Spring 2021

Clinical Test Versus Self-Test for Prediabetes: Outcomes in Diabetes Prevention Based on Mode of Diagnosis

Debra J. Rich
Central Washington University, debra.rich@cwu.edu

CLINICAL TEST VERSUS SELF-TEST FOR PREDIABETES: OUTCOMES IN DIABETES PREVENTION BASED ON MODE OF DIAGNOSIS

A Thesis

Presented to

Graduate Faculty

Central Washington University

In Partial Fulfillment

of the Requirements for the Degree

Master of Public Health

By

Debra J. Rich

May 2021

CENTRAL WASHINGTON UNIVERSITY

Graduate Studies

We hereby approve the thesis of

Debra J. Rich

Candidate for the degree of Master of Public Health

APPROVED FOR THE GRADUATE FACULTY

_____ _____
Dr. Jill Hoxmeier, Committee Chair

_____ _____
Dr. Amie Wojtyna

_____ _____
Dr. Casey Mace Firebaugh

_____ _____
Dean of Graduate Studies

ABSTRACT

CLINICAL TEST VERSUS SELF-TEST FOR PREDIABETES: OUTCOMES IN DIABETES PREVENTION BASED ON MODE OF DIAGNOSIS

by

Debra J. Rich

May 2021

Approximately 34.2 million U.S. adults were diagnosed with type 2 diabetes in 2018 and diabetes prevalence is projected to reach 60.6 million by 2060. A predicted 88 million adults have prediabetes, but only 15.3% have been diagnosed by a medical provider. Approximately 15-30% of the population with prediabetes will develop diabetes within 5 years without lifestyle modification to decrease risk. Reduced incidence of diabetes is an urgent priority for Healthy People 2030 and increased participation in lifestyle change programs is a primary objective. The Diabetes Prevention Program promotes behavior modification to prevent or delay diabetes. Despite evidence to support effective intervention, many individuals with prediabetes do not engage in behavior modification to lower their risk; therefore, it is critical to understand the factors that influence individual motivation to engage in risk reduction behaviors. A prediabetes diagnosis based on a clinical blood test or self-risk assessment is required for enrollment in the program and thus, the purpose of this study is to examine whether participants who completed the program have different outcomes based on their mode of diagnosis of prediabetes.

This research used archival data from participants (N =793) in Diabetes Prevention Programming, 46.7% (n = 370) reported clinical testing and 53.3% (n = 423) completed a self-test for program enrollment. A quantitative non-experimental cross-sectional design was

conducted to explore the association between mode of diagnosis—clinical blood test or self-risk assessment on outcomes of attendance, physical activity, and weight loss in a diabetes prevention program. Results for the measures of attendance, physical activity, and measures of goal completion outcomes indicate significant results that reject the null hypothesis that there is no difference in outcomes between the two sample groups. The study measures for percentage of weight loss were not significant and failed to reject the null hypothesis. Increased understanding of the mechanisms by which diagnosis method may impact outcomes could be used to inform screening procedures and policies as well as communication strategies for participation. The results may influence physician attitudes regarding patient self-assessment and provide new opportunity to analyze outcomes of diabetes prevention programming on population health.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER I

INTRODUCTION

Problem Statement

Diabetes mellitus, referred to as type 2 diabetes or diabetes, is a commonly known, irreversible, chronic disease approaching epidemic proportions in the United States (U.S.). Approximately 34.2 million adults in the U.S. were diagnosed with type 2 diabetes as of 2018 and an additional 7.3 million people have it but have not been diagnosed by a medical professional (Centers for Disease Control and Prevention [CDC], 2020a, 2020b). Adverse health conditions of diabetes are the result of excess blood glucose that damages blood vessels and severely increases risk for morbidities like stroke, cardiovascular disease, and renal (kidney) disease, as well as nerve, tissue, and eye damage. A medical status known as prediabetes proceeds the development of diabetes; it is a serious (but reversible) health condition that indicates a high risk for developing diabetes. Approximately 88 million—or 1 in 3—adults in the U.S. have this condition, but only a small amount (15.3%) report that a health professional told them that they have prediabetes and may be at risk (CDC, 2020a, 2020c). Approximately 15-30% of the population with prediabetes will develop type 2 diabetes within 5 years if they do not engage in lifestyle modification or interventions to decrease their risk. Behavior modification to prevent diabetes can improve health, reduce the incidence of diabetes and its associated complications, and save substantial medical costs (Institute for Clinical and Economic Review [ICER], 2016).

Despite general awareness of the health threat associated with diabetes and evidence to support effective intervention at the prediabetes stage, many individuals with prediabetes do not make or sustain modifications to behavior that will lower their risk (Paige et al., 2017; Warner,

2009). To minimize incidence and prevalence of type 2 diabetes in the U.S., it is critical to understand the factors that influence individual motivation to engage in risk reduction behaviors.

Background

Diabetes is a disease caused by elevated blood glucose levels and type 2 diabetes is the most common subtype. There is an increased risk of chronic health conditions, disease, and disability for people with diabetes and they die an average of 4.6 years earlier than people who are non-diabetic (Bardenheier et al., 2016; CDC, 2020a). Diabetes was the seventh leading cause of death in the U.S. in 2017 (CDC, 2020b). The direct and indirect costs associated with diabetes care in 2017 were approximately $327 billion and individuals with diagnosed diabetes have average medical cost up to 2.3 times higher than non-diabetic patients (American Diabetes Association [ADA], 2018; CDC, 2018a).

Diabetes Prevalence

Although 34.2 million adults in the U.S. were diagnosed with diabetes in 2018, an estimated 7.3 million people are undiagnosed, and 1 in 6 adults will develop diabetes by the year 2060 (CDC, 2020a, 2020c; Lin et al., 2018). Reduction of diabetes cases is an urgent priority for Healthy People 2030 (HP2030) and increased participation in lifestyle change programs is a key objective to lessen diabetes incidence (Healthy People [HP], 2020). Reduction of the incidence rate could lower the diabetes prevalence by 5 million within 10 years (Lin et al., 2018).

Prediabetes

Prior to developing diabetes, individuals have prediabetes, which is defined as a condition where blood glucose levels are elevated more than normal and the higher level can be detected through clinical testing. Individuals who are overweight, have a sedentary lifestyle, and a family history of diabetes are at higher risk for prediabetes along with women who experience

gestational diabetes and some racial and ethnic identities. Approximately 88 million U.S. adults over 18 had prediabetes in 2018, but only a small portion (15.3%) received a clinical diagnosis from a medical professional regarding their condition (CDC, 2020c). A person's increased risk for prediabetes may be identified by either a self-risk assessment test or by a clinical diagnosis determined by a medical professional based on results from blood glucose tests. Health care professionals and health organizations use different methods to identify, diagnose, and treat prediabetes. Health care providers may choose to monitor patient glucose levels over time rather than recommend a lifestyle modification program for diabetes prevention. Most individuals with prediabetes will eventually develop diabetes—some within 5 years—if they do not engage in lifestyle modification or interventions to decrease their risk (ICER, 2016; Tuso, 2014).

National Diabetes Prevention Program

Clinical trials have determined that weight loss and increased physical activity are effective ways to reduce risk for diabetes (Ely et al, 2017; Knowler et al., 2002). The Diabetes Prevention Program (DDP) is a one-year behavior modification class that has been successful in helping individuals prevent or delay diabetes (Knowler et al., 2002). Participants qualify for the program with either a clinical blood test of prediabetes or by completing an evidence-based diabetes risk assessment. Certified lifestyle coaches facilitate the DPP in weekly group sessions using a theory-based curriculum that supports positive lifestyle change through group interaction, skill-building, positive affirmation, and goal setting. Less than half of the participants who register for DPP complete the program and attrition is highest after the first session, which could be attributed to lack of motivation toward behavior change (Cannon et al., 2020; Ely et al., 2017).

The Use of Theory in Behavior Change

Health behavior theories identify factors that influence a person's behavior and provide a framework for intervention and health improvement. The Social Cogitative Theory (Bandura, 1986) is based on a model of environmental factors, individual behavior, and personal factors that intersect to influence individual health-related behaviors. This framework was used to develop the DPP curriculum and the session topics, interactive learning opportunities, and personal goal setting activities all serve to influence positive health behavior change. Theories such as the Transtheoretical Model of Change, Health Belief Model, Theory of Reasoned Action, and Theory of Planned Behavior are used to identify and explain specific factors that may influence a person to move towards adoption of new behavior. Once a person engages in behavior change, these factors may also influence their ability to successfully achieve the expected outcome(s) from the new behavior. Therefore, examination and application of theory constructs can be used to consider whether the method of diagnosis for prediabetes may influence participant outcomes due to behavior change in a DPP.

Implications for Research

The implications for this research are multifaceted and varied, regardless of whether the diagnosis method demonstrates a salient factor in participant outcomes from the prevention program. The upward trend of diabetes incidence and prevalence continues to drive healthcare needs and associated costs towards tertiary treatment of diabetes and related complications. If healthcare expenses and overhead are focused on disease management, it may jeopardize the organizational ability to promote and sustain effective prevention programming. An association between mode of prediabetes diagnosis and DPP outcomes could further inform the use of health behavior theory constructs as opportunity for intervention in program planning. An increased

understanding of the mechanisms by which diagnosis method may impact DPP outcomes may be used to inform screening procedures and policies as well as recruitment and retention communication. Thus, the research aim of this study is to explore the association between mode of prediabetes diagnosis— clinical blood test or self-risk assessment— on measured DPP outcomes of attendance, physical activity minutes, and percentage of weight loss. A theoretical application supports the directional hypothesis.

CHAPTER II

LITERATURE REVIEW

Diabetes in the United States

The purpose of this section is to illustrate the magnitude of diabetes as a major health concern and provide background information to support the importance of intervention tactics to reduce the incidence of disease. Diabetes is a metabolic disease related to elevated blood glucose levels. Increased blood glucose is the result of either defective insulin secretion (type 1 diabetes), or ability to effectively use insulin in the body (type 2 diabetes). Gestational diabetes (GMD) occurs when pregnancy hormones inhibit effective insulin use, resulting in insulin resistance and elevated blood glucose. Type 2 diabetes (indicted hereafter as diabetes) is the most common subtype of diabetes, accounting for approximately 90-95% of all diagnosed cases of adult diabetes (CDC, 2020a, 2020b, 2020c; Sapra & Bhandari, 2020).

Diabetes Impact on Health

When the body does not process excess glucose effectively, blood sugar levels increase, damage blood vessels, and may severely increase risk for developing life-threatening morbidities (ADA, 2020a). People with diabetes often develop additional risk factors for disease like above normal cholesterol, triglycerides, and/or blood pressure levels. Evidence shows that diabetes has been linked to an increased risk of developing stroke, heart disease, or kidney failure, and outcomes of blindness, amputations of lower extremities, development of dementia and Alzheimer's disease, and increased risk for disability and premature death (CDC, 2020a; Dolan et al., 2018; Giovannucci et al., 2010). Disability may develop up to 7 years earlier in adults with diabetes and as a result, experience more years in a disabled state than those without diabetes. Bardenheier and colleagues (2016) indicate men diagnosed with diabetes spend 20-24% of their

remaining life disabled and report similar associations for women. An additional 1 to 2 years spent in a disabled state may severely impact quality of life for people with diabetes (CDC, 2020a, 2020c; Bardenheier et al., 2016). In 2017, over 83,500 death certificates indicated diabetes as the cause of death in the U.S., making it the seventh leading cause of death (crude rate 25.7 per 100,000). Over 270,702 death certificates listed diabetes as contributing to or underlying the cause of death (CDC, 2020b). Individuals with diabetes die 4.6 years earlier and have 60% higher risk of premature death than people who are non-diabetic (Bardenheier et al., 2016).

Financial Impact of Diabetes

The American Diabetes Association (ADA) states that diabetes is a substantial economic burden on society. In the U.S., approximately $327 billion was spent on direct ($237) and indirect ($90) costs related to diagnosed diabetes in 2017; this was an increase of 26% in economic costs over the prior 5 years (ADA, 2018). Excess medical costs associated with diabetes increased between 2012 and 2017 from $8,417 to $9,601 per person. Indirect costs are not associated with the direct treatment of disease but they have a financial effect on society. Diabetes-related indirect costs include work absenteeism, less productivity due to disability or health conditions, and premature mortality. Direct medical costs include the increased cost of medical care that persons with diabetes often incur. People with diagnosed diabetes have average medical care costs of $16,750 annually, with $9,600 attributed to direct medical costs of diabetes. The increased average medical cost may be up to 2.3 times higher than non-diabetic patients due to health conditions related to diabetes and increased need for hospital services (ADA, 2018; CDC, 2018a).

