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LIVING SWEET: A MULTI-FUNCTIONAL MOBILE-PHONE APPLICATION STRATEGY FOR ADULTS WITH UNCONTROLLED TYPE 2 DIABETES MELLITUS

by

CHANTEL K. ANDERSON

EVIDENCE-BASED PRACTICE PROJECT REPORT

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DEDICATION

This project is dedicated to my husband, my children, and my mother and father. Their support and encouragement was especially important as I complete the final chapter of my higher education goals. This was certainly a career goal for me, and I was lucky to have all of them backing me along the way. I am hopeful our children have seen that if you want something bad enough you can achieve it. I am also hopeful that they learned by example, and will continue to reach for their dreams in whatever career path they take or life goal they make. I am certainly blessed to be surrounded by a loving family. I have to mention my dogs here as well. Taz and Gus were my co-pilots during countless late nights into the early morning hours.

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Living Sweet: A Multi-Functional Mobile-Phone Application Strategy for Adults with Uncontrolled Type 2 Diabetes Mellitus

Chantel Anderson DNP, APRN, FNP-BC

Type 2 Diabetes Mellitus (T2DM), one of the most common chronic diseases, is increasing worldwide, and once diagnosed, lifetime self-management is critical to maintain glycemic control (Vermeire et al., 2005; American Diabetes Association (ADA), 2018), Management of T2DM has been acknowledged as challenging due to the need for strict lifestyle adaptations. From a public health perspective, uncontrolled diabetes leads to increased healthcare costs, secondary complications, and ultimately severe disabilities (ADA, 2018). The purpose of this evidencebased practice (EBP) project was to evaluate the effectiveness of a diabetes-specific mobile health application (MHA) on glycated-hemoglobin (HbA1C), self-care perception (SCP), and self-care behaviors (SCB). The lowa model was used to guide this project in primary care settings in Northwest Indiana. A retrospective chart review determined that a high number adults had uncontrolled T2DM. A protocol was developed and implemented over an 8-week period. A within group design was used for pre and post-intervention evaluation of the HbA1C and SCP using paired-samples t tests. Statistically significant differences were noted in pre-HbA1C (M = 9.95; SD = 1.07) compared to post-HbA1C (M = 8.21; SD = 1.10) (t = 6.674, df = 1.0017. *p < 0.05), and in pre-SCP (M = 34.6; SD = 10.5) compared to post-SCP (M = 42.6; SD = 8.09) (t = -4.403, df = 17, *p < 0.05). A statistically significant difference in project-specific preand post- intervention SCBs were found with the behaviors of checking glucose (Z = 2.389, *p < .05), recording glucose (Z = 2.666, *p < .05), and medication adherence (Z = 2.313, *p < .05). There was not a statistically significant difference in the perception of activity engagement (Z =1.718, p > .05). Results indicated that a MHA intervention had a statistically and clinically significant impact on HbA1C, SCP, and SCBs with the exception of activity engagement.

CHAPTER 1

INTRODUCTION

Despite being the most expensive healthcare system among developed countries, the U.S. ranks the lowest in key health outcomes and in many aspects of access to care (Bondurant & Armstrong, 2016). Additionally, changes in reimbursement structure and challenges related to both quality and healthcare cost beg for a healthcare reform. Health care payment methods are changing from fee-for-service to value-based systems where payment is based on clinical quality outcomes and cost containment (Greenwood, Gee, Fatkin, & Peeples, 2017). From a public health perspective, uncontrolled diabetes leads to increased healthcare costs, secondary complications, and ultimately severe disabilities (ADA, 2018).

Chronic disease management has been acknowledged as challenging due to the need for strict lifestyle adaptations (Vermeire et al., 2005). Type 2 Diabetes Mellitus (T2DM), one of the most common chronic diseases, is increasing worldwide, and once diagnosed, lifetime self-management is critical to maintain glycemic control. Glycemic control is defined as achieving a HbA1C level that ranges from 6.0 % to 7.0 %, or blood glucose averages of 126 mg/dl to 152 mg/dl respectively, which has direct correlation with long-term prognosis for patients with T2DM (ADA, 2018). Glycemic control for diabetics who have experienced blood sugars less than 60 are expected to achieve less stringent HbA1C levels of < 8.0% (ADA, 2018). HbA1C measurement signifies the average blood sugar over a 8 to 12-week timeframe. Research has indicated that adherence to traditional interventions for the treatment of diabetes mellitus is poor, and as a result there has been little improvement of glycemic control (Vermeire et al., 2005).

The aim of managing T2DM is to attain glycemic control (ADA, 2018). Self-care behaviors and lifestyle modifications are aimed at overall reduction of HbA1C levels and are mainstays in the treatment and management of Diabetes Mellitus (DM) (ADA, 2018). Thus, the

diffusion into practice of the best evidence for the self-management of diabetes is essential as the management of chronic disease becomes a focus throughout health organizations.

Uncontrolled diabetes and chronic hyperglycemia are also associated with increased risk for cardiovascular disease, retinopathy, nephropathy, neuropathy (ADA, 2018; Vermeire et al., 2005), as well as increased mortality for those who suffer with this unforgiving disease (Wu et al., 2017).

Through an extensive literature search, evidence indicated that the use of mobile health applications (MHAs) was found to be the best practice for the encouragement of self-care practices for the management of adults with T2DM and found to a significantly reduce HbA1C levels (Alharbi et al., 2016; Bonoto et al., 2017; Clement et al., 2018; Cui, Wu, Mao, Wang, & Nie, 2016; Hou, Carter, Hewitt, Francisa, & Mayor, 2016; Pal et al., 2014; Wang, Xue, Huang, Huang, & Zhang, 2017; Whitehead & Seaton, 2016; Wu, Guo, & Zhang, 2019; Wu et al., 2017; Yoshida et al., 2018). In 2014 64 % of Americans were using smartphone technology. Research indicates that using a diabetes MHA through a smartphone can increase adherence to diabetes management and self-care efforts (Fu et al., 2017). MHA technology provides a platform for the rapid development of patient-centered care that supports the self-management of DM beyond traditional computer or web-based programs, and institution-based diabetes education programs (Greenwood, Gee, Fatkin, & Peeples, 2017).

The purpose of this evidence-based practice (EBP) project is to evaluate the effectiveness of a diabetes-specific mobile health application (MHA) on HbA1C levels, self-care perception, and self-care behaviors. The clinical question being addressed is, what is the best practice for adult T2DM patients to achieve glycemic control and improve self-care behaviors. Additionally, the clinical question also addresses the impact of a MHA on self-care perception. This project was posed to identify what intervention has been found in the best evidence, to achieve glycemic control in adult T2DM patients, thereby lessening debilitating complications related to chronically elevated HbA1C levels.

Data from the Literature Supporting Need for the Project

Currently, 30.3 million people have DM in the U.S., this number includes an alarming estimation of 7.2 million who have gone undiagnosed (ADA, 2018; CDC, 2017). T2DM affects 382 million globally, and the incidence of this disease is expected to increase to 500 million by 2030 (ADA, 2018; CDC, 2017; Fu, McMahon, Gross, Adam, & Wyman, 2017; Hou, Carter, Hewitt, Francisa, & Mayor, 2016). The percentage of adults with diabetes increases with age: 25.5% of those aged 65 and older have been diagnosed with this chronic disease (CDC, 2017). Of an estimated 1.5 million new cases diagnosed in 2015, more than half were aged 45-65 years and equally distributed among men and women (CDC, 2017). Coexisting conditions and complications secondary to uncontrolled diabetes include cardiovascular disease, stroke, diabetic ketoacidosis, kidney disease, eye disease, and amputation of a lower extremity (CDC, 2017). In the U.S., major cardiovascular diseases were found in 1.5 million diabetics which included 400,000 with ischemic heart disease, and 251,000 stroke events. Amoutations of the lower extremities as a result of uncontrolled diabetes occurred 11.5 per 1,000 persons with diabetes (CDC, 2017). In 2015, other uncontrolled diabetes-related events led to 14.2 million emergency department visits from hypoglycemia (very low blood sugar) and hyperglycemia (very high blood sugar) (CDC, 2017). This chronic disease was the seventh leading cause of death in the U.S. in 2015, and had an estimated cost of \$245 billion (CDC, 2017). Economic costs of untreated and uncontrolled DM increased 26% from 2012 to 2017 (ADA, 2018; Fu et al., 2017). Poor self-management practice lead to uncontrolled HbA1C levels (greater than 8.0), and have led to significant financial burden to the individual and to society (ADA, 2018). The ongoing responsibility of administering medication, testing blood glucose levels, and adhering to lifestyle modifications can be quite overwhelming, furthermore, patients often do not typically document self-management behaviors. From a clinical experience perspective, the lack of documentation creates a significant challenge for health care providers to identify the problem and adjust therapy to meet the needs of the individual.

Data from the Clinical Agency Supporting Need for the Project

This project is a pilot program that will be implemented in primary health care settings within the guidelines of certified rural health centers. These clinical sites are located in rural Indiana, are family practice focused, and have a medical group consisting of physicians and nurse practitioners. The four facilities are located in small rural towns in northwest Indiana. The clientele is generally one of lower socio-economic status with the main payor source received from Medicare and Medicaid Services. After an electronic medical record (EMR) query, it was found that well over 200 patients on service had either type I diabetes mellitus (T1DM) or T2DM (Melissa Jones, Personal Communication, May 23, 2019). Organizational data, obtained through personal communication with the project preceptor, indicated poor outcome measures in 2019 guarter-one and guarter-two for HbA1C measurements of patients with diabetes mellitus. Centers for Medicare and Medicaid Services (CMS) specifically evaluate HbA1C levels of greater than 9.0 as the quality outcome measure for health care organizations (CMS, 2017). However, for the purpose of this project the ADA recommendation of HbA1C of 8.0 will be the used for evaluation purposes (ADA, 2018). Quarter-one indicated that 59.3% of diabetics within the primary care organization had HbA1C results of greater than 9.0, while guarter-two indicated that 66% had HbA1C greater than 9.0. These are considered poor quality measure outcomes and are well above the expected national standard of 45% (CMS, 2017). These poor-quality outcome results were the impetus for this EBP project. As a primary healthcare organization, it is the duty of those rendering care to seek out the best evidence and improve quality and safety of the receiving population. Within the practice in which the DNP student works, HbA1C levels above 9.0 % were at an all-time high of 59% for the second quarter in 2019. The 59% was less than the overall primary care group's results of 66% of DM patients that had HbA1C of greater than 9.0%, but levels were still outside of the national standard (CMS, 2017).

The DNP student manages 40 adults with T2DM, and has over 10 years' experience treating and managing patients with this chronic disease. She has found it difficult to incite self-

care behavior practices that positively impact HgA1C levels. Through an extensive search of the literature, evidence was found to support an intervention to improve the self-management of adults with T2DM.

Purpose of the Evidence-Based Practice Project

The purpose of this EBP project is to evaluate the effectiveness of using a diabetes-specific MHA, with associated individualized preference settings, as an 8-week intervention for adult T2DM patients with HbA1C levels above 8.0 in a primary healthcare setting. There is a large body of evidence that supports the use of diabetes-specific mobile health smartphone applications to significantly reduce HbA1C in this population. Essentially, this EBP project will include an intervention designed to foster behavioral changes that promote improved HbA1C results, diabetes self-management habits such as; medication compliance, blood sugar monitoring efforts, and physical activity engagement, and improve self-care perception.

Evaluation will include determining if it significantly improved HbA1C results, self-care behaviors of blood glucose monitoring, physical activity engagement, medication adherence, and self-care perceptions for adult T2DM patients in a primary healthcare setting.

Living Sweet

The name of the new diabetes-specific MHA program was created through a competition held by the DNP student project leader. The competition was conducted through an email request not only to name the program, but also to entice staff engagement and interest. This approach was aligned with a transformational leadership model to motivate, inspire, and solicit buy-in of staff members who may be impacted by practice change (Brewer et al., 2016). The winning name of the competition, Living Sweet, was chosen by the mother of the DNP student project leader. Staff are key stakeholders and it is important for their participation in the adoption of new practice standards and for overall program success (Walston, 2017).

PICOT Question

In adult T2DM patients with HbA1C values higher than 8.0 in a primary healthcare setting (P) what is the effect of a diabetes-specific multi-functional mobile-phone application (I) compared to traditional diabetes education (C) on HbA1C results, self-care behaviors, and self-care perception (O), over an 8-week period (T)?

Significance of the EBP Project

According to Vermeire et al. (2005) irrespective of the type of chronic disease, adherence to treatment recommendations are poor despite known consequences. This EBP project is important because it is a proactive approach that encourages adult T2DM patients to increase self-care behaviors which are directly associated with a reduction in HbA1C values (Alharbi et al., 2016; Bonoto et al., 2017; Clement et al., 2018; Cui, Wu, Mao, Wang, & Nie, 2016; Fu, McMahon, Gross, Adam, & Wyman, 2017; Hou, Carter, Hewitt, Francisa, & Mayor, 2016; Pal et al., 2014; Wang, Xue, Huang, Huang, & Zhang, 2017; Whitehead & Seaton, 2016; Wu, Guo, & Zhang, 2019; Wu et al., 2017; Yoshida et al., 2018). Moreover, studies have shown use of MHAs have a positive impact on self-care perception and self-confidence that is essential for self-management of a chronic disease (Bonoto et al., 2017; Clement et al., 2018; Pal et al., 2014; Wu, Guo, & Zhang, 2019). Improvements in HbA1C is directly linked to a reduction of debilitating diabetes complications, cost burden, and associated mortality rates (Alharbi et al., 2016; Bonoto et al., 2017; Yoshida et al., 2018). The use of MHAs addresses the current clinical problem through a technological platform that has shown statistically significant improvements in HbA1C results and accompanying self-care behaviors (Alharbi et al., 2016; Bonoto et al., 2017; Clement et al., 2018; Cui, Wu, Mao, Wang, & Nie, 2016; Fu, McMahon, Gross, Adam, & Wyman, 2017; Hou, Carter, Hewitt, Francisa, & Mayor, 2016; Pal et al., 2014; Wang, Xue, Huang, Huang, & Zhang, 2017; Whitehead & Seaton, 2016; Wu, Guo, & Zhang, 2019; Wu et al., 2017; Yoshida et al., 2018). Additionally, use of this technology has been shown to be costeffective, readily available, and user friendly (Alharbi et al., 2016; Clement et al., 2018; Holtz &

Lauckner, 2012; Pamaiahgari, 2018). The ADA's Standards of Medical Care in Diabetes (2019) recommendations indicate that improving care and promoting health in the diabetic population is a standard of practice included in their evidence-based recommendations. Additionally, the ADA concluded that diabetes-specific technology, when applied appropriately, can improve the lives and health of people with diabetes (ADA, 2019).

CHAPTER 2

EBP MODEL AND REVIEW OF LITERATURE

Overview of EBP Model

Evidence-based practice (EBP) involves the use of reliable, explicit and judicious evidence to make decisions about the care of individual patients combining the results of well-designed research, clinical expertise, patient concerns and patient preferences (Titler et al., 2001). The best evidence is used as a guide to practice decisions which ultimately leads to high quality standards, controlled costs, and optimal patient care outcomes (Schmidt & Brown, 2019). Ingersoll (2000), defines EBP as, "the conscientious, explicit, and judicious use of theory-derived, research-based information in making decisions about care delivery to individuals or groups of patients and in consideration of individual needs and preferences" (p. 152).

The lowa model was originally developed and implemented at the University of Iowa Hospitals and Clinics. It was used as a framework that focused on organization and collaboration incorporating clinical practice and use of research (Titler et al., 2001). Since its inception this model has been used to guide project decisions while focusing on evidence to support best practice effort (Titler et al., 2001). Originally, it was developed in 1994 as a research utilization model, but has been updated to include more emphasis on EBP. Significant developments in the healthcare market and feedback from users was the impetus to revise the model. Revisions included: incorporating new terminology and feedback loops; address the dynamic changes within the health care market; and encourage the use of other forms of evidence such as expert opinion and case reports when primary research was not available to guide practice. The model was ultimately renamed to the lowa Model of Evidence-Based Practice to Promote Quality Care (Titler et al., 2001). This updated model allows nurses to focus on knowledge and problem-focused triggers that promoted critical thought about clinical practice effectiveness and operational efficiency, leading nurses to seek scientific knowledge to fill the

clinical and operational gaps within a unit or throughout an organization (Titler et al., 2001). The lowa Model of Evidence-Based Practice to Promote Quality Care consists of 7 steps to promote quality care in a systematic method that demonstrates how organizations change practice based on the most current evidence (Schmidt & Brown, 2019). Step I is the selection of a topic for an EBP project for which many factors need to be considered including assessment of the priority and magnitude of the problem, the application to the primary healthcare setting, the contribution to improving care, the current practice problem area, staff dedication to practice change, and multidisciplinary impact of the problem (Titler et al., 2001). Step II is the engagement of a team that will be responsible for the development, implementation, and evaluation of the project. The makeup of the team is driven by the chosen topic and include associated stakeholders (Titler, 2001). In this step the team will determine whether the problem at hand is a priority for the organization, department, or unit in which they work. Problems that have a higher volume or cost associated will likely have a higher priority from an organizational standpoint. During this step, organizational buy-in is crucial and knowing the prioritization of the problem will help focus team efforts when grooming key stakeholders (Titler et al., 2001).

Step III entails evidence retrieval. Brainstorming amongst the members should be held to identify available resources to guide the search for evidence (Titler et al., 2001). Once the priority has been determined, the team members will help develop, evaluate, and implement the EBP change. The team should include interested interdisciplinary stakeholders and leaders, which include those outside of nursing (Titler et al., 2001). Step IV is the process of gathering, critiquing and synthesizing pertinent research related to the desired practice change. This is a systematic process that exposes the best supportive evidence available which is then assessed and critiqued for level and quality (Titler et al., 2001). This ensures the overall body of evidence has strength and merit (Schmidt & Brown, 2019). One of the most important parts of this step is to formulate a good question using the PICOT method (Titler et al., 2001) that takes into account the population, intervention, comparison, outcome, and time frame (Melnyk & Fineout-

Overholt, 2015). Step V is the development of a patient-centered evidence-based practice standard that is highly individualized. Once the literature is critiqued, team members develop a set of recommendations that guide the new practice (Titler et al., 2001). The type and strength of evidence used in practice needs to be clear and based on the consistency of replicated studies (Titler et al., 2001). The development of a patient-centered EBP standard becomes a to guide clinical practice, assessments, actions, and treatment as required, and will be based on the group decision, considering the relevance for practice, its feasibility, appropriateness, meaningfulness, and effectiveness for practice (Titler et al., 2001). Evidence-based practice is ideally a patient-centered approach and when implemented is highly individualized (Titler et al., 2001). Practice that fails to consider individual preferences of the individual patient is not evidence-based. Evidence-based practice must take into account patient autonomy, choice, and allow personal preference to be expressed (Schmidt & Brown, 2019; Titler, 2001).

Step VI is the implementation of the EBP standard which begins with written policies, procedures, and guidelines. Policy development requires direct interaction between the team members, direct care providers, and organizational leaders to support the practice change (Titler et al., 2001). The evidence also needs to be disseminated with the focus on its strengths and perceived benefits. This can be achieved through various communication lines such as inservice education and hands on demonstration of the new practice change. Social and organizational factors can affect implementation and there needs to be support and value placed on the integration of evidence into practice and the application of research findings (Schmidt & Brown, 2019). The expertise of nurse champions can support the overall implementation of EBP into an organization. Nurse champions represent an untapped vital resource to change practice in today's metric-driven culture (Scanlon & Woolforde, 2016). Empowerment and a multidisciplinary approach are a few of the key attributes that have propelled the success of the nurse champion. Moreover, they have the ability to close the gap between evidence and practice as well as increase staff engagement in the work setting

(Scanlon & Woolforde, 2016). In some cases organizations are not ready or willing to assimilate EBP. Elements of system readiness include tension for change, EBP system fit, assessment of implications, support and advocacy for the EBP, dedication of time and resources, and the capacity to evaluate the impact of the EBP during and following implementation. Moreover, leadership support is critical for supporting EBP, and is expressed by providing necessary resources, materials, and time (Titler, 2006).

