# Innovative Approach to Diabetes Prevention: Utilization of a Multimedia Based Diabetes Prevention Program to Encourage Adherence to Lifestyle Modifications in Prediabetic Adults for Prevention of Type 2 Diabetes Mellitus

A Clinical Scholarly Project by

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#### **ABSTRACT**

Innovative Approach to Diabetes Prevention: Utilization of a Multimedia Based Diabetes

Prevention Program to Encourage Adherence to Lifestyle Modifications in Prediabetic Adults for

Prevention of Type 2 Diabetes Mellitus

## by Ebony Nicole Funches

The purpose of this doctoral project is to determine if the integration of a multimedia based education for diabetes prevention will encourage prediabetic adults to actively engage in making lifestyle changes that result in greater adherence to lifestyle modification (i.e. diet and exercise) and reduction of blood glucose levels in efforts to decrease the development of T2DM and its associated medical, psychological and financial burdens to the patient, family, community, and society as a whole. A quasi-experimental, quantitative design which included male and female adults between the ages of 21-64 years old with prediabetes in a community clinic was utilized. Prediabetes was defined as a glycated hemoglobin A1c between 5.7%-6.4%. Intervention involved three module diabetes prevention educational sessions delivered via multimedia. The control group received usual care for a diagnosis of prediabetes that consisted of brief diet and exercise patient education. The intervention group received the aforementioned multimedia diabetes prevention education. Reductions in weight and glycated hemoglobin A1c measurements were observed, the p-value demonstrated that the implementation of a multimedia based diabetes prevention program made no statistically significant differences between both the control and intervention groups in this project. Alternative formats for the delivery of diabetes prevention education have the potential to promote adherence to lifestyle modifications.

Keywords: innovation, leadership, prediabetes, lifestyle modification program

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#### **Innovative Approach to Diabetes Prevention**

Prediabetes is becoming more prevalent in the United States; in fact, the U.S. Department of Health and Human Services estimates that close to 86 million U.S. adults over the age of twenty had prediabetes in 2012 (National Institute of Diabetes and Digestive and Kidney Diseases, 2014). According to the Center for Disease Control and Prevention (CDC) (2014), 15-30 % of individuals with a diagnosis of prediabetes go on to develop Type 2 Diabetes Mellitus (T2DM) within five years in the absence of lifestyle modification programs. The majority of individuals living with prediabetes are asymptomatic and inadequate screening contributes to the progression of comorbid conditions such as: chronic kidney disease, cardiovascular disease, and cerebrovascular events (Centers for Disease Control and Prevention, 2014). The United States Preventative Services Task Force recommends routine screening every three to five years using a glycated hemoglobin A1c levels for adults determined to be high risk for type 2 diabetes (National Guideline Clearinghouse, 2012).

The progression to T2DM can be delayed or even prevented with lifestyle changes that include increasing physical activity, smoking cessation, eating a healthy and balanced diet, and maintaining a healthy weight. Many patients with prediabetes do not initially accept their diagnosis and fail to make the necessary dietary and lifestyle changes. The absence of symptoms in the prediabetic state contributes to patients' non-adherence to dietary and lifestyle changes. Patients often feel that since they do not have a formal diagnosis of diabetes, they do not have to make any changes. Failure to attend nutritional education courses and exercise programs offered by clinicians is a common phenomenon seen in primary care, and primary care providers are often not allotted enough time for extensive patient education. In a clinical audit Ariffin et al. (2017) assessed patient waiting times and physician consultation time in a primary health clinic

in efforts to formulate strategies for improvement. Results of this audit demonstrated that the average consultation time was 18.21 minutes, excluding the critically ill, aggressive patents, or those requiring repeat medication or procedures (Ariffin et al., 2017). In a non-experimental, exploratory research design involving a convenience sample of healthcare professionals employed at a large federally qualified health center (FQHC) in Connecticut, researchers explored clinical staff perceptions of barriers to providing patient education during primary care visits (Alicea-Planas et al., 2015). Results of the survey demonstrated that 80% of clinical staff felt there was not enough time allotted during patient visits for health education (Alicea-Planas et al., 2015). According to the American Association of Clinical Endocrinologists (2008), therapeutic lifestyle management should be discussed with all patients with prediabetes at the time of diagnosis and throughout their lifetimes. Therapeutic lifestyle management includes medical nutrition therapy (MNT) which is defined as the reduction and modification of caloric and saturated/hydrogenated fat intake to achieve weight loss in individuals who are overweight or obese. Primary care providers (PCPs) often take on the responsibility of encouraging behavior changes such as recommendations for increased physical activity, avoidance of tobacco products, adequate quantity and quality of sleep, limited alcohol consumption, and stress reduction.

While it is evident that progression to T2DM increases health care expenditures and contributes to increased morbidity and mortality rates, more research is needed to assist healthcare providers in motivating their patients to adhere to lifestyle modification programs. Current gaps in the literature surrounding methods to promote sustainability in lifestyle modifications programs have helped formulate the clinical question at hand. In a mixed group of English speaking male and female patients between the ages of 21 and 64 years old diagnosed

with prediabetes, does the implementation of a multimedia based diabetes prevention program versus usual care encourage adherence to lifestyle modifications within a 90-day time period?

A comprehensive literature search was conducted utilizing various electronic databases, including: CINAHL, Ovid Nursing Database, PubMed, ProQuest Nursing and Allied Health Database, and Medline. It was apparent there were active gaps in the literature surrounding this area of clinical interest. Utilization of several medical subject headings (MeSH) terms yielded studies that supported the notion that the implementation of diabetes prevention programs and other preventive programs in primary care may be an effective and feasible treatment for prediabetes.

One randomized control trial demonstrated through the use of aerobic and resistance exercise on the first and third day of the week, insulin sensitivity in individuals with prediabetes increased (Chipkin & Malin, 2011). Furthermore, the results of that study demonstrated that the addition of pharmacological agents such as Metformin did not result in maximizing insulin sensitivity. In a separate action research study, general practice staff provided lifestyle interventions as a series of consultations that occurred in phases (Maindal et al., 2013). The primary nurse consultations involved the distribution of educational pamphlets for study participants and included various themes. The themes to the consultations included: motivation, prediabetes, diet and physical activity, in addition to 24-hour diet recalls. One practice used follow up phone calls to support patients and promote adherence to lifestyle changes. This study resulted in a short-term impact on glycated hemoglobin A1c levels and body mass indexes. One systematic review examined several large scale national trials such as: The Finnish Diabetes Prevention Study, The US Diabetes Prevention Program, The Indian Diabetes Prevention Program, and The Asti Diabetes Prevention Program. According to Palermo et al. (2014), the

intervention studies reviewed demonstrated that the implementation of a healthy lifestyle through the promotion of regular physical activity, and adherence to a healthy diet tailored to the caloric needs of each individual can halt the progression to T2DM.

Sustainability in promoting adherence to lifestyle modification programs can result in delayed onset and even halt progression to T2DM. Ultimately, this will help to reduce the current healthcare expenditures needed to treat this disease and its multisystem complications. The challenges of promoting lifestyle modification programs in primary care include limited staffing and funding for interventional methods. The progressive nature of this disease requires the expertise of trained diabetic health educators that are often not readily available for the prediabetic patient population. Time constraints during office visits result in minimal prediabetes instruction, which is not effective for the low health literacy population. Pre-existing disability and chronic illnesses can deter the prediabetic patient's willingness to participant in exercise and dietary change

#### **Chapter I: Background and Significance**

## **Assessment of the Phenomena (Problem Statement)**

According to the CDC (2014), one out of every three adults living in the United States had a diagnosis of prediabetes in 2010. According to the National Institute of Diabetes and Digestive and Kidney Diseases (2014), prediabetes is a medical condition in which blood glucose or glycated hemoglobin A1c levels are abnormal, but not within the range for a diagnosis of diabetes.

Prediabetes is becoming more prevalent in the United States; in fact, the U.S. Department of Health and Human Services estimates that close to 86 million U.S. adults over the age of 20 had prediabetes in 2012 (National Institute of Diabetes and Digestive and Kidney Diseases, 2014). Prediabetes involves several abnormal processes in glucose transport, including insulin resistance. Insulin resistance encompasses the decreased sensitivity of tissue to absorb glucose with normal blood concentrations of insulin. As blood becomes more saturated with glucose, the body attempts to maintain homeostasis by stimulating the pancreatic beta cells to release more insulin. Primary insulin resistance is an aberration in the target cells of insulin receptors and post receptors, which results in altered insulin action and sensitivity (Buttaro et al., 2013).

According to the CDC (2014), 15-30% of individuals with a diagnosis of prediabetes develop T2DM within five years in the absence of lifestyle modification programs. The majority of individuals living with prediabetes are asymptomatic, and inadequate screening contributes to the progression of comorbid conditions, such as T2DM, cardiovascular disease, and cerebrovascular events (Center for Disease Prevention and Control, 2014). The United States Preventative Services Task Force (USPSTF) recommends routine screening every three to five years using a glycated hemoglobin A1c for adults determined to be high risk for diabetes

(National Guideline Clearinghouse, 2012). The progression to T2DM can be delayed or even halted with lifestyle changes that include: increasing physical activity, smoking cessation, eating a healthy and balanced diet, and maintaining a healthy weight. The absence of symptomology surrounding prediabetic states contributes to problem of non-adherence in making the necessary dietary and lifestyle changes. Patients often feel that since they do not have a formal diagnosis of diabetes, that they do not have to make any changes. Failure to attend dietician consults and exercise programs is a common phenomenon seen in primary care. According to McTigue and Conroy (2012), the allotted time for preventative care services is often inadequate. For example, if a clinician were to fulfill all of the USPSTF recommendations for preventive care alone it is estimated that it would take four to seven hours per day (McTigue & Conroy, 2012). In primary care, prevention is often delivered during acute care visits, given to that fact that primary care visits often are overburdened with addressing multiple other health related problems (McTigue & Conroy, 2012). Prediabetic patients need to be taught about carbohydrate exchange and the amount of exercise needed to maintain a healthy weight, in order to prevent the progression to T2DM.

It is evident that progression to T2DM increases health care expenditures, and contributes to increased morbidity and mortality. According to Davies et al. (2016), the life expectancy for individuals with T2DM may be shortened by as much as 10 years, mainly attributable to cardiovascular disease related deaths. A population based study Roper et al. (2017) compared the mortality in people with known diabetes living in South Tees with those living in England and Wales. Their results demonstrated that in a cohort comprised of 4842 people, 1205 died (24.9%) certifying diabetes as the underlying cause of death for 9.4% of men and 11.9% of women (Roper et al., 2016). The cohort also had significant excess in mortality from cardiovascular

disease, ischemic heart disease, cerebrovascular disease, and renal disease. Current gaps in the literature surrounding methods to promote sustainability in lifestyle modifications programs was the motivational force for the development of this scholarly project. More research is needed to assist healthcare providers in motivating their patients to adhere to lifestyle modification programs.

## **Historical and Societal Perspective**

According to O'Donnell (2015), textbooks dating as far back as the 13<sup>th</sup> century have alluded to the concept that irresponsible or debauched behavior might be the culprit to the onset of diabetes. Historically speaking, like obesity diabetes was thought to be rare in comparison to today's times. During the 19<sup>th</sup> century, diabetes was thought to be the direct result of overconsumption and lack of exercise (O'Donnell, 2015). During these times understanding of diabetes was based on cultural beliefs surrounding body size; medical accounts often depicted it as a voluntary and self-inflicted condition that could only be addressed by a personal transformation and lifestyle change (O'Donnell, 2015). Victorian physicians during this era argued that obese individuals would pay for their indulgences through illnesses such as diabetes, and consequently disability and early death (O'Donnell, 2015).

