

The Effectiveness of Nurse-Led Diabetes Self-Management Education among Adults with

Uncontrolled Type 2 Diabetes Mellitus

Submitted by

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A Direct Practice Improvement Project Presented in Partial Fulfillment

of the Requirements for the Degree

Doctor of Nursing Practice

Grand Canyon University

Phoenix, Arizona

August 28, 2019

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GRAND CANYON UNIVERSITY

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Abstract

Ample evidence has supported the efficacy of diabetes self-management education (DSME) in diabetes care. However, specific evidence that supports the effects of nurse-led DSME on glycemic control and prevention of diabetes complications remains limited. The purpose of this quantitative, quasi-experimental project was to determine if any, and to what extent a relationship existed between a nurse-led DSME intervention and the lowering of FBS levels to 100mg/dl or below, and the reports of improved self-efficacy among patients with poorly controlled T2DM at a primary care clinic located in an underserved community in Northwest, Texas. Theoretical support for the project was drawn from Ajzen's theory of planned behavior (TPB) and Orem's theories of self-care and self-care deficit. The target population was T2DM patients at the primary care clinic and the sample size was 10. Pre-intervention FBS levels: ($M = 196.7$, $SD = 52.3$) and after nurse-led DSME ($M = 176.40$, $SD = 55.1$) at the .05 level of significance ($t = 13.5$, $df = 9$, $n = 10$, $p < .05$, 95% CI for mean difference (16.893 to 23.707). Although, none of the participants reached the target FBS level of 100mg/dl, they all achieved significant reductions in their FBS levels of at least 20.3 points. Reported self-efficacy pre-DSME ($M = 42.5$, $SD = 14.3$). After nurse-led DSME ($M = 70.7$, $SD = 5.5$) at the .05 level of significance ($t = -9.0$, $df = 9$, $n = 10$, $p < .000$, 95% CI for mean difference (-35.2 to -21.1). Patients are more aware of the role of self-care in managing their condition and the clinic administrator is open to accepting nurse-led DSME and is considering hiring a diabetes-nurse educator. More work is needed to establish a definitive relationship between nurse-led DSME and glycemic control and diabetes self-efficacy.

Keywords: diabetes self-management, DSME, nurse-led self-care education and support.

Dedication

This project is dedicated to my late my father, Sir Damian E. Oronsaye (KSM), for his love and the values he instilled in me, and my late mother Princess, Dr. (Mrs.) Kate A. Oronsaye, whose love and belief in me was unwavering. To the question, you asked in 1998: “what about your nursing?” Iye, Look, I took it to the limits.

To my never-to-be-forgotten late sister Damiana, who left imprints of love and grace in my heart and my late brother Cosmas who filled my childhood with adventures.

And to my children, Jude, Daniel, Katherine, and Adesuwa; thank you for your stalwart support and love through the years. And last but not the least, “Girl” my faithful non-verbal companion who stayed quietly and patiently by my side through it all.

This is for all of you.

Acknowledgments

I want to express sincere gratitude to my committee members. Dr. Joyce Morrison (Chairperson), whose incomparable genius and kindness propelled and guided me through the direct practice improvement (DPI) courses. Dr. Morrison ceaselessly and convincingly expressed her belief in the Most-High YHWH of Host and in my ability to reach this academic goal. Dr. Victor Aghatise, without whose guidance and persistence this DPI Project would not have been possible. I would like to acknowledge and thank Nadia Bermudez, who supported me ceaselessly throughout the course of this project, my brother Professor Jude. A. Oronsaye, who gave me a head start in life, my brothers Patrick Oronsaye, Edward Oronsaye, Leonard Oronsaye, Damian Oronsaye, Dr. Chris Otoghile, Colonel Edward Oronsaye, United States Army (Ret), Osayande Akpata, Dr. Alphonsus Obayuwana, Princess Anthonia Eweka, Toni Osifo, Abieyuwa Emokpae, ChiChi Catherine Njigha, Mr. Osagie Odeh, Professor Greg Uche and a host of others, for their unwavering love and support.

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Chapter 1: Introduction to the Project

Ample evidence has supported the efficacy of diabetes self-management education (DSME) interventions in diabetes care. However, evidence that supports the particular effects of nurse-led DSME on glycemic control and prevention of diabetes complications has remained limited. The purpose of this quantitative, quasi-experimental project was to determine if any, and to what extent a relationship existed between a nurse-led DSME intervention and the lowering of FBS levels to 100mg/dl or below, and reports of improved self-efficacy among patients with poorly controlled T2DM at a primary care clinic located in an underserved community in Northwest, Texas. The primary focus was on how effectively a nurse-led DSME program helped adults with poorly controlled T2DM meet their diabetes management goal of glycemic control, referenced as FBS levels. The secondary focus was on patient-reported diabetes self-efficacy.

Diabetes complications are closely connected to patients' knowledge of appropriate lifestyle changes and engagement in the best and most beneficial activities (Oliveiral et al., 2016). Patients' adherence to recommended disease management activities and treatment reflects their attitude towards medications, foods, physical activities, behavioral modifications and the adoption of healthier lifestyles that support self-care (Oliveiral et al., 2016). Effective management of diabetes demands that caregivers and care recipients gain the needed knowledge for managing diabetes symptoms and DSME enable the acquisition of the needed knowledge, skills, and other support services for prediabetes and diabetes self-management (Beck et al., 2017).

DSME is evidence-based clinical practice that is founded on science and demonstrated in current research publications (Golden et al., 2017). DSME addresses the

daily difficulties of patients with uncontrolled diabetes and their risks for developing disease complication and even death. DSME is an ongoing, problem-solving process comprised of assessments, goals-setting, planning, performance and appraisals that enables patients' engagement in activities that empower them to acquire information, capabilities, and resources they need for the effective self-management of prediabetes and diabetes (Golden et al., 2017; Lavelle et al., 2016).

In nurse-led DSME programs, nurses bring their unique expertise and knowledge to the devising, delivery and supervision of structured interventions that focus on health preservation, health improvement and the self-care objectives of chronic disease management to diabetes care (Massimi et al., 2017). In this project, the real-world challenges and barriers to successful diabetes management were analyzed quantitatively using a quasi-experimental, one group, pre and post-test design. The beneficial effects of a nurse-led DSME on two important aspects of diabetes care among T2DM patients with uncontrolled diabetes (i.e., glycemic control and diabetes self-efficacy) were examined and compared with the effects of DSME in conventional diabetes management, usually comprised of medication therapy, follow-up office visits and written instructions provided by non-nurse healthcare providers (HCPs) (Pandey, Tripathi, Pandey, Srivatava, & Goswami, 2011).

Pre-intervention baseline data consisted of previously documented patients' clinical data in the project site's electronic health records (EHR) system, and primary data gathered from patients' answers in the pre-intervention questionnaire administered to assess participants' diabetes self-management behaviors, their perceived self-efficacy, and ability to comply with recommended diabetes treatment and management activities. The evidence-based diabetes self-management questionnaire (DSMQ) by Schmitt et al. (2016)

(see Appendix B) and the self-efficacy for diabetes (SED) (Appendix C) by the Self-management Resource Center (SMRC), were used to complete the project related pre and post-intervention assessments.

The DSMQ tool is considered a reliable and valid instrument that enables efficient assessments of self-care behaviors associated with glycemic control (Schmitt et al., 2016). The DSMQ is believed by researchers to be valuable for scientific as well as clinical analyses in both type 1 diabetes mellitus (T1DM) and T2DM patients (Schmitt et al., 2016). The SED tool has three subscales: diabetes-specific self-efficacy (SED-D), medical self-efficacy (SED-M), and general self-efficacy (SED-G) (see Appendix C) and it is also a widely used measure for diabetes-specific self-efficacy (Allen et al., 2018).

Pre-DSME intervention data collection was followed by a six-week nurse-led DSME intervention that consisted of a weekly one hour, forty-five minutes, up to two hours session of diabetes education. Post-DSME intervention clinical outcomes data (i.e., FBS levels) and post-DSME intervention survey data were collected after the last DSME class and coded numerically. Pre and post-DSME intervention clinical data and numerically coded survey data were analyzed and compared with the aid of the SPSS version 25 data analysis software using a paired sample *t*-test.

Background of the Project

Diabetes is an insidious and debilitating chronic disease that causes health deterioration over time, and eventually becomes a higher risk factor for morbidity and mortality (Powers et al., 2016). Globally, T2DM is currently one of the most common preventable chronic, noncontagious diseases (Dickson, Clark, Rabelo-Silva, & Buck, 2013). According to the Centers for Disease Control and Prevention (CDC) 2017 National Diabetes Statistics Report, an estimated 30.3 million people have diabetes (i.e.,

9.4% of the US population), 23.1 million people are diagnosed and 7.2 million people (i.e., 23.8% of people with diabetes are undiagnosed). In 2015, diabetes was the seventh leading cause of death in the US and was listed as any cause of death on 252,806 death certificates (CDC, 2017).

Diabetes is the foremost leading cause of renal failure, lower limb amputations and blindness among adults (Lavelle et al., 2016). Currently, the national estimated occurrences of diabetes are about 9.3% (Lavelle et al., 2016). The gravity and chronicity of T2DM, and the management of its complications result in tremendous increases in healthcare spending, higher rates of morbidity, diminished quality of life (QOL) and higher mortality rates (Powers et al., 2016). Annual healthcare spending on diabetes and its related disabilities and premature deaths are on the rise globally (Healthy People, n.d). For example, in 2017, diabetes cost the U.S. \$327 billion, including \$237 billion in medical costs and \$90 billion in lost productivity (Berry, 2019). It is therefore, necessary that patients with diabetes familiarize themselves with the different daily, complex self-management activities such as frequent monitoring of blood glucose levels, administration of blood glucose lowering medications like injections of insulin, as well as engagement and participation in vital healthcare decision-making activities that enable early recognition of signs and symptoms of serious complications (Powers et al., 2016).

DSME is one of the most favorable management strategies for DM patients who aim to achieve glycemic control, defined as HgbA1c level of 7% and below, or FBS level of 100mg/dl and below, to prevent complications (Lavelle et al., 2016). The American Association of Diabetes Educators (AADE) has designed seven vital focus spheres that must be prioritized and addressed in diabetes care to achieve favorable self-care outcomes and help individuals with diabetes reach their disease management goals of

glycemic control and prevention of complications (AADE, 2018). The seven focus spheres involve the definition of individual self-care behaviors that may need modification as follows: healthy eating, increased physical activities, problem-solving skills, regular monitoring of blood sugar levels, compliance with medications, risks reduction and coping skills (AADE, 2018).

Problem Statement

Among people diagnosed with diabetes, glycemic control (i.e., HgbA1c 7% and below) is necessary to reduce the risk factors for diabetes complications (Prescott et al., 2017). Researchers have found that 50% of individuals living with diabetes in the US struggle with reaching and maintaining the recommended HgbA1c goal of 7.0% or below (Prescott et al., 2017). Only about 14.3% of individuals in the U.S. reach the ideal ranges of the four core aspects of diabetes management objectives of glycated hemoglobin (HgbA1c) 7% or under, blood pressure (BP) 120/80mmhg or below, low density lipoprotein (LDL) cholesterol levels below 100 mg/dl, and smoking cessation (Prescott et al., 2017).

In the current healthcare arena, greater emphasis is being placed on the role of self-care in diabetes and other chronic diseases management (Shrivastava, Shrivastava, & Ramasamy, 2013). HCPs and healthcare organizations are tasked with delivery of comprehensive diabetes health education for sustained and positive self-care outcomes (Azami et al., 2018). In diabetes care, DSME programs provide T2DM patients opportunities to learn ways to control the symptoms of their disease to achieve clinically meaningful outcomes, such as lower HgbA1c levels and decreases in the occurrences of complications such as neuropathy, cardiovascular disease, nephropathy, retinopathy and skin and soft tissue disorders and when these complications are present, patients learn

ways to manage them with DSME (Golden et al., 2017). DSME programs have been shown to enable successful and sustained patient engagement in self-care behaviors of healthy eating, increased physical activities, regular blood sugar monitoring, medication compliance, and follow-up checkups that are defined in these programs as relevant to glycemic control (Chrvala et al., 2015). Numerous publications of DSME studies have continuously shown the efficacy of DSME in diabetes care. Findings indicate that DSME may be the most important aspect of diabetes care that can help patients, especially the elderly with poorly controlled HgbA1c, achieve positive care outcomes of glycemic control and prevention of complications (Azami et al., 2018; Chrvala et al., 2015; Marincic et al., 2017; Powers et al., 2016).

Different members of multidisciplinary healthcare teams including nurses, pharmacists, physicians and dieticians provide disease management education to patients with well-documented diabetes management successes (Azami et al., 2018). Evidence that support the beneficial effects of DSME delivered by registered nurses, pharmacists, and registered nutritionists in diabetes care is accumulating but studies that have compared the effectiveness of diabetes health education based on professional or specialty foci, have not found any distinctive differences in the quality of instructions provided by different HCPs (Azami et al., 2018). While the literature indicates a growing interest in nurse-led DSME and its efficacy, it is not known if, and to what extent a relationship exists between nurse-led DSME, glycemic control, and reports of higher levels of diabetes self-efficacy among T2DM patients with poorly controlled diabetes.

