EVALUATING THE UTILIZATION OF A COMBINATION THERAPY TO IMPROVE SELF-EFFICACY AND GLYCEMIC CONTROL IN PATIENTS WITH TYPE TWO DIABETES MELLITUS AND LOW HEALTH LITERACY

1

A Scholarly Project

Submitted to the

Faculty of Liberty University

In partial fulfillment of

The requirements for the degree

Of Doctor of Nursing Practice

By

Crystal Manus Masling

Liberty University

Lynchburg, VA

July, 2020

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ABSTRACT

Type 2 diabetes mellitus is a significant health issue, as it requires patients to perform daily selfmanagement activities. One in every three Americans with Type 2 diabetes has limited or low health literacy skills. Limited or low health literacy skills can impact a patient's overall health outcome; therefore, a critical element for disease management and patient adherence is health literacy. The purpose of this three-month scholarly project was to determine if the utilization of an educational intervention specific to one's level of health literacy, combined with a short message service reinforcement tool, could improve glycemic control and self-efficacy in Type 2 diabetes mellitus patients with limited and low HL. A sample of four participants was recruited for this scholarly project. Participants completed pre and post self-efficacy and health literacy questionnaires. During the three-month intervention phase, participants interacted with the project leader utilizing the text messaging reinforcement tool. After the three-month intervention phase, participants had an overall 9% increase in self-efficacy confidence, a 42% overall increase in health literacy knowledge, and an overall HbA1c mean value reduction of 0.5%. This combination therapy intervention is easy and convenient for health care providers and Type 2 diabetes mellitus patients with limited or low health literacy. This intervention is an efficient and effective method to improve patients self-efficacy and diabetes knowledge; furthermore, this method improves patient self-management skills, glycemic control, and patient longevity.

Keywords: diabetes mellitus, self-efficacy, self-management, short message service, health literacy

Dedication

To my husband, Hunter; my momma, Rhonda; and my daddy, Danny; I couldn't have done this

without you!

I love you all more than words could ever describe.

Acknowledgments

First, I want to thank my husband, Hunter, and my parents, Rhonda and Danny, for their love, support, and encouragement. Hunter, you have been my greatest supporter, encouraged me through every journey I have taken, and given me more courage than I ever imagined. You made me a lion.

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List of Abbreviations

American Diabetes Association (ADA)

Collaborative Institutional Training Initiative (CITI)

Diabetes mellitus (DM)

Evidence-based practice (EBP)

Health literacy (HL)

Human immunodeficiency virus (HIV)

Institutional Review Board (IRB)

MEssaging for Diabetes (MED)

National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Newest Vital Sign (NVS)

Randomized controlled trial (RCT)

Short message service (SMS)

Socioeconomic status (SES)

Statistical Package for the Social Sciences (SPSS)

Type 1 Diabetes Mellitus (T1DM)

Type 2 Diabetes Mellitus (T2DM)

SECTION ONE: INTRODUCTION

Diabetes mellitus (DM) is a significant, global health problem; 425 million people worldwide have diabetes, and cases are expected to rise by 204 million by 2045 (Abdullah, Liew, Salim, & Chinna, 2019). To achieve disease control, individuals with DM perform approximately 95% of their independent daily self-management activities (Abdullah et al., 2019). For patients to make appropriate health decisions and manage one's disease, fundamental health literacy (HL) is critical (Abdullah et al., 2019). Limited or low HL has been associated with poorer outcomes, less health-related knowledge, less adherence, and poor self-care behaviors (Abdullah et al., 2019; Koonce, Giuse, Kusnoor, Hurley, & Ye, 2015). Therefore, the purpose of this scholarly project was to identify if an HL-specific educational program, when combined with a short message service (SMS) intervention, could improve glycemic control and selfefficacy in a patient with Type 2 diabetes mellitus (T2DM) over a three-month period.

Background

In 2017, 30.3 million people (9.4% of the total population) in the United States had a diagnosis of DM (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2019). An estimated 23.1 million people (7.2% of the total population) have been diagnosed, while roughly 7.2 million adults have not (NIDDK, 2019). There are three classifications of diabetes: Type 1 (T1DM), T2DM, and gestational. For the purpose of this scholarly project, the primary focus was T2DM.

Based on the 83,564 death certificates in 2017, DM was the seventh-leading cause of death in the US (American Diabetes Association [ADA], n.d.). The total annual cost of diabetes-related treatment in 2017 was \$327 billion; of that value, \$237 billion was for direct medical costs (ADA, n.d.). The ADA (n.d.) indicates the average medical expenditures in 2017 for those

diagnosed with diabetes were 2.3 times higher than for those without a diabetes diagnosis. The National Diabetes Statistic Report from 2015 identified the following: (a) an annual diagnosis rate of 1.5 million new cases, (b) diabetes prevalence increases at age 65 and older (25%), (c) prevalence is higher among American Indians/Alaska Natives (15.1%), (d) prevalence varies with level of education, increasing with HL, and (e) the highest prevalence rates are in the southern and Appalachian areas of the US (National Center for Chronic Disease Prevention and Health Promotion [NCCDPHP], 2017).

Representing 90%–95% of all diabetes diagnoses, T2DM is a result of insulin resistance (NCCDPHP, 2017). Insulin resistance occurs as a result of weight gain, obesity, and physical inactivity (NIDDK, 2019). DM can lead to microvascular and macrovascular complications. Microvascular complications include neuropathy and retinopathy. Macrovascular complications include peripheral vascular disease, coronary artery disease, and cerebrovascular accident.

Bohyuun, Song, and Kim (2019) indicated the ultimate treatment goal for patients with T2DM is to maintain a healthy lifestyle while preventing chronic complications; this can be achieved through effective glycemic control, self-efficacy, and self-care management behaviors. Until recently, diabetes self-care management research has focused primarily on how to improve self-management behaviors; however, studies now suggest that in order to improve these behaviors and self-efficacy, educational programs need to be tailored to patient learning style and preferences (Bohyuun et al., 2019; Koonce et al., 2015). Self-efficacy is the belief that a specific outcome will occur as a result of a specific behavioral change; it is affected by self-management and problem-solving (Bohyuun et al., 2019; Gedik, 2017). Patient self-efficacy is positively associated with improved T2DM control through self-management behaviors (Amer, Mohamed, Elbur, Abdelaziz, & Elrayah, 2018; Tharek et al., 2018).

In 2010, the Centers for Disease Control and Prevention established the National Diabetes Prevention Program to encourage lifestyle modifications through diet and exercise to prevent or delay T2DM and/or complications (NCCDPHP, 2017). Additional partnerships to spread diabetes awareness include the National Institutes of Health, the ADA, the Ad Council, and the American Medical Association. All partnerships have been made in hopes of improving diabetes self-management education access (NCCDPHP, 2017).

The U.S. Department of Education (2019) revealed 43 million adults have low literacy skills, or approximately one in five Americans. Low literacy skills are strongly correlated with low socioeconomic status (SES); however, as of 2019, 96% of all Americans have a mobile device, and 26% of those classified as low SES have smart phones (Pew Research Center, 2019). Literature continuously identifies the significance of lifestyle modification through diet and exercise; yet, only 30% of T2DM patients achieve blood pressure, glycemic control, and cholesterol targets (Abdullah et al., 2019). In recognizing that current guidelines continue to stress the importance of simple lifestyle modifications, one must ask the question, why are these measures not being met? To achieve a therapeutic outcome in diabetes management, the key is to identify an individual's HL level, target patient-specific education, and utilize current resources (mobile devices) to improve self-efficacy, self-management behaviors, and glycemic control (Abaza & Marschollek, 2017; Amer et al., 2018; Koonce et al., 2015). Therefore, this scholarly project targeted T2DM patients with limited or low HL with an end goal of improving self-efficacy confidence and glycemic control using a basic HL educational pamphlet with a mobile reinforcement intervention tool.

Problem Statement

Despite treatment, prevention pursuits, and clinical awareness, T2DM is a continuously evolving disease. If the current trend continues, by year 2050, one in three American adults will have DM (Koonce et al., 2015). Diabetes is a threat to mankind; prevalence is found to be higher among minority and aging populations, individuals with low HL, and those classified as low SES. A clear association has been identified between diabetes knowledge and HL; therefore, to improve self-efficacy, self-management behaviors, and glycemic control, a tailored educational program is imperative to halt disease progression.

Purpose of the Project

The purpose of this scholarly project was to determine if the utilization of an HL-specific educational intervention combined with an SMS reinforcement tool could improve glycemic control and self-efficacy in T2DM patients. T2DM patients who are classified as having low HL and low SES often receive minimal disease education and self-management skill training. Therefore, the aim of this project intervention was to improve participant blood glucose levels, confidence in disease management, and overall quality of life.

Clinical Question

In patients with Type 2 diabetes and low health literacy, does HL-specific diabetes education combined with an SMS intervention, when compared to previous standard diabetes education, improve glycemic control and self-efficacy over a three-month period?

SECTION TWO: LITERATURE REVIEW

The purpose of this literature review is to explore DM and provide insight on the association between the chosen disease process and self-efficacy, self-management behaviors, and HL. Qualitative and quantitative research provide sufficient evidence to support a tailored,

HL-specific diabetes educational intervention and the importance of self-efficacy confidence in relation to positive self-care behaviors and glycemic control. This literature review identifies the benefits of automated text messages and tailored educational programs. To guide the writer through the evidence-based practice (EBP) process, the Iowa Model was utilized for the conceptual framework; to provide support and guidance for each project participant, the transtheoretical model was used. Chapter Two is divided into the following sections: search strategy, critical appraisal, synthesis, conceptual framework, theoretical framework, and summary.

Search Strategy

In an effort to provide the most applicable evidence, a comprehensive review of the literature using electronic databases was performed. The databases included CINAHL, Cochrane Library, Pubmed, Medline, and Google Scholar. For the purpose of this research topic, the following keywords were utilized: *diabetes mellitus, self-efficacy, self-management, health literacy*, and *short message service*. A total of 3,652 articles resulted; the addition of *health literacy* narrowed the search to 271 peer-reviewed articles. The original search that resulted in 3,652 articles was conducted a second time with the addition of keyword *SMS*; 232 articles resulted. Articles were then excluded using the following parameters: T1DM, gestational diabetes, pregnancy, and intellectual and developmental disabilities. Results were limited to articles published in the English language within the previous five years (2015–2019).

Critical Appraisal

Fifteen articles were chosen for this scholarly project; additional resources included the ADA and the NIDDK. Each article selected was analyzed using a summary and synthesis tool,

then evaluated according to Melnyk's levels of evidence (Melnyk & Fineout-Overholt, 2014). The table of evidence is provided in Appendix A.

Systematic reviews. A systematic review of 29 research studies involving 13,457 T2DM patients from seven different countries was conducted by Abdullah et al. (2019). This systematic review, a level one research study, was conducted to summarize and report the current global evidence on the prevalence of limited HL in patients with T2DM (Abdullah et al., 2019). The authors of the study completed an appropriate systematic review by searching five electronic databases: MEDLINE, PsychINFO, EMBASE, CINAHL, and ERIC (Abdullah et al., 2019). Authors concluded that HL tools and HL prevalence varied widely among different countries, and that one in every three patients in the United States with T2DM had limited HL.

Randomized controlled trials. Six randomized controlled trials (RCTs) were utilized for this literature review. Abaza and Marschollek (2017) completed a 12-week RCT to examine the impact of SMS education on self-management behaviors and glycemic control when compared to standard paper-based education methods among patients with T2DM in Egypt. Seventy-three English-speaking, Type 2 diabetes patients aged 18 years and older were included in this study, 34 in the intervention group and 39 in the control group. A 1% reduction in HbA1c values (p =0.003) was noted in the intervention group; secondary outcomes included improvements in medication adherence, knowledge scores, and self-efficacy values (Abaza & Marschollek, 2017).