Diabetes Distribution

Over 34.2 million adults in the U.S. in 2018 were diagnosed with diabetes and an estimated 7.3 million more were undiagnosed. The number of diagnosed persons is projected to reach 60.6 million (>1 in 6 adults) by 2060 (CDC, 2020a, 2020c; Lin et al., 2018). Prevalence of diabetes increased steadily from 1999 through 2016 for both men and women as well as all age groups, education levels, and racial and ethnic groups. A portion of the projected prevalence rates is assumed due to improvements in health care and diabetes self-management or lifestyle changes that result in people living longer with diabetes. Despite a decrease in the incidence rate for adults in the past ten years, there has been an upward trend in the rate among adolescents and children, as well as increased complications related to diabetes in younger adults aged 18-44 (CDC, 2020a, 2020b, 2020c; Lin et al., 2018). Slowing the incidence of diabetes has become an urgent priority. A reduction in the number of diagnosed diabetes cases each year is one of the Leading Health Indicator (LHIs) for health improvement and wellbeing by Healthy People 2030 (HP2030). The LHI goal is 5.6 new cases of diabetes per 1,000 adults aged 18 to 84 years; a reduction of 1 new case per 1,000 over cases reported in 2016-2018. One objective to achieve this goal is increased participation in lifestyle change programs (Healthy People, 2020). Analysis predicts a 20% reduction in the incidence rate of diabetes will reduce the diabetes prevalence by 5 million in 2030, and 10 million in 2060 (Lin et al., 2018).

Contributing Factors for Diabetes

Many of the risk factors for diabetes-related complications are behavior-related outcomes that may have contributed to development of the disease. Physical inactivity and smoking are common factors for hypertension, increased cholesterol measures, and overweight/obesity (CDC, 2020b). Diabetes may go undiagnosed until a person experiences health complications such as

fatigue, blurred vision, frequent urination, or increased hunger and thirst. People who develop diabetes go through a prediabetes status where rising blood glucose levels indicate an increase in risk before development of the disease. Because there is no known cure, and medical treatment cannot prevent most of the health complications that are associated with it, prevention is the preferred medical action for diabetes. Medical professionals have an opportunity to help patients achieve diabetes prevention if they intervene at the prediabetes stage (Tuso, 2014). This opportunity for intervention may be complicated by a lack of standard protocol and procedures for routine screening and perceptions of services available for prevention.

Prediabetes Status

This section describes the physical state that precedes onset of diabetes and explains how the pre-disease state provides opportunity to lower risk of diabetes. Prediabetes is a reversible medical status where blood glucose levels are higher than what is considered normal, but not high enough to be classified as diabetes. Several tests are used to determine whether a person's blood glucose is above normal levels. A fasting plasma glucose (FPG) test measures blood sugar after fasting overnight and a level of 100 to 125 mg/dL indicates prediabetes in the U.S. The oral glucose tolerance test (OGTT) is also conducted after an overnight fast, and measures a person's blood sugar before and after consumption of liquid glucose. Blood levels are checked at 1 and 2 hours, and prediabetes is determined if the levels are 140 to 200 mg/dL. The Hemoglobin A1c (A1c) test measures glucose levels in blood cells over time, usually 90 days; a score between 5.7-6.4% indicates prediabetes. Approximately 50.0% of women with GDM eventually develop diabetes and are generally considered to be at risk of prediabetes (CDC, 2020c).

Prediabetes Distribution

In 2018, approximately 88 million (34.5%) of U.S. adults aged 18 years or older had prediabetes, but only 15.3% were aware of their condition through a clinical diagnosis from a health professional (CDC, 2020c). Approximately 35 million adults with prediabetes are 45 to 64 years of age and 24 million are 65 years and older; however, the prevalence of prediabetes in young adults and adolescents in the U.S. has increased (CDC, 2020a). A 2005–2016 study found that 1 in 5 adolescents (18.0%) and 1 in 4 young adults (24.0%) had been diagnosed with prediabetes (Andes et al., 2019). Prevalence of prediabetes was similar among all racial/ethnic groups and education levels; however, a higher percentage of men (37.4%) than women (29.2%) had prediabetes based on age-adjusted data for U.S. adults aged 18 years or older 2013–2016 (CDC, 2020b). An estimated 15-30% of individuals with prediabetes will develop diabetes within 5 years, and up to 70% of individuals with prediabetes will eventually have diabetes if they do not engage in lifestyle modification or interventions to decrease risk (Institute for Clinical and Economic Review [ICER], 2016; Tuso, 2014).

Prediabetes Impact on Health

The measure of risk for developing diabetes is closely associated with an individual's A1c or FPG levels when they are diagnosed. If patient levels are in the higher range, with A1c near 6.4%, and FPG near 125 mg/dl, they are more likely to develop diabetes. A1c numbers closer to 5.7% and FPG numbers closer to 100 mg/dl are more likely to maintain or lower their glucose levels to a normal range although this likelihood may be impacted by the patient's level of insulin production and age at the time of diagnosis (CDC, 2020c; The diaTribe Foundation, n.d.).

In addition to increasing the risk of developing diabetes, evidence suggests that higher than normal blood glucose levels may result in above normal cholesterol, triglycerides, and/or blood pressure levels as well as kidney and nerve damage at the prediabetes stage (CDC, 2020a; Tabák et al., 2012).

Contributing Factors for Prediabetes

Family history, genetics, and a combination of lifestyle factors (food choices, sedentary lifestyle, stress levels, and sleep disturbances) may contribute to development of prediabetes, yet it is often simply the result of being overweight or obese. The prevalence of prediabetes for individuals with normal weight is 28%, and it increases to 36% for overweight, and 40% for those considered obese. Overweight/obese is a contributing factor for insulin resistance, but not all overweight individuals develop prediabetes or diabetes, and there are a minority of individuals with prediabetes who are not overweight (The diaTribe Foundation, n.d.). The ADA/CDC Prediabetes Risk Test (Figure 1) is used to indicate a likelihood of prediabetes status based on answers to questions related to risk factors for diabetes. The assessment surveys whether the individual is 45 years or older, overweight, physically active less than 3 times a week, and asks if they have a family member (parent or sibling) with diabetes. Women are asked to indicate if they had gestational diabetes, or gave birth to an infant weighing 9 pounds or more. Racial and ethnic identity demographics are also considered as African Americans, Hispanics, American Indians, and some Pacific Islanders and Asian Americans experience higher risk for diabetes than Caucasian identity. Individuals with scores that indicate increased risk are encouraged to talk to a medical provider to see if additional testing is needed to determine whether they have a higher risk for diabetes (CDC, 2020d; ADA, 2020a).

Clinical Diagnosis and Referral for Prediabetes

The information in this section is to expand on the role of health professionals in the diagnosis of patient diabetes risk and offer insight regarding barriers to intervention and prevention tactics. The clinical definition of prediabetes is a source of controversy and varies among health care professionals and health organizations. The World Health Organization (WHO) defines prediabetes with the criteria of an FPG of 110-125 as well as an oral glucose tolerance test (OGTT) of 140 to 200 mg/dL. The ADA criteria are the same for OGTT, but the FPG test has a lower value of 100-125 mg/dL to define prediabetes. In addition, the U.S. criteria use an A1c measure of 5.7% to 6.4% to indicate prediabetes (ADA,2020c; Barry et al, 2018). Clinical diagnosis of prediabetes in the U.S. usually starts with the FPG, then progresses to an OGTT test to confirm results. An A1C test may be preferred by providers because it does not require fasting or extended lab visits. A1c test ideally represents a person's average glucose level over 90 days, rather than a single point in time like the FPG and OGTT. However, certain genetic traits, separate from blood glucose, are known to substantially impact A1c levels and may make this an inaccurate measure for the total population (Bansal, 2015).

Potential to Impact Patient Health

Assessment of knowledge regarding prediabetes screening standards among primary care providers (PCP) revealed that only 6% were able to correctly identify the risk factors that indicate a need for screening for prediabetes and only 17% knew the fasting glucose and A1c laboratory parameters used for diagnosing prediabetes (Tseng et al., 2017). The survey participant responses indicated gaps in their knowledge related to ADA recommendations for lifestyle modifications to decrease risk of diabetes. Professional organizations that provide guidance to PCP's do not include prediabetes in their best practice guidelines and this may factor

in their lack of knowledge (Tseng et al., 2017). Results of a survey of self-reported prediabetes screening, testing, and referral among 1256 PCP's indicated that 97% of the providers tested for prediabetes with one of the ADA recommended blood glucose tests. One-third (27%) of the providers used the ADA/CDC Prediabetes Risk Test (Figure 1) and only 23% referred their patients to attend CDC-recognized LSM classes (Nhim et al., 2018). These results are consistent with the findings in a survey of family physicians (*n* 1248) to measure attitudes towards prediabetes and screening. Most physicians used blood glucose as their screening method for prediabetes (Mainous et al., 2016). A little more than half (52.4%) indicated that they followed the national guidelines for diagnosis, and one-third reported uncertainty regarding whether their patient care and screening was consistent with recommended guidelines.

Factors That Influence Prediabetes Screening and Intervention

The survey of family physicians (2016) revealed that physicians often perceived barriers to prediabetes treatment on their patient's behalf, including economic challenges (71.9%), ability to sustain motivation (83.2%), and the patient's ability to modify their lifestyle (75.3%). Seventy-five percent of those surveyed indicated that adequate time to educate patients regarding diabetes was a barrier to prevention methods (Mainous et al., 2016).

Analyses of 2016-2017 National Health Interview Survey (NHIS) data of adults with diagnosed prediabetes revealed 73.5% (95% CI, 71.6.5%-75.3%) reported their medical provider gave them advice or referral for behavior modification after their clinical diagnosis of prediabetes; however, only 35% (95% CI, 30.5%-39.8%) reported engagement in the recommended modification within a year of their diagnosis (Ali et al., 2019). Adults with risk factors of higher-than-normal BMI and ADA/CDC risk scores, but without a clinical diagnosis of prediabetes reported that only 50.6% (95% CI, 49.5%-51.8) received any risk-reduction advice

or referral from their medical provider and only 33.5% (95% CI, 30.5%-39.8%) reported engagement in the recommended modification within a year of receiving the advice.

Participation in LSM programs to prevent diabetes was low for both groups; only 4.9% (95% CI, 4.1%-6%) of those diagnosed with prediabetes and less than 1% (0.4%; 95% CI, 0.3%-0.5%) of adults at risk received referral or advice to engage in LSM program for diabetes prevention (Ali et al., 2019; Venkataramani, et al., 2018). Health care professionals gave general physical activity or dietary recommendations 2 to 3 times more often than they referred patients to formal behavior modification programs (Ali et al., 2019).

National Diabetes Prevention Program

This section introduces the specifics of the nationally funded program developed in response to the rising incidence of diabetes in the United States. The origin of the NDPP is a randomized, clinical trial sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The research aim was to determine if certain interventions could prevent or delay diabetes in adults with blood glucose levels that were higher than normal, but not diagnosed as having diabetes (Knowler et al., 2002). Research confirmed that minimal weight reductions of 5%-7% achieved through lifestyle modification, dietary changes, and increased physical activity of at least 150 minutes per week were effective in 58% (95% CI 48-66) reduction of incidence of diabetes (Ely et al, 2017; Knowler et al., 2002).

The Diabetes Prevention Program Outcomes Study (DPPOS) analyzed whether the results of the DPP trial would result in long-term diabetes risk reduction. Eighty-eight percent of the (surviving) individuals from the 1996-2001 DPP trial enrolled in the ten-year follow-up outcome study. Results of the DPPOS study showed that modest weight loss resulting from intensive lifestyle changes reduced risk of developing diabetes by 34% (compared with placebo)

and 49% in those over age 60 (National Association of Chronic Disease Directors [NACDD], n.d.; National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2002).

