

Pre-Diabetes Lifestyle Prevention Program to Decrease Development of Diabetes in Adults

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Abstract

This pilot quality improvement project for prediabetes adult patients in the family practice setting investigated if a lifestyle change intervention compared to no lifestyle intervention decreased hemoglobin A1C and body mass index and development of type 2 diabetes in three months. Approximately 86 million, a third of the United States population, are diagnosed with prediabetes and are at risk for developing type 2 diabetes. Lifestyle interventions, introduced in the primary care setting when the patient is identified to be at risk for developing diabetes, can reduce the risk of developing type 2 diabetes and decrease hemoglobin A1C. The project included fifteen participants in a Missouri primary care setting. The evidence based practice intervention was a three-month lifestyle intervention based on motivational interviewing and educational handouts that was provided to prediabetes patients by the healthcare provider. The primary outcome measured was pre and post intervention hemoglobin A1C. Secondary outcome measures included pre and post body mass index and nutrition and activity logs at three months. The findings were a decrease in hemoglobin A1C in one patient and body mass index by three participants. The lifestyle change initiative for adults with prediabetes will impact society by providing an accessible intervention program that can be utilized by primary care providers to increase patient's self-care and decrease development of type 2 diabetes.

Key words: prediabetes, lifestyle intervention, diabetes, healthcare providers

Pre-Diabetes Lifestyle Prevention Program to Decrease Adult Patient's Development of Diabetes

The nation has approximately 86 million Americans who are living with prediabetes (CDC, 2016 & Hays et al., 2016). Pre-diabetes individuals are at an increased risk to develop Type 2 Diabetes Mellitus (T2DM; CDC, 2016; Hays et al., 2016). Diabetic healthcare expenses place a huge burden on the nation's healthcare system cost and on the individual with the diagnosis (Hays et al., 2016). The patient diagnosed with T2DM will potentially experience significant disability as well as premature mortality (Hays et al., 2016). T2DM can be prevented with lifestyle interventions that reduce the patient's increased blood glucose and decrease the risk of the individual's morbidity and mortality associated with the disease diagnosis (Hays et al., 2016). The primary goal of the intervention was to improve self-care and implement an individualized lifestyle intervention in patients with prediabetes in order to decrease the development of T2DM in the primary care patient population.

Significance

Many reports reference the epidemic of obesity in the population as the leading cause of increased diabetes diagnosis in the general population (True et al., 2015). There are numerous risk factors that attribute to the increase in diabetes in the population such as high fat diets, lack of exercise, and obesity (CDC, 2016; Hays et al., 2016). Engaging in exercise is an important intervention to include in lifestyle interventions; however, many people with prediabetes do not routinely remain compliant with physical activity regimes that are self-regulated and/or community based educational tools (Kuo, 2013; Rowan 2013).

Pre-diabetes affects a large population in Missouri. (Diabetes, 2015). According to the Missouri Department of Health and Senior Services (2015), data from 2012-2013 indicates that 329,901 individuals were diagnosed with pre-diabetes at a rate of 7.1 per 100 people. The highest

rates were white females older than 65 years of age (Diabetes, 2015). As evidenced by statistics, individuals as well as the community are effected by the large patient population diagnosed with T2DM (True et al., 2015). Communities that are at high risk for developing T2DM are a research priority due to the high economic spending on healthcare costs and patient's comorbid conditions associated with the T2DM diagnosis (True et al., 2015). It was estimated in 2012 that Missouri spent over 300 million dollars in annual healthcare fees associated with diabetes and obesity of the military health system beneficiaries, which could have been utilized for lifestyle prevention programs (Diabetes, 2015; True et al., 2015).

This pilot quality improvement project, designed to improve care for adult patients at risk for prediabetes or prediabetes diagnosis in the project's primary care clinic, evaluated if a lifestyle change intervention, and individual session with the project team leader decreased hemoglobin A1C and body mass index (BMI.) The doctor of nursing practice (DNP) project intervention was designed to include a diverse patient population in Kansas City, Missouri. The patients at risk for developing type 2 diabetes are often older than 45 years of age, have a body mass index of 25 or greater, have a family history of diabetes, and are African American, Hispanic, American Indian and Asian ethnicity (True et al, 2015).

Problem

According to the American College of Education for diabetes, the number of people in the world that are diagnosed with diabetes is approximately 314 million (Garber, 2008). The primary problem is the increased rate of diagnosis of T2DM in the United States (Garber, 2008). Obesity, related to lack of dietary structure and decreased exercise lifestyles, has accounted for the majority of increased T2DM diagnosis (Healthy People 2020, 2016; Rowan, 2013). Patients who are diagnosed with high blood glucose during annual exams could benefit from lifestyle

interventions at the time of prediabetes diagnosis during annual physical exams (Healthy People 2020, 2016). The projected number of individuals in 2025 to be diagnosed with diabetes is approximately 418 million (Garber, 2008). It is important to implement change in the primary care setting to prevent prediabetes progression to diabetes diagnosis.

Type 2 diabetes costs the United States an average of 245 billion dollars a year (Healthy People, 2020). The prevalence of T2DM has increased to 9% of the population in the United States (Healthy People, 2020). Twenty-eight percent of the population has undiagnosed prediabetes that creates an increased risk of developing type 2 diabetes if there is no intervention in place (Healthy People 2020).

Purpose Statement

The purpose of this DNP project was to determine if evidence based educational lifestyle interventions focused on patients with high risk factors for prediabetes and patients diagnosed with prediabetes will decrease T2DM development in adult patients in the primary care setting (see Appendix A for definition of terms).

Project Facilitator

The project facilitator was a physician at the primary care clinic located in Kansas City, Missouri. Support of the program included collaboration with the diabetic educators and nutritionists. The internal medicine clinic location hired a diabetic educator in August 2017. The SI coordinated educational material the educator uses for diabetes patients and utilized the diabetes education material for the prediabetes population.

Barriers to Change

There were barriers that were identified by the SI after discussion with the facilitator and diabetic educator. Barriers to change regarding economic issues were related to insurance

coverage. Each patient had to be identified as at risk for prediabetes or previously diagnosed with prediabetes for A1C labs to be covered under private and state insurance. Proper documentation needed to be incorporated in the patient's electronic health record (EHR) for laboratory tests to be financially covered and follow up appointments billed as preventative care appointments. Additional barriers included patient nonadherence to treatment goals, self-reporting issues by individual patients on activity and nutrition logs, provider noncompliance with screening, and cancelation of follow up appointment.

Sustainability

A factor that promoted sustainability of the intervention is the clinical American Diabetes Association (ADA) guidelines that are in place for determining patients at risk for diabetes diagnosis (ADA, 2016). The screening of body mass index (BMI), hemoglobin A1C, lipids, blood pressure, and weight are measures that are included in insurance coverage under the ADA guidelines of prediabetes patients. The cost of the project was not anticipated to be an economic burden to the site due to funding required by ADA diabetic guidelines (ADA, 2016). Long term sustainability is highly likely due to the EBP guidelines that are already in place for prediabetes patients.

Review of Evidence

PICOTS

In adult patients with high risk factors for developing prediabetes and adult patients with prediabetes diagnosis in family practice setting, do lifestyle change interventions compared to no lifestyle intervention decrease patient's hemoglobin A1C and decrease risk of type II diabetes development in three month follow up?

Search Strategies

Databases included CINAHL, Medline, Cochran, and PubMed. Also, the search engine Google Scholar was searched. National guidelines that were used were from the American Diabetes Association guidelines, American College of Endocrinology, and the American Association of Clinical Endocrinologists. The search engines were used to explore Healthy People 2020 and the CDC. Twenty-two eligible self-care intervention studies provided evidence for the inquiry (see Appendix B for EBP research review).

Search terms and keywords utilized included type II diabetes, prediabetes, diabetes education, diabetic screening, annual screening, self-management, and lifestyle intervention. Hand searching of references of published studies was also done in search of studies that were related to the current national guidelines and intervention programs aligning with the inquiry.

Various types of research were included in the search for the evidence. The study designs included in the synthesis of evidence review were three evidence based practice guidelines (EBPG) level I, one systematic review (SR) of RCT level I, seven randomized control trials level II, two level III non-randomized control trials, four case control studies level IV, two quantitative descriptive reviews level V, two qualitative reviews level V, and one level VII opinion.

Evidence by Sub-topics

National guidelines and research study content was synthesized into subtopics and themes. The evidence was reviewed related to the inquiry and purpose of the project. The evidence subtopics that were included in this synthesis of evidence were clinical practice guidelines, interventions, healthcare provider education, patient adherence, and efficacy of improving self-care.

The twenty-two studies that were included in the evidence review represented approximately 10,068 individuals studied in the research. The studies that were included in this

synthesis of evidence were reviewed and included research design and evidence level, sample, measures and reliability, results, and analysis and limitations (Melnyk, 2015).

Clinical Guidelines

Three of the evidence based resources addressed clinical guidelines from the American Association of Endocrinologist Guidelines (American Diabetes Association, 2017; Garber et al, 2008; Handelsman et al., 2015). The guidelines are based on national guidelines and healthcare provider recommendations (American Diabetes Association, 2017; Garber et al, 2008; Handelsman et al., 2015). The ADA created recommendations for patients with prediabetes that are used to guide healthcare providers to enhance patient adherence and decrease diagnosis of T2DM (American Diabetes Association, 2017; Garber et al, 2008 & Handelsman et al., 2015). Creating a retrospective study of long term analysis was recommended due to limited short term project evidence and follow up is needed for outcome study analysis (American Diabetes Association, 2017; Garber et al, 2008 & Handelsman et al., 2015).