Two short-term RCTs provided significant evidence to support the utilization of automated text messages in the improvement of patient adherence and the importance of targeting HL when educating patients with T2DM. The mobile health system, an SMS intervention, created to target patient adherence was well accepted and utilized among T2DM patients after four short weeks (Fioravanti, Fico, Salvi, García-Betances, & Arredondo, 2015). The intervention resulted in an increase in medication adherence in both T1DM and T2DM patients. However, future outcomes could be affected due to the short time frame, small sample size (26 intervention patients), and limited clinical location (Fioravanti et al., 2015). Koonce et al. (2015) completed an RCT with 160 patients with T2DM to investigate the correlation of targeted HL education materials to learning styles in a community clinic. After two weeks, the mean value of diabetes knowledge questions answered by the intervention group had significantly increased (p = 0.0000), and after four weeks, the increase continued (p = 0.00). This RCT provided key evidence to support an increase in patients' diabetes knowledge after exposure to educational materials tailored to their learning style, preference, and HL level (Koonce et al., 2015).

An RCT to examine the effectiveness of SMS reminder messages on antiretroviral prophylaxis among human immunodeficiency virus (HIV)-positive youths was conducted on 332 participants from two HIV clinics in Kampala (Linnemayr et al., 2017). This study identified SMS reminder messages are not always as effective in behavioral change among HIV-positive youth (Linnemayr et al., 2017). To compare face-to-face interviews and text messages for a public health study, a secondary RCT was completed in several rural areas of China (van Velthoven et al., 2018). This study identified 1,014 potential participants. Of the gathered participants, 651 agreed to participate; however, only 356 completed the SMS survey (van Velthoven et al., 2018). The public health study revealed SMS data produced similar results when compared to face-to-face surveys in this middle-income area (van Velthoven et al., 2018). Both RCTs provided a useful evaluation of the SMS as an intervention tool; however, weaknesses identified among both studies were poor communication, short/unknown time frames, centralized locations, and poor response rates.

Quasi-experimental. Two quasi-experimental research studies utilized SMS interventions to authenticate short-term improvement with medication adherence, physical activity, self-efficacy, and perceived family support. Lari, Noroozi, and Tahmasebi (2018) evaluated 74 patients with T2DM over a 12-week period. When compared to the control group, the intervention SMS group produced changes in the "mean scores of perceived self-efficacy (p = 0.001) and family support (p = 0.046)" (Lari et al., 2018, p. 67); in addition, perceived barriers were significantly reduced over time (p < 0.001).

The MEssaging for Diabetes (MED) SMS intervention created by Nelson et al. (2016) utilized 80 patients with T2DM classified as low SES. When compared to baseline studies, patient adherence measures improved after four and eight weeks (Nelson et al., 2016). At the completion of week 12, the MED SMS intervention produced a positive short-term impact on medication adherence but not on glycemic control (Nelson et al., 2016). Both quasi-experimental studies were conducted in single primary care clinics over a short-term period; these limitations could affect future research.

Cross-sectional. To evaluate and examine the relationship between self-efficacy, selfcare behaviors, and glycemic control in a patient with T2DM, five cross-sectional research studies were evaluated. Self-efficacy among patients with T2DM is significantly associated with glycemic control and self-care activities (Amer et al., 2018; Tharek et al., 2018). A significant association between diabetes appraisal and diet knowledge (p = 0.047) was identified by Cheng, Sit, Leung, and Li (2016). Further research demonstrated a positive correlation between higher self-efficacy scores and diabetes self-care management behaviors (Bohyun, Youngshin, & Jong, 2019; Tharek et al., 2018). Huygens et al. (2017) investigated the relationship between patients' willingness to self-monitor and control of their chronic illnesses using 627 participants from a Dutch panel. A patient's willingness to self-monitor their disease depended highly on their disease type; patients with T2DM are more likely to self-monitor their disease(s) when provided appropriate self-monitoring applications (Huygens et al., 2017). Four of the five cross-sectional studies were conducted in one location, convenient nonprobable sampling methods were used, and self-reported measures were utilized for data collection; therefore, these limitations could affect research outcomes (Amer et al., 2018; Bohyun et al., 2019; Cheng et al., 2016; Tharek et al., 2018). The fifth study utilized a broad sample size containing various chronic illnesses; each chronic disease had a different number of participants, some more involved than others. The centralized location, broad sample size, and self-reported data measures were limitations within that study (Huygens et al., 2017).

Descriptive design. Gedik and Kocoglu (2018) collected data from April 2015 to June 2015 on 216 patients with T2DM. This nonexperimental, descriptive survey was conducted to assess the self-efficacy levels of T2DM patients living in rural Turkish areas. The nonexperimental survey utilized the Self-Efficacy for Type 2 Diabetes tool and found that individuals living in the rural areas of Turkey had moderate self-efficacy levels and poor disease management (Gedik & Kocoglu, 2018). Due to the localized sample and the sample size, findings from the survey are unable to be generalized; however, the survey could be used as evidence to support clinical change in that patients living in rural areas with T2DM who need diabetes education programs to improve self-efficacy levels.

Synthesis

T2DM is a chronic condition that can result in short-term and long-term complications. The project leader compiled four common themes from the literature review. The four dominant themes were HL interventions for patients with T2DM, diabetes self-efficacy and selfmanagement promotion techniques, mobile technology and automated text message use, and diabetes educational programs in rural locations. To improve self-efficacy, self-management behaviors, and glycemic control, each identified theme provided interventions to assist low-HL patients with T2DM.

Health literacy interventions for patients with T2DM. One in every three patients with T2DM in the United States are classified as having limited or low HL (Abdullah et al., 2019). Diabetes patient knowledge can significantly increase when patients are exposed to educational materials tailored to their learning preference, style, and HL level (Koonce et al., 2015).

Promotion of diabetes self-efficacy and self-management. Self-efficacy and selfmanagement are strongly connected with patient adherence and glycemic control improvements (Abaza & Marschollek, 2017; Amer et al., 2018; Bohyun et al., 2019). Cheng et al. (2016) emphasized that patients encounter numerous barriers in the course of diabetes self-management. A fundamental association was identified between self-efficacy barriers, diabetes knowledge, and an individual's willingness to self-monitor their disease (Cheng et al., 2016; Huygens et al., 2017). Higher self-efficacy scores in patients with T2DM were correlated with better self-care behaviors and improved glycemic control (Tharek et al., 2018).

Mobile technology and automated text message use. SMS interventions such as standard text messaging, the MED mobile app, and the mobile health system have proven to have positive outcomes when utilized with T2DM patients (Fioravanti et al., 2015; Lari et al., 2018; Nelson et al., 2016). When compared to standard face-to-face DM education, van Velthoven et al. (2018) revealed similar data were produced by education utilizing SMS interventions; however, a 1% reduction in HbA1c values was reported by Abaza and Marschollek (2017) during a 12-week RCT using non-standard methods (SMS education). A

previous study conducted by Linnemayr et al. (2017) reported SMS reminder interventions were helpful in the promotion of medication adherence, although it was not as effective in behavioral change. Additional research studies proved self-management behaviors are correlated with short-term improvements, including weight loss and reduction in waist circumference and lipid profiles (Lari et al., 2018; Silina, Tessma, Senkane, Krievina, & Bahs, 2017). When text messaging interventions were utilized, a positive association was seen with prescription adherence, diet, and physical activity (Abaza & Marschollek, 2017; Fioravanti et al., 2015; Nelson et al., 2016).

Diabetes education programs in rural locations. Gedik and Kocoglu (2018) found patients living in rural areas of Turkey had moderate self-efficacy levels and poor disease management skills. Diabetes education is a critical component of patient success for chronic disease management. Therefore, diabetes education programs should be established and tailored to patient needs and preference within specified (rural) areas. This scholarly project intervention created an HL-specific, DM educational program within a rural area of North Carolina with an objective to improve self-efficacy and disease management skills.

Conceptual Framework

The Iowa Model, created in the 1990s and revised in 2015, was utilized as the conceptual framework for this scholarly project (Iowa Model Collaborative, 2017). Frequently used to improve quality of care, the Iowa Model guides users through the EBP process using a seven-step algorithm (White, Dudley-Brown, & Terhaar, 2016). To promote health care excellence, Step 1 of 7 begins with the identification of a trigger. Once a trigger is identified, the purpose or clinical question is created, then a team is formed (Step 3), the evidence is evaluated (Step 4), an EBP intervention is designed (Step 5), the intervention is implemented (Step 6), and, finally, the

intervention is evaluated (Iowa Model Collaborative, 2017). If the intervention is successful and the change is proven to be effective, then the change can be integrated within clinical practice. Permission to use and/or reproduce the Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care for this scholarly project was granted by the University of Iowa Hospitals and Clinics on October 31, 2019 (see Appendix C).

Trigger identification and purpose statement. In the United States, 9.4% of the population has a diagnosis of DM. One in every five Americans is classified as having low HL; one in every three Americans diagnosed with T2DM has limited or low HL skills. DM is a chronic illness, requiring approximately 95% of independent daily self-management skills; therefore, adequate self-efficacy and self-management activities are essential for disease management. A patient who is classified with limited or low HL skills will often have poorer health outcomes, just as those who display poor self-efficacy and self-management abilities will (Abdullah et al., 2019; Abaza & Marschollek, 2017; Bohyun et al., 2019). The topic of interest for this project was the association between low HL and self-efficacy in patients with T2DM. Therefore, the project leader began communicating with local primary care offices to identify common management barriers between health care providers and patients with T2DM. Common barriers included low HL, low income, limited transportation, inadequate access to health insurance, and physician/provider shortage (Rural Health Information Hub, 2020). In the practice chosen for this scholarly project, the primary care provider had noticed a continuous increase in HbA1c values despite medication and educational interventions. The provider communicated to the project leader the difficulties he experienced daily due to the rural location of his clinic, including the inability to refer patients to specialty providers (i.e., endocrinologists, dieticians), provide adequate education, and provide management therapies. Due to these

reasons and common barriers, the purpose of this project was to create an HL-specific educational pamphlet with an SMS reinforcement tool that could be easily implemented in a rurally located primary care clinic. The goal of this project was to improve self-efficacy and glycemic control in T2DM patients with limited and low HL.

Team formation. Step 3 of the Iowa Model is the formation of a team. The project team leader began by identifying primary stakeholders, which included the project scholarly chair, the location for the project, and a primary care provider. The project team leader and the project chair communicated and collaborated to establish clear roles, guidelines, and recommendations for each stakeholder throughout the completion of the project. The project team for this scholarly project included the project team leader, the scholarly project chair, the primary care provider (a certified physician assistant), three nurses, three medical assistants, and one front desk ancillary staff member.

Assemble, appraisal and synthesis of evidence. Once the topic of interest was selected and the project team was established, the next step was to assemble, appraise, and synthesize the body of evidence (Iowa Model Collaborative, 2017). Step 4 included conducting a systematic review and evaluating the evidence, addressing the quality and strength of each research article (Doody & Doody, 2011; Iowa Model Collaborative, 2017). The team leader examined 15 articles for this scholarly project; each article was graded using Melnyk's levels of evidence. Melnyk's pyramid system of hierarchy contains six levels: the lower the number, the higher grade the evidence is. The literature review for this scholarly project contained Levels I, III, IV, and VI evidence. Level I evidence included a systematic review and RCTs examining the utilization of HL tools and mobile technology applications to improve self-efficacy and glycemic control in patients with T2DM. Level III evidence articles included two short-term, quasiexperimental studies. Level IV evidence articles included five cross-sectional studies that evaluated the relationship between self-efficacy, self-care behaviors, and glycemic control among T2DM patients. The Level VI evidence article was a nonexperimental descriptive survey that supported the existence of poor disease management and moderate self-efficacy levels in patients with T2DM. As evidence was found supporting glycemic control improvements, patient adherence, and self-efficacy confidence, this systemic review was proven successful to support the project leader in an EBP project. This literature review reinforced the use of tailored DM education, automated text messages, and diabetes educational programs in rural locations.

Developing an evidence-based practice standard. To create a set of practice standards, guidelines, and treatment options, the project leader developed a two-part intervention using information gained from the literature review. Conclusive evidence supported the utilization of tailored DM educational materials, mobile technology, and automated text messages for improving diabetes knowledge, self-efficacy, and glycemic control in T2DM patients.

Although positive evidence was discovered in an abundance regarding the identified themes, the project leader was unable to find literature combining the utilization of tailored DM educational materials for low-HL patients and automated text messages. Two critical components for patient adherence and disease management are diabetes education and identifying an individual's HL level. Therefore, the project leader utilized these two essential components to develop a two-part intervention: the first an HL-specific educational pamphlet, the second a text message reinforcement tool.

