflect the experience of a typical wait list population, [19] where as participants in the current study did not participate in self-monitoring during the pre-intervention delay.

The pre-intervention period of behavioral weight loss studies is often used as an intervention run-in where participants demonstrate their adherence with self-monitoring or medication taking [19,31,32]. As part of the DPP run-in period, participants were required to self-monitor diet and activity and follow medication taking protocols for three weeks [31]. This type of active run-in period likely identifies participants who will be more successful in behavioral lifestyle interventions [33]. In addition to demonstrating successful self-monitoring [19], it has been reported that participants in early investigations of weight management were asked to lose small amounts of weight prior to intervention to enhance success [32]. However, no publications evaluating a pre-intervention weight loss requirement were found. As a result of the discrepancy in the results of the current study and the study by West and colleagues further evaluation is necessary to confirm the impact of pre-intervention weight change and investigate the idea of requiring pre-intervention weight loss as part of a run-in period [19,32].

The current study has limitations that should be addressed. LATER participants were provided with monthly mailings to keep them engaged which may have impacted their outcomes and may not be generalizable in translation to the community. Self-selection bias may have impacted results due to this being a research study where participants volunteered to participate, versus a community based translation where participants may be referred by health care providers. Over 90% of study participants were Caucasian, therefore results may not be generalizable to other populations and data on PA was collected via a self-reported measure.

In conclusion, the current study demonstrates that a pre-intervention delay and weight changes during this delay are not associated with weight loss in a community based DPP translation study. Additionally, significant increases in self-reported leisure PA were documented

at 6 and 12 months when compared to baseline levels for both IMMEDIATE and LATER participants. These are important public health findings due to the probability that individuals may not have access to a community based DPP translation immediately upon receiving notification that they are at high-risk for diabetes. Equipped with the knowledge that pre-intervention delays may not adversely affect future, wait-listed participants, organizations with an interest in providing prevention services should not view limited staffing or group size and program availability as barriers to offering group-based diabetes prevention intervention.

Conflicts of interest:

The authors declare that they have no conflict of interest.

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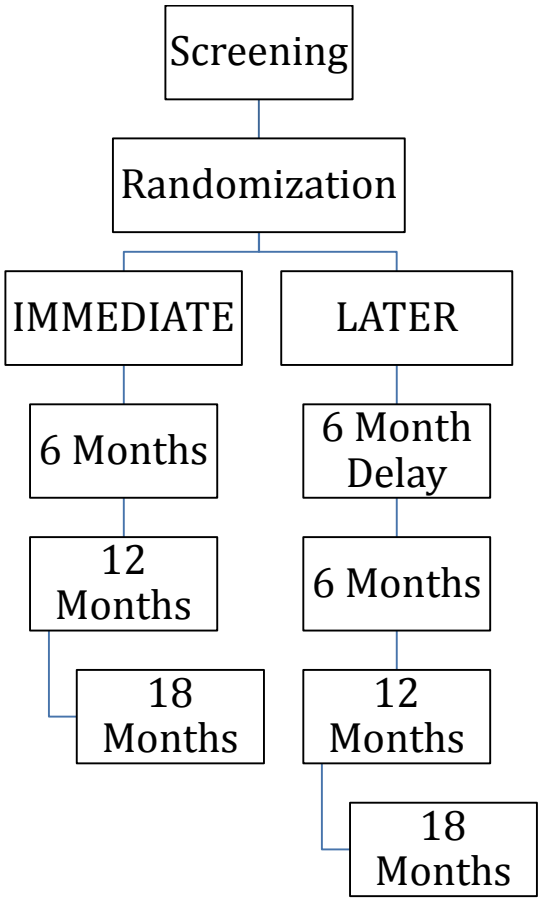

Figure 1: Randomized-delayed control group study design.

Table 1. Characteristics at the time of screening among participants who were randomized at baseline to take part in a behavioral lifestyle intervention at worksite and three community centers (N=174).

	Combined (N=174)
	Mean (SD) Median (IQR)
Age (n=174)	59 (11.1) 58.7 (51.8-67)
Body mass index, kg/m^2 (n=174)	33.1 (5.5) 32.1 (29.5-36.6)
Weight, kg (n=174)	92.9 (18.8) 89.1 (80.1-101.2)
Waist circumference, cm (n=174)	106.2 (13) 104.6 (99.1-111.8)
Total Cholesterol, mmol/l (n=174)	10.6 (2.0) 10.7 (9.3-12.0)
LDL Cholesterol, mmol/l (n=164)	6.1 (1.8) 6.0 (4.9-7.4)
HDL Cholesterol, mmol/l (n=169)	2.7 (0.8) 2.7 (2.2-3.2)
Triglycerides, mmol/l (n=171)	9.0 (4.5) 7.9 (6.2-11.0)
Glucose, mmol/l (n=174)	5.5 (0.5) 5.4 (5.1-5.8)
Hemoglobin A1c, mmol/mol (n=174)	38.8 (3.3) 38.8 (36.6-41.0)
Systolic Blood Pressure (n=174)	120.1 (12.1) 119 (111-128)
Diastolic Blood Pressure (n=174)	76.1 (10.4) 77 (68-84)
Gender	**% (n)**
Male	40 (70)
Female	60 (104)
Education	
Some High School	0.5 (1)
High School Graduate/GED	9.5 (17)
Some College or technical school	23 (40)
College graduate (bachelor's)	33 (58)
Graduate degree	33 (58)
Employed	
Full time (>=35hrs/week)	56 (98)
Part-time (<35hrs/week)	14 (8)
Unemployed/laid off & looking	2 (4)
Homemaker	3 (6)
Retired	28 (49)
Disable/unable to work	3 (6)
Smoke	
Never	61 (106)
Former	32 (55)
Current	7 (13)

Table 2. Weight loss, attendance, self-monitoring and self-reported leisure PA levels at 6 and 12 months among IMMEDIATE and LATER groups at both sites combined.