Purpose of the Project

The purpose of this quantitative, quasi-experimental project was to determine if any, and to what extent a relationship existed between a nurse-led DSME intervention

and the lowering of FBS levels to 100mg/dl or below, and reports of improved self-efficacy among patients with poorly controlled T2DM at a primary care clinic located in an underserved community in Northwest, Texas. Nurse-led DSME was measured by a total of 10 hours of contact, comprised of a weekly one hour, forty-five minutes to two hours class over a period of six weeks. Glycemic control was defined as FBS of 100md/dl or lower. Patient reports of improved diabetes self-efficacy was measured by numeric scores of the answers in the related project questionnaires.

Compared to DSME provided by other HCPs, nurse-led DSME may be more effective for helping patient reach their diabetes management goal of glycemic control, prevention of complications and improved diabetes self-efficacy. However, supporting evidence remains limited. This project provided an opportunity to examine and compare the effects of nurse-led DSME and DSME by other HCPs on glycemic control and reported diabetes self-efficacy of T2DM patients and contribute to the growing body of knowledge surrounding this subject. Previous documentations of FBS levels in participants' EHRs and primary data gathered from pre-intervention questionnaire answers represented effects of DSME by other HCPs and served as the baseline data. Post-intervention FBS levels and questionnaire answers represented effects of nurse-led DSME and served as the comparison data.

Clinical Questions

Pre-diabetic and diabetic patients must learn ways to control their blood sugar levels, to either prevent or delay diabetes onset, or onsets of its complications (Powers et al., 2016). Patients with diabetes increasingly suffer difficulties with self-care and compliance with treatment recommendations, their need for ongoing interventional support such as nurse-led DSME programs increase as their condition progressively

deteriorate and result in escalating need for changes in treatment and management stratagems (Sharp et al., 2015). The benefits and effects of DSME programs in the delay of diabetes onset and prevention of life-altering diabetes-related disabilities and premature deaths cannot be overstated (Sharp et al., 2015).

DSME programs provide ongoing learning that is helpful for the maintenance of health behaviors that result in positive health outcomes (Sharp et al., 2015). Participation in at least 10hrs of DSME program, have been linked to improved FBS levels and achievement of the ADA recommended HgbA1c levels of 7% or lower (Sharp et al., 2015). Patients who commit to and actively participate in DSME programs, are able to achieve improved HgbA1c levels by up to 0.6%, the same as levels achieved with multiple prescription drugs (University of Nottingham, 2017).

Ongoing nurse-led education, support and comprehensive nurse follow-ups enhance healthcare outcomes among patients with chronic diseases like T2DM (Lavelle et al., 2016). Nurse-led DSME programs are effective across the continuum of care and should be incorporated into diabetes plans of care as the programs are comprehensive and designed to be culturally sensitive and effective for encouraging and facilitating patients' acceptance, participation and adherence to treatment recommendations that result in enhanced patient-centered outcomes and satisfaction (Philis-Tsimikas & Gallo, 2014).

In this quantitative, pre and post-test quasi-experimental project, the effects and benefits of a nurse-led DSME and DSME by other HCPs on glycemic control and reported diabetes self-efficacy among adult T2DM patients with poorly controlled blood sugar levels were examined and compared. The independent variable was 10 contact hours of nurse-led DSME, comprised of a weekly one hour, forty-five minutes to two hours of DSME class over a period of six weeks. The measured dependent variables were

FBS levels of 100mg/dl or below and patient-reported diabetes self-efficacy, measured by numerically scored answers in the related questionnaires. The following clinical questions guided the project:

Q1: For patients with poorly controlled diabetes, will the implementation of a nurse-led DSME program that provides one hour, forty-five minutes to two hours per class up to a total of 10 hours of contact result in improved FBS of 100mg/dl or below after six weeks, compared to current diabetes care which includes written instructions by non-nurse health professionals?

Q2: For adult patients with poorly controlled T2DM, who have disease knowledge, and self-care deficits, will the implementation of a nurse-led DSME program that provides one hour, forty-five minutes to two hours per class up to a total of 10 hours of contact, result in reports of improved self-efficacy after six weeks, compared to current diabetes care which includes written instructions by non-nurse health professionals?

Advancing Scientific Knowledge

Diabetes is particularly distinct in its need for adequate self-care skills (Powers et al., 2016). Patients' survival and ability to maintain optimum QOL after being diagnosed with diabetes, depend on how knowledgeable they are about diabetes, its chronicity and gravity, and their awareness of the best available options for controlling its symptoms and managing its complications when they occur (Powers et al., 2016). DSME programs provide patients with the means to prevent diabetes, or delay the occurrences of its related co-morbidities, and optimize patients' QOL and care outcomes (CDC, 2018).

DSME can be provided by different members of healthcare teams including nurses, pharmacists, physicians and dieticians and there is no distinguishing evidence to

support the superiority of DSME by one health professional over the other. However, based on current literature, interest in nurse-led DSME and its efficacy in helping patient achieve and maintain glycemic control is limited, but growing. More so, because nurses are in the forefront of patient education in all healthcare settings (Azami et al., 2018). Furthermore, compared to other HCPs, nurses are the largest and most trusted group of health professionals and the mostly likely to encourage positive behavior changes, and engagement in preventive healthcare seeking behaviors and healthcare delivery transformation (Azami et al., 2018).

This quantitative, pre and post-test quasi-experimental project addressed and validated the efficacy of nurse-led DSME in closing gaps in diabetes care associated knowledge deficits that result in inadequate diabetes self-efficacy and failure to achieve glycemic control. Theoretical support for the project was drawn from the theory of planned behavior (TPB) by Ajzen, (1988; 2011) and the theories of self-care and self-care deficit by Orem (1959; 2001). The TPB provided the basis for the pre-intervention assessment of factors that influence self-management behaviors and self-efficacy among T2DM patients with poorly controlled blood sugar levels and Orem's self-care and self-care deficit theories, ensured full participants' engagement and completion of the program.

The DSMQ and SED questionnaires facilitated assessments of participants' health behaviors and diabetes self-efficacy pre and post-intervention, and the related data collection. Findings of this project contribute to the limited but growing evidence and support for nurse-led DSME as an effective and fundamental healthcare tool and component of quality diabetes care that is a distinctive contribution of the nursing profession in the global fight against diabetes and its disabling complications. The hope is

that the findings of this project, together with findings from prior studies, would compel additional investigations for the validation of nurse-led DSME as an essential aspect of care for T2DM patients.

Significance of the Project

The essential qualities of nurses, their academic qualifications and extensive knowledge of disease management enable them to play pivotal roles in the devising, delivery and supervision of structured interventional programs that focus on health preservation, health improvement and the achievement of self-care objectives of patients with chronic diseases like diabetes (Massimi et al., 2017). The focus of this project was on the benefits of nurse-led DSME programs to healthcare consumers, providers and healthcare systems in general. The role of nurses and the efficacy of nurse-led DSME in diabetes management, and the realization of self-care goals among T2DM patients was highlighted.

The project is significant because it provided an opportunity to examine and compare the efficacy of nurse-led DSME with DSME by other HCPS, in the achievement of sustained glycemic control, positive behavioral changes and reports of improved diabetes self-efficacy among T2DM patients. The Findings of the project add to the growing distinctive and supporting evidence of the efficacy of nurse-led DSME, that could instigate further investigation for its validation as an essential aspect of diabetes care. Additionally, the findings build support for potential proposals for the routine inclusion of nurse-led DSME programs in all diabetes care settings for more productive and unceasing diabetes care regimes that lead to sustained glycemic control and prevention of complications. Lastly, the findings of this project provide further endorsement and recognition of the unique evidence-based and theory supported

expertise, and experiences that nurses bring to the current multidisciplinary healthcare workforce and may gain support for proposals of policy changes to make DSME training and certification a mandatory part of nursing curricula.

Rationale for Methodology

A quantitative methodology was selected for this project in which the effects of a nurse-led DSME was examined and compared with effects of DSME by other HCPs on the glycemic control and reported diabetes self-efficacy among adult T2DM patients with poorly controlled blood sugar levels. The quantitative methodology is the most common and appropriate approach for answering questions about associations within variables that are measurable, and for explaining, predicting and controlling of issues and phenomena, with a principal objective to analyze and represent that relationship numerically through statistical analysis (Grand Canyon University, n.d). The two clinical questions asked involved the effects of the independent variable (i.e. 10 contact hours of nurse-led DSME) on the two defined independent variables defined and measured as FBS levels of 100mg/dl or below, and patient reported self-efficacy derived from the scored numerically coded primary data from the questionnaires administered before and after the intervention.

The quantitative methodology was considered most appropriate for this project which required a review and collection of previous documented clinical data from participants' EHRs, the numerical coding of primary data from participants' questionnaire answers and data analysis and comparison. When data is collected from patients' health records, and when answers in questionnaires are coded and during data analysis, a structured approach with high levels of consistency are needed in order to establish true relationships between independent and dependent variables (Grand Canyon

University, n.d). Researchers often employ the quantitative methodology to explain existing conditions of variables or phenomena. Quantitative approaches are most often employed in social science, academic and psychological investigations as they deliver ample datasets that frequently uncover fresh information and insights that would otherwise be overlooked (Grand Canyon University, n.d-b) Researchers do not start with assumptions but formulate them after data is collected (Grand Canyon University, n.d-b).

Nature of the Project Design

A quasi-experimental design was selected and applied in this quality improvement project. Quasi-experiments are particularly useful when sample sizes are small and randomized selection of participants is impractical, or when conformity with the rigorous step by step processes that are required in true experiments is difficult (Grand Canyon University, n.d-c). There are three main classifications of quasi-experimental designs, the non-equivalent control groups, the pre-test/post-test no control groups and the time-series (Grand Canyon University, n.d-c).

The non-equivalent control groups design involves at least one experimental group and a control group used for comparison and often uses already existing groups or creates groups for convenience because randomization is not possible (Grand Canyon University, n.d-d). The pre-test/post-test, no control groups design involves the identification of a single experimental group to receive a treatment, the whole group is pre-tested, exposed to a treatment or intervention, and the entire group is post-tested. If pre-treatment values are significantly different from the post-treatment values, the researcher is able to suggest that the change in values was due to the treatment (Grand Canyon University, n.d-d). Pre and-post-test quasi-experimental designs are the most often employed designs by behavioral researchers to determine the effect of treatments or

interventions on patient participants (Allen, 2017). In, dependent variables are measured once before an intervention is implemented and after it is implemented (Allen, 2017). The time-Series design involves the observation or testing of one group of subjects repeatedly both before and after the administration of treatment. This type of design is often chosen when the intent is to demonstrate long term effects of an intervention (Grand Canyon University, n.d-d).

Quasi-experiments test real-world effectiveness of interventions and may be used to support hypotheses that interventions are causally related to outcomes (Schweizer, Braun, & Milstone, 2016). Quasi-experimental designs are especially useful for evaluating the effectiveness of interventions implemented by hospital staff, rather than those implemented by research teams under research conditions, they have better external validity and are more generalizable than randomized control trials (RCTs) or true experiments. Quasi-experiments are more cost and resource efficient than RCTs but are subject to biases (Schweizer et al., 2016). These biases can be reduced by careful planning and choice of project designs. Other strategies to reduce biases include data analysis approaches and careful considerations, like the inclusion of control groups, or non-equivalent variables, collection of adequate observational data before and during interventions and applying appropriate data analysis methods (Schweizer et al., 2016).

For this short-term project that took place in a small primary care clinic located in an underserved community in Northwest, Texas, the one-group pre and post-test quasi-experimental design was considered the most appropriate and applicable because of the relatively small sample size of 10 patients and the limited data collection time frame of six weeks. The one-group pre and post-test design is characterized by two features, the use of a single group of participants, which means all the participants are part of a single

condition and all participants are given the same treatments and assessments; and the fixed, undeviating procedure that requires the assessment of dependent variables before and after a treatment is implemented (Allen, 2017).

The effects of a six-week nurse-led DSME on the FBS levels and the reported diabetes self-efficacy of 10 T2DM patients with poorly controlled blood sugar levels were examined and compared with effects DSME by other HCPs. Previous documentation of clinical data comprised of FBS levels in participants' EHRs and numerically coded primary data comprised of pre-intervention questionnaire answers related to diabetes health behaviors and self-efficacy were collected as baseline data. All participants were exposed to the same nurse-led DSME intervention for six weeks. Post-intervention, another set of FBS levels and numerically coded primary data were collected as comparison data. The two sets of data were analyzed and compared, the differences provided the answers to the clinical questions asked.

Definition of Terms

American Association of Diabetes Educators (AADE). The AADE a multi-disciplinary professional membership organization dedicated to improving diabetes care through innovative education, management, and support. With more than 14,000 professional members including nurses, dietitians, pharmacists, exercise specialists, and others, AADE has a vast network of practitioners working with people who have, are affected by, or are at risk for diabetes (American Association of Diabetes Educators, 2018)

American Diabetes Association (ADA). The ADA is a network of more than one million volunteers, a membership of more than 500,000 people with diabetes, their

families and caregivers, a professional society of nearly 14,000 healthcare professionals, as well as more than 800 staff members (American Diabetes Association, n.d).

Body Mass Index (BMI). Body Mass Index (BMI) is a person's weight in kilograms divided by the square of height in meters. A high BMI can be an indicator of high body fatness. BMI can be used to screen for weight categories that may lead to health problems, but it is not diagnostic of the body fatness or health of an individual (National Center for Chronic Disease Prevention and Health Promotion, 2018).

Diabetes Self-Management Education (DSME). The cornerstone of care for all individuals with diabetes who want to achieve successful health outcomes and avoid complications. The program is conducted in healthcare settings, such as physicians' offices and clinics, pharmacies and hospital outpatient settings (State of Utah , n.d).