Step VII is the evaluation step which is essential to seeing the value and contribution of the evidence into practice. Baseline comparison data prior to project implementation is beneficial to show how the new evidence-based practice standard has contributed to patient care (Titler, 2001). Audits and feedback should be conducted throughout the implementation process. It is essential that organizational leadership provide support during this step as success is not likely without support. Project evaluation will certainly bring to light the EBP project's impact, but the project's value to the organization can only be assessed against an actual change occurring with the desired outcome. For any change to take place, barriers that could hinder its progress need to be identified and addressed preferably before and during project implementation (Schmidt & Brown, 2019).

Application of EBP Model to DNP Project

The application of Step I of the Iowa model, which is the selection of a topic, consisted of the project leader identifying a problem-focused trigger which raised the question: Is this topic a priority for the organization? Consultation with the organization's quality and compliance director and project preceptor led the team to investigate quality metrics that surrounded HbA1C measures throughout the primary care organization. An internal data search revealed the priority and magnitude of the current problem directly related to elevated HbA1C measures and uncontrolled T2DM. Current practice problems were assessed and care rendered was found to be outdated and lacking EBP standards. First-quarter quality measures of 2019 indicated that 59% of diabetic patients within this primary healthcare organization in rural Indiana submitted

reports of HbA1C results of greater than 9%. Second-quarter quality measures reports for this same organization resulted in 66% of diabetic patients with HbA1C levels greater than 9%. These value translate into an average daily blood sugar of 215 mg/dl., and were the impetus for this EBP project. According to the ADA (2018) the goal HbA1C ranges from 6.0% - 7.0% or an average daily blood sugar of 115 mg/dl to 150mg/dl. However, there are multiple factors the dictate target HbA1C for those individuals with diabetes mellitus; for those with more severe disease, control of diabetes is to achieve a HbA1C of 8% is recommended (ADA, 2018).

Step II, forming a team, consisted of the project leader selecting key team players for the development, implementation, and evaluation of the project. The team composition was determined based on the project topic and includes key stakeholders such as primary care providers, senior leadership, and a compliance and quality director. Initiation of this step includes a PowerPoint presentation that will educate key stakeholders about the new practice change. The presentation is designed to provide project details and engender enthusiasm for the EBP project. This effort is to encourage buy-in from key stakeholders, as well as enhance recruitment of additional team members and champions within the organization.

Step III, evidence retrieval, entails an exhaustive literature search and active brainstorming with team members to identify resources available to support the evidence search process. The exhaustive literature search involves gathering the most current and relevant evidence to support the best practice for the treatment of HbA1C that is greater than 8% and is considered to be uncontrolled.

Step IV, grading the evidence, consisted of the project leader leveling and appraising evidence consistent with predetermined inclusion criteria. The focus is to get high-level and high-quality evidence to determine what the best practice should include and to support the reason for the change in practice. Literature that is high in level and quality adds substantial validity, strength, and merit to the new EBP standard, and this leads to improved patient quality and safety outcomes.

Step V, developing an EBP standard, will be completed by the team members of the project which includes the project leader, DNP Student, two primary care providers that will serve as project champions, a project preceptor who is the quality and compliance director, and a risk management director.

Step VI, implement the EBP, includes the execution of the written guidelines specific to the triggered problem. This phase necessitates the translation and application of evidence into practice. This process will include a multidisciplinary approach between team members, direct care providers, and organizational leaders.

Step VII, evaluation, will be ongoing during and after the implementation of the new EBP practice change. Internal individual baseline HbA1C data has been gathered prior to the launch of this 8-week pilot in order to evaluate the outcome of the new evidence-based practice change. This is essential to allow stakeholders and team members to see the value and contribution of applying evidence into practice.

Strengths and Limitations of EBP Model for DNP Project

Strengths of the model include the use of a pilot program launch to address barriers, redesign implementation processes, and fine tune the written and practice standards toward a final EBP protocol. Within the model are continuous feed-back, check and balance loops that evaluated different points as one proceeds through the steps. The inclusion of these key decision points are specific to this model, and help guide the project leader and the project team members to make determinations about the overall progression of the project. This process supports a project that is focused and valid, and one that is most likely to succeed and be in alignment with organizational priorities. An example within the model is a question that is posed: Is there sufficient research regarding the use of mobile phone applications for self-management of T2DM? If there is not sufficient research to support this theme then one may choose to conduct a study or choose a different problem. This check and balance system is infused

throughout the model to ensure the team efforts are not futile and will lead to a productive new practice change that is evidence-based.

The limitation of this model is the focus of a team approach to bring the new practice change to fruition. In a rural healthcare setting, resources, including nursing staff are not abundant by any means. Due to lack of resources and inadequate staffing many are reluctant to join a team of any kind, especially over a long period of time. Many feel overwhelmed with work and the addition of team involvement is perceived as additional work and commitment. Based on personal experience as a leader in other service excellence programs, it is best to keep the team small in a rural health setting. Dissemination of the new practice change may be a different story, but the planning, developing, and implementing will need to be kept to an intimate group of team members. The practice change will be instituted in the primary care office settings and not the organization as a whole. As reimbursement transitions from volume to value in which quality trumps quantity, HbA1C reduction and diabetic control is going to be critical to maintain a viable practice within a healthcare setting (Bondurant & Armstrong, 2016).

Literature Search

An exhaustive literature search was conducted within the electronic databases Cochrane Library, Cumulative Index of Nursing and Allied Health Literature (CINAHL), Joanna Briggs Institute, Medline with full text via EBSCO, U.S. Preventative Services Task Force (USPSTF) PsycINFO, and Turning Research Into Practice (TRIP). Citation chasing of a single-arm feasibility study by Koot et al. (2019) was completed and resulted in a relevant SR and meta-analysis by Bonoto et al. (2017). A hand search was completed in the Journal of Medical Internet Research (2016) and one article was found to be significant in the creation of this EBP project.

Keywords from the PICOT question were used in each respective database. Initial searches included several variances of those keywords to lead to a suitable relevant evidence search. The following keywords, phrases, Boolean Operators, and truncation options in various

combinations were used to retrieve the best evidence within each respective database; "mobile* phone" OR "mobile* app*" OR "cell* phone" OR "mobile application*" OR "smart phone" AND diabetes* OR diabetic* OR "diabetes mellitus".

Inclusion criteria were adult patients with T2DM who utilized mobile phone applications to foster ADA-approved diabetic self-care activities such as medication compliance, blood sugar monitoring efforts, and physical activity engagement to reduce HbA1C levels. Self-care perception was noted as a theme throughout the literature, therefore, studies that addressed self-care perception related to the use of MHAs for diabetic self-care were included. Limiters were peer-reviewed, research articles or Cochrane Reviews in English language conducted between January 2014 and June 2019. Exclusion criteria were children and adults with gestational diabetes, prediabetes, T1DM, and other telehealth technologies that were not MHA focused. Some of the evidence included data on theses exclusion grouping (Alharbi et al., 2016; Bonoto et al., 2017; Clement et al., 2018; Hou, Carter, Hewitt, Francisa, & Mayor, 2016; Mann, 2018; Pamaiahgari, 2018; Whitehead & Seaton, 2016; Wu et al., 2017; Wu, Guo, & Zhang, 2019; Yoshida et al., 2018), but subgroup analysis data were extracted when available from the literature to focus on the evidence related to inclusion criteria (Bonoto et al., 2017; Clement et al., 2018; Hou, Carter, Hewitt, Francisa & Mayor, 2016; Pal et al., 2014; Wang, Xue, Huang, Huang, & Zhang 2017; Whitehead & Seaton, 2016; Wu et al., 2017; Wu, Guo, & Zhang, 2019; Yoshida et al., 2018). Search of the CINAHL database produced 47 sources that had varying degrees of level, relevance and quality. References were read in two-phase process, first by reviewing titles and abstracts, and then by reviewing the full article, and five sources were selected. These sources were one meta-analysis of RCTs (Yoshida et al., 2018), one systematic review of RCTs (Whitehead & Seaton, 2016), two SRs and combined meta-analysis of RCTs (Pal et al., 2014; Hou, Carter, Hewitt, Francisa, & Mayor, 2016), and one integrative review of RCTs with four group pre-post-test studies (Fu, McMahon, Gross, Adam, & Wyman, 2017). The Cochrane Library yielded 73 sources and none were applicable to the focus of this

project. Additional pieces of evidence were excluded due to redundancy and lack of relevance to the focus of this project. Joanna Briggs Institute database resulted in 17 sources and three evidence summaries were selected for relevance (Mann, 2018; Nguyen, 2018; Pamaiahgari, 2018). Medline with full text EBSCO yielded 242 sources, and after applying a two-phase evaluation process a total of four evidence sources were found (Wu et al., 2017; Wu, Guo, & Zhang, 2019; Cui, Wu, Mao, Wang, & Nie, 2016; Wang, Xue, Huang, Huang, & Zhang, 2017). The two-phase evaluation process consisted of reviewing abstracts followed by a more in-depth analysis of each respective article. The pieces of evidence included one SR (Wu et al., 2017), two SRs with combined meta-analysis (Wu, Guo, & Zhang, 2019; Cui, Wu, Mao, Wang, & Nie, 2016), and one integrative review (Wang, Xue, Huang, Huang, & Zhang, 2017). This database search results included five articles duplicated from previous database. It was noted that other researchers within the literature searched the database PsycINFO within the articles, so this database was added to the search. The search of PsycINFO yielded 14 sources, in which none were relevant to this EBP project. Turning Research Into Practice (TRIP) clinical practice quideline database was utilized and yielded 10 sources, one clinical practice quideline was found to be relevant and qualified for inclusion into the pool of evidence (Clement et al., 2018). Finally, the U.S. Preventative Services Task Force (USPSTF) was included in the search, which resulted in two sources; however, neither was found to be relevant to this EBP project. In addition to searching the databases, citation chasing through a related article (Koot et al., 2019) outside of database-retrieved evidence, yielded 2 significant pieces of evidence (Bonoto et al., 2017; Cui, Wu, Mao, Wang, & Nie, 2016). Hand searching efforts were completed in the Journal of Medical Internet Research, Volume 18, 2016 to 2017, on related articles and yielded one significant piece of evidence (Alharbi et al., 2016). This particular year was selected in the hand search process due to the amount of new literature that was in support of MHAs for the support of chronic disease such as diabetes.

An exhaustive search of the literature resulted in 15 pieces of evidence involving the effect of MHAs to reduce HbA1C in patients with T2DM and perceptions of self-care in the management of T2DM. Using the leveling system by Melnyk & Fineout-Overholt (2015), 12 of the sources included were deemed level 1 evidence, and were either systematic reviews, evidence summaries, or systematic reviews combined with meta-analysis. Two pieces were deemed level II evidence and consisted of integrated reviews. One piece of evidence was a clinical practice guideline which was deemed level VII. The included 15 sources was comprised of three evidence summaries (Mann, 2018; Nguyen, 2018; Pamaiahgari, 2018), one meta-analysis (Yoshida et al., 2018), eight systematic reviews (Wu et al., 2017; Whitehead & Seaton, 2016; Hou, Carter, Hewitt, Francisa, & Mayor, 2016; Cui, Wu, Mao, Wang, & Nie, 2016; Alharbi et al., 2016; Wu, Guo, & Zhang, 2019; Pal et al., 2014; Bonoto et al., 2017), two integrative reviews (Fu, McMahan, Gross, Adam, & Wyman, 2017; Wang, Xue, Huang, Huang, & Zhang, 2017), and 1 clinical practice guideline (Clement et al., 2018) (see Table 2.1).

Table 2.1

Literature Search Results

Database	Keyword(s)	Limiters	Date Restraints	Results	Relevant Evidence
CINAHL	(Subject Heading: Diabetes Mellitus, Type 2. "mobile* phone" OR "mobile app*" OR "mobile application*" OR "cell *phone" OR "smart phone").	English Peer Reviewed Research article	May 2014- June 2019	47	5 (1 Meta-Analysis of RCTs, 1 Systematic Review, 2 Systematic Reviews and Meta-Analysis, 1 Systematic Review of RCTs and 4 group prepost-test).
Citation Chase Koot et al., 2019		English Peer Reviewed	May 2014- June 2019	2	2 (Systematic Reviews and Meta-Analysis of RCTs).
Cochrane Library	(Diabetes Mellitus, type 2, Explode all trees).	Cochrane Reviews	May 2014- June 2019	73	0(Redundancy of evidence or not relevant to topic).
Hand Search Journal of Medical Internet Research		English Peer Reviewed	Volume 18- 2016	1	1 (Systematic Review and Meta-Analysis of RCTs).
Joanna Briggs Institute	(diabetes mellitus, type 2 diabetes, mobile phone, application, app, smartphone, cell phone).	English Peer Reviewed	May 2014- June 2019	17	3 (Evidence Summaries).
Medline with Full text via EBSCO	("mobile*phone" OR "mobile* app" OR "cell" phone" OR	English Peer Reviewed Research article	May 2014- June 2019	242	3 (Systematic Review and Meta- Analysis,

	"mobile application*" OR "smart phone" AND diabetes* OR diabetic* OR "diabetes mellitus").				1 Systematic Review of RCTs, 1 Systematic Review of RCTs and Quasi- experiments).
PsycINFO	(Thesaurus: Diabetes "mobile*" phone OR "mobile app*" OR "cell* phone" OR "smart phone").	English Peer Reviewed	May 2014- June 2019	14	0 (none related to mobile phone applications' impact on clinical outcome or self-care perception).
TRIP Turning Research Into Practice	(smart phone diabetes).	Clinical Practice Guideline	May 2014- June 2019	10	1 (Clinical Practice Guideline).
USPSTF U.S. Preventative Services Task Force	(Diabetes Metabolic).		May 2014- June 2019	2	0 (published article for screening adults for diabetes. 1 article for screening for gestational diabetes).

Levels of Evidence

The level of evidence was evaluated by using the Pyramid of Evidence by Melnyk & Fineout-Overholt (2015). The Pyramid of Evidence is made-up of a seven-layer leveling system. Level 1 starts at the top of the pyramid and is indicative of the highest, strongest, and most reliable evidence. The leveling systems goes down the pyramid in succession to level II through level VII with level VII being the weakest sources of evidence. Included in level I are systematic reviews and meta-analysis of RCTs. Including level I evidence in an EBP practice would be considered gold-standard, however not all themes and projects are supported by level I sources (Melnyk & Fineout-Overholt, 2015). The fact that a study is located lower on the Hierarchy of

Evidence does not necessarily mean that the strength of recommendation made from that and other studies is low. When evidence shows consistency or is very compelling across studies, strong recommendations can be made from evidence found in studies even with lower levels of evidence (Melnyk & Fineout-Overholt, 2015). In other words, strong recommendations can be made from lower levels of evidence, and may be sufficient in the development of an EBP project leading toward a change in practice. Level II is just below Level I evidence on the pyramid and this includes RCTS that have solid design and methodology. Next is level III and it is made up of evidence from nonrandomized controlled trials. Level IV is inclusive of case-control or cohort studies. Level V encompasses evidence from systematic review of descriptive studies and/or qualitative studies. Level VI contains evidence from a single descriptive or qualitative study. Finally, Level VII is comprised of evidence from expert opinions, authority opinions, or guidelines (Melnyk & Fineout-Overholt, 2015). The Pyramid of Evidence was used as a leveling tool to determine the strength of evidence used for this EBP project, as well as, to add clarity and structure to the overall evaluation process. Additionally, the use of this tool demonstrates to the reader the comprehensive hierarchical level of support for this EBP project.

Appraisal of Relevant Evidence

Appraisal of the included studies was completed through the use of the Critical Appraisal Skills Programme (CASP) tool. This tool is not meant to replace considered thought and judgement, but for use as a guide and to aid memory. All CASP checklists cover three main areas: validity, results, and clinical relevance (Critical Appraisal Skills Programme, 2018). The overall quality of the evidence body was mainly made up of systematic reviews and meta-analysis of RCTS. Additionally, 2 integrated reviews were included in the evidence, as well as, 1 clinical practice guideline. The clinical practice guideline was appraised by use of the Appraisal of Guidelines for Research & Evaluation II (AGREE II) tool.

The CASP tool provided a clear structured path to critically appraise the studies used for this project. The appraisal tools add an overall quality rating for each source of evidence.

Quality rankings will be designated by using rankings of low, medium, and high. In general, 12 of the included sources of evidence received a high quality rank due to the soundness of design, methodology, statistical analysis, and relevance to mobile phone application impact on HbA1C and promotion of self-care practices.

Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances (Brouwers et al., 2010). They play an important role in health policy formation and systemrelated decisions that include health care practice across the illness-wellness continuum. Guidelines are only as good as their overall quality and rigor contained within the context of the practice standard. The Appraisal of Guidelines for REsearch & Evaluation (AGREE) Instrument was developed by an international team of guideline developers and researchers, known as the AGREE Collaboration, and was established to create a generic instrument to assess the process of guideline development, and the reporting of this process within the guideline (Brouwers et al., 2010). The domain scores are useful for comparing guidelines and will inform whether a guideline should be recommended for use to address the issue of variability in quideline quality, and has since then been refined. This refinement has resulted in the new AGREE II and is purposed for providing a framework to assess the quality of guidelines; provide a methodological strategy for the development of guidelines; and inform what information and how information ought to be reported in guidelines. Furthermore, the AGREE II assesses the methodological rigor and transparency in which a guideline is developed. The international consortium has not set minimum domain scores or patterns of scores across domains to differentiate between high quality and poor quality guidelines. These decisions should be made by the user and guided by the context in which AGREE II is being used (Brouwers et al., 2010). After appraisal of the clinical practice guideline it was determined that it was of moderate quality due to the lack of information in the domains of rigor and applicability.

Level I Evidence

Systematic reviews, SRs with associated meta-analysis, meta-analysis, and evidence summaries (Wu et al., 2017; Whitehead & Seaton, 2016; Hou, Carter, Hewitt, Francisa, & Mayor, 2016; Cui, Wu, Mao, Wang, & Nie, 2016; Alharbi et al., 2016; Wu, Guo, & Zhang, 2019; Pal et al., 2014; Bonoto et al., 2017; Yoshida et al., 2018; Mann, 2018; Nguyen, 2018; Pamaiahgari, 2018) included in this project were all level I evidence according to the Pyramid of Evidence (Melnyk & Fineout-Overholt, 2015), and CASP quality ratings of high due to the design and methodology of respective pieces of evidence. In all, the level and quality of the evidence will add merit, value, and reliability to this EBP project, and shows a great amount of support for the use of MHAs to attain glycemic efficacy, not to mention, supports the improvement of self-care perception of T2DM patients.

Level II Evidence

The integrative reviews included in this project (Fu, McMahan, Gross, Adam, & Wyman, 2017; Wang, Xue, Huang, Huang, & Zhang, 2017) were deemed level II evidence according to the Pyramid of Evidence, and CASP quality ratings of moderate and high respectively due to the design and methodology of each piece of evidence. Again, this level and quality of evidence will add merit value and reliability to this EBP project. These pieces shows support for the use of MHAs for the reduction of HbA1C, and positive outcomes were noted related to the reaching glycemic efficacy.