National Diabetes Prevention Program Impact on Health

The U.S. Congress authorized the CDC to develop NDDP infrastructure to support evidence-based, cost-effective intervention programs as a public/private partnership with qualified organizations in the U.S. (CDC, 2020e). In 2012, six national organizations—including the YMCA of the U.S.— received funding to implement the DPP across multiple states over a 4-year timeframe. The goal was to test whether the prevention program offered in a group setting would result in long-term diabetes risk reduction in a community setting. Nearly 15,000 participants were enrolled in the 165 sites established during the four years and program data was used to create best practice models for program delivery that are used today (Nhim et al., 2019).

In 2016, the Centers for Medicare and Medicaid Services (CMS) approved the national DPP program as a cost-saving, patient care improvement model. It then received certification as a preventative service model for expansion by The Department of Health and Human Services (HHS) and the Medicare Diabetes Prevention Program (MDPP) was made available to beneficiaries in 2018. As of December 2019, 185 organizations had enrolled as MDPP suppliers for program delivery in 760 locations, and 11 states had elected to include the NDPP as a health benefit for Medicaid beneficiaries (CDC, 2020a). These critical policy expansions were a step towards reducing diabetes incidence in the estimated 46.6% of seniors with prediabetes, as well as influence insurance industry standards and private coverage of DPP. (CDC, 2020b; Ely et al., 2017).

Diabetes Prevention Programming Delivery

To ensure fidelity of evidence collected from program delivery organizations, the CDC also established the Diabetes Prevention Recognition Program (DPRP) (CDC, 2019). To achieve recognition, organizations must use the NDDP curriculum (or approved adaptation) and ensure lifestyle coaches are trained in facilitation to support the theoretical concepts. Because the program was developed for persons known to be at risk for developing diabetes, a minimum of 35% of participants in a year-long program must be eligible for enrollment based on a clinical blood test determining prediabetes or a history of GDM. The remaining participants (65% maximum) must be eligible based on the ADA/CDC Prediabetes Risk Test (Figure 1) (CDC, 2018b; Ely et al., 2017). Recognized programs are required to submit annual data on participant attendance, weight, and duration of physical activity in minutes, which are used by CDC to assess program impact on preventing or delaying the onset of diabetes (CDC, 2019; ICER, 2016). According to the national registry of CDC-recognized diabetes prevention programs, there are approximately 1800 CDC-approved LSM programs in the U.S. (CDC, 2020f).

Yakima County Diabetes Prevention Programs

Washington State has over 50 CDC-recognized program locations (CDC, 2020f). Three programs—Yakama Indian Health Service, Yakama Nation Wak'ishwi Program, and Virginia Mason Memorial (VMM)—are located in Yakima County; the geographical location of this study (CDC, 2020f). Yakima Valley Memorial Hospital, a rural nonprofit hospital system (operating as VMM during the study period), implemented English and Spanish diabetes prevention programming in 2013 in partnership with YMCA of Yakima as part of the national expansion of NDDP (Nhim et al., 2019; Virginia Mason Memorial [VMM], 2020). The VMM

program received official recognition status in 2017 and has provided LSM programming to approximately 1400 participants through 2020.

DPP has been widely promoted within the Central Washington region through paid advertisement, direct mail, social media, news coverage, and patient education materials distributed at medical and health clinics. Community health educators meet frequently with providers associated with VMM to distribute program materials, share data outcomes, and streamline the process for patient referral to the program. VMM also participates in many community health and wellness events in Yakima County, offering fasting blood glucose screening and consultation along with education for health improvement that may include referral to DPP (VMM, 2020).

The VMM program requires attendance at a community orientation meeting or 1:1 counsel with the program coordinator before enrollment in DPP. Orientation attendees receive diabetes prevention educational materials, view or hear testimonials from former participants, and those without a clinical diagnosis of prediabetes are encouraged to complete the ADA/CDC Prediabetes Screening Test (Figure 1) to determine their risk of developing diabetes. VMM estimates that 99% of attendees who attend the orientation enroll in the program within two months (VMM, 2020).

Elements of Diabetes Prevention Programming

The requirements for enrollment in DPP include adult 18+, overweight, BMI ≥ 24 (≥ 22, if Asian), non-pregnant, and have not been diagnosed with type 1 or type 2 diabetes. Participants must have a diagnosis of prediabetes based on a clinical blood test, a previous diagnosis of GDM, or complete an evidence-based diabetes risk assessment (Figure 1). Enrollees in a

program covered by Medicare must have had a recent clinical blood test indicating prediabetes (CDC, 2020e).

The DPP curriculum is delivered by certified lifestyle coach/facilitators in a group environment of approximately 18 to 20 people. The structure of the 1-year program consists of 16 weekly 1-hour core sessions, 2 bi-monthly post-core sessions, then 4 monthly post-core sessions. Facilitators weigh and record the participant weight measures before each session and collect participant-reported measures of physical activity minutes starting in week 6. Participants are encouraged to attend every session and track their progress towards the program outcome goals of 5%-7% weight loss and 150 physical activity minutes per week (CDC, 2020e).

The curriculum used in the original clinical trial was developed and written at the University of Pittsburgh by the DPP Lifestyle Resource Core (University of Pittsburg, 2021). The Diabetes Training and Technical Assistance Center was established in 2009, at Emory University's Rollins School of Public Health to adapt the curriculum for delivery in a group format and create a training certification program for lifestyle coaches (Emory University, 2020). The lifestyle change curriculum is based on the Social Cognitive Theory (SCT) developed by Bandura (1986), who theorized a reciprocal relationship and determinism between a person's behavior, cognitive thoughts and abilities, and their environment. Six major constructs influence behavior within the SCT; outcome expectations and expectancies, behavioral capability, self-efficacy, the environment, and the perceived behavior of others (Bartholomew et al., 2020; DiClemente et al., 2013; Rimer, et al., 2005). Lifestyle coaches are certified in curriculum delivery that reinforces the SCT constructs and they support participants with weekly feedback to guide healthy eating decisions while forming new health behavior habits. Participants learn about positive lifestyle change through interactive lessons in food and nutrition management,

participate in group sharing and knowledge interaction, and set outcome goals based on their individual health needs. As participants achieve their goals, they build confidence in their ability to change behavior and model that behavior within their group and social environment. The group format and interactive learning environment encourage ongoing program attendance which is considered a best practice for attaining the goal outcome goals for the program. (Baker et al., 2011; CDC, 2018b; 2018c).

Diabetes Prevention Program Results

Participants who attend more than 17 DPP sessions and report >150 minutes of physical activity per week show median weight-loss rates of 6%, and weight loss of 0.31% (p <0.0001) for every additional session attended, as well as an additional 0.3% (p <0.0001) for every 30 minutes of physical activity reported by participants per week (Ely et al., 2017). Alva (2019) measured attendance among Medicare beneficiaries enrolled in DPP and compared the findings with claims data to determine the impact of attendance on weight loss and medical costs. The mean attendance was 14 (SD 6 sessions, 24 max), participants lost an average of .72 lbs. (.67 - .77 lbs.) per week, and saved approximately $58 (mean) in medical cost for each session they attended. Completion of at least 14 sessions is recommended to achieve a weight loss of 5% and obtain relevant medical cost savings (Alva, 2019).

Evidence shows increased positive outcomes associated with how long the individual is in the program and significant association with participation beyond the 16 core weekly sessions and achievement of >5% weight loss (Ely et al., 2017; Jeffers et al., 2019). However, less than half of the participants (43%) who register for DPP complete the 16-week core curriculum. Attrition is highest after the first session, which could be attributed to behavior constructs such as attendees' understanding of program outcome goals, perception of ability to meet the

expectations of the program, or their motivation and attitude toward behavior change (Cannon et al., 2020; Ely et al., 2017).

Health behavior theory is used to understand how constructs such as expectations, behavioral capability, and self-efficacy (among others) influence engagement and retention in DPP as well as behaviors prior to participation in health improvement strategies. They can provide insight regarding the factors that may influence an individual who has been diagnosed with prediabetes or has completed a self-test to determine their diabetes risk, to move towards participation in prevention opportunities.

Theoretical Frameworks to Influence Behavior Change and Program Outcomes

The purpose of this section is to describe some of the ways that individuals may move towards behavior change and illustrate how health improvement programs may benefit from using application of theory to understand those behaviors. The theoretical frameworks featured in this section will be applied to understand the ways that the method of diagnosis—clinical test or self-risk assessment—may influence outcomes attained through a lifestyle management program such as DPP.

In order to complete this analysis and application of theory, some assumptions have been determined that generalize the knowledge, experience, and expectations of individuals *prior* to their participation in DPP. (Enrollment in the program requires either a clinical diagnosis of prediabetes or a self-risk assessment that confirms a person's risk of developing diabetes.) If a person has received a clinical diagnosis of prediabetes it could be presumed that they were unaware of their condition prior to diagnosis and their initial perception would be influenced by the attitude, perceptions, and knowledge of the provider as it relates to diabetes risk and DPP as a mechanism for prevention. It may also be assumed that they are in a state of receiving

information rather than actively seeking a diagnosis. It is the expectation that the individual has a professional relationship with their provider and that they will have contact with the provider during or after they participate in the program.

The self-risk assessment has been extensively promoted through health improvement outreach at a national and local level and was also provided at monthly orientation sessions hosted by the DPP coordinator. If an individual completes a risk test as a prerequisite to participation in DPP, it could be presumed that they were aware of the prevention program and have a perception of the value of participation in the program. It could also be assumed that they are in a state of seeking information. If they completed the test after attending orientation, it could be assumed that it was their decision to attend the orientation, perhaps with the intention to enroll, before receiving information about the program. It can be expected that the individual used critical thinking and honest assessment when they completed the risk test and in a state of prediabetes.

Health behavior theories consist of key theoretical constructs that influence behavior and provide a framework for intervention. The constructs may work independently, concurrently, or in multiple layers and are applied at multiple points along a spectrum of behavior change from unawareness through behavior maintenance. Theories often share similar constructs although they are assumed to influence behaviors in different ways depending on when they are applied, therefore it is important to consider how theory-based curriculum may influence behavior change outcomes. Program planners often combine multiple theoretical frameworks to understand health behaviors that result in lack of engagement, guide development of programs, and implement curriculum to reinforce behavior change and maintenance (DiClemente et al., 2013; Rimer, et al., 2005). Commonly used health behavior theories include the Theory of Reasoned Action and

Theory of Planned Behavior, the Health Belief Model, Transtheoretical Model of Change, Social Cognitive Theory, and Diffusion of Innovation Theory.

Theory of Reasoned Action and Theory of Planned Behavior

Theoretical models like the Theory of Reasoned Action (TRA) and the Theory of Planned Behavior (TPB) are based on concepts of value expectancy. Individuals form decisions related to health behavior change based on their perception and measure it in terms of the benefit versus the cost. A person's perception of the benefit—what they will achieve by making behavior change— is measured against a perception of the effort they expect to make towards that change. These *costs* (efforts) may be measured by physical, social, emotional, or financial investment. The benefits may be directly related to health improvement, but they are often perceived in terms of physical ability or fitness, appearance and weight loss, or increased adoption of desired social norms such as participation in recreational sports and physical activities (Ajzen & Fishbein, 1980; DiClemente et al., 2013; Rimer, et al., 2005).

TRA, developed by Ajzen and Fishbein (1980), assumes that a person's health behavior belief and their social influences are factors that shape their behavioral intent. The endpoint of the theory is an intention to perform a particular behavior and the next action will be the desired behavior. TRA definition of behavioral intention includes a timeframe for the behavior to be performed, an exact description of the action of the behavior, the outcome that is desired from the behavior, and the context of the behavior. Behavioral intention is mediated by attitude which is shaped by individual beliefs and evaluation of outcomes related to the behavior. Subjective norms also impact intent as they are formed in part by a person's motivation to comply because of their perception of what people important to them would think about the behavior (Ajzen & Fishbein,1980; (DiClemente et al., 2013).

Ajzen (1988) expanded on the theoretical base of TRA to create the TPB model by adding a construct of perceived behavioral control. TBP assumes that perception of favorability towards a behavior, along with subject norms that support it, will influence the likelihood that a person will perceive control over the behavior. This perception is influenced by a number of external factors that may serve to either facilitate or inhibit the behavior. The factors that influence perception are not actualized but are part of evaluation of the value and benefit of behavior change and they may influence perception without cognitive thought (Ajzen, 1988; DiClemente et al., 2013).

