Multidisciplinary Interventions to Decrease Diabetes Prevalence

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Abstract

Problem statement: Having pre-diabetes may be undetected for years without the person ever knowing, they are at risk for diabetes. Without early identification of a person's risk factors, the window of preventative opportunity can slowly close.

Purpose: Healthcare providers are in a unique position to have a direct impact on patient health outcomes. Prevention is better than a cure, and trying to keep a person healthy for as long as possible is the reason for preventative practices (Hancock, 2018). If risk factors are identified early, diseases such as diabetes can be prevented or delayed.

Methods: Quantitative methods were used to evaluate if pre-diabetes education related to diet and exercise modification among those whose CDC pre-diabetes screening tool scores reflected their increased risk for acquiring diabetes. Inter-professional collaborative meetings with specialized healthcare professionals, including a doctoral level trained physical therapist, a licensed dietician, as well as a registered nurse, were held every 2-3 weeks. During these meetings adjustments were made to the participants' diet and exercise regimen. Participants were asked to repeat the screening test at the end of 8 weeks to verify if the education impacted their initial scores.

Results: A paired *t* test was conducted to compare pre-diabetes screening scores before and after the implementation of pre-diabetes educational interventions among 14 voluntary participants. The test was also used to identify how the education affected both the physical activity level of the participants and the body mass index scores. These two scores were the only two modifiable numbers on the screening tool. The repeated screening scores revealed with a 95% confidence interval, that the educational interventions reduced participants' risk factors.

Conclusion: Healthcare providers, who have direct care with patients can provide early

interventions. Early screening for pre-diabetes, with educational interventional tools such as proper diet and exercise regimens, can help to reverse or delay the onset of diabetes among those at risk.

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CHAPTER I

Multidisciplinary Interventions to Decrease Diabetes Prevalence

Each year, over 3.8 million people die from diabetes and its complications (Yoon, Kwok, & Magkidis, 2013). Having pre-diabetes is an indicator that one is at risk for diabetes. The purpose of this project will be to identify helpful interventions which have supported the prevention of diabetes in those with pre-diabetes. Such interventions include diet and exercise, along with proper education, with the assistance and guidance of a multidisciplinary health care team. Through interventions, education, and encouragement, individuals will be given the tools to modify their lifestyle in order to practice a healthier one.

Background and Significance

Before being diagnosed with diabetes, many people are diagnosed with pre-diabetes because they have blood glucose levels higher than normal but not high enough to have diabetes. According to the Centers for Disease Control and Prevention, "Over 100 million people are living with diabetes or pre-diabetes in the United States. Approximately, 84.1 million of these individuals have pre-diabetes, and if early interventions are not implemented they are at risk to develop Type 2 diabetes (T2D) within five years" (Centers for Disease Control and Prevention [CDC], 2017, para. 1). The impetus for this project is the enormous costs to the healthcare system related to complications from diabetes and the increase in the diagnosis of diabetes, where "1.5 million Americans are diagnosed with diabetes every year" (American Diabetes Association, 2018, para. 4). The factors that give rise are many, but this study will focus on the lack of knowledge for individuals with pre-diabetes. Understanding that pre-diabetes can be delayed or reversed through various interventions is what this study will address.

Pre-diabetes often has no symptoms. However, a screening questionnaire can assist in

identifying if one has pre-diabetes by answering a few basic questions. These questions include the individual's age, gender, family history, any history of gestational diabetes, if the individual has high blood pressure, level of physical activity, and weight.

It is important to identify pre-diabetes early as well as provide proper interventions because, with early intervention, risk factors can be reduced. The goals of the project are to provide educational services that will help lower risk and assist in preventing or delaying the onset of diabetes through education about appropriate diet and exercise. By losing 7% of one's body weight with proper diet and exercising in moderation (e.g., walking 30 minutes a day, 5 days a week), this diagnosis could be reversed. Considerable research has shown that pre-diabetes risk factors are reduced by 50% with these interventions (American Diabetes Association, 2014). This project will be done in an outpatient clinic in a small hospital in an Eastern state. The clinic treats patients with renal, HIV/Aids, and podiatric conditions. Many of these patients may not know that they are either at risk or have pre-diabetes. They are the patients which will be the focus of the study.

Problem Statement

Pre-diabetes is a significant indicator that, without proper intervention such as diet and exercise, becoming diabetic is a real possibility. The CDC (2017) stated that one can have pre-diabetes for years without knowing it because there are no clear symptoms. This is especially true in patients who are 45 years or older, overweight, have a close family member with T2D, are sedentary, have a history of gestational diabetes during pregnancy, or have polycystic ovarian syndrome. A report from the American Diabetes Association (2018), *Healthy People 2020*, seeks to reduce the incidence of diabetes by various interventions. Understanding that having pre-diabetes does not necessarily mean one will get diabetes, as long as proper interventions are

utilized. A lack of knowledge such as this will be the focus of this project.

Aim of the Project

The goal of this project will be to provide appropriate education and follow-up care for those at risk for diabetes, specifically those with pre-diabetes. In order to demonstrate that a diagnosis of diabetes can be prevented or delayed, volunteers with pre-diabetes will be educated on lifestyle modifications involving diet and exercise. A team of healthcare providers, including a physician, a doctor of nursing practice (DNP) student, dietician, and physical therapist presented plans for participants to follow. Participants visited the clinic routinely for other appointments and pre-diabetes services were added to pre-existing appointments. They were asked if they complied with the regimen suggested for them. If the team determined that more teaching was needed based on the participant's answers, more education was supplied.

Providing proper education was the main objective of this project and was done using educational material and detailed instructions prepared by the DNP student and the project team members. Providers discussed risk factors for diabetes and gave interventions recommended by the CDC. Project team members discussed with participants the appropriate diet to follow based on current diagnoses and any comorbid conditions. In addition, project team members shared beneficial exercise regimens according to the participants' abilities. The hope was that this education would increase awareness that prevention is possible. In order to assess if one is at risk for pre-diabetes, a screening tool provided by the CDC, entitled the *CDC Pre-Diabetes Screening Test*, was administered to participants to determine if they met the criteria for the project.

The study was done to support the premise that lifestyle modifications will help delay or reverse pre-diabetes, and is the basis for this project. Two other goals were the importance of

diet and exercise and their contribution to positive outcomes. Another project objective was to contribute to the reduction of the prevalence of diabetes and, according to *Healthy People 2020*, a goal is to reduce the number of new cases of diabetes diagnosed annually in the population. There are eight new cases of diabetes per 1000 people ages 18-84 each year. The target for *Healthy People 2020* is to reduce this to approximately seven new cases, which would be an estimated 10% reduction in the incidence of diabetes in the United States by the year 2020 (American Diabetes Association, 2010).

Clinical Question/PICOT

PICO/PICOT questions are directly relevant to the problem at hand. The format of the PICO/PICOT facilitated the search for these answers, which made the search process easier (Evidence-Based Practice: PICO, 2017). Having synthesized evidence from 10 research articles, the central PICOT question for this project was: How does a lifestyle having a healthy diet and exercise, compared to a sedentary one, influence the reversal or delay in acquiring diabetes over an 8-week period? The project focused on the results of the pre-test screening tool provided by the CDC. If the results added up to five or above, then one is at risk for pre-diabetes. The goal of this project was to reduce this number in order to suggest that the risk of developing pre-diabetes was lowered through interventional services. The hope was that participants accepted and used these services and continued to incorporate the interventions. Another hope was that these services will continue at the clinic after the project ended.

Congruence with Organizational Strategic Plan

The project was conducted in a clinic inside a small hospital in an Eastern state and was guided by the quality portion of the mission statement, which states, “We believe in continuous quality of care and performance improvement as the foundation for preserving and enhancing

healthcare delivery. Effective communication and education of our patients, physicians, staff, and the community we serve are essential elements in this process" (St. Mary's General Hospital, 2018, Missions and values, para. 2). The benefits of proper diet and exercise were evident in the data collected for this project and their results served as a foundation. The clinic provided a venue for this project.

To enable this project, the hospital which housed the clinic allowed the project team to screen volunteers using the CDC screening tool. Patients that were being seen in the clinic for other conditions and follow-up care were screened. The interventions for the DNP scholarly project were completed when the participants arrived for their scheduled appointments and were conjoined with their current treatments. Effective communication, with appropriate education from the interdisciplinary team, provided support and guidance for those with pre-diabetes, and thereby allowed them the opportunity to reduce their risk from this diagnosis and start the road to a healthier life. The project helped to promote interventions through education. This project supported the hospital's mission statement and provided a valuable asset for patients coming to the clinic.

