Introduction of Important Lifestyle Modifications to Prediabetes Patients

At an Urban Family Primary Care Setting

Aljenica Apostol

Rutgers, the State University of New Jersey – School of Nursing

DNP Chair: Dr. Gerti Heider, PhD, MSN, GNP-BC, ANP, APN

DNP Team Member: Dr. Irina Benenson, DNP, FNP-C
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Abstract

**Purpose:** The purpose of this DNP quasi-experimental project is to introduce important lifestyle modifications to prediabetes patients at an urban family primary care setting. With the introduction of a food and exercise log, weight monitoring pre and post-study and 2 remote 15-minute group counseling sessions in a 4-week study period, the end goals include weight loss, increase in physical activity and improved food choices in pre-diabetic patients.

**Methodology:** The Rutgers University Library, Pubmed and reputable organizations such as the CDC and the American Diabetes Association (ADA) websites were utilized and searched using key terms. In light of the Covid-19 pandemic, the methodology of this project was adjusted to adhere to Rutgers University’s social distancing guidelines. To avoid direct study participant contact, the co-principal investigator (PI) facilitated subject recruitment, requesting for consent and group counseling Zoom follow ups remotely at the project site for HIPAA compliance.

**Results:** Out of 20 potential participants, \( n=7 \) consented to participate as subjects in this research study. The results are as follows: 3 subjects dropped out mid-study, 2 subjects reported weight loss, 2 subjects reported weight gain, 4 subjects reported eating smaller portions and chose healthier options in their diet and 4 subjects reported at least 30 minutes of physical activity once a week. Unfortunately, 0 subjects completed the food and activity log and 0 subjects attended both group counseling sessions.

**Conclusion:** Utilizing evidence-based screening tools can be effective in recognizing patients who may be at risk for prediabetes. In that manner, referral for Hgb A1c testing, introduction of lifestyle modifications and continuing evaluation and education can help mitigate the progression of prediabetes to diabetes.

**Keywords:** Prediabetes, diabetes, nutrition, physical activity, weight loss, Hgb A1c
Introduction

About one in three Americans have prediabetes totaling to about 88 million adults nationwide (Centers for Disease Control and Prevention [CDC], 2020). It is a serious health condition that happens when the body is not responding normally to insulin. If the pancreas cannot work exceptionally hard as usual to produce more insulin, blood sugar increases and prediabetes becomes a precursor to diabetes (CDC, 2020). Not only does prediabetes increases one’s risk of developing type 2 diabetes mellitus (T2DM) but heart disease and stroke are associated consequences of it if left untreated (CDC, 2020).

Prediabetes sets the stage for diabetes. “Among those with prediabetes, the risk of developing type 2 diabetes (T2DM) may be 5% to 10% annually and 70% over a lifetime” (Holliday, Williams, Salcedo & Kandula, 2019, p.2). Diabetes is the 7th leading cause of death in the United States in 2017 according to the American Diabetes Association [ADA] (2018). Presently, there are about 30 million Americans diagnosed with this disease (ADA, 2018). 25% of the Medicare population suffer from it. It is a chronic disease and is associated with an increased risk of heart disease, stroke and other complications such as neuropathy, blindness or kidney failure (CDC, 2019). Diabetes is also a disease that consume higher healthcare utilization and spending (Nhim, Khan, Gruss, Wozniak, Kirley, Shumacher, Luman & Albright, 2018).

Because of the impact of diabetes, major government and healthcare institutions have created programs that are accessible to everyone. Awareness campaigns, public service announcements and other information outlets have been provided for public consumption to enhance cognizance and understanding of the chronic complications associated with diabetes.

The purpose and aim of this Doctor of Nursing Practice (DNP) quasi-experimental project was to introduce important lifestyle modifications to prediabetes patients at an urban
family primary care setting. With the introduction of a food and exercise log, weight monitoring pre and post-study and 2 remote 15-minute group counseling sessions in a 4-week study period, the end goals include weight loss, increase in physical activity and improved food choices in pre-diabetic patients.

**Background and Significance**

In the United States, 88 million Americans have prediabetes and 90% of those affected are not even aware that they are at risk of developing diabetes (CDC, 2019). Prediabetes is “a serious health condition in which blood sugar levels are higher than normal, but not high enough yet to be diagnosed as type 2 diabetes” (CDC, 2019). The diagnostic criteria for prediabetes according to the ADA include an elevated fasting plasma glucose level (100 mg/dL to 125 mg/dL), an elevated glucose level (140 mg/dL to 199 mg/dL) after an oral glucose tolerance test and a glycated hemoglobin (Hgb A1c) value of 5.7% to 6.5% (Tuso, 2014). Studies has shown that elevated Hgb A1c appears to correlate with T2DM and individuals with a Hgb A1c level of 5.5% to 6.0% or higher are at a significant risk. The National Health and Nutrition Examination Survey found that about 35% of adults in the United States age 20 years and older have prediabetes. About 50% of older adults 65 years and older have prediabetes. 5 to 10% of those with prediabetes will eventually progress to T2DM.

Murphy and Winmill (2013) states that prediabetes is a precursor to T2DM. It is a reversible condition but if left undiagnosed or untreated, and if the current trends continue, 1 in 3 adults will have T2DM by 2050 (Tuso, 2014). People who are at risk usually present with hallmark indicators such as obesity, age, an immediate family member with type 2 diabetes, reduced amount of physical activity, a history of gestational diabetes or are of the African
American, American Indian, Asian American or Hispanic heritage. Another risk factor is smoking (CDC, 2019).

Prevention of disease progression in prediabetic patients is especially important because of the chronic complications associated with diabetes and the social and economic impact of the disease (NJDOH, 2006). Prediabetes is not only a risk factor for heart disease and stroke but other complications such as hypertension, coronary vascular disease (CVD), kidney disease, diabetic ketoacidosis, neuropathy, foot complications such as amputation and foot ulcers and eye disorders such as glaucoma, cataracts and retinopathy are among the few of many issues that can define a diabetic’s health status (ADA, n.d.). Tuso found that long-term damage of end-organs have begun in prediabetes (2014).

T2DM patients also have a significantly higher morbidity and mortality rates (ADA, n.d.). These complications lead to disability which affects quality of life. In addition, the world changed when the Covid-19 pandemic struck worldwide. Research has shown that adults with certain underlying medical conditions, one of them being T2DM, or have prediabetes risk factors such as obesity and smoking, are at an increased risk for developing serious complications from contracting the virus (CDC, 2020).

The financial costs of diabetes can create a lasting impact on the quality of care that healthcare organizations provide. The “largest components of direct medical costs were hospital inpatient care and prescription medications” (Tuso, 2014, p.88). In 2017 alone, the CDC (2019) reported that a diabetes diagnosis cost $327 billion dollars; $237 billion of that is related to direct medical costs while roughly $90 billion is from decreased individual productivity. About “1 in every 3 Medicare dollars spent goes toward caring for people with diabetes and 1 in 5 healthcare dollars overall” (NJDOH, 2017, p.10). Individually, a patient diagnosed with diabetes can incur...
an average of $16,752 in medical expenditures per year. That amount is about “2.3 times higher than what expenditures would be in the absence of diabetes” (ADA, 2018).

According to the New Jersey Department of Health’s Action Plan, only 8.1% of the adults aged 20 years and older have been diagnosed with prediabetes in 2014. It has actually increased from 6.3% in 2012 (NJDOH, 2014). The lack of perception that prediabetes is a serious matter may be alarming. In New Jersey, diabetes was the 7th leading cause of death in 2017 with almost 2,000 deaths attributed to complications from this disease. In 2015, approximately 15,000 residents were admitted to the hospital for diabetes and its complications in New Jersey (NJDOH, 2017). Diabetes was the main reason for renal failure in 42.7% of end-stage renal disease patients in 2014, while over 3,000 limb amputations were attributed to diabetes complications in 2015 (NJDOH, 2017). Furthermore, about 145,000 diabetic adult patients were diagnosed with retinopathy or had eye issues due to disease progression (NJDOH, 2015). New Jersey’s Family Care, which is the state’s publicly funded health insurance including Medicaid and Medicare recipients, reported that the cost of caring for patients suffering from diabetes was $206 million dollars (NJDOH, 2017).

The chosen project site was located in Essex County. For a county with a population of 798,975 (United States Census Bureau, 2019), the prevalence of diabetes in adults 18 years and older is 10.4%. It is considered high on the list of counties with a prevalence of diabetic adults in New Jersey (NJDOH, 2017). Studies have shown that screening of prediabetes in patients is critical. Early detection and screening can mean early intervention and treatment.

**Needs Assessment**

**SWOT Analysis**
The need for this project implementation arose from a specific gap at the project site. The nurse practitioner (NP) generally sees about 15 to 20 patients per day in a primary family care setting. Currently, the project site has no resource to assess the patient’s level of activity and nutrition, especially those with a Hgb A1c of 5.6% to 6.5%. The current patient flow includes a verbal acknowledgement of both the NP and the patient regarding the latter’s elevated Hgb A1c result. There is extensive verbal counseling from the NP regarding important lifestyle modifications at the time of the visit once the patient is determined to be prediabetic but there is no follow up in place to determine the patient’s will in modifying their level of physical activity or nutrition patterns. The following were the study’s strengths, weakness, opportunities and threats:

**Strengths.** One of the strengths identified in this project was utilizing the expertise of the DNP project chair and team member. One of them specializes in social determinants of health, health inequities, cultural competence and immigrant health (Rutgers School of Nursing, n.d.) which made her a tremendous asset in the planning and implementation of this project. The latter has a specialization in hypertension and systematic reviews (Rutgers School of Nursing, n.d.) which gave great significance in relation to diabetes management in the specified population. Both are distinguished faculty.

Another strength identified in this research study is the cooperation of the project site and the provider. The provider is a Doctor of Nursing (DNP)-trained advanced practice nurse who has tremendous experience not only in patient care but also in conducting a research study having completed one herself in fulfillment of her DNP degree. The project site was another strength considering the location and the population that it served. It was in an urban setting in North Jersey with a maximum of 20 patients being seen during the day even in the midst of the
Covid-19 pandemic. Not only that the site currently utilizes Kareo, an electronic medical chart (EMR) provider which helped in subject recruitment as that had to be done remotely in order to comply with Covid-19 guidelines.

**Weaknesses.** Upon reviewing the patient flow, there was no concrete follow-up by the NP when it comes to important lifestyle modifications such as increased physical activity or proper nutrition in patients identified to have prediabetes and are at risk for T2DM.

**Opportunities.** Because there was no current practice in place at the project site to maintain patient accountability in regard to tracking lifestyle modification and changes to decrease their Hgb A1c level and avoid T2DM progression, there was an opportunity to introduce a food and activity log along with group counseling sessions to prediabetes patients. One of the opportunities that this research study has created is an ongoing conversation with both the NP and the patient about important lifestyle modifications to prevent T2DM. It also gave patients accountability for their health and wellness and provide them with awareness of the dangers of prediabetes if not resolved.