Theory of Planned Behavior and Current Study. Application of TPB to this research could align the mode of prediabetes diagnosis as one of the factors that influence attitude, subject norms, and perceived behavior control toward the behavioral intention to enroll in the DPP. Other factors that may influence behavioral intent include individual interpretation of promotional messaging, social interactions with people in the program, and their previous experiences or knowledge about prediabetes. Since the constructs of TPB applies to the *intent* to perform the behavior, the curriculum of the program would build on the factors that influenced their intention to participate, and could therefore lead to favorable outcomes from the program.

As discussed in the opening paragraph of this section, if a person receives a clinical diagnosis of prediabetes, their attitude toward behaviors, subject norm, and perceived control constructs could be influenced in part by the provider who provided the diagnosis. If the provider shares information about the program in a positive way, the patient may have a more favorable attitude toward the behavior expected from the program. The provider attitude may also influence the patient's perception of normative behavior following a diagnosis of prediabetes if they recommend enrollment in the DPP. The perception of behavioral control may be dependent

on their personal understanding of the elements of the DPP along with the knowledge and attitude of the medical provider towards the program (Mainous et al., 2016; Nhim, et al., 2018).

If a person completes a self-assessment for risk test as a prerequisite to participation in the DPP, they may be moving toward the TRA definition of behavioral intention as they consider the behavior timeframe, the behavior action, and desired outcome of the behavior. They may already have a positive attitude towards the new behavior and perception of their behavioral control. If they attended the orientation session, their subject norm will likely be influenced by motivation to comply with the invitation to enroll and also by those in attendance who support a normative belief and positive attitude towards the behavior.

Health Belief Model

Perception of threat and fear appeal theories build on the construct of value expectancy by adding perceptions that relate to threat or fear about the probability and severity of negative health outcomes. The Health Belief Model (HBM), developed by Rosenstock (1974), has been widely used in public health campaigns to motivate individuals toward behavior change (DiClemente et al., 2013; Rimer, et al., 2005). The Health Belief Model primary constructs are perceived susceptibility and severity, and perceived gain (benefit) from the behavior. These perceptions are influenced by personal moderators such as age, socioeconomic status, and knowledge about the health threat, as well as cues to action from events, or interventions that relate to the threat. An updated version of the model includes self-efficacy as an independent variable for health-related behavioral interventions because most people will not move toward new behavior unless they feel confident that they are capable of performing the behavior (Rosenstock, et al., 1988). The model suggests that a person's motive for change is based on

their perception of the severity of, and susceptibility to, the health problem (threat), and perception of gain from behavior change (DiClemente et al., 2013; Glanz & Bishop, 2010).

Health Belief Model and Current Study. Application of HBM to this research considers how the two different types of prediabetes diagnosis may impact individual perceptions of susceptibility and severity of disease. A person's perception and likelihood of action will also influence their overall perceived threat of disease and therefore factor in the likelihood of taking preventative action by participating in the DPP. Individuals with either diagnosis will receive cues to action from promotional messaging and social interactions, as well as draw on prior knowledge to shape their perception. Their perceived threat of diabetes may be limited by lack of knowledge of the disease or enhanced by information regarding the finality of prediabetes progression towards diabetes. Reinforcement of behaviors that reduce risk will have a positive impact on their self-efficacy and influence the likelihood that they will take preventative action.

If the person has clinical diagnosis of prediabetes, their perception may be influenced by the provider who gave the diagnosis. Patients may experience increased perception of susceptibility and severity of disease due to the tangible element of a clinical test and knowledge from a medical professional. Personal assessment of disease risk may vary among educational levels and cause misunderstanding or communication barriers between patients and medical professionals regarding the risk factors and health threats associated with prediabetes and diabetes.

If a person completes a self-assessment for risk test as a prerequisite to participation in the DPP, they may already have a perception of their susceptibility and the severity of disease, as well as a perceived benefit from engaging in prevention through DPP. If they attended the

orientation session, their perception of gain from behavior change will likely be influenced by the testimonial of prior participants and the availability of information to assess risk.

Transtheoretical Model of Change

The Transtheoretical Model of Change (TMC), developed by Prochaska & DiClemente (1983) has been used to facilitate motive for behavior change in a variety of health promotions (DiClemente et al., 2013; Glanz & Bishop, 2010; Rimer, et al., 2005). The TMC states that willingness to engage in a lifestyle change or behavior modification program occurs in stages of pre-contemplation, contemplation, preparation, action, and maintenance. Individuals may stop or step back at a particular stage rather than proceed sequentially towards a new health behavior. The processes of change are techniques or interventions that effectively enhance or promote movement to the next stage. Early stages of pre-contemplation to contemplation are reliant on awareness processes to affect change like consciousness-raising, or reevaluation. Other processes that are particularly effective at the contemplation stage include decisional balance - how a person evaluates and decides whether to adopt change - and self-efficacy. The TMC framework conceptualizes self-efficacy as both confidence and temptation, thus a person who has high confidence in their ability to resist temptation is considered to have resilient self-efficacy (DiClemente et al., 2013; Glanz & Bishop, 2010).

Transtheoretical Model of Change and Current Study. Application of TMC theory to this research could align mode of prediabetes diagnosis as factors that influence a process of change specific to stage levels and/or to the techniques prescribed for each process. The DPP program curriculum may support stage movement through self-efficacy as the participant gains new confidence in the program. A prediabetes diagnosis, regardless of mode—clinical or self-test—could facilitate consciousness-raising if it enhances the awareness of health risk and

external factors. In addition, cues to action from promotional messaging, social interactions, and prior knowledge could affect the decisional balance to adopt change.

If the person has clinical diagnosis of prediabetes, their perception of self-efficacy could be dependent on their understanding of the elements of the DPP at that time of the diagnosis as well as the knowledge and attitude of the medical provider towards the program. The information shared by the provider may not move the patient toward adoption of new behavior because it does not support the process needed for the patient's current stage of change. Or, they may have experienced fear about the serious side effects associated with diabetes, then felt relief when they learned that DPP is available as effective prevention. This process of dramatic relief can be influential in moving a person from contemplation stage to preparation stage for new behavior.

If an individual completes a self-assessment for risk test as a prerequisite to participation, they may be in the contemplation of new behavior stage and the self-assessment may provide new information that informs their decisional balance and moves them into preparation stage. Or, they may already be in a preparation stage, with intention to adopt new behavior in the immediate future. In order to move to the next stage— action— they may require new skills and resources which could be learned as they go through the DPP curriculum.

Social Cognitive Theory

Program planners may use a multilevel intervention strategy that includes messaging aimed at the population level in order to motivate the practice of positive health behaviors, or influence perceptions that will move people away from negative behaviors. The Social Cognitive Theory (SCT) developed by Bandura (1986) suggests that behavior is learned by observation and imitation of the behavior exhibited by other people, as well as observation of an expected

outcome from the behavior (Bandura,1986). This reciprocal relationship between an individual, their behavior, and their environment influences motivation and ability to adopt new behaviors. The key constructs of SCT are knowledge, perceived self-efficacy, outcome expectations, goal formation, and sociostructural factors. (DiClemente et al, 2013: Glanz & Bishop, 2010).

Social Cognitive Theory and Current Study. Application of SCT to this research is challenging as the constructs that influenced participation in DPP as a result of the prediabetes diagnosis will in turn influence new behavior expectations and the environment of the other participants in the DPP group. The prediabetes diagnosis regardless of mode—clinical or self-test—is likely influenced by the sociostructural factors in the individual's environment. If their environment and social interactions include people who model diabetes prevention behaviors (and have experienced expected outcomes from DPP) their behavior actions may be influenced by the collective self-efficacy in their environment.

If a person receives a clinical diagnosis of prediabetes they may not have any awareness of expected prevention-related behaviors or have opportunity to become knowledgeable about behaviors. SCT is like other theoretical applications to this research, in that individual perceptions and attitudes related to the expected outcomes can be influenced by the provider who provided the diagnosis. The patient's perception of self-efficacy and ability to set goals related to behavior change could be influenced by the medical provider's attitude and knowledge of DPP.

If an individual completes a self-assessment for risk test as a prerequisite to participation in DPP the person may already know about the program and an expectation of outcomes that could be obtained through participation. They may also have a greater prevention self-efficacy; the ability to exert control over their motivations, behavior, and social environment.

Diffusion of Innovation Theory

Diffusion of Innovation Theory (DIT) is a social participatory model developed by Everett Rogers (2014) comprised of four primary concepts of innovation, communication, social, and time, that explain the way novel ideas (innovation) diffuse into social practices within a population to create new behavioral norms. Innovation is defined as an idea, practice, or concept that is perceived as new or novel to a population. The premise is that societal modeling of new behaviors will promote increased adoption of those behaviors. Like other stages of change models, individuals move through levels before the behavior becomes diffused: awareness, decision to adopt or reject innovation, initial exploration, and continued use or practice of the behavior. Individuals will consider factors like the relative advantage of the behavior, compatibility with their values and experience, whether there is opportunity to try the behavior without commitment, ability to discontinue the behavior, and whether the results are tangible prior to adoption of the behavior. As individuals begin adoption, they may consider the complexity of new behavior and the time commitment. Factors of commitment, modifiability, and observability of the results are usually considered after the innovation has been adopted (DiClemente et al, 2013; Rimer et al., 2005; Rogers, 2014).

Public health application has typically focused on using the DIT framework to facilitate adoption of preventative health behavior in specific population groups. Successful adoption of HIV/AIDS prevention behavior in San Francisco during the 1980's AIDS epidemic has been attributed to use of interventions based on innovation theory (Bertrand, 2004). Similarly, a smoking cessation program modeled on innovation used multiple communication channels to increase awareness and positioned primary care physicians as influencers to change the normative behaviors and attitudes towards tobacco use (McManus, 2013)

Diffusion of Innovation and Current Study. Application of DIT to this research considers how the two types of prediabetes diagnosis may work as predictors to adopting an innovation - participation in the DPP.

If a person has received a clinical diagnosis of prediabetes, it can be assumed that they are either unaware of the DPP, or at a stage of awareness about the program through communication. Research shows successful outcomes from positioning primary care physicians as influencers to change normative behaviors and attitudes towards behavior change (McManus, 2013). Their ability to adopt the expected behavior may also be dependent on their interpretation of the complexity of the program and the time commitment.

If an individual completes a self-assessment for risk test as a prerequisite to participation in DPP they may be at the decision to adopt or reject innovation stage, or the initial exploration stage. They may be influenced by communication about the program within their social realm or by interaction with an innovator or early adopter. This person could benefit from the SCT-based DPP curriculum as facilitators affirm the advantage of the program (prevention of diabetes), the opportunity for tangible results (weight loss), and emphasize compatibility regarding how the program is designed to help everyone modify behaviors based on their lifestyle.

The Current Study

The research aim of this study was to explore the association between mode of prediabetes diagnosis—clinical blood test or self-risk assessment—on measured DPP outcomes of attendance, physical activity minutes, percentage of weight loss, and combined goal achievement of all three measures.

A number of common themes and assumptions were identified prior to the application of the theoretical frameworks to understand the ways that the method of diagnosis may influence

these outcomes. The assumed scenarios could indicate that the individual who completes a self-assessment for risk test is at a more advanced stage of readiness for change than the person who receives a clinical diagnosis. Research indicates that early success with outcomes of weight loss and physical activity are a predictor for retention in the DPP and increased outcomes are associated with how long the individual is in the program. (Cannon et al., 2020; Ely et al., 2017; Jeffers et al., 2019). Therefore, they may be more likely to implement the behavioral modifications promoted in the DPP curriculum and be more receptive to the influence of elements of SCT curriculum in the DPP. This movement towards behavior change at the beginning of the program could influence the likelihood of early success and retention in the program. Evidence shows increased positive outcomes associated with how long the individual is in the program (Ely et al., 2017; Jeffers et al., 2019).

The first hypothesis proposes that participants who use a self-risk assessment to determine their diabetes risk will attend a greater median number of sessions than participants with clinical diagnosis of prediabetes. The second hypothesis states that participants who use a self-risk assessment will also have greater median weekly physical activity minutes as of session 16 than those with clinical diagnoses. A third hypothesis states that participants use a self-risk assessment to determine diabetes risk have greater median percentage of weight loss than those with clinical diagnosis of prediabetes. The final hypothesis combines the goal outcomes of the program and claims that the number of participants who use self-assessment to determine diabetes risk and who achieve goal completion measures for attendance, physical activity, and percentage of weight loss is greater than participants with a clinical diagnosis of prediabetes who also achieve goal completion measures.