According to the national guidelines and evidence based practice recommendations, a lifestyle intervention and potential prescribing of pharmacotherapy is recommended for prediabetes patients to decrease blood sugar (American Diabetes Association, 2017; Garber et al, 2008 & Handelsman et al., 2015). There is a lack of evidence regarding pharmacotherapy (American Diabetes Association, 2017; Garber et al, 2008; Handelsman et al., 2015). The American Association of Clinical Endocrinologist (ACE) guidelines suggest providers acquire subjective and objective information to determine education on lifestyle alone versus pharmacology as appropriate for a lifestyle change (Garber et al, 2008 & Handelsman et al., 2015). There are guidelines regarding the current lifestyle intervention protocol with the initiation of lifestyle intervention as the first line treatment therapy. This protocol remains cost

effective, but there will need to be further information regarding cost effectiveness of the combination of interventions and risk factors of combined therapy (American Diabetes Association, 2017; Garber et al, 2008; Handelsman et al., 2015).

Diabetes guidelines also recommend increased funds for healthcare providers to educate prediabetes patients (American Diabetes Association, 2017; Garber et al, 2008; Handelsman et al., 2015). There is a lack of compensation to healthcare providers and facilities which makes it difficult for healthcare providers to educate lifestyle changes in patients (American Diabetes Association, 2017; Garber et al, 2008; Handelsman et al., 2015). Decreasing cost of diabetes is a key strategy when discussing the cost versus benefit of prevention programs (American Diabetes Association, 2017; Garber et al, 2008; Handelsman et al., 2015). The majority of diabetes costs are based on hospitalizations of patients once their disease has been diagnosed and the patient has developed microvascular and macrovascular complications (American Diabetes Association, 2017; Garber et al, 2008; Handelsman et al., 2015). Cost savings will be evidenced by the decreased need of diagnosis and hospitalization, which will save healthcare finances that can be used for further prevention strategies.

According to the Center for Disease Control (2016), lifestyle change programs offered by the National Diabetes Prevention Program can be utilized by patients with prediabetes and reduce an individual's risk by 58% to develop T2DM. The national guidelines provide intervention steps for the CDC program (CDC, 2016). The CDC guidelines suggest healthcare providers hire community based educators to educate the importance of healthy nutrition, physical activity and overall healthy lifestyle (CDC, 2016).

Interventions

The majority of evidence is related to intervention programs. The programs ranged from improving screening in the health departments to engaging with patients in the primary care setting (Rariden et al., 2015 & Kuo et al., 2014). Home based interventions and community based interventions conducted in evidence studies; however, regardless of the type of intervention that was noted, many used similar self-reported measurement tools (Hays, 2016; Huntriss et al., 2016; Morey, 2012; Rowan, 2013; The Diabetes Prevention Program Research Group, 2004). Intervention programs were conducted during different time frames including studies that lasted from 12 weeks to 2-3 years (Hays, 2016; Morey, 2012; Rowan, 2013; The Diabetes Prevention Program Research Group, 2004).

During the synthesis of research review, different types of intervention program guidelines existed in the studies. The CDC research prevention programs are yearlong programs that are developed specifically to prevent T2DM (CDC, 2106). The CDC (2016) discusses the criteria for a CDC recognized program that can decrease many health issues as well as the diagnosis of T2DM in individuals with prediabetes.

Engaging in exercise is an important health benefit to prevent or delay type 2 diabetes for people with prediabetes (CDC, 2016, Kuo et al., 2015; Whittemore, 2009). Studies exploring interventions addressed the impact of early timing of diabetes education initiation and continuation as part of intervention programs. Studies resulting in educational intervention protocols discussed the difficulty of developing a successful exercise program that patients will be compliant with throughout their intervention (CDC, 2016, Kuo et al., 2015; Whittemore, 2009). Combination programs that have nutrition and physical exercise in an intervention created compliance issues (CDC, 2016, Kuo et al., 2015 & Whittemore, 2009).

Weight loss, decrease in BMI, decreased blood pressure, normalized lipid lab results, and self-reported physical activity are some of the intervention program data that was collected pre and post intervention (Gilles, et al, 2007; Whittemore, 2009). Cultural and community based programs that target specific high risk patients are effective in reducing hyperglycemia (Whittemore, 2009). Interventions based on nutrition as well as interventions based on physical activity were conducted to analyze the effectiveness of the protocols (Whittemore, 2009). In a six month study conducted for weight loss in prediabetes patients, 25% of patients in the implementation program lost 5% of weight compared to 11% of patients that were not in their program (Whittemore, 2009).

Efficacy of Improving Self-Care

Self-care is a common theme among the majority of evidence studies analyzed in this research review. Self-care was frequently measured by individualized reports of physical activity as well as individualized nutrition changes (Chen, 2010 & CDC, 2016). Self-care of the individual patient is the first line of treatment in the intervention programs based on individual lifestyle changes without pharmacotherapy (Chen, 2010). The synthesis of evidence by Chen (2016) included information regarding patients perceived action benefits and barriers to intervention. Behavior self-regulation protocols that are individualized for each patient can delay or prevent the effects of diabetes diagnosis and decrease the patient's risk of developing macrovascular and microvascular complications (Chen, 2010). According to Chen (2010), lifestyle change interventions note a positive correlation between knowledge of prediabetes and lifestyle health promotion. These findings may suggest that improving self-care is the basis of individual patient intervention and different patients will require various types of interventions to have effective self-care.

Patient Adherence

Patient readiness is assessed in many studies due to adherence playing a major role in success of the intervention program (True et al., 2015). Treatment goals of the programs have been related to weight loss or increased physical activity (Whittemore, 2009, CDC 2016). The programs included lifestyle interventions such as one on one coaching, group classes, provider education, and YMCA based classes (True, 2015).

The diabetes risk score (DRS) is a scoring system that predicts the risk of prediabetes patient's likelihood to develop diabetes in a five-year timeframe (True, 2015). A patient's knowledge of their DRS score increases patient adherence to the intervention (True, 2015). DRS in the clinical trial conducted by True (2015) was divided into low, moderate, and high risk (True, 2015). The DRS did not have an impact on overall patient attendance and performance during the program intervention (True, 2015). However, adherence of individual patients was increased by improved lifestyle changes with a knowledge of the individual patient's DRS (True, 2015). These findings suggest that patient adherence can be increased with patient knowledge (True, 2015). Patients will benefit from individualized lifestyle changes and will be more adherent to their intervention if the patient is aware of the initial health status and goals of the program.

Healthcare Provider Education

Providers need education on intervention programs in rural healthcare locations as well as at risk patient population locations. There is a lack in compensation to healthcare associations and in healthcare provider resources making it difficult to implement and maintain prevention programs (CDC, 2016; Delahanty, 2012; Handelsman, et al, 2015). In studies, motivational

interviewing has been noted to be difficult with nurse practitioners and patients with prediabetes, and further education would be beneficial in relation to educator techniques (Whittemore, 2009).

As a healthcare provider, during annual exams, it is essential to assess patients for risk factors associated with T2DM (CDC, 2016; Delahanty, 2012; Handelsman, et al, 2015). Over 90% of patients with prediabetes are unaware of their diagnosis (CDC, 2016; Delahanty, 2012; Handelsman, et al, 2015). Literature suggests that screening and testing at risk patients for prediabetes improves patient's coping skills with early intervention and increases compliance (CDC, 2016; Delahanty, 2012; Handelsman, et al, 2015). The CDC (2016) discusses the importance of healthcare providers correctly and accurately referring patients to ensure compliance with the state licensing and board recertification requirements (CDC, 2016; Delahanty, 2012; Handelsman, et al, 2015).

Theory

Orem's self-care theory was the theoretical framework that guided this evidence-based practice project. Orem's self-care theory has been used in studies related to patients with chronic disease and in prediabetes (Kumar, 2007). Theory based nursing care can enhance the patient's ability to self manage care (Kumar, 2007). The prediabetes intervention program utilized patient's ability to incorporate the concept of self-care in their lifestyle based on interventions focused on lifestyle education provided by their physicians (Kumar, 2007; see Appendix C for theory diagram). A study, by Kumar (2007), discussed that by using theory based nursing care increased the patient's ability to provide self-care and manage their health and chronic illnesses.

Methods

IRB and Site Approval

The project was a quality improvement (QI) project. The goal of the project was to decrease the number of patients diagnosed with T2DM and improve the patient's quality of life. Based on the location of the project, the primary IRB, the primary care location Kansas City, Missouri, concluded the project was quality improvement. Site approval was confirmed in Summer 2017 from a health system administrator of the location prior to approval by the site location (see Appendix D).

Ethical Issues

Ethical issues regarding the patient's privacy was considered as a part of the initial and follow up data and subjective information collected. Approval to access the participant's charts, lab records and other objective data was necessary after approval from the location's IRB stating the project was a quality improvement project. There was not a selection bias, and all participants who met inclusion criteria were invited to participate in the project. The SI does not work at the site. All intervention participants were provided the same educational information provided, and exercise log and nutrition logs were all be based on the CDC educational tools with modifications available per provider decision based on patient's individual needs.

Funding

Funding of the program was from the site contribution and the SI funds. Providers were willing to volunteer the time that was required for the instructional time the student investigator required to discuss the intervention program's educational material. This was a low-budget project as there are few sources of expenses (see appendix E for cost table). One of the expenses that was necessary to implement this project was printed copies of informational handouts

regarding diabetes risk factors and guides for physical and nutritional change. Another source of expense was travel funds and poster printing for dissemination of the APNO conference.