Search Strategy

Evidence that diet and exercise can reverse or delay pre-diabetes to diabetes is indicated in many studies. The two main databases used to research these studies were Cochrane and CINAHL. In the CINAHL database, the keywords used were pre-diabetes and pre-diabetes prevention. When searching for pre-diabetes alone, the search resulted in 481 articles. Adding 'prevention' to the search, gave 144 articles, eliminating 337. Additional limits were placed to include only studies conducted from 2007-2017, which then yielded 136 studies. Similarly, the Cochrane database was used. However, the keywords used were 'diabetes prevention studies',

which gave 61 articles. These were then limited to the years 2007-2017, which then showed 56 results. In total, 192 studies were eligible for review. Of those, additional limitations were placed, yielding articles that discussed metabolic syndrome, lifestyle modification, and diabetes awareness. It was further narrowed because of the inability to access the full article, due to access limitations. Studies were kept because of their detailed analyses of interventions and results, many of which were randomized control studies. Some studies were eliminated because they did not provide enough significant support to report on, thus resulting in only 10 studies that were used.

Synthesis of Evidence

Evidence provided from the 10 articles was examined to support the idea that many factors affect the likelihood of those who have pre-diabetes going on to develop T2D. These articles included lifestyle modification, metabolic syndrome, and diabetes awareness that supported interventions and services to help individuals with pre-diabetes reverse or delay their risk of acquiring diabetes. These articles were grouped in order to provide proper services for those with pre-diabetes.

Lifestyle Modification

Lifestyle modification was addressed in many diabetes prevention studies. Adjustments during pre-diabetes help to reduce diabetes. These are exercise, diet modification, and proper monitoring. Studies conducted regarding a number of topics that support this hypothesis found a positive correlation indicating that these methods are effective. Orozco et al. (2007), Gilis-Januszewska, (2016), Penn et al. (2013), and Mutie, Giordano, and Franks (2017) conducted studies regarding the effect of lifestyle modification on pre-diabetes. Orozco et al. (2007) conducted a randomized control study for six months and Gilis-Januszewska (2016) conducted a

similar study in Europe which ran for over three years. Both studies revealed that the benefits of exercise and diet change together reduced the incidence of T2D for those with pre-diabetes. Penn et al. (2013) conducted a larger study that ran for over 3 years.

Researchers also addressed the positive benefits of lifestyle change for those with pre-diabetes. The study included weight loss and maintaining that loss, as well as an appropriate diet. Lastly, Mutie et al. (2017) provided strong evidence that lifestyle modification positively effects the pre-diabetes diagnosis, and referenced numerous randomized control trials and cohort studies. Using the combined results of these studies, Mutie et al. determined that biomarkers could be identified.

Orozco et al. (2007) used quality of reporting of meta-analyses (QUORUM), flow-chart of study selection to determine their results. The study revealed overall improvement from baseline to follow-up of fasting plasma glucose values. Gilis-Januszewska (2016) had 105 participants and approximately had impaired fasting glucose. Also, 14% had impaired glucose tolerance. The results of this study revealed that the mean weight of participants decreased by 2.27 kg after one year. After three years a weight gain of 1.13 kg was observed. In comparison with baseline data, however, mean total weight loss at the end of the study was 1.14 kg.

Diabetes risk declined after one year by 2.8kg and the decreases of 2.26 kg were maintained after three years. Body mass reduction by more than 5% was achieved after one year by 27% of participants and after three years by 19%. Repeated measures analysis revealed significant changes observed from baseline to year one and year three in weight, body mass index (BMI), total cholesterol, triglycerides, fasting glucose level, and Finnish diabetes risk score (FINDRISC) parameters. The conversion rate to diabetes was 2% after 1 year and 7% after 3 years (Gilis-Januszewska, 2016).

Penn et al. (2013) used studies from three European trial cohorts involving 749 adults with impaired glucose tolerance (278 men and 471 women). They had a mean age 56, mean BMI of 31, and were recruited between 1993 and 2003. The data was randomized for intensive lifestyle intervention (I) or lifestyle advice control (C). It was found that lifestyle modifications were major contributors to reducing diabetes. Results revealed the mean follow-up duration was 3.1 years. T2D was diagnosed in 139 participants (I = 45/379, C = 94/370). Cumulative T2D incidences were 57% lower in the intervention group compared to the control group. Participants with more than a 5% weight loss at one year had a 65% lower T2D incidence. Maintaining that level of weight loss for two and three years further reduced T2D incidence (Penn et al., 2013), indicating again that lifestyle modifications impact a diagnosis of pre-diabetes.

With the results that Mutie et al. (2017) obtained, they determined that biomarkers could be identified. Though no statistical data were available, the team found that the combined efforts of multiple studies revealed therapeutic targets to identify biomarkers that can be used to inform health decisions and/or design new therapeutic strategies. With such information, optimizing the design, timing, or delivery of lifestyle interventions is possible.

Metabolic syndrome. Metabolic syndrome was also researched because it is a group of risk factors that include high blood pressure, high blood sugar, unhealthy cholesterol levels, and abdominal fat. High blood sugar levels in metabolic syndrome relate to pre-diabetes risk factors. Four of the studies that were chosen for this project identified metabolic syndrome and the benefits of its early detection to facilitate intervention for those who met criteria for pre-diabetes. The studies involve those who are overweight due to the lack of physical activity, and who had high blood sugars. According to Hale et al. (2013), 79 million U.S. adults have pre-diabetes, and 10% of this population will develop diabetes each year. Their study was a randomized control

study conducted by the Healthy Living Partnerships to Prevent Diabetes and involved 301 individuals who were overweight and had pre-diabetes. Their research supported the hypothesis that physical activity can prevent metabolic syndrome. The results of this study lead us to believe that increasing physical activity not only helps those who are overweight or obese reduce the likelihood of acquiring metabolic syndrome, but can also prevent diabetes in those who have pre-diabetes (Hale et al., 2013).

Katula et al. (2011) and Kerrison et al. (2017) studied the effects of interventions in pre-diabetes and both teams provided support for them. Katula et al. (2011) conducted a yearlong study showing that a diabetes prevention program (along with results from FINDRISC) could give positive results from lifestyle changes. Kerrison et al. (2017) provided evidence that proper nutrition and exercise can prevent patients from developing diabetes, as reflected by their glycemic control. It also examined the effects that diet and exercise had on BMI and weight change when glycemic control was optimal. Kerrison et al. concluded that promoting healthy eating and moderate physical activity were beneficial for individuals with pre-diabetes.

Katula et al. (2011) examined the first-year results of a community-based diabetes prevention program. Lifestyle changes, including weight loss intervention, a focus on fasting glucose levels, insulin resistance, and adiposity of the subjects, were examined in the study. Kerrison et al. (2017) examined nine studies that strongly indicated that healthy eating and an increase in physical activity were beneficial and reduced pre-diabetes.

Katula et al.'s (2011) study involved 301 randomly assigned overweight and obese volunteers (BMI 25-40 kg/m) and fasting blood glucose values between 95 and 125 mg/dL results, charted in a flow chart, revealed that compared with usual-care participants, intervention participants experienced significantly greater decreases in blood glucose, and homeostasis model

assessment of insulin resistance. This study provided additional insight that suggested that physical activity can be an excellent preventative intervention to avoid diabetes (Katula et al., 2011).

Kerrison et al. (2011) included systematic review studies completed over a six-month to five- year period. Participants were followed-up for an additional 36 months. Researchers found the combined incidence of diabetes was significantly reduced in the intervention groups compared to control groups. Glycemic control was also improved in the short-term, with many participants reverting to normo-glycemic. Multiple results from a number of studies revealed that with reduced BMI through exercise, patients improved their likelihood of avoiding T2D. However, 16% of this population regained weight.

Katula et al.'s (2011) study emphasized the importance of continued monitoring. Their study ultimately revealed, like that done by Kerrison et al. (2017), that participants in weight loss intervention had significant decreases in blood sugar. Compared with usual care participants, those who altered their lifestyle had improvements in their homeostasis model assessment of insulin resistance. Weight, BMI, and waist circumference were all reduced significantly at $p <$ .001 (Katula et al., 2011).

Yoon et al. (2013) had positive findings in their study regarding the importance of diet, in conjunction with exercise, through a systematic review of randomized controlled trials. They reviewed studies conducted worldwide, which had a combined total of 5,663 participants. This large study reported statistically significant reductions in diabetes incidence because of lifestyle interventions, compared to control groups. There was a lower incidence of diabetes in intervention groups (3% to 46%) compared with control groups (approximately 9% to 67.7%). Five randomized control trials reported statistically significant reductions in diabetes incidence

because of lifestyle interventions compared to control groups (28.5% versus 64.7%). There were no significant differences between the makeup of intervention and control groups. Metabolic syndrome may be an indicator for certain individuals who are more susceptible to diabetes and that is why it is important to identify these individuals; they may have pre-diabetes.

Diabetes awareness. Diabetes awareness is a key component in identifying the need for intervention. Philips (2014) and Silfee et al. (2016) analyzed healthcare professionals' awareness of identifying pre-diabetes, so early prevention can take place. The awareness includes appropriate interventions, such as diet, exercise, proper monitoring, and follow-up care. Health care professionals are often the first line of defense for patients and this role should not be taken lightly. Understanding the complications of diabetes is highly relevant and should be discussed with all those who have pre-diabetes. T2D complications can include cardiovascular disease, damage to nerves, kidneys, eyes, feet, and skin, among others (Diabetes, 2014). Philips (2014) emphasized that educating healthcare professionals about the risks of diabetes will help them stay alert to the importance of intervention for these individuals. The results of Philips' study, which revealed a 50% increase in T2D due to an increased BMI and limited physical activity, is one reason diabetes awareness is important.