CHAPTER III

RESEARCH METHODOLOGY

Study Design

This research study was a secondary data analysis utilizing a quantitative non-experimental, cross-sectional design to investigate association between method of diagnosis of prediabetes—clinical blood test or self-risk assessment—and DPP outcomes.

Procedures

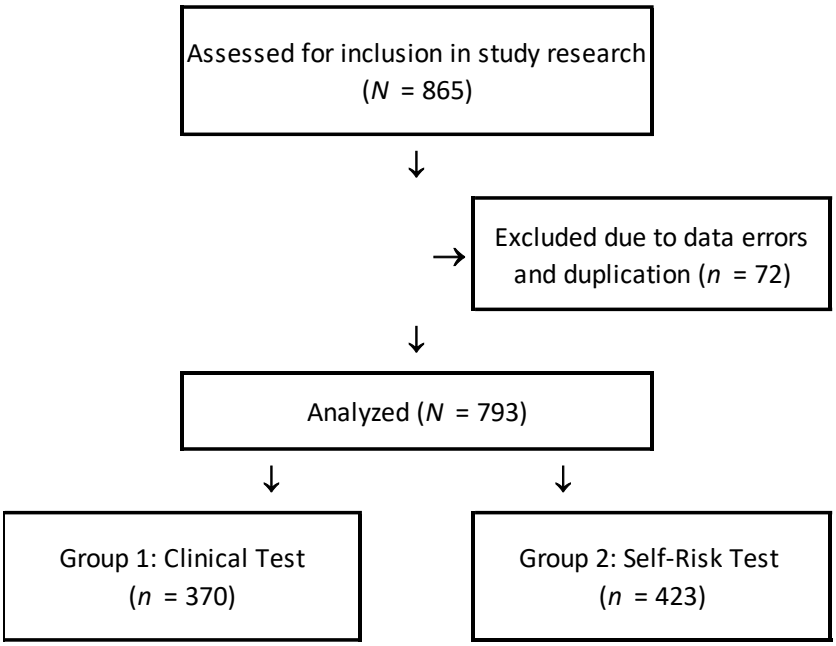
This research used archival data from adults enrolled in a Diabetes Prevention Program (DPP) from 2017 to 2020 at Virginia Mason Memorial in Yakima Washington. Participants were eligible to enroll upon attendance of an orientation session and completion of required intake document. Variable information includes participant enrollment source, payer type, participant's age, ethnicity, sex, height, education attainment, and prediabetes determination category. The prediabetes categories are clinical test, previous GDM, or self-risk assessment. Measures for clinical blood tests are either FG of 100 to 125 mg/dl, OGTT of 140 to 199 mg/dl, or A1c measure of 5.7% to 6.4%. Self-risk assessment is a positive screening for prediabetes risk using the ADA/CDC Prediabetes Risk Test (Figure 1).

Program facilitators weighed participants before each session and recorded weight measures starting week 1 and participant-reported measures of physical activity (PA) minutes starting week 6. Data were entered into a secure reporting system by the facilitator or DPP coordinator, and the de-identified data were submitted bi-yearly to the CDC per agreement as a CDC-recognized organization. Participants were included in this study if they attended at least one DPP session delivered by VMM and data was collected for the outcomes of PA and weight loss. The estimated total sample size was 1400 participants based on preliminary VMM program

enrollment data (2020) from 2017 to 2020; however, a number of participant files could not be retrieved and the number was reduced to 865 for analysis. An additional 72 records were removed due to duplication, or abnormalities in the data that could not be resolved. As shown in Figure 2, the final sample used for analysis was 793 participants, and 46.7% (n = 370) of participants qualify for DPP by clinical test or GDM, and 53.3% (n = 423) completed self-test.

Figure 2

Consort Flow Diagram



Sample Population

The demographic profile of study participants (N = 793) shown in Table 1, was 25% male (n = 201, 75% female (n = 592), aged 18 to 94 ($\overline{x}$ 60, $\tilde{x}$ 63). The racial and ethnic identity distribution was 83.6% White (n = 663), 14.8% Hispanic or Latino (n = 117), 1.5% American Indian or Alaska Native (n = 12), and 0.1% Other racial/ethnic identity which includes: Asian, Black, or African American, and Native Hawaiian or Other Pacific Islander. Group 1 (n = 370) included participants who were eligible for the DPP based on laboratory blood test (clinical test)

or previously diagnosed GDM. The Group included 37% male (*n* = 137), 63% female (*n* = 233), aged 18 to 84 ($\overline{x}$ 59, $\tilde{x}$ 61). The racial and ethnic identity distribution was 82.4% White, 16.2% Hispanic or Latino, 1.4% American Indian or Alaska Native. Group 2 (*n* = 423), includes participants who had a positive screening for prediabetes risk using the ADA/CDC Prediabetes Risk Test (Figure 1). Group 2 was 15% male (*n* = 64), 85% female (*n* = 359), aged 27 to 94 ($\overline{x}$ 62, $\tilde{x}$ 64). The racial and ethnic identity distribution was 84.6% White, 13.5% Hispanic or Latino, 1.5% American Indian or Alaska Native.

Table 1

Demographic Profile of Study Participants

Variables	Group 1 Clinical Test (*n* = 370)		Group 2 Self-Test (*n* = 423)		Full Study Sample (*N* = 793)	
	n	%	*n*	%	*n*	%
Gender						
Male	137	37	64	15	201	25
Female	233	63	359	85	592	75
Age						
Mean	59		62		60	
Median	61		64		63	
Range	18-84		27-94		18-94	
Racial/Ethnic						
White	305	82.4	358	84.6	663	83.6
Hispanic or Latino	60	16.2	57	13.5	117	14.8
American Indian or Alaska Native	5	1.4	7	1.7	12	1.5
Other racial/ethnic identity	2	0.05	1	0.02	1	0.4

Note. Other racial/ethnic identity includes: Asian, Black, or African American, and Native Hawaiian or Other Pacific Islander.

Preparation of Data

This research used a password-protected Microsoft Excel worksheet for management and analysis of the de-identified data. Raw data was organized to allow for identification of abnormalities in the data and statistical analysis of variables. Outliers and presumed data errors were fact-checked and verified by the program coordinator before inclusion in this research. A standard protocol for estimating missing data for measures of PA and weight loss was implemented. If participants missed one session (>6 <17) mean PA minutes from the two closest measures were entered for that date (609 missing data records [weeks 7-16] used estimated data). Participants who missed 2> consecutive sessions were documented as zero for the missing dates. Mean WL data was used for participants who missed session 16 but attended sessions 15 and 17. There were 37 entries with estimated weight loss.

Statistical Analysis

This research places the method of diagnosis for prediabetes, clinical test or self-test, as dichotomous independent variables and the median attendance, weekly PA, and WL% as dependent variables.

The independent variable (IV) was categorical with two Groups as shown in Figure 2. Group 1 (clinical test) includes participants who were eligible for the DPP based on laboratory blood tests within the past year, or previously diagnosed GDM. Group 2 (self-test) includes participants who had a positive screening for prediabetes risk using the ADA/CDC Prediabetes Risk Test (Figure 1).

Participants in both Groups were measured on dependent variable (DV) outcomes of 1) attendance, 2) PA, 3) percentage of weight loss (WL%), and 4) achievement of program goal outcomes for attendance, PA, and WL%. Table 2 shows the DV for attendance of weekly

sessions was measured as continuous interval data of the number attended (>1, <17). The DV for self-reported PA minutes per week was proposed as a categorical score based on continuous interval data of weekly PA minutes (>6, <17). 0= zero weekly PA minutes, 1= >0 to <59, 2= >60 to <150, 3= ≥151. This was proposed to reduce the range of distribution in the data. However, the method was changed to measure PA minute as continuous interval median data when analysis revealed non-parametric data and similar results. In addition, this measure aligns with DPP program goal outcomes of 150 mean PA minutes per week. The weight loss DV was measured as continuous interval data using percentage of WL from the starting weight through the highest attended session (>1, <17). The goal completion outcomes DV was based on the NDPP recommended outcomes to achieve maximum diabetes risk reduction: ≥16 weeks of session attendance, ≥150 mean weekly PA minutes, and >5% weight loss. The goal completion DV was measured using a discrete-binary variable (>16). 0= attendance <16, PA <150, and WL% <5%. 1= attendance ≥16, PA ≥150, and WL% ≥5%.

The data analysis ToolPak in Microsoft Excel (2016) was used to perform data analysis unless otherwise indicated. Dependent variable mean and median were assessed visually using Box and Whisker graphs, and statistical analysis used Skewness and Kurtosis measures to calculate departure from normality, and *Kolmogorov-Smirnov* (KS) calculator (Smirnov, 1948; AAT Bioquest, 2021) to determine variance (normalcy) of data. The variables for attendance, PA minutes, and WL% were asymmetrical (non-parametric) thus the *Wilcoxon Mann-Whitney U test* (Mann, & Whitney, 1947; Social Science Statistics, n.d.) was used to compare median outcomes. The alpha significance level of 0.5 was used for the 2-tailed hypothesis analysis. A *z* test for proportions was used for analysis for the binary variable for goal completion (Social Science Statistics, n.d.).

Table 2

Study Measures and Statistical Analysis

Dependent Variable	Data Measure	Statistical analysis	
		Normalcy test of data	Non-parametric (Median data)
Hypothesis 1: Attendance	Continuous interval data (<1,<17)	Visual analysis: Box and Whiskers graph Statistical analysis: Skewness and Kurtosis measures *Kolmogorov-Smirnov* (KS) calculator	*Wilcoxon Mann-Whitney U Test* = 0.5 alpha level
Hypothesis 2: Physical Activity Minutes	Continuous interval data (<6,<17)		
Hypothesis 3: Percent of weight loss	Continuous interval data (<1,<17)		
Hypothesis 4: Goal outcome attainment	Discrete binary variable: 0= Attendance <16, PA <150, and WL% <5.%. 1= Attendance ≥16, PA ≥150, and WL% ≥5.%.	n/a	*z* test for proportions

Note. The DV for participant self-reported PA minutes was proposed for research as a categorical score based on continuous interval data of weekly PA minutes reduce the range of normalcy. The method of analysis was changed to measure PA minute as continuous interval median data when analysis revealed non-parametric data and similar statistical results. In addition, this measure aligns more closely with the DPP program goal outcome of 150 mean PA minutes per week.

CHAPTER IV

RESULTS

The research aim of this study was to explore the association between mode of prediabetes diagnosis—clinical blood test or self-risk assessment—on measured DPP outcomes of attendance, physical activity minutes, percentage of weight loss, and combined goal achievement of all three measures.

Hypothesis 1: Participants with DPP eligibility using self-assessment to determine diabetes risk attend a greater median number of sessions (>1, <17) than participants with clinical diagnosis of prediabetes. μ Self-test > μ Clinical

The evaluation of attendance measures (Table 3) revealed that all participants achieved median attendance of 13 sessions; however, the calculation for Group 1 (clinical test) showed a higher average rank mean (416) than Group 2 (self-test) rank mean of 380. This indicates increased attendance values for those with a clinical diagnosis as a whole. The results were significant ($p < .0251$) but did not support the directional hypothesis. Participants who had a clinical diagnosis of prediabetes achieved increased outcomes of attendance in the DPP.

Hypothesis 2: Participants with DPP eligibility using self-assessment to determine diabetes risk have greater median weekly physical activity minutes (>6, <17) than those with clinical diagnosis of prediabetes. μ Self-test > μ Clinical

Group 1 (clinical diagnosis) achieved higher median self-reported minutes of physical activity ($\tilde{x}$ =110, mean rank 414) compared with Group 2 who completed the self-risk test ($\tilde{x}$ =90, mean rank 382). The results shown in Table 3 were significant ($p < .049$) and did not support the directional hypothesis. Participants who had a clinical diagnosis of prediabetes reported more minutes of weekly physical activity.

Hypothesis 3: Participants with DPP eligibility using self-assessment to determine diabetes risk have greater median percentage of weight loss (>1, <17) than those with clinical diagnosis of prediabetes. μ Self-test > μ Clinical

Table 3 shows no significant differences in the measures for percentage of weight loss between the clinical diagnosis Group 1 ($\tilde{x}$ =.051, mean rank 402), and the self-risk test Group 2 ($\tilde{x}$ =.048, mean rank 393). The results failed to reject the null hypothesis ($p < .610$).