In the 20<sup>th</sup> century, medical and public health domains grew increasingly more concerned over increased rates of diabetes due to longevity amongst middle-aged and elderly populations (Tuchman, 2011). Many believed other factors such as: rising obesity rates, increased sugar consumption, and greater stress on modern civilization was to blame for this epidemic. In 1942, Haven Emerson, a medical doctor, published "Sweetness is Death," which further linked the rise in diabetes rate to the fact that Americans were "the grossest feeders among all nations…bulging with the money bags of the world, fairly oozing with wealth, eating every day much more than

any of our allies or opponents of the war... and, as it were, dying of overeating" (as cited in Tuchman, 2011, p.27).

## **Supporting Evidence**

According to Muennig (2008), cost-effectiveness analyses are mostly used to compare different strategies for preventing or treating a single disease. In the context of scholarship and doctoral projects, cost-effectiveness analysis (CEA) can demonstrate the feasibility and potential impact of the project's implementation (Burson et al., 2014). Advanced practice nurses must focus on both the clinical effectiveness and cost effectiveness of a project. Providing an itemized list of what would be included in the total cost of implementing the project promotes sustainability as others attempt to replicate the findings (Burson et al., 2014). The cost should be inclusive of direct costs which are primarily used for implementing the project, and indirect costs which are often miscellaneous. According to Kleinpell (2013), in a CEA, healthcare costs are directly related to the intervention itself and associated costs or savings of future healthcare, which may be affected by the intervention.

Using a systematic review, Yu et al. (2016) explored the effectiveness, cost, and costeffectiveness of lifestyle diabetes prevention interventions and compared effects by intervention
delivery agent (dietitian vs non-dietician) and channel (in-person vs technology-delivered)
formats. A meta-analysis using 69 studies demonstrated that the average lifestyle intervention for
diabetes prevention cost \$385 per person (Yu et al., 2016). Interventions that used dieticians
ranged anywhere from \$314 per person to \$491 per person, with average telehealth interventions
costing \$90.17 per person (Yu et al., 2016). Examining four studies that reported sufficient
enough information, researchers were able to calculate an Average Cost-Effectiveness Ratios
(ACERs), which for 1 kilogram of weight loss over 6 months equated to \$34.06 in a study using

cluster randomized control trial of a 6-month lifestyle intervention among adults with prediabetes (Yu et al., 2016).

Therefore, the implementation of a doctoral project aimed to prevent and/or halt the progression of this disease offers long term cost savings and an overall reduction in healthcare expenditures. In a CEA surrounding the implementation of a multimedia based diabetes prevention educational program for prediabetic adults, the main costs were associated with the production of the video. Direct costs included supplies needed to obtain laboratory data such as vacutainers, needles, alcohol pads, cotton, tape, and tourniquets. Indirect costs include overhead such as salary for researchers, professional filmography, and hourly wages for professional consultations with specialists. This format for the delivery of diabetes prevention education has the potential to allow for more participants to receive the information asynchronously, versus the in-person formats. Results demonstrated that effect sizes were notably larger for weight loss in technology-delivered interventions than in-person interventions (Yu et al., 2016).

One alternative to performing a cost effectiveness analysis is a cost benefit analysis, which places a dollar amount on both the costs and effectiveness of an intervention (Muennig, 2008). The fact that all costs are considered may aid in obtaining buy in from key stakeholders who are often concerned with the cost of implementing a change in the organization. Providing stakeholders with a definitive end point may influence their willingness to invest in the project's goals.

#### **Incidence and Prevalence**

An expert committee conveyed by the American Diabetes Association (ADA) estimated that in 2010, 79 million U.S. adults had prediabetes as defined by the following objective data: a fasting plasma glucose level of 100 to 125 milligrams per deciliter (mg/dl), a glycated

hemoglobin A1c of 5.7-6.4%, or a 2-hour plasma glucose level after a 75-gram oral glucose tolerance test of 140 to 199 mg/dl (Bullard et al., 2013). According to ADA (2015), a normal glycated hemoglobin A1c level is less than 5.7%, and prediabetes is diagnosed when the glycated hemoglobin A1c is 5.7% to 6.4%. A diagnosis of diabetes ensues when the glycated hemoglobin A1c is greater than or equal to 6.5% (American Diabetes Association, 2015). In a cross-sectional design study, data from the 1999-2010 National Health and Nutrition Examination Survey was utilized to estimate prediabetes prevalence and its variations during an eleven-year time frame. Results of the study demonstrated a 21% increase in prediabetes prevalence from 1999 through 2010, as well as identified diverse demographic subgroups that would benefit from targeted diabetes prevention programs that promote healthy lifestyle modifications, including weight loss and maintenance, physical activity, and healthy diet (Bullard, 2013).

#### **Healthcare Cost**

Healthcare expenditures for patients in the United States diagnosed with diabetes totaled 245 billion dollars in 2012 (American Diabetes Association, 2015). Comprehensive care of a patient with diabetes inflicts a large number of economic burdens on the healthcare system and society as a whole. The estimated total economic cost of diabetes in 2012 was \$245 billion, including \$176 billion in direct medical costs and \$69 billion in reduced productivity (Zhou et al., 2013). In a cost analysis study, Zhou and his colleagues estimated an overall average lifetime medical cost of treating diabetes and its related complications was \$85,200 (Zhou et al., 2013).

In a study comparing the cost effectiveness of modest weight loss through dietary changes and increased physical activity, versus treatment with Metformin, an oral anti-hyperglycemic medication lifestyle intervention was proven to be more cost effective ("Cost-Effectiveness of Lifestyle Intervention or Metformin," 2003). From a societal perspective and

compared to the placebo intervention, the lifestyle intervention cost \$51,600 per quality-adjusted life year (QALY) gained, and the Metformin intervention cost \$99,200 per QALY gained ("Cost-Effectiveness of Lifestyle Intervention or Metformin," 2003).

In a quasi-experimental design measuring the impact of the Young Men's Christian Association's (YMCA) Diabetes Prevention Program on healthcare expenditures, regression analysis demonstrated total Medicare spending was statistically significantly lower for treatment than the control group for the first five of the eight quarters during the treatment period, with lower treatment costs averaging \$455/member/quarter or \$780/year for the entire treatment period (O'Donnell, 2016).

## **Supporting Evidence for Advanced Practice Registered Nursing**

As advanced practice registered nurses (APRNs) it is a vital component to acquire the ability to understand and critically analyze research in order to continuously advance all aspects of health care. According to Beck and Polit (2012), nurses are expected to understand and conduct research, and to subsequently base their professional practice on valid research evidence. APRNs identify gaps in clinical practice in efforts to advance healthcare. Gaps in knowledge regarding strategies to promote health and adherence to lifestyle modification programs for patients with prediabetes, has formed the basis of this clinical scholarly project.

#### **Introduction of PICOt Foundation**

According to Parikh et al. (2010), Blacks and Hispanics benefit more from lifestyle interventions than do Whites, and disparities in incident type 2 diabetes between these groups are eliminated with weight loss. Studies have shown that the most effective diabetes prevention strategy involves identifying people with prediabetes and encouraging lifestyle changes that promote modest weight loss. Many socio-economic factors, such as level of education, income,

and environment contribute to barriers with access to dietary and financial resources for T2DM prevention in at risk populations. Diabetes mortality for Blacks and Hispanics are nearly double that of Whites, and 30% of all Americans have prediabetes, which is more than double the prevalence of diabetes (Parikh et al., 2010). According to the Diabetes Coalition of California (2014), the percent of adults in California with diabetes is almost two times higher in those with family incomes below 200% of the federal poverty level compared to those whose income is at or above 300%. Community clinics similar to where this CSP was implemented at, provide healthcare access to impoverished minorities, but struggle to implement effective, feasible, and sustainable diabetes prevention interventions to combat this epidemic. Witnessing these barriers and disparities firsthand is what sparked a phenomenon of interest in diabetes prevention and control, and was the driving force to the clinical question at hand.

In a group of English speaking male and female patients between the ages of 21 and 64 years old diagnosed with prediabetes, does the implementation of a multimedia based diabetes prevention program versus usual care encourage adherence to lifestyle modifications within a 90-day time period?

#### **Chapter II: Literature Review**

## **Scope of the Evidence**

The articles selected to support the value of this clinical scholarly project yielded the following research themes:

Communities are in need of evidenced based diabetes prevention programs. Current research has demonstrated that type 2 diabetes risk can be reduced through diet and exercise programs. Many gaps in the literature surrounding diabetes prevention and control pertain to the feasibility and direct costs of implementing these types of programs in the community health arena. Funding within community health centers is often limited, which unfortunately has affected the rate at which diabetes prevention programs are being implemented.

One study of note involved an individual, randomized intervention trial to evaluate the effects of a modified version of the Weight Watchers program compared with self-initiated program developed by the National Diabetes Education Program on weight and glucose control as measured by glycated hemoglobin A1c. In this study, 225 participants were randomized into both control and intervention groups. The intervention consisted of a commercial based lifestyle modification program offered by Weight Watchers International. According to Marrero et al. (2016), the Weight Watchers core curriculum is evidenced based and offers similar behavioral topics used in the Diabetes Prevention Program (DPP), such as: self-monitoring of weight, intake, and activity, dietary modification, physical activity, stimulus control, and relapse prevention. Participants assigned to the control group were provided with type 2 diabetes educational materials on undertaking risk-reducing lifestyle modifications. Individual counseling by trained research staff was also provided to control group participants. The study demonstrated that controls lost 0.8% weight (SE=0.5%) at 6 months and 0.2% weight (SE=0.7%) at 12 months

and intervention participants lost 5.5% weight (SE=0.5%-0.6%) both at 6 and 12 months (Marrero et al., 2016). Data collected from this study demonstrated that the intervention group lost more weight than controls at both 6 and 12 months, in addition to showing greater improvements in glycated hemoglobin A1c levels and high-density lipoprotein (HDL). Data from the study further confirmed that the incidence of diabetes is increasing; therefore, the need to expand community access to evidenced based prevention programs is crucial. This study has offered an alternative to the utilization of commercial weight loss programs as an intervention to reduce diabetes risk. This study has further highlighted that communities are in desperate need of the implementation of cost effective and sustainable diabetes prevention programs worldwide.

In a separate research study aimed at the adolescent population, appropriately titled the EPIC Kids Study (Encourage-Practice-Inspire-Change), assessment in the feasibility, participant acceptance, and retention rates of the program using either a 12-week hybrid face-to-face or mobile device based program format was analyzed. Researchers anticipated a four to seven percent reduction in the percent of overweight youth after 12 weeks, as well as significant reduction in waist circumference over 12 weeks.

In a group-randomized, non-inferiority trail design based interventional study; 60 participants between the ages of 9 to 12 years old and their parents and/or primary caregiver were assigned to an intervention group led by two trained YMCA lifestyle coaches. Randomized by location, one group received a face-to-face weekly YMCA lifestyle coach-led program, while the other group receives five weeks of content led by YMCA coaches digitally delivered using study-provided mobile devices. The hybrid based intervention format with an alternating face-to-face/digital delivery involved 5 out of 12 EPIC kids session (40%) being delivered via study-provided tablet (Kindle Fire HDX7, Amazon). Behavioral interventions like this study offer

realistic alternatives for prevention of type 2 diabetes, given the cost, poor adherence, and risks associated with pharmacological and surgical interventions (Hingle et al., 2015). According to Hingle et al. (2015), expectations for the EPIC Kids Study included a four to seven percent reduction in the percent of overweight youth after 12 weeks, with significant reductions in waist circumference. The Epic Kids Study further demonstrates that the lack of effective community-based diabetes prevention programs inhibits risk-reduction practices across the lifespan.