Setting and Participants

This pilot quality improvement project, designed to improve care for adult patients at risk for prediabetes or prediabetes diagnosis in the primary care clinic, was conducted to evaluate if a lifestyle change intervention, individual session with the project team leader, decreases hemoglobin A1C and body mass index (BMI). If favorable outcomes, then continuation of the quality improvement intervention, independent of the DNP student as project team leader, may be sustained within the clinic practice environment. Adult patients at risk for prediabetes or diagnosed with prediabetes and receive care at the primary care clinic, was involved in the quality improvement pilot. Power analysis for a dependent sample t-test was conducted in G*Power to determine a sufficient sample size using an alpha of 0.05, a power of 0.80, and medium effect. Based on the assumptions, the desired sample size was 27. The patient provider was one of the fifteen physicians at the clinic, and the patients had appointments during the week the team leader was present in the clinic. The provider's patient population provided the majority of the patients. Convenience sampling was used to obtain a sample in three-months during Fall 2017.

Inclusion criteria consisted of patients with a diagnosis of prediabetes or patients that fall into the high risk category for prediabetes based on the ADA guidelines (2014). Charts were audited to identify potential participants. Follow up data was necessary for the intervention and required the patient's agreement to return in three months for a follow up appointment for post test data. The exclusion criteria were patient charts that indicate an age of 17 and younger and

patients who are not at risk for prediabetes or diagnosed with prediabetes. There were no additional exclusionary criteria.

Evidence Based Intervention

The intervention was a prediabetes educational lifestyle intervention program. The process prior to the educational intervention was that the primary care providers may or may not discuss prediabetes with patients or address lifestyle intervention to decrease diabetes risk. The pilot program in place at the clinic with the diabetic educator was only focused on patients who were diagnosed with diabetes, which excludes the patients at risk for prediabetes or prediabetes diagnosis who could also benefit from education.

The SI was present at the intervention site to educate providers about the interventions and patient eligibility. Recruitment of the participants was determined based on patient's previous diagnosis of prediabetes, individuals older than 45 with risk factors of prediabetes, and patients with a BMI of 25% or greater. The patients were entered into the study during Fall 2017 (see appendix F for Logic Model). A physician was the contact for the team leader for the project, and all providers in the clinic attempted to participate in the quality improvement project. The provider verbally indicated to the project team leader that a patient was at risk for prediabetes or diagnosed with prediabetes, based on the American Diabetes Association prediabetes risk assessment tool according to Cefalu (2016), the project team leader met with the patient in the patient exam room after the appointment with the provider was completed. The project team leader discussed the educational material, including lifestyle interventions, with the patient.

The data collection performed by the project team leader was obtained including the current BMI and A1C within the past three months of the appointment from the electronic health

record. If there was no A1C within three months, the provider potentially ordered an A1C lab if recommended by American Diabetic Association guidelines and the provider determined as appropriate for the patient. The baseline A1C had the potential to be missing data in this quality improvement project due to patient not obtaining the lab or provider decision.

During the improvement process, the project team leader was present in the clinic for two weeks and was available to providers as they saw patients that might benefit from the quality improvement project. After the project team leader received the baseline BMI and A1C, if available, the project team leader met with the patient in the patient room and provided the patient a welcome letter with contact information of the project team leader (Appendix G). The project team leader took approximately 15 minutes to discuss nutrition, activity, and diabetes pathophysiology with the patient. An activity and nutrition log was introduced to the patients during the intervention and the team leader utilized the diabetic educator's plate method model to discuss nutrition with the patient (Appendix H). The CDC handout on diabetes was used to discuss pathophysiology of prediabetes (Appendix I). The team leader and patient utilized the educational material to create a lifestyle change goal that the patient made a commitment to work on at home during the three-month timeframe until their next clinic appointment. Discussion included the importance of adhering to achievement of their goal. The project team leader discussed with the patient that the project team leader will conduct a six-week follow-up phone call to discuss the lifestyle goal progress.

After the intervention in the patient room, the project team leader accompanied the patient to lab if an A1C is ordered. Also, the team leader had the patient schedule a three month follow up appointment with the project team leader to obtain BMI, discuss goal achievement, and arrange for an A1C, if ordered by the providers.

Initial A1C lab values and BMI were obtained by the project leader from the electronic health record (EHR) prior to the intervention and was used in forming individualized activity and nutrition goals. Each patient had de-identified data entered, by the project leader, into a written data collection form. A de-identified code sheet was created and contained the patient code that was sequential by participant entry into the improvement process, including the medical record number (MRN), and the phone number. The code sheet and the data collection form were kept in separate locked cabinets in a physician office. The project team leader had access to the MRN number, which was used in data collection from the EHR which included A1C lab and BMI. The project team leader shredded the code sheet and the data collection form once the data was entered into REDCap, a secure database, and analyzed using SPSS. No other demographic data was obtained regarding individual patients.

At six weeks, the project team leader called the patient via phone to encourage the patient to continue to implement their activity and nutrition goals into their lifestyle and return for the follow up appointment. The team leader fielded any diabetes lifestyle management questions the patient had at that time.

At approximately three months, the patient followed up with the project team leader or the diabetic educator depending on scheduling availability with the patient. The appointment was with the team leader or diabetic educator to provide continuity of care for follow up and data collection. At the 3 month follow up appointment, A1C lab (if applicable), BMI, and the nutrition and activity log was discussed along with compliance with the patient's goal. The nutrition and activity log goal was discussed and entered as *yes* or *no* addressing if the patient reached their goal during the three-month timeframe. The A1C value was either obtained at this time from the EHR or within 2-3 days, if not yet drawn. The timeline of the evidence based

intervention included an introduction of the project during summer 2017 and completion of the project in spring 2018 (see Appendix K for further timeline information).

Change Process and Evidence Based Practice Model

The prediabetes lifestyle intervention program was based on Lewin's three-stage model of change. Organizational change is necessary for the development of the intervention and requires different steps to be completed for the program to be successful. The stage of unfreezing requires the healthcare providers to change their current practice (Weiner, 2009). The current and desired performance levels was discussed between healthcare providers to make sure all healthcare providers understand the key concepts and project goals regarding the intervention. Motivation for change from the organization prospective was necessary and helped with potential barriers associated with the project (Weiner, 2009).

The Health Belief Model (HBM) also supports this project which addressed a practice change, which was the focus of this EBP project. During the literature review of the project, the Health Belief Model was utilized in many lifestyle interventions used to improve self-management (Scollan-Koliopoulos, 2004; Solhi, Gharibnavax, Galilian & Motlagh, 2014). The lifestyle intervention program was based off the Health Belief Model evidenced by prior studies finding that the HBM can be effective in the prevention of diabetes complications (Solhi, Gharibnavax, Galilian & Motlagh, 2014).

The Iowa Model was the EBP model that was utilized with the project intervention. The project used practical data and translated it to practice from the system perspective (Lloyd, D'Errico & Bristol, 2016). There is a high likelihood for project sustainability with the implementation of the project based on the success from previous benchmark prediabetes studies (Lloyd, D'Errico & Bristol, 2016).

Study Design

Education about prediabetes and lifestyle interventions was the focus of this pilot quality improvement project. The primary outcome goal was to decrease patients A1C lab and to decrease overall risk factors that lead to development of T2DM diagnosis. Pretest data A1C and Posttest A1C at 3 month follow up was the obtained to measure the project impact. Supplemental outcomes were body mass index (BMI) and completion of the activity and nutrition log. The assessment tool was based on the American Diabetes Association prediabetes risk assessment tool.

Validity

Internal validity in this program was promoted by the accuracy of previous health history charting. A threat to internal validity included the possibility that patient participants may only include patients who are already concerned with their diabetes risk and already desire to pursue changes. Attrition posed a risk to internal validity of the project due to loss of participants at 3 month follow-up resulting in a small sample size. An internal validity threat was inaccurate patient history self-report of log completion in the chart review. An issue with replication of the study at other facilities and primary care offices was potentially based on the coverage of insurance on individuals and small sample size.

Outcomes to be Measured

The primary outcomes were the A1C pretest and the three-month post A1C change. The secondary outcome measurements were the pre- and post body max index. The activity and nutrition log was used as an educational material intervention to increase patient self-care and patient accountability for their lifestyle choices. The nutrition and activity log was self-reported

on a yes or no collection basis tool if the patient completed the logs during the three-month timeframe.

Measurement Instruments

The data collection for the primary and secondary outcomes were per EHR review in the health care settings and the self-report logs are (see appendix L for data collection). The student investigator reviewed the EHR and obtained baseline data. Validity and reliability were based on data collection processes from the records in preventative care studies (Ellsworth et al., 2016). There is limited data based on scientific use of electronic health record replication in future studies (Ellsworth et al., 2016). Participant completion was encouraged by reminder phone calls from the team leader to the participant to return for the three month follow up lab and provider appointment. Reminders to bring nutrition and activity log were included with the six week checkup phone calls.

Quality of Data

Demographic information was not collected as per decision of the project team. Outcomes were obtained pre- and post intervention in order to determine the impact of the intervention. The post test was the patients follow up primary outcome labs and the secondary test information. A quantitative study utilizing a screening tool, the Diabscreen, served as a benchmark for data comparison (Woolthuis et al., 2009).