	Combined site comparison	
	IMMEDIATE N=120	LATER N=54
Percent weight loss at 6 months	5.8 (4.8) 5.6 (2.8-8.6)	6.0 (4.6) 5.3 (2.3-9.2)
Percent weight loss at 12 months	4.8 (6.0) 4.5 (0.7-9.3)	6.0 (6.3) 4.8 (2.2-8.2)
Length of Intervention Delay*	107.8 (34.1) 109 (95-126)	282.3 (31.6) 282.5 (263-302)
Total number of sessions attended	17.2 (4.8) 19 (14-21)	18.3 (4.0) 19.5 (16-21)
Number of core sessions attended (Sessions 1-16)	13.6 (3.0) 14.5 (12-16)	14.2 (2.5) 15 (13-16)
Number of post-core sessions attended (Sessions 17-22)	3.8 (2.3) 5 (2-6)	4.1 (2) 4 (3-6)
Total number of diet records submitted	15.3 (11.9) 11.5 (6-22.5)	18.4 (12.8) 14.5 (9-24)
Number of core diet records submitted	11.5 (6.4) 11 (6-17)	13.9 (6.4) 12.5 (9-21)
Number of post-core diet records submitted	3.9 (6.8) 0 (0-5)	4.5 (8.0) 0 (0-5)
Total number of activity records submitted	11.3 (11.6) 7 (2-17)	13.3 (12.7) 9 (5-18)
Number of core activity records submitted	7.9 (6.2) 7 (2-13.5)	9.2 (6.2) 8 (4-14)
Number of post-core activity records submitted	3.5 (6.6) 0 (0-4)	4.1 (7.9) 0 (0-5)
Self-reported leisure PA at 6 months* (MET hrs)	34.3 (26.1) 27.5 (16.7-44.3)	16.8 (16.7) 11.5 (5.3-21.5)
Self-reported leisure PA at 12 months** (MET hrs)	21 (21) 12.2 (7.9-29.8)	28.8 (18.9) 25.5 (13-41.3)

*$p<0.0001$, **$p=0.002$

Table 3. Weight loss, attendance, self-monitoring and self-reported leisure PA levels at 6 and 12 months stratified by pre-intervention weight change from the time of screening to the first intervention session among all participants combined.

	Gainer N=61	**Maintainer N=73**	**Loser N=40**
Outcome Variable	Mean (SD) Median (IQR)	Mean (SD) Median (IQR)	Mean (SD) Median (IQR)
Percent weight loss at 6 months	4.9 (4.0) 4.4 (2.2-7.4)	6.0 (5.5) 6.0 (2.6-9.3)	6.9 (4.0) 6.4 (4.2-9.2)
Percent weight loss at 12 months	4.0 (5.3) 3.5 (1.1-7.1)	5.6 (6.6) 5.4 (0.6-10.4)	6.2 (6.2) 5.4 (2.3-9.4)
Length of Intervention Delay*	166.7 (89) 123 (105-259)	142.7 (80.7) 118 (96-175)	189.9 (90.7) 149.5 (118-278.5)
Total number of sessions attended	17 (4.7) 18 (14-21)	17.3 (5.1) 19 (15-21)	19 (3) 20 (17.5-22)
Number of core sessions attended (Sessions 1-16)	13.4 (2.9) 14 (12-16)	13.6 (3.3) 15 (13-16)	14.7 (1.5) 15.5 (13.5)
Number of post-core sessions attended (Sessions 17-22)	3.6 (2.2) 4 (2-6)	3.9 (2.2) 5 (2-6)	4.4 (1.9) 5 (4-6)
Total number of diet records submitted	15.6 (12.1) 12 (7-23)	16 (12.4) 13 (7-23)	17.5 (12.3) 12.5 (9-22.5)
Number of core diet records submitted	11.9 (6.6) 12 (7-18)	12.1 (6.7) 12 (7-18)	13.1 (5.7) 12 (9-18.5)
Number of post-core diet records submitted	3.7 (6.7) 0 (0-5)	4.1 (7.1) 0 (0-6)	4.5 (8.2) 0 (0-5)
Total number of activity records submitted	11 (11.9) 7 (2-15)	11.7 (11.8) 7 (2-18)	13.7 (12.3) 9.5 (5-18.5)
Number of core activity records submitted	7.6 (6.3) 7 (2-12)	8.2 (6.3) 6 (2-14)	9.4 (5.8) 9 (4.5-14)
Number of post-core activity records submitted	3.3 (6.6) 0 (0-2)	3.7 (6.7) 0 (0-4)	4.4 (8.2) 0 (0-4)
Self-reported leisure PA at 6 months (MET hrs)	30.6 (28.6) 22.6 (13-40.6)	26.7 (22.3) 21.8 (9.6-32.4)	30.5 (23.6) 25.6 (14.9-41.1)
Self-reported leisure PA at 12 months (MET hrs)	22.4 (23.1) 12 (8.2-30.3)	21.0 (16.8) 17.9 (8.9-29.3)	29.2 (22.5) 22.4 (9.0-45.1)

*$p = 0.01$

Appendix C: Paper 3

The Impact of Participant Characteristics, Cognitive Factors and Prescribed Lifestyle Behaviors on Achieving the Goals of a Community Based Diabetes Translation

Introduction:

The rise in the prevalence of overweight and obesity among adults in the United States (US) is well known[1]. These stages of excess adiposity are strongly linked with the presence of many chronic, debilitating conditions, particularly type 2 diabetes and cardiovascular disease (CVD), and are also associated with excess mortality from these diseases [2, 3]. Fortunately, research has demonstrated that weight loss through lifestyle change can lower the risk of type 2 diabetes development and reduce risk factors for CVD [4-8].

Participants in the US Diabetes Prevention Program (DPP) lifestyle intervention achieved a significant, 58% reduction in type 2 diabetes incidence compared to control group participants after an average of approximately 3 years of follow up [8]. The DPP lifestyle intervention was also successful in lowering risk for the metabolic syndrome and reducing risk factors for CVD [9]. Lifestyle intervention participants attended 16 core sessions in the first six months and were instructed to self-monitor diet, PA and weight while working towards the program goals of 7% weight loss and ≥150 minutes/week of physical activity (PA) [10].