Level VII Evidence

A clinical practice guideline by Clement et al. (2018) recommended the use of telehealth technologies, including mobile phone applications, to improve self-management in underserved communities, facilitate consultation with specialized teams as part of a shared-care model, improve clinical outcomes in T2DM, decrease HbA1C results, increase in quality of care, decrease health service use and cost, increase patient satisfaction and knowledge, and improved glycemic and cardiovascular risk factor control. The clinical practice guideline

(Clement et al., 2018) was deemed level VII on the Pyramid of Evidence (Melnyk & Fineout-Overholt, 2015), and an AGREEII quality rating of moderate due to lacking information in two of the six domains (Brouwers et al., 2010). (See Table 2.2).

Table 2.2

Evidence

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Authors/ Purpose	Population/ Duration	Intervention(s) /Design	Finding/ Results	LOE/ Appraisal
Alharbi et al., (2016)	40,454 participants.	Systematic Review/Meta- Analysis, 32	HbA1C changes with the use of MHA and	Level I
The object of this study was to assess the impact of information technology on changes in the levels of HbA1C.	Half of the studies only included T2DM. The other half included T2DM and T1DM Study duration range 3-36 months. Adults and children.	Information technology including mobile phone applications, which demonstrated the largest reduction of HbA1C. Intervention groups received selected types of technology to support diabetic management. Controls received standard diabetic education.	telemedicine. Resulted in a -0.50% reduction in HbA1C (95% C1). MHAs and telemedicine analyses were not reported individually.	High
Bonoto et al., (2017) The aim of the study was to evaluate to efficacy of MHA to assist the treatment of diabetic patients.	1.264 participants. T1DM and T2DM. Study duration 1-2 months. Adults and children.	Systematic Review/Meta- Analysis, 12 RCTs. Intervention group received MHA to support diabetic management. Controls received standard education.	Use of MHAs reduced HbA1C by -0.44% (95% CI).	Level I High

Clement et al., (2017)	T1DM and T2DM.	Clinical Practice Guideline.	Recommend telehealth, including MHAs	Level VII Moderate
Diabetes Clinical Practice Guideline	Adults and Children.	109 references were included. Multiple systematic reviews and six addressing MHAs, telehealth, telemonitoring, elearning, teleconference, website, and internet.	be used to improve self-management of DM. MHAs were not endorsed over other technologies.	in delicate
Cui, Wu, Mao, Wang & Nie (2016)	1.022 participants T2DM.	Systematic Review/Meta- Analysis, 13	MHAs pooled effect on reduction of	Level I High
The object of this study was to assess the effect of MHA on change in HbA1C, weight, and lipids.0.013- 0.027		RCTs	HbA1C was - 0.40% (95% CI).	
Fu, McMahon, Gross, Adam, & Wyman (2017).	905 participants in the clinical effectiveness	Integrative Review 19	Limited evidence to support the effectiveness of	Level II Moderate
This study aims to describe the usability and clinical effectiveness of diabetes apps related to HbA1C.	arm (T2DM).	RCTs, 1 pre- post-test design	MHA to improve glycemic control.	Moderate
	59 participants in the usability arm of the study.		HbA1C reduction from 0.15% to 1.9%	
	Study duration 2-12 months. Adults		(<i>p</i> <0.013-0.027).	
			Bias due to combining other interventions.	
			Subgroup analysis not reported.	

Hou, Carter, Hewitt, Francisa, & Mayor (2016). The aim of this study was to investigate the effect of MHAs on HbA1C.	1,360 participants T1DM and T2DM. Study duration 3-12 months. Adults and Children	Systematic Review/Meta- Analysis 13 RCTs	Evidence indicated reduction in HbA1C use and MHA was 0.49% (95% CI). After excluding subgroups of poor findings, HbA1C reduction was 0.41% (95% CI). Poor findings were studies with a reduction higher than expected, which questioned legitimacy of the findings. Ten studies of T2DM resulted in consistent 0.50% HbA1C reduction (95% CI).	Level I High
Mann, E. (2018). To determine the effectiveness of selfmanagement education for those with DM.	65,456 participants T1DM and T2DM. Study duration 6-12 months. Adults and Children.	Evidence Summary.	Those with DM should receive education that includes taking medications, monitoring glucose, and problem-solving. Education included selfmanagement with MHAs	Level I High
Nguyen, P. (2018). To determine the best evidence regarding self-	3,783 participants T2DM. Study duration 3-12 months.	Evidence Summary	Self-monitoring of blood glucose is an integral part of DM management. MHA research supported in the	Level I High

monitoring of blood glucose.			body of evidence that was foundational for this summary	
Pal, et al., (2014). This study aimed to evaluate the impact of computer-based DM self-management interventions of health status and quality of life.	3,578 participants T2DM. Study duration 10 minutes – 18 months. Adults	Systematic Review/Meta- Analysis, 16 RCTs. Intervention included MHAs, clinic education, and internet.	Mobile phone subgroup had the largest effect on glucose control, compared to other computer-based intervention. Pooled effect for this mobile phone subgroup was an HbA1C reduction of 0.50% (95% CI).	Level I High
Pamaiahgari, P. (2018). To determine the best evidence for the use of eHealth in the management of DM.	8,124 participants T1DM and T2DM. Study duration 3-12 months. Adults and Children.	Evidence Summary	Best practice recommends that mobile-based support programs should be considered in the management of DM in a rural or remote setting.	Level I High
Wang, Xue, Huang, Huang, Huang, Huang & Zhang (2017). The aim of this study was to determine the effectiveness of mobile devices on technology interventions on obesity and DM.	2.029 participants obese or T2DM. Study duration 1 week – 24 months. Adults	Integrative review 16 RCTs, 8 Quasi- experiments. Included MHAs, text messages, and portable monitoring devices.	MHA subgroup resulted in a reduction with HbA1C, with the greatest 1.0% (p,0.001).	Level II High
Whitehead & Seaton (2016) This study was conducted to assess the	Sample size range 48-288 participants. T1DM and T2DM.	Systematic Review, 9 RCTs.	Significant improvement relating to the reduction of HbA1C in four of five studies.	Level 1 High

effectiveness of MHA on DM.	Study duration 6 weeks – 12 months. Adults and children.		Improvement was found to be statistically significant. Results were HbA1C reduction of 0.40% (<i>p</i> < 0.019) to 1.9 (<i>p</i> < 0.001).	
Wu et al., (2017). The aim of this study was to develop and validate taxonomy, investigate glycemic control, and explore contributions of different MHA functions related to the reduction of HbA1C.	974 participants T1DM and T2DM Study duration 3-12 months. Adults and Children.	Systematic Review, 12 RCTs.	MHAs were associated with a clinically significant reduction of HbA1C 0.48 % (95% CI). No excessive adverse effects noted. Larger reductions of HbA1C were in T2DM group. Having a complication prevention module in the MHA was associated with a greater reduction 1.13% (95% CI) versus without. Inclusion of clinical decision function did not reduce HbA1C.	Level I High
Wu, Guo, & Zhang (2019). This study aimed to synthesize the clinical evidence	2.526 participants T1DM and T2DM. Study durations 3-12 months.	Systematic Review, 26 RCTs. 11 specific to T2DM.	Use of MHA showed an HbA1C reduction of 0.48% (95% CI).	Level I High

of the efficacy of MHAs for lifestyle modification in different diabetes subgroups.

Strong evidence for the efficacy of MHAs for lifestyle modification in T2DM. Evidence inconclusive for other diabetes subgroups.

Yoshida et al., (2018).

This study aimed to determine the effect of HIT on HbA1C. 3.982 participants T2DM.

Study duration 2-12 months.

Meta-analysis, 34 RCTs. 29 specific to T2DM.

HIT included mobile phone, web-based, short message text, telephone, and video conference. HbA1C Le reduction due to health H

information technology (HIT) were found across all studies.

MHAs had greatest pooled HbA1C reduction of -0.67% (95% CI). MHAs produced largest

reduction effect.

Level I

High

Synthesis of Critically Appraised Literature

Technology

Mobile health applications. The use of MHAs have been found to be the most effective tool to promote self-care behaviors that reduce overall HbA1C levels. The reduction of HbA1C have been found in other means of diabetic self-management technologies, but MHAs proved to have the greatest reduction pattern (Pal, et al., 2014; Pamaiahgari, 2018; Cui, Wu, Mao, Wang, & Nie, 2016; Hou, Carter, Hewitt, Francisa, & Mayor, 2016; Wang, Xue, Huang, Huang, & Zhang, 2017; Wu et al., 2017; Whitehead & Seaton, 2016; Yoshida et al., 2018). Within in the literature it was noted that all individuals with diabetes should have diabetic education that includes topics such as healthy diet, being physically active, taking medication, and monitoring glucose (Mann, 2018; ADA, 2018). Nguyen (2018), indicates that a structured self-monitoring of blood glucose is more beneficial than non-structured. MHAs support the ADA (2018) recommendations that lead to improved HbA1C levels. Another systematic review found that HbA1C decreased more in the MHA-only group than in the control or group that received counseling as an intervention (Whitehead & Seaton, 2016). Overall, findings in the literature point to the use of MHAs for best practice toward efforts to reduce HbA1C levels compared to other forms of technology. Moreover, MHAs appeared to be moderately effective in promoting lifestyle changes, including daily physical activity and medication adherence (Cui, Wu, Mao, Wang, & Nie, 2016).

Computer-based. In one study, computer-based or internet-based interventions to manage T2DM were shown to have a small benefit on HbA1Cs, but less than the MHA subgroup (Pal, et al., 2014). Computer-based intervention was also supported by an additional systematic review, however in that study the effect of MHAs on HbA1C levels resulted in a 0.40% reduction compared to a 0.2% reduction in the computer-based arm (Cui, Wu, Mao, Wang, & Nie, 2016). Yoshida et a. (2018) found that a computer-based intervention decreased HbA1C, however, in comparison MHAs produced a larger effect. Although MHA use has shown

to produce a greater decrease in HbA1C, where mobile-based programs are not available, computer-based programs should be considered for the management of T2DM (Pamaiahgari, 2018).

Text messaging. Text messaging was another form of technology that was identified in the literature (Wang, Xue, Huang, Huang, & Zhang, 2017; Yoshida et al., 2018). Text messaging was mainly used to provide knowledge and tips on diet, physical activity, and medications, whereas the MHA played a more concise role in disease control by providing feedback to reinforce positive behavior changes as well as serving as a data collection platform (Wang, Xue, Huang, Huang, & Zhang, 2017). The findings by researchers Wang, Xue, Huang, Huang, and Zhang (2017), that focused on T2DM indicated the greatest HbA1C reduction was a result of the use of MHAs rather than text messaging. Yoshida et al. (2018) found that text messaging decreased HbA1C, however, in comparison MHAs produced a larger effect.

Voice messaging. Voice messaging through use of automated services, interactive-voice systems, teleconferencing, and telephone-based services were also compared to MHAs. Researchers (Alharbi et al., 2016; Bonoto et al., 2017; Cui, Wu, Mai, Wang, and Nie, 2016; Wu, Guo, and Zhang, 2019; Wu et al., 2017; Wang, Xue, Huang, Huang, Zhang, 2017; Yoshida et al., 2018) found that MHAs produced a larger reduction in HgA1C compared to these various voice messaging interventions. MHAs used in the studies (Alharbi et al., 2016; Bonoto et al., 2017; Cui, Wu, Mai, Wang, and Nie, 2016; Wu, Guo, and Zhang, 2019; Wu et al., 2017; Wang, Xue, Huang, Huang, Zhang, 2017; Yoshida et al., 2018). included functions that were geared toward fostering behavioral lifestyle modifications to improve self-care management of T2DM. This was a feature not available through typical voice messaging systems (Alharbi et al., 2016; Bonoto et al., 2017; Cui, Wu, Mai, Wang, and Nie, 2016; Wu, Guo, and Zhang, 2019; Wu et al., 2017; Wang, Xue, Huang, Huang, Zhang, Zhang, 2017; Yoshida et al., 2018).

Telehealth services. Telemedicine, telehealth, Video-phone chat, interactive-video systems, were compared to MHAs throughout the literature. Researchers found that the MHAs

demonstrated the largest reduction in HbA1C. Use of MHAs brought the greatest standardized decrease in HbA1C and produced the largest effect on glycemic control (Cui, Wu, Mai, Wang, and Nie, 2016; Wang, Xue, Huang, Huang, Zhang, 2017; Alharbi et al., 2016; Yoshida et al., 2018).

Technology used for diabetes self-management exists in the form of many different platforms, such as internet, telemedicine, teleconference, mobile phone SMS (texting), computer-based programs, and MHAs. Throughout the evidence used to develop this project, the use of MHAs showed a statistically significant reduction in HbA1C reduction (Alharbi et al., 2016; Bonoto et al., 2017; Cui, Wu, Mao, Wang, & Nie, 2016; Hou, Carter, Hewitt, Francisa, & Mayor, 2016; Pal et al., 2014; Wang, Xue, Huang, Huang, & Zhang, 2017; Whitehead & Seaton, 2016; Wu, Guo, & Zhang, 2019; Wu et al., 2017; Yoshida et al., 2018).

Outcomes

Glycemic Efficacy

Glycemic control was consistently measured through HbA1C measurements throughout the literature, and is defined as a HbA1C level of less than 8.0 (ADA, 2018). The ADA (2018) suggests a more stringent HbA1C goal of < 6.5% if the patient can achieve this without significant hypoglycemia or adverse effects, and a less stringent goal of <8% if the patient has a history of hypoglycemia, limited life expectancy, long-standing diabetes, appropriate glucose monitoring, and effective doses of glucose lowering agents. For the purpose of this project and to err on the side of safety, the project will utilize the less stringent HbA1C goal of <8.0%.

HbA1C is a significant indicator because it reflects glycemia over eight weeks of time (Alharbi et al., 2016), and has a strong correlation in the occurrence of diabetic complications and increased mortality rates in people with diabetes (Bonoto et al., 2017; Yoshida et al., 2018). Glycemic control was statistically significant across most of the body of evidence that was included in the EBP project (Alharbi et al., 2016; Bonoto et al., 2017; Clement et al., 2018; Cui, Wu, Mao, Wang & Nie, 2016; Hou, Carter, Hewitt, Francisa, & Mayor, 2016; Nguyen, 2018;

Pal et al,. 2014; Pamaiahgari, 2018; Wang, Xue, Huang, Huang, & Zhang, 2017; Whitehead & Seaton, 2016; Wu et al., 2017; Wu, Guo, & Zhang, 2019; Yoshida et al., 2018). The exception was the limited evidence reported by Fu, McMahon, Gross, Adam, & Wyman (2017), the findings of which were believed to be due to confounding variables that infused the results with bias. However, HbA1C reduction was still found by the researcher, but were not statistically significant.

Alharbi et al. (2016) conducted a systematic review of 30 RCTs and concluded that by using MHAs, telemedicine, web-based, and telephone-based interventions, participants achieved significant reduction in HbA1C. T2DM participants that used these electronic selfmanagement technologies found the greatest impact on HbA1C reduction, which resulted in a -0.50% reduction of HbA1C (95% CI). Subgroup analysis was not included in this study so it is not clear which specific technologies had the greatest effect. Bonoto et al. (2017) concluded that the use of MHAs by adult T2DM participants could help improve the control of HbA1C. Of the 13 RCTs included in their study, six of them produced statistically significant reductions in HbA1C values. The meta-analysis of those studies resulted in a mean HbA1C reduction difference of -0.44 (CI -0.59 to 0.29 p < 0.001). Cui et al. (2016) concluded that there was a moderate effect on glycemic control after the mHealth app-based interventions. The overall effect on HbA1C showed a mean reduction difference of -0.40% (-4. 37 mmol/mol) (95% CI -0.69 to -0.11 p =0.007) and the standardized mean difference was -0.40 % (-4.37 mmol/mol) (95% CI -0.69 to -0.10% p = 0.008). Fu et al. (2017) concluded that MHAs that were used in the studies of their review reduced HbA1C, ranging from 0.15-1.9% from baseline. Statistical significance was found in four of the studies within the integrative review. The greatest interactive features were those included the application's design and consisted of MHA used in conjunction with a Bluetooth® enabled smart-glucometer, direct provider feedback capability, and website access. Hou et al. (2016) found that in all of the studies in their review, mean reduction of HbA1C was 0.49% (95% CI 0.30, 0.68 p = < 0.01). These results exhibited consistent findings with no

heterogeneity. After excluding subgroups of skewed findings, a mean reduction of 0.41% was found (95% CI 0.22, 0.61; p <0.001 l=0%). An example of a subgroup study with skewed findings that was excluded, was one that found a significantly higher reduction in HbA1C than any of the other studies included in the review. The researchers (Hou et al., 2016) concluded that the applications improved self-management by providing personalized feedback on selfmonitoring data such as blood glucose, food intake, and physical activity. Additionally, the use of the MHAs resulted in decreased consultation times. Pal et al. (2014) concluded that the mobile phone subgroup had the largest effect on glycemic control compared to the other computer-based self-management interventions. Pooled effect for this subgroup was a HbA1C reduction of -0.50% (95% CI -0.7% to -0.3%). There was no evident improvement in depression, quality of life, blood pressure, serum lipids, or weight in this study. Pamaiahgari's (2018) best practice recommendations indicate that mobile-based support programs, including MHAs, should be considered in the management of diabetic patients where available. Where mobilebased programs are unavailable, computer-based programs should be considered. The review by Wang et al. (2017) included five studies that used MHAs, which resulted in a reduction in HbA1C with the largest reduction being 1.0% at a 12-month follow up period. Whitehead et al. (2016) concluded statistically significant improvements in the reduction of HbA1C in two of the three studies included in their review that specifically focused on T2DM participants (-0.40 p =0.019, -1.9% p = 0.001). Moreover, the use of MHAs has the potential to improve health outcomes among those living with chronic diseases such as T2DM. Wu, Guo, & Zhang (2019) concluded that there is strong evidence for the efficacy of mobile phone applications for lifestyle modification in type 2 diabetes. This systematic review and meta-analysis conducted a subgroup analysis specific to adult T2DM participants. In the short-term effect group that showed virtually no heterogeneity, the MHAs group produced a -0.48 (95% CI -0.69 to -0.28) reduction in HbA1C. In the long-term group HbA1C reduction was -0.25 (95% CI -0.43 to -0.07) and both groups resulted in statistically significant reduction in HbA1C. The results were

inconclusive for the other diabetes subtypes. Wu et al. (2017) researchers concluded that using MHA interventions were associated with a clinically significant reduction of HbA1C with a mean difference of 0.48% (95% CI 0.19%-0.78%) without excess adverse events. The larger reductions of HbA1C were found among patients with T2DM. Having a complication prevention module in app-based interventions was associated with a greater HA1C reduction (MD 1.31%, 95% CI 0.66%-1.96%) versus without. Yoshida et al. (2018) completed a systematic review that included 16 RCTs and eight quasi-experiments and they found the overall reduction effect was -0.63. MHAs had the greatest pooled standardized decrease in HbA1c reduction of -0.67 (-0.90, -0.45). On average, MHA interventions produced larger effects compared to other forms of approaches. These researchers concluded that the findings from the meta-analysis suggest that health information technology, including MHAs, led to improvement of glycemic control.

Self-Care Behaviors

The ADA (2018) speaks to reaching glycemic efficacy through self-care behaviors such as monitoring blood sugars, physical activity engagement, and adherence to prescribed medications for those who suffer from chronic diseases such as diabetes. Cui, Wu, Mao, Wang, & Nie (2016) concluded that MHAs offer moderate benefits to T2DM self-management. These researchers recommended a follow up period of greater than 12 months to evaluate the long-term impact of MHAs for diabetes care and self-management. Mann (2018) determined best practice recommendations indicate that all individuals with diabetes should receive self-management education that includes topics such as healthy diet, being physically active, taking medication, monitoring of glucose, reducing risk and complications, and problem solving. Self-management education is recommended through the use of MHAs (Pamaiahgari, 2018; Wu, Guo, & Zhang, 2019; Wu et al., 2017). Nguyen (2018) indicated that self-monitoring is recommended as an integral part of diabetes self-management strategies. This evidence summary included a meta-analysis of RCTS in which the researchers found that compared to those who did not perform self-managed blood glucose (SMBG), individuals who performed

SMBG reduced HbA1C level by 0.17% (95% CI 0.25 to 0.09%, p <0.003). The comparison between structured and unstructured SMBG found a mean difference of HbA1C reduction of 0.27% (95% CI 0.49 to 0.04%, p < 0.018). The conclusion favored structured SMBG which indicated a structured SMBG was found to be more beneficial than non-structured SMBG. Structured SMBG consisted of scheduled monitoring and recording of blood glucose for tracking and evaluation purposes. (Mannucci, Antenore, Giorgino, & Scavini, 2018). MHAs have provided a structured-electronic platform for the monitoring and recording of blood glucose in adults with T2DM that leads to improved glycemic control.