Innovation, such as the use of mobile devices and similar technology can support health behavior change and serve as an alternative healthcare delivery model to diabetes prevention programs.

More research is needed in the field of creating sustainable, feasible evidenced based diabetes prevention programs in order to improve the health of the population.

Using technology to disseminate diabetes prevention education is feasible and effective. In a pilot intervention study, Cha et al. (2014) examined the feasibility and preliminary efficacy of an age specific diabetes prevention program in young adults using a one-group pre and post-test research design. The study utilized a technology-based lifestyle coaching program that focused on diet and exercise, while incorporating a handheld device and digital platform.

Applying the social cognitive theory and the American Association of Diabetes

Educators' AADE7 Self-Care Behaviors Framework as theoretical foundations for this 12-week
intervention, researchers designed an intervention to maximize the use of Web-based platforms,
mobile applications, and e-mail and phone correspondence (Cha et al., 2014). Weekly five to
twenty-minute counseling sessions preceded by identification of behavioral goals were to be
submitted online by participants. A review of case study activities was expected of study
participants every other week. A script was used to initiate the counseling session and discuss the
prior week's dietary and exercise behaviors on the basis of self-reported data via digital

platforms, as well as problem solving strategies to overcome barriers confronted (Cha et al., 2014).

The results of this study demonstrate significant decreases in body mass indexes, weight, and glycated hemoglobin A1c measurements. Of the 13 study participants, researchers noted a reduction of body mass index from 41.0 to 40.1 kg/m2. Glycated hemoglobin A1c reductions were tracked from 6.0% down to 5.6%. According to Cha et al. (2014), after 12 weeks, five of the study participants reverted back to euglycemia (fasting glucose <100 mg/dl [5.55 mg/dl], A1C < 5.7%).

According to McGuire (2007), a product that is within a person's reach and always fully functional will be available for immediate use, and it will translate frequently into value, more so than a product that is usually left at home or at the office. In the healthcare arena, that product is mobile applications for mobile devices. Mobile healthcare, also referred to as *m-health*, is the development, dissemination and application of mobile information and wireless telecommunication technologies in the healthcare arena (Siau & Shen, 2006). Offering mobility in healthcare delivery increases productivity by improving provider responsiveness and healthcare consumer satisfaction by streamlining the healthcare process. Mobile technologies can be applied to healthcare in a myriad of ways, such as voice communication, messaging, notification, asset tracking, and remote access (Siau & Shen, 2006). Perspectives surrounding the implementation of mobile applications vary throughout the clinical setting, but can serve as a sustainable and feasible delivery method for diabetes prevention programs.

In another study, Fisher et al. (2016) conducted a randomized comparative effective trial at a federally qualified health center (FQHC) in Denver, Colorado. A total of 163 participants were randomized by the research team to the text message-augmented intervention (n=82) or the

control group (n=81) (Fisher et al., 2016). Utilizing the principles of the National Diabetes Prevention Program, intervention group participants received six messages per week relating to nutrition, physical activity, motivation, as well as a once-weekly text message requests to self-report their most recent weight. Control group participants received the standard of care weight loss resources which included access to diabetes prevention program courses and individual appointments with the dietician (Fisher et al., 2016). Results of the study demonstrated a mean weight loss of 0.6 pounds (95% CI -2.7 to 1.6) in the control group and 2.6 pounds (CI-5.5 to 0.2) in text message group (*P*-value 0.05). Mean glycated hemoglobin A1c increased by 0.19% or 2.1 mmol/mol (95% CI -0.1 to 0.5%) and decreased by 0.09% or 1.0 mmol/mol (95% CI -0.2 to 0.0%) in both control and intervention participants (Fisher et al., 2016). Study results suggest that the use of text messaging as a modality to deliver diabetes prevention education could offer low-cost, wide-reaching, and effective ways to reduce the incidence of diabetes (Fisher et al., 2016).

#### **Scope of the Evidence**

A comprehensive review of the literature using electronic databases including: Pubmed, CINAHL, and Medline was performed in efforts to yield the most applicable studies. Using an effective search strategy and MeSH terms produced key studies that supported the idea that the implementation of diabetes prevention programs and other prevention programs in primary care is an effective treatment for prediabetes. Searches were not inclusive of grey literature and utilization of key words including: prediabetes, exercise, impaired fasting glucose, and adherence was used to guide literature searches. Several reference lists from published books were used in addition to credible websites, including the American Diabetic Association (ADA) and the

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Resulted searches were reported in English language and spanned from the years 2008 to 2014.

In its July 2014 issue, the *Journal of Clinical Nursing* published the results of a grounded theory research study, which analyzed the experiences, changes in mind and behavior, and subjective feelings of exercise engagement in individuals with prediabetes. Many authors concluded that engaging in regular physical exercise could either prevent or delay the onset of type 2 diabetes mellitus (Kuo et al., 2014). The literature supported the importance of promoting exercise amongst the prediabetic population, in which more than half of people diagnosed with prediabetes fail to develop regular exercise habits after diagnosis (Kuo et al., 2014). A grounded theory was used to gain insight on the study subject's experiences while engaging in exercise in promotion of health. A total of 20 participants, both male and female, were interviewed in a private location, using questions developed from theoretical sampling. Validation of participant's responses was justified by second interviews and clarification of concepts after a review of the interview audio recordings. The study concluded that once an individual is aware of the importance of exercise, a health blueprint is created, which is when attempts to integrate this activity into daily life commences (Kuo et al., 2013). This activity takes place up until the motivating force is removed, which is dependent on individual internal struggles and resistive factors. The results of the study concluded that health feedback motivated patients with prediabetes to engage in regular exercise. Analysis of the various interviews also attributed to the concept of self-discipline, and relationship to supervision of prediabetic individuals engaging in regular exercise. This study emphasized that sustainability in promoting adherence to lifestyle modification programs can result in delayed onset and even progression to diabetes. Ultimately, this will help to reduce the current healthcare expenditures needed to treat this disease and its

multisystem complications. Healthcare providers must motivate and assist patients in setting goals for improving health through exercise. Providing patients with individualized exercise options that conform to their lifestyle promote an enjoyable experience, which ultimately promotes adherence and sustainability. The results of this study can aid clinicians in motivating patients to spontaneously engage in exercise, with an intention to continue exercise and, ideally, prevent the onset of diabetes. Ultimately, this study supported the basis of this clinical problem, and proved more research is needed in determining what motivates prediabetic patients to adhere to lifestyle changes.

In a separate study, a group of researchers conducted a cross-sectional analysis of 5,991 participants greater than 53 years old from the 2006 wave of the Health and Retirement Study (Lee et al., 2013). The aim of the study was to highlight the prevalence of physical function limitations amongst a nationally representative sample of adults with prediabetes (Lee et al., 2013). Each of the subjects received a face to face interview in which random blood samples were collected by trained interviewers. After the subject's physical measures and biomarkers were recorded, each of them were required to self-report their commodities, inclusive of chronic diseases and geriatric conditions. As a result, the following six geriatric conditions were thoroughly analyzed: cognitive impairment, falls, urinary incontinence, visual impairment, hearing impairment, and chronic pain syndromes. The assessment of each participant's ability to perform activities of daily living and instrumental activities of daily living was used to determine whether physical function limitations were present. Conclusively, the study demonstrated that individuals with prediabetes generally had more physical function limitations and comorbid conditions than those with euglycemia, but fewer than those with diabetes (Lee et al., 2013).

Clinical trials such as the Finnish Diabetes Prevention Study and Diabetes Prevention

Program were referenced in this article to demonstrate that intensive lifestyle modifications can
delay or prevent diabetes. Statistical data from those studies failed to include subjects with
comorbidities and functional limitations that could pose as barriers to participation in lifestyle
modification programs. The results from this study emphasizes that the standard lifestyle
interventions such as brisk walking may not be feasible for every prediabetic patient. The
findings suggest that low rates of adherence to exercise programs amongst prediabetic adults,
may be attributed to lack of provider accommodation to physical function limitations.

Furthermore, exercise programs to prevent the onset of diabetes must be individualized to the
patient in order to promote adherence.

A comprehensive literature search yielded a paper that addresses prediabetes and the effectiveness of economical interventions to reduce the risk of diabetes. Greaves et al. (2008), examines the process of motivational interviewing, which is a well-defined and evidenced-based model for behavior change. Motivational interviewing involves exploration and exposing the excuses someone might utilize to engage in a particular behavior (Greaves et al., 2008). This process utilizes patient centered interviewing techniques to reduce some of the barriers to change. This particular study was identified as a pragmatic single-blind randomized controlled trial with researchers and statistician blinded to group allocation. The level of design was indeed the correct design needed for this type of study. Randomization and the use of blinding to participants and data researchers offered reliability to the results. Also solidifying the study's design was the randomization of participant's placement in study arms.

In a randomized controlled clinical trial, a group of researchers at primary care clinics located at the Durham Veterans Affairs (VA) Medical Centers examined the clinical effects of a

home based multicomponent physical activity counseling (PAC) intervention in older outpatients with prediabetes. The intervention consisted of a 12-month home based multicomponent PAC program including one in person baseline counseling session, regular telephone counseling, physician endorsement in clinic with monthly automated encouragement, and customized mailed materials (Morey et al., 2012). The study's design included an interim three-month assessment of physical activity participation and the assignment of counseling based on prescribed physical activity goals. A total of 302 study subjects were randomized in order to compare the effects of a one year home based physical activity telephone counseling intervention with usual care (Morey et al., 2012). Measurements of insulin action was assessed using the homeostasis model assessment of insulin resistance (HOMA-IR) combined with hemoglobin A1c as a secondary indicator of glycemic control. Results of this study concluded that healthcare providers need to focus on lifestyle modification programs that are low cost and accessible in order to promote adherence.

Furthermore, this study demonstrates that knowledge deficits exist for many prediabetic adults surrounding physical activity goals for glycemic control. Emphasis is placed on developing additional methods to maintain long term improvement and maintenance of efforts to prevent and or delay the onset of diabetes mellitus. Nonadherence continues to be a nationwide multifactorial phenomenon which poses further challenges in the prevention of the debilitating effects of diabetes mellitus.

Utilization of the Consolidated Standards of Reporting Trial (CONSORT) statement is aimed at facilitating critical appraisal and interpretation of randomized control trials (Altman et al., 2001). This acts as checklist to aid authors in improving the reporting of their trails. Greaves

article succinctly addresses each of the checklist items and demonstrates appropriate reporting, suggesting a high quality trial.

The current trends in evidenced based practice (EBP) relates to structured and purposive research scrutiny that is believed to be changing for the better. In current times, research is much more concerned with quality improvement, patient satisfaction, and outcomes. The growing focus on clinical research, where nurses can make a distinctive contribution, will continue to build on the knowledge base for the profession.