Analysis Plan

The scale data was analyzed in SPSS by paired t-tests based on the data collected pre and post after the three month follow up (see appendix M for statistical analysis template). The activity and nutrition log data was nominal data, *yes* or *no* self-report if the logs were completed by the participants. If there was no follow up data, the log data collection portion was left blank.

Power analysis for a dependent sample t-test was conducted in G*Power to determine a sufficient sample size using an alpha of 0.05, a power of 0.80, and medium effect. Based on the assumptions, the desired sample size was 27.

Results

Adult patients at risk for prediabetes or diagnosed with prediabetes and receive care at the primary care clinic were involved in the quality improvement pilot. The patients' providers were one of the fifteen physicians at the clinic, and the patients had appointments during the weeks the team leader was present in the clinic. The quality improvement project was projected to be successful if the baseline to post A1C and/or BMI indicated an improvement, whether or not statistically significant.

A paired-samples t-test was conducted to compare pre and 3 month post BMI ($n=5$). Only one patient of the 12 participants had a three month follow up A1C drawn. There was not a significant difference in the scores for pre BMI ($M=41.21$, $SD=10.03$) and post BMI ($M=40.78$, $SD=9.84$; $p = .411$. see Appendix N). These results suggest that BMI might not be directly linked to short educational interventions and completion of activity and nutrition logs due to limited participants. However, the results suggest that some BMIs did decrease with intervention and patients could benefit with more in person educational information and tools when at risk for prediabetes or diagnosed with prediabetes.

There were 26 participants during the two week period that the SI was in the clinic that would have qualified for the quality improvement intervention. Twelve of those agreed to meet with the team leader for the intervention. Of the twelve that met with the team leader for the intervention, all agreed to a follow up appointment and developing nutrition and activity goals. However, only five returned to the 3 month follow up appointment. Of those that returned, only

one qualified for an A1C according to the risk factors and the physician discretion. All patients that participated in the QI project had baseline A1C and BMI results. However, only one participant had a post A1C and five had post BMIs. Three of the five participants that returned for the follow up appointment stated that they were able to complete the nutrition and activity goal. The participants listed a variety of reasons for incompleteness of the goals such as health issues or stressors at home that deferred them from completing their goal.

Discussion

The lifestyle change initiative for adults at risk for prediabetes or with prediabetes diagnosis impacts society by providing an accessible intervention program that can be utilized by primary care providers to increase patient's self-care and decrease development of type 2 diabetes. The activity and nutrition log, plate model, and prediabetes handout were used as educational material to increase patient's self-care and increase patient accountability for their lifestyle choices. The expected outcome of the quality improvement project was a decrease development of diabetes, specifically a decreased or normalized A1C and/or BMI. Because the quality improvement project was not completely successful due to the limited participants, the project team leader adjusted the educational material using other ADA and CDC based intervention material and discussed with the facilitator and educator on how the information can be used in the future. The clinic may use this data to support continuation of patient education with at risk prediabetes and prediabetes patients beyond the initial pilot of the quality improvement project. The quality improvement initiative may also expand to other clinics within the health care system.

Currently at the project's primary care clinic, patients at risk for prediabetes may not be provided with prediabetes risk factor interventions unless the patient's presentation is

specifically related to risk factors for prediabetes or prediabetes issues. The partnership of the QI project leader and the diabetic educator with the physician creates an initiative of the facility to promote healthy patient change. The support of the location at the project location and the private room for patient education fostered a personalized intervention. The leadership at the project location, such as the Chief Nursing Officer involvement to approve the project and the Nursing Research Program Director to assist with the QI approval process with the team leader, were involved and helpful in the project implementation and success. The diabetic educator supported the project by providing educational material that the diabetes patients receive at their new diabetic nutrition and activity meeting.

Weight loss, decrease in BMI, decrease in blood pressure, normalized lipid lab results, and self-reported physical activity are outcomes that may result from diabetes lifestyle intervention programs (Gilles, et al, 2007; Whittemore, 2009). In a six month study conducted for weight loss in prediabetes patients, 25% of patients in the implementation program, which consisted of nutrition and physical activity intervention protocols, lost 5% of their weight compared to 11% of patients that were not in the program (Whittemore, 2009). In the QI project, the quality improvement outcome measurements were A1C and BMI comparison in a 3 month timeframe. In contrast to the Whittemore (2009) intervention, there is no comparative data between participants that were in the quality improvement interviewing and those who opted out.

Limitations

The project limitations were discussed with the diabetic educator and facilitator. A factor in the QI project that affected study outcomes was lack of post data. The patients that opted out of participation in the education intervention discussed that they did not have a desire to change their lifestyle and did not receive motivational interviewing and intervention. Patients also

discussed with the facilitator that they did not want to return to the clinic after 3 months to meet with the project facilitator.

In August 2017, the clinic implemented a year pilot program which added a diabetic educator in the clinic on Mondays and Tuesdays to meet with patients with diabetes and discuss lifestyle interventions that are recommended by the CDC. However, the current program does not address patients at risk for prediabetes or prediabetes. Although a quarterly education class is offered four times a year, many diabetic lifestyle intervention programs are not covered by insurance for prediabetes patients, and the educational class may cost the patient \$40. The diabetic educator could be present to meet with the patients in the future if the physician does not have the time because she is on site and available to all of the patients.

Potential gains that could weaken over time are related to the participants becoming complacent with their goals due to the lack of personal one and one education from the team leader in the future. Goal obtainment could be focused on and maintained by the help of the diabetic educator involvement with patients and the physician involvement. Addressing lifestyle issues at each visit and discussing their current BMI and A1C at each visit could help patients become aware of their current healthcare risks. Continuation of the project will enhance the internal processes of the primary care clinic to foster early intervention to patients at risk for prediabetes or with prediabetes. The education of early awareness of risk factors is known to decrease development of type 2 diabetes (Ackermann, Finch, Brizendine, Zhou, & Marrero (2008).

Interpretations

The expected results were a statistically significant data result between pre and post data collection which was not found in the project data. The problems that were encountered during

the quality improvement project are related to adherence to the goals. The patients expressed that extraneous factors, which were not anticipated, had an impact on their health changes and ability to complete the goals. Failures of the project were due to patients canceling their follow up team leader appointments; therefore, the team leader was unable to interview the patient and determine completion of goals and obtain the 3 month BMI post results.

A possible reason that there was a difference between the observed and expected outcomes was due to the commitment that the patient had to return to clinic for a nurse visit. Many patients have busy schedules and have been followed by their primary care provider for prediabetes prior to the quality improvement project; consequently, a 3 month follow up appointment proved to be a commitment that many did not want to complete. Also, patients reported, during motivational interviewing, that barriers to adherence were the upcoming holiday season surrounded by favorite foods. Casual mechanisms that affected the outcomes that supported the project were the availability of the team leader to the patient during their scheduled annual visit. The team leader was available in the same location as the annual appointment so participants were more likely to agree to meet and discuss nutrition and activity due to the easy access and they did not have to make a different appointment at a different location. Discussion with the provider and diabetic educator concluded that if there was an educator or provider time that allowed the role of the team leader to be included at every appointment the patient attends, the follow up data would be more readily available.

A setting where the quality improvement intervention would be effective would be primary care settings where patients have a relationship with their primary care provider. The pilot program that is in place at the primary care clinic for the diabetic educator to meet with patients is successful according to the physicians due to face to face meetings with a healthcare

provider. The accountability of face to face meetings increases the effectiveness of the project according to opinions of the providers in the clinic.

An intervention that might improve attainment of the desired outcomes includes expansion of the quality improvement measures to all patients that are classified as overweight or with the diagnosis of Type 2 diabetes. The project was intended for only patients with prediabetes but the physician could conduct the short educational portion of the project in their annual appointments and have the patient return for follow up as a nurse only visit to decrease billing burdens and patient cost.

The expected impact on the healthcare system was to decrease cost to patients due to decreasing development of diabetes. Decreasing development of diabetes complications will decrease the healthcare cost of the individual and healthcare. At this time, the actual impact on patient cost is unknown. There needs to be addition follow up with patients to continue to monitor patients and track reversal of risk factors and development of the disease. The estimated cost of the furthering the intervention for providers reflects the estimated cost of the quality based intervention. The project is sustainable due to the small cost burden of the patient and healthcare facility. The only cost that the physician, educator, and patient would have to absorb without the project team leader would be the printed educational material, billed educational time, and billed follow up time. Printed material is a minimal cost and very cost effective. At this time, there is no change to the patients billing charge of their scheduled billed annual appointment due to adding the intervention.

Conclusions

Diabetes places a major burden on the nation's healthcare system cost, as well as the individual (Hays et al., 2016). Based on research findings, healthcare of the United States is

impacted by the increased T2DM diagnoses (Hays et al., 2016). The outcome based intervention has the potential to be utilized at the primary care setting. The educational material has been provided to the primary care facility to continue to implement the program with their patients in collaboration with the diabetes educator's material. The continuation of the intervention has the ability to impact additional patients that are not seen during the intervention timeframe and may positively affect the patient and provider relationship as well as patient health status.

Dissemination of the quality improvement project consisted of a poster presentation at the Advance Practice Nurses of the Ozarks regional conference in November 2017.

Lifestyle interventions introduced in the primary care setting when the patient has risk factors for prediabetes or is diagnosed with prediabetes can prevent the diagnosis of type 2 diabetes and other comorbid disease processes. The research denotes various types of intervention related programs, and the evidence on lifestyle interventions was incorporated into this quality improvement project. The intervention provided a practical and useful intervention that can be replicated in other primary care settings for continuing health promotion. In summary, there are different types of community and individual interventions that improve lifestyles of patients with prediabetes. Healthcare providers need to be aware of the individualized lifestyle intervention plans that can decrease cost of healthcare for patients with prediabetes or T2DM. This evidence contributes to further understanding of the proposed inquiry intervention of a prevention program with adults with risk factors associated with prediabetes and prediabetes diagnosis to decrease patients A1C and decrease the risk of developing T2DM.