**Threats.** Two of the main issues that hindered the implementation of the project were subject participation and compliance in completing the food and activity log. Another big threat to the research study was very limited interaction between co-PI and subjects. Because the research study was restricted to remote communication with subjects, subject compliance in following through the study during the 4-week period affected the data gathered.

**Purpose Statement**

The purpose of this DNP quasi-experimental project was to introduce important lifestyle modifications to prediabetes patients at an urban family primary care setting. With the introduction of a food and exercise log, weight monitoring pre and post-study and 2 remote 15-
minute group counseling sessions in a 4-week study period, the end goals included weight loss, increase in physical activity and improved food choices in pre-diabetic patients.

**PICOT Question**

PICOT: Will implementation of a supportive group intervention (that include monitoring and counseling) (I) promote weight loss and increase in exercise (O) in patients with pre-diabetes (P) in an urban family primary care setting?

**Aim**

This project aimed to create awareness in pre-diabetic patients regarding the risk of progression to T2DM and to introduce important lifestyle modifications to prediabetes patients (weight loss and increase in exercise).

**SMART Objectives**

**Specific.** A needs assessment indicated the necessity to introduce a food and activity log along with supportive group intervention for patients found to have a Hgb A1c result between 5.6% to 6.5% within the last year. The objective was to determine if compliance with food and activity logging can impact the subject’s determination to increase the amount of physical activity weekly and if the individual has attained healthy diet changes with the support of a group counseling session.

**Measurable.** The outcome measures included the total number of subjects who were eligible to be in the research study. The other outcome measures also included the number of subjects who consented to the study, how many participated during the first and second group counseling sessions, the average increase of physical activity weekly, the number of subjects who submitted their completed food and activity log and the average weight loss.
Achievable. The objective was achievable because there was a definite need of a concrete follow up in patients identified to be at risk for T2DM. There was no system in place at the project site to determine if patients adhere to important lifestyle modifications in order to decrease their Hgb A1c level. Because the project site utilizes Kareo, an electronic medical record service, the recruitment and consenting of subjects was feasible in the setting of Covid-19 social distancing protocols.

Realistic. The food and activity log was very straightforward to use. A copy of the log was sent to the subject via email. The subject was required to track his or her food intake for breakfast, lunch and dinner. The subject was asked to log any amount of activity in minutes for the day. All subjects had access to a phone, internet and a computer in order to access the food and activity log as well as participate in the scheduled group counseling sessions. Furthermore, the subjects who consented to the research study had access to a weighing scale at home that they used to weigh themselves pre- and post-study.

Timely. The project commenced on April 23, 2021 and concluded on May 21, 2021. The plan was to present the completion of this project implementation to esteemed colleagues at Rutgers University by summer 2021 in order to complete the requirements of graduation in the DNP program.

Review of Literature

In order to conduct and simplify the literature review, five main points were given significance: 1) importance of prediabetes screening in a high-risk minority population; 2) PCP perspective regarding prediabetes screening; 3) efficacy of evidence-based tools in screening for prediabetes; 4) importance of Hgb A1c testing; and 5) importance and efficacy of lifestyle modifications, education and counseling in managing prediabetes and T2DM. Two main
university libraries were utilized in researching for appropriate literature, namely the Rutgers University and the Weill Cornell Medicine Library. Government and health department websites such as the CDC and the ADA, nursing journals and research articles were also reviewed.

PubMed and CINAHL were two of the main databases that were searched. PubMed yielded 59 potential sources while CINAHL yielded 21 sources after using the keywords prediabetes, screening, lifestyle modification and education in multiple combinations. To further refine the search, filters were applied to include full text, scholarly/peer reviewed, in the English language with the United States as the geographical subset and limited by age 18 to 64 years.

**Importance of Prediabetes Screening in a High-Risk Minority Population**

CDC states that minority groups are highly affected by prediabetes and diabetes more so than other groups. Different factors such as geography, health status, access to healthcare and other socioeconomic issues can be the reason for such health disparity (2019). This has caused a significant problem in screening for prediabetes promptly. Unfortunately, authors Galaviz, Narayan, Lobelo and Weber (2015) found that the highest prevalence of diabetes were seen in American Indians and Alaska Natives (16%). 13% of non-Hispanic blacks are also among the group with a high prevalence of diabetes along with 13% of Hispanics and 9% of Asians.

In a study done by Sheehy et.al, the authors found that minority status is often overlooked as an important risk factor for diabetes screening. Even when extensive research and data have been presented that minorities are more likely to be at risk for prediabetes and T2DM, national statistics show that minority patients still receive inferior care compared to non-minority patients. The authors found that minority patients are not screened for diabetes appropriately in accordance with the ADA guidelines (Sheehy et.al, 2011).
This is an issue that needs to be addressed comprehensively. Prediabetes has been associated with a two-fold increase in cardiovascular disease and all-cause mortality (Galaviz, Narayan, Lobelo & Weber, 2015). And if it has progressed, not only is the cost of a diabetes diagnosis burdensome and has affected about 415 million adults at the present, diabetes is also the leading cause of nontraumatic amputations, end stage renal failure, adult-onset blindness as well as cardiovascular morbidity and mortality (Haw et al., 2017). It has been proven that screening and primary prevention of diabetes can save a lot not only in terms of financial costs but also reduce the physical, social, mental and emotional challenges to the patient, families and the healthcare system as a whole (Haw et al., 2017).

This was agreed upon in study by Sheehy et.al. that “because minority status confers not only increased risk of having T2DM but also risk for having increased complications once diagnosed, it is critical that screening inequalities be identified and eliminated” (2011, p. 1292). Voelker also stated that “without knowledge of risk factors and diagnostic criteria, misdiagnoses occur” (2019, p. 1945). The reviewed literature showed that screening is critical because early detection and diagnosis of prediabetes can delay the progression of diabetes and avoid complications that can decrease the quality of life (U.S. Department of Health and Human Services, n.d.).

**PCP Perspective Regarding Prediabetes Screening**

Upon reviewing the literature, the consensus among providers about screening for prediabetes seem to be one of agreement that it is a benefit to the patient. According to a study done by Kandula, Moran, Tang and O’Brien (2018), a diagnosis of prediabetes is an opportunity to collaborate with, educate and motivate patients to initiate weight loss and lifestyle changes. Providers see prediabetes screening as a way to detect a potential issue before it became a
problem such as T2DM at a time when patients may be more receptive to this information (Kandula, Moran, Tang & O’Brien, 2018). It is crucial then, that PCPs are knowledgeable and have an understanding of screening tools like the ADA DRT and resources available to refer patients to. Authors Nhim, Khan, Gruss, Wozniak, Kirley, Shumacher, Luman and Albright (2018) found that PCPs who recognized resources such as the NDPP were more likely to screen patients for prediabetes and follow national guidelines for screening. In addition, authors Holliday, Williams, Salcedo & Kandula (2019) found that if PCPs and practices see prediabetes screening and lifestyle modification referrals as a quality improvement project, there were more inclined to be engaged in implementing the practices at their respective sites.

**Risk Tools as Part of the Prediabetes Screening**

According to Murphy and Winmill (2013), utilizing an evidence-based standardized risk screening tool in asymptomatic patients promotes the discovery of undiagnosed prediabetes prompting early preventive measures to avoid progressing to T2DM. According to Edelman et.al, opportunistic screening is one of the potential strategies for prediabetes screening. Opportunistic screening involves taking advantage of the patient who presents to the provider for any cause and then delivering a public health screening intervention at that visit (2002, p. 23). This kind of screening can easily be done in primary care settings because primary care providers already oversee their patient’s overall health and wellbeing (Edelman et al., 2002). Opportunistic screening of identified high-risk individuals and population can help lower undiagnosed diabetes risk (Galaviz, Narayan, Lobelo & Weber, 2015).

To efficiently facilitate prediabetes screening, one of the highly recommended screening tool is the American Diabetes Association Diabetes Risk Test (ADA DRT). The ADA DRT was comprised of six (6) questions that covered diabetes risk factors such as age, sex, race/ethnicity,
BMI, first-degree family history of diabetes, history of gestational diabetes, lack of physical activity or hypertension (Ali et al., 2019). This tool is simple, straightforward and noninvasive (Galaviz, Narayan, Lobelo & Weber, 2015).

According to Ali et.al, individuals who were diagnosed with prediabetes by utilizing the ADA DRT have a high likelihood of receiving diabetes risk-reduction advice or counselling by providers (2019). One of the risk-reduction advice that have been generated through counseling was lifestyle modification strategies (LSM). LSM have been shown to have a sustainable effect in preventing diabetes in at risk individuals and those who participated in interventions were at a lower risk in the disease progression over time as compared to the control group (Haw et al., 2017).

A study done by Poltavskiy, Kim and Bang (2016) compared the accuracy of the screening scores in prediabetes using the ADA DRT. The study findings showed that “the ADA DRT has a sensitivity of 78% and specificity of 54% with a positive predictive value of 57% and a negative predictive value of 76%” (Poltavskiy, Kim & Bang, 2016) (Hunley, 2018). The ADA DRT performed well and was considered to be an economical, easy and safe way to screen for prediabetes, promote patient empowerment, accountability and responsibility for their health.

In addition, by utilizing the ADA DRT, this allowed for a great collaboration between patient and provider. It was proven in a study by authors Carrasquillo, Lebron, Alonzo, Li, Chang and Kenya (2017) that in minorities with poorly controlled type 2 diabetes, there was a significant improvement in the patients’ Hgb A1c in a period of one (1) year after an intervention with a community health worker. The study also found that this collaboration with a provider has shown improvement in behavioral outcomes (Carrasquillo, Lebron, Alonzo, Li, Chang & Kenya, 2017).
Importance and Accessibility of Hgb A1c Testing

In prediabetes, glucose levels are higher than normal but lower than what is considered clinically diagnosed diabetes (Galaviz, Narayan, Lobelo & Weber, 2015). Hemoglobin A1c is one of the primary tests to assess and evaluate an individual’s glycemia status (Sacks, 2012) It is used to measure “the percentage of your red blood cells that have sugar-coated hemoglobin” (CDC, 2018). Hgb A1c testing is considered to be a convenient form of testing. Although it is also used in conjunction with glucose testing, “Hgb A1c in the blood reflects the average glucose over the preceding 8-12 weeks” (Sacks, 2012, p.2674) in contrast to glucose testing that can get modified by different factors such as food intake, stress level, medication or activity at the time of the test (Sacks, 2012).

Hgb A1c requires no fasting, blood samples can be taken at any time of the day, has very little biological variability and the samples are stable (Sacks, 2012). It is a more stable method of testing for chronic hyperglycemia compared to impaired fasting glucose and oral glucose test tolerance (Galaviz, Narayan, Lobelo & Weber, 2015). Chronic hyperglycemia valuing between 5.6% to 6.4% Hgb A1c levels clinically define prediabetes (Galaviz, Narayan, Lobelo & Weber, 2015). The ADA confirmed that a diagnosis of T2DM requires a Hgb A1c level of 6.5% or more (Gavin, Freeman, Shubrook & Lavernia, 2011). The ADA then recommends that high-risk patients of any age that fit the criteria (BMI >25 kg/m and who have one or more additional risk factors such as high-risk race, family history of diabetes or history of gestational diabetes) and/or had been diagnosed with prediabetes, should have their Hgb A1c level tested yearly (Galaviz, Narayan, Lobelo & Weber, 2015).