At the conclusion of the 16 session core, 49% of DPP participants achieved the 7% weight loss goal and 37% met the weight loss goal at the end of the intervention. The ≥150 minutes/week PA goal was achieved by 74% and 67% of participants at the end of the core and the end of the intervention, respectively [8, 11]. An investigation into factors (demographic, psychosocial, behavioral) related to achieving the weight loss and PA goals among DPP participants by Wing et al. suggests that older age, lower BMI, male gender, certain ethnicities and an increased frequency of self-monitoring are important for goal achievement [11].

The success of the DPP lifestyle intervention prompted implementation of community based translations across the US in health care settings, community centers, rural and urban communities and among a variety of racial and ethnic groups[12-16]. These translation efforts continued to emphasize the importance of self-monitoring and the weight loss and PA goals of the DPP [17]. In translation, one study identified older age, male gender, lower BMI and more frequent self-monitoring as important factors for achieving 7% weight loss; similar to the findings from the DPP [11, 18]. The association of more frequent self-monitoring (≥50% of the time) and achievement of the 7% weight loss is also supported by other community based translations [19, 20].

Although self-monitoring is a key component of community-based diabetes translation interventions, very little is known regarding participants' willingness to engage in self-monitoring or other healthy lifestyle practices. Previous research suggests that obese and overweight patients are less willing to change their lifestyle than their normal weight counterparts [21], and in an evaluation of motivators and barriers to exercise, investigators hypothesize that a lack of interest in exercise may be a surrogate to a lack of willingness to change exercise habits [22]. A study

evaluating the feasibility of a PA intervention found that increasing age was associated with an individual's willingness to participate [23], but did not address the impact of age on study outcomes [24]. In the same study, participants who were current smokers and who reported an insufficient amount of PA were more likely to enroll. These results may indicate that individuals who know they are at greater risk of future health issues are more likely and willing to participate in healthy lifestyle interventions [23], but none of these studies provide specific information regarding willingness to make healthy behavior changes and future success in meeting program goals.

The purpose of the current effort is to investigate the relationship between participant willingness to engage in healthy lifestyle practices and achievement of the weight loss and PA goals of a community based adaptation of the DPP intervention. In addition, other factors such as individual participant characteristics and program engagement (i.e. session attendance and self-monitoring) will be evaluated for their association with program success, defined as achievement of program goals.

Methods:

Study Design

A randomized delayed-control group study design, in which participants were assigned to begin intervention immediately after enrollment or in 6 months, was implemented to evaluate the effectiveness of the DPP Group Lifestyle Balance (DPP-GLB) program. The primary outcome for this study was change in weight; secondary outcomes included fasting glucose, insulin, blood pressure, waist circumference lipids, physical activity and quality of life.

Recruitment, Screening and Eligibility:

Recruitment to take part in this National Institutes of Health funded effort occurred at a local worksite and three community centers in Allegheny County, Pennsylvania. Notification of the upcoming intervention was disseminated via email, health fairs, information sessions and direct mailings. A two-step screening process was employed. The first step involved screening participants over the phone or in person to identify non-diabetic adults with a BMI $\geq$24kg/m^2, who were not pregnant or breastfeeding, and not planning to move away from the area during the projected study time period. Step two included an onsite screening to collect anthropometric data, demographics and a fasting lipid and blood glucose panel. Intervention eligibility criteria included: BMI $\geq$24kg/m^2 ($\geq$22 kg/m^2 for Asians), prediabetes (fasting glucose of 100-125mg/dl and/or HbA1C of 5.7%-6.4%), and/or the metabolic syndrome (National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) criteria or hyperlipidemia and 1 additional component of the metabolic syndrome) [25, 26]. In addition to the exclusion criteria addressed in step one, participants with blood glucose values in the diabetes range and those unable to provide physician approval to participate in moderate levels of PA were excluded. Considerable effort was made to ensure those without a primary care physician had access to a local clinic to receive free or reduced fee care. This project was approved by the University of Pittsburgh Institutional Review Board and all participants provided informed consent.

Assessment Visits:

Assessment visits were completed at baseline (randomization) and at three other time points: one during the one-year intervention (6 months),one at the conclusion of the intervention (12 months) and one 6 months after the conclusion of the intervention (18 months). At the 6 and

12 months assessments a trained research assistant following standard protocol collected weight, height, blood pressure and waist circumference. A venous blood draw, following a minimum 8-hour fast, was taken for a lipid and glucose panel. Prescription medication use, health history, current self-monitoring and PA habits and the Modifiable Activity Questionnaire (MAQ) were collected via participant interview and participants were asked to complete the EQ-5D quality of life measure and a cost survey. At the 18 month assessment, weight and waist circumference were measured by a trained research assistant and participants were interviewed regarding their current self-monitoring and PA habits.

Participants also completed a Willingness Questionnaire consisting of 16 questions to assess willingness to engage in healthy lifestyle practices at the 6 and 12 month assessment visits. The Willingness Questionnaire was adapted from the Weight Loss Behavior Questionnaire and has not been previously validated; however no other measure for evaluation of participant willingness could be found in the literature. The Willingness Questionnaire includes specific questions about willingness to self-monitor fat, calories and PA, engage in PA, measure portions, make healthy substitutions or modifications and change attitudes about healthy eating and PA. Participants were instructed to read each statement and rate their level of willingness to participate in the behavior by circling the number of days per week (0-7 days) they were willing to participate in the behavior.