Silfee et al. (2016) also emphasized that awareness is the first step in prevention. Identifying certain interventions for those with pre-diabetes can lead to their success. Awareness also helps individuals manage their pre-diabetes status and can have long-term benefits resulting from maintaining a healthy lifestyle. The researchers discussed how interventions to prevent T2D through lifestyle changes affect physiological measures, dietary behavior, and physical activity in adults who have pre-diabetes. Their study involved 30 adults with pre-diabetes in southern Taiwan who were assigned to either the intervention group (n = 15)

or control group (n = 15). The results revealed a significant improvement in physical activity and dietary behavior in the intervention group compared to those who had no awareness of the risk factors for diabetes. Three months after intervention, the intervention group showed a 3.80% mg decrease in mean fasting glucose (p = .008) and 0.43-kg decreases in mean BMI (p = .035). This determination was made using a quasi-experimental, pre-post-test design (Silfee et al., 2016).

Conclusion

Pre-diabetes is a diagnosis that has been on the rise and precedes Type 2 diabetes. However, with early intervention, this diagnosis does not have to be permanent. Many studies that were evaluated suggested that with proper intervention and education there is a good likelihood for a better future for those with pre-diabetes. These studies supported interventional services for those who have pre-diabetes in order to assist them to live healthier lives. Orozco et al. (2007), Gilis-Januszewska (2016), Penn et al. (2013), and Mutie et al. (2017) all conducted thorough investigations evaluating the effects that lifestyle modification can have on those who have pre-diabetes. Their studies supported the conclusion that proper diet and exercise significantly decreased the chances of developing diabetes.

Katula et al.'s (2011) and Kerrison et al.'s (2017) studies considered that those presenting with metabolic syndrome benefit from proper diet and exercise. Because metabolic syndrome includes diabetes as a risk factor, controlling symptoms associated with it might reduce the likelihood of acquiring diabetes as well. Philips' (2014) and Silfee et al.'s (2016) studies also provided evidence that diabetes awareness can predict a patient's outcome. If a healthcare professional or patient do not understand the severity of the diagnosis, then they may not seek any interventions.

Ultimately, all these studies identified and had supporting evidence that proper diet and

exercise are crucial in the effort to treat this diagnosis. One of the most important things to understand is that interventions should have continued follow-up care.

I chose this project because the objective is focused on the critical need for services in those with pre-diabetes. The synthesis of evidence helps to reinforce the numerous reasons why early intervention is needed and so important in the reduction of diabetes. Lifestyle change is a treatment that often is overlooked, and could, quite possibly, be the most challenging option, but probably one of the best options available. Through the process of interventions and collaboration among disciplines, which include the dieticians, physical therapists, medical doctor (mentor), and the DNP student, the hope is that the project highlights the benefits of early intervention.

Critique of Evidence

Strengths are seen in these studies because many were randomized control studies. Such studies are ranked near the top on the evidence-based pyramid (i.e., they are strong). Studies located at the top have the highest level of critical appraisal and analysis, while those on the bottom of the pyramid are subject to a lower level of critical appraisal (Evidence-Based Nursing Research Guide: Evidence Strength, 2017). In addition, these studies had results that were statistically significant, which adds to the objectivity of the data and confirms their confidence values.

Philips (2014) provided the reader awareness that prevention still needs to be addressed. Despite a lack of numerical or statistical data, the study did reflect the effectiveness of interventions.

Silfee et al.'s (2016) research had statistically significant correlations concerning interventions that were reflected in participants BMI and lab work, which revealed improvement

in the person's pre-diabetes status. However, the study had limitations, which included a lack of information about those enrolled in the programs. This made it difficult to determine if other factors contributed to their improvement.

For many studies, their strength was their research design. Kerrison et al. (2017), Hale et al. (2013), Orozco et al. (2007), Mutie et al. (2017), and Yoon et al. (2013) conducted studies using methodologies on the higher portion of the critical appraisal pyramid mentioned above. The weakness of these studies varied. For example, Yoon et al. did not include quality of life outcomes. A weakness was found in the research done by Hale et al.: the researchers did not discuss whether patients who were part of the study were aware of the benefits of interventions. This lack of knowledge could affect how seriously they pursued follow-up care.

Other studies (Gilis-Januszewska (2016), Katula et al. (2011), and Penn et al. (2013)) were strong in that follow-up was present, and they were conducted over an extended period. Time is an important factor when conducting this research because it reflects the benefits and long-term effects of the interventions. These studies, however, had similar weaknesses because they did not specify whether the patient was newly diagnosed with pre-diabetes or had a previous diagnosis. Newly diagnosed individuals are more likely to have not started any interventions, while those who know their diagnosis may have already attempted interventions and not succeeded. This can cause discrepancies because the evaluator will not have a true baseline for the subjects.

Implications for Practice

The implications for practice for this project were to monitor participants' progress throughout lifestyle modification interventions and reduction of BMI scores. This included

identifying any gaps in knowledge by the project team, after evaluating each participant's educational needs of diet and exercise regimens. Evaluations were based on responses to the CDC screening tool, as well as talking with participants about their current diet and what they interpreted as physical activity. This initial evaluation helped the project team provide appropriate educational needs so participants could truly benefit from the pilot project. The project team met every few weeks to determine if additional education was needed. The planned interventions for the DNP scholarly project were part of participants' current treatment.

The DNP student obtained IRB consent to conduct the project because human subjects were involved. Informed consent was also obtained from each person willing to participate. All members of the team were versed in HIPAA requirements in order to maintain patient confidentiality.

Theoretical Framework

Bandura's social learning theory was used as the framework for this project in order to understand and identify gaps in knowledge for those with pre-diabetes. The theory states that people are able to learn through experience or by observing others. Social learning theory is used to determine how people perceive information and if their experience will affect future decisions (Price & Archbold, 1995). This theory was used to identify educational needs and whether participants retained information. Bandura explained that the interpretation of experiences is affected by personal, social, and situational factors (Bandura, 1977).

Self-efficacy involves a mastery of experiences also known as performance accomplishments. The principle identifies the individual's willingness to change (Bandura, 1977). Individual self-efficacy is affected by personal motivation. An unmotivated individual compared to a highly motivated one would lack the self-efficacy needed to establish goals

(Bandura, 1977). The reason voluntary participation is important is because it shows willingness on one's part, which is a form of motivation. Willingness to learn about a condition is the first step to change.

Bandura's (1977) second principle, vicarious experience, is described as imitating actions in order to acquire the skills at which others excel. For this project, this principle applied to educating participants about the benefits of diet and exercise for those with pre-diabetes. Telling patients that their risk lowers with these changes helped convince them to pursue these options. If they chose to pursue these interventions, and were successful, they contributed to the project's success by becoming models. This can set a precedent for future patients in the clinic to also use these interventions.

Bandura (1977) theorized that verbal persuasion is the third portion of self-efficacy. This principle states that individuals maintain efficacy even when others who have the power to influence them, provide support. During this project, the role of the project team was to consistently encourage and support participants to reach their goals.

The final principle that Bandura (1977) discussed was a physiological and affective state, or emotional arousal. It is described as the reaction a person would have when in a stressful situation. If a reaction to a stressful situation were negative, then a poor outcome would result, and vice versa. After a screening process that indicated if one is at risk for pre-diabetes, individuals likely felt some anxiety about the results. This may have been the first time they were given such news and may have felt overwhelmed. The project team helped guide these individuals to look at the positive side of being screened early so that prevention was possible in order to alleviate any fears that would affect the outcome. These principles of self-efficacy helped the project team provide personalized interventions so each participant could achieve

optimal results.

CHAPTER II: Methodology

Needs Assessment

Diabetes has become increasingly prevalent and yet it seems that early interventions to prevent this are merely a recommendation by healthcare providers rather than a prescribed treatment plan. Adding interventions to reduce the incidence of diabetes to a patient's treatment plan, was a fundamental purpose of this project. Implementing the project created an increased awareness of the importance of pre-diabetes education needs. Some of the podiatrists and the clinic manager are considering requesting similar services at the clinic in the future.

The clinic services many patients in the community the main demographic that the project team educated were from the Hispanic community.

Project Design

A pilot project was implemented using a pre-diabetes risk test, before and after the interventions, in order to answer the PICOT question. The evidence provided from 10 articles, discussed interventions that support preventing diabetes. This project put into action interventions in an attempt to prevent diabetes in a population at risk. The main variable was choosing the appropriate interventions involving diet and exercise. To determine if the interventions were implemented correctly, initial scores on the CDC screening tool were compared to those obtained eight weeks later.