The International Expert Committee suggests that the ease of performing the Hgb A1c testing will allow for more at-risk individuals to be screened for prediabetes and/or diabetes. The
ADA agreed that a diagnostic test such as the Hgb A1c was appropriate as the test of choice for screening and routine health maintenance as there was a greater likelihood that the results will coincide with the prior test (Malkani & Mordes, 2011).

**Importance of Lifestyle Modification, Education and Counseling**

**A. Lifestyle Modification**

There is overwhelming evidence in research that shows lifestyle modifications that include weight reduction, physical activity and incorporating a healthy, well-balanced diet can prevent prediabetes and/or delay diabetes progression (Galaviz, Narayan, Lobelo & Weber, 2015). This parallels the goal of the National Diabetes Education Program to increase physical activity and improved nutrition for those with prediabetes (Daftarian & Bowen, 2020). A study noted in Tuso’s (2014) article showed that lifestyle modification had been effective in reducing the incidence of diabetes. This intervention also showed greater weight loss and an increase in the amount of physical activity in the subjects. Furthermore, it created long-term beneficial changes in subjects’ behavior when it comes to being accountable for adhering to their activity and nutrition routine after the study (Tuso, 2014). A recommended 5% to 7% body weight loss if the BMI exceeds 25 kg/m2, together with 150 minutes of moderate-intensity physical activity per week and diet modification have shown to decrease diabetes risk significantly (Koenigsberg & Corliss, 2017). If no intervention is implemented, 15 to 30% of patients with prediabetes will progress to T2DM (Koenigsberg & Corliss, 2017).

Authors Galaviz, Narayan, Lobelo and Weber (2015) have deduced that energy balance plays a critical role in diabetes development. This energy balance includes energy intake and expenditure. Energy intake means food intake and expenditure means physical activity. In the study by Galaviz, Narayan, Lobelo and Weber (2015), it was stated that adequate energy intake
had shown a significant increase in diabetes risk by 11 to 26%. But if there is positive energy balance in which energy expenditure by increased physical activity is higher than energy intake, the risk of diabetes is reduced to 8%. A structured form of exercise, at least 150 minutes a week including moderate brisk walk, swimming, running or any other form of cardio contributes to a 27% diabetes risk reduction regardless of BMI (Galaviz, Narayan, Lobelo & Weber, 2015).

Exercise and physical activity decrease a lot of risk factors for serious health concerns, predominantly CVD and diabetes. Obesity and a sedentary lifestyle contribute to fat deposition in the visceral, hepatic and muscle tissues. This excess in fat and adipose tissue causes interference with glucose transport that in turn produce toxic free fatty acids, oxidative stress and cytokines. This results in insulin resistance because the liver now cannot regulate glucose production and glucose uptake by the muscle is impaired (Galaviz, Narayan, Lobelo & Weber, 2015).

In contrast, increased physical activity have been shown to prevent insulin resistance, decrease lipotoxicity in the muscle and liver as well as reduce visceral fat. Exercise also improves adiponectin levels, “a hormone that promotes insulin sensitivity and is reduced in the presence of obesity”. Physical activity also improves increased glucose uptake and increase nonoxidative glucose disposal which improve glucose utilization (Galaviz, Narayan, Lobelo & Weber, 2015, p. 7).

Weight loss is the main predictor of reduced incidence of prediabetes and T2DM. An approximate 5 kg weight loss or 7% of total body weight is the recommendation in order to reduce diabetes incidence by 58%. Physical activity may be one component in decreasing the incidence of prediabetes but diet and nutrition take the bulk of the system. The quality of the diet and the amount of calorie intake drive obesity and diabetes. Many factors including urbanization
and economic growth have impacted the way the population have consumed food. Unhealthy diet has been seen as one of the major contributors to the development of diabetes. The rise of fast-food restaurants that promote high caloric menus with large portion sizes along with processed ingredients did not help deter the progression of the disease (Ley, Hamdy, Mohan & Hu, 2014).

The ADA recommends that a diet rich in whole grains, fiber and low saturated fat decrease the risk of diabetes and obesity. Keeping a low level of saturated fat in the diet along with minimizing the consumption of sugar-sweetened beverages decrease the incidence of prediabetes progressing to T2DM by 26% (Galaviz, Narayan, Lobelo & Weber, 2015). This data is in conjunction with multiple research studies that a diet rich in fruits, vegetables, wholegrains, nuts, legumes and some dairy have been effective in decreasing the risk of prediabetes and diabetes. Along with a lower consumption of alcohol, refined grains, sweetened beverages and processed meat, glycemic control and blood lipids have shown an improvement in diabetic patients (Ley, Hamdy, Mohan & Hu, 2014).

There is also strong recommendation from studies that dietary patterns such as the Mediterranean-style, DASH (Dietary Approaches to Stop Hypertension) diet, plant-based, vegan or vegetarian diet patterns were strongly associated with a lower risk of diabetes (Ley, Hamdy, Mohan & Hu, 2014). According to the American Heart Association (AHA), the Mediterranean diet is a diet that includes plenty of vegetables, bread, other grains, fruit, beans, nuts, seeds and potatoes. Olive oil is the primary fat source and dairy products, fish, poultry and eggs are only consumed in low to moderate amounts (AHA, 2020).

The DASH diet is very similar to the Mediterranean-style diet. It also includes the consumption of vegetables, fruits and whole grains. Fish, beans, poultry and fat-free or low-fat
dairy products are highly recommended. The DASH eating plan includes a maximum of 2,000 calories a day meal plan that should not include food that are high in saturated fats, red meat, processed sugars and sugar-sweetened beverages (National Heart, Lung and Blood Institute, n.d.). Both of the mentioned dietary patterns are highly recommended by the ADA and the AHA both for the prevention of prediabetes and diabetes but to avoid cardiovascular risks and diseases as well. Both dietary patterns feature a flexible and a balanced eating plan that should be accessible for everyone and that can be followed and maintained over time.

B. Education

“Successful interventions in individuals with prediabetes, therefore, can have important preventative public health impacts “(Daftarian& Bowen, 2020, p. 244). With the rate of morbidity and mortality caused by diabetes, it is crucial that those suffering from the disease are armed with the essential knowledge and education in managing their health and wellbeing. Programs such as the diabetes self-management education (DSME) and Prevent T2 need to be promoted especially in local health departments and primary care offices. DSME has shown to improve glycemic control which in turn decreases the incidence of diabetes and its complications (Dearinger et al, 2013, p. 783). Dearinger et al. reported that those who received DSME training were more adept and knowledgeable in better managing their diabetes compared to those who did not receive the training (2013, p. 784). In addition, Tomky (2013) stated that DSME are valuable in helping patients gain knowledge and confidence and overcame barriers in performing self-care behaviors. (p. 735).

Furthermore, provider referral to structured, evidence-based lifestyle change programs (LCP) such as the National Diabetes Prevention Program (NDPP) led by the CDC have been verified to mitigate clinical and economic risks in individuals with prediabetes. According to the
study by authors Nhim, Khan, Gruss, Wozniak, Kirley, Schumacher, Luman and Albright (2018), NDPP participants lost 5%-7% of their body weight on average and reduced their risk of developing T2DM by 58% in those age 25 years and older. The NDPP’s most recent program, Prevent T2, is a program that has a yearlong curriculum led by trained coaches. Those found to be at risk for T2DM are guided on making lifestyle changes that include exercise, healthy eating and stress coping strategies in order to lower their risk of developing T2DM (Daftarian & Bowen, 2020).

C. Provider Counseling

Authors Galaviz, Narayan, Lobelo and Weber (2015) have construed that the implementation of lifestyle modifications to prevent prediabetes and ultimately T2DM prevention rely heavily on the support of PCPs along with community members, peers, family and friends and indirectly, technology and advancement in research. Especially in the clinical setting, the authors found that nutrition and physical activity counseling during routine patient visits promote weight loss and waist circumference reductions in high-risk patients. Not only is lifestyle modification counseling cost-effective and easy to adapt for PCPs but eventually, this should be implemented as part of the reimbursement process (Galaviz, Narayan, Lobelo & Weber, 2015).

However, it is very important for PCPs to recognize that there may be barriers to implementing lifestyle modifications. Even if major health organizations such as the AHA and the US Preventive Services Task Force (USPSTF) recommend behavior change techniques “such as goal setting and self-monitoring for promoting lifestyle change” (Galaviz, Narayan, Lobelo & Weber, 2015, p. 11), it is crucial to understand that individuals still vary in how they perceive change and adherence to new dietary and physical activity patterns. Assessing how each patient
perceive their readiness and their will to create and maintain a change for their health should be part of the PCP’s counseling before any intervention can occur (Koenigsberg & Corliss, 2017).

Authors Koenigsberg and Corliss (2017) found that if PCPs address the confidence and conviction of at-risk patients in establishing a readiness to work toward change, introducing lifestyle modifications to prevent prediabetes are more effective. If trust is bridged between provider and patient, setting clear outcome goals and behavior targets will be much easier to obtain. This is where the SMART approach to goal setting comes into play. In order for patients to develop healthy and sustainable habits, individuals should start small goals and aim to progress gradually: may it be choosing healthier food options daily or increasing the number of minutes in their chosen physical activity. As authors Koenigsberg and Corliss stated, “the patient can build confidence in small steps, with each step having a higher likelihood of lasting success. Small steps also yield many opportunities for praise” (2017, p. 367).

Lastly, encouragement and empowerment by PCPs play an important role in patients maintaining their lifestyle modifications. Studies have shown that PCPs who invest in the lifestyle modification progress of prediabetes and T2DM patients have created an impact in how these patients manage their nutrition and physical activity habits (Koenigsberg & Corliss, 2017). Offering praise and acknowledging the efforts and accomplishments of these patients can be powerful motivators in pursuing a long-term goal of preventing T2DM. And while some individuals may encounter setbacks along the way, continued support by PCPs in a nonjudgmental and empathic way along with tangible follow up plans post-intervention have shown to be effective behavior change techniques (Galaviz, Narayan, Lobelo & Weber, 2015).

In summary, studies have shown that the ADA DRT were proven to be reliable and efficient in screening for prediabetes. The high likelihood of successfully screening for
prediabetes especially in high-risk populations can mitigate the progression of diabetes. The earlier that patients were screened, the better it was for PCPs to initiate education about lifestyle changes. Studies have also shown that patients who have proactive providers in regard to screening, education and lifestyle counseling about prediabetes have a better outcome in decreasing the risk of developing diabetes. These patients were more motivated to change their behaviors and work toward changing their modifiable risk factors.

**Theoretical Framework**

The University of Ottawa’s Knowledge to Action (KTA) model comprises of two components. First is Knowledge Creation by identifying a problem for review, synthesizing the knowledge and knowledge tools and products (Dearholt & Dang, 2012, p. 147). The objectives of this research study include creating an awareness in prediabetes patients regarding the risks of progression to T2DM. There was also no tangible process in introducing important lifestyle modifications to prediabetes patients in the practice.