Glycemic control. Regulation and maintenance of blood glucose levels within normal ranges; aim of the treatment of diabetes mellitus (by diet, oral hypoglycemic agents or parenteral insulin); long-term glycemic control reduces later incidence of secondary diabetic complications (Mooney, 2009).

HgbA1c. Also Known as A1C, HbA1c, Glycohemoglobin, Glycated Hemoglobin, Glycosylated Hemoglobin. Formal Name - Hemoglobin A1C. Hemoglobin A1C, also called A1C or glycated hemoglobin, is hemoglobin with glucose attached. The A1C test evaluates the average amount of glucose in the blood over the last 2 to 3 months by measuring the percentage of glycated (glycosylated) hemoglobin (The American Society for Clinical Laboratory Science , 2015).

Hypoglycemic Agents. Any of various agents that decrease the level of glucose in the blood and are used in the treatment of diabetes mellitus (Medical Dictionary for the Health Professions and Nursing, 2012).

Inter-disciplinary. Relating to more than one branch of knowledge (Oxford University Press, n.d-a).

Knowledge Deficit. A lack of cognitive information or psychomotor ability needed for health restoration, preservation, or health promotion is identified as Knowledge Deficit or Deficient Knowledge. Knowledge plays an influential and significant part of a patient's life and recovery (Wayne, 2016).

Medical Nutrition Therapy (MNT). Medical nutrition therapy is treatment based on nutrition. It includes checking a person's nutrition status and giving the right foods or nutrients to treat conditions such as those caused by diabetes, heart disease, and cancer. It may involve simple changes in a person's diet, or intravenous or tube feeding. Medical nutrition therapy may help patients recover more quickly and spend less time in the hospital (Gale Encyclopedia of Nursing and Allied Health, 2016).

Multi-disciplinary. Combining or involving several academic disciplines or professional specializations in an approach to a topic or problem (Oxford University Press, n.d-b)

Prediabetes. Prediabetes is a serious health condition where blood sugar levels are higher than normal, but not high enough yet to be diagnosed as type 2 diabetes. Approximately 84 million American adults—more than 1 out of 3—have prediabetes. Of those with prediabetes, 90% do not know they have it. Prediabetes increases risk for the development of type II diabetes, heart disease and stroke (Centers for Disease Control and Prevention, 2018).

Serum Lipids. Lipids are fat-like substances found in the blood and body tissues. The body needs small amounts of lipids to work normally (National Kidney Foundation, 2017).

Assumptions, Limitations, Delimitations

Some of assumptions of this project are related to the appropriateness of the methodology and design of the project, and the validity and reliability of the survey tools, the sample size and the inclusion criteria.

1. The first assumption in this project was that the choice of a quantitative methodology was the most appropriate approach for its findings to be generalizable and replicable. The main strength of the quantitative methodology lies in the consistent, precise data collection and data analysis processes and its objective of generalization that helps in the explanation and understanding of phenomena of interest.
2. The second assumption was that the project's sample was appropriate and representative of the general population of patients with T2DM. The inclusion criteria were appropriate and assured that all participants were experiencing the same health issues that are relevant to the project.
3. The third assumption was that the validity and reliability tests that established the DSMQ and the SED questionnaires as easy to use and efficient patient assessment tools, also ensured that project participants answered the survey questions truthfully. To ensure that participants answered the survey questions as truthfully as possible, participants were advised that they were participating in the project voluntarily and were free to withdraw from the project at any time with no consequences, their names and personal information would be left out, and their health data would be coded alphanumerically to maintain confidentiality.

4. The fourth assumption was that the sample size of 10 would be an accurate representation of the general population of T2DM patients since the sample was drawn based on the medical records of the target population who adults met the age and clinical criteria.
5. The fifth assumption was that the clinical outcome variable (i.e., FBS levels of 100mg/dl or below) defined in the project would be achievable in the short-term six-week project, since the more comprehensive HgbA1c levels variable requires at least three months to achieve meaningful changes.
6. The sixth assumption was that the findings of the project would provide positive answers to the two questions asked considering, that there were no guarantees that participants would comply with DSME instructions and achieve the target results within the short six-week time frame of the project.

The limitations defined in this project were mainly related to the size and scope of the primary care setting of the project site was in and of itself, an unavoidable limitation. The project drew on information from a single community clinic and a small sample size of ten participants, which may not be sufficiently representative of the general population of T2DM patients. Another limitation is the data collection timeframe of six weeks. This restricted the amount and type of data that could be garnered in terms of sustained DSME outcomes. The more comprehensive three monthly HgbA1c levels was omitted and FBS levels were referenced as substitute measures for glycemic control.

The delimitations of the project were related to its focus, which was the examination and comparison of relationships between a nurse-led DSME and DSME by

other HCPs in glycemic control and health behaviors that promote positive health outcomes among adult T2DM patients. The main delimitations of the project were related to the inclusion criteria that restricted participation to only established, adult English-speaking patients, with T2DM and uncontrolled blood sugar levels, in a single primary clinic. Participants had to verbalize interest and commit to completing the six-week program. Delimitation also applied to the outcome variable of FBS levels and patient-reported self-efficacy.

Summary and Organization of the Remainder of the Project

Chapter 1 presented, introduced and stated the purpose of the project which was to examine the effects of nurse-led DSME on glycemic control and reported diabetes self-efficacy among patients with uncontrolled T2DM in a primary care clinic located in an underserved community in Northwest, Texas. The primary and secondary foci, as well as the measured dependent variables of interest were defined (i.e., FBS levels and patient reported diabetes-related self-efficacy). The significance and contributions of the project and its findings to existing supporting evidence for nurse-led DSME as an indispensable element of diabetes care that leads to positive patient care outcomes was discussed and presented. The data collection and data analysis approaches of the project, its ethical considerations, assumptions, limitations and delimitations were briefly addressed in Chapter 1.

Chapter 2 addressed the relevant DSME research articles that were reviewed and synthesized under two themes related to the identified dependent variables of interest as followed: (i) Efficacy of DSME on metabolic markers and (ii) Effects of DSME on patient care outcomes and health behaviors. Some of the articles that were reviewed were related to DSME studies that applied Ajzen's TPB and Orem's theories. The information

gained advised and justified the application of these theories in this project. Ajzen's TPB provided the bases for the pre and post-intervention needs and self-efficacy assessments that identified factors that influenced participants' health behaviors and their reported self-efficacy. Orem's theories have been shown in prior studies to enable to enhance levels of patients' engagement in health education programs that resulted in sustained and positive post-intervention self-care behavior changes and treatment adherence (Oliveiral et al., 2016). Other reviewed articles were related to studies that applied the quantitative methodology and quasi-experimental designs, these articles advised the selection of the one group pre and post-test design as the most appropriate for the project and was expatiated on, in Chapter 3.

Chapter 4 presented the relevant data for the two variables of interest (i.e., participants' FBS levels and reported self-efficacy). Clinical collected from participants' EHRs and directly from participants and numerically coded primary data derived from questionnaire answers were analyzed and interpreted using the SPSS data analysis software to answer the project related questions. The findings of the project were summarized and presented in Chapter 5. Based on the existing body of knowledge regarding nurse-led DSME and the findings of the project, conclusions were reached, and recommendations that addressed the theoretical, practical and future implications of the findings were made for practice and future studies related to the effectiveness of nurse-led DSME programs for the adult diabetic patient.

Chapter 2: Literature Review

The purpose of this quantitative, quasi-experimental project was to determine if any, and to what extent a relationship existed between a nurse-led DSME intervention and the lowering of FBS levels to 100mg/dl or below, and reports of improved self-efficacy among patients with poorly controlled T2DM at a primary care clinic located in an underserved community in Northwest, Texas. The effectiveness and capacity of a nurse-led DSME programs to produce lasting physiological changes and positive healthcare outcomes that are clinically noteworthy, among adult patients with T2DM with uncontrolled blood sugar were reviewed, analyzed and quantified.

The effects of nurse-led DSME was compared with the effects of DSME by other HCPs, using previously documented clinical data from participants' health records as pre-intervention baseline data that represent effects of DSME by other HCPs. Post-nurse-led DSME intervention results were used as the comparison data and represented effects of nurse-led DSME. Pre and post-intervention FBS levels and reported self-efficacy of participants were analyzed and compared at end of six weeks. The differences in the findings provided the answers to the clinical questions that were asked.

Searches for research articles on DSME programs were conducted through the Grand Canyon University (GCU) library and various search engines that included Microsoft Network (MSN) Bing and Google. The GCU library search was conducted by applying the "SmartText hint" feature along with keywords like diabetes self-management, DSME, nurse-led self-care education and support. The search yielded 38,814,556 articles. MSN Bing and Google search engines generated results from ResearchGate, PubMed, ProQuest and PLOS using the same keywords and yielded 1,920,000 and 39,500,000 results respectively.

Fifty peer-reviewed articles that met the inclusion criteria were selected from the GCU library and several government and private organizations' websites such as the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Robert Wood Johnson Foundation and the Kaiser Family Foundation and were restricted to publication from the last five years. The DSME articles addressed the implementation processes of existing program that have had the most significant and most relevant supporting data on the benefits and effects of nurse-led DSME in diabetes management including Azami et al. (2018), Chvala et al. (2015), Drincic et al. (2017), Jutterströma et al. (2016) and Powers et al. (2016).

The history of diabetes and the challenges of its management were presented in this literature review from a historical perspective. The selected topics addressed the beneficial effects of DSME in general, and the particular benefits and relevance of nurse-led DSME interventions in the achievement of lasting diabetes management goals among adults with poorly controlled T2DM. Other topics addressed effects of DSME, especially nurse-led DSME programs on glycemic control, the regulation of diabetes metabolic markers in pre-diabetes, acquisition of diabetes knowledge, behavioral changes, diabetes self-care skills and self-efficacy. Publications of studies that employed evidence-based tools like the 16-item DSMQ self-management assessment questionnaire and/or the 8-item SED to comprehensively assess T2DM patients' health needs, disease knowledge, self-care skills and disease management objectives were included in the selected literature (Allen et al., 2018; Schmitt et al., 2016). The methodologies and the designs, data collection and data analyses approaches, as well as the assumptions, limitations and delimitations identified in each of the selected studies and different recommendations for future nurse-led DSME programs were taken into consideration in the choice of

methodology and design, other relevant steps taken in this project.

DM is a widespread chronic disease with a growing worldwide prevalence, that has been nicknamed the “silent epidemic” by the World Health Organization (WHO) as cited by Habibzadeh et al., 2017). According to Habibzadeh et al. (2017), in its most recent 2013 statistics, the IDF reported that there were more than 382 million people suffering from DM globally with an average global prevalence of 8.3% and 46% of undiagnosed cases. The 2020 Healthy People Campaign reports the following about diabetes: it is the 7th leading cause of death in the US, compared to deaths from other causes (Healthy People, n.d) The number of deaths resulting from diabetes and its complications are 1.8 times more than other causes and risks for myocardial infarctions or heart attacks are 1.8 times higher when a diagnosis of DM is present (Healthy People, n.d). Diabetes is a major cause of renal failure, lower limb amputations, and blindness among adults (Healthy People, n.d).

In 2012, the disease-burden of DM cost the U.S government approximately 245 billion dollars, including cost of care, lost productivity and loss of lives and these numbers are increasing each year globally (Healthy People, n.d).In the US, approximately 30.3 million individuals or 9.4% of the populations are living with diabetes and 23.1 million of these are diagnosed cases (Beck et al., 2017). Seventy-two million or 23.8% of people in America are undiagnosed and an estimated 84.1 million Americans are at increased risk for T2DM; more than 114 million individuals are in danger of developing diabetes and diabetes-related complications (Beck et al., 2017). However, DM is avoidable, and its complications can be delayed if patients are able to achieve and maintain proper glycemic control (Chaia et al., 2018).

According to Oliveiral et al. (2016), diabetes complications are closely connected to patients' knowledge of appropriate lifestyle changes and engagement in the best and most beneficial self-care activities (Oliveiral et al., 2016). Therefore, it is of the utmost importance that patients develop a deep understanding of diabetes and why self-care and adherence are vital and relevant components of diabetes management (Oliveiral et al., 2016). Patients' adherence to recommended disease management activities and treatment is often a reflection of their attitude towards medications, foods, physical activities, behavioral modifications and the adoption of healthier lifestyles that support self-care (Oliveiral et al., 2016). Effective management of diabetes demands that caregivers and care recipients gain the needed knowledge for managing the disease symptoms, such as uncontrolled blood sugar and elevated HgbA1c levels. DSME is the ongoing participation of patients in activities that enable the acquisition of the requisite knowledge, skills, and capabilities for self-management of prediabetes and diabetes, as well as other support services (Beck et al., 2017).

Patients, families, healthcare providers and community engagements in diabetes prevention and management educational programs and activities play vital roles in the prevention, control of diabetes symptoms and prevention of its complications (Oliveiral et al., 2016). Patients can prevent or delay the onset of complications through participation in DSME programs (Beck et al., 2017). DSME programs are evidence-based and evidence-guided interventions that incorporate patients' individual healthcare needs and healthcare goals as well as their lived experiences for creating tailored plans of care (Beck et al., 2017).