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Appendix A

Definition of Terms

Adult Patients: for the proposed study, adults between the ages of 18-80 years of age

Prediabetes: the preliminary stage before the diagnosis of type 2 diabetes, where the patient does not have all symptoms of diabetes diagnosis but has several risk factors

Primary Care: an ambulatory healthcare setting where healthcare providers treat day to day preventative care and acute care

Appendix B

Research Evidence Table

First author, year, title, Journal	Research Design ¹ & Evidence Level ²	Sample & Sampling	Measures & Reliability (if reported)	Results & Analysis Used	Limitations
<p><u>Clinical guidelines</u></p> <p>1. First author: Garber</p> <p>Year: 2008</p> <p>Title: Diagnosis and Management of Prediabetes in the Continuum of Hyperglycemia-When do the Risks of Diabetes Begin? A Consensus Statement from the American College of Endocrinology and the American Association of Clinical Endocrinologists</p> <p>Journal: Endocrine Practice</p>	<p>Clinical guidelines</p> <p>Melynk Level 1</p>		<p>improving glycemia and reducing cardiovascular risk factors.</p>		
<p>1. First author: Handelsman</p>	<p>Clinical guidelines</p>				

<p>Year: 2008</p> <p>Title: Diagnosis and Management of Prediabetes in the Continuum of Hyperglycemia—When do the Risks of Diabetes Begin? A Consensus Statement from the American College of Endocrinology and the American Association of Clinical Endocrinologists</p> <p>Journal: Endocrine Practice</p>	<p>Melynk Level I</p>				
<p><u>Intervention Program</u></p> <p>3. First author: Davies</p> <p>Year: 2017</p> <p>Title: A community-based primary prevention program for type 2 diabetes mellitus</p>	<p>RD: cluster randomized controlled trial (RCT)</p> <p>Melynk Level 2</p>	<p>44 general practices across Leicestershire, UK</p>	<p>primary outcome was progression to T2DM. The main secondary outcomes were changes in glycated hgb concentrations, blood glucose levels, cardiovascular risk, the presence of metabolic syndrome, step count and the</p>	<p>Results: primary outcome was progression to T2DM. The main secondary outcomes were changes in glycated hgb concentrations, blood glucose levels, cardiovascular risk, the presence of metabolic syndrome, step count and the cost-</p>	<p>Limited power of the study due to only 19% of those invited attended</p>

<p>integrating identification and lifestyle intervention for prevention: a cluster randomized controlled trial.</p> <p>Journal: NIHR Journals Library</p>			<p>cost-effectiveness of the intervention</p>	<p>effectiveness of the intervention.</p>	
<p>First author: Huntriss</p> <p>Year: 2016</p> <p>Title: Evaluation of a 12-week weight management group for people with type 2 diabetes and pre-diabetes in a multi-ethnic population.</p> <p>Journal: <i>Journal Of Diabetes Nursing</i></p>	<p>RD: pilot study</p> <p>Melynck Level III</p>	<p>25 Ethnic Groups; Adult: 19-44 years; Middle Aged: 45-64 years; community members</p>	<p>Measures: glycemic control, glycemia index</p>	<p>Results: This intervention was shown to be clinically effective, with those opting for further support achieving better clinical outcomes.</p>	<p>Limitations: pilot study, new previous information</p>

<p>1. First author: Han, B</p> <p>Year: 2016</p> <p>Title: Correlates of Physical Activity Among Middle-Aged and Older Korean Americans at Risk for Diabetes</p> <p>Journal: Journal of Nursing Scholarship</p>	<p>RD: cross sectional</p> <p>Melynk Level 4</p>	<p>292 middle-aged and older Korean Americans</p>	<p>Measures: social interaction measures and nutrition measures</p> <p>Reliability: Preliminary analysis found Cronbach's alphas of 0.622 for the barriers scale, 0.562 for the self-efficacy scale, and 0.831 for the social interaction scale.</p>	<p>PA interventions targeting this population may be beneficial and should consider the roles of sex, age, physical and social environment, motivation, and self-efficacy</p> <p>Analysis: bivariate analysis</p>	<p>Korean ethnicity</p>
<p>11. First author: Hays</p> <p>Year: 2016</p> <p>Title: Effects of a Community-based Lifestyle Intervention on Change in Physical Activity Among Economically Disadvantaged Adults with Prediabetes</p>	<p>RD: RCT</p> <p>Melynk Level 2</p>	<p>216 participants; patients at risk for diabetes from 9 metropolitan primary care clinics.</p>	<p>Measures: effects of treatment, baseline measures of outcome variables, demographic characteristics, and psychosocial and community-level measures on change in PA</p> <p>Reliability: PA estimates (mean ^ SD) varied from 33.6 ^ 52.7 min/day to 38.4 ^ 66.0 min/day depending on the required amount of wear</p>	<p>Results: Results suggest that changing dietary and PA behaviors simultaneously may adversely affect changes in PA</p> <p>Analysis: repeated measures mixed effects models were used to analyze the outcome variables of interest</p>	<p>Limitations: only 62% of RAPID participants wore the monitor as recommended at baseline and this % fell over the course of the study</p>

<p>Journal: American Journal of Health Education</p>			<p>time, thereby affecting the reliability of the PA estimates.</p>		
<p>10. First author: Rossen Year: 2015 Title: Physical activity promotion in the primary care setting in pre- and type 2 diabetes - the Sophia step study, an RCT Journal: BMC Public Health</p>	<p>RD: Physical activity promotion in the primary care setting in pre- and type 2 diabetes - the Sophia step study, an RCT Melynk Level 2</p>	<p>40-80 years and ability to communicate in Swedish. Either Pre-diabetes (HbA1c > 39- < 47 mmol/mol and/or fasting glucose >5.6 mmol/l) or diagnosed with type 2 diabetes with a duration of ≥1 year.</p>	<p>Measures: weight, body percentage, body fat</p>	<p>Results Analysis: statistical power analysis</p>	<p>None known</p>
<p>First author: Dunkley Year: 2014 Title: Diabetes Prevention in the Real World: Effectiveness of Pragmatic Lifestyle Interventions for the Prevention of Type 2 Diabetes and of the Impact</p>	<p>RD: A Systematic Review and Meta-analysis Melynk Level 1</p>	<p>Sample Twenty-five studies met the inclusion criteria. Sampling ata were extracted by one reviewer, and a second reviewer subsequently</p>	<p>Measures: blood glucose, BP, and some cholesterol measures Reliability: 11 studies achieved a high-quality score for external validity.</p>	<p>Results adherence to guidelines was significantly associated with a greater weight loss (an increase of 0.4 kg per point increase on a 12-point guideline-adherence scale). Analysis: meta-analysis scale</p>	<p>insufficient data to analyze outcomes beyond 12 months</p>

<p>of Adherence to Guideline Recommendations</p>					
<p>First author: Rowan Year: 2013 Title: The Prediabetes Detection and Physical Activity Intervention Delivery (PRE-PAID) program. Journal: Canadian journal of diabetes</p>	<p>RD: pilot intervention Melynk Level 6</p>	<p>691 PRE-PAID participants</p>	<p>Measures: Pre-diabetes Detection and Physical Activity Intervention Delivery Project (PRE-PAID) Reliability: self report</p>	<p>Results: Participants self reported they were much more willing to be involved in both the screening and PA intervention components knowing that there was alignment with a known community organization. Analysis: 15-point Borg Scale</p>	<p>Limitations: self report</p>
<p>First author: Anonymous Year: 2002 Title: Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin Journal: The New England Journal of Medicine</p>	<p>RD: RCT Melynk Level 2</p>	<p>3234 nondiabetic persons with elevated fasting and post-load plasma glucose concentrations</p>	<p>Measures: Self-reported levels of leisure physical activity were assessed annually with the Modifiable Activity Questionnaire Reliability: unknown</p>	<p>The lifestyle intervention reduced the incidence by 58 percent Analysis: intention-to-treat principle</p>	<p>Adherence to interventions</p>

<p>First author: Woolthuis</p> <p>Year: 2009</p> <p>Title: Yield of Opportunistic Targeted Screening for Type 2 Diabetes in Primary Care: The Diabscreen Study</p> <p>Journal: Annals of Family Medicine</p>	<p>RD: quantitative</p> <p>Melynk Level 3</p>	<p>11 family practices</p> <p>45 to 75 years by (1) identifying high-risk individuals (≥ 1 diabetes risk factor) and low-risk individuals using the electronic medical record, (2) obtaining a capillary fasting plasma glucose measurement, repeated on a separate day if the value was greater than 110 mg/dL, and (3) obtaining a venous sample if both capillary fasting plasma glucose values were greater than 110 mg/dL and</p> <p>at least 1 sample was 126 mg/dL or greater.</p>	<p>Low risk patients vs. high risk patients</p> <p>Reliability: (2.7%; 95% confidence interval [CI], 2.2%-3.3%; NNS = 37) and 2 low-risk patients (0.4%; 95% CI, 0.1%-1.6%; NNS = 233) had undiagnosed diabetes ($P < .01$).</p>	<p>Results: We found undiagnosed type 2 diabetes in 101 high-risk patients and 2 low-risk patients.</p> <p>Analysis: Analyzed with SPSS 16.0 for Windows. The χ^2 for categorical data and the student t test or kruskal-wallis test for means where appropriate.</p>	<p>Regular consultations</p>
<p><u>Patient Adherence</u></p>	<p>RD: prospective clinical trial pilot</p>	<p>Sample: 4 NP primary care practice sites</p>	<p>High internal consistency, acceptable test-retest reliability, and good</p>	<p>Mixed-model repeated measures analysis</p>	<p>Providers report limited time and limited training</p>