#### **Synthesis of the Evidence**

There is abundance of research in support of the feasibility of lifestyle modification programs for the prediabetic patient population, but a dearth of information surrounding adherence to these programs suggests a prevalent gap in the current literature. Critical appraisals of the key studies referenced throughout this paper demonstrate that more evidence is needed to explore methods to promote adherence to lifestyle modifications programs in prevention of the onset of T2DM. These studies present a plethora of reasoning to high attrition rates in exercise and lifestyle modification programs. According to Jiang et al. (2016), participant attrition in clinical trials is a complex, common, and costly problem that must be considered when implementing lifestyle modification programs. Through analysis of retention data for 36 healthcare programs and responses from questionnaires addressing socio-demographics, healthrelated behavior, and a range of psychosocial factors affecting participants was assessed. The following factors were identified as predicting attrition: gender, age, household income, comorbidity, chronic pain, marital status, and average age of staff (Jiang et al., 2016). Commonly, each study demonstrates that motivational forces must be constant throughout programs in order to change behavior definitively. The research presented in these studies will

provide for the elucidation of the proposed clinical problem. Review of the barriers and limitations mentioned in these studies, will aid in developing an intervention that is feasible at promoting client adherence to lifestyle modification programs for prediabetic adults in a primary care setting.

#### Conceptual/Theoretical Framework

A theoretical framework is a foundational perspective that guides the researcher in the complex analysis of a proposed topic of interest. Accord to Trent University (2015), theoretical foundations or frameworks often originate from various disciplines, which serves to beget new dimensions surrounding a particular topic. By definition, these frameworks are often broad subject approaches or viewpoints surrounding aspects of human existence. In order to effectively integrate evidence into practice, a theoretical basis must be utilized in order to enhance the understanding of a proposed clinical problem. Guidance for this clinical scholarly project was received utilizing the concepts of the Health Belief Model (HBM). This theoretical framework infers that an individual's belief in a personal threat of an illness or disease, combined with an individual's belief in the effectiveness of the recommended health behavior or action will predict if a person is likely to adopt the behavior. This framework is comprised of various constructs including: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cue to action, and self-efficacy. The constructs are used to further explain how an individual's course of action to disease is influenced by the individual's perceptions of the benefits and potential barriers to the adoption of a particular health behavior (Boston University School of Public Health, 2013).

Undeniably, health promotional interventions require a strong evidence base and applicable theory. The HBM was chosen for the purpose of analyzing the clinical problem

surrounding nonadherence to lifestyle modification programs in prediabetic adults. One of the most comprehensive lenses to view disease prevention and illness detection behavior is through the HBM (Bowden et al., 2003). This framework has been revised several times, and it serves as a useful tool for systematically analyzing personal health behaviors and compliance with medical regimens. This model suggests that health-seeking behavior is influenced by a person's perception of a threat posed by a health problem and the value associated with actions aimed at reducing the threat (Nursing Theories, 2012). The HBM enhances understanding surrounding preventative health actions that deter negative regions of illness and disease (Nursing Theories, 2012). The theory asserts that in order for a person to take preventive action to avoid illness, he or she must believe the following: he or she was personally susceptible to the disease state, the illness was moderately severe, and that taking action would reduce susceptibility and therefore be beneficial (Bowden et al., 2003). The individual outweighs benefits by the perceived barriers and the susceptibility and seriousness of the disease are solely dependent on personal beliefs (Bowden et al., 2003).

In 2001 the HBM was expanded into what is now called the Health Promotion Model (HPM). This model focuses on the concepts of health promotion, and its subsequent movement toward a positively valenced state of improved health and well-being (Bowden et al., 2003). The constructs of this theory suggest that the negatively valenced states of illness and disease fail to motivate individuals to perform health promotion activities. The revised model suggests that individual characteristics and experiences include the effect of prior related behavior and personal biological, psychological, and sociocultural factors (Bowden et al., 2003). Emphasis is placed on six behavior specific cognitions and affects that are thought to significantly influence an individual's motivation toward health promoting behaviors.

In regards to implications for the subjects used in this CSP, the HBM will serve as rational decision making model, which will examine some of the perceived threats and barriers prediabetic adults face with the implementation of lifestyle medication programs. The HBM will be used to explain the protective health actions and the cause of insufficient participation in lifestyle modification programs amongst prediabetic adults in a primary care clinic.

## **Chapter III: Methodology**

#### Overview

The design for this project was a quasi-experimental quantitative design. This design was chosen due to its congruency with the purpose of this CSP. According to Moran et al. (2014), this type of design is advantageous because it does not require randomization or a control group (Burson et al., 2014). This type of design was selected due to its capability of measuring change in health related outcomes after an intervention, when it is not always feasible to use a true experiment (Burson et al., 2014). Quasi-experimental designs compare groups created by some method other than random assignment, and can serve as an alternative to true experiments (Melnyk & Fineout-Overholt, 2011). This type of design has the potential to eliminate alternative explanations for the relationship between an intervention and the outcomes in the study (Melnyk & Fineout-Overholt, 2011).

## **Purpose Statement**

The purpose of this doctoral project is to determine if the integration of a multimedia based education for diabetes prevention will encourage prediabetic adults to actively engage in making lifestyle changes. The goal of this project is to encourage greater adherence to lifestyle modifications (i.e., diet and exercise) and reduction glycated hemoglobin A1c levels and weight, in efforts to decrease the development of type 2 diabetes mellitus and its associated medical, psychological and financial burdens to the patient, family, community, and society as a whole.

The quasi experimental design project will aim to provide a standardized and sustainable approach to diabetes prevention education to be used by primary care providers. The results of this project may aid primary care providers in reducing the burden from chronic disease management that is expected to ensue with the Affordable Care Act (ACA).

## **Population**

The population sampled in this CSP was that of convenience, which consisted of adult female and male patients between the ages of 21 to 64 years old at a community health clinic in Los Angeles, California. According to the Los Angeles County population demographics and statistics, currently 9,646,924 individuals live in Los Angeles County. Of those residing in Los Angeles County, 2,859,242 of those individuals are males between the ages of 21-64 years old (33.7%), and 2,938,963 (32%) are females between the ages of 21 to 64 years old (Suburban Stats, 2016). Each participant was required to understand the English language and meet diagnostic criteria for prediabetes which was defined as glycated hemoglobin A1c between 5.7-6.4%. The control group was conveniently selected utilizing a retrospective chart review. The intervention group was conveniently selected using flyers for recruitment (see Appendix D). The control group consisted of 20 (N=20); eight male and twelve female patients between the ages of 21-64 with glycated hemoglobin A1c levels between 5.7-6.4%. The intervention group consisted of 8 (N=8); three male and five female English literate patients of St. John's Well Child and Family Center in Compton, California, with glycated hemoglobin A1c readings between 5.7-6.4%. The intervention group sample size was smaller than originally anticipated due to exclusion criteria that eliminated the majority of patients served in the clinic that were not English literate. Throughout the implementation of this project many barriers and limitations were encountered, which will be further discussed in the 'Discussion' section of this paper.

#### Instrumentation

St. John's Well Child and Family Center is a Federally Qualified Health Center (FQHC) located in Compton, California. FQHCs are federally funded nonprofit health centers or clinics that serve medically underserved areas and populations (HealthCare.gov, n.d.). Based on the

CDC's framework for the National Diabetes Prevention Program, three multimedia based educational modules were recorded for participant viewing addressing key concepts for prevention of type 2 diabetes mellitus (see Appendix E). The lesson content for module one covered an introduction to prediabetes, risk factors, symptoms/diagnosis, description of the glycated hemoglobin A1c test, complications and treatment. The content covered in module two included: reading nutrition labels, carbohydrate foods, healthy eating habits, dining out, fatcontaining foods, sleep and weight loss, and the significance of water intake. This module featured a registered dietician on staff at the clinic who provided a scripted consultation for a patient presenting with prediabetes. Module three covered content surrounding physical activity, staying active, staying motivated, making an activity plan, and weight loss goals. For the purpose of the CSP, the modules were presented to participants in the lobby of the clinic during clinic afterhours using a 27-inch flat screen television. All participants were required to view the module in its entirety, and were given time after the video for additional questions. Educational handouts from the CDC website were available for each participant to take home to refer back to while implementing some of tools addressed in the video (see Appendix H).

The following instruments were used in this project: serum markers for measurement of glycated hemoglobin A1c performed at two accredited laboratories utilized by the facility, and a wall mounted professional digital scale for measurement of weight in pounds.

#### **Data Collection**

This project involved a retrospective chart review of medical records from patients at an FHQC in Los Angeles, California. The control group participants were not consented or contacted to provide any additional information beyond what was in their current medical records. The control group received usual care for a diagnosis of prediabetes, which is inclusive

of the distribution of educational brochures and minimal counseling during the follow-up visits.

The intervention group received a written informed consent for each participant (see Appendix C). All project related materials were approved by Brandman University's Institutional Review Board and a letter of support was gained from the organization where this CSP was implemented by the Medical Leadership Team (see Appendix G).

Upon arrival to the clinic, participants were placed in the waiting room by trained medical staff, per clinic policy. The staff measured each participant's weight and height using a digital scale and wall mounted stadiometer. The principal investigator determined eligibility of study participants and provided a brief introduction about the purpose of the project. Medical staff then obtained informed consent. All eligible participants in the intervention group watched the first module of multimedia education in a group setting. At the conclusion of the first module, an additional 30 minutes was provided for additional questions and handouts (see Appendix H) to all participants. The principal investigator provided light and low calorie refreshments, as a reminder to start making better dietary choices.

Data extracted from medical records included glycated hemoglobin A1c, weight, height, age and sex. At the end of the session, all participants were asked to sign up for the remaining sessions in two to four weeks. A chart review was performed to determine whether they returned for their scheduled follow-up. If the patient did not return for their follow-up sessions, several phone calls were made to determine reasons for not following through with the project.

Data collection for the control group was performed utilizing the process of a retrospective chart review of the electronic health records of participants who met inclusion criteria. The intervention group data was collected at follow-up office visits scheduled 90 days after implementation of the video based educational intervention. Variables collected included:

age, gender, weight in pounds, and glycated hemoglobin A1c measurements. All data was entered into the SPSS Database System by the primary investigator for statistical analysis and were also secondarily analyzed by a professional statistician.

#### **Data Analysis**

Data analysis was completed using Statistical Software IBM SPSS Statistics 23 (Armonk, NY). Independent *t* tests were used to assess weight loss from initial weight to final weight at the conclusion of the 90-day study in both intervention and control groups, as well as the change in glycated hemoglobin A1c from baseline to 90 days after the project's implementation in both groups. A *p*-value of less than 0.05 was required for statistical significance.

#### Limitations

There are many limitations to this clinical scholarly project that must be considered. There was a loss of participants to follow up at 3 months. Therefore, for the primary weight loss outcome, the efficacy of the intervention may have been overestimated if weight loss was lower in non-respondents. There were more participants lost to follow up in the intervention group versus the control group. As loss to follow up was greater in the intervention group, the group differences observed may have been greater if all participants were represented. The majority of the sample consisted of women of low socioeconomic and educational status, although recruitment targeted the both male and female gender. This may demonstrate the tendency of women to more readily adopt lifestyle modification programs.

#### **Chapter IV: Results**

#### **Evidence and Summary**

Data analysis was completed using IBM SPSS Statistics Version 23 (Armonk, NY). A descriptive analysis comparing the participant's weight and glycated hemoglobin A1c at 0 and 3 months was carried out using SPSS for both control and intervention groups. Independent t tests were used to assess reductions in both weight and glycated hemoglobin A1c measurements in both control and intervention groups. In this clinical scholarly project, the intervention group was comprised of 8 participants (N=8) and the control group was comprised of 20 participants (N=20) eight males and twelve females. A total of 11 participants enrolled in the study, while three participants withdrew from the study, citing job and health related reasons. The remaining participants completed only 33 percent of the video based educational curriculum.