In order to properly highlight the role and importance of DSME in the management of DM, it is necessary to present the history of diabetes, including how the disease was first discovered and managed, to help modern day HCPs understand how much is known about the disease and how well it is currently being managed (Wu, 2017). The name “diabetes mellitus” originated from the Greek word diabetes which means to “siphon or pass through” and the Latin word mellitus which means honey or sweet (McCoy, 2009). The first allusion to diabetes dates to as early as 1552 B.C., when an ancient Egyptian healer first recorded urinary frequency as a sign of a strange illness that resulted in loss of weight (McCoy, 2009). In approximately 250 B.C, the disease was referred to as diabetes by Apollonius of Memphis (Wu, 2017). By 150 A.D, when Arateus, a Greek physician, described what is now known as diabetes as the melting of flesh and limbs into urine, physicians began gaining better insights into diabetes (McCoy, 2009). Individuals who were thought to have diabetes had their urine tasted by designated "water tasters," if their urine tasted sweet diabetes was diagnosed in acknowledgement of this feature of diabetes (McCoy, 2009).

Diabetes was first recorded in an English textbook in 1425 AD. Hundreds of years later in 1675 A.D, Thomas Willis combined the words “mellitus” which means honey and “diabetes” and gave the disease the full name “diabetes mellitus” (McCoy, 2009). In 1776, Matthew Dobson noted a brown sugar-like substance in the urine of people with diabetes, which led him to confirm that people with diabetes had sweet tasting urine because their urine contained excess sugar. Dobson also noted that the disease was fatal in some individuals and in others it was chronic, identifying for the first time the distinctive difference between T1DM and T2DM (Wu, 2017).

Doctors and scientists have recorded data about diabetes from the time it was first discovered, including the first findings about its diagnosis and managements in the early 19th century (McCoy, 2009). Over the years, experts have gained better understanding of diabetes management as they learned more about diabetes itself. Early treatment recommendation of exercise, usually in the form of horse-back riding, which was believed to alleviate the excessive passage of urine associated with diabetes (McCoy, 2009).

The recommendation for exercise was followed by the 16th and 17th centuries recommendations of dietary modifications, after physicians began understanding that changes in the diet such as the consumption of only meats and fat from animals or the consumption of large quantities of sugar, could help in managing diabetes (McCoy, 2009). In the 1870s during the French and Prussian wars, Apollinaire Bouchardat a French doctor developed personalized diets as remedies for diabetes after noticing improvements in the symptoms of patients with diabetes with the wartime food rationing (McCoy, 2009). The 20th century heralded numerous scientific breakthroughs in the management of diabetes, such as the 1916 textbook by Elliott Joslin a leading diabetes expert in Boston *The Treatment of Diabetes Mellitus*, in which he asserted that consistent engagement in physical activities and a regulated diet could substantially decrease the risk of death in patients with diabetes (McCoy, 2009).

In 1920 to 1922, scientists discovered insulin which has remained to date the principal therapeutic agent for treating diabetes and for achieving glycemic control (McCoy, 2009). Drugs like the oral hypoglycemic medications have been produced for controlling blood glucose levels. Patients who are diagnosed with diabetes now have ability to self-manage their diabetes at home. They can monitor their own blood sugar

levels, make needed changes in their diet, exercise regularly, and precisely measure and administer their insulin and other medications that regulate their blood sugar levels and reduce their risk for complications (McCoy, 2009).

Theoretical Foundations

This project was built on the theory of planned behavior (TPB) by Ajzen (1988) and Dorothea Orem's theory of self-care and self-care deficit (1959, 2001). These theories were applied in this project as the basis for the pre-intervention data collection from patients' records and survey answers to identify the reasons for the clinical deficit of hyperglycemia, and diabetes knowledge and health behaviors deficits that result in poor self-efficacy. Orem's self-care and self-care deficit theories were applied in the planning and implementation of the nurse-led DSME intervention to ensure full participants' engagement, commitment to, and completion of the six-week program.

The theory of planned behavior (TPB). The TPB model is a self-awareness or an intra-personal concept of expectancy for value that was developed and introduced by Icek Ajzen in 1985. The TPB suggests that an individual's behavior is motivated by the purpose of the behavior and it is controlled by three factors including the individual's view of the behavior, the individual's values, and his or her perceived behavior control (Ajzen, 2011). According to Ajzen (2011), the TPB is one of the most influential models for predicting human social behaviors, it predicts a person's intent to engage in a behavior at a defined time and place, and Al-Washali et al. (2018) assert that the TPB is one of the most widely tested health behavior models that have been used with other health behavior theories like the theory of reasoned action (TRA) by researchers to gain better understanding of patients' rationales for acceptance or non-acceptance of health-related behaviors.

The TPB originated from the theory of reasoned action as a means for predicting a person's intent to engage in an activity at a specified place and time. It proposes that the most accurate predictor of a person's action is his or her pre-planned intention to participate in that activity (Blue, 2007). The TPB suggests that intentions are the most significant determinants of people's behaviors and intentions are determined by people's attitudes, their personal beliefs and their perceived behavioral control (Ajzen, 2011). According to Blue (2017), intention depends on a person's level of self-control and the ease or effort with which he or she engages in the behavior. Thus, intention is the reason for a person's engagement in positive or negative behaviors (Blue, 2007).

The theory was designed to explain behaviors that individuals can control and is focused on individual behaviors based on individual values and views, and individual behavioral influences, beliefs and goals (Blue, 2007). The main element of the TPB is in the intention to engage in a behavior. Intention is often induced by the viewpoint that an individual's behavior or action is likely to have an expected result after the risks and benefits of that result is estimated (Ajzen, 2011; LaMorte, 2018). TPB is comprised of six combined constructs that indicate an individual's self-control of a behavior: attitudes, behavioral intention, individual values, societal values, perception of self-control, and a perception of behavior control (LaMorte, 2018). The theory has been effectively utilized for the prediction and explanation of different health behaviors and objectives such as tobacco use, alcohol consumption, usage of healthcare services, breastfeeding, and drug use (LaMorte, 2018).

The potentials benefit of using the TPB as a theoretical basis for this project, has been demonstrated in prior projects that applied the it in health behavior assessments and in development of behavior change interventions. Findings from several studies that have

addressed the influence of self-care behaviors on glycemic control and prevention of complications in diabetic patients indicate that TPB based interventions aimed at improving self-care in individuals with diabetes resulted in significant reduction in HgbA1c levels over time (Chang, Choi, Kim, & Song, 2014).

For example, in a study that took place in Ahvaz, Iran, to evaluate the efficacy of a TPB based intervention to improve foot care among patients with T2DM, Beirandvand et al. (2016) found a significant increase in the average scores of attitudes, and foot care performance in the intervention which had higher scores than the control group ($p < 0.05$), after the intervention. Researchers concluded that the intervention was effective in improving the foot care in diabetic patients (Beiranvand, Asadizaker, Fayazi, & Yaralizadeh, 2016).

Also, in a randomized controlled trial by White et al. (2012), the efficacy of a four-week health intervention based on the TPB to promote regular physical activity and healthy eating among older adults diagnosed with Type 2 diabetes or cardiovascular disease was evaluated. The TPB was used to assess behavior change needs of patients, in planning and designing of educational interventions for physical activities. Based on the result of the study, researchers concluded that the TPB was effective for developing health-promotion intervention to encourage physical activities among older people with diabetes and cardiovascular disease (Beiranvand et al., 2016).

The effective self-care education and interventions require a good understanding of behaviors that need modification in different patient groups for a meaningful health education program (Al-Washali et al., 2018). When targeted behavioral interventions for different patient populations are being developed, determining the factorial elements of certain behaviors, contribute to a better understanding of behavioral change mechanisms

that are useful (Al-Washali et al., 2018). In diabetes self-care, assessment of determinants of self-care behavior is very important, in order to identify patient's intentions regarding modification of self-care behaviors; more so, because patients' intentions play a large and vital role when developing standards of diabetes self-management interventions. (Al-Washali et al., 2018).

In this project, the TPB informed the choice of the SED questionnaire that was used for the pre-DSME intervention self-efficacy assessment that helped identify participants' health behaviors and their perceived diabetes self-care efficacy in order to plan for their full participatory engagement in, and completion of the DSME program. Post-intervention assessment provided insights into the gains each participant achieved and confidence in individual capacity to engage in and maintain diabetes self-care activities long-term.

Dorothea Orem's Theory of self-care and self-care deficit. Orem's theory suggests that patients who are at risk for specific negative healthcare outcomes can be encouraged to involve themselves fully in self-management activities for sustained enhancement of their health and their QOL (Okorie, 2018). In healthcare, knowledge deficits regarding disease prevention and management, increase the potential for non-compliance with plans of care and prescribed treatments (Okorie, 2018). Orem's general theory of nursing involves three interrelated theories of self-care, self-care deficit and nursing system. The theory of self-care involves self-care, the self as self-care agency, therapeutic self-care demand and self-care requisites (Orem, 2001).

Orem (1991) described self-care as an individual's capacity to initiate and engage in activities in his or her own self-interest to preserve life, health and well-being. Self-care agency is a person's ability to engage in self-care activities. This ability results from

developmental age status, lived experiences, socio-ethnic tendencies, health condition and accessibility of resources (Orem, 2001).

Orem (1991) defined therapeutic self-care demand as the entire self-care activities engaged in by an individual for a period of time to meet self-care needs through the application of approved means and relevant processes and actions. According to Orem (1991), self-care requisites are comprised of three factors: (1) universal or basic self-care requisites such as adequate intake of air, water, food, elimination process, balance between activity and relaxation, between quietude and social interaction, avoidance of risks to life and well-being and promotion of human functioning. (2) Developmental self-care requisites that is associated with life changes and events such as adjustments to a new function in life or physiological change. (3) Health deviation self-care requisites that involve activities that are needed in disease and injury conditions (Orem, 2001). Health deviation self-care requisites include search for and acquisition of appropriate healthcare and support; awareness of and attention to the consequences and outcomes of diseases, and the efficient performance of prescribed treatment processes (Orem, 2001). This third factor also include the modification of the sense of self in the acceptance of being in a defined state of ill health, with specified types of healthcare needs and learning to live with the aftermaths of disease conditions (Orem, 2001).

An individual's awareness of potential healthcare issues is essential for the promotion of self-care behaviors that are often learned within socio-ethnic contexts (Orem, 2001). Orem's theoretical construct defines self-care as a human essential, and in that construct of self-care, she defined the function of nursing and when nursing is needed. The theory of self-care deficit indicates that nursing care is necessary when an

individual is unable or is hampered in the continued performance of efficient self-care (Orem, 2001).

Orem's self-care concepts are related to productive self-care practices defined as (i) therapeutic self-care demand, which is the ability to fully accomplish the demands of self-care in relationship to their life conditions. (ii) Self-care agency is described as an individual's ability to carry out self-care activities or health promoting behaviors by his or herself to maintain health. Self-care agency is multifaceted and is developed through daily repetitive practices that can be modified with help and guidance from healthcare providers. Self-care is an important and valuable principle because it emphasizes the active role of people in their own healthcare, rather than the passive (Oliveiral et al., 2016). Orem (1991) recognized five ways support can be provided: acting on behalf of and achieving for others; directing others; supporting others; providing environments that promote personal growth in relation to future needs and educating others (Orem, 2001). The objective of health education is patient-empowerment, and encourage patients' understanding of their disease conditions, and assume ownership and control of their healthcare needs (Oliveiral et al., 2016).

In a 2016 integrative review of research articles, Oliveiral et al. presented the evidence-base for the application of Orem's theory in nursing interventions to promote self-care for persons with T2DM. The eight-article review included the follow five articles: a randomized quasi experimental study that tested the effectiveness of structured patient-care interventions centered on instruction and advocacy to enhance glycemic control in adults diagnosed with T2DM in an outpatient care setting by Gallegos et al. (2007). Another article detailed the results of a randomized clinical trial that compared the HgbA1c level, risk of coronary heart disease (CAD) and the QOL of patients with

diabetes who partook in diabetes self-management program and those who received the usual nursing care by Wattana et al. (2007). Other articles included a comparative longitudinal and prospective study that compared and monitored the impact of two educational interventions on the disease knowledge, QOL and the acceptance of self-care actions by a patient with T2DM by Imazu et al. (2015), and a 2012 pre and post-test study to establish the effect of DSME on self-care of patients with T2DM by Karakurt et al. (2012) as well as a descriptive study to understand the effect of nursing interventions and diabetes education on the self-care and self-efficacy of patients with T2DM by Alpirez et al. (2006). Findings from the studies showed that after participating in DSME interventions that applied Orem's theories, participants achieved enhanced self-efficacy and metabolic control (Oliveiral et al., 2016).

Orem's (2001) concept of self-care agency involves the capacity to respond to and recognize the meaning of specific situations to see the need for change or modification of observed activities. This theory is founded on the idea that an individual's ability to meet self-care needs is learned and people have the capacity learn and develop themselves. Nurses must continually strive to assess patients for gaps and deficits in care and provide instructions and reinforcements to address and close identified gaps (Okorie, 2018). Orem's theory of self-care has been used by providers and diabetes educators to guide, identify, plan and implement DSME for higher levels of patient participation that produce positive changes to patient health statuses (Oliveiral et al., 2016).