Given that the project site has no system in place to determine if identified patients with prediabetes are proactive in modifying their lifestyle habits, the aim of this study is to introduce a food and activity log and supportive group intervention to promote weight loss, increase in physical activity and improved nutritional choices in an urban family primary care setting.

The second part of the KTA model includes Action. Dearholt and Dang (2012) stated that appraising the problem, identifying known research, assessing successes and barriers as well as executing and evaluating problem outcomes should be given importance just as much importance as knowledge creating. There were foreseen barriers that hindered the implementation of the food and activity log and group counseling sessions at the practice. Non-adherence or participation from the provider and the patient can cause missed chances in collaboration
regarding prediabetes prevention. Following up with the patient and reinforcing the education component about lifestyle changes can hopefully increase compliance in those at risk for prediabetes and decrease the barriers indicated. Lastly, if significant benefits arose from this project after the evaluation of outcomes, the plan was to encourage the practice site to implement the food and activity log to all patients in the practice.

Methodology

The purpose of this DNP quasi-experimental project was to introduce important lifestyle modifications to prediabetes patients at an urban family primary care setting. With the introduction of a food and exercise log, weight monitoring pre- and post-study and two remote 15-minute group counseling sessions in a four-week study period, the end goals included weight loss, increase in physical activity and improved food choices in prediabetic patients.

In the setting of Covid-19, the methodology to this project was adjusted to adhere to social distancing guidelines. At no point before, during and after the study did the co-PI have an in-person interaction with any of the participants. This was in conjunction with social distancing guidelines as mandated by the State of New Jersey and Rutgers University. Prior to the initiation of the project, the study proposal approval was granted by Rutgers University’s Institutional Review Board (IRB) on April 10, 2021. When the implementation date was finalized, the co-PI reviewed the project site agreement form with the PCP. All project components including but not limited to recruiting subjects, requesting for consent for project participation, accessing subjects’ electronic medical records (EMR) and accessing the facility of the project site (use of office Wi-Fi and phone) were discussed with the PCP.

Subject recruitment started on April 23, 2021. The project site’s EMR, Kareo, was accessed for subject recruitment. The co-PI had secured access to Kareo that was granted by the
project site prior to the start of the research study. The subject’s telephone number was accessed from the EMR. The systematic sampling method was adopted to obtain the sample size. A systematic sample is “similar to simple random sampling but is usually easier to conduct. Every member of the population is listed with a number, but instead of randomly generating numbers, individuals are chosen at regular intervals” (Laerd Dissertation, 2012). In the alphabetical order list of patients in the EMR, starting from patient number 2 onwards, every 2nd patient on the list was selected (patient 2, 4, 6, and so on) until 20 subjects (N=20) were obtained. The main inclusion criteria for subject recruitment include a subject’s Hgb A1c result between 5.6% to 6.5% within the last year.

The IRB granted a Waiver of Documentation in obtaining subject consent. In place of a signed, physical consent, a telephone consent was obtained from potential subjects (see Telephone Consent Script in Appendices). A copy of the consent was also sent to subjects’ email addresses at their request. Included in the consent form were the following information:

- the objective of the research project
- who was involved in the research project
- the benefits of participating in the research project
- if the subject qualified to participate in the study (see inclusion and exclusion criteria).
- if the subject agreed to take part in the research project
- the project timeline
- The subject agreed to participate in the data collection remotely (via telephone and email correspondence).
• The subject consented or declined to participate in the study. The subject can also withdraw from the study at any time without any repercussions.

• The subject was informed that there will be two data collection (pre and post intervention). The subject provided their most recent weight (scale-based) and document it on their initial food and activity log. The second data collection required the subject to provide via email their completed 4-week food and activity log and most recent weight (scale-based) at the culmination of the study. The subject will send it to the co-PI’s official Rutgers University Connect email address.

• The subject was informed that two 15-minute group counseling sessions will be done remotely at the 2-week and 4-week study mark. This will be completed via Zoom. The subject agrees to provide their email address for this part of the study. The co-PI will provide assistance to subjects on how to install Zoom on their devices. If the subject has no access to Zoom, a phone number connected to the Zoom meeting will be provided to the subject in order to participate during the group counseling sessions.

• The subject will be compensated with a $5 Target gift card for completing the study.

In order to collate the collected information, the co-PI designated an identification number to every subject that was included in the study. All data points were collated in an Excel spreadsheet (see Appendix). The group counseling sessions via Zoom were scheduled on May 7, 2021 (week 2) and May 21, 2021 (week 4) respectively. The data collection formally concluded on May 21, 2021. The co-PI had preliminary discussions with the PCP regarding the initial results of the data collection at the end of the data collection.

**Setting**
The project site took place in a private urban family primary care office specializing in chronic disease management, preventive care, episodic care and minor urgent care in northern New Jersey. The hours of operation were Monday to Friday from 9:00 AM to 5:00 PM and Saturday, 9:00 AM to 2:00 PM. The office was staffed by one DNP-trained family nurse practitioner under a collaborating PCP. Other team members include a front desk staff and one phlebotomist. Laboratory specimens collected on site were collected by lab representatives at the end of clinic hours. Patients seen in this practice range from age 18 years and older, of any gender, religion, literacy level and health insurance status. The office saw scheduled and walk-in patients.

**Project Participants**

The proposed sample population for this project include the following inclusion and exclusion criteria:

**Patient Inclusion Criteria:**

- Registered patient in the EMR (In the alphabetical order list of patients in the EMR, starting from patient number 2 onwards, every 2nd patient on the list is selected (patient 2, 4, 6, and so on) until N=20 is obtained.
- New or established patient
- Non-pregnant
- Hgb A1c result between 5.6% to 6.5% within the last year
- English speaking patient
- Phone and Internet access

**Patient Exclusion Criteria:**

- Diagnosis of diabetes with Hgb A1c of >6.5%
• Less than 18 years of age
• Currently pregnant
• Non-English speaking patient
• No phone or internet access

Subject Recruitment

Any patient who fit the inclusion and exclusion criteria were included in the study. Any subject included in the study was assigned an ID number and the data was collated in an Excel spreadsheet. No patient identifier such as name, date of birth, medical record number, insurance information or photograph were used in completing the food and activity log or used at any point in the study. The co-PI communicated with the subjects by telephone using the project site’s secured landline. Kareo was accessed inside a secured conference room only accessible to authorized staff inside the project site. The co-PI also communicated via Rutgers University’s official Connect email using the project site’s secured Wi-Fi internet connection. The group counseling sessions via Zoom were conducted inside the secured conference room at the project site with only the co-PI present.

A total of 20 participants were contacted to participate in the study. The co-PI obtained seven (7) subjects who consented to partake in the research study. On Week 2, five (5) subjects attended the group counseling sessions via Zoom (all via telephone) but two (3) subjects dropped out of the study. On Week 4, only three (2) subjects attended the group counseling sessions via Zoom (all via telephone). Unfortunately, no subject completed and submitted their food and activity log.

Consent Procedure
The co-PI obtained a Waiver of Documentation from the IRB. In lieu of a signed consent, a telephone consent was requested from the subjects. The telephone consent script is documented on the approved IRB protocol and is included in the Appendix section of this document. A copy of the consent was also sent to the subjects’ email address through the co-PI’s official Rutgers University Connect email address. The subject was given reassurance that whether they participated or declined participation in the project, their plan of care or length of visit will not be affected in any way. No paper/written consent was required as there was no direct contact or in-person interaction between the co-PI and the subject. HIPAA laws were strictly enforced at all times.

**Risks or Harms**

Prior to the beginning of this research project, the co-PI obtained approval from the Institutional Review Board of Rutgers University on April 10, 2021 (Appendix B). CITI training regarding Human Research and Biomedical/clinical Research Investigators had also been completed by all team members. There were no extraneous data collected. Only the PCP and the co-PI have knowledge of the subjects that were involved in the project. One risk that was addressed accordingly was the risk to the subject about knowing the diagnosis of prediabetes. Prediabetes diagnosis and the consequent Hgb A1c results were part of their patient records permanently.

Risks were minimized through education regarding prediabetes and how to prevent it from progression to T2DM. Subjects were also advised in advance that the research project will include participating in a physical activity of their choosing and will also involve altering their usual diet by incorporating more fruits, vegetables and lean protein.

**Subject Costs and Compensation**
There was no cost to the subject for inclusion in the project. There was also no cost to the project site for agreeing to participate in hosting the research study. The co-PI offered a $5 Target gift card as compensation for subjects who completed the food and activity log. In the end, no gift card was distributed to any subject as no subject has completed the intervention in full.

**Study Interventions**

The plan was to introduce a food and activity log to any subject identified to be a risk for prediabetes. The food and activity log were sent to the subjects’ email addresses for easy accessibility and to comply with Covid-19 social distancing guidelines. On week 2, halfway through the four-week intervention, a 15-minute group counseling session via Zoom was scheduled to follow-up with subjects. At the end of the intervention, on week 4, another 15-minute group counseling session via Zoom was scheduled as a final follow-up with the subjects and to also collect the completed food and activity log.

**Outcome Measure**

The outcome measures expected from the completion of this research project focused on healthcare improvement by introducing important lifestyle modifications to prevent prediabetes. Primary outcome measures included:

- 7 total number of subjects who consented to participate in the study
- 3 patients dropped out mid-study
- 0 total number of subjects who completed the food and activity log in full
- 0 total number of subjects participated in both group counseling sessions via Zoom
- 2 patients reported weight loss in a four-week study period
- 2 patients reported weight gain in a four-week study period
• 4 subjects reported an increased average of at least 30 minutes of exercise both indoors and outdoors, a minimum of once a week

• 4 subjects reported of eating smaller portions and choosing more fruits and vegetables in their diet

**Project Timeline**

1. Requested Team Chair’s assistance with the project – 9/27/18
2. Requested Team Member’s assistance with the project – 1/28/20
3. Finalization of question development – 2/2/20
4. Theoretical Models, Review of Literature and Tables of Evidence – 01/2020 to 03/2020
5. Revision of DNP Parts I-III – 05/2020 – 08/2020
6. Permission Granted by the ADA to Use the ADA DRT Form – 08/19/2020
7. Team Proposal Presentation – August 21, 2020
8. Submission of Proposal to the IRB – September 1, 2020
9. IRB Approval Granted – September 12, 2020
10. Subject Recruitment Commenced – September 15, 2020
11. Subject Recruitment Completed – September 20, 2020
12. Study Conclusion – October 9, 2020
13. Data Collection – October 10, 2020
14. Data Analysis – November 4 to November 23, 2020
15. Finalizing presentation with Team – Not Applicable/Denied
17. Protocol Deviation Resolved – March 12, 2021
18. Requested New Team Member – March 23, 2021
20. New IRB Approval Granted – April 12, 2021
21. Subject Recruitment Completed – April 23, 2021
22. Week 2 Group Counseling Follow up – May 7, 2021
23. Week 4 Group Counseling Follow up – May 21, 2021
24. Data Collection Conclusion – May 21, 2021
25. Data Analysis – May 22 to May 27, 2021
26. Finalizing Team Presentation – May 28, 2021
27. Submission of Final DNP Document – May 28, 2021
28. Submission of Final DNP Poster – May 28, 2021
29. Submission to Close Research Study – TBD
30. Final DNP Presentation - TBD

Resources Needed/Economic Consideration

The project took place for a total of 5 weeks including recruitment and intervention. The estimated total cost for this project was approximately $50 including light refreshments that were provided to the practice site at the conclusion of the study for their participation and assistance in the project.