Hypothesis 4: The number of participants with DPP eligibility using self-assessment to determine diabetes risk who achieve goal completion outcomes of attendance ≥16 weeks, median weekly physical activity ≥ 150 minutes, and percentage of weight loss ≥ 5% is greater than participants with a clinical diagnosis of prediabetes who achieve goal completion. μ Self-test > μ Clinical

The measures of goal completion in Table 4 show less than 5% (n = 38, 4.79%) of the study participants (N = 793) completed the DPP goal completion outcomes of 16 weeks of attendance, 150 median minutes of physical activity, and 5% weight loss. The largest proportion (n =24, $\hat{p}$ =.0649) were participants from Group 1 versus participants from Group 2 (n =14, $\hat{p}$ =.0331). This was a significant result ($p < .018$) that rejected the null hypothesis that the sample portions are equal and supports that more participants with a clinical diagnosis of prediabetes achieved all of the goal outcomes of attendance in the DPP.

Table 3

Statistical Results for Measures of Attendance, Physical Activity, and % of Weight Loss

Statistical Measure	Attendance		Physical Activity Minutes		% of Weight Loss	
	Group 1: Clinical Test	Group 2: Self Risk Test	Group 1: Clinical Test	Group 2: Self Risk Test	Group 1: Clinical Test	Group 2: Self Risk Test
Median	13	13	110	90	0.051	0.048
Range	15	15	998	997	0.210	0.238
Mean of Ranks	416	380	414	382	402	393
Sample Mean of Ranks	397		397		397	
p-value	0.025		0.049		0.610	
U-value	71062		71905		76608	
Z -score	-2.23506		-1.97294		-0.51165	
r value	0.99		0.91		0.99	
	Result is significant at $p < .05$. Rejects Null Hypothesis		Result is significant at $p < .05$. Rejects Null Hypothesis		Result is NOT significant at $p < .05$. Accepts Null Hypothesis	

Table 4

Statistical Results for Measures of Goal Outcome Achievement

Statistical Measure	Goal Achievement	
	Group 1: Clinical Test	Group 2: Self Risk Test
Proportion	0.0649	0.0331
CL (95%)	0.0438-0.0859	0.0188 - 0.0474
Z -value	2.0894	
p value	0.018	
	Result is significant at $p < .05$. Rejects Null Hypothesis	

CHAPTER V

DISCUSSION

Diabetes is an irreversible, chronic disease that is estimated to affect 1 in 6 adults in the United States by the year 2060. Diabetes will continue to have a negative impact on health, quality of life, and the economy unless the incidence rate is decreased. There is no known cure for diabetes, so prevention is the preferred medical action at the prediabetes stage. Clinical trials support that behavior modification techniques resulting in weight loss and increased physical activity are effective in preventing or delaying the development of diabetes. The DPP is a valuable program for behavioral change, but many participants struggle to adopt lifestyle modifications necessary to achieve the outcomes of the class. Many of the barriers to behavioral change are factors that could be influenced by increased awareness, motivation, perception of individual ability and likelihood of success, and attitudes of the people who hold positions of influence in a person's life.

As identified in the introduction, despite general awareness of the health threat associated with diabetes, and evidence to support effective intervention at the prediabetes stage, many individuals with prediabetes do not make or sustain modifications to behavior that will lower their risk. In order to minimize incidence and prevalence of type 2 diabetes, it was critical to assess possible factors that influence individual motivation to engage in risk reduction behaviors. This research focused on a moment in time when the threat of developing diabetes became a reality for many people regardless of their mode of prediabetes diagnosis. Since the data available for analysis was gathered from a diabetes prevention program, it could be assumed that the clinical diagnosis or confirmation of risk based on the self-test was a driving force for participation in the program. The research aim of this study was to explore associations in that

relationship. Specifically, whether one method of prediabetes diagnosis is associated with greater outcomes from the program, measured by attendance, physical activity minutes, and weight loss.

The main study findings were that the group of people who had a clinical diagnosis of prediabetes had greater measures of attendance, physical activity, and measures of goal completion than the group of people who completed a self-risk assessment to determine diabetes risk. The study measures for percentage of weight loss indicated that there was no significant difference between the Groups.

The development of the directional hypothesis for this research was based on study of theoretical frameworks that influence behavior change and how they could be applied to individuals based on their mode of diagnosis. As shared at the beginning of that section, several assumptions were used to rationalize the possible behavior of individuals before participation in DPP.

It was presumed that when a person receives a clinical diagnosis of prediabetes that they are unaware of their condition, and they will be greatly influenced by the health professional that delivers the diagnosis. Their initial perceptions may be influenced by the attitude, perceptions, and knowledge of the provider as it relates to diabetes risk. It was also assumed that they were in a state of receiving information rather than actively seeking a diagnosis or confirmation of health threat. Because of the demographic makeup of individuals in the program, it was assumed that they have a relationship with their provider and would likely have contact with them at some point during the program.

Because enrollment in the DPP program requires either a clinical diagnosis of prediabetes or a self-assessment test that confirms risk of diabetes, it was assumed that intent to participate in the program was the primary reason for self-assessment of risk. The risk test has been promoted

extensively in the Yakima Valley in conjunction with messaging about diabetes risk and Virginia Mason Memorial community health events. Attendees at the DPP informational/orientation meeting are given an opportunity to take the assessment if they want to enrollment in the class. If an individual completes a risk test as a prerequisite to participation in DPP, it could be presumed that they were aware of the prevention program and have a perception of the value of participation in the program. It could also be assumed that they are in a state of seeking information. If they completed the test after attending orientation, it could be assumed that it was their decision to attend the orientation, perhaps with the intention to enroll, prior to receiving information about the program. It can be expected that the individual used critical thinking and honest assessment when they completed the risk test and in a state of prediabetes.

Research indicates that early success with outcomes of weight loss and physical activity are a predictor for retention in the DPP and increased outcomes are associated with how long the individual is in the program. (Cannon et al., 2020; Ely et al., 2017; Jeffers et al., 2019). The assumed scenarios could indicate that the individual who completes a self-assessment for risk test is at a more advanced stage of readiness for change than the person who receives a clinical diagnosis. If they attended the orientation session, their perception of gain from behavior change will likely be influenced by the testimonial of prior participants and the information shared. They may be more readily influenced by positive communication about the program within their social circle. This person could benefit from the SCT-based DPP curriculum as facilitators affirm the advantage of the program (prevention of diabetes), the opportunity for tangible results (weight loss), and emphasize compatibility regarding how the program is designed to help individuals modify behaviors based on their lifestyle. Therefore, the premise of the directional hypothesis was that participants who complete self-assessment test would be more likely to implement the

behavioral modifications at the beginning of the program, which would influence the likelihood of early success as well as retention, which would lead to increased outcomes from the program.

This choice of hypothesis direction was based on a variety of assumptions about both of the methods of diagnosis. Many of the presumed scenarios for those who receive a clinical diagnosis were also considered influential for positive behavior change in DPP.

For example, providers who routinely refer to the diabetes prevention program have access to health education materials and resources developed specifically for promotion of DPP. These resources can be beneficial in influencing the perception of favorable attitudes and expectations related to behavioral change and move patients towards intent to engage in health prevention behavior as described in the literature review on Theory of Planned Behavior. The patient/provider relationship may have the most influence within the framework of the Health Belief Model. Patients may experience increased perception of susceptibility and severity of disease due to the tangible element of a clinical test and knowledge from a medical professional.

Ethical Considerations and Limitations

Ethical considerations for this study are minimal due to the observational nature of the data. A letter of cooperation for data sharing was obtained from VMM, and exempt status was granted from Human Subjects Research Council at Central Washington University.

Threats to validity may include data collection errors and facilitator bias. Data collection errors related to weight loss may occur during the collection and preliminary documentation of the measures taken at each session. Participants are requested to wear similar clothing each week and remove their shoes for weighing, but the recommendation is not enforced. The facilitator may misread the weight, or incorrectly document the data in the tracking sheet at the time, or when entered into the VMM program, or the data may be misread if entered by another

facilitator or the program coordinator. Weekly PA minutes are self-reported by participants without evidence of intensity or duration and the same documentation errors may occur as with the WL measures. There may be inconsistent methods for rounding fractional weight measurements and weekly PA minutes up or down, and there may be unconscious bias to reward or confirm expectations of the participants with higher weight loss results, or increased PA.

Participants may not attend every class, resulting in missing data for some weeks. These threats were addressed by using Scatterplot and Standard deviation tests to determine outliers. Data was cross-referenced and verified by the diabetes program coordinator at Virginia Mason Memorial. A protocol was developed for estimating data that was missing from participant records and the occurrence was included in the study results.

These threats to validity may be mitigated through increased oversight during the weight data collection such as two-person validation at the time of collection. Other process improvement steps could include immediate data entry into the VMM data program, or digital scales networked to a data system to automatically record weight into a participant file. Participant PA minutes could be measured using approved activity tracking devices and documentation uploaded to a data system or printed out for manual data entry.

The study sample is not appropriate for generalization because it does not fully represent the racial and ethnic profile of the community (see Table 2). In addition, the study participants may be more likely to have a primary care provider, or medical home, because the program is coordinated by a large health care organization affiliated with multiple family practice clinics in Yakima Valley. The majority of physicians who refer patients to DPP are associated with this healthcare system and have increased awareness of the program due to direct outreach and access to referral mechanisms.

The assumptions used in the theoretical analysis are limited to the sample and scope of this study and do not reflect the needs of historically underrepresented populations or those negatively affected by social determinates of health.

Implications for Further Research

The implications drawn from this study may provide valuable insight into the ways that health behavior theory can be used to understand an individual's possible reaction to a diagnosis of disease. Further research is necessary to explore the assumptions that were considered to understand ways that method of diagnosis may influence outcomes attained through DPP. The assumptions may be valid; however, due to the historical nature of the data used in this study they cannot be tested with reliability. Recommendations for further research involve robust multi-point data collection to better understand and define the mechanisms that influence individuals at the point of diagnosis by clinical testing, including identification of factors may that prevent or deter those persons from participation.

There is opportunity for increased understanding of the factors that motivate people to complete the self-risk test. Supplemental questions could identify if the assumption used in this study—desire to attend DPP—is the most salient factor, or whether there are barriers to clinical access and referral to the program. If participants identify that weight loss was the motivation, (rather than diabetes prevention) it may indicate a need for effective WL programming in the community.

Further research could also expand the statistical analysis of the data to measure correlations between the participant variables, their mode of diagnosis, and the outcomes of the program. Additional analysis could also reveal if there are patterns of retention based on goal attainment as well as patterns of attrition that may correlate to specific lessons or activities.

Conclusion

The National Diabetes Prevention Program is an effective way to decrease risk and incidence of diabetes. Although the results of this study reflect the impact of secondary prevention, they could be used to move intervention upstream to increase primary screening procedures and referral with medical professionals. Practical application of the relative association between clinical blood test and goal outcomes will inform health educators and providers regarding potential for increased benefit from participation in DPP. Programmers may see value in expansion of screening and streamlined referral methods to ensure access to clinical diagnosis. Providers may explore methods of clinical referral outside of the primary care setting such as dental or ophthalmology prescreening.

The association could also guide communication and marketing efforts to promote DPP through patient interaction and support creation of educational materials for clinic use. Additional resources may be put into position to aid in the transition from diagnosis to DPP attendance. The results may influence physician attitudes regarding patient self-assessment and provide new opportunity to analyze positive outcomes of LSM programming on population health, regardless of prediabetes or diabetes risk status. In addition, the association may influence coverage options for insurance and workplace health and wellness programs, as well as support and funding for DPP on the County, State, and Federal policy levels.

Many health care organizations are severely impacted by medical care and associated costs directed towards tertiary treatment of diabetes incidence. This has the potential to limit their ability to offer prevention programming that will decrease risk of developing diabetes. Therefore, strategies to increase effectiveness in diabetes prevention programming are of critical importance and should continue to be the subject of public health research.

REFERENCES

AAT Bioquest, Inc. (2021). *Quest Graph™ Kolmogorov-Smirnov (K-S) test calculator*. https://www.aatbio.com/tools/kolmogorov-smirnov-k-s-test-calculator

Ajzen, I. (1988). *Attitudes, personality, and behavior*. Dorsey Press.