MHAs that have the greatest interactive features which encourage blood glucose monitoring, physical activity engagement, and adherence to medication regimens are directly related to improvements in glycemic control glycemic control (Pal et al., 2014; Fu, McMahon, Gross, Adam, & Wyman, 2017; Mann, 2018; Nguyen, 2018). This provides a convenient reminder and documentation system that is more accurate then depending on memory alone. Pamaiahgari (2018) produced an evidence summary that recommended mobile-based support programs should be considered in the management of diabetic patients. Mobile-phone based interventions (including MHAs) were included in this recommendation. Other researchers have found that mobile phone interventions for diabetes self-management have been able to reduce HbA1C levels, and this may be related to the enhanced feedback and provider-patient interactions, the convenience of the MHA usage, the intensity of the intervention, or the behavior-change techniques instilled in the applications. Behavioral reminders through the use of MHAs encourage blood sugar monitoring efforts and improve physical activity engagement (Cui, Wu, Mao, Wang, & Nie, 2016; Wu et al., 2017; Wu, Guo, & Zhang, 2019; Yoshida et al., 2018; MyFitnessPal, 2019). Also included in the MHAs were behavior-change techniques or reminders to promote adherence to medication regimens. The use of MHAs interventions have suggested a moderate effect in promoting lifestyle changes, including daily physical activity and medication regimen adherence (Cui, Wu, Mao, Wang, & Nie, 2016; Clement et al., 2018; Hou,

Carter, Hewitt, Francisa, & Mayor, 2016; Pamaiahgari, 2018; Wang, Xue, Huang, & Zhang, 2017; Wu et al., 2017; Wu, Guo, & Zhang, 2019; Yoshida et al., 2018).

Self-Care Perception

MHA's had a mixed impact on self-care perception for adults with T2DM (Bonoto et al., 2017; Pal et al., 2014; Wu, Guo, & Zhang, 2019). Bonoto et al. (2017) found that MHAs seem to strengthen the perception of self-care by contributing better information and health education to the patient that ultimately boosts self-confidence to care for this devastating disease. Ultimately, self-confidence in personal care may support self-care behaviors for those with chronic diseases Bonoto et al. (2017) measured this using the Disease-Specific, Quality-of-Life (DSQOL), Diabetes Quality of Life (DQOL), Diabetes Quality of Life for Youth (DQOLY) and Self-Care Revised 36-item Short-Form. Pal et al. (2014) found there was no evident improvement in self-care perception and various tools to measure this were not mentioned. Improved self-care perception was found to be strengthened by the MHAs ability to contribute to better information and health education, increased patient satisfaction, and increased self-confidence to the user (Bonoto et al., 2017; Clement et al., 2018; Wu, Guo, & Zhang, 2019).

Best Practice Model Recommendation

Best practice recommendations include a multi-functional, user-friendly MHA that is adaptable to the feedback of the provider (Wu et al., 2017; Nguyen, 2018; Mann, 2018; Fu, McMahon, Gross, Adam, & Wyman, 2017). Provider feedback included the use of MHAs, webbased, computer-based, and telephone-based interventions. The iHealth® and Dario® smart glucometer bundles offer a mobile smartphone application that allows for individualized patient-provider selected alert settings for reminders to check blood sugar, take medication, and engage in activity. Additionally, these bundles include a smart glucometer that pairs with mobile smartphone technology for convenient uploading and downloading of glucose readings, physical activity, and medication adherence practices (Dario® Blood Glucose Management System, 2019; iHealth® Smart Wireless Gluco-Monitoring System, 2019). Moreover, the addition of a

MHA shows an improvement in the perception of self-care management behaviors such as blood glucose monitoring efforts, medication adherence, and physical activity engagement of adults with T2DM.

Three options of MHAs were considered for this EBP. Regardless of the MHA selected it will include glucose monitoring capability, physical activity monitoring, and medication adherence monitoring. Notification alert reminders for blood sugar monitoring, medication adherence and physical activity engagement will be patient-driven and individualized according to the specific need of each participant in regards to these activities. The overall functionality options of the MHA, provider feedback loop of communication, and the promotion of self-care practices can foster glycemic control and theoretically reduce incidence of diabetic complication and decreased mortality (Alharbi et al., 2016; Bonoto et al., 2017; Clement et al., 2018; Cui, Wu, Mao, Wang, & Nie, 2016; Fu, McMahon, Gross, Adam, & Wyman, 2017; Hou, Carter, Hewitt, Francisa, & Mayor, 2016; Mann, 2018; Nguyen, 2018; Pal et al., 2014; Pamaiahgari, 2018; Wang, Xue, Huang, Huang, & Zhang, 2017; Whitehead & Seaton, 2016; Wu et al., 2017; Wu, Guo, & Zhang, 2019; Yoshida et al., 2018). The use of MHAs may also result in improved self-care perception which may also contribute to improved self-care practices such as blood sugar monitoring efforts, adherence to medication regimens, and physical activity engagement.

CHAPTER 3

IMPLEMENTATION OF PRACTICE CHANGE

The purpose of the EBP project was to evaluate the effectiveness of a diabetes-specific MHA on HbA1C and on self-care behaviors such as blood glucose monitoring efforts, physical activity engagement, and medication adherence. A secondary purpose of the EBP project was to evaluate cumulative self-care perception before and after the intervention. The implementation of EBP to drive practice changes is a challenging process and needs to strategically address organizational complexities, administrative leaders, clinicians, and ultimately the healthcare culture (Titler, 2001). Quality outcomes and positive patient experiences are demanded by consumers, required by payees, and transparently reported to the public (Creehan, 2015). Healthcare is changing at a rapid pace and the diffusion of evidence into practice is essential as the shift in quality and safety practices become the focus throughout all health organizations. This dynamic movement is not new and is becoming increasingly urgent as challenges related to both quality and cost persist (Bondurant & Armstrong, 2016). Doctorally prepared nurses are uniquely skilled and highly qualified to change practice by improving quality and safety and decreasing cost burden through the implementation of EBP.

Setting and Participants

Setting

The EBP project was conducted at certified rural healthcare centers in northwest Indiana. The medical group consists of 13 primary healthcare providers. Six of the primary care providers are medical doctors and seven are family nurse practitioners. Five of the medical doctors are employed at the Winamac, Indiana location, while one is located at the North Judson, Indiana location. Four nurse practitioners are employed at the Winamac, Indiana location, while one is employed at each of the satellite offices in northwest Indiana. All of the providers provide care for patients with T2DM that fall within the inclusion criteria for this project. The project preceptor is the director of quality and compliance for the organization. She was

selected due to her expertise in quality and safety reporting that is mandatory when an organization accepts payment from the Centers of Medicare and Medicaid Services (CMS, 2019) (M. Jones, personal communication, May 24, 2019). She has an associate's degree in business administration, and has been employed with the organization for eight years. She has direct access to the EMR driven quality measures and was able to obtain the CMS specific outcome measures that indicated a high percentage of patients with HbA1C above 9.0.

The MHA project was led by a doctor of nursing practice (DNP) student who has a board certification as a Family Nurse Practitioner. Her career encompasses 28 years of nursing experience, which included a special interest in the management of adults with T2DM. The DNP student led the MHA pilot program with the assistance of two additional nurse practitioner champions, a project preceptor, and a corporate compliance/quality assurance leader. The project preceptor and the DNP student had initial meetings early on to determine the greatest, most pressing organizational need. Consultations were continuously made within the group to brainstorm and determine the best direction for the practice change. Practice champions included two nurse practitioners who have agreed to assist with the creation and implementation of the protocol (See Appendix A). The lead nurse practitioner at the healthcare center in Monterey, Indiana has been employed in family practice for 11 years. He completed his education at Valparaiso University and is a master's prepared, board certified family nurse practitioner. The healthcare center is a rural satellite primary care practice that strives to offer high quality care to the local and surrounding communities. Additionally, the nurse practitioner of this clinic is a veteran who proudly served in the Army. He has been a nurse for over 20 years and has special interest in pain management and management of adults with T2DM.

A nurse practitioner at the Winamac healthcare center completed her education at Indiana State University, and is a master's prepared, board certified family nurse practitioner.

She has been employed as a family nurse practitioner in primary care for 3 years and strives to offer high quality care to the local and surrounding communities. She has been a nurse for over

20 years and has special interests in women's health services and management of adult T2DM patients.

Participants

The focus population was English reading and speaking patients that are 18 years and older within the organization's medical group diagnosed with T2DM, having an HbA1C of greater than 8.0, and owners of a smart phone. Generally, middle aged individuals are more likely to have T2DM, but it has been found in obese children (ADA, 2018). For this project pregnant women and children were excluded, as well as those who did not own or have access to a mobile smart phone or tablet. Additionally, patients with dementia, addictions, or other mentally or physically incapacitating medical conditions were excluded.

Pre-Intervention Group Characteristics. Demographic data were collected and recorded (See Appendix B) at a special initial start-up meeting using the participant information sheet (See Appendix C) to collect the participant's age, date of birth, gender, race, years diagnosed with T2DM, current diabetes-specific medication, how often they normally engaged in physical activity, the email address of their provider, pre-intervention HbA1C, and their personal email address. This information will be used to assess the characteristics of the project sample to that of the adult T2DM in the general population. Twenty-five participants joined the project and seven were lost to attrition. The mean age for the group was 52.2 years made up of five white males and 13 white females, and mean number of years of having the diagnosis of T2DM was 12.72.

Intervention

The intervention consists of the use of a diabetes-specific MHA for the self-management of T2DM. The EBP practice program developed is called Living Sweet: An Adult Type II Diabetes Mellitus Management Program. The project will utilize a MHA platform to deliver self-care behavior awareness toward the promotion glycemic control. The application selection process was a challenge due to the many different functionality qualities of the various

applications. For instance, most of them allow for logging blood sugar readings, recording physical activity events, and medication adherence trackers (MySugr®, 2019; Health2Sync®, 2019; Diabetes Connect®, 2019). Multiple applications were evaluated for this project, however the one that was the most user friendly, cost-effective, technologically equipped, and aligned with ADA diabetes mellitus self-management recommendations was selected (ADA, 2018)

The diabetes-specific MHA utilized for this project is MySugr®. The attractions of MySugr® diabetes-specific mobile health application is that it is cost-efficient, user-friendly, capable of monitoring the three different self-care behaviors that were evaluated in this project, Android® and iPhone® compatible, congruent with ADA (2018) self-management recommendations, and has the capability to upload and transfer or export the documented results electronically as a spreadsheet (MySugr®, 2019). In some cases, MHAs may not be advantageous for certain participants such as those with learning deficits (Fu, McMahon, Gross, Adam, & Wyman, 2017). To enhance usability for these participants, access to the DNP student project leader or designee will be offered throughout the entire project time span. The MHA will be used as a reminder system that will include patient-centered, individualized goals to encourage self-care behaviors such as blood glucose monitoring efforts, medication adherence, and physical activity engagement. Adherence will be assessed by determining the total number of met self-care behaviors each week.

Each participant was given a one-on-one enrollee learning session by the DNP student project leader. This session included a review of the participant information sheet (See Appendix C) education and demonstrations regarding the use of the MHA, as well as discussion about individual personal self-care behavior goals. In Addition, a pre-intervention self-care inventory-revised tool (See Appendix D) was completed to record self-care perception prior to the onset of using the MHA. This will help determine the impact of the intervention of participant self-care perception.

Due to the nature of the sensitive information being discussed, 1-on-1 sessions were more fitting to minimize potential discomfort that may accompany a group setting. This session will allow participants to meet and build rapport with the DNP student project leader, received clear explanation of the program, allow for question and answer opportunities, obtain demographic information, complete the initial self-care revised-inventory tool, and determine personal goals for blood glucose monitoring efforts, physical activity engagement, and medication adherence.

One challenge noted during the process was that the phones of participants were not current with phone updates. This resulted in the DNP student spending extra time assisting with the updating of the smart phones. This prompted a verbal reminder to each participant to update the operating system of their phone prior to the initial startup meeting. Additionally, this step was added to the protocol. In many cases participants could not remember the password that was connected to their smart phone application store. This was imperative, because without the password the application could not be downloaded. This certainly slowed the initiation process considerably and a prompt was added to the protocol to remind users to be aware of the password to their phones prior to the initial setup date. In one case a participant did not own a smart phone, however she did own an Android© tablet which worked identical to the smart phone application. An isolated challenge included a participant that did not have an email address or password to her email. This is important when downloading applications because the personal email is used by the application to verify the identity of the person wanting to place it on their smart phone. There was a significant delay in the startup process for this participant because she had to connect with her daughter who set up the initial email and password for her smart phone. Again, a prompt was added to the protocol to remind users to be aware of the username and password to their personal email for verification purposes.

The program included a tracking form with built-in check points (See Appendix E) to determine if the participant has any questions or needs assistance troubleshooting the

application. These check points will occur at week 1, week 2, week 3, week 4, week 5, week 6, and week 7 to determine adherence and need for assistance and troubleshooting of the application (see Table 3.1). Check points and data exportation will occur on different dates for each participant due to staggered start to the program. Therefore, to direct participants to meet the weekly data exportation request to the DNP project leader and their respective primary care provider, reminders were written on a pre-printed calendar (See Appendix F) and given to each of them. During this time each participant has been instructed to electronically upload and export their recorded data to the DNP student project leader and primary care provider when applicable. In the event the DNP student project leader has not received exported data from a participant or participants at these designated time-frames or has missing data, a text or phone call will be completed. The scheduled check points will help to further guide and define the MHA program by heightening awareness of unforeseen barriers and variables that may deter adherence. Week 8 will be the completion of the program and includes an arranged meeting with the project leader. At this time a patient satisfaction survey (See Appendix G), a repeat selfcare inventory-revised tool (See Appendix D), and a post-intervention HbA1C will be completed to evaluate impact of MHAs on selected outcome measures. The potential benefits of the MHA program include HbA1C reduction, improved self-care behaviors, and improved self-care perception. Risks were not associated with the use of MHAs. However, lack of experience with technology and learning deficits may hinder the use of the application for some participants (Fu, McMahan, Gross, Adam, & Wyman, 2017).

Table 3.1

Diabetes-specific MHA Program Outline

Check Point	Topic
Initial (Special Session)	Program introduction. Document most recent HbA1C. Intervention education. Self-Care Inventory-Revised: Pre. Patient-driven goal determination of self-care behaviors entered into the app. Review participant information sheet.
Check Point 1 (Week 1)	Assess adherence based on patient upload data. Troubleshoot.
Check Point 2 (Week 2)	Assess adherence based on patient upload data. Troubleshoot.
Check Point 3 (Week 3)	Assess adherence based on patient upload data. Troubleshoot.
Check Point 4 (Week 4)	Assess adherence based on patient upload data. Troubleshoot.
Check Point 5 (Week 5)	Assess adherence based on patient upload data. Troubleshoot.
Check Point 6 (Week 6)	Assess adherence based on patient upload data. Troubleshoot.
Check Point 7 (Week 7)	Assess adherence based on patient upload data. Troubleshoot.
Check Point 8 (Week 8)	Satisfaction Survey Self-Care Inventory-Revised: Post Obtain HbA1C: Post

Comparison

The high percentage of HbA1C results greater than 9.0 within the medical group was the motivation for this project. In Quarter 1 of 2019, 59.3% of adult T2DM patients had an HbA1C greater than 9.0, and this trend rose in the second quarter to 66%. The outcome measure of 9.0 is specifically requested by and reported to CMS as a quality indicator, and the medical group are not meeting the standard risking loss of reimbursement for services (CMS, 2019).

Outcomes

Two major outcomes were evaluated for the diabetes-specific MHA intervention: (a) effect on HbA1C levels, and (b) effect on self-care behaviors. For this project, glycemic control is measured through obtaining HbA1C by capillary blood tests comparing individuals' results to prior test result to results after an 8-week MHA intervention. The statistical test used to evaluate the HbA1Cs was the paired t-test which is used to determine if the pre-intervention mean results are significantly different from the post-intervention mean results. The paired sample t-test, sometimes called the dependent sample *t*-test, is a statistical method used to determine whether the mean difference between two sets of observations is zero. In a paired sample t-test, each subject or entity is measured twice, resulting in pairs of observations (Statistic Solutions, 2019). Frequency analysis expressed in percentage was used to examine weekly self-care behaviors goals that were met or not met (Statistic Solutions, 2019). Self-care behaviors will be evaluated based on self-selected individualized goals chosen by each participant. Individualized goal assessments will determine if the participant met or did not meet blood sugar monitoring, medication adherence, and physical activity engagement. A behavior tracking form was created to monitor individualized weekly self-care behavior goals (See Appendix H). Glucose monitoring, medication adherence, and physical activity were considered met if the participant recorded 100% of their self-selected goals, and not met if the participant recorded less than 100% of their expected goals. As participants complete the self-care behaviors monitored in this project, then will be record results through manual data entry by tapping an icon specific to

medications, blood glucose monitoring, and physical activity within the MHA. This information will then be digitally exported to the DNP student project leader's and participant primary care provider's email for review.

Self-care perception with use of MHAs were collected using the Self-Care Inventory-Revised (SCI-R) tool (See Appendix D) completed before and after an 8-week MHA intervention. The SCI-R is a psychometrically sound measure of perceptions of adherence to recommended self-care behaviors of adults with T1 and T2DM (Weinger, Welch, Butler, & La Greca, 2005). The tool is a Likert-scale survey that allows for self-assessment of diabetes self-care behaviors (Weinger, Welch, Butler, & La Greca, 2005). Through self-reporting what each participant achieves regarding diabetes-specific self-care behaviors over the previous 1-2 months. Scoring of the survey quantifies reported behaviors in the following fashion: never = 1, rarely = 2, sometimes = 3, usually = 4, and always = 5. This tool was found to have sound reliability and validity through a psychometric analysis and reflects the internal consistency of the SCI-R tool (α = 0.87). Correlation with a measure of frequency of diabetes self-care behaviors r = 0.63 supports concurrent validity of the SCI-R (Weinger, Welch, Butler, & La Greca, 2005). The statistical method that was used to evaluate pre- and post-SCI-R tool results was the paired sample t-test (Cronk, 2018).

Time

Prior to the launch of this EBP project, three Power Point presentations were given to medical staff with a provider-specific information sheet (See Appendix I) to highlight project details and clarify the referral process. Following the EMR-directed referral (See Appendix J), a retrospective search of the referred participants within the EMR was completed to ensure participants met inclusion criteria. After inclusion criteria were confirmed, each participant was contacted, and a special meeting was arranged to initiate the MHA program. During this special meeting, a participant information sheet (See Appendix C) that clearly explains the program was reviewed, a pre-intervention SCI-R was completed, and the MHA was downloaded to each

participant's mobile phone. Respective forms were developed to facilitate the introduction of the MHA program and keep the process consistent and reproducible. The implementation began on September 6, 2019. Successful completion consisted of being enrolled for 8 weeks of MHA usage and completing the post- intervention HbA1C, SCI-R, and satisfaction survey. Participants remained in the same cohort, in a staggered start-up arrangement. To ensure each participant will receive 8-weeks of MHA usage, the final participant was enrolled by October 30, 2019. Participants may stop using the MHA at any time without recourse. Those who did not complete at least 1 week of usage will be excluded from statistical evaluation. The plan is to enroll 25 participants in the launch of this pilot EBP project, in hopes to have 20 participants complete the 8-week program.