Review of the Literature

Findings from prior studies of DSME and other diabetes support programs, have consistently demonstrated that these programs are effective for managing diabetes. Patients who participate in DSME program frequently experienced lower HgbA1c

readings, decreases in body mass indexes (BMIs), decreased blood pressure readings, and enhanced healthcare results (ChangeLab Solutions, 2017). The literature review criteria included articles that addressed and supported the role and efficacy of nurse-led DSME in the achievement of lasting biological, behavioral and functional changes that are required for clinically noteworthy care outcomes. Others were articles that addressed the effects of DSME on health behaviors that result in glycemic control, sustained weight loss and absence of complications as well as articles that compared DSME led by nurses and non-nurse health professionals, and those that employed the DSMQ and the SED or similar tools (Azami et al., 2018; Chrvala et al., 2015; Drincic et al., 2017; Jutterströma et al., 2016; Powers et al., 2016). The following were the clinical questions asked in the project:

Q1: For patients with poorly controlled diabetes, will the implementation of a nurse-led DSME program that provides one hour, forty-five minutes to two hours per class up to a total of 10 hours of contact compared to current diabetes care which includes written instructions by non-nurse health professionals, result in improved FBS of 100mg/dl or below after six weeks?

Q2: For adult patients with poorly controlled T2DM and disease knowledge, and self-care knowledge deficit, will the implementation of a nurse-led DSME program that provides one hour, forty-five minutes to two hours per class up to a total of 10 hours of contact compared to current diabetes care which includes written instructions by non-nurse health professionals, result in patient self-report of improved self-efficacy after six weeks?

The choice of methodology and design, data collection and data analysis approaches employed in the project were advised by the methodologies, designs, data

collection tools and procedures, and the data analyses processes employed in the literature articles that were reviewed. Selected articles were reviewed and synthesized around two themes pertinent to the clinical questions. Each theme was supported with three existing literature related DSME as followed: (1) Efficacy of DSME on metabolic markers and (2) Effects of DSME on patient care outcomes and health behaviors.

Efficacy of DSME on metabolic markers. DSME programs have been linked to enhanced healthcare behaviors and healthcare outcomes that are validated by research findings; in general, most study participants experienced decreases in HgbA1c levels, body weight and BMI, LDL cholesterol levels, blood pressure, and self-reported improved health-care outcomes (ChangeLab Solutions, 2017). Existing works clearly show that DSME is effective for diabetes care. Patients who participate in DSME often experience lowered HgbA1c levels, lowered BMI, lowered BP readings, and better healthcare outcomes (ChangeLab Solutions, 2017).

Effects of DSME HgbA1c levels. In a 2014 randomized and controlled clinical study, researchers systematically evaluated the potential ameliorating effect of a low-intensity DSME comprised of eight 2-hour DSME sessions on metabolic markers of HgbA1c, body weight and atherosclerotic parameters of carotid intima-media thickness (CIMT), and carotid arterial stiffness (CAS) in 72 patients with T2DM (Yuan et al., 2014). Seventy- six patients with T2DM were recruited in the study and were randomly assigned to an intervention group ($n = 36$) and control group ($n = 40$) (Yuan et al., 2014). Patients in the intervention group received a 3-month intervention, which included 8 weeks of education on self-management of diabetes mellitus and a subsequent 4 weeks practice with the self-management guidelines. Patients in the control group received standard advice on medical nutrition therapy. Metabolic markers, carotid intima-media

thickness (CIMT), and carotid arterial stiffness (CAS) of the patients in both groups were assessed before and after the 3-month intervention (Yuan et al., 2014).

Study results showed significant decreases in HgbA1c levels (HgbA1c, $-0.2 \pm 0.56\%$ versus $0.08 \pm 0.741\%$; $p < 0.05$) and body weight (-1.19 ± 1.39 kg versus -0.61 ± 2.04 kg; $p < 0.05$) in the intervention group when compared to the control group. There were no significant improvements found in other metabolic markers, CIMT or the CAS ($p > 0.05$). However, there were marked decreases in the hemoglobin HgbA1c levels (HgbA1c, % versus %) and body weight (kg versus kg) in the intervention group (Yuan et al., 2014). Effects of DSME were mostly shown in HgbA1c and body weight changes but not in the other metabolic markers, likely due to the short duration of the program. Researchers concluded that DSME, even in low intensity can significantly improve the glycemic and body weight control in patients with type 2 diabetes (Yuan et al., 2014). Further investigations of the long-term effect of the DSME and with a larger sample size was recommended by researchers (Yuan et al., 2014).

In a 2018 quasi-experimental (pretest-posttest) study conducted in four primary healthcare clinics (PHCs) in Binjai city of North Sumatera, Indonesia, the effect of a short-term DSME on HgbA1c and FBS levels in 80 patients with T2DM was evaluated (Rusdiana, Savira, & Amelia, 2018). Patients received the usual advice on dietary management of diabetes along with a 3-month-long intervention, which included an 8-week DSME and a 4-week follow-up practice using the DSME guidelines. Baseline HgbA1c, FBS levels, blood pressure readings, weight, and height and waist circumference data were collected (Rusdiana et al., 2018).

A survey interview was used to collect information about the family health history related to the disease, education level and type of job. Patients in the intervention

participated in a DSME program in which they were required to attend a two-hour lesson weekly for eight weeks and practice the self-management guidelines of the education program daily during the study period. Instructions were centered on skills, diet, exercise blood sugar monitoring, medication, problem-solving, risks reduction and coping skills (Rusdiana et al., 2018). Researchers found significant decreases in HgbA1c levels. Using the *t*-test statistical analysis, researchers found substantial differences in HgbA1c value between pre and post education among the patients ($p < 0.005$) in spite of the short duration of the study time, suggesting that the DSME intervention was successful in achieving some significant changes in the lifestyles of participating subjects (Rusdiana et al., 2018).

In a 2015 mixed methods study conducted by Huxley et al. (2015), researchers attempted to predict the diabetes-related outcomes of people engaged in a T2DM DSME program from their baseline data. Secondary outcomes included the effects of gender, duration of diagnosis, HgbA1c of over 9%, health insurance coverage, and self-reported literacy level. The average HgbA1c before DSME was 10.2% or more (Huxley et al., 2015). The average HgbA1c immediately up to 1 year after DSME was 7.8 or less ($p < 0.0001$), a 23.5% decrease. One and two years later after DSME, the average HgbA1c was 7.8 or less for each year and remained unchanged from immediately after DSME, up to one and two years after DSME ($p > 0.05$). Patients with diagnoses durations under one year had significantly greater reductions in average HgbA1c levels than those with a duration of diabetes over 1 year who were at 28.7% and 20.2%, respectively, $p = 0.001$ (Huxley et al., 2015).

It can be noted in the different studies that DSME programs improved HgbA1c levels, BMI and other metabolic makers. The most common identified limitations in the

studies included duration of the studies, short intervals between baseline and follow-up assessments. Thus, potential changes to other diabetes-related metabolic markers were not reflected and the potential lasting effects of DSME on T2DM patients were not fully evaluated. Another limitation was the small sample sizes. Recommendations for future investigations include programs with longer duration and larger sample sizes for more effective measurement of the long-term effects of DSME and more accurate generalization.

Effects of DSME on BMI, LDL cholesterol and BP. Diabetes mellitus is associated with various atherosclerotic complications, including cerebro-vascular and cardio-vascular diseases, resulting in significant morbidity and mortality (Yuan et al., 2014). The monitoring of metabolic markers, such as blood glucose and HgbA1c levels, body weight, serum lipid profile and blood pressure readings are indispensable in the clinical management of patients with diabetes as high BP, overweight, and dyslipidemia are recognized as risk elements of atherosclerosis and are frequently seen patients with diabetes. The monitoring of these risk element helps in treatment response evaluation these patients (Yuan et al., 2014).

In a 2016 study, 19 adult diabetic patients comprised of 12 females and 7 males were randomly selected from the diabetes registry of a primary care clinic. Participants included five Hispanic, seven African American, three Caucasian, and four Asian/other, between 40 and 90 years of age, with a mean age of 62 years (Lavelle et al., 2016). In addition to the services received at their primary care clinic, all the participants engaged in a home-based DSME program conducted by doctoral students from the nursing School of a local University, (Lavelle et al., 2016). Home visit activities included knowledge evaluations, DSME, review of foods in the home, instructions about appropriate use of

home glucose and blood pressure monitoring devices and documentation of vital signs (Lavelle et al., 2016).

Baseline data on HgbA1c, fasting blood sugar, body weight and BMI, BP, demographic data, and personal treatment objectives were collected; participants were followed from the beginning of the in-home interventions until the collection of post-intervention biomarkers at their usual follow up office visit two to four months after the intervention (Lavelle et al., 2016). Exclusion criteria included incomplete post-intervention biomarkers within four months after the intervention (Lavelle et al., 2016). At baseline, 23% of the participants were classified as overweight (BMI 25 to 29.9 kg/m²), and 38% of the patients were classified as obese (BMI 30 kg/m² or greater). Thirty-eight percent of the participants had normal weight at baseline. The average BMI decreased by 2% from 27.7 to 27.2 kg/m² ($p = 0.1490$). Post-intervention follow-up showed that 31% of the participants were classed as overweight, another 31% of the participants were classed as obese, and 38% were of normal weight, 46% of participants exhibited decreases in weight over the study period (Lavelle et al., 2016). At the end of the study, participants showed decreases in blood sugar and HgbA1c levels, body weights and BMI as well as in systolic and diastolic BP readings; researchers concluded that in-home support DSME programs could improve self-management of diabetes and lead to improvements in healthcare outcomes markers (Lavelle et al., 2016).

In a 2014 prospective before and after quasi-experimental study that involved 203 participants with T2DM from two local government units in the Northern Philippines, researchers examined the effects of the First Line Diabetes Care (FiLDCare), a context-adapted DSME and support project on patient disease knowledge, attitudes, perceptions, self-management practices and glycemic control. The project which was based on chronic

care models and its effects on the overweight/obesity among people with T2DM was also examined by researchers (Ku & Kegels, 2014).

One hundred and sixty-four diabetes patients' outcome measures that included changes in knowledge, attitudes and self-management practices, body mass index, waist circumference, waist-hip ratio (WHR) and HgbA1c were measured after a year of full participation in a context-adapted DSME and support program administered by local the government trained healthcare personnel (Ku & Kegels, 2014). Due to multiple independent variables, data analysis involved non-parametric and parametric descriptive and inferential statistics including logistic regression analysis (Ku & Kegels, 2014). Significant improvements in glycemic controls, waist circumferences, WHR, knowledge, some behaviors such as adherence to medications and exercise and fear of diabetes were noted by researchers (Ku & Kegels, 2014).

Decreases in HgbA1c, regardless of level of control, were noted in 60.4%. There were significant increases in knowledge ($p < 0.001$), positive attitude ($p = 0.013$), perceived ability to control blood glucose ($p = 0.004$) and adherence to medications ($p = 0.001$) among patients with improved glycemic control (Ku & Kegels, 2014). Substantial differences were noted between the groups whose HgbA1c levels improved and those whose HgbA1c deteriorated, for example, among males ($p = 0.042$), with shorter duration of diabetes ($p = 0.001$) and increased perceived ability to control blood glucose ($p = 0.042$). Significant correlations to improved glycemia were found among males ($OR = 2.655$; $p = 0.034$) with over 10 years of diagnosis with diabetes ($OR = 0.214$; $p = 0.003$) and fear of diabetes ($OR = 0.490$; $p = 0.048$). Researchers concluded that introduction of context-adapted DSME/S and the use of established health personnel in resource-

constrained settings may improve care-recipients' disease knowledge base, attitudes, self-management practices and glycemic control (Ku & Kegels, 2014).

In a 2013 study involving 73 patient participants at a low-income primary care clinic, Ryan et al. (2013) attempted to establish the viability and efficacy of a nurse-led DSME program for low-income patient population that was 57.5% non-Hispanic black and 35.6% Hispanics (Ryan et al., 2013). Patients' medical records were reviewed for LDL levels, co-morbidity and diabetes plan of care. Baseline data including HgbA1c, blood pressure, weight, and body mass index and data from patients' interviews were collected to establish existing diabetes self-care behaviors after each DSME session and at 6 months (Ryan et al., 2013). Knowledge related to each of the 4 core diabetes management aspects of diet ($p = 0.001$), diabetes management ($p = 0.003$), blood glucose monitoring ($p = 0.001$), and risk reduction for complications ($p = 0.001$), was significantly improved (Ryan et al., 2013).

In the long-term outcomes, average HgbA1c was significantly reduced (0.82%), from 8.60% to 7.78% ($p = 0.007$), with 26.67% of patients showing decreases in HgbA1c from 7.0% at baseline to 7% at follow up ($p = 0.001$) and all patients demonstrated a significantly improved readiness to improve dietary behaviors ($p = 0.016$). Statistically significant changes were also found in the number of patients whose blood pressure readings were 130/80 mm/Hg at baseline compared with 130/80 mm/Hg at follow-up. Ten out of 24 patients (41.67%) had BP readings below 130/80 mm/ Hg at follow-up (χ^2 , 6.34; $p = 0.012$) compared with 2 out of 13 (15.4%) patients who had readings above 130/80 mm/Hg at follow-up (χ^2 , 6.34; $p = 0.012$). Five of 13 patients (38.46%) with LDL = 100 mg/dL at baseline decreased their levels to under 100 mg/dL at follow-up, but, 8 of 16 (50%) patients with LDL = 100mg/dL at baseline increased to above 100 mg/dL at

follow up (χ^2 , 0.386; $p = 0.711$). Although not statistically significant, there was a clinically significant difference from baseline to follow-up in the proportion of patients who moved from the LDL cholesterol category of under 130 to above 130 mg/dL (χ^2 , 4.49; $p = 0.056$); 2 of 6 (33%) patients had decreases in LDL cholesterol levels from over 130 to under 130 mg/dL, and 5 of 23 (22%) patients had increases in LDL cholesterol from under 130 to above 130 mg/dL (Ryan et al., 2013).