The CDC screening tool suggests that persons are at risk for pre-diabetes if their score is five or above. Questions on the screening tool that cannot be influenced include age and gender. The two questions on the screening tool that can be affected are BMI and activity level. The questions that can be affected were the focus of the project and used in order to suggest

appropriate educational interventions to influenced participants' risks for pre-diabetes. The participants were evaluated, at their scheduled follow-up appointments about their understanding of the education that was provided and their compliance with it. The initial project goal was to recruit a sample of at least 20 individuals with pre-diabetes. However, only 14 participants were willing or able to participate for the duration of the project.

We wanted to know whether a positive impact could be made with proper education regarding diet and exercise in those with pre-diabetes. To determine if the education was beneficial, a decrease in the re-screen scores on the CDC tool would be needed.

Setting and Population

The setting of this project was an outpatient clinic in a small Northeastern hospital whose demographics data was: 45.06% White, 10.64% Black or African American, 1.07% Native American, 4.36% Asian, 0.04% Pacific Islander, 33.37% from other races, 5.47% from two or more races, 71.02% Hispanic or Latino of any race. The median age for this community, is 29.2 (Passaic, NJ, 2018).

The clinic provides care for patients who have renal, podiatry and HIV/AIDS needs. The majority of the participants for this project were Hispanic/Latino. In the U. S., among Hispanic or Latino groups, roughly 16.9% of both men and women have diabetes, compared to 10.2% for non-Hispanic Whites with diabetes (Alexandria, 2014). Therefore, the setting for the project created a focus towards Hispanic or Latino groups who are at high risk for developing diabetes.

Project Plan

After IRB consent was received, interventional services were provided to assist those who have pre-diabetes. They visited the outpatient clinic, in order to improve their ability to avoid T2D or reversing their risk of doing so**.** The interventions were an adjunct service to those

already being provided to current or former podiatry patients of the clinic. Those who took the CDC screening test for pre-diabetes and fit the criteria were given educational interventions about appropriate diet and exercise plans. A physical therapist provided education for increasing activity levels using a Rating of Perceived Exertion (RPE) scale in order to help participants identify their limits. A nutritionist provided information about diet and portion control techniques for those at risk for pre-diabetes or had other comorbidities. At the end of the 8-week project, participants were asked to repeat the pre-diabetes screening test and their scores were compared to their initial screening score.

Implementation Process

Interventional services that were provided included education on how long and what kind of physical activity should be attempted, what kinds of foods should be eaten, as well as the portion and frequency. Throughout the project, participants returned to the clinic for appointments for other conditions, and were given reinforcement or additional educational assistance by the DNP student about what they should do to minimize pre-diabetes risk factors. A project team member saw each participant at least three times during the project. Collaboration took place with team members about each participant's plan of care. Team members assisted in planning effective interventions every three weeks (Moran et al., 2016). The meetings between team members helped determine if participants needed additional education or reinforcement, based on their initial education.

During team meetings, a determination of appropriate diet and exercise regimen was made and documented, along with goals for each participant. All information, which included team members' progress notes and educational needs of participants were documented every three weeks. The education provided by the team came directly from the CDC curriculum to

prevent T2D. The CDC has provided permission for public use of their material, so long as no alterations or revisions were made.

Outcomes

The overall goal of *Healthy People 2020* is to reduce the prevalence of diabetes. Another goal is to reduce the CDC's prediction that 40% of Americans will develop diabetes in their lifetime (CDC, 2014). The DNP student analyzed the results of the education component and compared it with the literature chosen for this project by using the CDC's pre-diabetes risk tool. Scores from the initial screen were compared to a screen done at the end of the project

Diagnosing an individual with pre-diabetes gives the clinician a unique opportunity to provide early intervention to delay or reverse the prospects of having T2D (Eikenberg & Davy, 2013). Once the project launched, data collection included the scores of each participant on the CDC pre-diabetes risk test. Those who scored a five or higher were asked if they would like to participate in the project and were asked to sign an informed consent, which outlined the project thoroughly. There were 20 volunteers who qualified and signed consent forms initially, but only 14 completed the project. The recruitment process was initially scheduled for two weeks but had to be extended an additional week because some participants did not disclose that they already had been diagnosed with T2D. This was discovered when analyzing patients' medical charts to obtain medical histories. Seven participants were then released from the project.

Volunteers were initially seen in private rooms after their doctor appointments. They were weighed, and asked about their level of activity. Based on their responses, they were given preliminary diet and exercise education from the *Prevent T2* curriculum provided by the CDC and based on their current recommendations. Participants were also asked about their eating habits. Based on this feedback, project team members made adjustments which included portion

control, plate size, and between meal snacking options.

Those who completed the entire project remained focused and positive, and many did reduce their initial scores by one point. The hope is that this education will continue to be used by these individuals throughout their lives, so they may prevent or delay becoming T2D.

Procedures for Data Collection

Evaluation and sustainability plan. Individuals coming to the outpatient clinic were given a questionnaire that evaluated their risk for diabetes. Volunteers who scored a five or more on the screening test were asked to participate in the project. After consent forms were signed, charts were created using only the participants' dates of birth and initials as identifiers. The charts contained the education that was provided to the participant, as well as the progress notes from project team members during the project. The initial pre-diabetes screen was also placed in the participants' chart. At the completion of the project it was compared to the second screening, and used to determine if the interventions were successful. The DNP student educated each participant on proper diet and exercise routines, based on their individual cases. Input was also received from the dietician and physical therapist throughout the project. The hope was that after the project has ended, the clinic will incorporate pre-diabetes teaching to all those who use the clinic.

Timeline. The project officially received IRB approval on June 5, 2018, and was fully launched on July 2, 2018. The duration of the project, including recruitment, was eleven-weeks. Evaluation of the results took place in September 2018. During this time, volunteers returned to the clinic for their usual appointments, and the DNP student followed-up with them after their appointment. Though the dietician and physical therapist were unable see them due to their own schedules, they evaluated each participant's chart with the DNP student every two to three

weeks, during the project. At these meetings, adjustments to each participant's regimen took place, if needed. Final analysis of the impact of these services, were evaluated at the end of the eleventh week.

Data analysis. The pre-test/post-test design was chosen for this pilot project. The criteria for participants included individuals age 18 and above that had the qualifying factors for pre-diabetes based on the CDC screening tool. A paired *t* test was used to calculate two results in one sample population. A paired *t* test is often used as a before-and-after observation of the same subject or population. The research question for the project was if the participants before pre-diabetes education scores were greater than the participants after pre-diabetes education score. Final results revealed a significant lowering in the post education score at a 95% confidence interval, suggesting that the education contributed to lowering the scores.

Ethical Issues

Food and Drug Administration regulations require that all biomedical research involving human subjects be reviewed by an IRB and be given approval before research begins (Guidance for Institutional Review Boards and Clinical Investigators, 2016). The reason for this is to protect the rights of research subjects, which includes informed consent and a detailed explanation of the research in which they will participate.

In addition to IRB approval for this project, the clinic manager and physician needed to give their approval in order to proceed. They were given a presentation and provided with the curriculum that was intended for the participants. A one-time written agreement was obtained, as requested by the clinic manager, chief nursing officer, and chief of podiatry so the project could begin. The agreement included the CDC curriculum that was used as the educational intervention and a list of all members of the project team. Without the agreement form being

signed by prospective team members, the pilot project could not proceed. The purpose of the agreement was to confirm in writing that only the CDC curriculum would be used and to verify who would be providing the interventions. This written agreement was also requested in order to confirm that an experimental diet or exercise regimen was not being endorsed, or used as part of the education.

Once the agreement forms were signed by the healthcare professionals, the pilot project began with the recruiting process and volunteers were asked to take a pre-diabetes CDC screening test. Individuals who qualified for the project, were asked to sign an informed consent. Individuals who did not speak English, or those who requested translation into their native language, were provided a translation via a translation phone to verify that the participant understood the project and consent form. The translation phone was readily available at the clinic and was used by the project team when needed. Participants were asked to sign only if they were in full agreement and were notified that they could withdraw from the project at any time without penalty. If a translation was used, the translator's identification number was recorded and placed on the consent forms as well.

Participants were notified that they would need to take a pre-diabetes screening test if they qualified for the project because the test suggested they fit the criteria for pre-diabetes. Participants who agreed to participate in the project were given education regarding the importance of diet and exercise. The education was adjusted to fit their needs for the next eight weeks. They were also notified that the results of the project will be disseminated to the public; however, their personal information will not be. The DNP student also verified that all members of the team would follow HIPAA guidelines.

Institutional Review Board Approval

Initial IRB approval was received on June 5, 2018, and the pre-diabetes pilot project was fully launched on July 2, 2018, at the designated outpatient clinic in a northeastern state. Due to word of mouth, former podiatry patients asked to participate in the project from the start. The Committee on the Use of Human Subjects in Research allowed this revision.