Patients with T2DM can benefit instrumentally from education programs when they are tailored to their learning style, preference, and HL level (Koonce et al., 2015). T2DM is a chronic, self-limiting disease requiring patients to perform approximately 95% of their

independent daily self-management behaviors. Self-efficacy and self-management behaviors are positively associated with patient adherence and glycemic control improvements (Abaza & Marschollek, 2017; Amer et al., 2018; Bohyun et al., 2019). However, evidence concluded patients living in rural locations often have poor disease management skills and moderate selfefficacy levels (Gedik & Kocoglu, 2018). Therefore, an HL-specific educational intervention was created for the limited- and low-HL patient with T2DM. The project leader created the educational intervention using resources from the ADA, the Centers for Disease Control and Prevention, the NIDDK, the Diabetes Plate method, and several diabetes specialty providers.

Living in an era of continuously evolving technology, the project leader evaluated the use of mobile technology and automated text message use. Mobile applications and standard text messaging have been shown to produce favorable outcomes when utilized with T2DM patients. Research has found a reduction in HbA1c values and an increase in positive self-management behaviors, including prescription adherence, physical activity, and diet compliance when mobile applications and text messaging are used (Abaza & Marschollek, 2017; Fioravanti et al., 2015; Lari et al., 2018; Nelson et al., 2016). Given the clear associations between mobile technology and favorable outcomes for patients with T2DM, the project leader designed an SMS reinforcement tool as a second part of the EBP project. Using information from the HL-specific educational diabetes pamphlet, the project leader created 12 "pop quiz" questions. Every Friday at 10:30 a.m. during the implementation phase, enrolled participants received a pop quiz question. The purpose of the weekly pop quiz was to reinforce an educational environment for the limited- and low-HL patient with T2DM.

The project leader designed a combination therapy for limited- and low-HL patients with T2DM with intent to improve self-efficacy and glycemic control. Patients who reside in low-

income and rural areas often lack access to proper health care, specialty providers, diet management, physical activity, and transportation. One in five Americans is classified as having limited or low HL skills, whereas one in three Americans with T2DM has limited or low HL (Abdullah et al., 2019; U.S. Department of Education, 2019). The purpose of this scholarly project was to create an educational pamphlet tailored to the learning style, preference, and low HL level of the average T2DM patient. This scholarly project aimed to increase a patient's diabetes knowledge and HL level to improve self-efficacy, self-management behaviors, and glycemic control.

Implementation of the evidence-based practice standard. After the scholarly project was designed, Institutional Review Board (IRB) approval was granted on January 20, 2020. The project leader then began meeting with the primary stakeholders to discuss project details and begin advertising. Advertisement flyers were posted two months prior to the commencement of the intervention phase (see Appendix G).

The project team leader aimed to recruit 30 participants; therefore, to gain interest from established patients, the primary care provider compiled a list of all patients with DM for the team leader. The project leader mailed each potential candidate a patient recruitment form (see Appendix I) explaining the purpose of the project, participant requirements, and potential prizes for participation. The participant recruitment form included the enrollment eligibility questionnaire (see Appendix J). Participants were provided a pre-stamped envelope with instructions to return the completed form if interested by February 28, 2020, allowing them one month to complete the task.

The scholarly project was divided into three phases: pre-intervention, intervention, and post-intervention. During the pre- and post-intervention phases, each eligible participant met

with the project leader for an allotted time. All participants completed a consent form, an enrollment eligibility form, and several questionnaires pertaining to self-efficacy and HL. During the pre-intervention visit, each participant was provided the HL-specific DM educational pamphlet and instructions for the SMS reinforcement tool. Additional measurements collected during the pre- and post-intervention phases included blood pressure, weight, and an HbA1c sample.

Phase two, implementation of the scholarly project, began March 16, 2020, and concluded June 18, 2020. During the three-month intervention phase, each participant received two daily text messages and one weekly pop quiz question. The daily text messages were removed after week three. Twelve pop quiz questions were generated from the HL-specific DM educational handout. Questions were sent to each participant every Friday morning at 10:30 a.m. All text message data were recorded and stored in Microsoft Excel.

At the conclusion of this scholarly project, the three participants with the greatest improvement scores in self-efficacy, HL, HbA1c values, and SMS involvement received prizes. The grand prize winner received a 40-inch Onn. Roku FHD smart television. The follow-up winner received a Fire HD Amazon tablet, while the third overall winner, received a pair of wireless Bluetooth Skull headphones. The purpose of this scholarly project was to combine two evidence-proven methods, mobile technology and tailored educational materials, into one intervention to improve self-efficacy and glycemic control in the low-HL patient with T2DM.

Evaluation. All data collected during the three-month time frame were stored in Microsoft Excel and analyzed utilizing the Statistical Package for the Social Sciences (SPSS) software program, version 25.0. Outcome data were analyzed and evaluated using descriptive statistics. Project data from the three-month pre-intervention period found that participants with lower educational levels, compared to those with an education level of some college (no degree), had higher HbA1c control values and lower self-efficacy confidence scores. Additionally, baseline HL values were correlated with lower educational levels. Post-intervention data analysis identified an increase in self-efficacy confidence and HL knowledge and a reduction in HbA1c values. Secondary evaluations included change in participant weight and blood pressure values between pre- and post-intervention comparison data. The greatest individual improvements witnessed during the three-month intervention were a 1.9% HbA1c reduction, a 12-pound weight loss, and an 18.75% increase in a self-efficacy confidence level.

When utilized and implemented correctly, diabetes self-management education tools can improve diabetes knowledge, skills, and patient adherence (Russell, Vess, Durham, & Johnson, 2016). The findings from this scholarly project demonstrate the successful application of diabetes self-management education tools. Therefore, EBP research should be evaluated further among patients with low HL and the increasing prevalence of T2DM.

Theoretical Framework

Developed in 1984 by Prochaska and DiClemente, the transtheoretical model of behavior change, also known as the stages of change model, was utilized for the theoretical framework (as cited in White et al., 2016). The original linear model consisted of four stages: precontemplation, contemplation, preparation, and action. In 1986, the model became a cyclic process when a fifth stage was added, the maintenance phase (White et al., 2016). To predict and move through the stages of change model, 10 processes of change were created in 1992 by Prochaska, DiClemente, and Norcross (as cited in White et al., 2016). The transtheoretical model has been successfully used to improve adherence in patients receiving counseling for HIV therapy, antihypertensive medication treatment, smoking cessation, and T2DM medication adherence (Arafat et al., 2019; White et al., 2016).

Self-efficacy and self-management behaviors have been identified as two of the most common reasons for uncontrolled T2DM; therefore, due to the behavioral nature of acceptance, the transtheoretical model was selected for this scholarly project. The transtheoretical model aids individuals at every stage of readiness (Ruggiero, 2000). The purpose of this chosen model was to identify the current level of readiness of an individual and select their health care interventions accordingly (Ruggiero, 2000). This method provides motivation for the patient who is ready to take control of their HbA1c value (action) but also provides autonomy for the individual who is about to make a change (preparation for action). Proven to increase patient satisfaction and patient outcomes, the chosen framework provided support and guidance throughout the scholarly project phases.

Summary

The purpose of the literature review was to provide compelling evidence to support the importance of self-efficacy and self-management behaviors in patients with T2DM. Through the literature review, evidence reflected the importance of two key interventions: the utilization of technological advancements and tailored educational materials for T2DM patients. The utilization of technological advancements such as mobile applications and SMS interventions improve glycemic control, patient adherence, self-efficacy, and self-management behaviors (Abaza & Marschollek, 2017; Fioravanti et al., 2015; Nelson et al., 2016). Similarly, tailored educational materials, such as DM and self-management tools, enabled patients to avoid complications by managing and controlling their diseases more efficiently (Abaza & Marschollek, 2017; Koonce et al., 2015).

Research studies demonstrated that HL is a critical component of patient adherence and disease management, yet minimal research has combined the two elements. Approximately 33% of all patients with T2DM are classified as having low HL, yet despite the evolution of technology, research implies SMS applications for educational use are lacking (Abaza & Marschollek, 2017; Abdullah et al., 2019). Considering the importance of HL in DM management and patient awareness, an intervention combining mobile technology and HL-specific education was vital for patient success.

Therefore, the purpose of this scholarly project was to utilize an HL-specific educational intervention combined with a SMS reinforcement tool to improve glycemic control and self-efficacy in patients with T2DM. The combination therapy intervention reinforced initial diabetes teaching by providing participants an easy and convenient method to improve their diabetes knowledge and education and therefore increase their self-efficacy confidence, improve their HL, and improve their overall glycemic values.

SECTION THREE: METHODOLOGY

The purpose of this scholarly project was to identify if the utilization of an HL-specific DM educational pamphlet, when combined with an SMS intervention, would increase selfefficacy and glycemic control in a T2DM patient with limited or low HL. The project utilized a descriptive, quasi-experimental design to evaluate the association between patients with T2DM and HL. A convenience sample of four T2DM patients was utilized in this project. Participants were recruited from a rurally located, private primary care office located in the Piedmont region of North Carolina. The aim of this scholarly project was to utilize mobile technology and tailored DM educational materials to improve self-efficacy and glycemic control in the low-HL T2DM patient over a three-month timeframe.

Design

The Iowa Model was used as the conceptual framework in the step-by-step guided analysis, and the design for this scholarly project was an EBP model. A quasi-experimental, pilot intervention was conducted at a privately-owned physician's office in the Piedmont region of North Carolina. The goal of this scholarly project was to improve self-efficacy and HL while reducing HbA1c values in the low-HL patient with T2DM. Two months prior to the implementation of this scholarly project, advertisement flyers were posted. The project team leader aimed to recruit 30 participants; however, out of the 17 responses received, six met inclusion criteria, and only four completed the pre- and post-intervention questionnaires. For a baseline evaluation and a post-intervention data comparison analysis, the project team leader met with each eligible participant for 45 minutes pre-intervention and 30 minutes post-intervention. During the scheduled office visits (pre- and post-intervention), the project leader collected enrollment eligibility questionnaires, demographic forms, and study questionnaires (the Self-Efficacy for Diabetes Likert questionnaire and the Newest Vital Sign [NVS] were used). Secondary data collected during the scheduled office visits included blood pressure, weight, and an HbA1c sample. During the pre-intervention office visit, each project participant received the HL-specific DM educational pamphlet, in addition to text message usage instructions, including a trial text message with the project leader. During the three-month intervention, each project participant received two daily text messages and one weekly pop quiz text message. Daily text messages included "Did you take your blood sugar medicine?" and "Did you check your blood sugar?" were sent at 10:00 a.m. and 10:15 a.m., respectively; these text messages were removed from the intervention after Week 3. The weekly pop quiz question was sent every Friday morning at 10:30 for 12 weeks.

Measurable Outcomes

Outcome 1. After the completion of this evidence-based intervention, T2DM patients with low HL would demonstrate an improvement in self-efficacy confidence. This outcome would be evidenced by an increase in all self-efficacy Likert scores on the Self-Efficacy for Diabetes post-questionnaire when compared to the pre-questionnaire.

Outcome 2. At the completion of this evidence-based intervention, T2DM patients with low HL would demonstrate an increase in HL scores. This outcome would be evidenced by an increase in the total value score on the NVS tool on the post-assessment when compared to the pre-assessment.

Outcome 3. At the completion of this evidence-based intervention, patients would demonstration a reduction in HbA1c values. This outcome would be evidenced by comparing HbA1c values drawn pre- and post-educational intervention implementation.

Setting

This scholarly project was conducted at a small, privately owned, family medical practice located in the Piedmont region of North Carolina. The estimated population of the Piedmont region is 142,088 (U.S. Census Bureau, 2019). The majority of the residents of the region are White (79.4%), while 16.9% are Black or African American, 9.4% are Hispanic or Latino, and less than 2% are Native Hawaiian, Asian, American Indian, Alaskan Native, or two or more races (U.S. Census Bureau, 2019). The median age is 40 years (13%); majority of the residents are between 18 and 64 years; 85.3% of persons 25 years and older have a high school diploma, while only 18.7% have a bachelor's degree or higher (U.S. Census Bureau, 2019). The National Health Literacy Mapping to Inform Health Care Policy (University of North Carolina at Chapel Hill, 2014), indicates the county where the practice is located is listed among the lowest quartile

for HL in North Carolina. The median household income is \$48,667; the percentage of persons living in poverty is 16.3% (North Carolina Department of Commerce, 2019).