Evaluation Plan

Data Maintenance/Security

The patient’s identity was protected at all costs. The patient’s phone number and email address were collected in order to participate in this research study. An assigned identification number not related to the subject’s PHI was used throughout the study. Unfortunately, there were
no completed food and activity log submitted by the subjects. The Excel spreadsheet has no patient identifier and will be secured electronically by the PI for 6 years. All collected/submitted information by the subject was stored digitally via Rutgers University’s approved cloud-based file storage, Box. After 6 years, the data collected after the completion of the study will be properly destroyed. The PI, team member and the IRB are the only authorized personnel/governing body who has access to the research data.

Data Analysis

This quasi-experimental project did not result in a successful intervention in subjects. On May 21, 2020, data collection was completed. The study duration lasted for a total of five weeks which included the recruitment process and the 4-week study period. Systematic sampling method was utilized to obtain the number of subjects. Data analysis was completed using the SPSS Version 27 software.

Findings

Subject Recruitment

When the recruitment process started on April 23, 2021, there were a total of 20 electronic charts that were reviewed for eligibility. 20 eligible participants were contacted by phone. All or a 100% of eligible participants were established patients that had been seen in the clinic between 2019 to 2021. Out of the 20 eligible participants, \( n=10 \) or 50% did not respond to the phone call. \( N=3 \) or 15% of the eligible participants declined participation because they have the following commitments: “I will be observing Ramadan and cannot commit to the four-week study period”, “I will be traveling to Ghana for three weeks due to a death in the family” and “I am going to undergo hip surgery in two weeks”. \( n=7 \) or 35% of the participants responded and gave consent to be part of the research study.
Although not a major indicator of eligibility in the research study, all of the subjects \((n=7)\) identified as female and varied in age. There were no male participants in the study. The minimum age of the sample population was 23 years of age and the maximum age was 62 years. The mean age of the study participants was 43.28 years. The mode of the ages includes 23, 29, 34, 47, 53, 55 and 62. The median age is 57. No other identifying characteristics such as race/ethnicity, occupation, marriage status, insurance coverage and others were collected or had any bearing in the data needed for the research study.

**Hgb A1c Levels**

All 20 eligible participants had a Hgb A1c level between 5.6 to 6.5%. The following are the percentage breakdown between the potential subject and their Hgb A1c levels:

- 5 subjects (25%) - 5.6%
- 1 subject (5%) - 5.7%
- 4 subjects (20%) – 5.8%
- 2 subjects (10%) – 5.9%
- 1 subject (5%) – 6.0%
- 3 subjects (15%) – 6.1%
- 2 subjects (10%) – 6.2%
- 2 subjects (10%) – 6.4%

A total of seven subjects consented to the study. However, three were lost to mid-study leaving a total of four. The mean serum Hgb A1C value was 6.01 with the minimum being 5.60 and the maximum 6.40 (SD = .36). This data was retrieved via the subject’s EMR. The Hgb A1c results were from the subjects’ most recent office visit and were collected between 2020 and 2021.
Table 1

*Hgb A1c*

<table>
<thead>
<tr>
<th>Hgb A1c</th>
<th>Frequency</th>
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<th>Valid Percent</th>
<th>Cumulative Percent</th>
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Figure 1

*Hgb A1c Level*

**Weight Loss**

Pre-intervention weights of the subjects varied significantly from 185 to 275 lbs. with the mean being 213.25 (SD = 41.76). Post-intervention weights were similar ranging from 180 to 281 lbs. with a mean weight of 212.75 (SD = 46.05). Total weight loss among the four subjects
was two lbs. and a mean of .50 lbs. (SD = 6.46). Two subjects lost weight. One lost seven lbs. (A01) and the other lost five (C03). The other two subjects on the other hand, gained weight with one gaining six (B02) and the other four lbs. (E05).

**Table 2**

*Pre-Intervention Weight*

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**Table 3**

*Post-Intervention Weight*

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<td>Total</td>
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**Table 4**

*Total Weight Loss (Lbs.)*

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<th>Cumulative Percent</th>
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</table>
Figure 2

*Subject Pre & Post-Intervention Weight*

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<th>Subject</th>
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<th>Post-Intervention Weight</th>
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<td>C03</td>
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<td>180</td>
</tr>
<tr>
<td>E05</td>
<td>191</td>
<td>195</td>
</tr>
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</table>

**Increase in Physical Activity**

Only one subject reported doing a physical activity during all four weeks of the study. The subject who lost the most weight (A01) had the highest mean exercise duration of 52.5 minutes and the participant who gained the most (B02) also had the lowest mean exercise duration of 30 minutes. Overall, the mean duration of physical activity was 43.13 minutes (SD = 9.44) ranging from 30.0 to 52.5 minutes.

**Table 5**

*Week 1 Mean Physical Activity (Minutes)*

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### Table 6

**Week 2 Mean Physical Activity (Minutes)**

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<tr>
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### Table 7

**Week 3 Mean Physical Activity (Minutes)**

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### Table 8

*Week 4 Mean Physical Activity (Minutes)*

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### Table 9

*Mean Physical Activity (Minutes)*

<table>
<thead>
<tr>
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<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
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<td>100.0</td>
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</table>
Further Correlation

A Spearman’s rank-order correlation was run to assess the relationship between Hgb A1c levels, subjects’ pre- and post-intervention weights, total weight loss, and time spent exercising. There were no statistically significant correlations found between these variables, $p > .05$.

Subjects, on average, weighed more pre-intervention ($M = 213.25$ lbs., $SD = 41.76$) than post-intervention ($M = 212.75$ lbs., 46.05). However, the difference between the two groups was not statistically significant, 95% CI $[-10.771, 9.771]$, $t(3) = -.155$, $p = .887$. 
Table 10

**Paired Sample T-Test**

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>N</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pair 1</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Post-Intervention Weight</td>
<td>212.75</td>
<td>4</td>
<td>46.046</td>
<td>23.023</td>
</tr>
<tr>
<td>Pre-Intervention Weight</td>
<td>213.25</td>
<td>4</td>
<td>41.764</td>
<td>20.882</td>
</tr>
</tbody>
</table>

Table 11

**Paired Differences**

<table>
<thead>
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<th>Std. Error Mean</th>
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<tr>
<td><strong>95% Confidence Interval of the Difference</strong></td>
<td>Lower</td>
<td>Upper</td>
<td>t</td>
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<tr>
<td>Pair 1 Post-Intervention Weight - Pre-Intervention Weight</td>
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<td>6.455</td>
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**Discussion of Findings**

**Economic/Cost Benefits of Project**

With 88 million Americans diagnosed with prediabetes (ADA, 2018), it is highly important that screening patients should be done by PCPs as 70% of those found to be prediabetic will develop T2DM (Kandula, Moran, Tang & O’Brien, 2018). Screening for prediabetes can prevent a costly diabetes diagnosis which was now estimated at $245 billion
annually (CDC, 2018). By screening using an evidence-based tool combined with laboratory testing in patients who are asymptomatic, early detection of prediabetes can facilitate early preventive care and treatment plans for patients intended to prevent the progression to T2DM (Weber et al., 2016).

Obtaining Hgb A1c is an efficient, easy and economical way of screening for prediabetes as well. It requires no fasting, blood samples can be taken at any time of the day, has very little biological variability and the samples are stable (Sacks, 2012). For those with risk factors, the ADA recommends yearly testing. Furthermore, once patients are screened and identified to be at risk for prediabetes, lifestyle modifications can be recommended right away. There are multiple cost-effective and easy physical activities that individuals can partake with slowly until they develop healthy habits. Modifications to their diets do not have to be abrupt or require an excessive change. The recommendation of most studies is to incorporate more servings of fruit, vegetables, grains, nuts and healthy fats can help decrease their risk of prediabetes.

**Healthcare Practice**

Given that more than 350 million adult ambulatory care visits are recorded yearly, primary care practices represent an important setting for addressing prediabetes prevention (Kandula, Moran, Tang & O’Brien, 2018, p.59). Screening for prediabetes will give PCPs the opportunity to collaborate with individuals who were found at risk for timely and early counseling and education regarding lifestyle changes. With a baseline Hgb A1c level, it is also easy for the PCP to monitor the patients accordingly and manage their care as they are evaluated over time. This may create an awareness in patients who were screened and identified to follow up regularly with their providers.
Tuso (2014) stated that “increasing awareness and risk stratification of individuals with prediabetes may help physicians understand potential interventions that may help decrease the percentage of patients in their panels in whom diabetes develops” (p. 88). Early intervention may contribute to ongoing efforts to make healthcare more affordable and accessible, avoid disease progression to diabetes and complications such as cardiovascular diseases, neuropathy and amputations and possibly save the patient’s life (Tuso, 2014, p. 91).

Policy

Authors Bergman, Buysschaert, Schwarz, Albright, Narayan and Yach (2012) stated that the following three sectors; the government, the public health and clinical sectors have critical roles to play in helping curb the diabetes epidemic. Policies should be in place in that risk reduction strategies such as facilitation of LSM and practicing healthy behaviors should be accessible to community environments (Bergman, Buysschaert, Schwarz, Albright, Narayan & Yach, 2012). Whereas the clinical sector is responsible for early screening and referral to community-based lifestyle programs and nutrition counseling, the public health sector must monitor risks and to make sure that there are quality partnerships with prevention services that are accessible to those identified at risk for prediabetes (Bergman, Buysschaert, Schwarz, Albright, Narayan & Yach, 2012).

Furthermore, policies should be strengthened in that a uniformed and validated screening instrument should be implemented in all primary care offices. The authors also recommend that “policy development requires utilization of evidence-based, standardized lifestyle intervention recommendations that are customized to reflect cultural and individual circumstances” (Bergman, Buysschaert, Schwarz, Albright, Narayan & Yach, 2012, p. 7). In addition, the authors also stressed the importance of policies in which providers should have the necessary
knowledge of the screening instrument and education interventions in order to be effective in their education and referral of lifestyle modifications to patients (Bergman, Buysschaert, Schwarz, Albright, Narayan & Yach, 2012). Lastly, there is an urgency globally to secure policies that “require implementation of evidence and evidence-based strategies in modifying the environment and infrastructure to improve nutrition, decrease weight, increase physical activity and facilitate tobacco cessation” (p. 7). Because if left untreated, the enormous economic and social burdens of prediabetes and diabetes can create consequences not only to patients but also to healthcare systems all over the world (Bergman, Buysschaert, Schwarz, Albright, Narayan & Yach, 2012).