The final meeting included a satisfaction survey (See Appendix G) related to the enrollment into the MHA program and a post-intervention Self-Care Revised-Inventory tool, which was completed by December 31, 2019. The satisfaction survey provides significant information about positive and negative experiences of the MHA program. These reported experiences are critical when developing a protocol that is patient-centered and individualized. Satisfaction surveying opens a dialogue with patients and lets them know providers are listening, identifies issues with intervention, and recognizes opportunity to make improvements and be more efficient (Coville, 2011). The Self-Care Revised-Inventory tool is specific to diabetes mellitus (DM). Post-intervention assessments in comparison to pre-intervention assessments will help determine if the MHA program improves self-care perception.

Researchers found that MHA's lead to improvements in patient satisfaction, a stronger perception of self-care practices, and satisfaction with treatment suggesting this type of technology may be an effective strategy for changing patient self-care behaviors (Bonoto et al., 2017).

Protection of Human Subjects

Protection of human subjects is of high priority with any type of research or EBP project. According to the Belmont Report of 1979, scientific research has produced social benefits as well as some troublesome ethical practices (Beauchamp, 2008). From this report three principals have been found to be most relevant to research involving human subjects. Those principles include respect for the person in which that individual should be treated as an autonomous agent and protection allotted for those with diminished autonomy (Beauchamp, 2008). A second principle is beneficence and is understood as the kindness that goes beyond stand obligation to a person, in which the research shall maximize benefits, and do no harm to the human subjects. The final principle is justice and is understood as a sense of distributed fairness in which each person has an equal share according to individual need, individual effort, each person's societal contribution, and to each person according to merit (Beauchamp, 2008). The DNP student for this project completed a certification program by the National Institutes of Health (NIH) for the protection of human research participants. Additionally, a class on ethics was completed to solidify the significance of ethical interactions with human participants.

Anonymity was maintained through use of an ordinal number coding system (See Appendix K) as the participants consented to join the EBP project. They were instructed to keep their number confidential and only identify themselves by that number. The participant names and associated numbers were documented and kept confidential in a locked cabinet at the DNP student's office. The number identification process would also be utilized by the DNP student or designee during check point follow-ups to maintain anonymity. Compliance tracking tools and excel spreadsheets will only reflect the code number of each corresponding participant in the project. Participants were given full disclosure at the initial meeting and the ability for them to consent and emphasizing the ability to withdraw from the MHA program for any reason. This particular project allows patients to continue with MHA usage even in the event they want to withdraw from the project without cost or penalty. Participants that agreed to partake in the

project did not receive any money or coercion tactics; joining was completely voluntary. An exempt review application was pursued and approved by the Institutional Review Board at Valparaiso University for this project.

CHAPTER 4

FINDINGS

To determine the effects of a MHA on adults with uncontrolled T2DM in the primary care setting statistical testing was completed to analyze the impact on HbA1C, SCP, and SCB. SPSS 22 was used to perform paired sample *t* tests to compare the primary outcome measure of preand post-intervention HbA1Cs. Two secondary outcome measures were also analyzed in this EBP project. A paired sample *t* test was used to compare pre- and post-intervention SCP, and a Wilcoxon Matched Pairs analysis was performed on this data to determine the effect of a MHA on participant perception on SCB activities.

Participants

A retrospective chart audit produced 150 potential participants who met inclusion criteria for the project. The project leader made telephone contact with 40 individuals who met inclusion criteria. Twenty-five participants agreed to participate the *Living Sweet* pilot program of which 18 completed the program. The seven that did not start the program, complete the final HbA1C, complete the final SCI-R, or satisfaction survey were excluded from statistical analysis (See Figure 4.1). Pre- and post-intervention characteristics were identical as discussed in Chapter 3, and the statistical analysis used was selected based on a within group design. Those who participated in the intervention were reflective of the adult uncontrolled T2DM population within the organization. Eighteen patients, five men and 13 women with a mean age of 52.2 years (*SD* = 8.02, range 43-71), completed the *Living* Sweet MHA program. All participants were Caucasian. Their mean duration with T2DM was 12.7 years (*SD* = 7.9, range 0.5-31) (See Table 4.1). All of the advanced practices nurses of the organizational completed referrals to the *Living Sweet* MHA program, and the physicians did not participate.

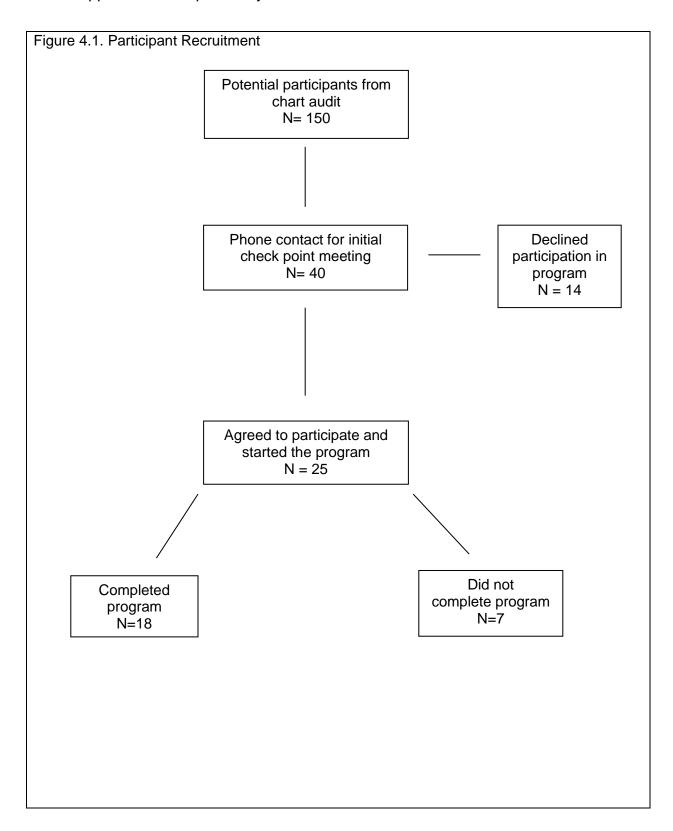


Table 4.1

Participant Demographic Data

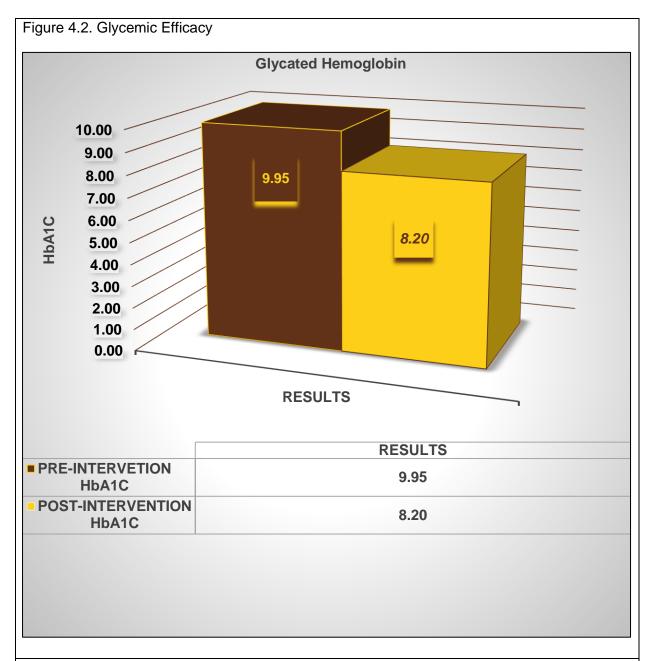
Characteristic	Frequencies/Results
N = Age, mean, (SD), range Sex, women/men Years with T2DM, mean, (SD), range Weeks of data input, mean, (SD), range	18.0 52.1 (8.02), 43-71 13/5 12.7 (7.9), 0.5-31 6.7 (2.0), 3-8

Changes in Primary Outcomes

The effects of a MHA on glycemic control was evaluated using the statistical test of paired sample t test to determine the difference between the pre- and post- intervention outcome measure of HbA1C. Paired t tests are used to make comparisons of within group designs at two different points in time (Cronk, 2018). Pre-intervention data were collected through a retrospective chart audit of all adults with T2DM, and those with HbA1C of greater than 8.0 who met inclusion criteria were invited to participate. Phone contact was made to each qualified participant to inquire about joining the EBP project, and those that agreed attended an initial check point meeting describing the program details and responsibilities. During an 8-week period, participants recorded SCB outcome measures daily into the MHA. This data included glucose monitoring results, activity engagement efforts, and medication adherence efforts that each participant completed. The project leader received the data through the export function of the MHA. Exported data would be reviewed by the project leader, and at that time it would determine if participants met or did not meet the goals that they had set for themselves at the initial start-up meeting. Participants were expected to meet their self-determined goal 100% in order for the SCB to be considered met. Nurse practitioners also received exported data from the project leader to keep them informed of their patient progress in the program. At the 8-week final check point meeting a post-intervention HbA1C, SCI-R and a satisfaction survey was completed.

Glycemic Efficacy

The measures of glycemic efficacy, obtained from retrospective chart audits of preintervention HbA1C (M = 9.95, SD = 1.07) and post-intervention HbA1c results (M = 8.20, SD = 1.10) were evaluated using paired t tests. The decrease in the HbA1C was found to be statistically and clinically significant (t = 6.674, df = 17, *p < .05). See figure 4.2



Pre- Intervention: M = 9.95, SD = 1.07Post- Intervention: M = 8.20, SD = 1.10

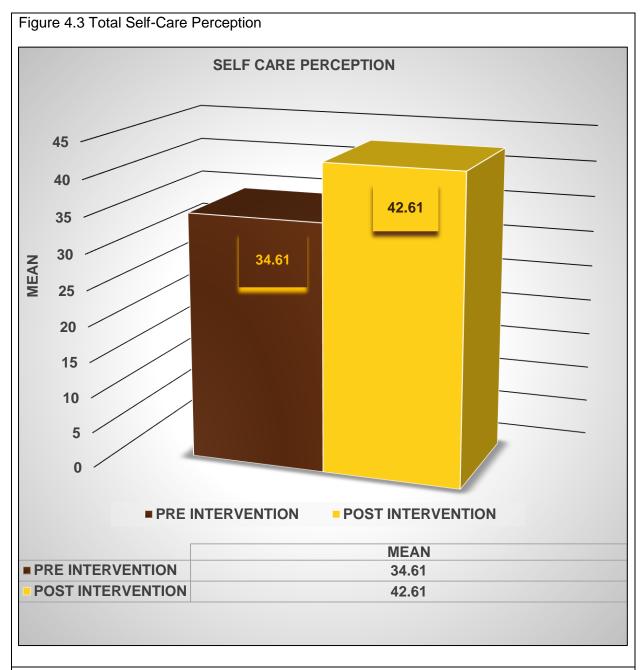
t = 6.674, df = 17, *p < .05

Changes in Secondary Outcomes

Two secondary outcomes were analyzed. Evaluating the effects of the MHA on SCP and SCBs were secondary purposes of this EBP project. Patient satisfaction was an outcome of interest because utilizing a MHA that produced dissatisfaction would be counterproductive to the improvement of SCP and SCB.

Self-Care Perception

A SCI-R survey was completed at the initial and final check point meeting for each participant who completed the program (N = 18). This tool was reported within the literature as being valid and reliable (Weinger, Welch, Butler, & La Greca, 2005). Reliability testing was completed using Cronbach's Alpha analysis, which found the tool reliable (.796). Validity testing was also completed using a 1-tailed Pearson's Correlation Coefficient. Pre-intervention SCI-R indicated significant validity of the tool (.683, p = .001) as did post- intervention validity testing (.683, p = .001). The survey scores were totaled and a paired t test analysis was completed on pre-intervention scores (M = 34.6, SD = 10.5) and post-intervention scores (M = 42.6, SD = 8.09). The findings indicated that there was a statistical and clinical significance in SCP (t = -4.403, t = 17, t > < .05) (See figure 4.3) Pre- and post- intervention SCP comparisons were also made of the behaviors that were the focus of this EBP project. This included personal perception of checking glucose, recording glucose, activity engagement, and medication adherence (See figures 4.4, 4.5, 4.6, 4.7).



Pre- Intervention: M = 34.6, SD = 10.5Post- Intervention: M = 42.6, SD = 8.09).

t = -4.403, df = 17, *p < .05

Self-Care Behaviors

Participants recorded behaviors of medication adherence, glucose monitoring, and activity engagement according to the personal goals set by each participant. Over the course of the 8-week program, behaviors entered into the MHA across all three domains. Frequency analysis was completed to determine adherence to the use of the MHA, and expressed as percentages. Across all three domains the highest frequencies were at week 1 and week 2 for glucose monitoring (72.2%, 72.2%) and medication adherence (88.9% and 94.4%). Glucose monitoring declined by week 8 (55.6%) as did medication adherence at week 8 (72.2%). Activity engagement was highest at week 1 (72.2%), and declined significantly by week 8 (38.9%) (See Figure 4.4). Behaviors monitored throughout the 8-week period were important to evaluate program adherence of participants while using the MHA, but statistical analysis were not able to be performed due to lack of pre-intervention behavior assessment for comparison. However, pre- and post- intervention SCP comparisons were made of the behaviors that were included in this EBP project. Behaviors included participant perception of glucose checking, recording the glucose result into the MHA, medication adherence, and activity engagement, and results were drawn from pre- and post- intervention SCI-R surveys (See figures 4.5, 4.6, 4.7, 4.8). A Wilcoxon test examined the results of pre-intervention and post-intervention of checking glucose. A significant difference was found in the results (Z = 2.389, *p < .05). Post- intervention results were significantly better than pre- intervention results. A Wilcoxon test examined the recording of glucose results pre- intervention and post- intervention. A significant difference was found in the results (Z = 2.666, *p < .05). Post- intervention results were significantly better than pre- intervention results. A Wilcoxon test examined pre- and post- intervention of participant adherence to their prescribed medications specific to the treatment of their T2DM. A significant difference was found in the results (Z = 2.313, *p < .05). Post- intervention results were significantly better than pre- intervention results. A Wilcoxon test examined pre- and postintervention of engagement of activity. A significant difference was not found in the results (Z = 1.718, p > .05). Post- intervention results were not better than pre- intervention results.

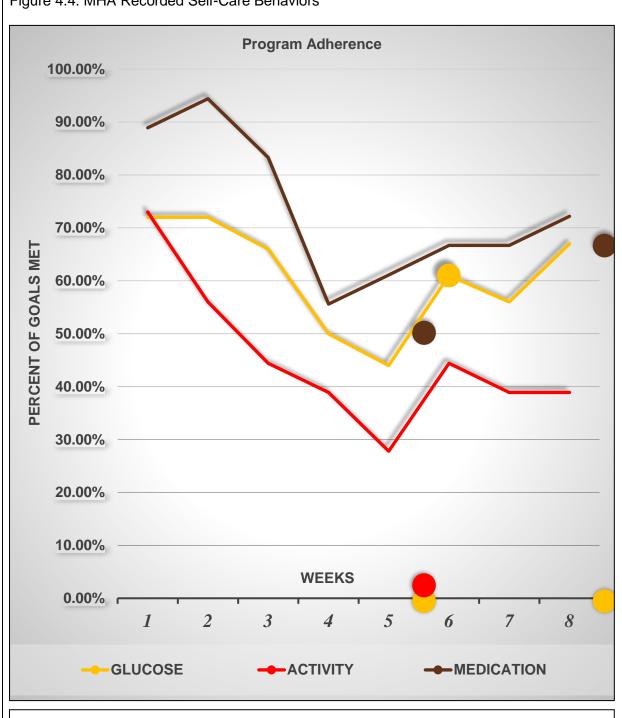
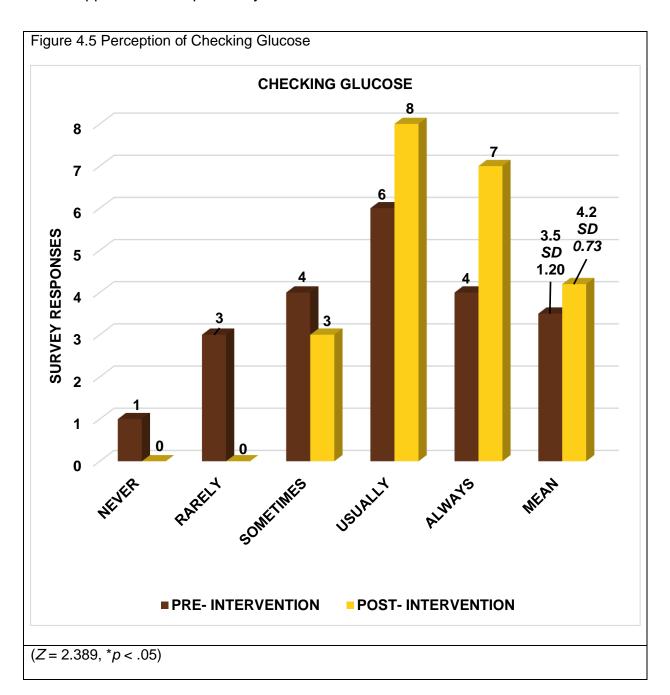


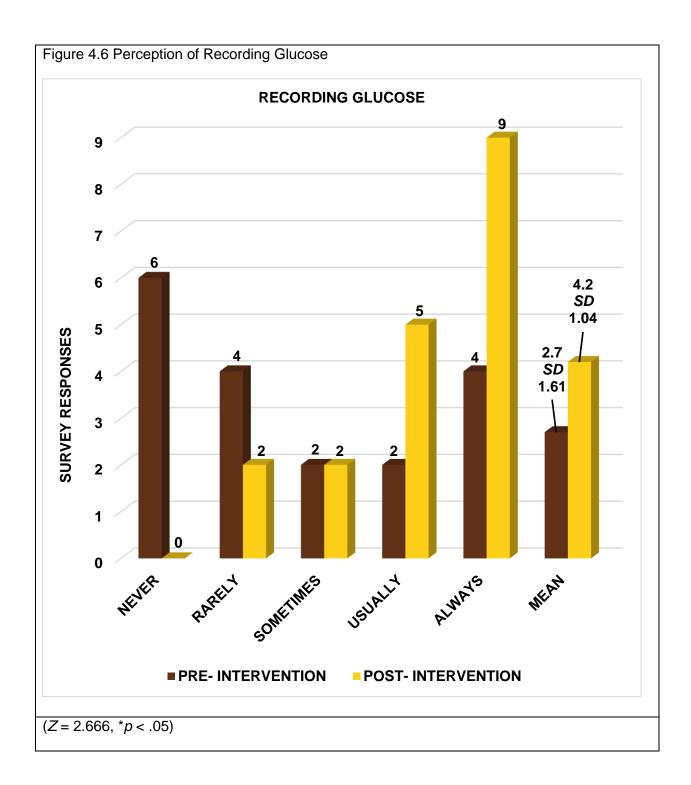
Figure 4.4. MHA Recorded Self-Care Behaviors