The selected health care facility was chosen for this scholarly project due to the rural location and interprofessional collaborative support offered by the medical practice. The private family practice is a patient-centered medical home. Identified as a care delivery model, a patient-centered medical home ensures patients receive the necessary care and treatment they need when they need it (American College of Physicians, 2019). With over 20 years' experience, the primary care provider of the selected location provides general services, prevention and wellness screening, physical examinations, chronic care, and disease management services. The location has co-management agreements with a mental health facility and an urgent care office, which provide behavioral health and urgent care services. Located in a rural area with a high level of low HL and a high disease prevalence of T2DM, the family practice was an ideal location for this scholarly project. This scholarly project aimed to implement an HL-specific DM educational pamphlet that would improve self-efficacy and glycemic control over a three-month time frame. The primary care provider of the office provided a letter of support for the scholarly project to take place at the chosen site (see Appendix E).

Population and Sample

The project included a convenience, purposeful sample of T2DM patients with limited and low HL. The project team leader aimed to recruit 30 participants. However, out of the 17 responses received, six met inclusion criteria, and only four completed the pre- and postintervention analysis measurements. Participants in the scholarly project were required to have a health care diagnosis of T2DM for a least a one-year duration, be 18 years of age or older, have access to a mobile device, be able to read, write, and speak in English, and have an associate's degree or less in education. Exclusion criteria were any DM diagnosis other than T2DM (T1DM, gestational), being non-English speaking, or having an education level greater than an associate's degree (i.e., bachelor's or higher).

Ethical Considerations

The Doctor of Nursing Practice project team, including the project team leader and the project chair, completed extensive research ethics training to ensure protection of human subjects. This research training was completed through the Collaborative Institutional Training Initiative; a certificate was awarded for completion (see Appendix D). To ensure all ethical considerations and standards for research involving human subjects were met throughout the implementation and duration of this scholarly project, an approval was granted by the IRB of Liberty University on January 20, 2020 (see Appendix B).

Ethical considerations addressed included patient consent, protection of human subjects, and data confidentiality. During the first encounter with each participant, the project team leader obtained an informed consent signature from each participant for their participation in the scholarly project (see Appendix F). A copy of the informed consent document was provided to each participant. Per the informed consent, personal information would only be shared with the project team chair. To ensure confidentiality, each project participant was assigned a coded number and letter for data collection. All personal information collected through questionnaires and text messaging was encrypted through data codes, protected, and stored in Microsoft Excel on a password protected laptop.

Data Collection

Data collection tools for this scholarly project included an enrollment eligibility questionnaire, a patient demographic evaluation, a self-efficacy Likert-ranking questionnaire, and an HL questionnaire. Excluding the enrollment questionnaire and the patient demographic evaluation, all pre-data intervention components were re-collected post-implementation. The enrollment eligibility questionnaire required participants to provide their date of birth, highest level of completed education, diabetes diagnosis, access to a mobile device (with text messaging capabilities), and ability to read, write, and speak the English language (see Appendix J). The patient demographic evaluation provided the participant's date of birth, gender, and race/ethnicity (see Appendix K). The project team leader collected all enrollment eligibility and demographic questionnaires. Pre- and post-intervention, each participant's blood pressure, weight, and HbA1c were collected. Blood samples for the pre- and post-HbA1c evaluation were collected by the clinic staff in a secured, clean environment. Once collected, the samples were transported to Quest Diagnostics for evaluation, and results were delivered within 24-48 hours. The project team leader was provided the resulted HbA1c values from direct staff at the primary care clinic for each participant. All text messaging activity completed by each study participant was recorded in Microsoft Excel for data collection and analysis.

Tools

To evaluate self-efficacy and HL of patients with T2DM, several tools were utilized for this scholarly project. The Self-Efficacy for Diabetes scale and the NVS tool were used during the pre- and post-intervention segments. Permissions were not needed for the use of the Self-Efficacy for Diabetes scale (Self-Management Resource Center, 2020) nor the NVS tool (Weiss, 2018). To evaluate self-efficacy in patients with T2DM, the Self-Efficacy for Diabetes Likert questionnaire tool was used. This eight-question tool was originally created and tested in Spanish for the evaluation of diabetes self-management (Self-Management Resource Center, 2019). The Self-Efficacy tool is a 10-item Likert scale which aims to identify how confident an individual is in completing certain activities or tasks. A score of 1 represents not confident at all, and a score of 10 indicates "totally confident;" the mean of all eight items provides the total score. A higher score indicates higher self-efficacy (Self-Management Resource Center, 2019).

The NVS was used to identify each participant's HL level. To administer the NVS, the project team leader provided each participant an ice cream label and asked them six questions. The NVS was to be completed in two to three minutes and required the test taker to perform simple mathematical equations and interpret basic text (Weiss, 2018). The participant could ask for paper, writing devices, or to use a calculator; however, these things were not allowed to be offered up front (Weiss, 2018). For each correct response, one point was rewarded for a maximum score of six. A score of 0-1 was highly suggestive of limited HL (50%), 2-3 indicated a possibility of limited HL, and a score of 4-6 indicated adequate HL (Pfizer, 2019; Weiss, 2018).

As evidenced by the extensive literature review, automated text messages and mobile technology education applications have proven to be effective for improving medication adherence, self-efficacy, self-management behaviors, and glycemic control (Abaza & Marschollek, 2017; Fioravanti et al., 2015; Lari et al., 2018; Nelson et al., 2016). That being so, to reinforce learning, an automated text message was sent to every participant. In the beginning, the project leader sent each participant two reinforcement text messages daily and one weekly pop quiz question. After Week 3, the daily text messages were discontinued. The initial daily
text messages were sent at 10:00 a.m. asking, "Did you check your blood sugar," and at 10:15 a.m. asking, "Did you take your blood sugar medication?" Each participant replied with a (1) for yes or a (2) for no. The weekly pop quiz question was sent every Friday morning at 10:30 a.m. Twelve questions were created from the HL educational pamphlet for a total of 12 weeks (see Appendix L). The participant received a question with answer choices 1 through 4. If the participant replied with the correct answer, a follow-up text message would be sent such as "Way to go!" If the participant answered incorrectly, an encouraging statement such as "Better luck next time," or "You almost had it," followed by a short text message with the correct answer and page number for reference was sent.

During the pre-intervention encounter, the project team leader provided all participants with a text message instruction guide for reference, and a trial text message was exchanged between the project leader and participant (see Appendix M). Weekly text messaging activity was collected and stored in Microsoft Excel on a password-protected computer.

Intervention

The first part of the intervention was the creation of the HL-specific DM educational pamphlet. The project leader chose to concentrate on four specific areas for education purposes: T2DM education, disease management, dietary recommendations, and exercise considerations. T2DM education and disease management included a disease overview, T2DM causes, prevention measures, normal and abnormal blood sugar values, and what to do when one's blood sugar is too high or too low. Dietary recommendations included nutrition suggestions, the Diabetes Plate Method, instructions for measuring food portions, and information on how to interpret a nutrition label. Exercise and physical activity considerations included recommended goals per week with examples, types of exercises, and safety tips. To ensure information was correct and up to date, the project leader used accredited resources from the ADA, the Centers for Disease Control and Prevention, the NIDDK, and several diabetes specialty providers; no information was more than two years old.

To create this easy-to-read handout, the project leader had to consider the target audience and goals of the document. The target audience for this pamphlet was low-HL patients with T2DM; therefore, education information was written at or below the eighth-grade level (MedlinePlus, 2019). Information was written in plain, simple English; all medical jargon, complex wording, abbreviations, and abstract language was avoided. Additional considerations used by the project leader during the creation of the documentation were illustrations, bright colors, bold headings, and simplified fonts (MedlinePlus, 2019). The HL educational pamphlet included an eight-page spread, each page presenting different content. Page 1 contained the title of the scholarly project and the name of the project leader, Page 2 included participant name, month, date, and a blood sugar tracker for the three-month timeframe, and Page 3 presented a colorful nutrition label with instructions on how to interpret it and helpful diabetes tips. Page 4 contained the diabetes Plate Method with colorful pictures and examples for each category, Page 5 provided instructions on how to measure food using portion sizing with examples compared to one's hand and familiar items (e.g., deck of cards), and Pages 6 and 7 presented insightful diabetes tips including information on normal/abnormal blood sugar values, treatment for abnormal blood sugar values, nutrition, and exercise recommendations, and Page 8 provided the references utilized in the making of the educational pamphlet.

The second part of the scholarly project intervention was the creation of the SMS reinforcement tool. Also utilized as a data collection measure, the SMS reinforcement tool was used to send each participant two daily text messages and one weekly pop quiz question. The

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daily text messages were removed after two weeks for reasons to be explained in the results and discussion sections. Twelve weekly pop quiz questions were created from the HL-specific DM educational intervention.

The project team leader met with each participant during a scheduled 45-minute time slot for the pre-intervention data collection phase. During this time, the team leader collected consent forms, enrollment eligibility forms, demographic questionnaires, pre-intervention questionnaires (the eight-question Self-Efficacy for Diabetes scale and six-question HL assessment), blood pressure, weight, and an HbA1c sample. Each participant was provided with the HL DM educational pamphlet and instructions for the SMS reinforcement tool (see Appendix M). During this time, all participant questions were answered, a trial text message was exchanged between each participant and the project team leader to ensure adequate understanding, and a follow-up meeting was scheduled between the participant and the team leader for June 18, 2020 (post-intervention). This scholarly project was implemented from March 16 to June 18, 2020, a three-month period. During the intervention phase, all SMS data collected were stored in Microsoft Excel.

At the conclusion of this project, all participants returned to the clinic to meet with the project team leader during a scheduled 30-minute appointment. During this time, each participant completed the same questionnaires as at the pre-intervention meeting, the eight-question Self-Efficacy for Diabetes Likert questionnaire and the six-question HL assessment. An HbA1c sample was collected in addition to the participant's blood pressure and weight. At the completion of the scholarly project, the project leader analyzed the data collected from each phase; an evaluation was completed, and the results were disseminated. Three individuals were rewarded grand prizes were based upon highest improvement scores in self-efficacy and HL,

reduction in HbA1c, and involvement in text messages over the three-month intervention. All participants who completed the scholarly project for the three-month duration were sent a thank you letter and a \$5.00 Walmart gift card.

Timeline

The project team leader spent approximately one year completing this project. The timeline for this scholarly project was divided between four phases: (1) planning; (2) preimplementation; (3) implementation; and (4) evaluation. A detailed timeline for each phase with activities and completion dates can be found in Appendix N.

Feasibility Analysis

To ensure the most cost-effective methods were utilized, the project team leader completed a feasibility analysis to evaluate office personnel, resources, technology, and strict budgeting. The office personnel were paid directly though the clinic; the only interactions staff had with the project participants were during the pre- and post-intervention evaluations and for acute visits (if needed). All supplies needed to collect the pre- and post-intervention HbA1c samples were provided by the clinic and processed through Quest Diagnostics.

The HL educational pamphlet was created by the project team leader using free resources. The educational pamphlet and advertisement flyers were printed by the project team leader. Text messages sent during the three-month intervention were sent from the project team leader's personal cellular device. Project participants were not required to download a mobile device application. All participants were informed no additional charges would be charged to their mobile device, other than standard text messaging data charges, as specific in the consent form. The three grand prizes for this scholarly project were a 40-inch Onn. Roku FHD smart television purchased for \$100.00, a Fire 7 HD Amazon tablet purchased for \$29.99, and a pair of wireless Bluetooth Skull headphones purchased for \$19.99. All participants received a \$5.00 Walmart gift card for a total of \$20.00. The total financial cost for this scholarly project was \$170.00, which, when compared to chronic DM treatment and direct medical costs, is relatively reasonable.