**Sustainability**

One of the biggest recommendations to this project in order to maintain its sustainability is to utilize an evidence-based and proven food and activity mobile app. Majority of the population now have access to smart phones and the internet that they can automatically log their food intake and activity easily. Using these mobile apps are accessible and most are not for profit and therefore will not cost individuals any money. This is in conjunction with what authors Galaviz, Narayan, Lobelo and Weber (2015) recommended in their study that low-cost strategies such as group-based formats and technology-based interventions that can be implemented in a real-world setting can create a significant impact that can reach a heterogenous population.

The rate of diabetes in the United States is rapidly increasing yearly and screening of prediabetes and prevention are the key components in mitigating the impact of the disease. By screening prediabetic patients, providers are more likely to implement attainable interventions first. Screening will not only avert out of pocket costs for patients but will invoke lifestyle changes that can be less costly and create lesser complications. This is in congruence with the
U.S. Preventive Services Task Force’s (USPSTF) recommendation that screening for prediabetes along with a subsequent referral to lifestyle intervention programs that promote increased physical activity and a healthy diet, can reduce the incidence of diabetes by as much as 58% (Kandula, Moran, Tang, & O’Brien, 2018, p. 59).

Translation

The data gathered and studied through this project will be presented to colleagues, team members, stakeholders and the School of Nursing faculty at Rutgers University during Poster Day and the final project presentation.

Dissemination and Professional Reporting

The results of this project along with the completed document will be submitted to the university. The final DNP Project Paper will be submitted to and approved by the DNP chair and team member. A detailed summary of this project will be presented during the final project presentation and on Poster Day that will be attended by faculty and students alike. Due to social distancing guidelines brought on by the Covid-19 pandemic, the Poster Day and final project presentation will be held remotely. The final document will be published and accessible via the university online repository RUcore provided by the school. For further dissemination, one of the plans for this project includes submission of the project abstract to the American Diabetes Association who are accepting abstract applications from October 1, 2021 to January 11, 2022.

Limitations

The Covid-19 pandemic hampered the original methodology planned for this research project. In order to follow Rutgers University’s social distancing guidelines, the co-PI had to perform subject recruitment, group counseling sessions and other communication strategies remotely. This research project was unsuccessful hugely in part because of the lack of in-person
interaction with the participants. Majority of the subjects voiced concern that the food and log activity was not doable when it was sent to them remotely by email. The preference of majority of the subjects was to have either a food and activity mobile app or a printed document that they can bring with them at all times in order to log in their food and activity. It seemed to be a general consensus that logging their food and activity intake daily manually was not a workable solution because they have to access and save the Word document through their personal devices which may not be on hand at all times.

Furthermore, another limitation that this study faced include a low number of subjects. Out of the 20 subjects that were contacted, only seven individuals agreed to participate in the study. Halfway through the intervention, three patients also dropped out of the study which greatly affected the results. Time was the greatest hurdle that the subjects reported in terms of completing their food and activity log as well as attending the scheduled group counseling sessions. The subjects either missed the two-week group counseling or the four-week group counseling sessions which also affected the results.

Lastly, Galaviz, Narayan, Lobelo and Weber (2015) suggested that any group or individual weight loss counseling should at least have a four to six-month continuous weekly follow up to achieve a clinically meaningful weight loss. Per the authors, “high intensity counseling strategies (>360 minutes of total patient time) show greater effects on lifestyle and health outcomes” (p. 11). In this particular study, the intervention period was only four weeks. The subjects had only four weeks to log their food and activity and had a limited time to fully implement healthy habits in order to see a significant decrease in weight or follow through with modifications in their nutrition patterns. Majority of the subjects though stated that they are now more aware of the consequences of prediabetes. They are more conscious of including healthy
food choices to their daily diet as well as incorporating any kind of physical activity into their day-to-day schedule.

**Conclusion**

Prediabetes is a precursor to diabetes and needs to be taken with serious care. Screening for prediabetes in primary care is a reliable, easy and quick process to start a provider-patient conversation about the importance of evaluation, baseline Hgb A1c level, education, lifestyle changes and follow up. Utilizing an evidence-based screening tool can be effective in recognizing patients who may be at risk for prediabetes. In that manner, referral for Hgb A1c testing, continuing evaluation and education can help mitigate the progression of prediabetes to diabetes. Introducing lifestyle modifications that include weight reduction, physical activity and incorporating a healthy, well-balanced diet can prevent prediabetes and/or delay diabetes progression.

The Covid-19 pandemic has greatly affected the initial methodology plan for this project. It has affected the number of subjects that were planned to be included in the food and activity log intervention. Remote recruitment, intervention and group counseling sessions proved to be a major factor in the success of this project. The lack of in-person interaction decreased the success rate of this study. This is all due to the reality that because of social distancing guidelines and state lockdowns, the project methodology had to be modified for compliance.

The overall takeaway and lesson learned from this project is that the patient’s health remains a priority. PCPs have resources available to them to aid in proper screening and evaluation of risk factors as such in prediabetes that if not adhered to early, can eventually lead to a complicated, chronic disease. A good patient-provider relationship is important to reach an effective management of patient health and wellbeing.
References


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Caffrey, M. (2019, December 3). *Prediabetes seen in 20% of adolescents, 25% of young adults.*


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https://www.state.nj.us/health/chs/hnj2020/chronic/diabetes/


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The importance of early diabetes detection.


https://jamanetwork.com
### Appendix A

**Food and Activity Log**

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Appendix C

SWOT Analysis

**Strengths**
- Expertise of team chair and members
- Majority or patients at project site are at-risk for prediabetes
- Simplicity of the food and activity log

**Weaknesses**
- No tangible implementation of lifestyle modification measures onsite

**Opportunities**
- Opportunity to implement food and activity log
- Opportunity to provide group intervention remotely

**Threats**
- Participation compliance
Appendix D

Knowledge to Action Model Diagram

(University of Illinois at Chicago, 2019, December 12)
Appendix E

Tables

Table 1

Hgb A1c

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Figure 1

Hgb A1c Level
**Table 2**

*Pre-Intervention Weight*

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**Table 3**

*Post-Intervention Weight*

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**Table 4**

*Total Weight Loss (Lbs.)*

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Figure 2

*Subject Pre & Post-Intervention Weight*

![Figure 2: Pre and Post-Intervention Weight](image)

Table 5

*Week 1 Mean Physical Activity (Minutes)*

<table>
<thead>
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<th>Valid Percent</th>
<th>Cumulative Percent</th>
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<td>Total</td>
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<tr>
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</table>

Table 6

*Week 2 Mean Physical Activity (Minutes)*

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### Table 7

*Week 3 Mean Physical Activity (Minutes)*

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### Table 8

*Week 4 Mean Physical Activity (Minutes)*

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<th>Valid Percent</th>
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<td></td>
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</tr>
<tr>
<td>30</td>
<td>1</td>
<td>25.0</td>
<td>33.3</td>
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<td>45</td>
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<td>Total</td>
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### Table 9

*Mean Physical Activity (Minutes)*

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<tr>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
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<td></td>
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</tr>
<tr>
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<td>25.0</td>
<td>33.3</td>
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<td>Total</td>
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### Table 10

**Paired Sample T-Test**

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>N</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pair 1</td>
<td></td>
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<tr>
<td>Post-Intervention Weight</td>
<td>212.75</td>
<td>4</td>
<td>46.046</td>
<td>23.023</td>
</tr>
<tr>
<td>Pre-Intervention Weight</td>
<td>213.25</td>
<td>4</td>
<td>41.764</td>
<td>20.882</td>
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</tbody>
</table>

### Table 11

**Paired Differences**

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
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<th>95% Confidence Interval of the Difference</th>
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<td>Upper</td>
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<td></td>
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<td>Post-Intervention Weight</td>
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<td>6.455</td>
<td>3.227</td>
<td>-.155</td>
<td>9.771</td>
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<td>Pre-Intervention Weight</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
Appendix F

CONSENT TO TAKE PART IN A RESEARCH STUDY

**Title of Study:** Introduction of important lifestyle modifications to prediabetes patients at an urban family primary care setting.

**Principal Investigator:** Dr. Gerti Heider, PhD, MSN, GNP-BC, ANP, APN

**STUDY SUMMARY:** This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research is to:** introduce important lifestyle modifications to prediabetes patients at an urban family primary care setting. You are being invited to take part in this study because you are determined to be at risk for type 2 diabetes. The co-PI will obtain your phone number from the electronic medical record (EMR). The co-PI will introduce to you a food and activity log. You have the option of printing the food and activity log at home or a copy will be mailed to your residence. You will take note of your daily food intake during breakfast, lunch, dinner and snacks. You will also keep track of the number of minutes of a physical activity of your choosing. You will also need to weigh yourself using a scale before the start of the study and also at the end of the study.

The co-PI will follow up with you twice at different intervals during the study duration. This follow up will be a 15-minute group counseling session that will be done remotely. At this time, you will be asked to provide your email address in order for you to receive a link for a Zoom meeting. The group counseling session will include informative discussions about your progress and is a safe and judgement-free zone.

At the end of the study, you will be asked to submit your completed food and activity log. The co-PI will discuss your results with you. Your results will also be compiled in an Excel spreadsheet for data analysis. Your results will also be forwarded to [redacted] for future reference and follow up.

Your time in the study will take a total of 4 weeks. The co-PI will check in with you at the 2 and 3-week mark for your group counseling sessions. You do not need to visit the office in order to take part in the study. All correspondence will be done remotely in order to maintain and adhere to safe, Covid-19 social distancing guidelines.

**Possible harms or burdens** of taking part in the study may include tiredness, dizziness, increased heart rate and sweating due to increased physical activity. You may also experience hunger pains and decreased tolerance from a change in your diet.

But the benefits of taking part in this study include possible weight loss, increase in physical activity and choosing smarter and better food choices that can help you to avoid from progressing from pre-diabetes to T2DM. You will also be compensated with a $5 Target gift card after completing the research study.
An alternative to taking part in the research study: Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Dr. Gerti Heider is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Dr. Heider may be reached at:

Rutgers, The State University of New Jersey
Stanley S. Bergen Building
65 Bergen Street
Newark, NJ 07103
(973) 972-9603

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?
The purpose of this study is to introduce important lifestyle modifications to patients identified as pre-diabetic (if your hemoglobin A1c [Hgb A1c] result is between 5.6% to 6.5% within the last year). These lifestyle modifications include an increase in physical activity and smarter food choices that you need to log daily in a 4-week study period. The goal at the end of the study is to see if you have increased your physical activity, have made better food choices that you incorporated in your daily diet and if you have lost weight.

Who may take part in this study and who may not?
- **Inclusion Criteria**
  - Registered patient in the EMR
  - New or established patient
  - Non-pregnant
  - Hgb A1c result between 5.6% to 6.5% within the last year
  - English speaking patient
- **Exclusion Criteria**
  - Diagnosis of diabetes with Hgb A1c of >6.5%
  - Less than 18 years of age
Why have I been asked to take part in this study?
You have been asked to participate in the study because your Hgb A1c, a blood test that measures your average blood sugar level over the past 3 months, is between 5.6% and 6.5%. If you Hgb A1c level is between the numbers specified, you are considered prediabetic. Prediabetes means that your blood sugar level is higher than normal but not high enough to be diagnosed as Type 2 Diabetes (T2DM).