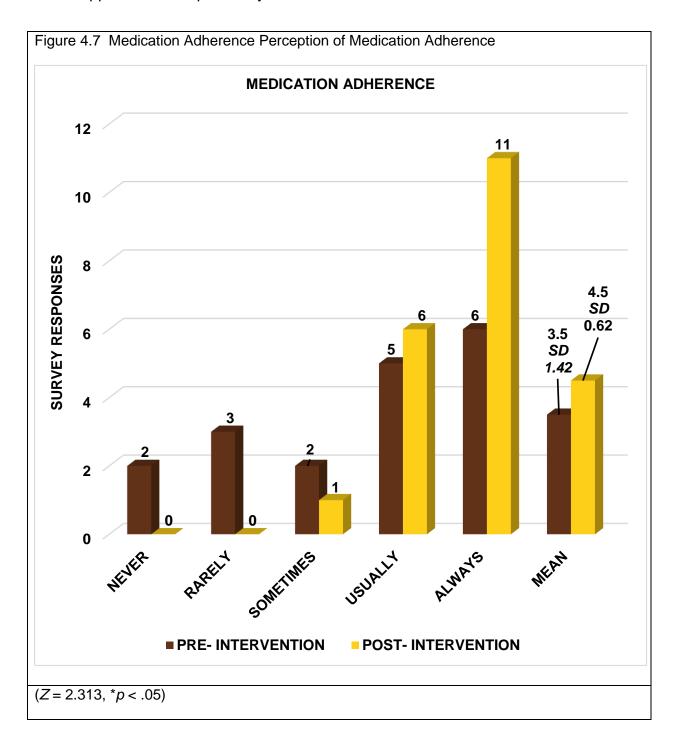
Glucose Goals Met: Week 1-8: 72.2, 72.2, 66.7, 50.0, 44.4, 61.1, 55.6, 66.7

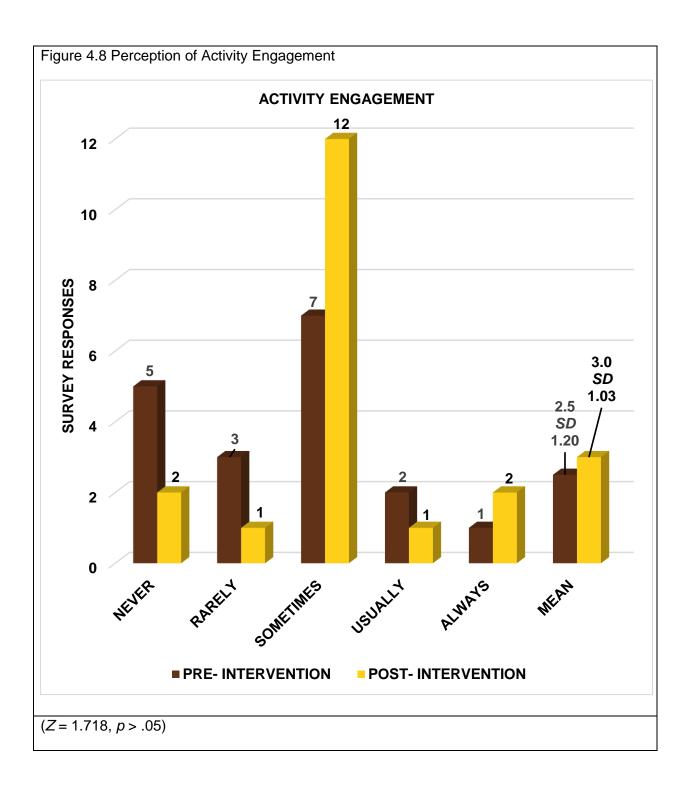
Activity Goals Met: Week 1-8: 72.2, 55.6, 44.4, 38.9, 27.8, 44.4, 38.9, 38.9

Medication Goals Met: Week 1-8: 88.9, 94.4, 83.3, 55.6, 61.1, 66.7, 66.7, 72.2









Participant Satisfaction

A Likert-scaled satisfaction survey was created that focused on the MHA used for this project (MySugr®). Individual scores for each category on the satisfaction survey determined that participants were satisfied with the use of the MHA (See Table 4.2). Participants rated a relatively high score for cumulative satisfaction for the use of a MHA (M = 31.94, SD = 3.81). High score for the survey was 35. (See Table 4.2).

Table 4.2

Participant Satisfaction

Category	Range	Mean	SD	
Download Application	3, 5	4.6	0.70	
Use of Application	4, 5	4.7	0.49	
Exporting Data	3, 5	4.6	0.70	
Track Glucose	4, 5	4.7	0.49	
Track Activity	3, 5	4.6	0.70	
Track Medication	4, 5	4.7	0.49	
Overall Satisfaction	4, 5	4.7	0.49	
Cumulative Score	22, 35	31.94	3.81	

Conclusion

In summary, statistically and clinically significant results were found with use of a MHA regarding the effect on HbA1C and SCP. Interestingly, there was a notable inverse relationship between HbA1C and SCP. When SCP was at the lowest point, HbA1C was at the highest, and when SCP was at the highest point, HbA1C was at the lowest point. There was a statistically significant difference for participant SCB perceptions for checking glucose, recording glucose, and medication adherence. However, activity engagement was not found to be significantly different. Satisfaction scores were high, and according to survey results participants' expressed liking the application's overall functionality and ease of use.

CHAPTER 5

DISCUSSION

The EBP project was completed to examine the clinical research question: What is the best practice for adult T2DM patients to achieve glycemic control and improve self-care behaviors. Additionally, the clinical question addressed the impact of a MHA on self-care perception. This project was posed to identify what intervention has been found, through best evidence, to achieve glycemic control in adult T2DM patients, thereby lessening debilitating complications related to chronically elevated HbA1C levels. High level literature supports the use of mobile-phone technology to improve glycemic outcomes for those adults with uncontrolled T2DM. The goal of this EBP project was to implement an intervention that utilized a multi-functional MHA to encourage self-care behaviors of glucose monitoring, activity engagement, and medication adherence. This chapter will explore the project findings, describe the benefits of the selected EBP framework, strengths and weaknesses, and implications for the future.

Explanation of Findings

The PICOT question for this project asked: "In adult T2DM patients with HbA1C values higher than 8.0 in a primary healthcare setting (P) what is the effect of a mobile-phone diabetes support application (I) compared to traditional diabetes education (C) on HbA1C results, self-care behaviors, and self-care perception (O), over an 8-week period (T)?" The findings will reflect the answers to the burning question that was the impetus for this EBP project.

Initially, a total of 40 participants were selected for this EBP project, 25 of which agreed to participate. Of the 25 participants, 18 completed the program and eight of them did not start or did not complete the final check point evaluation at week eight making the completion rate 72%. Completing the final check point was critical to the project evaluation because at that point post-intervention data was collected for comparison purposes. This data collection included

post-intervention collection of a HbA1C, SCI-R survey, assessment of behaviors recorded by the participant, and a satisfaction survey.

Glycated Hemoglobin

After 8-weeks of the intervention, the final HbA1C, SCI-R, SCB, and satisfaction surveys were recorded by the project leader. The primary outcome measure was to determine the difference between pre- and post- intervention HbA1C results. A statistical analysis was performed using a Correlated t test, and the findings resulted in a statistically and clinically significant improvement (t = 6.674, df = 17, *p < .05) in the reduction of HbA1C. The data revealed a mean reduction of HbA1C of the post-intervention results (M = 8.20, SD = 1.10) compared to the pre-intervention results (M = 9.95, SD = 1.07). The mean reduction in HbA1C was 1.75%. This finding was higher than what was found in some of the literature (Hou, Carter, Hewitt, Francisa, and Mayor, 2016; Pal et al., 2014; Wang, Xue, Huang, Huang, and Zhang, 2017), and in some pieces of literature the findings were similar (Fu, McMahon, Gross, Adam, and Wyman, 2017; Wu, et al., 2017. The higher reduction in HbA1C may be attributed to the Hawthorne effect that is frequently associated with people when they know their performance is being closely monitored (Kenton, 2019). According to the integrative review by researchers Fu, McMahon, Gross, Adam, and Wyman (2017), HbA1C was reduced 0.15-1.9% from baseline, and statistical significance was found in studies in which MHAs were multi-functional and interactive. A systematic review by Wang, Xue, Huang, Huang, and Zhang (2017), found that the use of MHA technology resulted in a decreased HbA1C of 1.0 %. Researchers of another systematic review found that the MHA-based intervention was associated with HbA1C reductions of 0.66% - 1.96% (Wu, et al., 2017). Pal et al. (2014) found a modest HbA1C reduction of 0.50% with use of a MHA, and Hou, Carter, Hewitt, Francisa, and Mayor (2016) found a mean HbA1C reduction of 0.41%.

Self-Care Perception

Uncontrolled T2DM places the individual at risk for severe complications and complex comorbid conditions including, heart disease, stroke, renal disease, vascular disease, neuropathy, amputations, and death (ADA, 2018). T2DM is a chronic disease that demands daily assessment and care by those afflicted with the disease. The daunting task of self-care management for this chronic disease is challenging and overwhelming in many cases (Vermeire et al., 2005). For this reason, SCP was evaluated in this EBP project to determine the impact of the MHA. SCP is one's belief people can care for themselves, and the use of MHAs seems to strengthen perception of self-care by contributing better information and health education to participants (Bonoto, et al., 2017). The higher the SCP score the better one believes they can care for themselves. The tool used to assess SCP was the SCI-R self-report survey. This tool was found to be reliable and valid in the literature (Weinger, Welch, Butler, & La Greca, 2005) and through statistical testing. A Correlated t test was calculated to compare the mean preintervention SCP to the mean post-intervention for the 8-week intervention. A statistically significant increase in SCP results were found post- intervention (M = 42.6, SD = 8.09) compared to pre- intervention (M = 34.6, SD = 10.5) (t = -4.403, df = 17, *p < .05). For comparison purposes, pre- and post- intervention data specific to the SCP of checking glucose, recording glucose, activity engagement, and medication adherence were analyzed (Figures 4.5, 4.6, 4.7, 4.8). This comparison was not reported individually within the literature, however the changes between pre- and post-intervention perceptions in these areas illustrates how SCP was impacted through the use of a multi-functional MHA. The improvement in SCP with the use of a MHA was similar to the results found within the literature. A systematic review found the use of MHA seemed to improve SCP by increasing information and health education of patients.(Bonoto, et al., 2017). Clement et al. (2018) suggested that technology such as MHAs increased patient satisfaction and knowledge improving self-management perceptions. The findings provide evidence that using a MHA improves SCP and suggests participants feel more

confident when preforming self-care activities for the management of their uncontrolled T2DM. For the purpose of this project, analysis of specific behaviors related to this project within the SCI-R tool were completed to compare self-reported pre- and post- intervention results (see figures 4.5, 4.6, 4.7, 4.8).

Self-Care Behaviors

SCBs for this project were glucose monitoring/recording, activity engagement, and medication adherence. These are three of the self-care management behavior domains recommended by the ADA that lead to the reduction of HbA1C (ADA, 2018). A frequency analysis for each week was completed on each behavior to determine participant adherence to the use of the MHA. Initial percentages were high with a steady decline that occurred over the course of the 8-week period (see figure 4.4). This may be have been due to the lack of evaluating participant recorded SCB practices prior to the initiation of the MHA. Evaluating this prior to starting the MHA may have demonstrated a more accurate representation of participation patterns. This should be a consideration for future EBP projects and organizational outcome measures that focus on evaluating SCB practices related to the use of a MHA. One week after participants used the MySugr® MHA, recorded behaviors were reviewed. High completion percentages which were most likely due to the Hawthorn effect. This phenomenon occurs when people feel their performance is being monitored, thus causing an excessively high performance of activity or completion of duties (Kenton, 2019). Weeks 2-4 showed a decrease in SCB's, between week-5 and week-6 there was a slight increase in the percentage of successfully met behavior goals. This was most likely due to staggered start process in which all participants completed the 8-week program but joined and finished at different points in time. Participants who joined during the initial participants' weeks 5 and 6 were also subject to the Hawthorn effect. During this particular timeframe, seven new participants joined the program, and I believe this relates to the spike in SCB adherence.

Analysis of specific behaviors related to this project within the SCI-R tool were completed to compare self-reported pre- and post- intervention results (see figures 4.5, 4.6, 4.7, 4.8). There was a statistically significant improvement in the perception of SCBs for checking glucose, recording glucose, and medication adherence when comparing pre- and postintervention results. There was not a statistically significant difference in perception of activity engagement between pre- and post- intervention data. According to Bonoto et al., (2017), participants reported that they felt like they engaged in these key behaviors and when preformed consistently led to improvements in glycemic control and patient outcomes. Literature supported the use of MHA's to enhance SCB practice for adults with T2DM (Bonoto et al., 2017; Clement et. al., 2018; Mann, 2018; Nguyen, 2018; Pamaiahgari, 2018). Findings in in the literature indicated that integration of a MHA for the self-management of T2DM may result in reductions of HbA1C and glycemic and cardiovascular risk factors (Clement et. al., 2018). Selfmonitoring of glucose is a main strategy to attain glycemic control, which is a main component of MHA's. Thus, MHA's encourage SCBs that result in reductions in HbA1C which emphasizes the importance of using this technology in the primary healthcare setting (Bonoto et al., 2017). The literature used in this project identified 11 different MHAs that were used by the intervention groups. Application features included health data storage, positive feedback parameters, and motivational feedback for glucose, activity, and medication recording, all of which were present in the MySugr® MHA. All of these features were found to contribute to glycemic control (Fu, McMahon, Gross, Adam, & Wyman, 2017; Hou, Carter, Hewitt, Francisa, & Mayor, 2016; Wu et al., 2017;). Subgroup analysis determined that MHAs with features such as positive feedback and glucose, activity, and medication recording generated better and statistically significant improvements in HbA1C (Bonoto et al., 2017). A clinical practice guideline (Clement et al., 2018) did not report individual SCBs as an outcome, but noted that the MHAs with the features mentioned above improved SCB adherence, improved access to health care professionals, and contributed to better glycemic control. A systematic review indicated that MHA engagement

decreased over time, however statistically significant reductions in HbA1C were achieved (Bonoto et al., 2017). It was noted that reductions in HbA1C may have been due to factors unrelated to the MHA, such as increased knowledge regarding the implementation of the MHA platform to record and encourage behaviors related to reducing HbA1C. This reinforced knowledge about behavior changes that lead to improved HbA1C, which may have caused improvements in self-care changes leading to improved HbA1C. Interestingly these researchers found generally high participant engagement for all components of the MHA the first week and then decreased engagement progressively overtime consistent with the behavior pattern observed in this EBP project. Additionally, they found that blood glucose monitoring had a statistically significant improvement while activity engagement did not (Bonoto et al., 2017). These findings were similar to the findings of this EBP project, (Bonoto et al., 2017). Best practice recommendations include MHA-based support programs for the management of diabetic patients (Pamaiahgari, 2018), and structured self-monitoring of blood glucose was found to be more beneficial than non-structured self-monitoring of blood glucose testing in reducing HbA1C (Nguyen, 2018). Structured self-monitoring means that glucose checks are not only encouraged but a technologically platform is provided to record, store, and export selfmonitored blood sugars. A systematic review by Hou, Carter, Hewitt, Francisa, and Mayor (2016) promoted MHAs to improve patient self-management with the enhanced ability to monitor blood glucose, physical activity, and medication adherence.

Participant Satisfaction

Participant satisfaction was also evaluated because this is an important aspect when selecting a MHA as patients desire one that is considered easy to use and understand (Fu, McMahon, Gross, Adam, & Wyman, 2017). Researchers suggest that MHAs that are user friendly and multi-functional are best for improving SCB's that lead to improved glycemic control (Fu, McMahon, Gross, Adam, & Wyman, (2017).

Cumulative patient satisfaction results for the use of a MHA in this project reflect high satisfaction (M = 31.94, SD = 3.81) with a range of 22,35. Individual satisfaction domains specific to the focus of this EBP project included tracking glucose, activity, and medication adherence and recording. Interestingly, tracking glucose and inputting data onto the MHA were ranked the top two domains in satisfaction. This may be due to the user-friendly aspects of the device, and to the positive reinforcement in real-time elicited by the application when data was entered. MySugr® has a "sugar monster" on the application and he smiles and giggles or frowns and scowls accordingly to normal or abnormal blood sugars. The "sugar monster" also turns colors based on the blood sugar number entered with green signifying a normal range, yellow approaching out of range, and red representing a result that was out of range. This was a unique positive reinforcement system and immediate feedback system specific to this MHA. Tracking activity and medications had lower satisfaction ratings, but only by a slim margin. The "sugar monster" would consistently be green, smile and giggle anytime activity and medications were entered into the MHA. Again, this provided consistent positive reinforcement in real-time. Literature suggests that MHA use increased patient satisfaction of self-care management behaviors by enhancing knowledge and promoting improvement in quality of life and selfconfidence to manage T2DM (Bonoto et al., 2017; Clement et al., 2018). The heightened SCB practices, self-confidence, and self-care knowledge fosters improvements in HbA1C and decreased risk of complex comorbid complications.

Strengths and Limitations of the DNP Project

EBP Model

The EBP framework used to guide this EBP project was the lowa model of evidence-based practice to promote quality care. The lowa model provided a conceptual framework for the selection and development of this EBP project. It consists of seven steps: selection of a topic, forming a team, evidence retrieval, grading the evidence, developing an EBP standard, implementing the EBP standard, and evaluation (Titler et al., 2001). Step I was the selection of

a topic which included the task of identifying an organizational quality measure that was falling below metric standards set forth by key reimbursement agencies such as CMS. Included in this selection process was the consideration of current policy, organizational mission, and key stakeholder influence that may produce limitations for the project. It was found that in quarterone of 2019 that 59.3% of diabetics within the primary care organization had HbA1C results of greater than 9.0, while guarter-two indicated that 66% had HbA1C greater than 9.0. These are considered poor quality measure outcomes and are well above the expected national standard of 45% or less of adults with diabetes mellitus having a HbA1C of less than 9.0 (CMS, 2017). Uncontrolled diabetes mellitus is directly linked to complex conditions and complications that include: Cardiovascular disease, stroke, diabetic ketoacidosis, kidney disease. eye disease, and amputation of a lower extremity (CDC, 2017). The use of a MHA to encourage adults with uncontrolled T2DM to improve completion of self-care behaviors ultimately leading to improved HbA1C results. Reducing HbA1C was a priority for the stakeholders of this organization, i.e., physicians, nurse practitioners, quality management, risk management, and senior leadership. The idea of using a MHA in the primary care setting did not take hold as the project leader expected it would. Several meetings and presentations occurred with individuals and groups of stakeholders to promote the EBP project. Support for the project development was mainly provided from quality and risk management leaders, while nurse practitioners heavily supported the implementation process. Physicians did not want to engage in any of the development, implementation or evaluation phases due to the time involved. One physician voiced opposition of adding a MHA as a primary care provider-driven tool, due to time constraints and how this may negatively impact quarterly revenue bonuses. The original protocol was primary care provider-driven, but senior leadership thought it would be better utilized as a nursing intervention standard in the diabetes education program that was needing serious revisions. It is now recognized that the diabetes outcome metric is not being met within the organization, and loss of reimbursement by CMS is at risk. The Chief Nursing Officer (CNO) recommended use of the MHA as an evidence-based tool for the management of adults with uncontrolled T2DM, and to improve outcomes for the organization. The project is now being integrated into the diabetic chronic care management and transitional care management programs of the organization. The protocol will need to be reviewed by medical staff for approval and modifications will occur as recommended. Modifications may include setting different target ranges for blood glucose results and blood glucose monitoring intervals for those on insulin and those who do not use insulin. These target ranges would need to be determined by the patient care review committee as a guide to the diabetes care team.