Ajzen, I., & Fishbein, M. (1980). *Understanding attitudes and predicting social behavior*. Prentice-Hall.

Ali, M. K., McKeever Bullard, K., Imperatore, G., Benoit, S. R., Rolka, D. B., Albright, A. L., & Gregg, E. W. (2019). Reach and use of diabetes prevention services in the United States, 2016-2017. *Journal of the American Medical Association Network Open, 2*(5), e193160–e193160. https://doi.org/10.1001/jamanetworkopen.2019.3160

Alva, M. (2019). How much does attendance impact weight loss and health care spending in a diabetes prevention program serving older adults? *American Journal of Health Promotion, 33*(7), 1067-1072. https://doi.org/10.1177/0890117119848985

American Diabetes Association. (2018). Economic costs of diabetes in the U.S. in 2017. *Diabetes Care, 41*(5), 917-928. https://doi.org/10.2337/dci18-0007

American Diabetes Association. (2020a). *Diabetes risk.* https://www.diabetes.org/diabetes-risk/prediabetes

Andes, L. J., Cheng, Y. J., Rolka, D. B., Gregg, E.W., & Imperatore, G. (2019). Prevalence of prediabetes among adolescents and young adults in the United States, 2005-2016. *Journal of the American Medical Association, Pediatrics, 174*(2), e194498. https://doi.org/10.1001/jamapediatrics.2019.4498

Baker, M., Simpson, K., Lloyd, B., Bauman, A., & Singh, M. (2011). Behavioral strategies in diabetes prevention programs: A systematic review of randomized controlled trials. *Diabetes Research and Clinical Practice, 91*(1), 1-12. https://doi:10.1016/j.diabres.2010.06.030

Bandura, A. (1986). *Social foundations of thought and action: A Social Cognitive Theory*. Englewood Cliffs, NJ: Prentice-Hall.

Bandura, A. (2004). Health promotion by social cognitive means. *Health Education & Behavior, 3*(1), 143-164. https://doi: 10.1177/1090198104263660

Bansal, N. (2015). Prediabetes diagnosis and treatment: A review. *World journal of diabetes, 6*(2), 296–303. https://doi.org/10.4239/wjd.v6.i2.296

Bardenheier, B. H., Lin, J., Zhuo, X., Ali, M. K., Thompson, T. J., Cheng, Y. J., & Gregg, E. W. (2016). Disability-free life-years lost among adults aged ≥50 years with and without diabetes. *Diabetes Care, 39*(7), 1222–1229. https://doi.org/10.2337/dc15-1095

Barry, E., Greenhalgh, T., & Fahy, N.s. (2018). How are health-related behaviours influenced by a diagnosis of pre-diabetes? A meta-narrative review. *Biomed Central (BMC) Medicine, 16*(1), 121-17. https://doi.org/10.1186/s12916-018-1107-6

Bartholomew Eldredge, L., Markham, C.M., Ruiter, R.A., Fernández, M.E., Kok, G., & Parcel, G.S. (2020). *Planning health promotion programs: An intervention mapping approach* (4th ed.). Jossey-Bass.

Cannon, M. J., Masalovich, S., Ng, B. P., Soler, R. E., Jabrah, R., Ely, E. K., & Smith, B. D. (2020). Retention among participants in the National Diabetes Prevention Program Lifestyle Change Program, 2012–2017. *Diabetes Care, 43*(9), 2042–2049. https://doi.org/10.2337/dc19-2366

Centers for Disease Control and Prevention. (2018a). *National Diabetes Prevention Program/ Learning about the national DPP/ FAQ: Offering a program*. https://nationaldppcsc.cdc.gov/s/article/FAQ-Offering-a-Program-1525311979893

Centers for Disease Control and Prevention. (2018b). *Diabetes Prevention Recognition Program: Standards and operating procedures*. [Report]. http://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.

Centers for Disease Control and Prevention. (2018c). *National Diabetes Prevention Program/Curricula and Handouts*. https://www.cdc.gov/diabetes/prevention/resources/curriculum.html

Centers for Disease Control and Prevention. (2019, June 7). *Requirements for CDC recognition*. https://www.cdc.gov/diabetes/prevention/requirements-recognition.htm

Centers for Disease Control and Prevention. (2020a). *Diabetes report card 2019*, [Report]. https://www.cdc.gov/diabetes/pdfs/library/Diabetes-Report-Card-2019-508.pdf

Centers for Disease Control and Prevention. (2020b). *National diabetes statistics report 2020*, [Report]. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

Centers for Disease Control and Prevention. (2020c). *Diabetes/basics.* https://www.cdc.gov/diabetes/basics/diabetes.html

Centers for Disease Control and Prevention. (2020d). *Diabetes*. https://www.cdc.gov/diabetes/risktest/index.html

Centers for Disease Control and Prevention. (2020e). *National Diabetes Prevention Program: Lifestyle change program.* https://www.cdc.gov/diabetes/prevention/lcp-details.html

Centers for Disease Control and Prevention. (2020f). *Registry of all recognized organizations*. https://nccd.cdc.gov/DDT_DPRP/Registry.aspx

The diaTribe Foundation. (n.d.). Prediabetes. https://diatribe.org/prediabetes

DiClemente, R. J., Salazar, L. F., & Crosby, R. A. (2013). *Health Behavior Theory for Public Health: Principles, Foundations, and Applications*. Jones and Bartlett Learning.

Dolan, C., Glynn, R., Griffin, S., Conroy, C., Loftus, C., Wiehe, P. C., Healy, M. L., & Lawlor, B. (2018). Brain complications of diabetes mellitus: a cross-sectional study of awareness among individuals with diabetes and the general population in Ireland. *Diabetic Medicine, 35*(7), 871–879. https://doi.org/10.1111/dme.13639

Ely, E., Gruss, S., Luman, E., Gregg, E., Ali, M., Nhim, K., Rolka, D.B., & Albright, A. (2017). A national effort to prevent type 2 diabetes: Participant-level evaluation of CDC's National Diabetes Prevention Program. *Diabetes Care, 40*(10), 1331-1341. https://doi.org/10.2337/dc16-2099

Emory University. (2020). *Diabetes training and technical assistance center*. http://www.tacenters.emory.edu/focus_areas/diabetes/index.html

Healthy People 2030. (2020). *Home*. Office of Disease Prevention and Health Promotion. https://health.gov/healthypeople

Institute for Clinical and Economic Review. (2016). *Diabetes Prevention Programs: Final Evidence Report and Meeting Summary*. [Report]. https://icer-review.org/material/final-report-dpp/

Giovannucci, E., Harlan, D. M., Archer, M. C., Bergenstal, R. M., Gapstur, S. M., Habel, L. A., Pollak, M., Regensteiner, J. G., & Yee, D. (2010). Diabetes and cancer: A consensus report. *Diabetes Care, 33*(7), 1674–1685. https://doi.org/10.2337/dc10-0666

Glanz, K., & Bishop, D. B. (2010). The role of behavioral science theory in development and implementation of public health interventions. *Annual Review of Public Health, 31*(1), 399–418. https://doi.org/10.1146/annurev.publhealth.012809.103604

Jeffers, K. S., Castellon-Lopez, Y., Grotts, J., Mangione, C. M., Moin, T., Tseng, C., Turk, N., Frosch, D. L., Norris, K. C., Duke, C. C., Moreno, G., & Duru, O. K. (2019). Diabetes Prevention Program attendance is associated with improved patient activation: Results from the Prediabetes Informed Decisions and Education (PRIDE) study. *Preventive Medicine Reports, 16*, 100961–100961. https://doi.org/10.1016/j.pmedr.2019.100961

Knowler, W. C., Barrett-Connor, E., Fowler, S. E., Hamman, R. F., Lachin, J. M., Walker, E. A, & Nathan, D.M. (2002). Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *The New England Journal of Medicine, 346*(6), 393–403. https://doi.org/10.1056/NEJMoa012512

Lin, J., Thompson, T., Cheng, Y., Zhuo, X., Zhang, P., Gregg, E., & Rolka, D. (2018). Projection of the future diabetes burden in the United States through 2060. *Population Health Metrics, 16*(1), 9. https://doi.org/10.1186/s12963-018-0166-4

Mainous, A. G., Tanner, R. J., Scuderi, C. B., Porter, M., & Carek, P. J. (2016). Prediabetes screening and treatment in diabetes prevention: The impact of physician attitudes. *Journal of the American Board of Family Medicine, 29*(6), 663–671. https://doi.org/10.3122/jabfm.2016.06.160138

Mann, H. B.., & Whitney, D. R. (1947). On a test of whether one of two random variables is stochastically larger than the other. *Annals of Mathematical Statistics, 18*(1), 50–60. https://doi:10.1214/aoms/1177730491

McManus, A. (2013). Health promotion innovation in primary health care. *Australasian Medical Journal, 6*(1), 15–18. https://doi.org/10.4066/AMJ.2013.1578

National Association of Chronic Disease Directors. (n.d.). *Diabetes Prevention Program/The National Diabetes Prevention Program*. https://www.chronicdisease.org/mpage/domain4_ndpp

National Institute of Diabetes and Digestive and Kidney Diseases. (2002). *Diabetes Prevention Program Outcomes Study* (*DPPOS*). Identifier: NCT00038727. https://clinicaltrials.gov/ct2/show/NCT00038727

Nhim, K., Gruss, S. M., Porterfield, D. S., Jacobs, S., Elkins, W., Luman, E. T., Van Aacken, S., Schumacher, P., & Albright, A. (2019). Using a RE-AIM framework to identify promising practices in National Diabetes Prevention Program implementation. *Implementation Science, 14*(1), 81–81. https://doi.org/10.1186/s13012-019-0928-9

Nhim, K., Khan, T., Gruss, S. M., Wozniak, G., Kirley, K., Schumacher, P., Luman, E. T., & Albright, A. (2018). Primary care providers' prediabetes screening, testing, and referral behaviors. *American Journal of Preventive Medicine*, *55*(2), e39–e47. https://doi.org/10.1016/j.amepre.2018.04.017

Paige, S. R., Bonnar, K. K., Black, D. R., & Coster, D. C. (2018). Risk factor knowledge, perceived threat, and protective health behaviors: Implications for type 2 diabetes control in rural communities. *The Diabetes Educator*, *44*(1), 63-71. https://doi.org/10.1177/0145721717747228

Prochaska, J. O., & DiClemente, C. C. (1983). Stages and processes of self-change of smoking: Toward an integrative model of change. *Journal of Consulting and Clinical Psychology, 51*(3), 390–395. https://doi.org/10.1037/0022-006X.51.3.390

Rimer, B. K., Glanz, K., & National Cancer Institute (U.S.). (2005*). Theory at a glance: A guide for health promotion practice*. Bethesda, MD: U.S. Dept. of Health and Human Services, National Institutes of Health, National Cancer Institute.

Rogers, E.M. (1983). *Diffusion of innovations*. New York, NY: Free Press.

Rosenstock, I. M. (1974). The Health Belief Model and preventive health behavior. *Health Education Monographs, 2*(4), 354–386. https://doi.org/10.1177/109019817400200405

Rosenstock, I. M., Strecher, V. J., & Becker, M. H. (1988). Social Learning Theory and the Health Belief Model. *Health Education Quarterly*, *15*(2), 175–183. https://doi.org/10.1177/109019818801500203

Sapra, A., & Bhandari, P. (2020). *Diabetes Mellitus*. In StatPearls. StatPearls Publishing.