If you have prediabetes, you are more at risk to develop T2DM, heart disease and stroke. This research study will introduce you to lifestyle modifications that will avoid or delay for your prediabetes to progress to T2DM.

How long will the study take and how many subjects will take part?
The goal of this study is to recruit 20 participants from your provider’s office. Your provider is aware of this research study and has provided her permission for the co-PI to implement this research study at her office. The duration of this study from recruitment to the conclusion of your participation is 4 weeks.

What will I be asked to do if I take part in this study?
You are being invited to take part in this study because you are determined to be pre-diabetic or at risk for type 2 diabetes. The co-PI will introduce to you a food and activity log. You have the option of printing the food and activity log at home or a copy will be mailed to your residence. You will take note of your daily food intake during breakfast, lunch, dinner and snacks. You will also keep track of the number of minutes of a physical activity of your choosing. You will also need to weigh yourself using a scale before the start of the study and also at the end of the study.

The co-PI will follow up with you twice at different intervals during the study duration. This follow up will be a 15-minute group counseling session that will be done remotely. At this time, you will be asked to provide your email address in order for you to receive a link for a Zoom meeting. The group counseling session will include informative discussions about your progress and is a safe and judgement-free zone. The Zoom sessions will not be recorded.

At the end of the study, you will be asked to submit your completed food and activity log. The co-PI will discuss your results with you. Your results will also be compiled in an Excel spreadsheet for data analysis. Your results will also be forwarded to [redacted] for future reference and follow up.

What are the risks of harm or discomforts I might experience if I take part in this study?
Possible harms or burdens of taking part in the study may include tiredness, dizziness, increased heart rate and sweating due to increased physical activity. You may also experience hunger pains and decreased tolerance from a change in your diet.

The benefits of taking part in this study may include possible weight loss, increase in physical activity and choosing smarter and better food choices that can help you to avoid from progressing from pre-diabetes to T2DM. You will also be compensated with a $5 Target gift card.
after completing the study. However, it is also possible that you may not receive any direct benefit from taking part in this study.

**What Are My Alternatives If I Do Not Want To Take Part In This Study?**
Your alternative is not to take part in this study.

**How Will I Know If New Information Is Learned That May Affect Whether I Am Willing To Stay In The Study?**
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

**Will I Receive The Results Of The Research?**
Your Hgb A1c results will be discussed with you at the start of the study and why you are eligible to participate. Your continued progress will be discussed during the 2 group sessions required. At the end of study, your pre and post-study weight will be compared to see if you achieved any weight loss. Your food and activity log pre and post-study comparison will also be discussed with you at the last Zoom session.

**Will There Be Any Cost To Me To Take Part In This Study?**
Participating in this study will be at no cost to you.

**Will I Be Paid To Take Part In This Study?**
You will receive a $5.00 Target gift card for taking part and completing this study.

**How Will Information About Me Be Kept Private Or Confidential?**
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Your food and activity logs will be maintained by the PI and will be destroyed 6 years after the completion of the study.

The co-PI will call you through your provider’s office phone number to make sure it is through a secured line. Your email address will only be used to send you a Zoom link. It will not be provided to any third party. The group counseling sessions through a secured Zoom meeting will not be recorded and distributed to any third party.

The research team may use or share your information collected or created for this study with the following people and institutions:
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

**What Will Happen To My Information—data, recordings and/or images Collected For This Research After The Study Is Over?**
The information collected about you (or from you) for this research will not be used by or distributed to investigators for other research.
What Will Happen If I Do Not Wish To Take Part In The Study Or If I Later Decide Not To Stay In The Study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Gerti Heider at 65 Bergen St. Newark, NJ 07103. **OR** Any data that has already been collected cannot be withdrawn because there may not be any identifiers to link the data with you.

Who Can I Contact If I Have Questions?
If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator:

Rutgers, The State University of New Jersey
Stanley S. Bergen Building
65 Bergen Street
Newark, NJ 07103
(973) 972-9603

You can also contact my team member, Dr. Irina Benenson at:

Irina Benenson, DNP, FNP-C
Assistant Professor
Division of Advanced Nursing Practice
Rutgers School of Nursing
65 Bergen Street, 1115, Newark, NJ 07107
Email: *reddacted*
Phone: 973-972-3222

If you have questions, concerns, problems, information or input about the research or would like to know about your rights as a research subject, you can contact the Rutgers IRB Director at:

Newark HealthSci IRB, 65 Bergen St., SSB 511, Newark, NJ 07107, (973)-972-3608 or the Rutgers Human Subjects Protection Program at (973)972-3608 or (732)235-9806, email us at human-subjects@research.rutgers.edu or write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

**PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY**
The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What Information About Me Will Be Used?

- Age
- Hgb A1c result within the last year
- Phone number on record
- Email address

Who May Use, Share or Receive My Information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved In The Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- [Redacted]

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I Be Able To Review My Research Record While The Research Is Ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of
your information in the research, you must write to the researcher and tell him or her of your decision:

Rutgers, The State University of New Jersey  
Stanley S. Bergen Building  
65 Bergen Street  
Newark, NJ 07103  
(973) 972-9603

**How Long Will My Permission Last?**

Your permission for the use and sharing of your health information will last until the end of the research study.
# Appendix I

## Project Timeline

<table>
<thead>
<tr>
<th>Completion:</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/27/2018</td>
<td>Team Chair Request</td>
</tr>
<tr>
<td>01/28/2020</td>
<td>Team Member Request</td>
</tr>
<tr>
<td>02/02/2020</td>
<td>Question Development Finalization</td>
</tr>
<tr>
<td>01/2020 to 03/2020</td>
<td>Theoretical Models, Review of Literature and Tables of Evidence</td>
</tr>
<tr>
<td>05/2020 to 08/2020</td>
<td>Revision of DNP Parts I-III</td>
</tr>
<tr>
<td>08/19/2020</td>
<td>Permission Granted by the ADA to Use the ADA DRT Form</td>
</tr>
<tr>
<td>08/21/2020</td>
<td>Team Proposal Presentation</td>
</tr>
<tr>
<td>09/01/2020</td>
<td>Submission of Proposal to the Rutgers University IRB</td>
</tr>
<tr>
<td>09/12/2020</td>
<td>IRB Approval Granted</td>
</tr>
<tr>
<td>09/15/2020</td>
<td>Subject Recruitment Commenced</td>
</tr>
<tr>
<td>09/30/2020</td>
<td>Subject Recruitment Completed</td>
</tr>
<tr>
<td>10/09/2020</td>
<td>Study Conclusion</td>
</tr>
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<td>10/10/2020</td>
<td>Final Data Collection</td>
</tr>
<tr>
<td>11/04/2020 to 11/23/2020</td>
<td>Data Analysis</td>
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<td>Not Applicable</td>
<td>Final Team Presentation</td>
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<tr>
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<td>Final Defense</td>
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<td>12/11/2020</td>
<td>Protocol Deviation Submitted</td>
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<tr>
<td>03/12/2021</td>
<td>Protocol Deviation Resolved</td>
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<td>Event</td>
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<tr>
<td>------------</td>
<td>------------------------------------------------------------</td>
</tr>
<tr>
<td>03/23/21</td>
<td>Requested New Team Member</td>
</tr>
<tr>
<td>04/03/21</td>
<td>New IRB Approval Submitted</td>
</tr>
<tr>
<td>04/12/21</td>
<td>New IRB Approval Granted</td>
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<tr>
<td>04/23/21</td>
<td>Subject Recruitment Completed</td>
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<tr>
<td>05/07/21</td>
<td>Week 2 Group Counseling Follow Up</td>
</tr>
<tr>
<td>05/21/21</td>
<td>Week 4 Group Counseling Follow Up</td>
</tr>
<tr>
<td>05/21/21</td>
<td>Data Collection Conclusion</td>
</tr>
<tr>
<td>05/22/21 to 05/27/21</td>
<td>Data Analysis</td>
</tr>
<tr>
<td>05/28/21</td>
<td>Finalizing Team Presentation</td>
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<tr>
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<td>Submission of Final DNP Document</td>
</tr>
<tr>
<td>05/28/21</td>
<td>Submission of Final DNP Poster</td>
</tr>
<tr>
<td>TBD</td>
<td>Submission to Close Research Study</td>
</tr>
<tr>
<td>TBD</td>
<td>Final DNP Presentation</td>
</tr>
</tbody>
</table>
Appendix G

Site Letter of Cooperation

Date: 03/29/2021

Re: Letter of Cooperation From

Dear Aljenica Apostol,

This letter confirms that I, as an authorized representative of (name of institution), allow the co-Principal Investigator access to conduct study related activities at the listed site, as discussed with the co-Principal Investigator and briefly outlined below, and which may commence when the co-Principal Investigator provides evidence of IRB approval for the proposed project.

- **Research Site:**

- **Study Purpose:**
  The purpose of this DNP quasi-experimental project is to introduce important lifestyle modifications to prediabetes patients at an urban family primary care setting. With the introduction of a food and exercise log, weight monitoring pre and post-study and 2 15-minute remote group counseling sessions in a 4-week study period, the end goals include weight loss, increase in physical activity and improved food choices in pre-diabetic patients.

- **Study Activities:**
  Procedure:

  1. When IRB approval is obtained, the co-primary investigator (PI) will inform the project site of the start date of the project implementation.

  2. The co-PI will initiate the implementation on April 20, 2021 (tentative) and will commence on May 31, 2021.

  3. The project site agreement form will be reviewed by the co-PI with the PCP at the initiation of the project implementation. All project components including but not limited to recruiting subjects, requesting for consent for project participation, accessing subjects’ electronic medical records (EMR) and accessing the facility of the project site (use of office Wi-Fi and phone) will be discussed with the PCP.

  4. Covid-19 social distancing protocols per Rutgers University and the project site will be discussed with the PCP and will be strictly followed.

  5. The electronic patient chart will be accessed.

*Letter of Cooperation for Study: Introduction of the ADA Diabetes Risk Test Tool to Identify Prediabetes in Primary Care*
6. The co-PI will invite patients that have a documented Hgb A1c laboratory result between 5.6% - 6.5% within the last year.

7. The target subjects will then be contacted via the office phone number to request for consent to be included in the research project.

8. The consent form will include the following information for the subject:
   - The objective of the research project.
   - Who is involved in the research project.
   - The benefits of participating in the research project.
   - The subject agrees to take part in the research project.
   - The project timeline.
   - The subject agrees to participate in the data collection remotely (via telephone and email correspondence).
   - The subject can consent or decline by telephone to participate in the study. The subject can also withdraw from the study at any time without any repercussions.
   - The subject will be informed that there will be data collection (pre and post intervention). The subject will provide their most recent weight (scale-based) and document it on their initial food and activity log. The second data collection will require the subject to provide their completed 4-week food and activity log and most recent weight (scale-based) at the culmination of the study.
   - The subject will be informed that 2 group counseling sessions will be done remotely at the 2-week and 3-week study mark. This will be completed via Zoom. The subject agrees to provide their email address for this part of the study.
   - The subject will be compensated with a $5 Target gift card for completing the study.