Step II is the engagement of a team that will be responsible for the development, implementation, and evaluation of the project. The makeup of the team is driven by the chosen topic and include associated stakeholders (Titler, 2001). The project leader determined that a small interdisciplinary team would be best for the development of this EBP project. The organization is considerably small and generally functions on a more intimate level of communication. The team included the project leader, project preceptor/quality manager, and the risk manager. It was impressive to see the level of attention that was given to the project by the project preceptor/quality manager and the risk manager. The project preceptor/quality manager was involved in the development and workflow of initiating the MHA. She came to the office of the project leader on a few occasions to discuss the literature findings, protocol development, and recruitment efforts. Additionally, she integrated the program into the EMR to streamline the referral process for the nurse practitioners. The risk manager reviewed the IRB from Valparaiso University, all of the forms that were created for the project, and the focus of the project. The project leader was impressed with the enthusiasm of these team members and appreciated the recommendations from these leaders. The nurse practitioners were considered the key stakeholders due to the probability that the majority of the referrals would be coming from them. Two of the nurse practitioners who originally said they would start participants on the program did not do so. The project leader ended up meeting with all 26 of the potential

candidates and then followed the 18 participants for 8 weeks without participation of the other two nurse practitioners. Their assistance may have increased the number of participants that joined the program. The physicians showed extreme resistance to the project, and the project leader's collaborating physician stated he did not want to take the time to start a patient on the MHA. He indicated from the start that the MHA may have a place in the organization, but should not be physician or nurse practitioner driven. The project leaders does not agree with this and believes the use of the MHA to reduce HbA1C should remain a primary care provider-driven practice guideline as nurses cannot make medication adjustments that are often needed to improve glycemic control. Activity adjustments and glucose monitoring would also need to come from the primary care providers. Advanced practice nurses are well suited to make these adjustments based on exported data and improve outcome measures while reducing risk of secondary complications. The project leader did not receive any referrals from a physician. However, the project leader was able to speak to some of the physicians' patients, and they agreed to join the program. The physicians did not resist their patients being in the program and accepted the exported data by email from the project leader without issues. When a participant joined the program, their provider was made aware of their patient's informed decision and instructed to expected exported data in their email weekly. This information kept them prepared and helped them understand what to expect from the project leader.

Step III entails evidence retrieval. Brainstorming amongst the members should be held to identify available resources to guide the search for evidence (Titler et al., 2001). Once the priority was established, the quality and risk leader team members assisted in the development of the EBP project. The project leader retrieved and evaluated the level and quality of the evidence and explained it to the quality and risk team members. This was a lengthy and exhausting process, but necessary to assist the other team members' full understanding of what EBP entails. Much of the discussion focused on the project implementation process and retrospective chart review. The quality leader was able to pull the names of the patients with

T2DM that had HbA1C greater than 8.0, which was essential to evaluate the full scope of the problem within the organization. The risk leader was essential in making sure the written forms for the project were clear and did not put the hospital at risk or litigation. The project leader's main role was to ensure the evidence was at the highest level and quality available and to keep the other team members informed of the findings.

Step IV is the process of gathering, critiquing and synthesizing pertinent research related to the desired practice change (Titler et al., 2001). In this case, the project leader was required to appraise the strength and quality of the evidence that was found as a result of an exhaustive literature search. Through this search it was determined that there was an large amount of high evidence available to support change in practice. Evidence was leveled through Melnyk and Fineout-Overholt's Hierarchy of Evidence (Melnyk & Fineout-Overholt, 2015). Critical appraisal of the evidence was completed through use of the CASP tool (CASP, 2017), and the AGREE II tool for clinical practice guidelines (Brouwers et al., 2010).

STEP V is the development of a new practice based on a patient-centered evidence-based practice standard that is highly individualized. Once the literature is critiqued, team members develop a set of recommendations that guide the new practice (Titler et al., 2001). The project leader created an individualized patient-centered EBP protocol/ practice standard for the organization that was revised continually throughout the implementation process as barriers were encountered. The first barrier was experienced as the new practice standard was introduced to the organization came with a significant barrier. The *Living Sweet* MHA program was recommended to be initiated as a nursing intervention, but because nurses cannot adjust medications, glucose testing intervals, or activity recommendations at this organization, the primary care providers had to manage these aspects of the program. This meant the practice change would need to go through the patient care review committee before it could be added to the approved diabetes education regimen. The patient care review committee is comprised of only physicians. This barrier will be addressed through a presentation at a future patient care

review committee meeting. Additionally, selecting a MHA for this project also became a challenge due to the abundant options to choose from. The project leader sampled and reviewed roughly ten applications before selecting MySugr®. This particular MHA was free to use, was multi-functional and included the ability to document all three behaviors being monitored in the EBP project, was very user-friendly, came with a color-coding system to help the user determine if the blood sugar was in good range (green), moderate range (yellow), or poor range (red).

The start-up meeting consisted of a complete in depth instructional in-service for each participant with emphasis on the use of the MHA, selecting personal goals for each behavior, and specific project leader and participant responsibilities. Weekly check points were used as a teaching moments to reinforce the proper use of the MHA, self- selected behavior goals, and to clarify any concern or question a participant had regarding the MHA. The new practice standard protocol was reviewed after implementation by all team members, and it was suggested that it is more relevant and feasible as a nursing intervention for the diabetes education program rather than a provider-driven practice protocol. This means that when a primary care provider sends a referral to the diabetic education team, they will utilize the MHA protocol as an additional tool to promote glycemic efficacy. The reason behind the creation of the EBP protocol is to improve the quality and consistency of diabetic education throughout the organization. This was suggested by senior leadership and eliminated a significant barrier that was resistance from medical staff members. The protocol will still need to be approved by medical staff, which is made up of physicians, but will likely be accepted as an evidenced-based tool for improved diabetic care glycemic outcomes. The primary care providers', including nurse practitioners', role will be to medically manage medication types and dosages, activity engagement, and glucose monitoring intervals based on the exported data they receive from the patients that are using the MHA. Once the medical staffs approves the integration of the MHA into the diabetes education program, the nurses will start participants on the program and track their progress. Diabetes

nursing staff will forward export data to primary care providers when exported data results are consistently falling out of target ranges. The significance of this is the sooner the nurse practitioner makes adjustments, the sooner the patient will reach glycemic control.

Step VI is the implementation of the new EBP standard which begins with written policies, procedures, and guidelines. Policy development requires direct interaction between the team members, direct care providers, and organizational leaders to support the practice change (Titler et al., 2001). The protocol was developed and implemented with continual revisions to meet limitations and barriers that were encountered throughout the launch of the *Living Sweet* program. Revisions included adding a prompt within the protocol for the designated staff implementing the MHA to contact the patient before the initial meeting to request their phones are updated with the most current operating system. Another revision added was a prompt to request patients know the email and password that corresponds to the application store on their smart phone. Also, the protocol was changed from a provider-driven tool to a nursing intervention for the improvement of diabetes outcome measures.

Step VII is the evaluation step which is essential to seeing the value and contribution of applying the evidence to practice. Baseline comparison data prior to project implementation is beneficial to show how the new evidence-based practice has affected patient care (Titler, 2001). Data collection flowsheets were created to track the data for all outcome measures and group demographic characteristics. The project leader completed eight check-points for each participant (N = 18), and was available by phone for consultation regarding any concern or any trouble shooting issues related to the use of the MySugr® MHA. The time involved in preforming check-points depended specifically on the needs of the participants and how well they comprehended the MHA functions. Additional time was spend reinforcing the three SCBs that were being monitored and the steps for exportation of the data to the project leader. Initial check points lasted between 30-45 minutes and as the program progress the check points occurred over 10-20 minutes. Check points were integrated into the program to determine and address

barriers and limitations. This was helpful in revising the protocol to make it more streamlined and functional for those that were going to be providing education about the program to future patients. This approach was not intended to be sustainable long term as once participant and workflow issues were identified and resolved, the checkpoints would no longer be needed. In future practice, primary care providers could set exportation expectations for each patient that utilizes the MHA program. The project leader evaluated the outcome measure data using statistical tests with SPSS 22 software.

Strengths

There were many strengths of this EBP project. The most profound strength was the collaborative efforts between advanced practice nurses, senior leadership, and quality and risk management departments. The support by key stakeholders had significant influence in the development, implementation, and evaluation processes of this EBP project. For instance, the quality leader volunteered an abundant amount of time to help determined the number of that adults with uncontrolled T2DM that were well above the HbA1C benchmark according to CMS guidelines. She also recommended that the best way to elicit provider referrals was through the established EMR. Making the referral process streamline and simple was clearly an attraction to the primary care nurse practitioners. Implementation was supported by risk leadership as she critiqued the data tracking forms, instructional forms, and educational forms to keep structure and consistency to the entire implementation process. The project leader was the member who created the forms, contacted patients, implemented the program, and evaluated the outcome measures of the EBP project. The literature used for this project added clarity and confidence which was found to be a significant strong point when grooming key stakeholders and clinical staff. For example, the high level and quality of literature found was explained and reviewed with the primary care providers at four different meetings. These meetings were geared to sparking interest, garnering support, and eliciting qualified participant referrals. The MySugr® basic application was free to use for all participants which is a huge strength in the rural health care

setting, not to mention the multi-function capabilities of the MHA to be used as an individualized patient-centered intervention. In the event MySugr® would become cost prohibitive, there are other free multi-functional applications with similar features and are user-friendly such as Glucose Buddy (Glucose Buddy, 2017).

The MySugr® application allowed for simplistic data entry by simply tapping on the my sugar icon. The user was able to enter blood sugars manually or through blue tooth technology if their monitor was compatible. After the number was entered or uploaded from the glucometer the user would tap the green check mark to record the data. The name of each diabetes medication was pre-selected for each participant and by simply tapping on the medication and then the green check mark, the data were recorded. Activities were recorded in a similar fashion. The MHA had other functions available, but for the purpose of this project these three SCBs were the only ones utilized. The MHA estimated the HbA1C for each participant if they submitted six glucose results for the week. This feature was helpful as the number may have encouraged participants to improve food selections, increase activity, or adhere to medications based on the results produced from current blood glucose results entered. An additional strength of the application is the participant was able to review seven days, 14 days, 30 days, and 90 days of data, and this included cumulative blood glucoses, physical activity engagement, and medication adherence at each data point. Furthermore, the MHA has no geographical barriers and promoted access to the healthcare provider through the exportation function. The opportunity to export real-time data was a significant advantage for those participants who did not have transportation to attend a traditional office visit.

Limitations

The primary limitation was the small number of participants for the project (N = 18). Additionally, the project was short in duration and a longer time many have resulted in different outcomes for the primary and secondary objectives for this EBP project. Another limitation was that many of the participants engaged in the project over two major holidays in which there is an

abundant supply of nutritionally poor foods. People tend to increase consumption of sweets, eat larger portions of food, and increase alcohol consumption over holidays, all of which can increase blood glucose and HbA1C. Regardless of the limitations faced in this EBP project, participants experienced a statistically and clinically significant decrease in HbA1C, improved SCP and SCB. The project lacked objective pre- intervention data regarding the SCB's included in this project. A better approach may have been to collect SCBs from each participant prior to initiating the MHA, and compare them to post intervention SCBs that were recorded into the MHA. This would have reflected a more accurate representation of how SCBs were impacted by the use of the MHA. Finally, prospective participants that did not have a cell phone or tablet were unfortunately not able to participate in the project and were not able to benefit from the Living Sweet program. This specific limitation only was applicable to five of the participants that were originally contacted.

A participant related limitation was encountered early in the program. Internet connection was found to significantly impact the time involve when uploading the MHA to the smartphone and when inputting data. This did not cause a deterrent for the participants, but caused a barrier for the project leader. The first participant for this EBP project was started in the program in his home setting and it was extremely difficult to get the MHA downloaded onto his smartphone due to poor satellite connection and download speeds. The future recommendation is that participants start the program in the office setting with sound, consistent internet connections. The office setting in this organization has a broadband fast internet and uploading of the MHA took minutes versus hours with satellite internet services. Participants also seemed to have a difficult time remembering the email and password associated with uploading applications to their phones or tablets. The initial meeting with the first participant this was a significant issue. This limitation was addressed early during the initial phone call by the project leader by requesting that each participant have their email and password ready for the initial program start-up meeting. SCBs and SCPs were self-reported, which can be a limitation because self-

reporting is subjective and may not have been accurately reported by the participants. Despite limitations related to self-reporting, SCBs, with the exception of activity engagement, and SCPs showed statistically significant improvements.

Implications for the Future

Practice

Improving HbA1C using a multi-functional diabetes specific MHA could be helpful in achieving glycemic efficacy, self-care perception, and self-care behaviors. The EBP project had a short duration of 8-weeks, but the MHA strategy demonstrated a statistically and clinically significant reduction in HbA1C and improvements in SCP and SCBs, with the exception of activity engagement. Regarding adherence to the use of the MHA, post- intervention recorded SCB activities declined over an 8-week period. Due to the suspected Hawthorne effect that frequently occurs during monitored projects, recorded activities may have been skewed during the initial weeks participants were using the MHA. Evaluating SCBs prior to the implementation of the MHA would have made a better reflection of the impact that the application had on recorded post- implementation SCBs. This was a flaw in the design of the project. Participants recording SCB practice data prior to the use of the MHA would have been a better comparison and provided more insight of how the application impacted SCBs. It is possible that even the lowest percentages of the post-intervention recorded SCBs could have been higher than preintervention recorded percentages. This would have resulted in an increase in recorded SCB activities rather than the resulting decline that was found. Within the SCI-R tool, SCBs specific to this project were self-reported pre- and post- intervention by each participant, and those results were individually analyzed. Findings indicated that SCBs of checking glucose, recording glucose, and medication adherence demonstrated statistically significant outcomes. Activity engagement was not found to be statistically significant.

Participants reported high satisfaction regarding the use of the MHA which is a bonus attribute that may lead to better adherence to a program geared at improving HbA1C. This EBP

project mean HbA1C result surpassed the primary outcome benchmark set by CMS of 9.0. This is clinically and statistically significant and suggests that providers should consider using the MHA to improve glycemic control in adults with uncontrolled T2DM in a primary care setting. Due to the lack of medical staff support it was suggested by senior leadership to transition the protocol into a nursing intervention. This was a significant suggestion, and the protocol was adopted by the organization as an additional tool to support adults with uncontrolled T2DM. At this time, the basic functions of the MySugr® MHA is free to anyone who would like to use it. Basic functions included recording of glucose, activity, medications, carbohydrates, weight, and HbA1C results. The lowa model used as a guide for the creation of this EBP project supports the team collaboration concept. This was clearly demonstrated by the collaborative healthcare team involved in the development, implementation, evaluation, and dissemination of the project. The importance of a team approach when establishing EBP protocol is due to the need for interdisciplinary engagement the new practice standard brings to the organization and brings other disciplines into the rollout process of the new practice standard. An example is the process of training the nurse-driven diabetes education team about the *Living Sweet* program. It is essential for these nurses to be well versed on how to download, use, and export data for the MySugr® application to an Android® or an iPhone® efficiently and effectively. Additionally, they will need to know how to change medication profiles and target blood sugar ranges as requested by primary care physicians, nurse practitioners, and physician assistants. The information technology leader was also brought into the project design portion. During the pilot the project leader received all of the EMR referrals, and this needed to know be delegated to the diabetic education team. Including the information technology leader in this project was essential to streamline the referral process to the appropriate people. The lowa model has distinct team building attributes and that is why it was selected for this EBP project.

Theory

This project was guided by the lowa model of evidence-based practice to promote quality care because of the team approach that is encouraged by the model to promote organizational change. The lowa model guided the integration of the weekly check-point evaluations which encouraged continual revisions of the project until an efficient sustainable protocol was reached. Much like the lowa model's internal check and balance system, these check points were an internal evaluation of the project as it progressed. The model added clarity to the process and encouraged project leaders to assess and address barriers and limitations throughout the evaluation process.

Research

Further research and education are needed to determine if reduction of HbA1C, SCP. and SCB improvements are sustainable using a diabetes-specific multi-functional MHA. The exportation of participant data to providers was instrumental to encourage accountability and positive impact on HbA1C, SCP, and SCB. An extended timeframe would be especially helpful in determining the impact on primary and secondary outcomes as well as participant engagement and attrition. Including a larger number of participants of different races, socioeconomic status, and different healthcare settings would help determine generalizability and feasibility. Recorded SCBs showed a decline over the 8-week implementation, however this was not a true reflection of adherence to the use of the MHA because pre-intervention SCB analysis was not completed in this project. Evaluating pre-intervention recorded SCBs and comparing them to post- intervention recorded SCBs would have added more value and clarity to this data. Perceived SCBs showed an increase in over the 8-week implementation period, with the exception of activity engagement, which did not show improvement after the MHA was implemented. Also, an extended follow-up evaluation of six to 12 months of the HbA1C results, SCPs, and SCBs by the project leader may add merit and speak to sustainability of the use of a MHA for the self-management of adults with uncontrolled T2DM.

Education

Participant education was provided throughout this EBP project. The initial start-up meeting included printed material, and from that material dialogue was initiated by the project leader. Additionally, printed material was also created to guide the providers about the details and goals of the *Living Sweet* MHA program. This was designed to help them introduce the program to potential participants. The printed material included explanation of the referral process that was embedded in the electronic medical records. The material also informed providers that they would be receiving exported weekly data from their patients who decided to join the program. Prior to this EBP project the project leader and the other providers at the organization had not used smartphone applications to promote glycemic efficacy, SCPs, or SCBs. The nurse practitioners were key for educating their patients about the program and for initiating referrals through the electronic medical record and secured email system. They provided the project leader with warm referrals to the *Living Sweet* program and this allowed for a successful pilot.

Primary care physicians, nurse practitioners, and physician assistants have the responsibility to stay educated on technologic advancements that may empower individuals to not only manage their chronic disease, but to make improvements on outcome measures and prevent complex comorbid conditions. It is imperative they attend continuing education conferences and stay engaged in high level and high-quality literature.

Conclusion

The findings of the EBP project determined that the diabetes-specific multi-functional MHA contributed to improving HbA1C, SCP, and SCB with the exception of activity engagement in the primary care setting. Moreover, use of a MHA for adults with uncontrolled T2DM is a feasible, sustainable, evidence-driven intervention that can contribute to diabetes self-care practices and prevention of comorbid conditions related to uncontrolled T2DM. This EBP project

used MySugr® smartphone application, but use of other MHAs are expected to reach similar outcomes to those found in this project. Other applications that are free of charge and multifunctional similar to MySugr® are Glucose Buddy®, Diabetes Pal®, and Diabetes: M®.

Findings from the EBP project were congruent with those reported in the literature and answered the PICOT question: "In adult T2DM patients with HbA1C values higher than 8.0 in a primary healthcare setting (P) what is the effect of a mobile-phone diabetes support application (I) compared to traditional diabetes education (C) on HbA1C results, self-management behaviors, and self-care perception (O), over an 8-week period (T)? It was determined that the use of a MHA should be encouraged by primary care providers to promote glycemic efficacy, improve self-care perception, and promote self- care behaviors, such as glucose monitoring and recording and medication adherence, ultimately leading to a reduction in complex comorbid conditions. Nurse practitioners will monitor data exported by patients using the information to change medication regimens and dosages, activity recommendations, and glucose monitoring intervals to promote glycemic control and improve SCP and SCB practices.

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BIOGRAPHICAL MATERIAL

Chantel K. Anderson

Mrs. Anderson completed her Associates of Science in Nursing degree at Purdue University North Central in 1994, and worked in various emergency departments throughout Northwest Indiana. After some encouraging words from Dr. Janet Brown, she decided to enroll into the Bachelors of Science in Nursing program at Valparaiso University and completed this degree in 2001. Mrs. Anderson returned to Valparaiso University to earn her Masters of Science in Nursing degree in 2008 and a post-master's certificate as a Family Nurse Practitioner in 2009. Currently she is earning a Doctor of Nursing Practice degree with the intent of graduating in May, 2020. As an Advanced Practice Nurse, Mrs. Anderson has chosen the rural healthcare setting with special interest in adults with type II diabetes mellitus, pediatrics, women's health, prevention, and wellness. Serving the undeserved has also been a passion for her, with the intent to bring hope, holistic healthcare, and humanity into less privileged communities. She is an enthusiast of nursing theorist Betty Neuman and her current practice supports Neuman's belief that health is equated with wellness. Chantel has been a member of Sigma Theta Tau International Zeta Epsilon chapter, and ANCC certified for ten years. She co-authored an article with Dr. Kristen Mauk, Dr. Julie Brandy, Dr. Sara Garcia, and Anna Kennel MSN, that was a qualitative study regarding the health beliefs of the frail elderly, and it was published in *Jacobs* Journal of Gerontology. Additionally, she has successfully presented her doctoral evidencebased practice project, Living Sweet: A Multi-Functional Mobile-Phone Application Strategy for Adults with Uncontrolled Type 2 Diabetes Mellitus, for the Coalition of Advanced Practice Registered Nurses of Indiana at their state conference in Indianapolis.