Smirnov, N. (1948). Table for estimating the goodness of fit of empirical distributions. *The Annals of Mathematical Statistics, 19*(2), 279-281. https://doi.org/10.1214/aoms/1177730256

Social Science Statistics. (n.d.). *The Kolmogorov-Smirnov Test of Normality.* https://www.socscistatistics.com/tests/kolmogorov/default.aspx

Social Science Statistics. (n.d.). *Mann-Whitney U Test Calculator.* https://www.socscistatistics.com/tests/mannwhitney/default.aspx

Tabák, A.G., Herder, C., Rathmann, W., Brunner, E. J., & Kivimäki, M. (2012). Prediabetes: A high-risk state for developing diabetes. *The Lancet (British Edition), 379*(9833), 2279–2290. https://doi.org/10.1016/S0140-6736(12)60283-9

Tseng, E., Greer, R.C., O'Rourke, P., Yeh, H., McGuire, M. M., Clark, J. M., & Maruthur, N. M. (2017). Survey of primary care providers' knowledge of screening for, diagnosing and managing prediabetes. *Journal of General Internal Medicine 32*, 1172–1178. https://doi.org/10.1007/s11606-017-4103-1

Tuso, P. (2014). Prediabetes and lifestyle modification: Time to prevent a preventable disease. *The Permanente journal, 18(*3), 88–93. https://doi.org/10.7812/TPP/14-002

University of Pittsburg. (2021). *DPP Group Lifestyle Balance curriculum.* https://www.diabetesprevention.pitt.edu/for-the-public/for-health-providers/group-lifestyle-balance-curriculum/

Venkataramani, M., Pollack, C. E., Yeah, H. C., & Maruthur, N. M. (2018). Prevalence and correlates of diabetes prevention program referral and participation. *American Journal of Preventative Medicine, 56*(3):335-342. https://doi: 10.1016/j.amepre.2018.10.005

Virginia Mason Memorial. (2020). *Diabetes prevention*. https://www.yakimamemorial.org/community-education-diabetes-education.asp

Warner, A. S. (2009). Diabetes risk perception and intention to adopt healthy lifestyles among primary care patients, [BRIEF REPORT: Clinical Care/Education/Nutrition/Psychosocial Research]. *Diabetes Care, 32*(10), 1820. https://doi.org/10.2337/dc09-0720

Youngs, W., Gillibrand, W. P., & Phillips, S. (2016). The impact of pre-diabetes diagnosis on behaviour change: An integrative literature review. *Practical Diabetes, 33*(5), 171–175. https://doi.org/10.1002/pdi.2030

APPENDIXES

Appendix A - Tables

Table 1

Demographic Profile of Study Participants

Variables	Group 1 Clinical Test (n = 370)		Group 2 Self-Test (n = 423)		Full Study Sample (N = 793)	
	n	%	*n*	%	*n*	%
Gender						
Male	137	37	64	15	201	25
Female	233	63	359	85	592	75
Age						
Mean	59		62		60	
Median	61		64		63	
Range	18-84		27-94		18-94	
Racial/Ethnic						
White	305	82.4	358	84.6	663	83.6
Hispanic or Latino	60	16.2	57	13.5	117	14.8
American Indian or Alaska Native	5	1.4	7	1.7	12	1.5
Other racial/ethnic identity	2	0.05	1	0.02	1	0.4

Note. Other racial/ethnic identity includes: Asian, Black, or African American, and Native Hawaiian or Other Pacific Islander.

Table 2

Study Measures and Statistical Analysis

Dependent Variable	Data Measure	Statistical analysis	
		Normalcy test of data	Non-parametric (Median data)
Hypothesis 1: Attendance	Continuous interval data (<1,<17)	Visual analysis: Box and Whiskers graph Statistical analysis: Skewness and Kurtosis measures *Kolmogorov-Smirnov* (KS) calculator	*Wilcoxon Mann-Whitney U Test* = 0.5 alpha level
Hypothesis 2: Physical Activity Minutes	Continuous interval data (<6,<17)		
Hypothesis 3: Percent of weight loss	Continuous interval data (<1,<17)		
Hypothesis 4: Goal outcome attainment	Discrete binary variable: 0= Attendance <16, PA <150, and WL% <5.%. 1= Attendance ≥16, PA ≥150, and WL% ≥5.%.	n/a	*z* test for proportions

Note. The DV for participant self-reported PA minutes was proposed for research as a categorical score based on continuous interval data of weekly PA minutes reduce the range of normalcy. The method of analysis was changed to measure PA minute as continuous interval median data when analysis revealed non-parametric data and similar statistical results. In addition, this measure aligns more closely with the DPP program goal outcome of 150 mean PA minutes per week.

Table 3

Statistical Results for Measures of Attendance, Physical Activity, and % of Weight Loss

Statistical Measure	Attendance		Physical Activity Minutes		% of Weight Loss	
	Group 1: Clinical Test	Group 2: Self Risk Test	Group 1: Clinical Test	Group 2: Self Risk Test	Group 1: Clinical Test	Group 2: Self Risk Test
Median	13	13	110	90	0.051	0.048
Range	15	15	998	997	0.210	0.238
Mean of Ranks	416	380	414	382	402	393
Sample Mean of Ranks	397		397		397	
p-value	0.025		0.049		0.610	
U-value	71062		71905		76608	
Z -score	-2.23506		-1.97294		-0.51165	
r value	0.99		0.91		0.99	
	Result is significant at $p < .05$. Rejects Null Hypothesis		Result is significant at $p < .05$. Rejects Null Hypothesis		Result is NOT significant at $p < .05$. Accepts Null Hypothesis	

Table 4

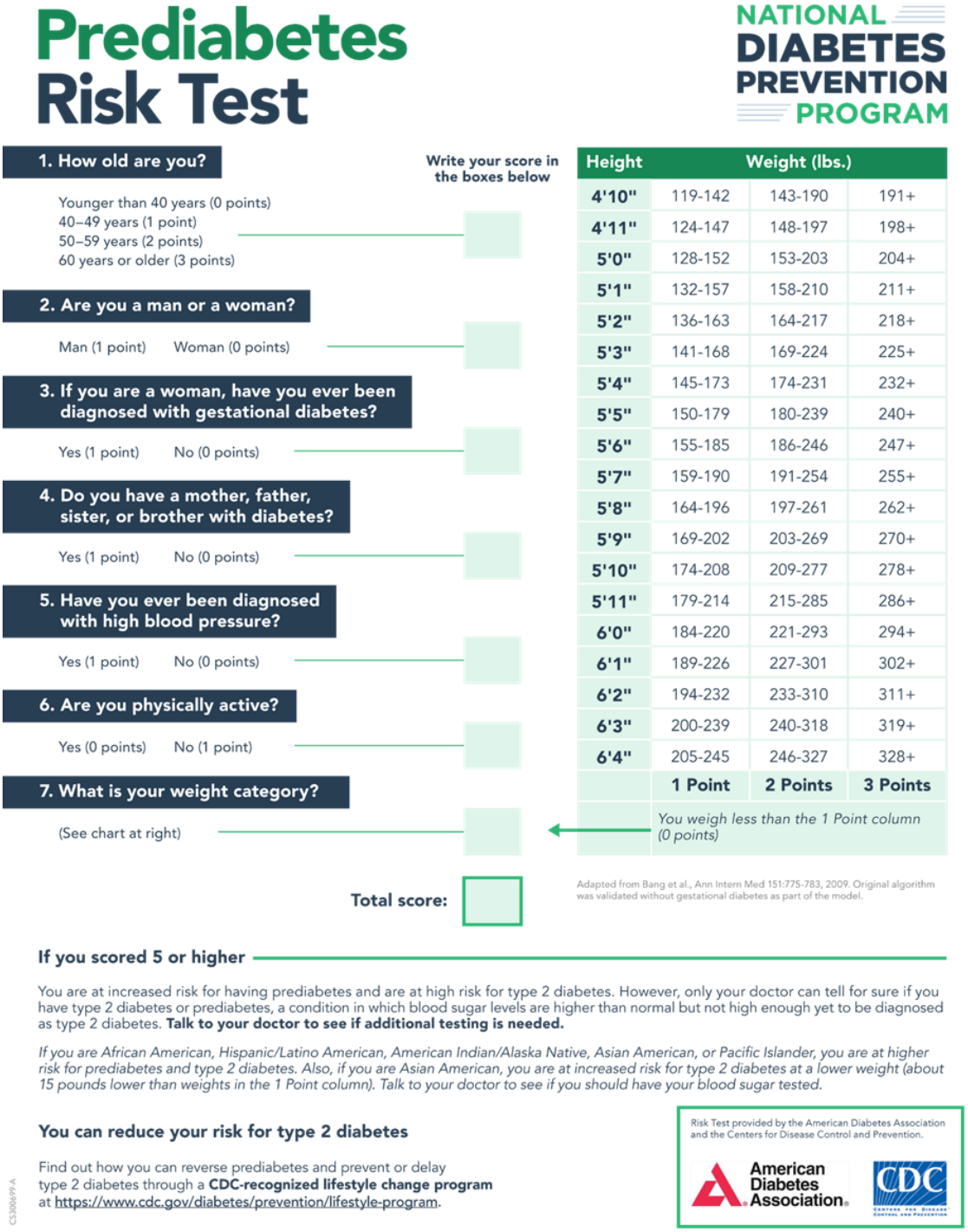
Statistical Results for Measures of Goal Outcome Achievement

Statistical Measure	Goal Achievement	
	Group 1: Clinical Test	Group 2: Self Risk Test
Proportion	0.0649	0.0331
CL (95%)	0.0438-0.0859	0.0188 - 0.0474
Z -value	2.0894	
p value	0.018	
	Result is significant at $p < .05$. Rejects Null Hypothesis	

Appendix B – Figures

Figure 1

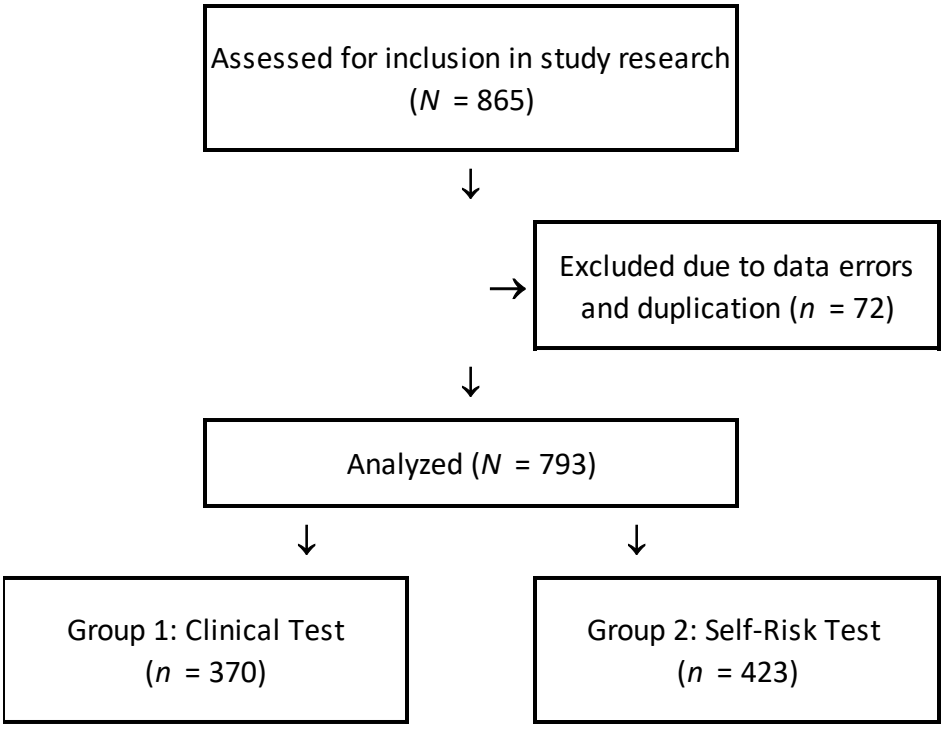
ADA/CDC Prediabetes Risk Test



Note. (https://www.cdc.gov/diabetes/prevention/pdf/Prediabetes-Risk-Test-Final.pdf). In the public domain.

Figure 2

Consort Flow Diagram



Appendix C - List of Acronyms

A1c	Hemoglobin A1c
ADA	American Diabetes Association
BMI	Body mass index
CDC	Centers for Disease Control and Prevention
CI	Confidence interval
DIT	Diffusion of Innovation Theory
DPP	Diabetes prevention program
DPRP	Diabetes Prevention Recognition Program
FPG	Fasting plasma glucose
GDM	Gestational diabetes mellitus
HBM	Health Belief Model
HHS	Health & Human Services
LSM	Lifestyle Management
MDPP	Medicare Diabetes Prevention Program
NDPP	National Diabetes Prevention Program
NHIS	National Health Interview Study
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
$\overline{x}$	Mean
$\tilde{x}$	Median
OGTT	Oral glucose tolerance test
PA	Physical Activity
PCP	Primary Care Physician
SCT	Social Cognitive Theory
TMC	Transtheoretical Model of Change
TPB	Theory of Planned Behavior
TRA	Theory of Reasoned Action
VMM	Virginia Mason Memorial
WL%	Weight Loss Percentage