Data Analysis

To evaluate each of the project's measurable outcomes, data were collected during each phase of the scholarly project. Utilizing SPSS software and descriptive statistics, pre- and postintervention data analysis were performed for each measurable outcome. Post-intervention data were compared to pre-intervention data to determine if a significant difference had occurred in participant self-efficacy confidence, HL scores, and HbA1c values. Additional measurements included a comparison of pre- and post-intervention blood pressure and weight. Text messaging data collected during the three-month intervention phase were stored in Microsoft Excel. A data analysis was completed identifying user responses' and text message frequency.

Outcome 1. At the completion of this evidence-based intervention, T2DM patients with low HL would demonstrate an improvement in self-efficacy confidence. This outcome was evidenced by an increase in self-efficacy Likert scores. Descriptive statistics compared pre- and post-intervention scores from the Self-Efficacy for Diabetes pre- and post-questionnaires.

Outcome 2. At the completion of this evidence-based intervention, T2DM patients with low HL would demonstrate an increase in HL scores. This outcome was evidenced by a substantial increase in the total average value score on the NVS assessment. Descriptive statistics compared pre- and post-intervention values. **Outcome 3.** At the completion of this evidence-based intervention, patients would demonstrate a reduction in HbA1c values. This outcome was evidenced by a comparison of HbA1c values drawn pre- and post-combination therapy intervention.

SECTION FOUR: RESULTS

The project leader acquired 17 responses using the patient recruitment form (Appendix I); of those, six individuals met inclusion criteria. Only four participants completed the enrollment eligibility form (Appendix J), consent form (Appendix F), demographic questionnaire (Appendix K), Self-Efficacy for Diabetes scale (Self-Management Resource Center, 2020), and NVS evaluation tool (Weiss, 2018), and had the required miscellaneous procedures completed (blood pressure, weight, and blood sample for HbA1c) pre- and post-intervention evaluation. One of the three total project participants requested to be removed from the SMS intervention portion for personal reasons; however, the patient completed all pre- and post-intervention data analysis measures.

The utilization of a combination therapy for T2DM patients with limited or low HL demonstrated positive results with improving self-efficacy confidence, HL values, and glycemic control. This scholarly project yielded the following demographics. The four participants had an average mean age of 63 years. Minimum participant age was 49 years, and maximum participant age was 78 years. See Table 1 for project participants' gender characteristics, ethnicities, and highest levels of completed education.

Table 1

Participant Demographics

Demographic	п	Percent
Gender		
Male	4	100
Ethnicity		
Caucasian or White	3	75
Hispanic	1	25
Education level		
Less than high school	1	25
High school diploma or GED	1	25
Some college, no degree	2	50
Note. $N = 4$.		

The project leader sent two daily text messages at 10:00 a.m. and 10:15 a.m. followed by a weekly pop quiz question every Friday at 10:30 a.m. After two weeks, one project participant requested to be removed from the SMS intervention portion. The project leader continued the daily text messages with the other participants for one additional week. After three weeks, a continuous response trend was identified among the remaining participants; for that reason, the daily text messages were discontinued. Of the remaining three participants, two responded 100% of the time (12/12), and one responded 92% of the time (11/12). For the weekly pop quiz questions, two participants answered correctly 100% of the time (12/12), and one participant answered correctly 42% of the time (5/12). Evidence identified a correlation between participant response and overall improvement; individuals who responded more often experienced superior improvements when compared to those who did not.

Evidence reflected individuals with an educational level of some college (no degree) had lower HbA1c control values and higher baseline self-efficacy confidence values when compared to those with lower education levels (see Table 2). These results demonstrated that lower participant educational levels were associated with lower baseline HL scores. Limited or low HL knowledge was associated with poor self-efficacy confidence, poor disease management skills, and poor glycemic control, which are directly and indirectly associated with T2DM complications and increased mortality rates.

Table 2

Highest Level of Completed Education and Average Self-Efficacy Confidence and HbA1c

Education level	п	Mean self-efficacy confidence	Mean HbA1c (%)
Less than high school	1	55	10.5
High school diploma or GED	1	68	12.6
Some college, no degree	2	70	7.3
Note. $N = 4$.			

Descriptive Statistics

The HL-specific DM educational pamphlet combined with the SMS intervention demonstrated positive results with improving self-efficacy confidence, HL knowledge, and glycemic control in limited- or low-HL patients with T2DM over the three-month timeframe. A 9% overall increase in self-efficacy confidence levels was found based on the Self-Efficacy for Diabetes Likert questionnaire. Before the intervention, the average number of correct answer choices on the NVS was 3 out of 6, and the total sum for all participants was 12 out of 24 (50%). After the three-month combination therapy intervention, the mean value of correct answers increased to 5.5 (+2.5) and the total sum statistic increased to 22 (92%), a 42% overall increase. The initial mean HbA1c pre-intervention was 9.4% and post-intervention was 8.9%, creating a 0.5% mean reduction.

Measurable Outcome 1

After the completion of this evidence-based intervention, T2DM patients with low HL were expected to demonstrate an improvement in self-efficacy confidence. This goal was met, as

evidenced by an overall 9% average increase in the self-efficacy Likert scores on the Self-

Efficacy for Diabetes questionnaire (see Table 3).

Table 3

Self-Efficacy Confidence Pre- and Post-Intervention Data Analysis Measures

					Percentage		
Confidence	Minimum	Maximum	Sum	Total	of select	Mean	SD
level	statistic	statistic	statistic	statistic	categories	statistic	statistic
Pre-	55	80	263	320	82	65.75	10.905
intervention							
Post-	59	80	292	320	91	73.00	9.557
intervention							
Difference					+9		

Note. N = 4. SD = standard deviation. Min/max = minimum self-efficacy confidence level/maximum self-efficacy confidence level. Sum statistic = total participant self-efficacy value, total statistic = total self-efficacy value, percentage = sum statistic/total statistic, difference = pre- and post-combination therapy intervention.

Measurable Outcome 2

After the completion of this three-month evidence-based intervention, T2DM patients with low HL were expected to demonstrate an increase in HL scores. The most significant accomplishment of this study was the overall 42% average improvement in the HL scores of the participants. The average number of correct answers increased overall by 2.5. The lowest number of correct answers pre-intervention was two of six, and the highest was four; post-intervention, the lowest number of correct answers was four, and the highest was six (maximum score). The outcomes of this goal were calculated by comparing the pre- and post-intervention HL score values for each participant (see Table 4).

Table 4

					Percentage		
Literacy	Minimum	Maximum	Sum	Total	of select	Mean	SD
value	statistic	statistic	statistic	statistic	categories	statistic	statistic
Pre-	2	4	12	24	50	3.0	1.155
intervention							
Post-	4	6	22	24	92	5.5	1.000
intervention							
Difference					+42	+2.5	

Pre- and Post-Intervention Health Literacy Data Analysis Measures

Note. N = 4. SD = standard deviation. Min/max = minimum self-efficacy literacy value/maximum self-efficacy literacy value. Sum statistic = total participant literacy value. Total statistic = total literacy value. Percentage = sum statistic/total statistic. Difference = pre- and post-combination therapy intervention.

Measurable Outcome 3

After the completion of this evidence-based intervention, it was expected that patients would demonstrate a reduction in HbA1c values. The highest HbA1c value collected during the pre-intervention phase was 12.6%; the participants' mean HbA1c value was 9.4%. Post three-month combination implementation therapy, the highest HbA1c value collected was 10.7%; the participants' mean value HbA1c was 8.9%. Therefore, there was a 0.5% mean value reduction. The greatest HbA1c reduction value over the three-month combination therapy intervention was 1.9% (see Table 5).

Table 5

HbA1c Pre- and Post-Intervention Data Analysis Measures

HbA1c	Minimum HbA1c (%)	Maximum HbA1c (%)	Group mean (%)	SD
Pre-intervention	7.0	12.6	9.425	2.6107
Post-intervention	6.2	10.7	8.900	2.0928
Difference			+0.525	

Note. N = 4. Min/max HbA1c = minimum hemoglobin A1c/maximum hemoglobin A1c. Difference = pre- and post-combination therapy intervention

Short Message Service

At the completion of this three-month combination intervention therapy, the project leader evaluated the association between participant outcomes and SMS interactions. Although a positive association was evident between participant response and individual improvement, it is difficult to determine if the text messages made a significant difference in the overall outcome of the scholarly project. Two of the four participants indicated they felt the weekly text messages were helpful and beneficial with learning their diet and exercise recommendations. One participant stated, "I looked forward to my pop quiz every Friday morning just so I could prove to my wife what I had learned." Three of four participants interacted weekly for the duration of the scholarly project. When compared to pre-intervention data analysis, two participants reflected remarkable improvements with self-efficacy confidence, HL knowledge, and glycemic control. The third participant displayed improvements with HL knowledge, blood pressure, and weight loss.

SECTION FIVE: DISCUSSION

This quasi-experimental study sought to identify if an HL-specific combination therapy, compared to standard DM education, could improve self-efficacy and glycemic control in patients with T2DM over a short time frame. The findings of this project support and further clarify results of the small body of research regarding tailored education for improving DM patient outcomes. Key findings of this scholarly project included an increase in self-efficacy confidence, an increase in HL knowledge, and a decrease in HbA1c values. Additional encouraging findings include weight loss, blood pressure reduction values, and positive participant feedback. The results of this scholarly project indicate an HL-specific combination

therapy is an effective approach for improving self-efficacy, HL, and glycemic control in a patient with T2DM and limited or low HL.

Implications for Practice

Based on the positive results of this scholarly project, it is safe to conclude that current practice guidelines should consider this intervention or a similar approach for clinical practice. Combination therapy is not a feasible approach for every health care clinic due to budgetary constraints; however, the HL-specific DM educational pamphlet should be further evaluated for consideration. This project can be easily replicated, implemented, and updated as necessary with ADA guidelines. As evidenced by this project, the educational tool can promote disease management, improve self-efficacy confidence, and improve disease knowledge. Recognized as a global health threat, DM directly affects patients and their families while costing health care systems billions of dollars annually. T2DM represents 90%–95% of all diabetes diagnoses, yet it can be prevented and/or delayed through diet and exercise. This project, similar to other published studies, supports the utilization of tailored educational materials for DM patients and automated SMS, as well as the importance of self-efficacy and self-management behaviors for improving patient longevity.

Implications for Research

While studies similar to the one conducted by Koonce et al. (2015) support these project findings, additional studies would be effective in strengthening the evidence to support the consistent use of tailored educational learning materials to improve diabetes knowledge. Although this scholarly project was designed around patients with limited and low HL skills, the positive results could be duplicated in other EBP projects. Therefore, further research utilizing the combination therapy should be explored on a larger scale with a broader DM demographic sample.

Furthermore, a challenge or consideration for future research is participant recruitment, including but not limited to time and advertisement. The project leader had a difficult time recruiting participants for this project. Given the limited timeline, two months prior to the implementation phase, advertisement flyers were posted, and patient recruitment letters were mailed to the established patients of the medical clinic. The intended population for this study was low-HL patients with T2DM. In regard to the low response rate, the probability that the targeted population did not comprehend or read the material sent to them is very high, and this issue hindered the overall recruitment process.

Although the scholarly project was a two-part combination intervention, it may not be as effective or financially viable for some providers. However, the educational pamphlet is provider friendly and cost-effective and would be easy to implement, replicate, and update as necessary in any primary care office or outpatient facility that works directly with T2DM patients. Therefore, a health care provider and/or facility looking to improve T2DM patient outcomes should consider additional research on the utilization of tailored educational materials for DM patients.

Limitations

Several limitations were identified during the course of this scholarly project. First, the small convenience participant sample and the project setting were limitations. The sample was all male and the setting was one local, rural primary care clinic. Secondly, due to time constraints, the recruitment strategy was limited; therefore, the final participant sample was minimal. To prevent and/or reduce attrition, the project leader provided all participants

monetary prizes for their participation during the three-month study; however, this can serve as a limitation. Additionally, project participants were required to read, write, and speak in the English language, another limitation of the research. Two-way communication between participants and the project leader for the SMS interventions was established through personal cellular devices. A mobile group SMS technology tool was going to be used initially; however, due to budgetary constraints, this was not plausible. This could serve as a limitation, although the project leader informed all participants of the means of communication up front and established reminders to ensure correct Microsoft data entry. The final limitation identified was the lack of a professional relationship between the project leader and the established patients of the primary care clinic. This served as a limitation due to the inability to gain trust from the established population, despite positive collaboration with the provider and staff.