Intervention:

The DPP-GLB program was updated and adapted for group delivery by members of the team who developed the original DPP lifestyle intervention, and focuses on achieving 7% weight loss and increasing physical activity (PA) to ≥150 minutes/week, while emphasizing self-

monitoring of diet, PA and weight [27]. The program consists of 12 weekly and 4 bi-weekly sessions (core), followed by 6 monthly sessions (post-core). Participants [10, 27] were given the choice to complete the first 12 sessions in a face-to-face group or via DVD.[28]

The face-to-face group convened weekly for the 12 initial sessions with a DPP-GLB trained lifestyle coach and were weighed, submitted self-monitoring records, received new materials and took part in a 1 hour lesson covering the current session. Participants who missed a weekly group session were provided with the DVD and materials for that session.

DVD intervention participants viewed one session each week and received phone or email support from a DPP-GLB trained lifestyle coach. DVD participants were also invited to attend monthly group meetings during the core intervention. At the in-person DVD meetings the lifestyle coach discussed issues from the previous sessions, weighed participants, provided them with new materials for the upcoming DVD sessions and collected self-monitoring records.

Following the initial 12 weekly sessions participants from both the face-to-face group and DVD intervention were invited to attend bi-weekly followed by monthly group meetings for the remainder of the year.

During the six-month delay, control group participants received handouts that were mailed to them approximately every six weeks to help promote engagement and retention. The handouts covered topics such as the importance of staying hydrated during physical activity, selecting a good pair of shoes and tips for being active outdoors.

Self-Monitoring:

During DPP-GLB core sessions participants were instructed to begin daily self-monitoring of diet and weight following session 1, daily physical activity minutes following session 4 and

daily steps following session 10. Participants were encouraged to continue self-monitoring throughout the program. Methods of self-monitoring included paper keeping track books or other readily available online tracking programs that could be printed out or submitted via email or postal mail to their lifestyle coach. Coaches documented diet and physical activity monitoring frequency on a scale of 0-7, based on the number of days per week the participant monitored each behavior. Coaches also documented the total number of activity minutes and steps per week.

Statistical analysis:

Participants who completed an in-person meeting, phone call or email interaction with discussion including that week's session were considered to have attended the session. During the core and post-core intervention participants who self-monitored PA on ≥3 days/week and diet ≥4 days/week were considered self-monitors of that specific behavior for the week, while those who monitored less frequently were not considered self-monitors for that week.

Differences in baseline characteristics among those who attended all assessment visits (completers), i.e., baseline, 6,12 and 18 months, and had complete data were compared to those who did not attend the 6, 12 and 18 month visits using two sample independent t-tests for normally distributed variables and the Wilcoxon-Mann-Whitney test for variables not normally distributed. The Chi-square or Fisher's exact test was used to test for differences among categorical variables.

Willingness to engage in each healthy lifestyle practice was dichotomized into two categories: participants who were willing (≥4 days/week) and participants who were not willing (<4 days/week). To evaluate change, willingness to engage in health lifestyle practices at 6 and 12 months was compared to baseline willingness using the McNemar's test. Simple logistic regression was used to identify willingness to engage in health lifestyle practices at six months that were

associated with achieving 5% or 7% weight loss and ≥150 minutes/week of PA at 12 and 18 months. A similar analysis was conducted for willingness at 12 months and achievement of 5% or 7% weight loss and ≥150 minutes/week of PA at 18 months.

The association between self-monitoring and attendance during the core and post-core and achieving 5% or 7% weight loss and ≥150 minutes/week of PA at 6, 12 and 18 months was evaluated using simple logistic regression.

To identify individual characteristics (i.e. age, education, employment) unique to participants achieving 5% and 7% weight loss and ≥150 minutes/week of PA at 6, 12 and 18 months a two sample independent t-test, Wilcoxon-Mann-Whitney test, Chi-square or Fisher's exact test were used.

Finally, based on the results of simple logistic regression and evaluation of factors unique to those achieving weight loss and PA benchmarks multivariate regression was used to identify independent predictors of success at 12 and 18 months.

Results:

Of the 223 participants enrolled at baseline, 187 completed the 6, 12 and 18 month follow-up visits and are included in this analysis (completers). Among completers, mean age at baseline was 58.4±11.5 years, mean BMI was 33.8±6 m/kg^2, and mean weight was 208.8±38.6 lbs (Table 1). The 36 participants not included in the analysis were significantly younger (54.1±11.2 years; p=0.01), and had significantly greater mean BMI (36.4±7 m/kg^2; p=0.006), weight (222.1±38.6 lbs; p=0.04) and diastolic blood pressure (79.6±10.6;p=0.02) at baseline compared to completers.

Willingness to engage in healthy lifestyle practices was high at baseline, with over 80% of participants willing to engage in all behaviors on 4 or more days per week with the exception of

recording fat grams, measuring portions and eating out at restaurants less frequently (Table 2). At six months, willingness to eat smaller portions, substitute water for high calorie/sugar-filled beverages, plan meals, modify the cooking an preparation of food, make PA a priority, change thoughts about eating and PA and self-weigh remained similar to baseline, while all other behaviors decreased significantly compared to baseline. At 12 months, willingness to engage in all healthy lifestyle practices at 12 months decreased significantly compared to baseline except for willingness to eat smaller portions, substitute water for high calorie/sugar-filled beverages and plan meals (Table 2). Among participants randomized to the six month delay willingness to engage in healthy lifestyle practices generally remained the same at the conclusion of the delay when compared to baseline.

In simple logistic regression participants willing to use a keeping track book and to be active even when not feeling like it at 6 months were significantly more likely to achieve both 5% and 7% weight loss and ≥150 minutes/week of PA at 12 months compared to participants not willing to engage in these practices at 6 months (Table 3). Additionally, participants willing to record calories and fat grams at 6 months were significantly more likely achieve 7% weight loss at 12 and 18 months compared to participants who were not willing to engage in these practices at 6 months (Table 3).

The association between willingness to use a keeping track book, record calories, record fat, measure portions, and to be active even when not feeling like it at 6 months and achieving 5% and 7% weight loss at 12 months remained significant after adjusting for age, gender, education and employment. However, after further adjustment for core and post-core diet and PA self-monitoring no willingness behaviors were associated with 5% weight loss at 12 months, and only

willingness to be active even when not feeling like it (OR=4.1 95% CI 1.2-13.9) remained significantly associated with 7% weight loss at 12 months.