Ten of 24 patients (41.67%) with blood pressure above 130/80 mm/Hg at baseline lowered their BP to under 130/80 mm/Hg at follow up (χ^2 , 6.34; $p = 0.012$). Two patients with blood pressure under 130/80 mm/Hg, increased to above 130/80 mm/Hg at follow-up (Ryan et al., 2013). There was a likely clinically significant decrease in the number of patients' BP above 140/90mm/Hg at baseline, with more than half (10 of 16 patients, 62.5%) decreasing to under 140/90mm/Hg at follow-up (χ^2 , 3.48; $p = 0.62$). Two of 16 patients had increases from under 140/90 mm/Hg at baseline to above 140/90 mm/Hg at follow-up (Ryan et al., 2013).

There were statistically significant changes in the proportions of patients in the obese and overweight BMI categories, with 3 of 36 patients (8.33%) moving from the obese category (BMI = 30.0 kg/m²) to the overweight category (BMI 25.0 – 29.0 kg/m²), (χ^2 , 68.87; $p = 0.001$). Two patients moved upward in BMI categories: 1 patient with a normal BMI at baseline moved to the overweight category at follow up, and 1 patient with an overweight BMI at baseline moved to the obese category at follow-up (Ryan et al., 2013). Researchers concluded that minority patients with a high risk for poor diabetes outcomes should engage in a multi-session DSME program to benefit from increased diabetes knowledge (Ryan et al., 2013).

Clinical researchers agree that diabetes is a chronic, multifaceted condition that requires unrelenting engagement in self-care activities alongside long-term support from healthcare providers to ensure that patients acquire efficient self-care skills to manage their disease. An in-depth understanding of the importance of self-care on the part of patients is necessary to encourage their readiness to learn and engage in diabetes self-management activities that will help them achieve glycemic control and reduce risk factors for complications and death (Veliyathumalil, 2017). Some of the most significant concerns experts have about diabetes include its growing prevalence, its chronic and disabling complications and the related costs of care (Habibzadeh et al., 2017).

Healthcare providers must therefore seek out effective interventions such as patient referrals to ensure full patient engagement in available DSME and support services (Habibzadeh et al., 2017). DSME programs are developed and employed in the prevention of diabetes, or to delay the onset of its complications by helping patients achieve and maintain glycemic control and manage diabetes complications when they occur (Habibzadeh et al., 2017). DSME participation enhances patients' QOL by enabling them to live satisfactorily, meaningfully and productively, even when diabetes complications are present (Habibzadeh et al., 2017).

Effects of DSME on patient care outcomes and health behaviors. DSME programs are developed and employed for the prevention of diabetes, or to delay the onset of its complications by helping patients achieve and maintain glycemic control and manage diabetes complications when they occur. DSME enhances patients' QOL by enabling them to live satisfactorily, meaningfully and productively, even when the disease and its complications are present (Habibzadeh et al., 2017).

Effects of DSME on self-efficacy and patient satisfaction. A single-blinded randomized experimental study that involved 1243 patients was included in studies that addressed the efficacy of DSME programs led by trained diabetic educators that resulted in enhanced healthcare outcomes of reduced distress, patient-empowerment, reports of improved self-efficacy and increased satisfaction (Luan et al., 2017). In the study, the impacts of diabetes education and self-management support on the 4D series (5- and 10-year self-management skills, glucose and lipid metabolism changes, incidences of acute and chronic complications, and medical spending) of diabetes patients treated at the Affiliated Chenggong Hospital of Xiamen University from March 2000 to November 2002, ($n = 1,243$), were examined by Luan et al. (2017). Patients were randomly assigned to experimental and control groups per random number table with 732 participants in the experimental group. A total of 124 patients did not complete the study, 69 dropped out, 40 lost contact, and 15 died (Luan et al., 2017). Six hundred twenty-two patient participants comprised of 312 males and 310 females, aged 19 to 65 years, with disease duration of 1 to 15 years completed the study (Luan et al., 2017).

In the control group 728 patients were recruited. One hundred and thirty patients did not follow-up, 69 patients dropped out, 42 lost contact, and 21 died (Luan et al., 2017). Six hundred twenty-one patients comprised of 312 males and 309 females, aged 20 to 65 years old, with disease duration one to 15 years completed the program and were included in the final analysis (Luan et al., 2017). The experimental group received health education, which included diabetes self-management support, while the control group received traditional health education (Luan et al., 2017).

Through questionnaires, observations, and other sources of data, the self-management skills, blood glucose and lipid levels, incidences of complications, cost

issues, and other aspects of the two groups were compared. The five and 10-year self-management skills, glucose and lipid metabolism changes, incidences of acute and chronic complications and medical costs (i.e., 4D series observations) in the experimental group were found to be significantly better than those in the control group ($p < 0.01$ for all). Researchers concluded that provision of DSME as a self-management support can effectively improve the self-management skills of diabetes patients, reduce the medical costs, and improve patients' quality of life (Luan et al., 2017).

In a cross-sectional study conducted in four randomly selected diabetes clinics in Kuching and Samarahan Division of Sarawak in Malaysia, researchers attempted to determine the predictors for diabetes self-management among T2DM patients (Gunggu, Thon, & Lian, 2016). Four hundred respondents with T2DM were recruited using a systematic random sampling method. Inclusion criteria were patients (a) with T2DM for more than one-year duration, (b) aged 18 years to 65 years, (c) ability to understand English or Bahasa Melayu, and (d) residence in either of the two districts for at least six months (Gunggu et al., 2016). Exclusion criteria were patients with vision and cognitive problems. Sample size was determined using the formula by Naing et al. where $n = Z^2 p(1 - p)/d^2$. Based on the mean prevalence of good control of 38.9%, p was determined at 0.389, d was set as +0.05, and the level of statistical significance, α was 0.05. A 10% of attrition rate was added to determine a sample size of 400 (Gunggu, Thon, & Lian, 2016). Data collection sources included face-to-face interviews and questionnaires that involved female respondents (68.6%), with a mean age of 58.77 years ($SD = 11.46$), (50.6%) were estimated to have had T2DM for six years ($SD = 4.46$) (Gunggu et al., 2016). The mean fasting blood glucose (FBG) was 8.06mmol/L ($SD = 2.94$); most of the patients (76.1%) had levels higher than 6.1mmol/L (Gunggu et al., 2016).

Multiple logistic regression tests showed significant linear relationship between DSM and belief in treatment effectiveness ($p = 0.001$), family support ($p = 0.007$), and self-efficacy ($p = 0.027$) (Gunggu et al., 2016). Researchers concluded that healthcare personnel must convince patients with T2DM of the effectiveness of the treatment, to encourage and improve their self-efficacy and family support is needed for sustained engagement in DSME efforts (Gunggu et al., 2016).

In a comparative effectiveness study, Siminerio et al. (2013) compared diabetes self-management support (DSMS) methods to determine which was most effective in helping patients attain improved and sustained healthcare outcomes and self-care behaviors, decrease distress, and increase satisfaction post DSME delivered in primary care. One hundred and forty-one patient participants were randomly selected post participation in DSME programs led by a trained supporter, such as an educator, peer, practice staff, or usual education (Siminerio, Ruppert, & Gabbay, 2013). During a six-month follow-up period, DSMS groups were compared to determine which supporter helped participants to achieve sustained improvement in HgbA1c levels, BP readings, cholesterol levels, weight, self-care, and distress; participants' satisfaction with DSMS was also examined (Siminerio et al., 2013).

Researchers noted significant improvements in HgbA1c levels, self-efficacy aspects of self-care, and levels of distress following the six weeks of DSME (Siminerio et al., 2013). Patients in the DSME educator group showed sustained improvement in HgbA1c levels. Although those in the other DSMS groups maintained glycemic improvements, they had begun to show worsening decline trends in their HgbA1c levels, BP readings, cholesterol, weight, self-care and distress (Siminerio et al., 2013). The program reinforcement impacts self-management (PRISM) study demonstrated that

following up with DSME participants results in sustained improved glycemic control, lipid, weight, self-care behaviors and reduction in distress throughout the delivery of DSMS interventions regardless of the title of DSMS supporter (Siminerio et al., 2013). All participants reported satisfaction with DSMS, and researchers concluded DSME delivered in primary care is effective and having multiple DSMS agents is reasonable (Siminerio et al., 2013). Findings from study confirmed the vital role of educators but suggested that others may serve as DSMS supporters (Siminerio et al., 2013).

Effectiveness of nurse-led Vs non-nurse-led DSME on patient care outcomes.

Evidence from different research studies show that nurse-led DSME programs that last longer, up to 14 to 26 weeks in duration, had greater effects on participants and may be most effective in helping patients reach diabetes management goals than programs of shorter duration as demonstrated in the findings from the three projects below. In an integrative review of literature, Oliveiral et al. (2016) attempted to analyze and identify available evidence in the literature of nursing interventions for self-care promotion among T2DM patients. The initial search identified 239 articles and eight of which met the selection criteria. Data was collected from the Latin American and Caribbean Health Sciences (LILACS), MEDLINE (via EBSCO), Cumulative Index to Nursing and Allied Health Literature (CINAHL) and SCOPUS. Study articles surveys by two separate reviewers took place in July and August 2015 (Oliveiral et al., 2016).

Researchers found that health education emerged as a strategic means for implementing nursing interventions. Other interventions that involved patient supervision and care-time were more satisfactory when incorporated with self-care practices. The study results showed that intervention sessions that allowed more time with participants than the usual showed satisfactory results regarding self-care practices. Interventions in

the context of the different studies not only provided educational contents, they also individualized guidelines according to patient needs; the interventions provided support and ideal situation for fulfilling those needs (Oliveiral et al., 2016). Findings from the review show that nurse-led health educational programs were not limited to transmission of information only, there were wider approaches to the achievement of self-care among this patient population, depending on various influencing factors such as health beliefs, behaviors, knowledge of the disease and perceived self-efficacy and DSME is the perfect process for promoting self-care, self-efficacy and right health behaviors for persons with T2DM (Oliveiral et al., 2016).

In a 2013 meta-analysis, Klein et al. (2013) assessed how successfully DSME interventions helped people with T2DM achieve sustained glycemic control. Researchers suggested that DSME programs that are longer in duration, and delivered by nurses, may be most effective. Fifty-two DSME programs with 9,631 patients who reported post-intervention HgbA1c levels in randomized controlled trials were included in the study (Klein, Jackson, Street, Whitacre, & Klein, 2013).

Patients in the training conditions had significant reductions in HgbA1c levels in comparison to those in the control conditions. The effect of the intervention was however moderate, with only 7.23% of participants shifting from diabetic status to pre-diabetic or normal glycemic status, relative to the control condition (Klein et al., 2013). Many participants did not reach healthy HgbA1c levels. Additionally, few DSME studies measured sustained maintenance of HgbA1c improvements; prior tendencies suggested that improvements are hard to sustain over time (Klein et al., 2013). The results of the study indicated that DSME provided by nurses were more effective than those provided by non-nursing health professionals. Researchers found that most DSME programs

depend largely on guidelines and procedures to direct decisions about diet, exercise, and weight loss. Findings from the study led to suggestions that DSME programs could produce better results if they are conducted without procedural boundaries. DSME should include comprehensive innovative approaches that create behavioral guidelines in future DSME programs, to help patients engage in positive health behaviors (Klein et al., 2013). For example, purposeful planning, self-monitoring and self-diagnosis skills for detecting abnormalities and the possible reasons for the abnormalities, so that remedial activities can be developed for the prevention of potential barriers to sustained and acceptable HgbA1c levels (Klein et al., 2013).

In a 2018 two-arm parallel-group randomized controlled trial study by Azami et al. (2018), researchers sought to examine the research gaps related to the effectiveness of nurse-led DSME on glycemic control, compared to DSME led by non-nurse health professionals. The primary study hypothesis was that a nurse-led DSME intervention, compared with the usual care, would result in improved HgbA1c. The secondary hypothesis was that the nurse-led DSME intervention would lead to improved lipid profiles, blood pressure, body weight, self-management behavior, self-efficacy, quality of life, depression, and social support (Azami et al., 2018).

The study was conducted in an urban primary and secondary outpatient endocrine clinic located within a teaching hospital in Ilam City in Iran. One hundred forty-two (142) adults with T2DM were randomly selected into a control and an intervention group by researchers (Azami et al., 2018). Seventy-two (72) participants were assigned to the control group, to receive usual diabetes care based on the Iranian Ministry of Health guidelines that involved self-care, lifestyle modification, and medication adherence (Azami et al., 2018). Scheduled 20 to 30 minutes individualized education was provided

at three-monthly intervals and included face to face consultations, provision of educational pamphlets on diabetes care, physical examinations and laboratory tests as well as prescription reviews and/or renewals. The other 72 participants were assigned to the intervention group to receive usual care as well as a nurse-led DSME for a duration of 12 weeks (Azami et al., 2018).

The primary outcome of the study was HgbA1c values and its secondary outcomes were changes in BP, body weight, lipid profiles, self-efficacy (efficacy expectation and outcome expectation), self-management behaviors, quality of life, social support, and depression (Azami et al., 2018). Outcome measures were assessed at baseline and at 12 weeks and 24 weeks post randomizations. Patients in the intervention group showed significant improvement in HgbA1c, blood pressure, body weight, efficacy expectation, outcome expectation, and diabetes self-management behaviors. Researchers concluded that the beneficial effect of a nurse-led intervention accrues beyond the end of the trial and results in sustained improvements in clinical, lifestyle, and psychosocial outcomes (Azami et al., 2018).