<p>5. First author: Whittemore</p> <p>Year: 2009</p> <p>Title: Translating the Diabetes Prevention Program to Primary Care: A Pilot Study</p> <p>Journal: National Institute of Health</p>	<p>study with cluster randomization</p> <p>Melynk Level II</p>	<p>Sampling cluster randomization procedure using a computerized table of random numbers randomized 4 sites: 2 sites into the lifestyle change program and 2 sites into an enhanced standard care</p>	<p>construct validity have been demonstrated</p>		
<p>First author: True</p> <p>Year: 2015</p> <p>Title: Impact of Diabetes Risk Score on Lifestyle Education and Patient adherence (IDEA) in Prediabetes: A multisite randomized controlled trial</p> <p>Journal: Military Medicine</p>	<p>RD: RCT</p> <p>Melynk Level 2</p>	<p>Subjects from 4 clinics. 230 eligible (230 enrolled and randomized)</p>	<p>Measures: Diabetes Risk Score (DRS)</p> <p>Reliability: statistically significant data only recorded</p>	<p>Results: The knowledge of an improvement in risk score, and the timing of this information, may impact future adherence.</p> <p>Analysis: using R statistical analysis software</p>	<p>Limitations: exclusion criteria and lack of large intervention group</p>

<p>7. First author: Delahanty</p> <p>Year: 2013</p> <p>Title: Pretreatment, Psychological, and Behavioral Predictors of Weight Outcomes Among Lifestyle Intervention Participants in the Diabetes Prevention Program (DPP)</p> <p>Journal: American Diabetes Association</p>	<p>RD: Multivariate models using hierarchical logistic regression</p> <p>Melynck Level II</p>	<p>Sample 25% of DPP lifestyle intervention participants (n = 274)</p> <p>Sampling DPP participants in the lifestyle intervention arm were recruited for this sub-study</p>	<p>Measures: Psychological, Behavioral</p> <p>Reliability: Change in variables from baseline was tested with t tests. Multivariate models were constructed using hierarchical logistic regression to assess the association of weight outcomes</p>	<p>Results 40.5% had achieved the DPP 7% weight loss goal</p> <p>Analysis: multivariate analysis</p>	<p>Limitations: Al- though we conducted longitudinal analyses, the design is observational because we did not have a control group.</p>
<p>8. First author: Zhuo</p> <p>Year: 2014</p> <p>Title: The Lifetime Cost of Diabetes and Its Implications for Diabetes Prevention</p>	<p>RD: retrospective, cross sectional</p> <p>Melynck Level IV</p>	<p>1079 participants</p> <p>We used data from the 2006–2009 Medical Expenditure Panel Survey (MEPS), which were linked to 2005–2008 data from the National Health</p>	<p>Measures:</p> <p>Reliability: Reliable to due retrospective data</p>	<p>Discounted excess lifetime medical spending for people with diabetes was \$124,600 (\$211,400 if not discounted), \$91,200 (\$135,600), \$53,800 (\$70,200), and \$35,900 (\$43,900) when diagnosed with diabetes</p>	<p>Limitation of data due to retrospective data used</p>

<p>Journal: Diabetes Care</p>		<p>Interview Survey (NHIS) to estimate annual medical spending by diabetes status</p>		<p>at ages 40, 50, 60, and 65 years, respectively. Analysis: two-part model was used to estimate the annual medical spending for all participants in the study</p>	
<p>9. First author: The Diabetes Prevention Program Research Group Year: 2004 Title: Achieving Weight and Activity Goals Among Diabetes Prevention Program Lifestyle Participants Journal: Obesity Research</p>	<p>RD: Multivariate models using hierarchical logistic regression Melynk Level III</p>	<p>3234 persons at 27 centers who were at high risk for developing diabetes</p>	<p>Measures: self-monitor minutes of physical activity and fat grams consumed every day during the core curriculum and then one week over the remainder of the trial Reliability: unknown</p>	<p>Results Forty-nine percent met the weight loss goal and 74% met the activity goal initially, while 37% and 67%, respectively, met these goals long-term. Analysis: multivariate analysis</p>	<p>Self-report of physical activity</p>

<p>First author: Hsia</p> <p>Year: 2015</p> <p>Title: Impact of Lowering BMI Cut Points as Recommended in the Revised American Diabetes Association's Standards of Medical Care in Diabetes-2015 on Diabetes Screening in Asian Americans</p> <p>Journal: Diabetes Care</p>	<p>RD: cross sectional analysis</p> <p>Melynk Level IV</p>	<p>Non-Hispanic Asians, aged 45 years and older, with available DMI, HbA, and fasting glucose data. Overall, 341 participants</p>	<p>Measures: available BMI, HbA1c, and fasting glucose data</p> <p>Reliability: BMI cutoff in Asians participating in the National Health and Nutrition Examination Survey (NHANES) from 2011 to 2012 to increase reliability of data</p>	<p>Results: Lowering the screening BMI to 23 kg/m² increased the sensitivity of screening for prediabetes and diabetes from 50.2 to 74.1% ($P < 0.0001$) but decreased the specificity from 62.9 to 38.7% ($P < 0.0001$)</p> <p>Analysis: Sensitivity and specificity were compared with the McNemar test. Statistical analyses were performed using SAS 9.4 software (SAS Institute, Inc., Cary, NC). P values < 0.05 were considered statistically significant</p>	<p>Limitations: our sample size was small, despite using NHANES data from a year when Asians were oversampled. HbA1c and fasting glucose were measured on one occasion, which limits the validity of the diagnosis of prediabetes and diabetes because abnormal laboratory values should be repeated to confirm the diagnosis.</p>
<p><u>Efficacy of improving self-care</u></p> <p>First author: Chen</p> <p>Year: 2010</p> <p>Title: The predictors of adopting a health-promoting lifestyle among work site</p>	<p>RD: cross sectional study</p> <p>Melynk Level IV</p>	<p>260 adults at four work sites in southern Taiwan</p>	<p>Measures: perceived action benefit, perceived action barriers, perceived susceptibility and perceived severity</p>	<p>Results: The study found that over age 45 and BMI above 25 are risk factors for prediabetes</p> <p>Analysis: Multiple stepwise regression analysis</p>	<p>Limitations: only male subjects were analyzed</p>

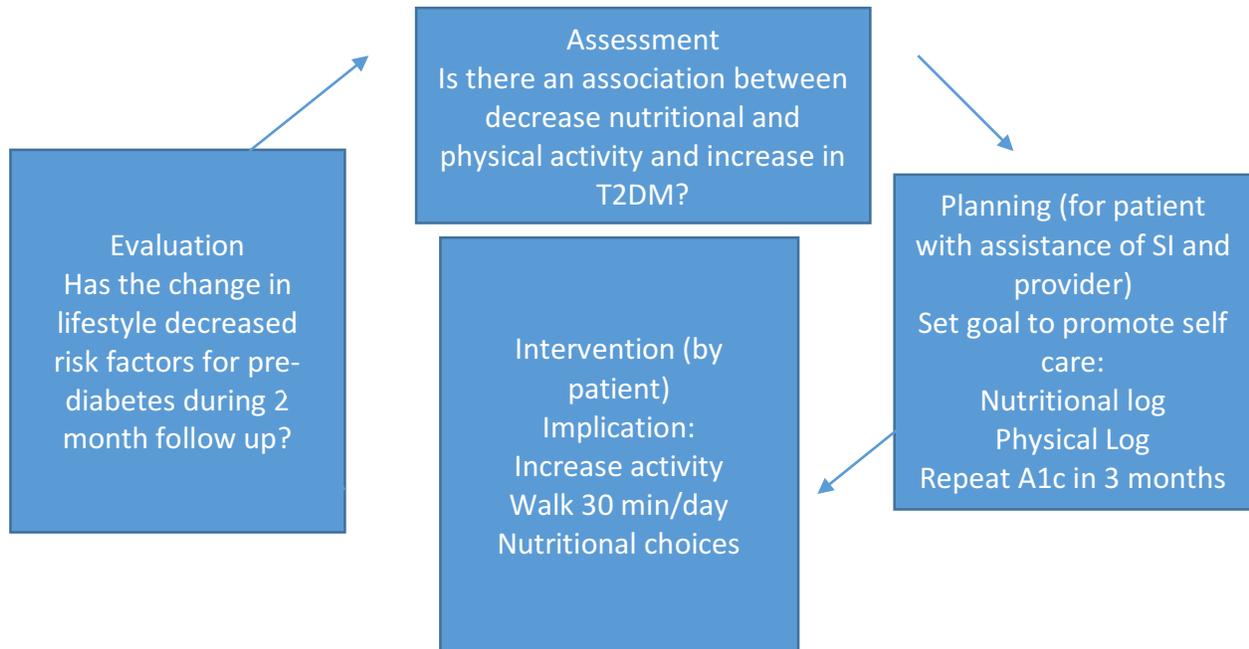
<p>adults with prediabetes</p> <p>Journal: Journal of Clinical Nursing</p>					
<p>First author: Morey</p> <p>Year: 2012</p> <p>Title: Enhanced Fitness: A Randomized Controlled Trial of the Effects of Home-Based Physical Activity Counseling on Glycemic Control in Older Adults with Prediabetes Mellitus</p> <p>Journal: The American Geriatrics Society</p>	<p>RD: Randomized controlled clinical trial</p> <p>Melynk Level II</p>	<p>VA participants in Raleigh VA clinics. BMI between 25-45. 302 participants were included after exclusion criteria was completed</p>	<p>Measures: HOMA-IR</p> <p>Reliability: SF-36</p>	<p>Results: No significant differences between the PAC and control groups over time for any of the glycemic indicators. However, phone based improved physical activity.</p> <p>Analysis: Multiple stepwise regression analysis</p>	<p>Limitations: self report of physical activity</p>