Sustainability

The sustainability of this project depends upon the primary care provider and nursing staff of the primary care clinic. It is important to note, due to limited resources and funding, this clinic does not currently utilize mobile technology applications. Therefore, even though this project was designed as a combination therapy using both the educational pamphlet and an SMS reinforcement tool, the continued use of the HL-specific DM educational pamphlet is dependent upon the health care providers. This project and the positive results were shared with the clinic provider and staff. This HL-specific DM educational pamphlet can be used with current and newly diagnosed T2DM patients. Although the educational pamphlet is HL specific and eight pages long, only four pages present core DM content regarding dietary recommendations, disease management, and exercise considerations for patients with T2DM. This pamphlet takes less than 15 minutes for a health care provider to read to a patient and can be integrated into

routine chronic care visits. As recommended by the ADA, follow-up medical evaluation visits for patients with DM should include nutrition counseling, information on self-management behaviors, immunizations, and routine health maintenance screening, in addition to other wellness components (ADA, 2019). To increase diabetes patient knowledge, the HL-specific educational pamphlet can be used during routine follow-up visits, which can decrease the risk for acute and chronic diabetes complications. To help maintain the positive outcomes of the project and current participant success, the health care clinic providers will need to promote and maintain current measures. Otherwise, the benefits of the project will degrade over time.

Dissemination Plan

This scholarly project reinforced the importance of utilizing a tailored combination therapy for patients with T2DM and low HL. By designing a tailored educational DM pamphlet and reinforcing it with an SMS intervention, this scholarly project effectively helped manage and improve T2DM in patients of a rural primary care clinic. This project achieved three measurable outcomes over the three-month intervention time frame: increased self-efficacy confidence, increased HL knowledge, and decreased average glycemic value. Additional measurable outcomes achieved during this project included weight reduction and blood pressure improvements. These pilot findings were shared with the primary care provider, site manager, and nursing staff. Based on submission recommendations and guidelines, the team leader is developing a manuscript for the ADA *Diabetes Care* journal for publication. Manuscript publication is an option for pilot results and findings to be shared with communities and other health care professionals.

Conclusion

Tailored DM education is an indispensable strategy for improving diabetes knowledge and patient outcomes. Current literature supports the use of tailored diabetes education, automated text messages, and mobile technology applications; however, combining these methods had not been considered until this project nor consistently utilized on an individualized basis. T2DM is a rapidly evolving disease, costing health care systems billions of dollars annually. With a high diagnosis rate and a high mortality rate, DM was the seventh-leading cause of death in 2017. Unlike other DM classifications, Type 2 can be prevented or delayed through self-care management behaviors. Therefore, it is reasonable to conclude through continued provider and staff enforcement, this scholarly project can continue to improve the diabetes knowledge of T2DM patients who use this tailored educational approach. With improved diabetes knowledge, patients can achieve self-efficacy confidence, self-management behaviors, and glycemic control.

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Appendix A

Evidence Table

Article	Study Purpose	Sample	Methods	Study Results	Melnyk Level of	Study Limitations	Would Use as Evidence to Support
					Evidence		a Change?
Abaza, H., & Marschollek, M. (2017). SMS education for the promotion of diabetes self- management in low & middle income countries: A pilot randomized controlled trial in Egypt. <i>BMC Public</i> <i>Health</i> , <i>17</i> , 1–19. doi:10.1186/s12889- 017-4973-5	To examine the impact on self- management behaviors and glycemic control, of SMS education when compared to standard paper-based methods among T2DM patients in Egypt	73 Total participants (English speaking, T2DM, 18yrs and older) -34 intervention -39 Control	12-week Randomized control trial	A clear association between the intervention group was identified with a 1% reduction in HbA1c values ($p =$ 0.003); knowledge scores, medication adherence, and self-efficacy scores were identified as secondary improvement outcomes	Level 2: Well- designed RCT	Short time frame (3 months), small sample size; therefore, inability to generalize findings; lack of incentives to reduce drop-out rate	Yes, this article does provide significant evidence to support change in the promotion of diabetes self-management and self-efficacy
Abdullah, A., Liew, S. M., Salim, H., & Chinna, K. (2019). Prevalence of limited health literacy among patients with type 2 diabetes mellitus: A systematic review. <i>PLoS One, 14</i> (5),	To summarize and report the current evidence on the prevalence of limited health literacy in patients with type two	29 studies involving 13,457 T2DM from 7 different countries	Systematic Review Searching:M EDLINE PsychINFO, EMBASE, CINAHL, and ERIC published up	Health literacy tools and prevalence of health literacy varied widely among differing countries; In the United	Level 1: Systematic Review	No limitations were identified	Yes, this systematic review provides significant evidence to support change in the promotion of health literacy interventions and tools among patients with type two diabetes

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e0216402. doi:10.1371/journal.p one.0216402	diabetes globally and the associated factors		to January 2017	States, 1 in 3 patients with type two diabetes had			
				limited health literacy			
Amer, F. A., Mohamed, M. S., Elbur, A. I., Abdelaziz, S. I., & Elrayah, Z. A. (2018). Influence of self-efficacy management on adherence to self- care activities and treatment outcome among diabetes mellitus type 2 Sudanese patients. <i>Pharmacy Practice</i> (1886-3655), 16(4), 1–7. doi:10.18549/PharmP ract 2018 04 1274	To identify the influence of management self-efficacy on adherence to self-care activities and treatment outcome among Sudanese patients with type two diabetes	A convenience sample of 392 patients two health care facilities in Sudan from April to May 2016	A cross- sectional study	Self-efficacy was significantly associated with adherence to glycemic control and self-care activities; Self- efficacy was associated with receiving health education and with high level of education	Level 4: Cross- Sectional Study	Conducted in only two settings in one state; therefore, inability to generalize sample; convenient sample; data was collected with a self- reported method	Yes, this study is helpful as it provides sufficient evidence to support my scholarly project to improve diabetes self-care management
Bohyun K., Youngshin S., & Jong, I. K. (2019). Psychological insulin resistance and low self-efficacy as barriers to diabetes self-care management in patients with type 2 diabetes. <i>Korean</i>	To identify the association among diabetes self- efficacy, psychological insulin resistance, and diabetes self-care	This study was a part of another parent study, Data collection from December 2015 to March 2016; 192 T2DM	A cross- sectional design	Positive correlation between Self- care management and diabetes self-efficacy; One should consider psychological resistance and	Level 4: Cross- Sectional Design	Small sample size using only one homogeneous group in South Korea, inability to generalize findings	Yes, this study could be useful as it provided a positive correlation between self-care management and self-efficacy of a patient with T2DM

Journal of Adult Nursing, 31(1), 61– 67. doi:10.7475/kjan.201 9.31.1.61	management in T2DM Korean patients requiring insulin therapy			diabetes self- efficacy when educating and counseling patients			
Cheng, L., Sit, J. W. H., Leung, D. Y. P., & Li, X. (2016). The association between self-management barriers and self- efficacy in Chinese patients with type 2 diabetes: The mediating role of appraisal. <i>Worldviews on</i> <i>Evidence-Based</i> <i>Nursing</i> , <i>13</i> (5), 356– 362. doi:10.1111/wvn.121 59	To examine the potential role of diabetes appraisal on the association of self-efficacy and self- management barriers in patients with type two diabetes	346 Adults with type two diabetes mellitus from 4 hospitals in China	A cross- section study	Significant associations were detected between diabetes appraisal and diet knowledge, <i>p</i> value of 0.047	Level 4: Cross- Sectional Study	Inability to generalize findings, sample size was obtained from only four teaching hospitals in China; Data were self- reported	Yes, this research study provides evidence in the relationship between self-efficacy and diet knowledge; utilizing this information will be of great use for future research
Fioravanti, A., Fico, G., Salvi, D., García- Betances, R. I., & Arredondo, M. T. (2015). Automatic messaging for improving patients engagement in diabetes management: An exploratory study. <i>Medical & Biological</i>	To identify if a text message with the proper context, sent at the proper time, has an impact on a patient's adherence to therapy	51/54 patients completed (T1DM 1 and T2DM) -26 Intervention -25 Control	An exploratory randomized control trial	The mobile health system (METABO) was well accepted and utilized among the patients; prescription adherence increased during the short time frame	Level 2: Well- designed RCT	Small sample size, short- time frame (4 weeks); therefore, inability to generalize findings	Yes, this article provides evidence to support the use of automated text messages for the improvement in patient adherence, self-management, and self-efficacy; however, additional studies are needed due to the

<i>Engineering &</i> <i>Computing</i> , <i>53</i> (12), 1285–1294. doi:10.1007/s11517- 014-1237-8							short time frame of this particular study
Gedik, S., & Kocoglu, D. (2018). Self-efficacy level among patients with type 2 diabetes living in rural areas. <i>Rural</i> & <i>Remote Health</i> , <i>18</i> (1), 4262. doi:10.22605/RRH42 62	To determine the disease management self-efficacy level of patients living in a rural area of Turkey with T2DM	216 Adult patients with T2DM; data collections from April to June 2015 using the Self-Efficacy Scale for Type 2 Diabetes	A non- experimental , descriptive survey	T2DM patients living in rural areas of Turkey had moderate self-efficacy levels and poor disease management levels	Level 6: descriptive design	Inability to generalize findings, due to the collection of patients from one hospital in one area	Yes, this study does provide helpful information that could assist in future research; this study identifies the need to improve self-efficacy through diabetes education programs in rural areas
Huygens, M. W. J., Swinkels, I. C. S., de Jong, J. D., Heijmans, M. J. W. M., Friele, R. D., van Schayck, O. C. P., & de Witte, L. P. (2017). Self- monitoring of health data by patients with a chronic disease: Does disease controllability matter? <i>BMC Family</i> <i>Practice</i> , 18, 1–10. doi:10.1186/s12875- 017-0615-3	To investigate the relationship between patients' willingness to self-monitor and control chronic diseases	627 participants from a Dutch Panel -17 Chronic diseases (diabetes, heart failure, asthma, COPD, hypertension, migraines, etc.)	Cross- Sectional Study	Patients willingness to self-monitor their disease depends highly among their type of disease; patients with diabetes, asthma, and hypertension are more likely to self-monitor their disease when provided appropriate self-monitoring parameters and applications; an association	Level 4: Cross- sectional Study	Broad sample size with multiple chronic disease processes'; different sample sizes per each chronic disease	Yes, this article provides evidence that DM patients are willing to self-monitor their chronic disease when provided appropriate parameters and tools; this study can be used to support diabetes education, self-management, and self-efficacy in future research

				between disease controllability and self- monitoring revealed an association that should be further investigated			
Koonce, T. Y., Giuse, N. B., Kusnoor, S. V., Hurley, S., & Ye, F. (2015). A personalized approach to deliver health care information to diabetic patients in community care clinics. <i>Journal of the</i> <i>Medical Library</i> <i>Association</i> , <i>103</i> (3), 123–130. doi:10.3163/1536- 5050.103.3.004	To investigate if educational materials targeted to health literacy levels and learning styles in a community clinic could improve diabetes knowledge	160 Participants (English or Spanish speaking, 18yrs or older, with type 2 diabetes) -81 Intervention -79 Control	Randomized control trial	After 2 weeks (p = 0.0000 and after 6 weeks (p = 0.00) the mean number of diabetes knowledge questions were increased significantly in the intervention group; this study identified that diabetes knowledge significantly increases after exposure to educational materials targeted to their learning style preference and health literacy levels	Level 2: Well- designed RCT	The average patient in this study was tested to have "adequate" health literacy; short-term study (6 weeks)	Yes, this study provides evidence that targeting health literacy, learning styles can improve disease management