In analysis of the baseline weight and glycated hemoglobin A1c measurements, an independent sample t-test was utilized to compare values between the control group (N=20) and intervention group (N=8) (see Table 1). The results demonstrate that there was no statistically significant difference between the two groups glycated hemoglobin A1c at baseline [t (26) = -0.332, p=0.742], A1c post-intervention [t (26) = -1.277, p=0.213], weight at baseline [t (26) = -0.026, p=0.980], and weight post-intervention [t (26) = -0.363, p=0.719] (see Table 2).

Group descriptive statistics revealed that the mean weight for participants in the intervention group (M=194.8) was not significantly different from that of the participants in the control group (M=202.3), t (26)= 0.3918, p= 0.69. The t test revealed that the mean glycated hemoglobin A1c for participants in the intervention group (M=5.8) was also not significantly different from that of the participants in the control group (M=5.9), t (26)=1.14, p= 0.26 (see Table 1).

According to descriptive statistics, baseline weight for the intervention group (*N*=8) was on average 204.5 pounds, and baseline glycated hemoglobin A1c on average for this group was 5.9%. The control group (*N*=20) had a baseline weight of 204 pounds, and a baseline glycated hemoglobin A1c of 5.9%. Assessment at 3-months post intervention demonstrated that participants in the intervention group had a weight on average of 195 pounds, and a glycated hemoglobin A1c of 5.8%. In the control group participants 3 months after receiving usual care had an average weight of 202 pounds, and a glycated hemoglobin A1c of 5.9%. The intervention group on average lost 9.7 pounds and the control group lost an average of 2 pounds during the 90-day project. These findings suggest that the implementation of a multimedia based diabetes prevention program may encourage adherence to lifestyle modifications thus reducing modifiable risk factors for diabetes.

Although reductions in weight and glycated hemoglobin A1c levels were observed, the *p*-value demonstrated that the implementation of a multimedia based diabetes prevention program made no statistically significant differences between both the control and intervention groups in this project.

Table 1: Changes in Glycated Hemoglobin A1c and Weight Descriptive Statistics

**Group Statistics** 

			p Statistics		
					Std. Error
	Group	n	Mean	Std. Deviation	Mean
A1c baseline	1	8	5.9500	.22678	.08018
	2	20	5.9800	.21176	.04735
Alc post	1	8	5.8000	.18516	.06547
	2	20	5.9150	.22542	.05041
Weight	1	8	204.50	50.754	17.944
baseline	2	20	204.00	44.896	10.039
Weight post	1	8	195.38	50.142	17.728
	2	20	202.35	44.192	9.882

Table 2: Independent Samples t-test: Changes in glycated hemoglobin A1c and Weight

	Tes Equa	rene's st for slity of							
	Vari	ances	1		t-tes	t for Equality	of Means		
					р-			95% Cor	nfidence
					value			Interval	of the
		p-			(2-	Mean	Std. Error	Diffe	ence
	f	value	t	df	tailed)	Difference	Difference	Lower	Upper
A1c Baseline									
Equal variances assumed	.030	.865	332	26	.742	03000	.09032	21566	.15566
Equal variances not assumed			322	12.188	.753	03000	.09312	23254	.17254
A1c Post									
Equal variances assumed	1.35 1	.256	-1.277	26	.213	11500	.09008	30016	.07016
Equal variances not assumed			-1.392	15.724	.183	11500	.08262	29040	.06040
Weight Baseline									
Equal variances assumed	.319	.577	.026	26	.980	.500	19.472	-39.525	40.525
Equal variances not assumed			.024	11.647	.981	.500	20.562	-44.451	45.451
Weight Post									
Equal variances assumed	.046	.832	363	26	.719	-6.975	19.189	-46.418	32.468
Equal variances not assumed			344	11.613	.737	-6.975	20.296	-51.361	37.411

#### **Chapter V: Discussion**

#### **Implications for Optimized Care**

The findings of this clinical scholarly project have implications for both community health and nursing research. Prior studies have demonstrated the reduction of barriers to diabetes education through the use of multimedia modalities. According to Ackerman et al. (2014), television is a potentially powerful medium for influencing consumer behaviors. The reductions in weight and glycated hemoglobin A1c measurements that were observed in this project suggest that multimedia can be utilized to promote healthier lifestyles and weight loss. The delivery of diabetes prevention education through multimedia assisted programming has the potential to expand access to care to a larger subset of people. This innovative approach to diabetes prevention is cost effective, and has the ability to reduce barriers to care in the community health settings that lack specialized resources for diabetes prevention. Similar modalities can be used to disseminate diabetes prevention education at multiple sites simultaneously or asynchronously. Using multimedia to convey basic disease risk information has the ability to reduce some of the health education barriers related to clinician time constraints in the primary care arena.

#### **Implications for Advanced Practice Registered Nursing**

Advanced Practice Registered Nurses (APRNs) are passionate about advancing the field of nursing, and often find themselves spearheading change projects within their organization. This specialized group of nurses value collaboration with other disciplines in order to provide optimal care to patients, while enhancing productivity within the organizational structure. Innovation is no longer an optional skill set in healthcare, as the vitality and construction of the organization depends on it (Malloch & Porter-O'Grady, 2015). In order to promote a culture of innovation, the APRN must possess specific skills that inspires and motivates people to

challenge the status quo. The APRN is confident in making decisions and is viewed by others as a risk taker. APRNs must be willing to show their true self by demonstrating vulnerability, which allows them to connect with multiple disciplines within the organization (Malloch & Porter-O'Grady, 2010). Searching for various ways to revolutionize health care, the APRN is viewed as an innovative leader, and due to courage is not afraid of toxic behaviors that present as barriers to the change process. This leader anticipates future trends in healthcare, and remains proactive in order to promote the organizational context for innovation.

Type 2 Diabetes Mellitus continues to be viewed as a major public health problem, due to its adverse effects on healthcare expenditures, and both morbidity and mortality rates. The identification of at risk patient populations is paramount to preventing or halting the development of type 2 diabetes mellitus. Patients with prediabetes are at high risk for developing type 2 diabetes mellitus, thus efforts must be geared toward early screening and preventive measures. According to ADA (2016), clinicians should screen individuals with the following characteristics: sedentary lifestyle, body mass index (BMI) greater than 25 kg/m² and greater than 23 kg/m² for Asian Americans, family history of diabetes mellitus, high risk race (African American/Hispanic/Pacific Islander), history of gestational diabetes or delivery of a baby over 9 pounds, history of hypertension, high cholesterol, Acanthosis Nigricans, or a history of cardiovascular disease.

Healthy People 2020 have proposed an objective to reduce the annual new cases of diabetes in the population (HealthyPeople.gov, 2014). Outcomes of this clinical scholarly project emphasized the critical role APRNs play in health promotion and disease prevention. According to the Health Belief Model, a person's health related behavior depends on the person's perception to the benefits to taking preventative action (Nursing Theories, 2012). Therefore,

APRNs must continue to find innovative modalities that motivate patients to adhere to lifestyle modifications. Although the outcome measures for this project proved to be statistically insignificant, the reductions in weight and glycated hemoglobin A1c measurements in the intervention group demonstrates that multimedia diabetes prevention education has an impact on encouraging lifestyle modifications. The findings of this project have vast implications for APRNs to dedicate time in the clinical setting towards teaching lifestyle modifications to patients at risk for diabetes mellitus.

#### Limitations

This clinical project has several limitations. Firstly, the small sample size may have influenced the results, while the use of convenience sampling in this project may have also impacted the results gathered by the principal investigator. Convenience sampling is generally not preferred over random sampling, because samples of convenience often fail to eliminate selection bias, which in turn affects the validity of study's results. Attrition with participants was high, and there was minimal variability in the time participants returned for their 90-day follow-up visit. Although reductions in weight and glycated hemoglobin A1c measurements were observed, this may be attributed to enrolling in the study, subsequently resulting in a phenomenon known as the Hawthorne Effect. This is where individuals modify their behavior in response to their awareness to being observed (Melnyk & Fineout-Overholt, 2011).

#### **Incorporating DNP Essentials**

According to the American Association of Colleges of Nursing (AACN) (2004), doctorally prepared nurses with a blend of clinical, organizational, economic and leadership skills are more likely to be able to critique nursing and other clinical scientific findings and design programs of care delivery that are locally acceptable, economically feasible, and which

significantly impact health care outcomes. The Doctor of Nursing Practice (DNP) scholar possesses a wide knowledge base of scientific concepts, and has the skills to translate that knowledge quickly and efficiently in order to benefit patients in daily practice environments (American Association of Colleges of Nursing, 2015). The scholar is prepared as a clinical leader at the highest level in nursing, and has a sound understanding of the human condition, the environment in which clients live, the systems of care delivery, and the political realm of healthcare (Barker, 2009). Development and implementation of this DNP clinical scholarly project has resulted in the opportunity to demonstrate advanced knowledge in the field of nursing. The *DNP Essentials* address the foundational competencies that are paramount to all advanced nursing practice roles (American Association of Colleges of Nursing, 2004). Thus, the DNP scholar should use the constructs of the CSP to demonstrate achievement of all eight *DNP Essentials*.

Essential I: Scientific Underpinnings for Practice. DNP scholars possess a wide knowledge base that stems from the sciences, and have the ability to translate that knowledge quickly and effectively to benefit patients in daily practice environments (American Association of Colleges of Nursing, 2004). Through implementation of the CSP, maintaining moral principles proved to be a challenging task due to the propensity to conflict with the desire to produce robust evidence. When human subjects are used as study participants, care must be exercised to ensure that their rights are protected (Beck & Polit, 2012). Ethical standards in research are based on the following principals: beneficence, respect for human dignity, and justice. When applied to nursing research beneficence requires researchers to minimize harm and maximize benefits, and human research should be aimed to produce benefits for subjects (Beck & Polit, 2012).

Those participating in this CSP received informed consents, and were able to exercise their rights to self-determination at all times (see Appendix C). Participants were also informed that a voluntary decision on whether to take part in the project without risk of prejudicial treatment or coercion was guaranteed. Full disclosure of the nature of the project including the risks and benefits, rights to refuse participation at any time, and the principal investigator's responsibilities was clearly articulated. Finally, participants were treated fairly regardless of their vulnerability or ethnic background. As a DNP scholar, safeguarding the privacy of subjects was paramount, and ensuring that data obtained in this project is kept confidential remains a priority. Utilization of ethical principles to implement this CSP allowed for the evaluation of how knowledge from other disciplines is integrated into nursing science in order to perform at the highest level of nursing practice.

Using the major concepts of the HBM, that was borrowed from the discipline of psychology; this project demonstrated an innovative approach to diabetes prevention has the potential to advance nursing science. For the purpose of this CSP the HBM further explained reasoning for the unfavorable results of this project, as well as examined some of the perceived threats and barriers prediabetic adults face with implementation of lifestyle medication programs.

Essential II: Organizational and Systems Leadership for Quality Improvement and Systems Thinking. The structure of an organization must remain conducive to the needs of the patients they serve. The organizational climate or the characteristics of the organization such as: physical attributes, organizational structures, lines of communications, policies and procedures affect the way patient care is delivered (Decker & Sullivan, 2001). This creates an environment in which healthcare providers share similar values and perform care the right way. Client centered care is the end result of effective management and a supportive work environment

where patient care is the number one priority. Continuous emphasis on satisfying the needs of patients by using all the necessary resources, processes, and components within the structure will aid in delivery of client centered care. Remaining sensitive to the specific needs of the patient population your organization serves is integral to maintaining an environment that supports quality care. A positive culture maintains a focus where everyone's role is geared toward providing patient satisfaction and improved patient outcomes.