<p>First author: Ackermann</p> <p>Year: 2008</p> <p>Title: Translating the Diabetes Prevention Program into the Community. The Deploy pilot study</p> <p>Journal: American Journal of Prevention Medicine</p>	<p>RD: pilot cluster-randomized trial study</p> <p>Melynk Level II</p>	<p>92 participants that had an ADA score risk score >10 and CCBG of 110-199.</p>	<p>Measures: percent change in body weight</p>	<p>Results: body weight decreased by 6%</p> <p>Analysis: ordinary least squares multivariate regression</p>	<p>Limitations: does not compare the use of multiple recruitment channels</p>
<p><u>Healthcare Provider Education</u></p> <p>First author: Rariden</p> <p>Year: 2015</p> <p>Title: Improving Prediabetes Screenings at Rural Missouri County Health Departments</p> <p>Journal: Journal of Community Health</p>	<p>RD: pre/post test</p> <p>Melynk Level III</p>	<p>convenience sample of twenty-two nurses from seven rural Missouri health departments participated</p>	<p>Measures: population, procedures</p> <p>Reliability: general nursing knowledge divisions each showed statistically significant improvement with a p 0.05</p>	<p>Results: The pre-test revealed that over half (54.5 %) of the nurses did not feel comfortable with their understanding of prediabetes; the post-test scores showed an improvement that most nurses (95.4 %) felt comfortable</p> <p>Analysis: non parametric statistical testing best suited for the small sample size</p>	<p>Limitations: limited access to healthcare providers due to rural healthcare</p>

<p>First author: Kuo</p> <p>Year: 2014</p> <p>Title: Exercise engagement in people with prediabetes - a qualitative study</p> <p>Journal: <i>Journal Of Clinical Nursing</i></p>	<p>RD: qualitative study; A grounded theory study.</p> <p>Melynk Level IV</p>	<p>Twenty participants with impaired fasting glucose from a medical center in Taiwan were enrolled in this study for in-depth interview</p>	<p>Measures: developing awareness, creating the health blueprint, action cycle of internal struggle and developing spontaneous regular exercise</p> <p>Reliability: NVivo 8 0 qualitative data management software after transcription</p>	<p>Results: It is not easy for people with prediabetes to develop a regular exercise regime. Exercise behavior will be either continued or discontinued secondary to driving and resistive forces.</p> <p>Analysis: constant comparative method</p>	<p>Limitations: motivation can be reduced due to forced behavior</p>
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Appendix C

Orem's Theory Model and Process



Appendix D
QI Confirmation Letter

Thursday, October 12, 2017

Alexandra Paffenroth,
4401 Wornall Road
Kansas City, MO 64111

Dear Ms. Paffenroth,

Thank you for your submission entitled "Pre-Diabetes Lifestyle Prevention Program to Decrease Development of Diabetes in Adults" to the IRB office. After review, it has been determined that your submission, as submitted, does not meet the definition of research and can be considered a quality improvement project. As a quality improvement project, your proposal does not require IRB review or approval.

Please note that if you make any changes to the design of your proposal, you should re-submit the amended proposal to the IRB to ensure that the changes do not change the nature of the project in such a way that would require IRB review or approval.

Sincerely,

Appendix E

Cost Table

Table 1-Itemized Budget for Educating About Prediabetes

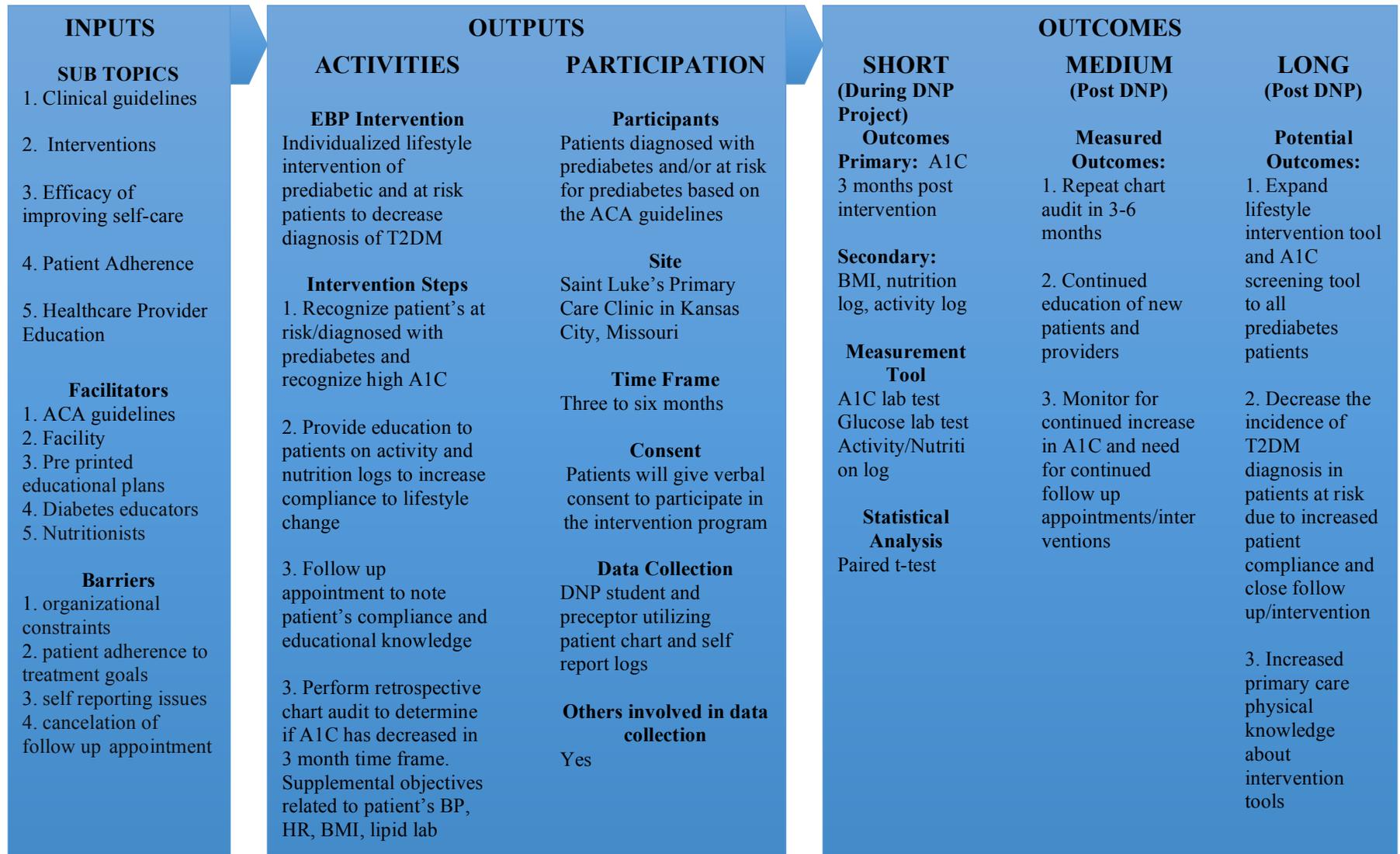
Pamphlets for education	\$50
Educational time for providers	volunteered time
Flyers for advertisement of in-services in primary care	\$50

Totals	\$100
--------	-------

Table 2- Direct and Indirect Cost

Direct Cost		Indirect Cost	
A1C (Pre/post)	Covered by insurance	Office Space	\$0.00
Vital signs	\$0.00	Phone	\$0.00
Weight recording		Computer access	\$0.00
		Dissemination Poster	\$80.00
Direct Cost Subtotal	\$0.00	Indirect Cost Subtotal	\$80.00
		Total	\$80.00

Appendix F
Logic Model Applied to T2DM Lifestyle Interventions
Alexandra Paffenroth, RN, BSN CPN



Appendix G
Welcome Letter



Hello!

Saint Luke's Health System Plaza Clinic is participating in a quality improvement project led by a UMKC Doctor of Nursing Practice student as the project team leader on prevention of type 2 diabetes. At your appointment, you will be given educational material. The material will include activity and nutrition information for you to use to decrease your risk of developing diabetes. With help of the student, we will encourage you to create a lifestyle change goal for the next three months. We will collect data at your appointment, and in three months, we will recheck to see if the lifestyle changes you have done at home have decreased your risk to developing type 2 diabetes. The student will call you at 6 weeks to see how your interventional change is going and to remind you to attend the follow up appointment.

Thank you for your time and for choosing Saint Luke's Health System!
If you have any questions you may contact your doctor or the student at
amp7yd@mail.umkc.edu.