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Lari, H., Noroozi, A., & Tahmasebi, R. (2018). Impact of short message service (SMS) education based on a health promotion model on the physical activity of patients with type II diabetes. <i>Malaysian Journal of</i> <i>Medical Sciences</i> , 25(3), 67–77. Retrieved from doi:10.21315/mjms2 018.25.3.7	To evaluate the impact of a short message service (SMS) based on a health promotion model on the physical activity of diabetes patients	74 T2DM; 37 in SMS group, 36 in a control group	Quasi- Experimental Study	When compared to the control group, the SMS/training group had changes in mean scores of family support (p = 0.001) and self-efficacy $(p$ = 0.001) of physical activity and perceived barriers were significantly	Level 3: Quasi- Experiment al Design	Small sample size, inability to generalize findings	Yes, this study demonstrates that SMS can change beliefs and physical activity behaviors in DM patients
				reduced over time ($p < 0.001$)			
Linnemayr, S., Huang, H., Luoto, J., Kambugu, A., Thirumurthy, H., Haberer, J. E., Mukasa, B. (2017). Text messaging for improving antiretroviral therapy adherence: No effects after 1 year in a randomized controlled trial among adolescents and young adults. <i>American Journal of</i>	To assess the effectiveness of short message service (SMS) reminder messages on antiretroviral and cotrimoxazole prophylaxis adherence among HIV- positive youths	332 Participants from 2 HIV clinics in Kampala	Year-long, parallel, individual- randomized control trial	Previous evidence reported SMS reminder interventions were helpful in the promotion of antiretroviral adherence; however, this study revealed that SMS is not always effective in behavioral change	Level 2: Well- designed RCT	No limitations identified; per study the African setting could be generalizable to other settings in Africa	This study was useful in the evaluation of SMS reminder messages; this study did not provide sufficient evidence for future use

<i>Public Health</i> , <i>107</i> (12), 1944–1950. doi:10.2105/AJPH.20							
17.304089							
Nelson, L. A., Mulvaney, S. A., Gebretsadik, T., Johnson, K. B., & Osborn, C. Y. (2016). The MEssaging for diabetes (MED) intervention improves short-term medication adherence among low-income adults with type 2 diabetes. <i>Journal of Behavioral Medicine</i> , <i>39</i> (6), 995–1000. doi:10.1007/s10865- 016-9774-2	To assess the efficacy of a short message service (SMS) text message and interactive voice response (IVR) intervention to promote adherence in T2DM patients	80 Adults classified with low socioeconom ic status (SES) and type two diabetes	Quasi- Experimental Design	Compared to baseline measures, adherence measures improved at one and two months; the Messaging for Diabetes (MED) SMS intervention had a positive, short-term impact on adherence but did not improve glycemic control	Level 3: Quasi- Experiment al Design	Participants received monetary compensation; small sample size, inability to generalize findings	This study provides sufficient evidence to use in future studies
Silina, V., Tessma, M. K., Senkane, S., Krievina, G., & Bahs, G. (2017). Text messaging (SMS) as a tool to facilitate weight loss and prevent metabolic deterioration in clinically healthy overweight and obese subjects: A	To examine whether a short message service (SMS) text messaging facilitates a reduction in waist circumference (WC), weight, insulin levels,	123 overweight and obese men and women, with no diabetes or cardiovascul ar disease	A randomized controlled trial	SMS messaging in a clinically health overweight and obsess subject does facilitate a slight decrease in WC, weight, and BMI.	Level 2: Well- designed RCT	Small sample size, subjects with comorbid conditions were excluded, inability to generalize findings	This study provides sufficient evidence to support the use of SMS in self- management promotion behaviors; this would be a good source to support future evidence

randomized controlled trial. <i>Scandinavian</i> <i>Journal of Primary</i> <i>Health Care</i> , <i>35</i> (3), 262–270. doi:10.1080/0281343 2.2017.1358435	and lipid profiles in clinical healthy overweight and obese subjects						
Tharek, Z., Ramli, A. S., Whitford, D. L., Ismail, Z., Zulkifli, M. M., Ahmad Sharoni, S. K., Jayaraman, T. (2018). Relationship between self- efficacy, self-care behaviour and glycaemic control among patients with type 2 diabetes mellitus in the Malaysian primary care setting. <i>BMC</i> <i>Family Practice</i> , 19, 39. doi:10.1186/s12875- 018-0725-6	To determine the relationship between self- efficacy, self- care behavior, and glycemia control among patients with type two diabetes in a Malaysian primary care clinic	340 Patients with type two diabetes	Cross- Sectional Study	Higher self- efficacy was correlated with improved glycemic control and better self-care behaviors	Level 4: Cross- Sectional Study	Non- probability sampling method, self- reported methods	This study does provide a good source of evidence in the correlation of self- efficacy and glycemic control
van Velthoven, M.	To compare	1014	Cluster,	This study	Level 2:	Poor	This study would not
\square \square , wang, w., wu, \square \square \square \square \square \square	messaging	only 662	Kandomized-	text messaging	designed	n challenging	be useful for future
Scherpbier, R. W.,	and face-to-	responded,	Study	data produces	RCT	situations;	this student
Du, X., Rudan, I.	face	651 agreed to	-	similar data		inability to	
(2018). Comparison	interviews for	participate;		when compared		generalize	
of text messaging	a public	Only 356		to face-to-face		findings due	
data collection vs	health survey	completed		interviews in a		to the	

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face-to-face	on childhood	the text	middle-income	collection area	
interviews for public	pneumonia	message	setting	being from	
health surveys: A	and diarrhea	survey		one rural area	
cluster randomized				of China, this	
crossover study of				study could	
care-seeking for				not be	
childhood pneumonia				generalized to	
and diarrhea in rural				other rural	
China. Journal of				areas in China	
<i>Global Health</i> , 8(1),				with similar	
1–14.				socio-	
doi:10.7189/jogh.08.				economic	
010802				characteristics	

Appendix B

Institutional Review Board Approval Letter

LIBERTY UNIVERSITY.

INSTITUTIONAL REVIEW BOARD

January 20, 2020

Crystal Manus Masling

IRB Approval 4123.012020: Evaluating the Utilization of a Combination Therapy to Improve Self-Efficacy and Glycemic Control in the Low Health Literate Type Two Diabetic Patient

Dear Crystal Manus Masling,

We are pleased to inform you that your study has been approved by the Liberty University IRB. This approval is extended to you for one year from the date provided above with your protocol number. If data collection proceeds past one year or if you make changes in the methodology as it pertains to human subjects, you must submit an appropriate update form to the IRB. The forms for these cases were attached to your approval email.

Your study falls under the expedited review category (45 CFR 46.110), which is applicable to specific, minimal risk studies and minor changes to approved studies for the following reason(s):

- 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. <u>45 CFR 46.101(b)(2)</u> and (b)(3). This listing refers only to research that is not exempt.)

Thank you for your cooperation with the IRB, and we wish you well with your research project.

Sincerely,

G. Michele Baker, MA, CIP Administrative Chair of Institutional Research Research Ethics Office



Appendix C

Permission to Use and/or Reproduce the Iowa Model

к	Kimberly Jordan - University of Iowa Hospitals and Clinics <noreply@qu altrics-survey.com> Thu 10/31/2019 1:53 PM Masling, Crystal Manus ⊗</noreply@qu 	ᡌ	5	«)	\rightarrow						
	You have permission, as requested today, to review and/or reproduce The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care. Click the link below to open.										
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	Citation: Iowa Model Collaborative. (2017). Iowa model of evidence-based practice: Revisions and validation. Evidence-Based Nursing, 14(3), 175-182. doi:10.1111/wvn.12223	World	tview:	s on							
	In written material, please add the following statement: Used/reprinted with permission from the University of Iowa Hospitals and Clinics, copyright 2015. For p reproduce, please contact the University of Iowa Hospitals and Clinics at 319-384-9098.	permis	sion (to use	or						
	Please contact or with questions.										

Appendix D

CITI Program Completion



Appendix E

Letter of Support



Appendix F

Consent Form

The Liberty University Institutional Review Board has approved this document for use from 1/20/2020 to 1/19/2021 Protocol # 4123.012020

CONSENT FORM

EVALUATING THE UTILIZATION OF A COMBINATION THERAPY TO IMPROVE SELF-EFFICACY AND GLYCEMIC CONTROL IN THE LOW HEALTH LITERATE TYPE TWO DIABETIC PATIENT Crystal Manus Masling Liberty University School of Nursing

You are invited to be in a scholarly research project on type two diabetes mellitus. The following scholarly project will provide an educational document tailored to you, to provide nutritional facts, exercise recommendations, and friendly tips on your disease process. The scholarly project will use daily and weekly text messages to help your success during the 3-month timeframe. You were selected as a possible participant because you are at least 18 years or older, you have a diagnosis of type two diabetes mellitus, you have had the diagnosis for at least 1 full year, you have an educational level of an associate's degree or less, you have access to a mobile device, and you can read, write, and speak in English. Please read this form and ask any questions you may have before agreeing to be in the scholarly project.

Crystal Manus Masling, a doctoral student in the School of Nursing at Liberty University, is conducting this study.

Background Information: The purpose of this scholarly project is to determine if the utilization of a low literacy educational intervention combined with a short message service (SMS) will improve glycemic control and self-efficacy in the type two diabetic patient. This scholarly project will provide type two diabetic patients with low-literacy tools and daily reinforcements using mobile text messaging.

Procedures: If you agree to be in this study, I would ask you to do the following things:

- During a pre-scheduled meeting, I will ask to collect your vital signs (blood pressure and pulse) and weight, you will be asked to fill out a demographic survey, complete a 6-question health literacy evaluation, an 8-question self-efficacy questionnaire, and you will be asked to have your A1c collected (1 cc of blood by way of finger prick). Once this is complete, I will provide you with the GroupMe text messaging tool and directions. This is a FREE text messaging service. It will not require you to download an APP. I will also give you an educational pamphlet. All questions you may have will be answered. Estimated time to complete this procedure is 45 minutes.
- 2. During the three-month scholarly project, I will send you 2 daily text messages and 1 weekly text message. These messages will require you to respond. You will be provided instructions on how to respond during your initial meeting with the project leader. These messages will only require short simple responses that will be explained in detail as previously described. Estimated time to complete daily text messages is approximately 2 minutes per question and 5 minutes for the weekly text message.
- 3. At the completion of the 3 months, I will ask you to return for a follow-up meeting. During this visit, I will ask to collect your vital signs (blood pressure and pulse) and weight, I will ask you to complete the 6-question health literacy evaluation, I will ask you
to complete the 8-question self-efficacy questionnaire, and I will ask you to have your A1c value collected (1 cc of blood by way of finger prick). Estimated time to complete this procedure is 20-30 minutes.

Note All blood samples collected for A1c testing will be disposed of immediately after testing in biohazard bins located in the physician's office.

Risks: The risks involved in this study are minimal, which means they are equal to the risks you would encounter in everyday life.

Benefits: The direct benefits participants should expect to receive from taking part in this scholarly project may include an increased knowledge of type two diabetes mellitus, an increased knowledge in self-efficacy and self-management behaviors, an improvement in glycemic control including HbA1c (3-month blood sugar average), and a potential improvement in weight, cholesterol, and blood pressure.

Benefits to society include: Approximately one in five Americans have low health literacy. The following scholarly project may identify if targeting education styles can improve low health literacy with minimal risk efforts. If these efforts are successful in the type two diabetic patient, they may be useful in other chronic disease processes to benefit society.

Compensation: Participants will be compensated for participating in this study. Each participant who completes the study entirely will receive a \$5.00 Walmart gift card. Three grand prize winners will be chosen based on (1) self-efficacy & health literacy score improvements; (2) HbA1c reduction values; and (3) involvement in text messages. The first grand prize winner will receive a 40-inch smart television (\$100.00 value). The second grand prize winner will receive an Amazon Fire 7 HD Tablet (\$29.99 value), and the third grand prize winner will receive a pair of wireless Bluetooth Skull headphones (\$19.99 value).

Confidentiality: The records of this study will be kept private. In any sort of report or presentation I might publish, I will not include any information that will make it possible to identify subjects. All information gathered through questionnaires and text messaging will be protected under encrypted codes and stored in Microsoft Excel. All information will be encrypted with no personal information related to project participants. Research records will be stored securely, and only the researcher and the researcher's faculty chair will have access to the records. I may share the data I collect from you for use in future research studies or with other researchers; if I share the data that I collect about you, I will remove any information that could identify you, if applicable, before I share the data.

- Participants will be assigned a randomized number and letter that will be used to conceal their identity. I will conduct the meetings in a location where others will not easily overhear the conversation.
- All hard copy data will be stored in a locked filing cabinet. Electronic data will be stored on a password locked computer and may be used in future presentations. After three years, all electronic records will be deleted and all hard copy data will be shredded in accordance with federal law.