Chapter III: Organizational Assessment and Cost-Effective Analysis

The clinic is supported by the health insurer used by many of its patients as well as the

state's charity care program. Charity care is provided for those who do not have insurance and fit certain financial criteria. Charity forms are processed and sent to the state's department of health, which approves charity applications, but reviews them to verify the continuing need for funding.

Readiness for Change

The clinic serves many individuals, and the clinic staff and podiatrists gladly received the additional free services. The clinic manager, nurse, and unit secretary provided office space, a private room where the education took place, office supplies, and a scale. The staff was excited to see beneficial results among project participants.

Barriers

There were several issues to overcome after the project started. A major barrier occurred in the first week of recruiting participants, when individuals who already had T2D wanted to take part in the project, but did not disclose that fact. Upon reviewing these individuals' medical charts, after the consents were signed, the discovery was made that seven individuals did not qualify for the project. Thus, the timeline for recruitment had to be extended an additional week, making the recruitment process three weeks. The seven individuals were given initial education, and a detailed explanation, along with an apology as to why they did not qualify for the project.

After the recruitment process was completed, I had 20 participants. Of these 20 individuals, two declined to resume participation after two weeks because they no longer wanted to be weighed. The two participants were given other options, such as being weighed only every other visit or only at the end of the project, but still refused to continue. An additional two participants could no longer participate due to unscheduled surgeries. Finally, two participants declined to resume services because it was going to be difficult for them to return to the clinic

since their podiatry services were completed in the third week of the project. Data from these six individuals' progress, was not used because it was insufficient to analyze.

Fortunately, there were 14 participants willing to proceed with the project. Eight of them were former podiatry patients who were introduced to the project by word of mouth. Adding these patients, was approved by the IRB, and because they had signed consent forms at the outset of the project, these individuals' results were eligible to be used for data analysis.

Risks or Unintended Consequences

One risk that was of concern was the integrity and honesty of the participants. There is no way to ensure compliance other than placing full trust in them, and restating the importance of diet and exercise, with education.

Role of Inter-Professional Collaboration

The team members for this project were from different disciplines and their input and expertise helped create and adjust the patient's regimens. The physical therapist helped identify proper workout plans based on the participant's capabilities using the RPE scale. The nutritionist was able to suggest a balanced generic meal plan, which incorporated alternative foods, based on the patient's likes and dislikes. Plans also considered the participant's other comorbidities. The physician, who was the project mentor, supervised the DNP student throughout and assisted in identifying and resolving issues that arose. The DNP student spoke with the participants and obtained informed consent, a medical history, documented changes in paper charts, and arranged for follow-up appointments. All disciplines came together at least once every three weeks and went through the charts to document progress and determine if more education was needed.

Cost Factors

The cost of this project was minimal, because supplies, including paper for the charts, binders, pens, copy paper, photocopies and the scales were provided by the clinic. Also, the team members volunteered their services. The project was free for participants and was an extra service to them.

Chapter IV: Results

Analysis of Implementation Process

Upon receiving approval from the university's Committee on the Use of Human Subjects in Research (CUSHR), the first step was to provide the clinic manager, the chief of podiatry, and the chief nursing officer with the approval letter via email. After all parties had read the approval letter, the approved agreement form was distributed to these individuals, and signed. The DNP student arranged a date and time to start the recruitment process at the designated organization. Upon arriving at the organization, a work station was already set up. As patients entered the clinic, the DNP student greeted each person and asked if the individual would like to take a pre-diabetes screening test. The recruitment of seven voluntary participants was received on the first day of recruitment; however, these individuals were disqualified because they already had diabetes and did not qualify for the project. Due to this unfortunate incident, recruitment was extended for an additional week and a total of 20 voluntary participants, who qualified for the project was reached. Through the first several weeks of the implementation process, the loss of participation of six individuals occurred due to various reasons, such as unscheduled surgeries, some participants not wanting to be weighed, and the inability to return to the clinic because their clinic services had ceased. The final participant count was 14.

Paper charts were created which included the participants' initial pre-screen test, progress notes from the team members, and the CDC pre-diabetes education that was provided to the participant by the DNP student. The participant's date of birth and initials were placed on the front of each chart as their identifiable factors. At the end of the day the charts were placed in a locked office that only the clinic staff and the DNP student had access to. A repeat screen of the same CDC tool was given to the participants at the end of the project and those scores were placed in the participants' charts as well. At the end of the project, the charts will be shredded, as discussed with the participants during the consent process.

Analysis of Project Outcome Data

Quantitative data were collected from the pre and post educational intervention scores on the CDC pre-diabetes screening tool to identify the impact of the education. The questions were used before educational interventions were implemented and again after (see Appendix A). The paired *t* test was used to determine if the means of two conditions differ when the same groups of individuals were tested twice, before and after the pre-diabetes education was implemented.

There were 14 participants in the study. The age of the participants ranged from 36 to 70 with a mean age of 55.35 (*SD* = 11.16).

The descriptive statistics for their score pre-intervention, post-intervention, and the difference between the scores appear in Table 1. The pre-intervention scores ranged from 5.00 to 7.00 with a mean of 5.78 (*SD* = 0.89). The post-intervention scores ranged from 4.00 to 6.00 with a mean of 4.85 (*SD* = 0.86). The pre-post difference scores ranged from 0 to 2.00 with a mean of 0.92 (SD = 0.47).

Table 1

Descriptive Statistics (N = 14)

Variable	Minimum	Maximum	Mean	*SD*
Pre-Intervention Score	5.00	7.00	5.78	0.89
Post-Intervention Score	4.00	6.00	4.85	0.86

Paired *T* Test

A paired samples *t* test was used to examine the difference between pre and post intervention scores. The average pre-intervention score was 5.78 (*SD* = 0.89) and the average post-intervention scores was 4.85 (*SD* = 0.86) indicating a mean difference of 0.93. The difference between the scores was statistically significant ($t(13) = 7.32$, $p < .01$). The intervention elicited a decrease of 0.93 (95% CI, 0.65 to 1.20) in scores from pre to post-intervention, which is a large effect size ($d = 1.97$), see Table 2.

Table 2
Paired Samples T-Test Comparing Pre-Intervention and Post-Intervention Scores (N = 14)

Pair				95% Confidence Interval of the Difference				
	Mean	*SD*	S.E. Mean	Lower	Upper	*t*	*df*	*p*
Pre-Intervention Score	5.78	0.89	0.23	0.65	1.20	7.32	13	.001*
Post-Intervention Score	4.85	0.86	0.23					

There was a statistically significant difference between means ($p < .05$), and therefore, we can answer the PICOT question and conclude that a lifestyle of healthy diet and exercise, compared to a sedentary one, influences the reversal or delay in acquiring diabetes, in an eight week time period.

Chapter V: Discussion

Limitations or Deviations from Project Plan

A major deviation in this project was a delay in gaining approval from the IRB, which resulted in time constraints for data collection. This allowed the DNP student only one day/week to educate participants, as opposed to two or three days each week.

Another limitation was the unexpected loss of six participants, which resulted in a sample size of only 14. Limiting participation to a single outpatient clinic, involving only current or former podiatry patients, and requiring only an eight-week participation were further limitations.

Initially, a two-week recruitment process was scheduled. However, this timeline was extended because seven individuals did not initially disclose they already had diabetes. These participants were disqualified from the project and an additional week was needed for recruiting replacements.

Implications

The importance of providing education to patients in the clinical setting is intuitive. However, demonstrating that education alone could impact a patient's future health outcomes was a challenge. Fortunately, there were numerous studies in the literature that guided the project to a successful conclusion.

Question six on the CDC pre-diabetes screening tool asked, "Are you physically active?" A zero indicated not active, and a one indicated that the participant is active. The activity level score showed the greatest improvement, as all participants reduced their score by one point because they increased their activity level based on perceived exertion (see Appendix B) according to their specific medical condition, or disability.

The second modifiable question was the BMI score. The participants were given the choices of zero, one, two, or three points based on their weight and height. One of the 14 participants lowered the score by two points because of increased physical activity and lost

enough weight to fall one point on the BMI scale.

Chapter VI: Conclusion

Value of the Project

Improving educational guidance for those with pre-diabetes appears to have improved participants' outlooks on their future health and well-being. Though it is uncertain if participants will continue to follow all the educational material they were given over the eight-week period, the hope is they will continue the basics of good health—such as staying active, eating healthy and setting healthy weight goals—in order to prevent diabetes.

DNP Essentials

Several DNP essentials were met during the course of this project. These essentials include II, III, VI, and VII. DNP essential II, organizational and systems leadership, is a crucial element that aims to promote patient health out comes, and eliminates health care disparities. DNP essential III, clinical scholarship and analytical methods for evidence based practice, ensures that up to date science, is applied when evaluating results. DNP essential VI, inter-professional collaboration for improving patient and population healthcare outcomes, prepares the DNP graduate for collaboration and leadership within an interdisciplinary team. Lastly, DNP essential VII, clinical prevention and population health for improving the nation's health, promotes health maintenance and disease prevention (Doctor of Nursing Practice, 2019).