Self-monitoring and Attendance

The mean number of sessions attended was 13.4±3.3 and 3.8±2.2 during the core and post-core, respectively. Participants completed a mean of 11.7±6.7 diet records and a mean of 7.9±6.2 PA records during the 6 month core intervention. During the post-core, participants completed a mean of 3.8±7.0 diet records and a mean of 3.5±6.8 PA records.

The association of self-monitoring and attendance categories to achieving 5% and 7% weight loss and ≥150 minutes/week of PA at 6 ,12 and 18 months suggests that more frequent monitoring and attendance results in a greater likelihood of participants achieving weight and PA goals at 6, 12 and 18 months (Table 4). For example, compared to participants attending <12 core sessions, participants attending all 16 core sessions were 6.8 (95% CI 2.6-17.4) times more likely and participants attending 12-15 core sessions were 3.8 (95% CI 1.5-9.2) times more likely to achieve 5% weight loss at 6 months. At 18 months, a significant relationship among participants completing the most self-monitoring records and attending all core sessions and meeting the 5% weight loss goal was still present compared to the least frequent self-monitors and participants attending <12 sessions (Table 4).

The relationships between core self-monitoring and core attendance and achieving 5% and 7% weight loss and ≥150 minutes of PA/week at 6 months remained similar to the results of simple logistic regression (Table 8-17) after adjusting for age, gender, education and employment, with the exception of the relationship between core-dietary self-monitoring and achievement of ≥150 minutes/week of PA at 6 months, which was no longer significant. Similarly, after adjusting for

age, gender, education and employment the relationships between core and post-core self-monitoring and core and post-core attendance and 12 month outcomes were similar to the results of simple logistic regression

Individual Characteristics

The evaluation of individual characteristics among participants achieving/not achieving 5% or 7% weight loss and ≥150 minutes/week of PA at 6, 12 or 18 months identified significant differences in age, education and employment. Participants achieving 5% weight loss at 12 or 18 months and participants achieving 5% weight loss at 6, 12 and 18 months were significantly older than those not achieving 5% weight loss at these time points. Also, participants achieving 5% weight loss at 6, 12 and 18 months had significantly different employment status (employment =part-time/full-time, employment=all others) ($p=0.02$) than those not achieving 5% weight loss at these time points, with a greater frequency of those employed less than full or part-time achieving the 5% weight loss goal compared to those employed full or part-time. However there were no significant differences noted in achievement of the 5% weight goal at any time point when stratified by age (age<55 and age≥55). At 18 months, employment ($p=0.007$) and education ($p=0.003$) (education < bachelor's degree, education ≥ bachelor's degree) were significantly different among participants who achieved 5% weight loss compared to those who did not achieve 5% weight loss, with a greater frequency of those employed less than full or part-time and those with less than a bachelor's degree achieving the 5% weight loss goal compared to those employed full or part-time or with a bachelor's degree or higher. However, when stratified by age these relationships were no longer significant. Additionally, education was significantly different ($p=0.02$) among participants who did and did not achieve 7% weight loss at 18 months, with a

greater frequency of those with less than a bachelor's degree achieving the 7% weight loss goal compared to those with more education. Again, this relationship was no longer significant when stratified by age.

Discussion:

In the current study, willingness to engage in healthy lifestyle practices was high at baseline for almost all queried behaviors. However, at 6 months the proportion of participants willing to engage in healthy lifestyle practices decreased significantly for approximately half of the behaviors and at 12 months all behaviors except willingness to purposely eating smaller portions, substitute water for calorie/sugar-filled beverages and plan meals experienced a significant decrease in the proportion of willing participants. During the core and post core intervention session attendance was high, while the high levels of dietary and activity self-monitoring observed during the 6 month core were not sustained during the 6 month post-core. Not surprisingly, participants who attended more sessions and self-monitored diet and PA more frequently met weight loss and PA goals at a higher rate.

Individuals who participate in lifestyle intervention studies are often already committed to making healthy lifestyle changes or identify more positive results associated with a healthy lifestyle than those who do not volunteer[29, 30]. This mindset is likely related to their willingness to engage in healthy lifestyle practices, so it comes as no surprise that the overwhelming majority of participants in the current study were willing to engage in healthy lifestyle practices at baseline. However, a significant proportion of these same highly willing participants report a reduction in willingness to engage in healthy lifestyle practices at 6 and 12 months. Specifically, the healthy lifestyle practices believed to be important for success in behavioral lifestyle interventions, such

as using a keeping track book, recording calories, fat and PA and measuring portions, all declined significantly [31]. Further evaluation of willingness to engage in specific healthy lifestyle practices, like using a keeping track book or recording calories, for the duration of the study (baseline, 6 and 12 months) indicated that a significantly greater number of those willing to engage in these practices at all time points achieved 5% and 7% weight loss compared to those who were not willing to engage in these practices for the duration of the study.

The association of willingness to engage in healthy lifestyle practices at 6 months and achieving 5% and 7% weight loss and 150 minutes/week of PA at 12 and 18 months suggests that willingness to self-monitor and participate in PA is important for achieving weight loss and PA goals. These results are similar to what has been found in other weight loss and weight maintenance studies regarding the importance of self-monitoring and being physically active. Successful participants in the National Weight Control Registry, a cohort that has maintained significant weight loss over a long period of time, report engaging in high levels of physical activity and maintaining a low-fat, low-calorie diet [32]. Similarly, a DPP translation investigating achievement and long-term maintenance of the weight loss goal demonstrated that successful participants engaged in high-levels of physical activity and identified and corrected poor dietary choices before they led to weight gain [33]. The results of the current investigation suggesting participants who are willing to be active even when not feeling like and to use a keeping track book further demonstrate the importance of these behaviors for weight maintenance.