The success of an organization lies on several factors, one being the information systems utilized within the structure. The parallel structure of this organization is consistent with the information systems implemented into the various departments within this facility. Due to the high volume of patients seen in this community clinic, a highly technical task-oriented environment is required. According to Decker and Sullivan (2001), organizational culture manages information technology processes that contribute to organizational growth and success.

Communication methods affect the productivity of any organizational structure. Leaders must consider the culture and organizational structure of the agency when communicating with staff. Maintaining effective, consistent, and meaningful communication promotes empowerment of staff as well as interpersonal relationships between leaders and followers. The size and complexity of the organization contributes to the use of formal communication methods such as professional email or in a meeting. Organizational effectiveness relies on the communication among professionals to meet the goals and needs of the facility.

This essential was exercised continuously throughout this project, in efforts to gain key stakeholder buy in. Healthcare expenditures for patients in the United States with diagnosed diabetes totaled 245 billion dollars in year 2010 (American Diabetes Association, 2010).

Therefore, the implementation of a doctoral project aimed to prevent and/or halt the progression

of this disease offers long term cost savings and a reduction in healthcare expenditures. A costeffectiveness analysis surrounding the implementation of this CSP was presented to the Medical
Leadership Team (MLT) at the clinic this CSP was implemented at and the main costs of the
project were associated with the production of the video. Direct cost include supplies need to
obtain baseline laboratory data such as vacutainers, needles, alcohol pads, cotton, tape, and
tourniquets. Indirect cost included overhead such as salary for medical assistants and laboratory
staff, filmography, and hourly wages for professional consultations with experts. Clarification
with the MLT required utilization of advanced communication skills in efforts to enhance
rapport and gain clinical support for this CSP. As DNP scholars and leaders in healthcare having
the ability to communicate effectively is vital to the safety of the patient population in which you
serve.

#### Essential III: Clinical Scholarship and Analytical Methods for Evidenced-Based Practice

Advanced practice registered nurses have a vital role in the evidenced based practice process. The process involves the integration of best research evidence combined with clinical expertise, and patient values in order to deliver optimal and client centered care (Barker, 2009). These nurses must possess advanced skills in accessing and critically analyzing research, in order to propose significant changes in clinical practice. Healthcare related research is continuously being produced, which has a potential to adversely affect healthcare expenditure, quality, and patient outcomes if not supported by valid data. Through the process of conducting a comprehensive literature review during the implementation of this CSP, allowed for the exemplification of more than one of the components of *DNP Essential III*. During the research process, use of several validated rapid critical appraisal tools for both qualitative and quantitative evidence were used to identify the strengths and weaknesses of various studies in efforts to

determine its validity, reliability, and applicability. The previous work of the CDC in the context of diabetes prevention, allowed for the development of an evidenced based diabetes prevention program using multimedia. The CSP process allows the DNP scholar to exercise every construct of this particular essential, and ultimately improve nursing practice.

# Essential IV: Information Systems/ Technology and Patient Care Technology for the Improvement and Transformation of Health Care

The health care delivery system is shaped and promoted by technology. Advances in health care technology are driven by several factors including: patient safety, consumer demands, and quality care based on best practices. According to Patton (2001), technological advances have improved medical practice. Technology supports the work of health care professionals and improves health care quality by reducing the incidence of medical errors and improving communication among healthcare providers. The use of computer software has been employed at health care institutions to support healthcare professionals by providing them with information to facilitate rational decision making in the patient's plan of care. The knowledge base in computer software is formulated to aid clinical decision making in conjunction with the expertise of the health care professional. Decision aids refer to a variety of computerized support tools used to assist individuals in reaching an optimal decision. In healthcare these aids help professionals make medical diagnosis, while taking into account individual preferences and several options and or aspects. A decision aid is a sub category of the decision support system. According to Ball et al. (2006), a decision support system supports individuals by providing them with the data necessary to make informed decisions about patient care. Decision support systems are used to diagnose and manage patients who present with complex medical problems that exceed the

knowledge and expertise of the primary care provider. Technology plays a major role in maintaining the infrastructure of quality health care.

DNP Essential IV was exercised through the use of eClinical Works, which is the electronic health information systems used at the community health center this project was implemented at. As a DNP scholar, use of advanced technical skills to access retrospective data for the control group in this CSP allowed for monitoring of outcomes of care. Use of this information technology resulted in the analysis of usual care for prediabetes management, and the development of additional programs of care to improve quality of care for this patient population. Leadership as it relates to DNP Essential IV was demonstrated through compliance with the constructs of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in the process of accessing patient information systems for data collection.

#### **Essential V: Health Care Policy for Advocacy in Health Care**

According to Chaffee et al. (2012), public policy can be either made by the public or government officials in order to address public problems. In public policy, making legislative, judicial, or executive branches of government translate its visions into actions, while promoting change to resolve an issue is paramount. According to Milstead (2008), public policy involves the directing of organizational problems to the government in order to elicit a response. That response is often in the form of a bill or law that is expected to achieve goals or formulate programs to assist with a proposed problem. Private healthcare policy differs in the essence that it deals with the insured population and issues such as long term care sector and standards of care. Nurses have a major role in influencing healthcare policy in both the public and private sectors by speaking out on healthcare issues that affect society such as prevention of disease and

patient safety. Collaborating with legislators allows nurses to advocate for their patients and the community through implementation of new laws and policies that improve healthcare.

The process of policy making is a complex process that involves input from legislators at the local, state, and national levels. Local policy makers often introduce legislation brought to their attention by community members. State legislators shape policy on health by determining who is eligible for care under specific programs and providing leadership in defining problems for both public and private sectors to address (Chaffee et al., 2012). Ultimately the president holds the final decision in policy making. The president is at the top of the national level of policy making and often taking proposed issues to the top of the nation's policy agenda.

Educating fellow providers, ancillary staff, and policy makers within the setting where this CSP was conducted was one example of exercising *DNP Essential V*. Educating the staff allowed for the dissemination of an existent health disparity within the community, and the needs to improve health care deliver for prediabetic adults through innovative modalities.

# Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes

Health care environments today are dependent on the contributions of highly skilled and knowledgeable individuals from multiple disciplines. The DNP scholar is a key member of the multidisciplinary team, and must utilize advanced knowledge and leadership skills in efforts to mandate patient centered care (American Association of Colleges of Nursing, 2006). According to Bridges et al. (2011), patients in today's healthcare environment have complex medical issues that require input from various disciplines to address issues regarding health status. The premise surrounding this professional model is healthcare professionals sharing each other's expertise

and perspectives to form a common goal of restoring or maintaining an individual's health, and improving outcomes while combining resources (Bridges, 2011).

Clinical insight surrounding nutrition and its role in reducing risk factors for diabetes was gained through collaboration with the clinic's Registered Dietician (RD). Having an RD featured on the educational video added credibility to the nutritional module for the program, and provide insight to the dietician's role in diabetes prevention. During the data analysis component of this CSP, a statistician was consulted as a third party to further analyze each participant's data. Collaborating with a professional with expertise in statistical knowledge allowed for sharing of knowledge and skills in efforts to improve clinical outcomes with the results from this CSP. Essential VII: Clinical Prevention and Population Health for Improving the Nation's

# Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health

Doctors of Nursing Practice in today's dynamic society are finding themselves working in an increasingly diverse society. Concepts involving the delivery of cultural competent care are crucial to the health and wellness of clients. According to Castro & Ruiz (2009), culturally competent care or sensitivity to issues surrounding culture, race gender, and sexual orientation is a major contributor for enhanced medical outcomes and overall patient compliance. As a DNP scholar health promotion and disease prevention must be customized to the values and beliefs of the client's culture in order to be effective. The APRN must be open to learning about the norms and values of various cultures which will strengthen the provider-client relationship and yield empowerment. The patient is often more willing to accept accountability for his/her own healthcare. Delivery of culturally sensitive care ultimately increases patient satisfaction, and reduces the disparities to healthcare experienced by many of the vulnerable populations present in our society.

According to Washington (2009), disparities to healthcare is of much concern for healthcare providers due to recent research results that demonstrate inconsistencies between length of life and quality of life associated with specific cultural groups. Many of the members of various cultural groups are associated with stigmas and stereotypes that contribute to their mistrust amongst providers and the healthcare system in general. Immigrants from foreign countries where access to quality healthcare is scare and poverty is prevalent, come into the US with complex medical problems and chronic diseases that require a regimen consistent with their cultural needs. Barriers to communication must be addressed by using medical interpreters in order to perform accurate healthy histories and exams that can aid the patient in returning to an optimal health state.

Statistics show that in 2014 Los Angeles County had an estimated 536,000 adults diagnosed with T2DM. It was noted that 7.2 % of the Los Angeles County population had T2DM, while an estimated 1,831,000 adults were also estimated to qualify as being obese (California Department of Public Health, 2014). It has been well studied that low socioeconomic status, gender, race, and level of education all influence prevalence rates in the epidemiology of T2DM. Gaps in the literature for diabetes prevention and the role of innovation and technology in promotion of adherence to lifestyle modification programs formed the purpose for the CSP. Through a community analysis, it was found that the community where this project was implemented at was in need of access to programs for diabetes prevention. Ensuring the intervention used in this project incorporated culturally sensitive examples for making lifestyle modification, seemed to resonate well with the participants. All concepts discussed in the video intervention were communicated in layman's terms to ensure equal understanding for the various levels of education in the intervention group.

#### **Essential VIII: Advanced Nursing Practice**

According to Barker (2009), advanced practice nursing is the application of an expanded range of practical, theoretical, and research-based competencies to phenomena experienced by patients within a specialized clinical area of the larger discipline in nursing. Although the role of the APRN varies, these nurses possess a greater breath of knowledge and complexity of decision making to the problems of nursing care (Barker, 2009).

According to Sullivan (2009), evidenced based practice is the integration of best research evidence with clinical expertise and patient values to deliver optimal care. Best research is further defined as originating from clinically relevant and patient centered research studies. APRNs are clinical experts who implement a holistic approach to healthcare while applying evidenced based practice to manage the health needs of patients in a variety of health care settings. The scope of the APRN is often so broad, that continued education and a vast knowledge base of evidenced base practice is integral to providing optimal patient care. Evidenced based practice requires that scientific research be published on the specific topic of interest and that the clinician utilizing it possess the necessary skills in accessing and critically analyzing research (Sullivan, 2009). One of the main principals is that the area of practice using evidenced based research must have an immediate need for implementing changes based on evidence.

Implementation of this CSP in a community health center allowed for not only the application of DNP *Essential VIII*, but for high levels of critical thinking, independence, and decision making. The intense review of the literature required of this CSP, resulted in the refinement in the ability to critically appraise research articles before integrating findings into daily practice. While planning for this CSP collaborating with policy makers allowed for systems

thinking, while demonstrating the cost and potential benefits of making evidenced based changes to our approach to diabetes prevention. As a DNP scholar, encouraging other nurses to advance the profession through attainment of advanced knowledge and skills is a personal mission of mines. Implementation of this project geared toward disease prevention not only demonstrated dedication towards facilitating optimal patient outcomes in the community health setting, it also fosters a culture of community awareness and education. Implementing this project resulted in the demonstration of sustainable therapeutic relationships with patients, by making it a priority to put systems in place to prevent diseases they were at highest risk for.