Identifying the needs of the participant population, providing quality education to voluntary participants, and working together with other professionals to provide up-to-date education, highlights DNP essentials II and VI. The project promoted improving the health of participants by providing structured and consistent education with changes based on the participants' specific needs, which aligned with DNP essential III. DNP essential VII was met by the pre-diabetes education, promoted the prevention of diabetes, and added to the nation's effort to reduce diabetes prevalence.

Plan for Dissemination

The plan to disseminate this project includes a formal virtual synchronous presentation that will be open to the students, faculty, administrators, and community members. No later than one week before the oral presentation, a Bradley University Public Notice of Defense, will be submitted to the graduate school. The final paper will also be submitted to the DNP repository. In addition, a complete final status report of the study will be submitted to CUHSR.

Attainment of Personal and Professional Goals

The project leader intentionally put together this project due to a general lack of understanding that individuals have about diabetes prevention and risk factors that can be reversed. Thus, the goals of this project was to highlight the role of patient education, support healthcare promotion, prevent diabetes, and counter the predictions of the CDC (2014) concerning the increase in diabetes, specifically Type 2. Inter-professional collaboration with project team members, hospital administration, and the clinic team contributed greatly to the success of reaching the goals of this project. Devising alternative plans and working within a timeline and limited schedule helped achieve a personal goal of efficient time management and efficient interdisciplinary collaborative practices. Another goal that was met was providing continued education to participants in order to maintain a continuity of goals in preventing diabetes.

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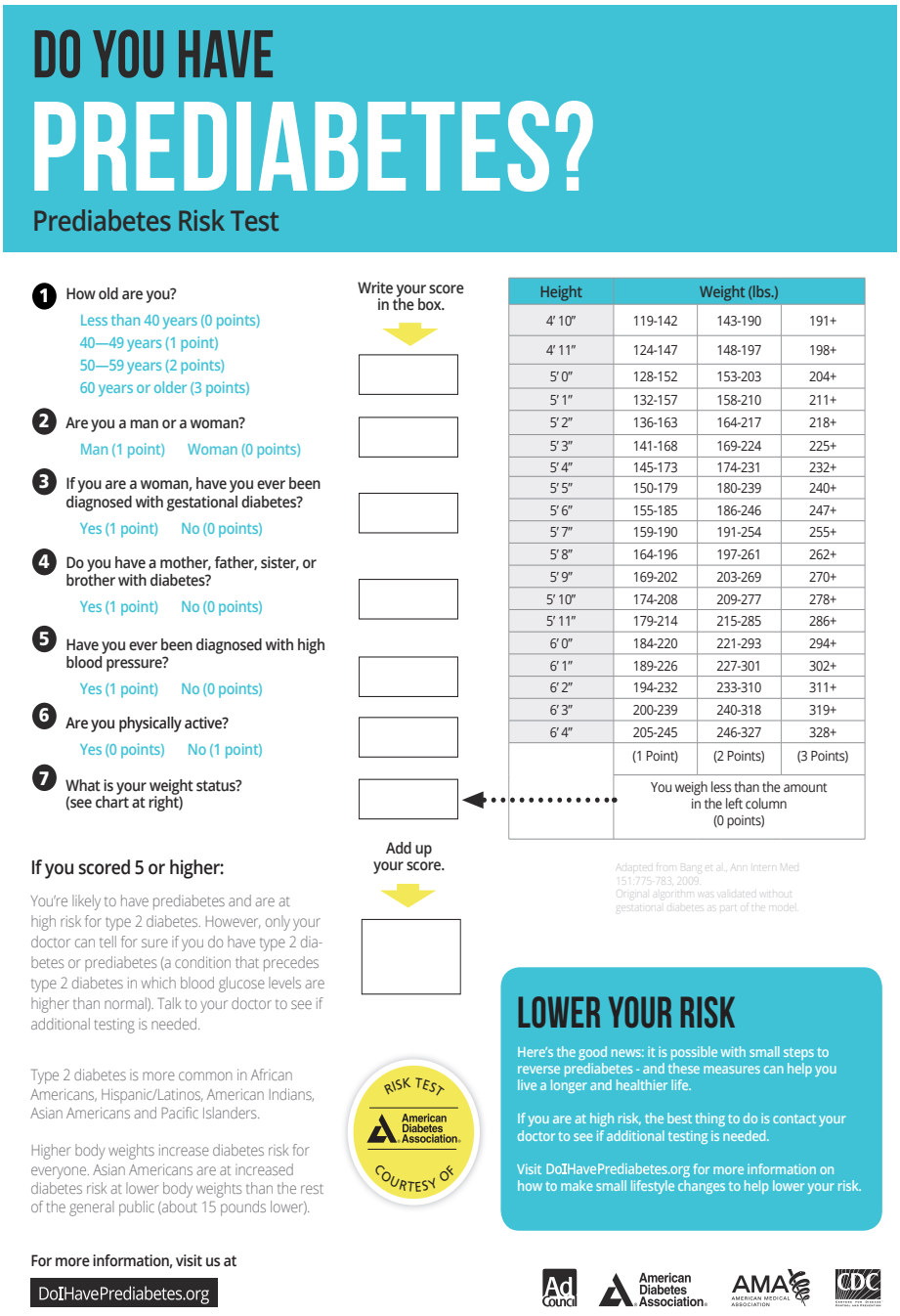
APPENDIX A: CDC Pre-Diabetes Risk Test



DO YOU HAVE PREDIABETES?

Prediabetes Risk Test

1. How old are you?
   - Less than 40 years (0 points)
   - 40—49 years (1 point)
   - 50—59 years (2 points)
   - 60 years or older (3 points)
2. Are you a man or a woman?
   - Man (1 point)
   - Woman (0 points)
3. If you are a woman, have you ever been diagnosed with gestational diabetes?
   - Yes (1 point)
   - No (0 points)
4. Do you have a mother, father, sister, or brother with diabetes?
   - Yes (1 point)
   - No (0 points)
5. Have you ever been diagnosed with high blood pressure?
   - Yes (1 point)
   - No (0 points)
6. Are you physically active?
   - Yes (0 points)
   - No (1 point)
7. What is your weight status? (see chart at right)

Write your score in the box.

Add up your score.

Height	Weight (lbs.)		
4′ 10″	119-142	143-190	191+
4′ 11″	124-147	148-197	198+
5′ 0″	128-152	153-203	204+
5′ 1″	132-157	158-210	211+
5′ 2″	136-163	164-217	218+
5′ 3″	141-168	169-224	225+
5′ 4″	145-173	174-231	232+
5′ 5″	150-179	180-239	240+
5′ 6″	155-185	186-246	247+
5′ 7″	159-190	191-254	255+
5′ 8″	164-196	197-261	262+
5′ 9″	169-202	203-269	270+
5′ 10″	174-208	209-277	278+
5′ 11″	179-214	215-285	286+
6′ 0″	184-220	221-293	294+
6′ 1″	189-226	227-301	302+
6′ 2″	194-232	233-310	311+
6′ 3″	200-239	240-318	319+
6′ 4″	205-245	246-327	328+
	(1 Point)	(2 Points)	(3 Points)
	You weigh less than the amount in the left column (0 points)		

Adapted from Bang et al., Ann Intern Med 151:775-783, 2009.
Original algorithm was validated without gestational diabetes as part of the model.

If you scored 5 or higher:

You're likely to have prediabetes and are at high risk for type 2 diabetes. However, only your doctor can tell for sure if you do have type 2 diabetes or prediabetes (a condition that precedes type 2 diabetes in which blood glucose levels are higher than normal). Talk to your doctor to see if additional testing is needed.

Type 2 diabetes is more common in African Americans, Hispanic/Latinos, American Indians, Asian Americans and Pacific Islanders.

Higher body weights increase diabetes risk for everyone. Asian Americans are at increased diabetes risk at lower body weights than the rest of the general public (about 15 pounds lower).

RISK TEST — American Diabetes Association. — COURTESY OF

LOWER YOUR RISK

Here's the good news: it is possible with small steps to reverse prediabetes - and these measures can help you live a longer and healthier life.

If you are at high risk, the best thing to do is contact your doctor to see if additional testing is needed.

Visit DoIHavePrediabetes.org for more information on how to make small lifestyle changes to help lower your risk.

For more information, visit us at

DoIHavePrediabetes.org

Ad Council · American Diabetes Association. · AMA American Medical Association · CDC

APPENDIX B: **RPE Tool**

APPENDIX C: Information and Consent Form

Education to Help Decrease Diabetes

INVITATION TO BE PART OF A PILOT PROJECT

I am inviting you to be a part of a research project for my Doctor of Nursing Practice Family Nurse Practitioner degree program. In order to qualify, you must be a volunteer who is 18 years old or older, who scores a five or above on the Centers for Disease Control (CDC) pre-diabetes risk test.