During the 6 month core intervention participants completed a mean of 11.7 and 7.9 dietary and activity records, respectively. This was similar to the mean of 10.1 and 9.2 dietary records reported in two other diabetes prevention translation studies [15, 19]. As shown in table 5, the

association between greater frequencies of self-monitoring and weight loss and PA outcomes is consistent with what has been reported in other diabetes prevention translation studies [18-20]. Session attendance is a frequently reported outcome among diabetes prevention translations, but the association of attendance and future weight loss and PA outcomes is not often explored in translation. In the current study, attending all 16 core intervention sessions was significantly associated with achieving 5% and 7% weight loss at 6, 12 and 18 months. Additionally, attending all 6 post-core intervention sessions was significantly associated with achieving the same weight loss outcomes at 12 and 18 months. Although it is difficult to discern whether attendance at the intervention sessions promotes weight loss or those who are doing well are attending the sessions and those who are not doing well are not attending, it appears that encouraging participants of diabetes prevention translations to attend frequently will aid in success.

In the DPP, other factors that were significantly related to achieving 7% weight loss included older age, lower BMI at baseline and male gender [11]. In a DPP translation study evaluating other characteristics associated with meeting the 7% weight loss goal the findings were similar to that of the DPP, suggesting that older participants and men were more likely to meet the weight loss goal than participants without these characteristics [18]. In the current study, age was significantly different among participants who achieved 5% weight loss at 12 or 18 months and participants who achieved 5% weight loss at 6, 12 and 18 months compared to those not achieving 5% weight loss at these time points. However, the current study did not see a significant difference in gender among those achieving and not achieving weight loss or PA goals.

There are limitations to the current study that should be addressed. The Willingness Questionnaire that was used has not been validated, however very little exists in the literature

regarding assessment of participants' willingness to engage in important healthy lifestyle practices. The measure of physical activity reported in this study was collected via a subjective, self-report survey. Also, the study population was composed of over 90% Caucasians and may not be generalizable to other groups or settings.

Although baseline willingness, as assessed in the current study, was of limited value as a predictor for future achievement of weight loss and PA goals, the notion that willingness to participate in these important healthy lifestyle practices decreases over time in a behavioral lifestyle intervention is a novel finding. Also, the high levels of willingness at baseline may lend support to the assertion that participants who volunteer for intervention studies are more motivated than those who do not. Results related to the importance of self-monitoring and attendance for success with weight loss and PA goal achievement in the current study reinforced what has been demonstrated previously in the relatively few studies that reported on this outcome in diabetes prevention translation. However, the independent importance of attendance in the post-core and achievement of weight loss is a novel finding. Moving forward in diabetes prevention translation it will remain important to continually encourage participants to self-monitor, but programs may see even greater success by encouraging participants to attend more post-core follow-up sessions.

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Table 1. Baseline characteristics of participants who attended the 6, 12, (18) month visits at worksite and three community centers.

	Combined (N=187)
	Mean (SD) Median (IQR)
Age (n=187)	58.4 (11.5) 57.5 (50.4-66.4)
Body mass index, kg/m^2 (n=187)	33.8 (6) 32.8 (29.6-37)
Weight, lbs (n=187)	208.8 (41.8) 200 (179.4-232.2)
Waist circumference, in (n=187)	41.8 (5.3) 41.3 (38.3-44.5)
Total Cholesterol (n=186)	194.4 (38.7) 188 (166-217)
LDL Cholesterol (n=183)	114.5 (34.2) 113 (90-135)
HDL Cholesterol (n=186)	50.8 (13.9) 49 (41-58)
Triglycerides (n=186)	147.1 (69.4) 129 (100-172)
Glucose (n=186)	94.4 (11.1) 93 (87-100)
Hemoglobin A1c (n=186)	5.7 (0.3) 5.7 (5.5-5.9)
Systolic Blood Pressure (n=187)	119.4 (11.9) 118 (111-126)
Diastolic Blood Pressure (n=187)	75.9 (10.1) 77 (69-82)
Gender	**% (n)**
Male	38 (84)
Female	62 (139)
Education	
Some High School	0.5 (1)
High School Graduate/GED	10 (23)
Some College or technical school	26 (58)
College graduate (bachelor's)	30.5 (68)
Graduate degree	33 (73)
Employed	
Full time (>=35hrs/week)	58 (129)
Part-time (<35hrs/week)	8 (18)
Unemployed/laid off & looking	2 (4)
Homemaker	3 (7)
Retired	26 (59)
Disable/unable to work	3 (6)
Family History of Diabetes	48 (108)
Family History of Heart Disease	46 (103)
Smoke	
Never	61 (135)
Former	33 (74)
Current	6 (14)

Table 2. Percent of all participants combined who are willing to engage in behaviors from the willingness questionnaire on the majority of days per week (>=4 days) at baseline and following six and twelve months of intervention (N=187).

Willingness Survey Question	Baseline % >= 4/week	Following 6 months of intervention % >= 4/week	Baseline vs Six month p-value	Following 12 months of intervention % >= 4/week	Baseline vs Twelve month p-value
To use a Keeping Track book to write down everything I eat & drink.	91	73	<.0001	60	<.0001
To record the number of calories that I eat.	83	67	<.0001	61	<.0001
To record the amount of fat grams that I eat.	78	66	0.01	58	<.0001
To measure my food portions using scales, spoons, cups, etc.	74	64	0.02	50	<.0001
To purposely eat smaller portion sizes of food.	96	93	0.1	94	0.5
To substitute water for high calorie/sugar-filled beverages	96	94	0.5	92	0.2
To record the physical activity that I do (in minutes or steps).	97	79	<.0001	75	<.0001
To exercise at least 30 minutes at a moderate intensity.	89	81	0.03	83	0.02
To take time to plan out my meals.	83	79	0.5	76	0.1
To try a different physical activity than I usually do or increase the intensity of the activity.	81	66	<.0001	62	<.0001
To modify the way I cook & prepare food (use low-fat substitutes, limit high calorie ingredients, use less salt/sodium, etc.	93	92	1.0	87	0.02
To eat out at restaurants less often than I currently do.	75	66	0.04	64	0.01
To make physical activity a priority as much as possible.	94	89	0.05	85	0.001
To be physically active even when I don't feel like it.	90	80	0.006	76	<.0001
To change my thoughts related to eating and physical activity.	96	92	0.2	90	0.02
To weigh myself.	86	81	0.2	74	0.006

Table 3. Odds ratios and CI's for the relationship of willingness at six months and weight loss and PA at 12 and 18 months.