Findings from study indicated DSME led by trained diabetic nurse educators may be more effective in improving healthcare outcomes, reducing distress, increasing patient satisfaction and empowering patients to be self-efficient (Azami et al., 2018). In the literature review of journal articles that highlight the significance and efficacy of nurse-led DSME in the achievement of patient diabetes self-management goals, and the particular effectiveness of nurse-led DSME in comparison to the usual diabetes management regime of office visits and written instructions by non-nurse HCPs were discussed and a synthesis of past studies was presented.

Summary

Studies that have examined specialty-based DSME programs provided by registered nurses, pharmacists, and registered nutritionists have found no distinctive differences in the quality of instructions provided by these healthcare professionals (Azami et al., 2018). However, many studies shown that when health education programs are presented by nurses, patients are more like to accept the information and adhere to the health instructions and report higher levels of positive healthcare outcomes and satisfaction (Philis-Tsimikas & Gallo, 2014). Nurses are trusted expert facilitators of healthcare programs; they are often at the forefront of patient education in all healthcare settings and are most likely to promote patient engagement in self-care and disease prevention behaviors compared to other HCPs (Philis-Tsimikas & Gallo, 2014).

Findings that support nursing role in DSME delivery is limited but growing. Existing literature provide the bases for nurse-led DSME as an effective means for closing gaps in diabetes care related to knowledge deficit and inadequate self-efficacy. A thematic synthesis of select publications of nurse-led DSME studies, demonstrated the effects of DSME on some defined aspects of T2DM care including (i) metabolic markers of HgbA1c, LDL cholesterol, BMI and BP readings and (ii)' diabetes health behaviors and self-efficacy (Azami et al., 2018; Hakimian et al., 2016; Jutterströma et al., 2016; Powers et al., 2016; Rise et al., 2013; Zeng et al., 2016). The literature advised the steps and process employed in the project including, target population, the problem and purpose statements, the clinical questions, variables of interest, the methodology and design, the data collection, coding and analysis tools, and the implementation theories.

The findings of the project contribute to the existing body of knowledge and provide additional supportive data for nurse-led DSME as an effective and viable tool in

diabetes care that could result in future proposals for routine inclusion of nurse-led DSME programs in all diabetes care settings for more enhanced diabetes care outcomes of sustained glycemic control and prevention of complications. Additionally, the findings of the project lend more support for the recognition of the unique expertise and experiences that nurses bring to healthcare and has the potential to trigger proposals for policy changes that would make DSME training and certification a mandatory part of nursing curricula. Chapter 3 offered an in-depth look at the project methodology and design, presented the rationale for the choice of a quantitative methodology and the one group pre and post-test quasi-experimental design, as well as the implementation and data collection processes of this project.

Chapter 3: Methodology

In this quantitative, quasi-experimental project, the effects of nurse-led DSME on the FBS levels and reported diabetes self-efficacy of T2DM patients with uncontrolled blood sugar in primary care clinic in an underserved community in Northwest, Texas was examined and compared with the effects of DSME by other HCPs. The purpose of this quantitative, quasi-experimental project was to determine if any, and to what extent a relationship existed between a nurse-led DSME intervention and the lowering of FBS levels to 100mg/dl or below, and reports of improved self-efficacy among patients with poorly controlled T2DM at a primary care clinic. Data for this project, was collected from participants' EHRs and questionnaires administered pre and post- intervention.

Previous clinical data (i.e., FBS levels) documented in participants' health records and data gathered from participants' answers in a pre-intervention questionnaire, represented the effects of DSME by other HCPs and served as the baseline data. Post-intervention FBS levels and participants' answers in the post-intervention questionnaire served as the comparison data and represented effects of Nurse-led DSME. The differences between the pre and post-intervention data provided the answers to the two clinical questions relating to glycemic control and patient reported self-efficacy that were asked in the project. The independent variable was nurse-led DSME measured by 10 hours of contact, comprised of weekly one hour, forty-five minutes to two hours class over a period of six weeks. The project's dependent outcome variables that were measured included FBS levels and patient reported self-efficacy.

Statement of the Problem

Diabetes is a complex and severe condition for which daily management is often difficult. DSME programs provide the needed information to guide the various processes

for achieving improved or normal blood sugar levels and for making lifestyle changes such as smoking cessation, weight loss and weight maintenance, dietary modifications, increased physical activities and compliance with the recommended medications that are essential to the achievement of glycemic control and reduction of risks factors for the occurrences of micro-vascular diseases, myocardial infarctions and deaths (Powers et al., 2016).

Among adult patients diagnosed with T2DM, with poorly controlled blood sugar, self-management is the most vital component in the management of their condition, to achieve the desired care outcomes of glycemic control and prevention of complications (Powers et al., 2016). Proper glycemic control is key to reducing the occurrences of micro-vascular diseases and risks for myocardial infarctions and deaths (Powers et al., 2016). Yet, recent research findings have shown that 50% of individuals living with diabetes struggle with achieving and maintaining the recommended HgbA1c goal of 7.0% or below (Chrvala et al., 2015). Only about 14.3% of patients reach the ideal ranges of those core aspects and elements of diabetes management goals of normal levels of HgbA1c, LDL cholesterol, BP readings and smoking cessation (Chrvala et al., 2015).

T2DM patients' survival and ability of to maintain optimum QOL depend on how knowledgeable they are about the chronicity and gravity of their diabetic condition, and the best treatment options available to them, for control of the disease symptoms and management of its complications when they occur (Chrvala et al., 2015). Until now, glycemic control (i.e., HgbA1c below 7% or 53mmol/mol) was only achievable through the use of high-risk hypo-glycemic medications like insulin to reduce the risk factors for diabetes complications (Chrvala et al., 2015). DSME programs now provide vital information to guide lifestyle changes such as smoking cessation, weight loss and weight

maintenance, dietary modifications, increased physical activities, and compliance with recommended medications essential to successful glycemic control and prevention of complications (AADE, 2017; Azami et al., 2018; Chrvala et al., 2015; Drincic et al., 2017; Jutterströma et al., 2016; Powers et al., 2016).

When patients lack adequate self-care information for disease prevention and the management of disease complications, they are less likely to comply with their plans of care and recommended treatments (Okorie, 2018). Nurses must therefore provide ongoing support and education to patients by educating them to close deficits and gaps in self-care knowledge and self-care skills they need for maintaining the requisite level of self-care essential to disease management (Okorie, 2018). DM patients are provided opportunities to learn ways to control the symptoms of their disease and achieve clinically meaningful decreases in blood sugar levels that result in decreased occurrences of complications (Golden et al., 2017). When diabetes complications such as neuropathy, cardiovascular disease, nephropathy, retinopathy, and skin and soft tissue disorders are present, patients learn ways to manage them (Golden et al., 2017).

Evidence that support the beneficial effects of DSME delivered by registered nurses, pharmacists, and registered nutritionists in diabetes care is accumulating but studies that have compared the effectiveness of diabetes health education based on professional or specialty foci, have not found any distinctive differences in the quality of instructions provided by different HCPs (Azami et al., 2018). While the literature indicates a growing interest in nurse-led DSME and its efficacy, it is not known if and to what extent a relationship exists between nurse-led DSME, glycemic control, and reports of higher levels of diabetes self-efficacy among T2DM patients with poorly controlled diabetes. Compared to other HCPs, nurses are the largest, most trusted, most

collaborative group of health professionals and they are the mostly likely to encourage patients to engage in positive behavior changes and preventive healthcare seeking behaviors. Nurses are more uniquely poised for healthcare delivery transformation and are at the forefront of patient education (Azami et al., 2018).

Findings from different studies of DSME, indicate that DSME programs help patients with poorly controlled blood glucose levels achieve glycemic control (i.e., HgbA1c 7% or FBS of 100mg/dl and below). However, evidence that support the particular effectiveness of nurse-led DSME on glycemic control and prevention of complications among newly diagnosed adult patients and patients already living with the burdens of diabetes remains limited. This project that took place at a primary care clinic in an underserved community in Northwest, Texas provided an opportunity for further examination of the effects of nurse-led DSME on the FBS levels of T2DM patients with poorly controlled blood glucose levels and their reported diabetes self-efficacy.

Clinical Questions

Two questions were asked and answered in this project:

Q1: For patients with poorly controlled diabetes, will the implementation of a nurse-led DSME program that provides one hour, forty-five minutes to two hours per class up to a total of 10 hours of contact compared to current diabetes care which includes written instructions by non-nurse health professionals, result in improved FBS of 100mg/dl or below after six weeks?

Q2: For adult patients with poorly controlled T2DM, with disease knowledge and self-care deficits, will the implementation of a nurse-led DSME program that provides one hour, forty-five minutes to two hours per class up to a total of 10 hours of contact, compared to current diabetes care which includes written

instructions by non-nurse health professionals result in reports of improved self-efficacy after six weeks?

Data collection began after approval was obtained from Grand Canyon University's Institutional Review Board (IRB) (see Appendix A). To answer the project's clinical PICOT questions, pre-DSME intervention data, from previous documentations that included FBS levels participants' EHRs were accessed, reviewed and collected, and were established as the baseline clinical data. Primary data and other data elements that were not present in participants' EHRs were obtained from participants' answers in the pre-intervention DSMQ and SED questionnaires administered by the PI before the initial DSME class.

The questions in the questionnaires were related to health behaviors, diabetes-related knowledge, diabetes self-care skills and activities. Other aspects of the questionnaires addressed patients' perceived ability to make and integrate behavioral changes into lifestyles, patients' attitude towards diabetes and diabetes management activities with respect to blood glucose monitoring, safe use of prescription medications, ability to interpret and use test results to avoid, recognize and treat potentially severe complications like extremely high or low blood sugar levels, as well as patients' ability to set and meet personal goals for behavioral changes and adherence to recommended diabetes management activities (Allen et al., 2018; Schmitt et al., 2016).

Evidence-based and tested DSMQ and SED questionnaires were used to collect primary data from participants. The Grand Canyon University-issued DPI project master code (Appendix E) was employed to guide data collection from the clinic's EHR system. A familiar clinic staff was informed by the PI about the type of data that was needed, project inclusion criteria, variables of interest and the ranges for data comparison to show

the effects of nurse-led DSME programs vs the effects DSME by other HCPs on uncontrolled blood glucose levels of T2DM (i.e., FBS 100mg/dl and above) and patients' reports of inadequate self-efficacy.

Project Methodology

A quantitative methodology was employed in this project. This is the most common and most appropriate method for answering questions about associations within variables that are measurable, and for the manipulation of variables, the prediction and explanation of phenomena (Grand Canyon University, n.d). Quantitative approaches are used to examine relationships between variables with a principal objective to analyze and represent that relationship numerically through statistical analysis (Grand Canyon University, n.d). Researchers do not start with assumptions but formulate them after data is collected (Grand Canyon University, n.d). Quantitative approaches are most often employed in social science, academic and psychological investigations as they deliver ample datasets that frequently uncover fresh information and insights that would otherwise be overlooked (Grand Canyon University, n.d).

Project Design

A quasi-experimental design was implemented for this project. Quasi designs are the approaches most often employed by researchers to examine cause and effect relationships between existing independent variables and how they affect the dependent variables (Allen, 2017). Quasi-experimental designs are used to establish the relationships of interventions or treatments within target populations (Grand Canyon University, n.d-b). Quasi designs are convenient and less disruptive to participants than true experimental designs. Statistical controls can be substituted in the absence of physical control of the investigational situation (Grand Canyon University, n.d-c).

When researchers seek to establish cause-effect relationships between two or more variables, they employ quasi-experiments (Grand Canyon University, n.d-c). Researchers use existing groups participants are not assigned to groups, researchers test for causality with minimal variable control, the independent variables are not manipulated, and interventions are applied (Grand Canyon University, n.d-b). Quasi designs may be more viable in cases when the usual time and logistical limitations of true experimental designs do not apply and to reduce the difficulty and ethical concerns that may be involved in pre-selection and random selection of participants Quasi-experiments may be timelier and more cost and resource efficient since extensive pre-screenings and randomizations are eliminated and threats to validity are more easily identified and addressed to minimize their influences. Examples of quasi-experimental designs are pre and posttest designs, posttest only designs and interrupted times-series design (Grand Canyon University, n.d-c).

The one-group pretest and post-test design was applied in the project. This design is most often used by behavioral researchers to determine the effect of treatments or interventions on participant groups (Allen, 2017). The one group, pre-test and post-test design is characterized by two features: (i) It applies a single group of participants, which means that all participants are part of a single condition and are given the same treatments and subjected to the same assessments. (ii) The procedure is fixed and undeviating, it requires the assessment of dependent variables before and after a treatment is implemented (Allen, 2017). The dependent variables are measured once before and once after interventions are implemented and the effects of interventions are determined by calculating the differences between baseline and the post-intervention assessments of the dependent variables (Allen, 2017)

Weekly face to face DSME classes were held with participants every Tuesday morning for six weeks. Each class lasted between one hour, forty-five minutes to two hours, for a total of 10 to 10.5 hours of contact. The AADE education materials developed to address the seven focus spheres of diabetes self-care behaviors (Appendix F) were utilized with author's permission (Appendix D), to make the concepts more real for the participants. Beginning with healthy eating, and followed by physical activities, monitoring, taking medications, problem-solving, risks reduction and healthy coping, all seven topics were addressed. Each class began with a focus sphere topic introduction by the PI. Participants were provided the related pamphlets and the class ended with 10 to 15 minutes of questions and answers sessions that provided participants opportunity to ask questions and verbalize their understanding.