KEY INFORMATION REGARDING THE PROJECT

The purpose of this research project is to provide prevention education in diet and exercise for people who are risk for developing diabetes. If your score on the CDC pre-diabetes risk test indicate that you are at risk for diabetes, you will be asked to participate in an eight-week prevention education program. The program will include the CDC preventT2 curriculum that provides up-to-date education that has been shown to be effective for those with pre-diabetes. Along with me who is a registered nurse, the other professionals that we'll be teaching you will be a physical therapist and nutritionist. During the eight weeks, you will learn about correct exercises you should do and the right foods to eat. I will help you with making appointments with me, on the same days as your existing appointments with your doctor at the clinic and I will also see you afterwards for approximately 15 minutes. I will see you at least two to three times during the entire project. I would like to meet with you two to three times in the 8-weeks in person at the clinic after your scheduled doctor's appointment. Each time I see you I will ask you how you have used my education in your daily life and if you are having any difficulties or need more guidance. If you're having any difficulties, my team and I will help to create a better plan for you, to better fit your life. Please keep in mind taking part in this project is voluntary,

there is no cost to for this program and if you choose to stop the program you're free to do so at any time without any penalties. Your doctors and nurses at the clinic will not change their care for you or penalize you if you do not want to participate in the project.

Please keep in mind taking part in this project is voluntary, you do not have to participate and if you do, you can choose to stop at any time, and it will not interfere with your regular clinic appointments. Please take the time to read this entire form and ask questions before deciding to participate in this research project.

RISKS

No risks are expected if you decide to participate. You may stop at any time from the project. The nurse is willing to answer any questions or discuss any concerns that you may have during these eight-weeks.

BENEFITS

The project will help you and others who participate become more aware of pre-diabetes and how you might delay getting it or reverse your risk for diabetes. If the education you receive helps you decrease your risk, it could also help others who are at high risk also.

CONFIDENTIALITY

All your information will be confidential. Only your initials and birth date will be placed on your own personal paper chart so your privacy is protected. Your personalized chart will be stored in a locked office, which only the family nurse practitioner student has access to and will be only available to the professionals at the clinic and the project. These professionals include the physical therapist, nutritionist, registered nurse, the clinic manager, chief nursing officer, chief of podiatry, and the doctor caring for you at the clinic. If you would like anyone else to be able to have your information you will need to give written permission. Nothing will be stated or written

in reports that would link you to the project. You may stop your participation in the project at any time during the eight-week time line. After the project is done, your chart will be shredded which will be 15- weeks after the start of the project.

STATEMENT OF AGREEMENT

By signing this consent form, I agree that a full explanation of the project to help decrease my chances of diabetes was provided to me. I agree that my questions and concerns regarding the entire project have been answered. I also understand the risks and benefits of the project and I am voluntarily participating in the project. **I agree that I am at least 18 years old**, and a copy of the signed consent has been given to me.

Project Contact Information:

Nisha Prince-Mattathil, RN, BSN

nprincemattathil@mail.bradley.edu

If you have any questions about your rights as a research project participant, or wish to obtain information, ask questions, or discuss any concerns about this project with someone other than the pilot project team members, please contact the following.

Committee of the Use of Human Subjects in Research (CUHSR)

Bradley University

1501 W Bradley Avenue

Peoria, IL 61625

309-677-3877

Consent to take part in this Research Project

_____ Date: _____

Name of Participant (Print)

_____ Date: _____

Name of Participant (Signature)

The Research Project and consent form have been explained to the participant.

By signing this form, I am indicating that I have answered the participant's questions, and they have agreed to take part in this pilot project and they are legally authorized to consent on their own participation.

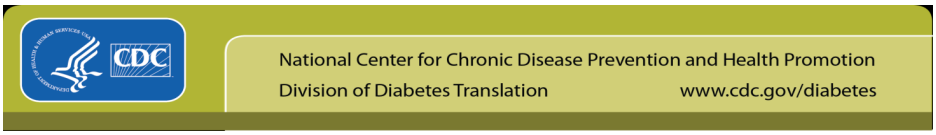
_____ Date: _____

Name of Person Obtaining Consent (Print)

_____ Date: _____

Name of Person Obtaining Consent (Signature)

APPENDIX D: CDC Terms and Conditions for Using the CDC Diabetes Prevention Program Curriculum



Terms and Conditions for Using the CDC Diabetes Prevention Program Curriculum

The CDC Diabetes Prevention Program Curriculum (CDC DPP Curriculum) is based on the curriculum from the Diabetes Prevention Program (DPP) research study1 supported by the National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Disease.

Credits

Use of the CDC DPP Curriculum must be properly attributed and credited with the following copyright credit line: © 2012, University of Pittsburgh, based on the DPP research trial supported by cooperative agreement number U01-DK48489 from the U.S. Department of Health and Human Services, which has certain rights in the material.

Terms and Conditions of Use

With proper attribution and credit, the CDC DPP Curriculum may be used as follows without further permission or license from the University of Pittsburgh:

a) Non-profit research and non-commercial education purposes;
b) Charging a fee solely for cost recovery of materials and operations related to delivery of the curriculum;
c) Use of the curriculum for the purpose of third- party reimbursement so long as no profit is made on this specific effort by the party delivering the lifestyle change intervention or administering these curricula as it is described above, for third- party reimbursement.

Conditions in which usage of the CDC DPP Curriculum requires obtaining written permission and/or license from the University of Pittsburgh:

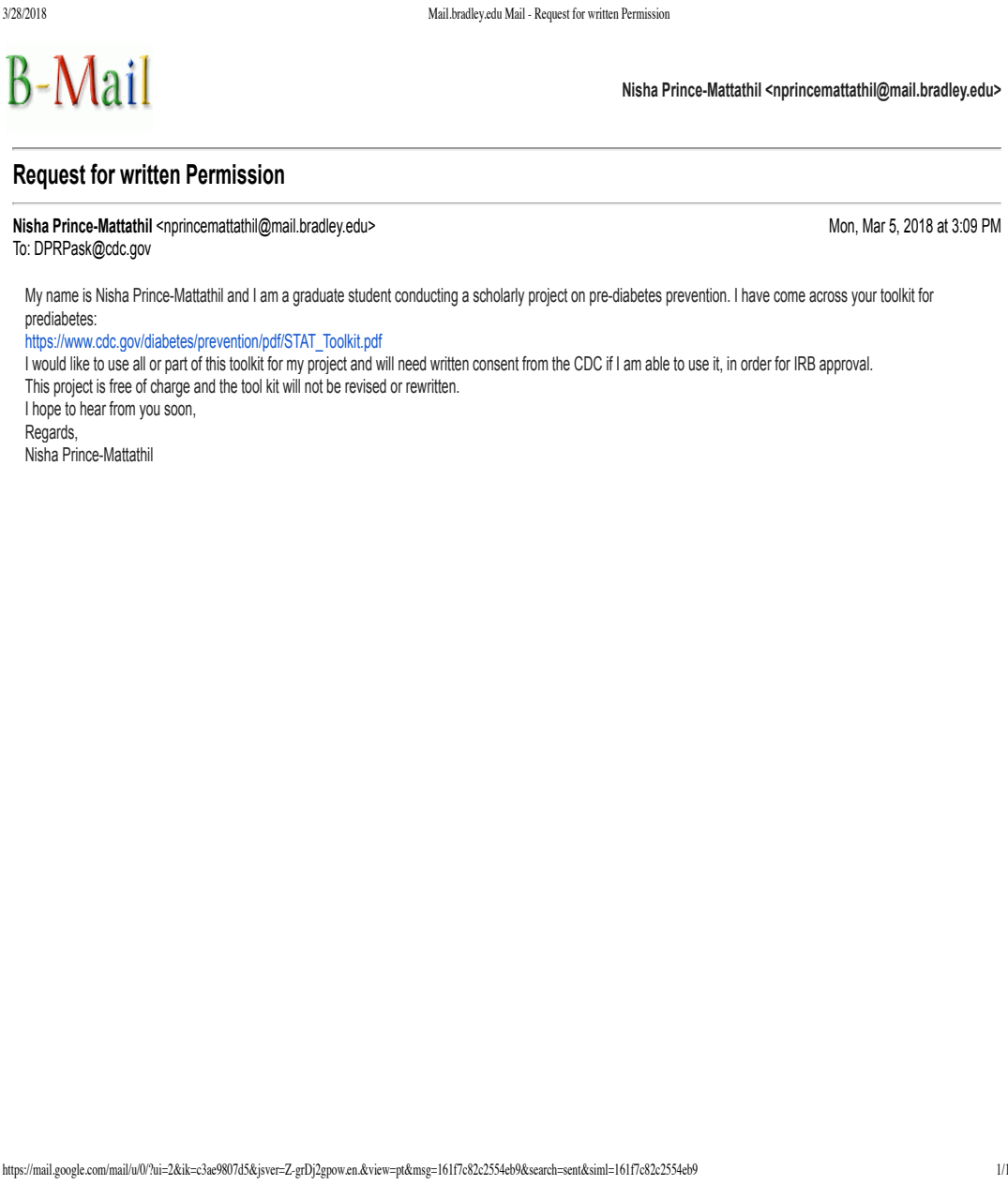
a) For-profit research or for-profit education activities; and
b) Sale or use of the CDC DPP curriculum for any commercial purpose other than as described above.