	Weight Loss and Activity Goals											
	At 12 months						At 18 months					
	5% weight loss		7% weight loss		150 minutes		5% weight loss		7% weight loss		150 minutes	
Willingness Question	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI
To use a Keeping Track book to write down everything I eat & drink.	2.2	1.1, 4.3	3.0	1.4,6.7	2.0	1.0, 3.9	1.6	0.7,3.8	3.1	1.0,9.7	1.3	0.6,2.9
To record the number of calories that I eat.	2.2	1.2, 4.2	3.3	1.6,6.9	1.7	0.9, 3.1	1.9	0.9,4.2	3.5	1.2,9.8	1.6	0.8,3.4
To record the amount of fat grams that I eat.	2.6	1.3, 4.9	4.0	1.8,8.5	1.2	0.7, 2.2	1.9	0.9,4.2	3.5	1.2,9.7	1.4	0.7,2.4
To measure my food portions using scales, spoons, cups, etc.	1.8	1.0, 3.4	2.4	1.2,4.7	0.8	0.4, 1.5	1.6	0.7,3.3	1.7	0.7,4.1	1.3	0.7,2.8
To purposely eat smaller portion sizes of food.	2.9	0.8, 11.0	3.0	0.6,14.0	1.9	0.6, 6.2	4.9	0.6,40.7	2.6	0.3,21.9	10.4	1.2,87.4
To substitute water for high calorie/sugar-filled beverages	4.0	0.8, 18.9	2.4	0.5,11.4	2.1	0.6, 7.5	1.7	0.3,9.1	0.9	0.2,4.9	1.8	0.4,8.5
To record the physical activity that I do (in minutes or steps).	1.4	0.7, 3.0	2.0	0.9,4.5	2.4	1.1, 4.8	1.3	0.5,3.1	1.6	0.6,4.7	0.8	0.3,1.9
To exercise at least 30 minutes at a moderate intensity.	0.9	0.5, 2.0	1.6	0.7, 3.6	3.2	1.4, 6.9	1.2	0.4,3.0	4.2	0.9,19.1	4.5	1.6,12.5
To take time to plan out my meals.	1.5	0.7, 3.1	2.1	0.9,5.0	1.6	0.8, 3.2	1.4	0.6,3.7	1.5	0.5,4.4	1.5	0.6,3.5
To try a different physical activity than I usually do or increase the intensity of the activity.	1.1	0.6, 2.1	1.2	0.7,2.4	1.8	0.97, 3.3	1.6	0.7,3.3	1.7	0.7,4.1	2.0	0.98,4.2
To modify the way I cook & prepare food (use low-fat substitutes, limit high calorie ingredients, use less salt/sodium, etc.	3.6	0.97, 13.1	3.6	0.8,16.3	1.4	0.5, 4.0	--	--	--	--	1.3	0.3,5.6
To eat out at restaurants less often than I currently do.	1.0	0.5, 1.8	0.9	0.5,1.6	0.9	0.5, 1.6	1.1	0.5,2.4	0.8	0.4,1.8	1.7	0.8,3.6
To make physical activity a priority as much as possible.	1.6	0.6, 4.1	3.1	0.9,11.1	2.4	0.9, 6.2	1.7	0.5,5.8	5.2	0.7,41.6	1.9	0.6,5.9
To be physically active even when I don't feel like it.	2.6	1.2, 5.8	5.3	1.8,15.9	3.0	1.4, 6.5	2.9	1.1,7.7	3.6	1.0,12.9	1.4	0.6,3.3
To change my thoughts related to eating and physical activity.	5.9	1.3, 27.0			1.9	0.6, 5.4	7.2	0.9,58.4	--	--	1.1	0.3,3.8
To weigh myself.	1.2	0.6, 2.5	1.2	0.6,2.6	1.1	0.5, 2.2	0.9	0.4,2.1	1.0	0.4,2.5	2.1	0.9,5.1

Table 4. Odds Ratios and 95% confidence intervals for self-monitoring and attendance during the core, post-core and total and 5% and 7% weight loss and 150 minutes of self-report activity at 6 and 12 months.