Appendix H
Activity Log and Plate Model

Game plan Activity Tracker; Small Steps Big Rewards- Prevent Type 2 Diabetes- Copyrighted

Your Healthy Plate

A quick easy guide to help you eat better and lose weight

Fruit
(tennis ball size)
Or
1/2 cup fresh fruit
1 cup berries or melon
1/2 cup fruit juice
1/2 cup grapes / cherries
1/2 cup canned *(no added sugar)*



Nonstarchy Vegetables
(Unlimited)

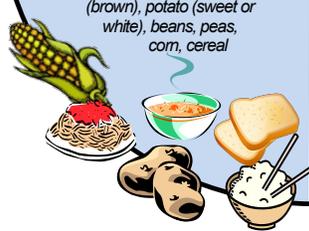
Asparagus Broccoli Beets Brussels sprouts Cabbage Carrots Cauliflower Celery Cucumber Eggplant	Greens (turnip, collard) Green Beans Mushrooms Onions Peppers Radishes Salad greens (lettuce) Summer Squash Tomatoes Tomato Juice
---	--



Milk/Yogurt
Low fat or fat-free
(1 cup)
Or
1/2 cup of pudding
1/2 cup light ice cream
or frozen yogurt



Starch
(1/2 cup to 1 cup)
Pasta *(whole grain)*, rice *(brown)*, potato *(sweet or white)*, beans, peas, corn, cereal



Meat/Meat Substitute
(3 oz. = deck of cards)

Chicken *(no skin)*
Fish *(salmon, tuna, etc.)*
Beef *(loin/round cuts)*
Pork *(loin/round cuts)*
Cheese *(3-5 g.fat /oz.)*
Cottage Cheese *(low-fat)*
Egg (1)
Peanut butter (1 Tbsp)
Nuts (1/4 cup)



Eating for good health and weight control:

Eat at least 3 meals per day with healthy snacks as needed. Distribute your food intake evenly throughout the day. Avoid large meals.

Choose lean protein sources (chicken, fish, loin/round cuts of beef and pork, low-fat cheese/cottage cheese). Remove visible fat and grill, bake & broil instead of frying.

Choose wholesome carbohydrates like whole fruit, vegetables, whole grains, beans/legumes & low-fat milk/yogurt. Limit highly refined starches (chips, crackers, pastries) and sugary foods.

Choose fats wisely—Limit sources of unhealthy solid fat (saturated & trans fats). Instead use small amounts of healthy fats like olive & canola oil, soft tub margarine made w/healthy fats, nuts & nut butters, avocado.

Choose calorie-free drinks, instead of sugary soft drinks and large amounts of fruit juice.

Control portion sizes of all foods. Avoid overeating

Use the "Plate Method" at meals. Fill 1/2 plate with non-starchy vegetables, 1/4 plate with lean protein, 1/4 plate with healthy carbohydrates.

Fat
1-2 tsp.



Developed by Diana Rodenberg MS, RD, CDE
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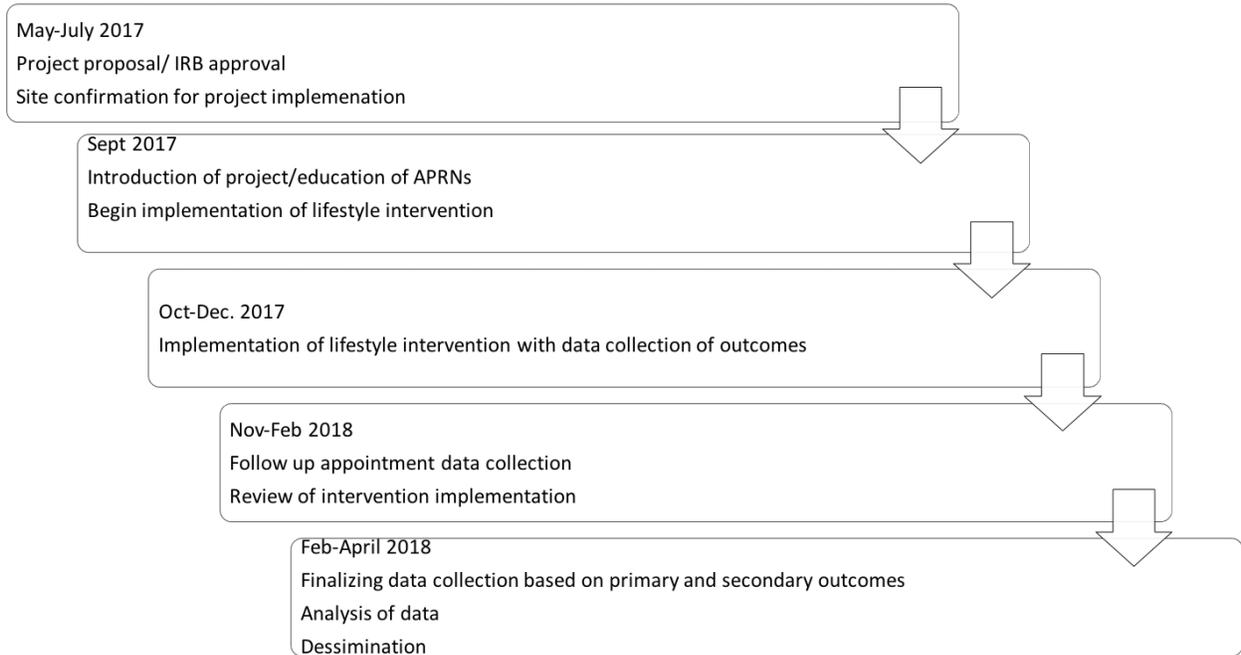
Rodenberg, D. (2017). Your healthy plate.

Appendix I
Prediabetes: Could it be you? CDC- Copyrighted

Appendix J
Intervention Flow Diagram

Recruitment (Fall 2017)	Agreement	Pre-Data	Intervention	Post-Data (Spring 18)
<p>On days SI scheduled in one primary care clinic, SI will screen, via the EHR, scheduled patients for inclusion (per ADA guidelines)</p> <ul style="list-style-type: none"> • adults with prediabetes, or • adults high risk for prediabetes, or • adults >45 years with risk for prediabetes, or • adults with BMI>25. <p>SI provides welcome letter with information on the improvement process to patients meeting inclusion.</p>	<p>SI obtains verbal agreement with desire to participate in improvement initiative.</p>	<p>SI will collect A1C within prior 3 months, prediabetes risk factors of patients current overweight or obese per BMI</p> <p>If no A1C, then provider will determine if A1C to be drawn using existing Standard of Care. If no A1C, then data will be missing.</p>	<p>At appointment, the SI will conduct motivational interviewing on lifestyle changes related to risk factors for prediabetes or current prediabetes. SI provides nutrition and activity log to patients over 15 minutes.</p> <p>Educational material printed is printed by SI and given to patients after motivational interviewing by SI during appointments.</p> <p>Phone call by SI at 6 weeks post appointment to answer questions and encourage lifestyle interventions.</p>	<p>At the 3 month post intervention appointment, provider will obtain A1C per existing Standard of Care (or missing data if not ordered), BP, lipids (ordered per standard of care or considered missing data), and BMI. SI will collect the data from the EHR.</p> <p>The SI will view and discuss the nutritional and activity logs with the patients and record yes or no regarding completed.</p>

Project Timeline Flow Graphic



Appendix L
Data Collection Template

PaffenrothSPSS.sav [DataSet1] - IBM SPSS Statistics Data Editor

File Edit View Data Transform Analyze Direct Marketing Graphs Utilities Extensions Window Help



	Name	Type	Width	Decimals	Label	Values	Missing	Columns	Align	Measure	Role
1	A1Cpre	Numeric	8	2		None	None	8	Right	Scale	Input
2	A1Cpost	Numeric	8	2		None	None	8	Right	Scale	Input
3	BMIpre	Numeric	8	2		None	None	8	Right	Scale	Input
4	BMIpost	Numeric	8	2		None	None	8	Right	Scale	Input
5	Nutritionlog	Numeric	8	2		{.00, Compl...	None	8	Right	Nominal	Input
6	ActivityLog	Numeric	8	2		{.00, Compl...	None	8	Right	Nominal	Input

Appendix M

The screenshot shows the Microsoft Excel interface. The 'Home' ribbon is active, displaying options for text formatting (font face: Calibri, size: 12, bold, italic, underline), alignment, and styles. The formula bar shows the function 'Paired Sample t-Test' in cell A1. The spreadsheet below has columns A through F and rows 1 through 8. Row 1 contains the title 'Paired Sample t-Test' spanning from column A to F. Row 2 contains the headers 'Predata' (B2), 'Postdata' (C2), and 'Significance' (D2). Rows 3 and 4 contain the variables 'A1C' and 'BMI' respectively, with corresponding data entry cells in columns B, C, and D.

	A	B	C	D	E	F
1	Paired Sample t-Test					
2		Predata	Postdata	Significance		
3	A1C					
4	BMI					
5						
6						
7						
8						

Appendix N
Results

T-Test

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	BMIpre	41.2100	5	10.02923	4.48521
	BMIpost	40.7800	5	9.83804	4.39970
Pair 2	A1Cpre	6.4000	1 ^a	.	.
	A1Cpost	6.2000	1 ^a	.	.

a. The correlation and t cannot be computed because the sum of caseweights is less than or equal to 1.

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	BMIpre & BMIpost	5	.995	.000

Paired Samples Test

		Paired Differences							
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)
					Lower	Upper			
Pair 1	BMIpre - BMIpost	.43000	1.04738	.46840	-.87049	1.73049	.918	4	.411