#### Recommendations

Innovation is needed in health promotion and disease prevention programs in today's society. Patients at highest risk for developing type 2 diabetes mellitus may benefit from the availability of alternative care delivery models similar to the intervention conducted for the purpose of this clinical scholarly project. Although limitations including the small sample size and short duration of the intervention resulted in the inability to demonstrate the achievement of clinically significant outcome measures, the innovative approach to diabetes prevention serves as a basis for larger projects. Larger studies of longer duration are needed to assess the feasibility and cost effectiveness of implementing similar interventions in the community health arena (Ackerman et al., 2014). Additional research is needed in assessing the use of multimedia in the delivery of lifestyle intervention services, and its impact on patient motivation and adherence to lifestyle changes. Research is also needed to evaluate whether the weight loss obtained from similar interventions is sustainable over longer durations. Future studies should prioritize incorporating ways to maximize adherence. Additional research is needed to compare the weight

loss and change in glycated hemoglobin A1c levels seen in media assisted interventions with that of in- person formats.

#### **Sustainability**

In a similar action based research study, Majid et al. (2012) developed an educational video narrated by U.S. Surgeon General Dr. Regina Benjamin in efforts to provide accessible and usable information about the importance of incorporating physical activity into the lives of individuals with type 2 diabetes mellitus. Study results proved that the video was engaging and informative, and is currently being used as a tool in a problem solving self-management training program for African Americans in poor metabolic control (Majid et al., 2012).

According to Malloch and Porter O'Grady (2015), sustainable change rarely operates from the top of a system. Providers and clients will work together to make healthcare decisions and determine ways to individualize treatment plans to ensure adherence with lifestyle modification programs. Sustainability workgroups consisting primarily of clinical champions and organization stakeholders such as the Chief Medical Officer and Chief Operations Officer can provide the support needed to sustain the goals of this CSP. Conducting periodic in-services and training new staff members to implement this intervention into their daily practice will ensure prediabetic patients consistently receive a standardized approach to care even after implementation of this project. Gaining support from local organizations has the potential to allow this intervention to serve as a healthcare model for other communities plagued by prediabetes.

The diabetes prevention education modules developed for this clinical project will be available online via YouTube for patients to continuously access. This acts as an additional educational resource that will be provided for patients to combat the onset of type 2 diabetes.

The project also serves as a group visit model for prediabetes management in the setting of a formal support group. Collaborating with other disciplines such as a diabetic educators and registered dieticians is needed to make enhancements and modifications for this CSP that support the dynamic changes in healthcare and technology. Identifying clinical champions within the organization that are eager to adopt and advocate for this change in practice will help to fill the gaps in prediabetes management. Collaborating with credible organizations such as the CDC to launch a larger DPP that integrates multimedia and CDC curriculum for diabetes prevention would ensure future sustainment of this CSP.

#### **Dissemination**

As described in the Doctor of Nursing Practice (DNP) essentials, dissemination of findings from evidenced based practice and research is paramount to improve health outcomes (American Association of Colleges of Nursing, 2006). Through electronic submission of this manuscript to Brandman University Library the results of this clinical scholarly project will be open access for interested parties. The manuscript will be available to the public for years to come, and can serve as a model for larger studies of longer duration. Considering that this project was conducted at a local community health clinic, the outcomes and results of this scholarly project will be shared with the relevant stakeholders at our clinical quality improvement committee meetings. An abstract will also be submitted to the American Diabetes Association (ADA) conference review committee. If accepted the results from this project will be communicated in the form of a poster presentation to ADA conference attendees. Upon completion of the degree requirements, the completed manuscript will be submitted to the Doctors of Nursing Practice Incorporated online repository of doctoral projects in efforts to further advance the profession of nursing and improve health related outcomes.

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## Appendices

## Appendix A. IRB Approval Form

Page 3 of 3

#### BRANDMAN UNIVERSITY INSTITUTIONAL REVIEW BOARD IRB APPLICATION ACTION – APPROVAL COMPLETED BY BUIRB

#### IRB ACTION/APPROVAL

Name of Investigator/Research	er:Ebony Fur	nches
Returned without review	w. Insufficient detail t	to adequately assess risks, protections and benefits.
Approved/Certified as E	xempt form IRB Revie	w.
Approved as submitted		
Approved, contingent o	n minor revisions (see	attached)
Requires significant mo-		ocol before approval. Research must resubmit with
Researcher must contact	ct IRB member and dis	cuss revisions to research proposal and protocol.
Level of Risk: No Risk	✓ Minima	al Risk More than Minimal Risk
IRR Comments:		
Dr. Michael IRB Reviewer:Moodian	Opathy agencity the Monae Models (b) on-D. Monae Models of-Brackers Privates conflict Commisse Monae, Institutional Reportments on US Case 2019-0425 (RDS24-0750)	
Telephone:		Email: moodian@brandman.edu
Dr. Douglas BUIRB Chair: <u>DeVore</u>	Control signed so for Compact Devices (St. or Col. Compact Devices (St. or Col. Compact Devices (St. or Col. Col. Col. Col. Col. Col. Col. Col.	Date: 4/21/16
REVISED IRB Application	Approved	Returned
Telephone:	Email:	Date:
BUIRB Chair:		_
Brandman University IRB Rev, 11	.14.14 Add	opted November 2014

TO THE SUBJECTS? Increase Decrease No change
Explain (attach sheets as necessary):
4. WILL THE MODIFICATION(S) ALTER THE APPROVED CONSENT FORM? Yes IN No
If yes, attach original and one copy of a revised consent form, with additions and deletions clearly marked, to this form for review and approval.
<ol> <li>DID ANY UNANTICIPATED PROTOCOL DEVIATIONS (INCLUDING ERRORS AND ACCIDENTS) OCCUR SINCE THE LAST REVIEW?</li> <li>Yes</li> <li>No</li> </ol>
If yes, summarize all protocol deviations (attach sheets as necessary):
6. HAVE UNANTICIPATED RISKS OR SIGNIFICANT NEW FINDINGS BEEN DISCOVERED SINCE THE PREVIOUS BUIRB REVIEW THAT MIGHT AFFECT THE SUBJECTS' WILLINGNESS TO CONTINUE PARTICIPATION? ☐ Yes ■ No
If yes, complete the following:  a) Explain the risks or findings in detail (Attached sheets as necessary):  b) Do these risks or finding require modification of the informed consent form?  Yes No
c) Were subjects notified of these risks or findings? Yes No d) Were subjects reconsented? Yes No
I certify that none of these changes have been made and that no changes will be implemented prior to IRB review and approval.
Ebony Funches Capath spreetly Ebony Furches 12/19/2016
Principal Investigator:DateDateDateDateDate
Brandman University IRB Adopted November 2013
BRANDMAN UNIVERSITY INSTITUTIONAL REVIEW BOARD REQUEST FOR MODIFICATION OF APPROVED PROJECT  The modification/amendment described on page 1 qualifies for and has been approved by expedited review.
The modification/amendment described on page 1 has been reviewed and approved by the Brandman University Institutional Review Board.
The modification/amendment described on page requires additional changes to secure approval.
COMMENTS:

Chair, Brandman University Institutional Review Board

1-9-17

Date

Brandman University IRB Adopted November 2013

Appendix B. Information Letter

Date: March 27, 2016

**Dear Participants:** 

My name is Ebony Funches and I am a Doctor of Nursing Practice Student at Brandman

University in Irvine, California. I am conducting a doctoral project on the use of a video based

educational intervention in prediabetic adults in efforts to prevent and/or halt the onset of Type 2

Diabetes Mellitus.

I am asking for your assistance in this project by participating in a group based educational

session monthly over the course of 3 months. Each session will require approximately 30-60

minutes of your time. If you agree to participate in the educational intervention, you may be

assured that your personal information will be completely confidential. No names will be

attached to any notes or records from the data that will be collected throughout the project. All

information will remain in locked files accessible only to the principle investigator and clinic

staff assisting with this project. No (employer, supervisor, agency-whatever is applicable) will

have access to the data that is collected. You have the right if you chose to withdraw from the

project at any time. Further, you may be assured that the principle investigator or staff assisting

with this project is not in any way affiliated with (the administration, the employing agency, the

applicable supervisory organization etc.).

The doctoral project chair Dr. James Morgan, or principal investigator Ebony Funches is

available via email at morg1102@brandman.edu or efunches@mail.brandman.edu to answer any

questions you may have. Your participation would be greatly valued.

Sincerely,

Ebony Funches FNP-C

60

#### Appendix C. Informed Consent

**Information about:** Innovative Approach to Diabetes Prevention: Utilization of a multimedia based diabetes prevention program to encourage adherence to lifestyle modifications in prediabetic adults for prevention of Type 2 Diabetes Mellitus

Principal Investigator: Ebony Funches MSN, FNP-C

**Purpose of Project**: The purpose of this doctoral project is to determine if the integration of a multimedia based education for diabetes prevention will encouraged prediabetic adults to actively engage in making lifestyle changes, resulting in greater adherence to lifestyle modification (diet/exercise) and reduction of blood glucose levels in efforts to decrease the development of type 2 diabetes mellitus and its associated medical, psychological and financial burdens to the patient, family, community, and society as a whole.

The project will aim to provide a standardized and sustainable approach to diabetes prevention education to be used by primary care providers. The results of this project may aid primary care providers in reducing the burden from chronic disease management that is expected to ensue with the Affordable Care Act (ACA).

By participating in this project I agree to attend one of the multimedia integrated diabetes educational session per month for a total of three months, at St. John's Well Child and Family Center in Compton, California. You will be in a class with other participants and asked to demonstrate some of the exercises and dietary changes you have learned from each session. You will be given educational materials, individually explained by the principal investigator, Ebony Funches APRN, MSN, FNP-C, which will allow you to follow a lifestyle modification program for the purpose of improving your blood sugar levels and preventing the onset of type 2

diabetes mellitus. You will be randomly assigned to one of the two groups, the experimental group or the control group by one of the staff members.

The principal investigator or medical facility attending physician will not know which participant has been assigned to each group. There is no other time commitments required of you besides one session per month for three months.

#### I understand that:

- a) That there are minimal risks associated with participating in this project. I understand that the principal investigator will protect my confidentiality by keeping the identification codes and data collection materials in a locked file drawer that is available only to the principal investigator.
- b) The potential benefits of participating in this project may include the adoption of healthier dietary and exercise habits with a reduction in blood sugar levels. Long term benefits may be that participants prevent or delay the onset of type 2 diabetes mellitus. This may result in a decrease in associated healthcare expenditures, psychological and financial implications to the patient, family, community and society as a whole. I understand that I will not be compensated for my participation.
- c) If you have questions or concerns about this project, do not hesitate to contact Ebony Funches MSN, FNP-C via email at efunches@mail.brandman.edu\_or\_telephone (310) 603-1332; or Dr. James Morgan (Academic Chair) @ morg1102@brandman.edu
- d) My participation in this doctoral project is voluntary. I may decide to not participate in the project and I can withdraw at any time without any negative consequences. Also the principal investigator may choose to stop the study at any time.

e) No information that identifies me will be released without my separate consent and all identifiable information will be protected to the limits allowed by law. If the project design or the use of data is to be changed, I will be so informed and consent re-obtained. I understand if I have any questions, concerns, or comments about the study or informed consent process I may write or call the Office of the Executive Vice Chancellor of Academic Affairs, Brandman University, at 16355 Laguna Canyon Road, Irvine, CA 92618, (949) 341-7641. I acknowledge that I have received a copy of this form and the "Research Participants Bill of Rights". I have read the above and understand it and herby consent to the procedure(s) set forth.