Use of the CDC DPP Curriculum for commercial purposes, other than as described above, is prohibited without the further written permission and/or license of the University of Pittsburgh. For further information on commercial use of the CDC DPP Curriculum, contact the University of Pittsburgh's Office of Technology Management at 412-648-2206.

[1]Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, et al. 2002. *N Engl J Med* 346: 393-403.

APPENDIX E: Email Requesting Permission for Use of CDC Diabetes Prevention Program Curriculum

Link to Curriculum https://www.cdc.gov/diabetes/prevention/lifestyle-program/curriculum.html.



3/28/2018 Mail.bradley.edu Mail - Request for written Permission

B-Mail

Nisha Prince-Mattathil <nprincemattathil@mail.bradley.edu>

Request for written Permission

Nisha Prince-Mattathil <nprincemattathil@mail.bradley.edu> Mon, Mar 5, 2018 at 3:09 PM
To: DPRPask@cdc.gov

My name is Nisha Prince-Mattathil and I am a graduate student conducting a scholarly project on pre-diabetes prevention. I have come across your toolkit for prediabetes:
https://www.cdc.gov/diabetes/prevention/pdf/STAT_Toolkit.pdf
I would like to use all or part of this toolkit for my project and will need written consent from the CDC if I am able to use it, in order for IRB approval.
This project is free of charge and the tool kit will not be revised or rewritten.
I hope to hear from you soon,
Regards,
Nisha Prince-Mattathil

https://mail.google.com/mail/u/0/?ui=2&ik=c3ae9807d5&jsver=Z-grDj2gpow.en.&view=pt&msg=161f7c82c2554eb9&search=sent&siml=161f7c82c2554eb9 1/1

APPENDIX F: Response to Request for Permission to use CDC Diabetes Prevention Program Curriculum

B-Mail

Nisha Prince-Mattathil <nprincemattathil@mail.bradley.edu>

Regarding your email: Request for written Permission

DPRPDoNotReply (CDC) <dprpdonotreply@cdc.gov> Tue, Mar 6, 2018 at 10:03 AM
Reply-To: "DPRPDoNotReply (CDC)" <dprpdonotreply@cdc.gov>
To: Nisha Prince-Mattathil <nprincemattathil@mail.bradley.edu>

Workflow Notification

Dear Nisha Prince-Mattathil ,

Thank you for your email.

The DPRP does not provide written permissions. The toolkit and CDC-developed PreventT2 curriculum is freely available for use and can be found at https://www.cdc.gov/diabetes/prevention/lifestyle-program/curriculum.html.

If you have additional questions or comments, please email us at dprpAsk@cdc.gov.
Do not reply directly to this email as it is sent by an application that cannot receive emails.

Thank you,

The DPRP Team

APPENDIX G: Agreement Form

Multidisciplinary Interventions to Decrease Diabetes Prevalence

INTRODUCTION

Eligible participants are invited to participate in a scholarly project for Bradley University's DNP-FNP program. The purpose of the project is to provide educational services for proper monitoring and follow-up care for those at risk for diabetes, specifically those with pre-diabetes.

PROCEDURES

Those who have voluntarily taken the CDC pre-diabetes questionnaire risk test and whose results reveal that they are at high risk, will be given the opportunity to join a pilot project, to receive education on how to delay or reverse their risk. The project will run for eight-weeks, where educational interventions provided by CDC PreventT2 curriculum will be used by a licensed physical therapist, licensed nutritionist and doctorate of nurse practitioner student (DNP) who is a licensed registered nurse. During the 8 weeks the DNP student, physical therapist and nutritionist will educate and adjust the voluntary participant's education based on their needs, which will be overseen by the project mentor. The education will focus on diet and exercise regimens and education about pre-diabetes. The DNP student, will coordinate appointments at the clinic, in accordance with pre-existing scheduled appointments, and see the voluntary participants immediately after, for approximately 15 minutes. The DNP student will arrange for three appointments before the end of the eight-week period, per participant. If the other team members are unable to make any or all the appointments, the DNP student will be able to provide the professional educational piece to the voluntary participants, because all the team members prior to the appointment will have updated the DNP student on any changes to the voluntary participants' regimen. At the end of the project, voluntary participants will be asked to take the

same pre-diabetes risk test again to compare it to the initial score.

RISKS

No risks are foreseen with this project. Voluntary participants may withdraw at any time. The DNP student is willing to answer any questions or address any concerns that the voluntary participant, clinic manager, chief nursing officer, chief of podiatry, and the doctor caring for the patient at the clinic may have during the eight-weeks. This will help to ensure that the project is running in accordance with the CDC PreventT2 curriculum and that no experimental diet or exercise regimen are being used.

BENEFITS

The project will aspire to help participants gain awareness of pre-diabetes and provide proper interventions in the hopes of delaying or reversing their risk for diabetes. The information gathered will also, potentially assist in the clinic resuming these services after the project ends, so that they can help others who have pre-diabetes.

CONFIDENTIALITY

The information gathered for this project will be kept confidential. Only initials and date of birth will be placed on the charts as identifiers to preserve the voluntary participants' privacy. Data will be stored securely in a locked office, which only the DNP student has access to and will be only available to the project team members, clinic manager, chief nursing officer, chief of podiatry and the doctor caring for the patient at the clinic, unless the participant gives permission in writing to do so otherwise. No references will be made in oral or written reports that would link the participant to the research project. The participant may withdraw from the research project at any time during the eight-week time line. Only the numerical data collected from the voluntary participant's pre-diabetes risk test will be calculated and documented in the project's

final paper. After the project has ceased and the final paper is complete the entire chart will be shredded.

STATEMENT AGREEMENT

By signing this agreement, I am confirming that I, Nisha Prince-Mattathil, will be conducting a DNP scholarly project, which will be providing interventional education regarding pre-diabetes to voluntary participants. This will be done at St. Mary's outpatient clinic, in Passaic New Jersey, and education will come directly from the CDC PreventT2 curriculum. The education includes diet and exercise interventions. The project team includes the project mentor Dr. Adesuwa Okesanya MD, Cheryl Betelho DPT, Elaina Finkle RD, and Nisha Prince-Mattathil RN (DNP student).

_____ Date: _____

Name of DNP Student (Print)

_____ Date: _____

Name of DNP Student (Signature)

By signing this consent, I have agreed that a full explanation of the multidisciplinary interventions to decrease diabetes prevalence, pilot project was provided to me. I agree that my questions and concerns regarding the entire project have been addressed. I also understand the risks and benefits of the project and I am aware of all of the disciplines involved that will be providing educational interventions to voluntary participants. I am aware that the DNP student is conducting a scholarly project, as it is required for partial fulfillment of Bradley University doctorate of nurse practitioner program. I am agreeing for the project to be conducted at the

outpatient clinic at St. Mary's hospital, located in Passaic New Jersey, so long as the project team follows the above-mentioned information.

_____Title:_____Date: _____
Chief of Podiatry (Print)

_____Title:_____ Date: _____
Chief of Podiatry (Signature)

_____Title:_____Date: _____
Chief Nursing Officer (Print)

_____Title:_____ _Date: _____
Chief Nursing Officer (Signature)

_____Title:_____Date: _____
Clinic Manager (Print)

_____Title:_____Date: _____
Clinic Manager (Signature)

Appendix H: CUHSR Approval

B-Mail

<nprincemattathil@mail.bradley.edu>

Re: CUHSR 34-18: Multidisciplinary interventions to decrease

diabetes prevalence.

Ross Fink <rf@fsmail.bradley.edu> Tue, Jun 5, 2018 at 6:03 PM

To: Nisha Prince-Mattathil <nprincemattathil@mail.bradley.edu> Cc: Cindy Brubaker

<cindyb@fsmail.bradley.edu>, Peggy Flannigan <pnflan@fsmail.bradley.edu>

Dear Investigators:

Your study (CUHSR 34-18) Multidisciplinary interventions to decrease diabetes prevalence has been reviewed and was found to be expeditable under Category 4.

All vita and ethics certificate are on file.

Be aware that future changes to the protocol must first be approved by the Committee on the Use of Human Subjects in Research (CUHSR) prior to implementation and that substantial changes may result in the need for further review.

While no untoward effects are anticipated, should they arise, please report any untoward effects to CUHSR promptly (within 3 days).

As this study was reviewed and approved for one year, the maximum allowed under regulations.

Please complete a final status report when the study is completed. If the study is not completed within one year, please submit a Continuing Review form before the one-year date (June 5, 2019) with adequate time for CUHSR to review to prevent a lapse in approval. These forms can be found on our website, http://www.bradley.edu/academic/cio/osp/policies/cuhsr/forms/

This email will serve as your written notice that the study is approved unless a more formal letter is needed. Just let me know.

Ross L. Fink, Chairperson, CUHSR