9. The co-PI will designate an identification number to every subject that will be included in the study. The information (data points) will be collated in an Excel spreadsheet.

10. A final meeting via Zoom with the subjects will take place at the 4-week study mark. The co-PI will request the subjects to submit their completed food and activity log along with their most updated weight.

11. The following data will be collated in an Excel spreadsheet:
   - The total number of prediabetic subjects who participated in the research project
   - The total number of subjects who completed the research project.
   - The average weight loss.
   - The average number of minutes of physical activity.
   - The total number of subjects who lost weight in a 4-week study period.
   - The total number of subjects who had a 90-minute increase of physical activity a week.

12. The co-PI will discuss the results of the study with the provider and discuss the benefits of introducing food and diary logs to prediabetes patients in the practice.

   - **Subject Enrollment:**
Inclusion Criteria:
- Registered patient in the EMR
- New or established patient
- Non-pregnant
- Hgb A1c result between 5.6% to 6.5% within the last year
- English speaking patient

Exclusion Criteria:
- Diagnosis of diabetes with Hgb A1c of >6.5%
- Less than 18 years of age
- Currently pregnant
- Non-English speaking patient

- Site Support:

[Name redacted] allows the co-PI to implement her research project as outlined above. This practice allows the co-PI to access the electronic medical records for the purpose of subject recruitment and chart review. The co-PI was provided a username and password to access Kareo, the EMR provider of the practice. The practice also allows co-PI access to the office telephone and Wi-Fi in order to communicate with potential subjects.

- Data Management:

No subject identifier will be used in this study. An assigned identification number not related to the subject’s PHI will be used throughout the study. Any signed consent and food and activity log submitted electronically by subjects will be secured at Rutgers University’s repository for six (6) years. The Excel spreadsheet has no patient identifier and will be secured electronically via Rutgers University’s repository for 6 years. Electronically signed consents by subjects submitted electronically will be stored securely via the Rutgers University’s online repository. The PI, team member and the IRB are the only authorized personnel/governing body who has access to the research data.

- Anticipated End Date:
The anticipated date to conclude the research study is by May 31, 2021.

We understand that this site’s participation will only take place during the study’s active IRB approval period. All study related activities must cease if IRB approval expires or is suspended. I understand that any activities involving Personal Private Information or Protected Health Information may require compliance with HIPAA Laws and Rutgers Policy.

Our organization agrees to the terms and conditions stated above. If we have any concerns related to this project, we will contact the Principal Investigator. For concerns regarding IRB policy or human subject welfare, we may also contact the Rutgers IRB (see orra.rutgers.edu/hspip).

Regards,
<table>
<thead>
<tr>
<th>Signature</th>
<th>Date Signed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Name</td>
<td>Advanced Practice Nurse</td>
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<tr>
<td></td>
<td>Job Title</td>
</tr>
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</table>
Appendix H

Group Counseling Zoom Invitation

Nica Apostol is inviting you to a scheduled Zoom meeting.

Topic: Food and Activity Log Follow Up
Time: May 7, 2021 10:00 AM Eastern Time (US and Canada)
Every 2 weeks on Fri, until May 21, 2021, 2 occurrence(s)
May 7, 2021 10:00 AM
May 21, 2021 10:00 AM
Please download and import the following iCalendar (.ics) files to your calendar system.
Weekly: https://zoom.us/meeting/tJEvfuGurzotE9AiT4bMkECibz2hB9ulKDF-/ics?
icsToken=98tyKuC트DiIiHNWUtxCDRowMAIr4We7zmH5aj_p8ISuxAQ1YRYD_NPgQOpAmBdT7

Join Zoom Meeting
https://zoom.us/j/95298611794?pwd=eTJIQmp0VzZGeXVMejNvYTFuTmFEUT09

Meeting ID: 952 9861 1794
Passcode: 8z1Pnt
**EBP Question:** Will implementation of a supportive group intervention (that include monitoring and counseling) (I) promote weight loss and increase in exercise (O) in patients with pre-diabetes (P) in an urban family primary care setting?

<p>| Table 1 |
|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
| <strong>Article #</strong> | <strong>Author &amp; Date</strong> | <strong>Study Method</strong> | <strong>Interventions</strong> | <strong>Outcomes</strong> | <strong>Limitation/Notes</strong> | <strong>Evidence Level &amp; Quality</strong> |
| 1 | Cheng et al. (2019) | Cross-sectional study with samples representing the noninstitutionalized, civilian US population. | 3 cycles of NHANES data were combined for this study. Participants 20 years and older who were eligible for the study visited the mobile examination center for HgA1C measurement. A random group was selected for FPG levels after 8 to 24 hours of fasting. 2hPG levels were also measured after a 75-g oral glucose test. Post-stratification reweighting using an inverse probability weighting approach was used to account for participants excluded from | The study showed that between 2011 to 2016, Hispanics were among the highest in prevalence of undiagnosed and total diabetes. The 2hPG test detected the greatest proportion of undiagnosed diabetes in this particular study. | Cause-effect inferences are not possible due to cross-sectional study. Limited small sample size Diabetes type was not defined, diagnosed diabetes was self-reported and sample from noninstitutionalized civilians could mean underrepresentation some segments. | Level I-A |</p>
<table>
<thead>
<tr>
<th>No.</th>
<th>Author(s) (Year)</th>
<th>Study Design</th>
<th>Description</th>
<th>Findings</th>
<th>Level</th>
</tr>
</thead>
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<tr>
<td>2</td>
<td>Ali et al. (2019)</td>
<td>Cross-sectional study</td>
<td>Patient eligible for the study, those who are 18 years or older, nonpregnant, non-institutionalized civilian patients, provided informed oral consent before participation.</td>
<td>Data generated from the study showed that individuals with prediabetes are more likely to gain diabetes-risk reduction advice by providers as compared to those who are not prediabetic. The study also found 3 specific gaps why efforts to expand the diabetes prevention lifestyle modification (LSM) programs are insufficient.</td>
<td>Cross-sectional data used are for the present and does not account lifestyle changes that may have occurred after a patient was diagnosed with prediabetes years ago. Self-reported data may be subject to recall and biases.</td>
</tr>
<tr>
<td></td>
<td>Authors</td>
<td>Study Type</td>
<td>Methods</td>
<td>Findings</td>
<td>Level</td>
</tr>
<tr>
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<td>--------------------------</td>
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<td>--------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>3</td>
<td>Haw et al. (2017)</td>
<td>Systematic Review and meta-analysis</td>
<td>Databases such as MEDLINE, EMBASE, Cochrane Library and Web of Science were searched for articles that are eligible.</td>
<td>This study showed that even though medication were effective in preventing diabetes, LSM strategies were the ones that are sustainable in the long run. Individuals who participate in LSM interventions had lower risk for diabetes than the control group. The study also found that “every kilogram of weight lost was associated with an additional 7% decrease in risk of progression to diabetes”.</td>
<td>Level I - A</td>
</tr>
<tr>
<td>4</td>
<td>Shahraz, S., Anastassios, G.P., &amp; Kent, D. M. (2016)</td>
<td>Cross-sectional study</td>
<td>Data was extrapolated from the National Health and Nutrition</td>
<td>Those found at risk were advised to visit their providers for “A valid method to examine for prediabetes should avoid”</td>
<td>Level I - A</td>
</tr>
</tbody>
</table>
### Examination Survey from 2013 to 2014 and those older than 18 years without type 2 diabetes had their risk scores calculated for prediabetes risk through 7 questions.

### a blood glucose test.

### unnecessary medicalization by labeling a disease predecessor as a medical condition…”

<p>| | | | | |</p>
<table>
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<tbody>
<tr>
<td><strong>5</strong></td>
<td>Carrasquillo, O., Lebron, C., Alonzo, Y., Li, H., Chang, A., &amp; Kenya, S. (2017)</td>
<td>Single-blind, randomized clinical trial</td>
<td>CHW intervention consisted of 1 year of home visits, phone calls and group-level activities.</td>
<td>The study showed that a community health worker intervention lowered the HgA1c levels in participants by 0.51%. The study was limited to a year. Per the authors, to be more effective in the future outcomes, CHW interventions may need to be ongoing.</td>
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<td><strong>6</strong></td>
<td>Balducci et.al. (2019)</td>
<td>Open-label, assessor-blinded, randomized clinical superiority trial</td>
<td>Participants were divided between intervention and standard group. The intervention group received “1 individual theoretical counseling session and 8 individual biweekly theoretical and practical counseling sessions each year”. Those in the standard group only received general physician recommendations.</td>
<td>The intervention group had a notable increase in physical activity and decrease in sedentary time when the intervention was implemented.</td>
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<tr>
<td>#</td>
<td>Author(s)</td>
<td>Methodology</td>
<td>Findings</td>
<td>Study Limitations</td>
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<td>7</td>
<td>Dearinger, A., Ingram, R.C., Pendley, R., &amp; Wilding S. (2013)</td>
<td>Pre and post intervention surveys</td>
<td>An on-site QI training and facilitation was delivered to six local health departments. A QI project was implemented after to see if there in an improvement in outreach and delivery of DSME. Participants who completed the entire DSME course increased by 100%. There was also an increase in referrals and healthcare providers, about 15% increase, had referred patients to local health departments for Diabetes Self-Management Education (DSME). Only a small amount of local health departments participated. The local health departments (LHD) were also only located in one state. In addition, the study had no control groups for comparison.</td>
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<td>8</td>
<td>Tomky, D. (2013)</td>
<td>Scientific literature review</td>
<td>Reviews of DSME, its current challenges, importance of integration in clinical care, were discussed. DSME faces challenges in the current fee for service environment. The paper is not a systematic literature review or meta-analysis of diabetes education.</td>
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<tr>
<td>9</td>
<td>Shaak et al. (2018)</td>
<td>Bilingual cross-sectional mailed survey</td>
<td>A 34-question survey was mailed to a registry of Hispanic adults with a diagnosis of prediabetes and HgA1c between 5.7-6.4. Study showed that participants had moderate knowledge of reasons that can cause diabetes. There is an increase in worry and personal control about progression of the</td>
<td>Study is limited to one health system in one geographic area which could mean limited generalizability.</td>
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</tbody>
</table>
disease. Those with higher educational attainment have increased overall knowledge about risk of developing diabetes. Level of education plays a role.

<table>
<thead>
<tr>
<th>10</th>
<th>Voelker, R. (2019)</th>
<th>Article</th>
<th>Identifying gaps and barriers in primary care regarding Type 2 diabetes prevention</th>
<th>Gaps include lack of referral and resources in obtaining the basic necessities such as grocery stores that sell healthy food or spaces for physical activity.</th>
<th>Non-research article</th>
<th>Level V - B</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Centers for Disease Control and Prevention</td>
<td>Website</td>
<td>What is prediabetes</td>
<td>Guidelines regarding prediabetes.</td>
<td>Non-research article</td>
<td>Level IV - A</td>
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