Signature of Participant of Responsible Part
Signature of Principal Investigator
22g
Date

#### Appendix D. Recruitment Flyer

#### Recruitment Flyer

Innovative Approach to Diabetes Prevention: Utilization of a multimedia based diabetes prevention program to encourage adherence to lifestyle modifications in Prediabetic adults for prevention of Type 2 Diabetes Mellitus

You are invited to be a part of an important clinical project

You may be eligible to participate IF:

- You are between the ages of 21-64
- Have a fasting blood sugar between 100-125 or a hemoglobin a1c between 5.7% and 6.4% in the last 3 months
- Understand English Language

The purpose of this project is to compare an intervention between two groups, which may increase adherence to routine lifestyle interventions (diet/exercise) for prediabetes in order to prevent the onset of type 2 diabetes mellitus. Benefits include receiving an individualized lifestyle intervention program. The program does not involve any medications and there is no cost to participants.

This project is being conducted at St. John's Well Child and Family Center Compton 2115 N Wilmington Ave Compton, California 90222. For more details about this project or if interested in participating, please notify any staff member to sign up or call Ebony Funches FNP at (310) 603-1332

When: September 9, 2016-December 9, 2016 Location: St. John's Compton Clinic

#### Appendix E. Video Manuscript

#### Video Manuscript

#### Session I/Video I

- What is Pre-Diabetes
- Risk Factors
- Symptoms/Diagnosis
- What is a Hemoglobin A1c
- Complications
- Treatment

#### Session II/Video II

- Nutrition labels
- Carbohydrate foods
- Healthy eating habits
- Dining out
- Fat containing foods
- Sleep and weight loss
- Water intake

#### Session III/ Video III

- Physical activity
- Staying active
- Ways to stay motivated
- Making an activity plan
- Weight loss goals

#### Video Consent

#### Appendix F. Consent for Video and Sound Recording

# Brandman University PHOTO, VIDEO AND SOUND RECORDING RELEASE AND CONSENT FORM

By signing this Photo, Video and Sound Recording Release and Consent Form, you are irrevocably giving permission to the Regents of Brandman University and the University's officers, agents, employees, successors, students, licensees, and assigns to take and use photographs, video or sound recordings of you for the following project: Innovative Approach to Diabetes Prevention: Utilization of a multimedia based diabetes prevention program to encourage adherence to lifestyle modifications in pre-diabetic adults for prevention of Type 2 Diabetes Mellitus

. This is completely voluntary and up to you.

Your consent to the use of the photographs, video and sound recordings and your image, likeness, appearance, and voice is for forever. You will not receive compensation for the use of your image, likeness, appearance, and voice now or in the future. The University may use the photographs, video and sound recordings containing your image, likeness, appearance and voice in any manner or media, including use on web pages such as Youtube. The photographs, video and sound recordings may be used in whole or in part, alone or with other recordings. The photographs, video and sound recordings may be used for any educational, institutional, scientific or informational purposes whatsoever, but not for any commercial uses. The University has the right and may allow others outside the University to copy, edit, alter, retouch, revise and otherwise change the photographs, video and sound recordings at the University's discretion. All right, title, and interest in the photographs, video and sound recordings belong solely to the Regents of Brandman University

You further give permission to the University to use your name, biography, and any other personal data, events, or other material in or in connection with any such uses of the photographs, video and sound recordings.

I understand and agree to the conditions outlined in this photograph, video and sound recording release and consent form. I irrevocably give consent to the Regents of Brandman University and the University's officers, agents, employees, successors, licensees, and assigns forever to make use of my image, likeness, appearance, and voice in photographs, video and sound recordings as described above. I acknowledge that I am fully aware of the contents of this release and am under no disability, duress, or undue influence at the time of my signing of this instrument.

66

Printed Name of Participant		
Signature of Participant	Date	

#### Appendix G. Letter of Support



April 5, 2016

Re: Letter of Support for Clinical Scholarly Project

To Whom It May Concern:

As Director of Social Medicine and Health Equity at St. John's Well Child and Family Center it gives me great pleasure to write this letter of support for the Clinical Scholarly Project proposed by DNP Candidate Ebony Funches FNP: "An innovative approach to diabetes prevention: utilization of a multimedia based diabetes prevention program to encourage adherence to lifestyle modifications in pre-diabetic adults for prevention of type 2 diabetes mellitus."

Of note, project implementation and data extraction for the purposes of human-subjects research is pending formal approval of the Business Affiliation Agreement between St. John's Well Child and Family Center and Brandman University, as well as formal approval by Brandman University's Institutional Review Board.

Shom Dasgupta-Tsinikas MD

Director of Social Medicine & Health Equity

sdasgupta@wellchild.org

Sincerely,



#### STUDENT PLACEMENT AGREEMENT

This Student Placement Agreement ("Agreement") is entered into between Brandman University (the "University") and St. John's Well Child & Family Center ("Facility") for the purpose of providing a clinical learning opportunity for students in The Marybelle and S. Paul Musco School of Nursing and Health Professions at the Facility.

#### RECITALS

- A. University wishes to participate with Facility in providing student experiences at Facility and its affiliated facilities in healthcare-related programs for students enrolled in programs at University.
- B. Facility wishes to cooperate in the development of settings for student experiences in healthcare related programs of mutual interest to University and Facility

#### **SECTION I: GENERAL TERMS**

- The purpose of this Agreement is to establish a relationship between the University and the Facility to enable an educational experience for students at Facility's site which may qualify for University academic credit as determined by University.
- 2. The University and the Facility will agree on a schedule for student participation at the Facility.
- The student's participation should complement the service and educational activities of the Facility. The student will be under the supervision of a Facility employee while on premises.
- 4. Each student is expected to perform with high standards at all times and comply with all written policies and regulations of the appropriate department of the Facility, copies of which shall be provided to each student prior to the beginning of the student's clinical training.
- Either the Facility or the University, in consultation with the other, may require withdrawal
  or dismissal from participation at the Facility of any student whose performance record
  or conduct does not justify continuance.
- 6. Neither the University nor the Facility is obligated to provide for the student's transportation to and from the Facility or for health insurance for the student.

- agree at such time. The provisions of this Section shall survive the termination of this Agreement.
- 14. The parties may revise or modify this Agreement only by a written amendment signed by both parties
- 15. All notices required under this Agreement shall be deemed to have been fully given when made in writing and deposited in the United States mail, postage prepaid, certified mail, return receipt requested, and addressed as follows:

#### If to University:

Brandman University School of Nursing and Health Professions 16355 Laguna Canyon Rd. Irvine, CA 92618

Attn: MSNaHP contracts/C Trobiani

#### If to Facility:

St. John's Well Child & Family Center 808 W. 58<sup>th</sup> Street Los Angeles, CA 90037 Attn: Shom Dasgupta, M.D. Medical Director

#### **TERMS OF THE AGREEMENT**

This Agreement shall commence upon the first date on which it has been signed by both parties (the "Effective Date"), and continue until March 30, 2018 or until terminated by either party giving written notice to the other.

The parties may renew this agreement by signed written agreement.

#### **SECTION V: SIGNATURES**

"UNIVERSITY": BRANDMAN UNIVERSITY	"FACILITY": St. John's Well Child & Family Center
PHILLIP L. DOOLITTLE	Monica Iriarte
Executive Vice Chancellor of Finance & Admin/CFO Title	Human Resource Director Title
Date	Date

#### Toolkit No. 3

### **All About Prediabetes**

#### What is prediabetes?

Prediabetes is a condition that can lead to type 2 diabetes and heart disease. When you have prediabetes, your blood glucose (sugar) levels are higher than normal but are not high enough to be called diabetes. Diabetes can lead to many health problems, so it's better to prevent it in the first place. You can take steps to prevent or delay type 2 diabetes and heart disease.

#### Why do I have prediabetes?

You are likely to develop prediabetes when you have certain risk factors. Your chances of having prediabetes go up if you

- are age 45 or older
- are African American, Hispanic/Latino, American Indian, Asian American, or Pacific Islander
- · have a parent, brother, or sister with diabetes
- · are overweight
- · are physically inactive
- have high blood pressure or if you take medicine for high blood pressure
- have low HDL cholesterol and/or high triglycerides
- · are a woman who had diabetes during pregnancy
- have been diagnosed with Polycystic Ovary Syndrome (PCOS)

#### How can I prevent or delay diabetes?

You can prevent or delay type 2 diabetes from developing by

- · cutting back on calories and saturated fat
- · losing weight
- · increasing your daily physical activity

If you're overweight, losing 7% of your total weight can help you a lot. For example, if you weigh 200 pounds, your goal would be to lose 15 pounds.



Work with your health care provider to take care of your prediabetes.

#### How do I decide what to do?

You don't have to make big changes. Small steps can add up to big results. Check out the ideas for eating less and moving more.

Your health care team can help you make a plan. Talk about ways to be active, such as

- walking briskly for at least 30 minutes a day, 5 days a week
- being more active throughout the day by parking further from the store, or taking the stairs.

Make a plan to eat less fat and calories. You can meet with a dietitian to talk about what to eat and how to lose weight. You might try

- starting each dinner with a salad of leafy greens. Salad provides nutrients and fills you up. Then you might eat less of any high-calorie foods that might come later.
- switching from regular soda and juice to no-calorie water.

American Diabetes Association 1-800-DIABETES (342-2383) www.diabetes.org ©2012 by the American Diabetes Association, inc. 3/14

#### Are there any medicines to treat prediabetes?

If you're at very high risk for diabetes, your health care provider might give you a medicine to help prevent or delay diabetes. For most people, eating less, being more active, and losing weight work better than taking medicines.

#### How often should I be checked for prediabetes?

If you have been told you have prediabetes, have your blood glucose levels checked every year. Your health care provider may want to check your glucose levels more often, especially if you're taking a medicine for prediabetes.

#### What else should my health care provider check?

When you have prediabetes, your health care provider should also check for signs of heart disease and blood vessel problems. For example, your health care provider might check your blood pressure and your cholesterol. Talk with your health care team about what to do if your blood pressure or cholesterol levels are too high. Making wise food choices, staying active, and taking medicines (if needed) can help you stay healthy.

#### What does having prediabetes mean for my health in the future?

Having prediabetes is your early warning system. Take action now and avoid the problems that diabetes and heart disease could bring. Small steps can make a big difference in your health. Choose 2 or 3 small steps today.

#### Real-Life Stories from People with Prediabetes

I had my blood glucose level checked last year and was shocked to find out I had prediabetes. I was a little overweight then. And I hadn't been exercising because I was busy working and taking care of the kids. But it really scared me to learn I was at risk for type 2 diabetes. I cut back on sweets and ate veggies and fruit instead. I also bought a pedometer—a step counter. When I first started, my goal was 7,500 steps every day. Then after a couple of months I changed my goal to 10,000 steps, 5 days a week. I lost 15 pounds! I feel much better now. Today I found out my blood glucose level is back to normal. I feel good about what I've done for my health.

> -Julia B., age 49 diagnosed with prediabetes last year

#### Online resources from the **American Diabetes Association**

- Visit diabetes.org/prediabetes to learn more about managing your prediabetes.
- Learn about CheckUp America, the Association's program to help people lower their risk for type 2 diabetes and heart disease, at checkupamerica.org.
- For recipes and information about meal planning. see Recipes for Healthy Living at diabetes.org/recipes.

Provided By	