ACRONYM LIST

ADA: American Diabetes Association

AGREE II: Appraisal of Guidelines for Research & Evaluation II

ANA: American Nurses Association

CASP: Critical Appraisal Skills Programme

CMS: Center for Medicare and Medicaid Services

DM: Diabetes Mellitus

DNP: Doctor of Nursing Practice

EBP: Evidence-Based Practice

EMR: Electronic Medical Record

HbA1C: Hemoglobin A1C

LOE: Level of Evidence

MHA: Mobile Health Application

NIH: National Institutes of Health

T2DM: Type 2 Diabetes Mellitus

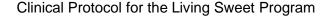
T1DM: Type 1 Diabetes Mellitus

SCB: Self-care Behavior

SCP: Self-care Perception

SMBG: Self-Management of Blood Glucose

Appendix A





Living Sweet: An Adult Type 2 DM Management Program

Patients must know their email and password that is associated with the app. store on their phones. Ensure phone updates are completed prior to initial visit. Ensure email and password is known for app. verification purposes.

PURPOSE: The is an evidence based project aimed at reducing glycated hemoglobin, while fostering self-care perception and self-care behaviors such as medication adherence, blood glucose monitoring, and physical activity engagement through the use of a diabetes-specific mobile smart phone application.

INCLUSION CRITERIA: Participants must be 18 years or older, have type II diabetes, have the most recent HbA1C of greater than 8.0, and have access to a mobile smart phone. Pregnant women are not eligible to be in this program.

- A referral is to be made through the secure electronic medical record to the designated program staff member.
- The designated program staff member will confirm inclusion criteria, discuss participant guidelines, and provide hands-on and written instructions.
- The designated program staff member and participant will determine personalized goals for blood glucose testing, physical activity, and medication administration (other self-care activities may be added upon request).
- Participants will utilize the diabetes-specific mobile smart phone application to upload blood sugars, physical activity events, and medication administration events that are patient-driven and individualized.
- Participants will send their uploaded results to the designated program staff member based on a pre-determined time not to exceed 2 weeks.
- The designated program staff member will place reminder calls or texts in the event results are not received at the timeframe that was decided upon at initiation of the program.
- Designated program staff member will review and communicate exported data to respective primary care providers. Providers will order specific medication regimens, activity goals, and glucose testing intervals. This will then be communicated to the patients by the designated staff member.



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Project Advisor

Appendix B Demographic Collection Form

CODE	PRE-	AGE	DOB	SEX	RACE	MEDICATION	YEARS	POST-
	HbA1C			1=	1=	1= ORALS	DX	HbA1C
				FEMALE	WHITE	2= INSULIN	WITH	
				2=	2=	3= ORALS AND	T2DM	
				MALE	BLACK	INSULIN		
					3=	4= ORALS AND		
					HISPANIC	NON-INSULIN		
					4=	INJECTIBLE		
					OTHER	5= NON-		
						INSULIN		
						INJECTIBLE		
						6= ORALS,		
						INSULIN, AND		
						NON-INSULIN		
						INJECTIBLE		
001	10.0	52	7/10/67	2	1	2	3	8.9
002	11.0	47	2/20/72	1	1	3	10	9.0
003	9.7	58	4/7/61	1	1	1	15	7.4
004	11.5	65	2/10/54	1	1	1	15	7.5
005	8.9	57	12/14/61	1	1	6	15	7.5
006	10.9	51	12/27/67	1	1	1	0.5	8.7
007	9.2	54	7/24/65	2	1	1	15	7.7
008*	0	0	0	0	0	0	0	0
009	9.4	45	6/2/45	1	1	2	15	6.7
110	10.0	43	7/14/76	1	1	3	15	8.3
120	8.9	47	1/27/72	1	1	3	22	6.7
130**	10.6	49	5/21/70	1	1	1	11	0
140**	8.4	36	1/2/83	2	1	2	10	0
150**	12.4	42	8/5/76	2	1	1	7	0
160*	0	0	0	0	0	0	0	0
170	8.9	45	2/25/74	2	1	1	10	7.2
180**	11.0	45	12/14/73	1	1	2	8	0
190*	0	0	0	0	0	0	0	0
200	9.9	62	7/27/57	1	1	4	18	8.9
210	9.6	43	5/30/76	1	1	2	3	9.7
220	11.8	55	3/24/64	2	1	2	21	10.4
230	9.8	44	1/27/75	1	1	3	10	8.1
240	8.4	48	11/9/71	1	1	1	0.5	6.8
250	10.3	71	9/1/48	1	1	3	31	8.5
260	9.0	52	6/25/67	2	1	3	10	9.7

^{*} Participant did not start the program as intended ** Participants did not finish the program

Appendix C

Participant Information Sheets



Living Sweet: An Adult Type 2 Diabetes Mellitus Management Program

Type 2 diabetes mellitus is one of the most chronic diseases, and the number of people who have it is getting higher.

Staying on a treatment plan for diabetes is very hard, even when you know the bad health events that are because of high blood sugars and glycated hemoglobin (HbA1C).

A HbA1C above 8.0 is diabetes that is not under control. This causes diabetic problems such as heart attacks, strokes, bad sight, loss of limbs, pain to nerves in the feet, and bad kidneys.

The use of a mobile smart phone application (APP) has shown to lower blood sugars, increase workouts, help with medication plans, and lower HbA1C.

Living Sweet is a program at Pulaski Memorial Hospital Clinics and was made because of research results that showed that APPs lower HbA1Cs and help to take medication, blood sugars, and doing workouts.

When you join the 8-week program you will get hands-on and written details for downloading the free application to your smart phone, using the APP, setting reminders that are just about you and your goals, and uploading your information for your health care provider to review at a time that is easy for you. The project leader will come to you for this training.

In general, the program will use an APP that is user-friendly, time-friendly, and can be used with an Android or iPhone. There is no cost to me.

Please ask your provider if they think you could be in this program. You must be 18 years or older, have type 2 diabetes, have a HbA1C of more than 8.0, and have a smart phone. Pregnant women are not able to be in this program.



Chantel Anderson MSN, FNP-BC Program Leader



219-863-9298

-Melissa Jones

Project Advisor



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Pulaski Memorial Hospital Clinical Site Preceptor -Dr. Christine Kurtz Valparaiso University Project Advisor -Dr. Nola Schmidt Valparaiso University



I agree to join the 8-week Living Sweet Program, and I know that I can leave at any time for any reason without a problem.

I know that this program will not change regular health care services that I receive from my current provider.

I know that I can join for free, and it will stay free even if I stop the program before the end of the 8-weeks.

I know that my info will remain private and the HIPPA rules will be used with all services that I get. My name will always be kept secret by using a number code for the information about to me.

I agree to let the project leader get the diabetic APP data that I offer or upload during the 8-week program.

I understand that this program is meant to help change the way I take care of my daily diabetes by blood sugar checking, taking medication, and physical workouts.

I understand using this phone APP is to lower a high HbA1C results.

I understand that the data gathered from this program will be talked about at Valparaiso University and possibly other places. This is important to help other people care for their diabetes.

I will keep in touch with the project leader during the 8-week program, and when I have questions about the APP or about the program.

I agree to work with the project leader to select personal goals I want to reach by using the APP. These goals will be about taking medication, working out, and blood sugar testing that will help lower HbA1C levels.

NAME:
DATE OF BIRTH:AGE:
SEX:
EMAIL:
PROVIDER EMAIL:
RACE:
HOW MANY YEARS HAVE YOU KNOWN YOU HAD DIABETES?
HOW OFTEN DO YOU EXERCISE?
MEDICATIONS:

Appendix D

Self-Care Inventory-Revised

Self-Care Inventory-Revised Version (SCI-R) This survey measures what you actually do , not what you are advised to do. How have you followed your diabetes treatment plan in the past 1-2 months?

dre davise	NEVER	RARELY	SOMETIMES	USUALLY	ALWAYS	I months:
1 Check blood	1	2	3	4	5	
	1	2	3	4	3	
glucose with						
monitor	4		2	4		
2 Record blood	1	2	3	4	5	
glucose results						
3 If type 1:	1	2	3	4	5	Have Type 2
check ketones						diabetes
when glucose						
level is high						
4 Take the	1	2	3	4	5	Not taking
correct dose of						diabetes pills
diabetes pills						or insulin
or insulin						
5 Take	1	2	3	4	5	Not taking
diabetes pills						diabetes pills
or insulin at						or insulin
the right time						
6 Eat the	1	2	3	4	5	
correct food	•	_		'		
portions						
7 Eat	1	2	3	4	5	
meal/snacks on	1	2	3	4	3	
time	1	2	2	4	-	
8 Keep food	1	2	3	4	5	
records	4		2	4		
9 Read food	1	2	3	4	5	
labels						
10 Treat low	1	2	3	4	5	
blood glucose						
with just the						
recommended						
amount of						
carbohydrate						
11 Carry quick	1	2	3	4	5	Never had low
acting sugar to						blood glucose
treat low blood						
glucose						
12 Come in for	1	2	3	4	5	
clinic						
appointments						
13 Wear a	1	2	3	4	5	
Medic Alert ID	-	_		· ·		
14 Exercise	1	2	3	4	5	
15 If on	1	2	3	4	5	Not on insulin
insulin: Adjust	1			- T		110t on mount
insulin dosage						
based on						
glucose values,						
food, and						
exercise						

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Appendix E

Check Point Tracking Form

PC/ DOB	IA1C	SD	ED	WK 1	WK 2	WK 3	WK 4	WK 5	WK 6	WK 7	WK 8	EA1C	WC
001	10.0	9/6	11/2	9/14	9/21	9/28	10/5	10/12	10/19	10/26	11/2	11/2 8.9	8
002	11.0	9/12	11/8	9/20	9/27	10/5	10/12	10/19	10/26	11/1	11/8	11/11 9.0	8
003	9.7	10/6	12/2	10/14	10/21	10/28	11/4	11/11	11/18	11/25	12/2	12/2 office	3
004	11.5	9/26	11/22	10/4	10/11	10/18	10/25	11/1	11/8	11/15	11/22	11/22 home	8
005	8.9	9/28	11/24	10/6	10/13	10/20	10/27	11/3	11/10	11/17	11/24	11/24 7.5	8
006	12.3/	9/13	11/9	9/21	9/28	10/6	10/13	10/20	10/27	11/2	11/9	11/11 8.7	8
007	8.9/	9/17	11/13	9/25	10/3	10/10	10/17	10/24	10/31	11/6	11/13	11/15 7.7	8
008	x	X	х	х	х	x	x	х	х	х	X	X	x
009	9.4	9/26	11/22	10/4	10/11	10/18	10/25	11/1	11/8	11/15	11/22	11/22 home	3
110	10.0	9/27	11/23	10/5	10/12	10/19	10/26	11/2	11/9	11/16	11/23	11/23 home	6
120	8.9	10/1	11/24	10/9	10/16	10/23	10/30	11/6	11/13	11/20	11/27	11/27 home	4
130	10.6	10/8	12/4	10/16	10/23	10/30	11/6	11/13	11/20	11/27	12/4	12/4 home	X
140	8,4	10/16	12/12	10/24	10/31	11/7	11/14	11/21	11/28	12/5	12/12	12/12	X
150	12.4	10/1	11/27	10/9	10/16	10/23	10/30	11/6	11/13	11/20	11/27	home 11/27	X
160	X	Х	X	X	X	X	X	X	X	X	X	home x	X
170	8.9	10/1	11/27	10/9	10/16	10/23	10/30	11/6	11/13	11/20	11/27	11/27	4
180	11.0	10/1	11/27	10/9	10/16	10/23	10/30	11/6	11/13	11/20	11/27	call 11/27	х
100				Х	Х	X	X	X	X	X	X	home	
190	X	Х	Х	Х	X	X	Х	Х	Х	Х	X	X	X
200	9.9	10/11	12/7	10/19	10/26	11/2	11/9	11/16	11/23	11/30	12/7	12/7 office	5
210	9.6	10/10	12/5	10/17	10/24	10/31	11/7	11/14	11/21	11/28	12/5	12/5 home	6
220	11.8	10/8	12/4	10/16	10/23	10/30	11/6	11/13	11/20	11/27	12/4	12/4 home	0
230	9.8	10/8	12/4	10/16	10/23	10/30	11/6	11/13	11/20	11/27	12/4	12/4 home	3
240	8.4	11/7	1/9/2 0	11/15	11/22	11/29	12/6	12/13	12/20	12/27	1/2/ 20	1/2/ 20	8
250	10.3	11/25	1/15/20	11/27	12/4	12/11	12/18	12/24	1/2/2	1/8/2	1/15/20	office 1/15/2 0	8
260	9.0	11/14	1/9	11/21	11/28	12/5	12/12	12/19	12/26	1/2/20	1/9/ 20	1/9/	8
CODES											<u> </u>		

CODES:

X= DID NOT START OR FINISH THE PROGRAM

PC= PARTICIPANT CODE. DOB= DATE OF BIRTH.

IA1C= INITIAL HBA1C, INITIAL SELF-CARE INVENTORY-REVISED TOOL, PATIENT-DRIVEN BEHAVIOR GOAL SETTING.

SD= START DATE. ED= END DATE.

WK1= WEEK 1 CHECK POINT COMPLETED.

WK2= WEEK 2 CHECK POINT COMPLETED.

WK3= WEEK 3 CHECK POINT COMPLETED.

WK4= WEEK 3 CHECK POINT COMPLETED.

WK5= WEEK 3 CHECK POINT COMPLETED.

WK6= WEEK 5 CHECK POINT COMPLETED.

WK7= WEEK 7 CHECK POINT COMPLETED.

EA1C= (WEEK 8 CHECK POINT COMPLETED) END OF PROGRAM, FINAL HBA1C, REPEAT SELF-CARE INVENTORY-REVISED TOOL, PARTICIPANT SATISFACTION SURVEY.

WC= WEEKS COMPLETED: 1=1 WEEK, 2=2 WEEKS, 3=3 WEEKS, 4=4 WEEKS, 5=5 WEEKS, 6=6 WEEKS, 7=7 WEEKS, 8=8 WEEKS.

Appendix F

Tracking Calendar

		Jl	JLY 2	019					AUC	GUST	Γ 201	9			S	EPTI	EMBI	ER 20	19	
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Appendix G

Patient Satisfaction Survey

PLACE 1 CHECK FOR EACH LINE

Please rate your experience with the use of the diabetes-specific mobile phone application MySugr®

		T	T	1	1
	STRONGLY	AGREE	UNDECIDED	DISAGREE	STRONGLY
	AGREE =5	= 4	= 3	= 2	DISAGREE=1
I found the					
application					
easy to upload					
on my phone.					
I found the					
application					
easy to use.					
I found the					
application					
made it easy					
to upload my					
results to my					
provider.					
I found					
application					
helped me to					
track my blood					
sugar results.					
I found the					
application					
helped me to					
track my					
physical					
activity.					
I found the					
application					
helped me to					
track my					
medications.					
OVERALL, I					
found the					
application					
helped me to					
manage my					
diabetes.					

Appendix H

Behavior Tracking form

Living Sweet: A Multi-Functional Mobile-Phone Application Strategy for Adults with Uncontrolled Type 2 Diabetes Mellitus

CODE	WEEK#	GLUCOSE	PHYSICAL	MEDICATION
		1=MET	ACTIVITY	ADHERENCE
		2= NOT MET	1=MET	1=MET
			2=NOT MET	2 = NOT MET
INITIAL A1C	WEEK 1			
Glucose/Goal:	WEEK 2			
	WEEK 3			
Activity/Goal:	WEEK 4			
	WEEK 5			
Medication/Goal:	WEEK 6			
	WEEK 7			
FINAL A1C	WEEK 8			
WEEKS:				

CODE	WEEK#	GLUCOSE	PHYSICAL	MEDICATION
		1=MET	ACTIVITY	ADHERENCE
		2= NOT MET	1=MET	1=MET
			2=NOT MET	2 = NOT MET
INITIAL A1C	WEEK 1			
Glucose/Goal:	WEEK 2			
	WEEK 3			
Activity/Goal:	WEEK 4			
	WEEK 5			
Medication/Goal:	WEEK 6			
	WEEK 7			
FINAL A1C	WEEK 8			
WEEKS:				

Appendix I

Provider Information Sheet

Living Sweet: An Adult Type 2 DM Management Program

PROVIDER INFORMATION:

PURPOSE: This is an evidence driven project aimed at reducing glycated hemoglobin, while fostering self-care perception and self-care behaviors such as medication adherence, blood glucose monitoring, and physical activity engagement through the use of a diabetes-specific mobile smart phone application.

INCLUSION CRITERIA: Participants must be 18 years or older, have type II diabetes, have the most recent HbA1C of greater than 8.0, and have access to a mobile smart phone. Pregnant women are not able to be in this program.

GENERAL INFORMATION FOR PARTICIPANTS:

PROGRAM OVERVIEW:

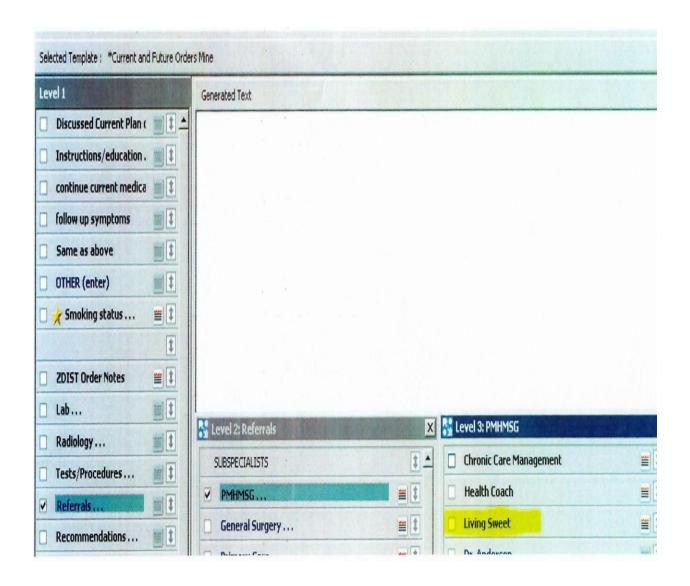
- Free diabetes-specific mobile application to be down loaded to the participant's mobile smart phone. (Android and iPhone compatible)
- In person, hands-on and written instructions will be provided by the project leader or designee. Access to the project leader will be available 7 days a week for trouble shooting and questions.
- Patient-centered, individualized reminders and goals will be set for each participant at the initial meeting and can be adjusted throughout the pilot program to meet individual needs of each participant.
- Each participant will be encouraged to use the application for a minimum of 8 weeks, and upload and send results to the project leader or designee. After 8 weeks an HbA1C will be recorded. They may choose to stop the program at any time for any reason.

PRODUCT:

A diabetes-specific mobile application: Mysugr® will be used for this pilot program to encourage selfmanagement behaviors that ultimately lead to improved HbA1C results.

Appendix J

EMR Referral Page



Appendix K

Participant Privacy Log

Living Sweet: A Multi-Functional Mobile-Phone Application Strategy for Adults with Uncontrolled Type 2 Diabetes Mellitus

CODE	DATE OF BIRTH	PHONE NUMBER
001		
002		
003		
004		
005		
006		
007		
008		
009		
110		
120		
130		
140		
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170		
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