	Weight Loss and Activity Goals											
	At six months						At twelve months					
	5% weight loss		7% weight loss		150 minutes		5% weight loss		7% weight loss		150 minutes	
Predictors	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI
Core Diet												
<7	1.0	--	1.0	--	1.0	--	1.0	--	1.0	--	1.0	--
7-18	4.8	2.1,11.0	2.5	1.0,6.2	2.2	1.1,4.5	2.7	1.2,6.1	5.4	1.8,16.3	2.8	1.4,5.8
>18	20.0	6.7,59.5	8.7	3.1,24.1	2.5	1.1,6.0	11.2	4.1,30.3	16.4	4.9,54.6	2.9	1.2,7.0
Core Activity												
<2	1.0	--	1.0	--	1.0	--	1.0	--	1.0	--	1.0	--
2-13	2.0	0.9,4.2	1.2	0.5,2.9	2.2	1.1,4.6	1.1	0.5,2.3	2.3	0.9,6.1	2.5	1.2,5.4
>13	10.3	3.8,28.2	6.6	2.6,17.3	4.0	1.6,10.0	7.0	2.7,18.1	10.9	3.8,31.3	4.4	1.8,10.9
Core Attendance												
>12	1.0	--	1.0	--	1.0	--	1.0	--	1.0	--	1.0	--
12-15	3.8	1.5,9.2	3.2	1.0,10.0	2.2	0.9,4.8	2.3	0.9,5.4	5.7	1.6,20.1	1.5	0.7,3.4
16	6.8	2.6,17.4	8.5	2.7,27.0	2.3	0.9,5.4	3.9	1.6,9.5	9.1	2.5,32.8	3.0	1.3,7.1
Post-Core Diet												
0							1.0	--	1.0	--	1.0	--
>=1							5.3	2.8,10.3	5.4	2.8,10.6	2.3	1.3,4.5
Post-Core Activity												
0							1.0	--	1.0	--	1.0	--
>=1							4.7	2.4,9.2	4.4	2.3,8.5	3.4	1.7,6.6
Post-Core Attendance												
<2							1.0	--	1.0	--	1.0	--
2-5							4.1	1.6,10.3	--	--	2.2	1.0,4.6
6							13.8	5.2,36.7	--	--	3.1	1.4,6.9
Total Diet												
<7							1.0	--	1.0	--	1.0	--
7-22							2.4	1.1,5.4	4.8	1.6,14.8	2.7	1.3,5.6
>22							13.0	4.8,34.9	17.9	5.5,58.7	3.2	1.4,7.5
Total Activity												
<2							1.0	--	1.0	--	1.0	--
2-16							1.0	0.5,2.2	2.4	0.9,6.2	2.3	1.1,4.9
>16							8.2	3.1,21.7	10.2	3.6,29.3	5.7	2.3,14.2
Total Attendance												
>14							1.0	--	1.0	--	1.0	--
14-21							4.7	1.8,12.1	--	--	2.3	1.1,4.7
22							15.9	5.0,50.4	--	--	3.9	1.5,10.3

Table 4 (cont). Odds Ratios and 95% confidence intervals for self-monitoring and attendance during the core, post-core and total and 5% and 7% weight loss and 150 minutes of self-report activity at 18 months.

	At eighteen months					
	5% weight loss		7% weight loss		150 minutes	
Predictors	OR	95% CI	OR	95% CI	OR	95% CI
Core Diet						
<7	1.0	--	1.0	--	1.0	--
7-18	1.4	0.5,3.4	1.2	0.4,3.4	2.1	0.9,4.8
>18	5.1	1.7,15.0	4.2	1.3,13.2	1.5	0.5,4.0
Core Activity						
<2	1.0	--	1.0	--	1.0	--
2-13	0.6	0.2,1.5	0.8	0.3,2.5	1.2	0.5,2.9
>13	3.0	1.1,8.4	3.4	1.1,10.5	1.5	0.6,4.1
Core Attendance						
>12	1.0	--	1.0	--	1.0	--
12-15	2.0	0.6,6.1	8.2	1.0,65.8	1.0	0.4,2.7
16	3.9	1.3,12.3	12.1	1.5,97.4	1.7	0.6,4.6
Post-Core Diet						
0	1.0	--	1.0	--	1.0	--
>=1	3.9	1.8,8.2	3.9	1.7,8.9	0.6	0.3,1.2
Post-Core Activity						
0	1.0	--	1.0	--	1.0	--
>=1	3.8	1.8,8.2	3.4	1.5,7.7	1.1	0.5,2.2
Post-Core Attendance						
<2	1.0	--	1.0	--	1.0	--
2-5	4.6	1.2,17.1	3.0	0.6,14.7	1.5	0.6,3.9
6	14.8	3.9,56.3	12.4	2.6,58.2	2.3	0.9,6.0
Total Diet						
<7	1.0	--	1.0	--	1.0	--
7-22	1.2	0.5,3.0	1.0	0.3,2.9	2.7	1.1,6.5
>22	5.1	1.8,14.4	4.3	1.4,12.8	1.0	0.4,2.6
Total Activity						
<2	1.0	--	1.0	--	1.0	--
2-16	0.6	0.2,1.4	0.7	0.2,2.1	1.2	0.5,3.0
>16	2.9	1.1,8.0	3.8	1.3,11.6	1.5	0.5,3.9
Total Attendance						
>14	1.0	--	1.0	--	1.0	--
14-21	4.5	1.2,16.5	3.6	0.8,16.6	1.2	0.5,3.0
22	13.9	3.3,58.2	10.7	2.1,54.1	3.4	1.1,10.8

Appendix D: Willingness Questionnaire

Appendix D is the Willingness Questionnaire and can be found in its entirety on the next page.

Willingness Questionnaire

Directions: The following items relate to how willing you are to participate in specific behaviors that contribute to successful weight loss and a healthy lifestyle. Please read each statement carefully and answer all the items. For each item, please indicate the number of times per week you are willing to do the specific behavior.

		Circle the number indicating how many times per week you are willing to do the behavior							
1.	**To use a Keeping Track book to write down everything I eat & drink.**	0	1	2	3	4	5	6	7
2.	**To record the number of calories that I eat.**								
3.	**To record the amount of fat grams that I eat.**								
4.	**To measure my food portions using scales, spoons, cups, etc.**								
5.	**To purposely eat smaller portion sizes of food.**								
6.	**To substitute water for high calorie/sugar-filled beverages**								
7.	**To record the physical activity that I do (in minutes or steps).**								
8.	**To exercise at least 30 minutes at a moderate intensity.**								
9.	**To take time to plan out my meals.**								
10.	**To try a different physical activity than I usually do or increase the intensity of the activity.**								
11.	**To modify the way I cook & prepare food (use low-fat substitutes, limit high calorie ingredients, use less salt/sodium, etc.)**								
12.	**To eat out at restaurants less often than I currently do.**								
13.	**To make physical activity a priority as much as possible.**								
14.	**To be physically active even when I don't feel like it.**								
15.	**To change my thoughts related to eating and physical activity.**								
16.	**To weigh myself.**								

* *This has been adapted from Weight Loss Behavior Questionnaires by Tina Mathur, MPH.*

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