The Liberty University Institutional Review Board has approved this document for use from 1/20/2020 to 1/19/2021 Protocol # 4123.012020

Voluntary Nature of the Study: Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with Liberty University or If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

How to Withdraw from the Study: If you choose to withdraw from the study, please contact the researcher at the email address/phone number included in the next paragraph that you wish to discontinue your participation. Should you choose to withdraw, data collected from you will be destroyed immediately and will not be included in this study.

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher, **you are encouraged** to contact the Institutional Review Board, 1971 University Blvd., Green Hall Ste. 2845, Lynchburg, VA 24515 or email at <u>irb@liberty.edu</u>.

Please notify the researcher if you would like a copy of this information for your records.

Statement of Consent: I have read and understood the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature of Participant

Date

Signature of Investigator

Date

Appendix G

Advertisement



Appendix H

Physician Recruitment Letter

[Insert Date]



Explained my role and topic: As a graduate student in the School of Nursing at Liberty University, I am conducting research as part of the requirements for a Doctor of Nursing Practice – Family Nurse Practitioner degree. The purpose of my research is to identify if a health literate specific diabetic education program when combined with a daily short message service (SMS) intervention can improve glycemic control and self-efficacy in the type two diabetic patient over a 3-month time frame.

Explained my project inclusion and exclusion criteria: participants must be 18 years of age or older, have a diagnosis of type two diabetes, have had diabetes for at least one year or longer, have access to a mobile device, English-speaking, have the ability to read and write in English and have an associate's degree or less.

Explained project guidelines: participants will be asked to complete the following: (1) attend two meetings with the project leader (2) perform daily blood sugar checks; and (3) interact through text messages with the project leader.

expressed great interest in project topic and gave verbal consent to use medical practice. Together collaborated to identify appropriate times for participant meetings, time length, and advertisement options.

Physician Script for Recruitment:

- will inform patients that the study is being conducted by Crystal Masling, a Family Nurse Practitioner Student at Liberty University. He will inform the potential participant that the study has no association with **Student Student**. He will then inform the individual of eligibility requirements: patients diagnosed with type two diabetes mellitus for at least one year, at least 18 years old, access to a cell phone, ability to read, write, and speak English, and have an associate's degree or less.
- will tell the individual that the clinical study will require two meetings with the nurse practitioner student over a 3-month period; one in the beginning and one at the

end. He will inform them that they will have their HbA1c value collected (1cc of blood via finger stick), their vital signs, and weight documented at no charge. During the scheduled meeting, the nurse practitioner student will go over an education document and provide a 3-month clinical study overview; which will include daily blood sugar checks, weekly and daily text messages.

- will inform the potential participant of the monetary and grand prize compensation. If he/she expresses interest, will provide him/her with the prestamped recruitment and <u>enrollment eligibility</u> survey that will need to be completed and mailed back to the medical office.
- will be prepared to answer all questions regarding the clinical study.

Appendix I

Patient Recruitment Form

[Insert Date]

[Recipient] [Address 1] [Address 2] [Address 3]

Dear [Recipient]:

As a graduate student in the School of Nursing at Liberty University, I am conducting research as part of the requirements for a Doctor of Nursing Practice – Family Nurse Practitioner degree. The purpose of my research is to identify if a health literate specific diabetic education program when combined with a daily short message service (SMS) intervention can improve glycemic control and self-efficacy in the type two diabetic patient over a 3-month time frame, and I am writing to invite you to participate in my study.

If you are 18 years of age or older, have a diagnosis of type two diabetes, have had diabetes for at least one year or longer, have access to a mobile device, English-speaking, have the ability to read and write in English, have an associate's degree or less, and are willing to participate, you will be asked to: (1) attend two meetings with the project leader (2) perform daily blood sugar checks; and (3) interact through text messages with the project leader. During the two schedule meetings your vital signs will be taken including weight, blood pressure, and pulse. You will be asked to complete two questionnaires and have your A1c value drawn; all free of charge (no insurance charges). The meetings will take place at the beginning of the study and at the end; approximately 90 days (3 months) apart. The first meeting will also include the receipt of an educational packet and will take approximately 45 minutes to complete the procedures listed. The second meeting will take approximately 20-30 minutes to complete. During the 90 days, you will be asked two SMS (text message) questions each day and one SMS (text message) question each week. The daily text messages should take no longer than 4 minutes to complete, the weekly text message should take no longer than 5 minutes to complete. Your name and other identifying information will be requested as part of this study, but the information will remain confidential.

To participate, please complete the attached enrollment eligibility document and return it to in the pre-stamped envelope by the indicated date. You will be contacted by phone to schedule the first meeting with the researcher once eligibility requirements have been reviewed.

A consent document will be given to you at the time of the first meeting. The consent document contains additional information about my research. You will be asked to sign the consent document and return it to me at the time of the meeting.

If you choose to participate, you will be entered to win one of three grand prizes. The overall grand prize winners will be chosen based upon (1) self-efficacy & health literacy score improvements; (2) A1c reduction values; and (3) involvement in text messages over the 90-day time frame. The grand prize winner will receive a 40-inch smart television (\$100.00 value). The second grand prize winner will receive a Fire 7 HD Tablet (\$29.99 value), and the third grand prize winner will receive a pair of wireless Bluetooth Skull headphones (\$19.99 value). All participants who complete the study entirely will receive a \$5.00 Walmart gift card.

Sincerely,

Crystal Manus Masling RN, BSN, CCRN Liberty University, DNP-FNP Student

Appendix J

Enrollment Eligibility Questionnaire

Name:					
Addres	ss:				
Date o	f Birth:				
Home	Phone:				
Cell Pl	hone:				
Highes	st Level of C	ompleted Education	:		
Less	s than high school	High school or GED	Some college, no degree	Associate degree	Bachelor's degree or higher
Please 1.	<u>circle</u> yes or Have you be Yes	no for the following een diagnosed with	g questions: type 2 diabetes for No	one year or longer?	
2.	Do you have Yes	e a cell phone?	No		
3.	Can you rec	eive text messages?			
	Yes		No		
4.	Are you cor	nfortable with recei	ving text messages?	?	
	Yes		No		
5.	Can you ser	nd text messages?			
	Yes	U	No		
6.	6. Are you comfortable with sending text messages?				
	Yes		No		
7.	Can you spe	eak English languag	e?		
	Yes		No		

8. Can you read English language?

	~	<u> </u>	
1	Yes		No

9. Can you write English language?

Call you write Eligish hanguage?	
Yes No	0

Appendix K

Patient Demographic Questionnaire

Name:			
Address:			
Date of Birth:			
Home Phone:			
Cell Phone:			
Gender:			
Race/Ethnicity:			
White	Black	Hispanic	Other

Appendix L

Short Message Service (SMS) Document

SMS Part One: Daily Text Message

When	Question	Response
Daily	1. Did you take your blood sugar medicine?	(1) Yes (2) No
Daily	2. Did you check your blood sugar today?	(1) Yes (2) No

SMS Part Two: Weekly "Pop-Quiz"

Week	Question	Response
1	If your blood sugar is low (less than 70mg/dL) what can you eat for a "quick-fix"?	 (1) Hard Candy (2) 4oz. of Juice (3) 2 tbsp. of raisins (4) All of the above
2	How should your meal plate be proportioned to follow the Diabetes Plate method?	 (1) ¹/₂ Vegetables, ¹/₂ Carbohydrates (2) ¹/₂ Vegetables, ¹/₂ Protein (3) ¹/₂ Vegetables, ¹/₄ Carbohydrates, ¹/₄ Protein (4)1/2 Protein, ¹/₂ Carbohydrates
3	A 4oz serving size of meat can be compared to what?	 (1) A deck of cards (2) A tennis ball (3) The palm of your hand (4) A softball
4	Half of your plate should be filled with what type of foods?	 (1) Carbohydrates (2) Non-Starchy Vegetables (3) Protein (4) Fats
5	What is the normal blood sugar range before a meal?	(1) 80-100 mg/dL (2) 80-130 mg/dL (3) 70-120 mg/dL (4) 80-140 mg/dL

6	Type two diabetes is caused by?	 (1) Insulin resistance (2) Weight loss (3) Genetics (4) Hereditary
7	Type two diabetes can be prevented through?	 (1) Proper Diet (2) Exercise (3) Blood Pressure below 140/90mmHg (4) All of the above
8	An A1c value shows an average blood sugar over how many months?	 (1) Two to three months (2) One to three months (3) One month (4) Six months
9	How many minutes a week should you exercise?	(1) 200 (2) 100 (3) 150 (4) 30
10	What type of exercise is best for a diabetic patient?	 (1) Low intensity (2) Moderate intensity (3) High intensity (4) Non-Strenuous
11	All of the following are considered moderate intensity exercises except which one?	 (1) Yard work (2) Cleaning house (3) Walking (4) High Intensity Interval Training
12	Physical activity improves	 (1) Heart Health (2) Insulin Sensitivity (3) Weight Loss (4) All of the above

Notes:

- All answers are highlighted in yellow except for the daily questions.
- There are 12 total questions equally divided; 4 for nutrition, 4 for exercise, and 4 for type two diabetes.
- All participants will be asked to answer the questions to the best of their abilities. All questions have been derived from the health literacy document. If the participant selects the wrong answer, then they will be provided an automated response with the correct answer.

Appendix M

Instructions for Short Message Service (SMS)

Question One:

Did you take your blood sugar medicine? Reply on your cellphone Number/Key One for Yes if you took for your medicine Number/Key Two for No if you did not take your medicine

Question Two:

Did you check your blood sugar? Reply on your cellphone Number/Key One for <u>Yes</u> if you checked your blood sugar today Number/Key Two for <u>No</u> if you did not your blood sugar today

Weekly Friday Pop-Quiz Question:

Each week the question will change, you will receive an image with a question such as: Example:

What is the normal blood sugar range before a meal?

(1) 80-100 mg/dL
 (2) 80-130 mg/dL
 (3) 70-120 mg/dL
 (4) 80-140 mg/dL

Reply on your cellphone with the **number/key** of the answer you think is the correct answer *For this example: **You would reply 2 and hit send.**

The normal blood sugar range before a meal is 80 – 130 mg/dL

***Note:** if the answer you choose is incorrect, the correct answer will be sent back in a text message

Appendix N

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Completion Date	Planning	Pre-Implementation	Implementation	Evaluation
7/11/2019	Meet with scholarly project chair to present project idea and development			
8/07/2019	Receive project chair approval, then identify key stakeholders to individually obtain their support			
8/16/2019	Liberty University School of Nursing affiliation agreement with Private Family Practice and primary care provider, PA-C received			
8/19/2019	Meet with primary care provider, PA-C to present project topic, receive verbal endorsement letter of support from Private Family Practice			
8/21/2019	Meet with scholarly project chair to discuss proposal, project outcomes, and measurement tools			
10/2019	Begin and draft pre-proposal for IRB submission			
10/26/2019		Submit pre-proposal to scholarly project chair		

Scholarly Project Timeline

COMBINATION THERAPY FOR TYPE TWO DIABETES MELLITUS

11/2019	Perform mini-project presentation to scholarly	
	project chair	
12/2019	Submit IRB application	
01/2020	Receive IRB application	
	Meet with primary care	
	provider, PA-C and office	
	staff, provide project overview,	,
	post advertisement flyers	
	Print hardcopies of diabetes	
	education	
03/16/2020		Implement diabetes HL
		project for three months
03/16/2020		Obtain consent from all
		participants and complete
		all pre-study
		questionnaires; complete
		trial text message while in
		office "Did you take your
		blood sugar medicine
		today?"
03/16/2020		Send daily and weekly
		SMS engagement text
06/18/2020		messages to enrolled
		participants during three-
		month period; input
		response data into
		Microsoft Excel

COMBINATION THERAPY FOR TYPE TWO DIABETES MELLITUS

06/18/2020		Conclude three-month diabetes HL scholarly project; Meet with project participants, collect post- study data	Analyze SMS data in Microsoft Excel
06/18/2020			Utilize SPSS software to analyze data; prepare presentation
06/26/2020		Notify winners, compensate accordingly, mail "thank you" letters to all participants	
07/2020			Present data