In week one, healthy eating was addressed. Participants were educated on the need for high nutrient foods such with low glycemic indexes as complex carbohydrates, fiber from beans, whole grains, fruits and vegetables especially the green, leafy ones like Kale and spinach that only cause moderate elevation of blood sugar levels (AADE, 2018). Other acceptable foods under healthy eating were lean protein, such as skinless chicken and fish, including a limited amount of heart-healthy fats, such as olive, peanut or canola oil, walnuts, almonds and flax seed with limit sugars, dairy, salt, saturated oils and trans fats, with moderate consumption of alcohol (AADE, 2018).

The importance of eating breakfast daily to jumpstart metabolism and calorie-burning processes that leads to weight loss and weight maintenance was stressed as well as the inclusion of small snacks between meals as part of daily food intake to help maintain metabolism and needed energy throughout the day (AADE, 2018). Healthy

eating also addressed avoidance of patterns of excessive hunger and overeating and the need for spaced out meals every four to five hours during waking hours (AADE, 2018).

Some examples of healthy eating patterns were provided, such as the Mediterranean, with more fruit and seafood and less dairy products; vegetarian-Style with more legumes, soy products, nuts, seeds and whole grains, no meat, poultry or seafood; and heart healthy diet, with more whole grains, fruit, vegetables, beans, nuts, seeds, poultry, fish, low-fat dairy and vegetable oil and lower in red meat, saturated fats, sugar, and sodium(AADE, 2018). Participants were advised on the necessity for collaboration with their healthcare provider to set goals for healthy eating, such as selection of the most appropriate eating style, creation of the most appropriate, individualized and easy meal plans. Other important aspects of healthy eating included development of calorie counting skills and activities, reading of food labels, portion and serving size measurements, recognition and avoidance of foods that cause excessively high or low blood sugar (AADE, 2018).

In week two, being active was address. Participants were educated on the importance of physical activities in diabetes care, and simple ways to engage in daily physical activities that help the body utilize blood sugar and burn calories. Other elements addressed in being active included the importance of healthcare provider involvement in plans for physical activities, checking blood sugar levels before and after engaging in physical activities as blood sugar levels could be too high or too low for safe exercise as hypoglycemia could develop rapidly during exercise, depending on the blood sugar level before physical activities. Extra food or insulin dosing adjustments may be needed to maintain blood sugar during and after physical activity (AADE, 2018). Examples of recommended frequency and intensity of physical activities were provided

such as five or more days a week, normal talking should be effortless, but intense enough to interfere with singing during the activity; time or duration, commence with five or ten minutes, up to 30 minutes; type of activities that can be sustained such as dancing, walking or gym activities and for motivation, partnering with friends or taking the dog out for a walk (AADE, 2018).

In week three, monitoring was discussed. Participants were taught the importance of blood sugar monitoring on a regular basis as well as monitoring of general health as a vital component of diabetes self-care (AADE, 2018). Other monitoring activities that were addressed included long-term blood sugar control such as HgbA1c to measure the average blood sugar levels in the previous 2-3 months. HgbA1c level should be monitored regularly, at least once every six months if blood glucose level is stable, otherwise once every 3 months. Cardiovascular health including BP readings and cholesterol levels at each follow up visit. Kidney health such as urine and blood tests for early detection of renal changes. Vision care to monitor changes in the retina and foot care including daily monitoring with a hand-held mirror and regular consultations with a podiatrist for foot examinations and sensory testing for neuropathic changes (AADE, 2018). Other vital aspects of monitoring that were addressed included the importance of hand washing with soap and water to remove dirt, food, or lotion and drying them thoroughly before checking blood sugar for accurate results and travelling with diabetes supplies (AADE, 2018). Available resources for financial constraints and difficulties accessing diabetes supplies, such as the toll-free number on the back of meter for manufacturer's coupons and free glucose monitors (AADE, 2018).

In week four, the focus was on taking medication. Participants were educated on the different medications they may be taking for managing their diabetes and its

complications such as insulin, oral blood sugar lowering medications, BP medications, cholesterol-lowering medication. The importance of adherence and taking medications as prescribed to reduce your risk of complications such as extremely low blood sugar levels or adverse drug interactions was stressed (AADE, 2018). Participants were also educated about the importance of having a copy of the list of their medications on hand, and/or knowing the names, doses and instructions for medications, the side effects and other unusual effects of their medications and actions to take (AADE, 2018). Information was provided regarding available resources that patients may be unaware of, such as consultations with their pharmacist, doctor, nurse practitioner, or diabetes educator regarding concerns such as side effects, difficulty with treatment compliance, financial inability to afford medication, over-the-counter products, supplements, or natural remedies can that can interfere with the effectiveness of prescription medicines (AADE, 2018).

In week five, two focus spheres, problem-solving and risk reduction were taught together, to ensure that all seven focus spheres were addressed by the end of the program in week-six. In problem solving, emphasis was placed on problems that may arise such as low blood sugar and recognition of the causes and activities that reduce future risks were addressed. Participant were provided information on problem-solving skills and diabetes self-care that help patients to recognize and react to high and low blood sugar levels as well as how to manage on sick days and in situations that can destabilize blood sugar control, such infections and when to contact providers and seek immediate help. Information was provided for online resources such DiabetesEducator.org (AADE, 2018).

Risk reduction included education on how diabetes increases the risk for

developing other health problems such as kidney damage, nerve damage and loss of vision. The causes of complications and how they can be avoided, self-awareness and alertness to physiological changes such as feelings sick, prompt notification of provider about any abnormalities or unusual changes or potential health issues were stressed (AADE, 2018). Actions that lower the risk of diabetes-related complications were also addressed, including regular medical checkups and medical tests to track overall health to reduce risks for some complications like tobacco/smoking cessation, annual eye examinations, foot care, including self- examination with a hand-held mirror for redness or skin breakdown and reporting abnormalities immediately to healthcare provider, keeping feet dry and clean, avoidance of tight shoes and walking barefooted (AADE, 2018).

In week six, the last of the focus sphere healthy coping addressed the physical and emotional effects of diabetes and the importance of early recognition of feelings discouragement, stress and/or depression and steps to reduce the negative impact of these emotions on self-care (AADE, 2018). Education was provided on key healthy coping mechanisms including faith-based activities, exercise, meditation, enjoyable hobbies, support groups and network as well as family and friends (AADE, 2018). At the end of the last class, post-intervention clinical FBS levels and post-intervention questionnaire data on self-care behavior and self-efficacy were collected for numerical coding and statistical analysis, and comparison with pre-intervention baseline clinical and primary data.

Population and Sample Selection

Nineteen T2DM patients were identified by the clinic staff, ten met the age and clinical inclusion criteria of FBS levels above 100mg/dl (see Table 1 below). The project

involved a sample size $n = 10$ participants that was determined by the number of those who met the clinical inclusion criteria of FBS level 100mg/dl and above, and who agreed to partake in and complete the program. All ten participants were females, English speaking and able to read and write above third-grade level. Their ages ranged from 34 - 67 years.

The general population were adult T2DM patients in an underserved community in Northwest, Texas. The targeted population were established patients of a primary care clinic in that community. Participants had to be 18 years and older with confirmed diagnoses of T2DM with FBS 100mg/dl or above and at risk for developing complications. Other criteria for inclusion in project required participants to be, English-speaking and able to read and write at or above the third-grade level, be established patients at the clinic who visit regularly for follow-up every three or six months, with no reports of cognitive impairment or active mental health crises and participants to express interest in engaging in and completing the DSME program. Patients with no confirmed diagnosis of T2DM, non-T2DM, or whose DM was well managed with FBS at 100mg/dl or below were excluded. Non-English-speaking patients, those unable to read and write at or above third grade level were also excluded, as well as patients with active mental health crisis and cognitive impairment, women who were pregnant or breastfeeding, children and adolescents.

Instrumentation

The data collection instruments for this project included the GCU-issued DPI project master code, the DSMQ (Appendix B) and the SED questionnaires (Appendix C). The DSMQ and SED tools enabled primary data collection from participants' perspectives. Author's permission was obtained for the DSMQ (Appendix E) but the

SED questionnaire needed no permission. The DPI project master code was employed for the collection of clinical data (i.e., FBS levels) from the project site's EHR system and for numerical coding of the primary data collected from participants' answers in the DSMQ and the SED questionnaires that were administered before and after the nurse-led DSME intervention.

The DSMQ is a new psychometric tool developed and introduced at the Research Institute of the Diabetes Academy, Mergentheim, Germany in 2013. It is the first ever German instrument that was designed to target diabetes self-care and assessment of behaviors associated with metabolic control within the context of the usual treatment regimens for T1DM and T2DM in adult patients (Schmitt et al., 2016). The tool is considered a reliable and valid instrument that enables efficient evaluations of self-care behaviors associated with glycemic control and is valuable for scientific analyses by researchers, as well as for clinical assessments of both T1DM and T2DM patients (Schmitt et al., 2016).

The DSMQ questionnaire is used to assess self-care behaviors associated with HgbA1c measurements to ensure that collected data are suitable for interventional analysis (Schmitt et al., 2016). The DSMQ is an appropriate tool for research involving an array of data collection instruments and clinical trials that address those important diabetic management domains that are mainly focused on activities that are related to glycemic control and the assessment of diabetes self-management, such as diet, medication, blood glucose monitoring, physical activities and contact with healthcare providers (Schmitt et al., 2016). The tool has been used in studies in Germany, the United Kingdom and in the US and has been thoroughly vetted and is supported by researchers as the preferred tool for analyzing behavioral problems associated with poor or

inadequate glycemic control as well as other factors that concern associations between self-management behaviors and glycemic control. It is comprised of 16 items that address five aspects of diabetes self-management (Schmitt et al., 2016).

All 16 items of the DSMQ are framed as behavioral descriptions from the individuals' points of view (see Appendix B). With references to the previous eight weeks, responders rate the degree to which each description applies to them on a four-point Likert scale of 0-3, with 3 being applies to me very much and 0 does not apply to me (Schmitt et al., 2016). Item scores are converted so that higher scores indicate more desirable self-management behavior which requires a reversal of scores of negative keyed in items that are converted to five scale scores that range from 0 to 10 (Schmitt et al., 2016).

The items in the DSMQ scales are intended to reflect patients' attitude towards the following five aspects of diabetes self-management: dietary control, medication adherence, blood glucose monitoring, physical activity and physician contact (Schmitt et al., 2016). Dietary control scale has four items; such as, "the food I choose to eat makes it easy to achieve optimal blood sugar levels." Medication adherence scale has two items; one of the items is "I tend to forget or skip my diabetes medication." Blood glucose monitoring scale has three items; an example is, "I check my blood sugar levels with care and attention." Physical activity has three items; an example is, "I am less physically active than would be optimal for my diabetes." Physician contact has three items; an example of the items is, "I keep all doctors' appointments recommended for my diabetes treatment" (Schmitt et al., 2016).

Researchers consider the DSMQ a promising, reliable and valid tool that is useful in the assessment of diabetes self-management with regards to glycemic control (Schmitt

et al., 2016). In its validation study, researchers reported their support for the DSMQ's reliability and validity (Schmitt et al., 2016). The reliability coefficients of the DSMQ were observed as follows (Cronbach's α ; stratified by scale): dietary adherence 0.79; medication adherence 0.75; blood glucose monitoring 0.83; physical activity 0.74; appointment adherence 0.72 (Schmitt et al., 2016).

In testing the DSMQ as a statistical predictor of glycemic control of patients with T1DM and T2DM, researchers found many noteworthy results, including the fact that diabetes self-management as measured by the DSMQ's self-management behaviors were indeed strongly related to glycemic control as reflected by HbA1c, in total explaining between 21 and 28 percent of glycemic variation (Schmitt et al., 2016). This finding suggests that the DSMQ may be a valuable assessment tool for professionals seeking to understand causes of hyperglycemia in patients by evaluating their self-management behaviors (Schmitt et al., 2016).

When the focus is on self-management in relation to glycemic control, the DSMQ is the measurement tool of choice, shown in a comparison test with an earlier scale-summary of diabetes self-care activities (SDSCA) tool, to determine the validity and reliability of the DSMQ's items-scale and characteristics (Schmitt et al., 2016). All the factors and convergent validity of the DSMQ with HgbA1c were analyzed. The DSMQ showed a stronger association with the behaviors that usually impact glycemic control such as diet, blood glucose monitoring and medication adherence (Schmitt et al., 2016). Researchers have suggested that the questionnaire could be valuable for scientific analyses as well as for clinical use in both type 1 and type 2 diabetes patients (Schmitt et al., 2016).

In an Urdu version of the DSMQ, its reliability was measured rigorously by Bukhsh et al. (2017), using Cronbach's α coefficient. Internal consistency was appraised by the following criteria: > 0.9 = Excellent, > 0.8 = Good, > 0.70 = Acceptable, > 0.6 = Questionable, > 0.5 = Poor and < 0.5 = Unacceptable (Bukhsh et al., 2017). Item characteristics were evaluated by corrected item-total correlations, corrected item-subscale correlations, potential increases of the scale's reliability coefficient (Cronbach's α) in case of item deletion and the item's correlation with the HbA1c value (Bukhsh et al., 2017). The scale was considered reliable when all its items correlated with the total. Items that showed poor correlation (< 0.3) were considered for exclusion. Pearson correlation (two-tailed test) was applied to HgbA1c and DSMQ total scores (Bukhsh et al., 2017).

The Steiger's z -test was used to test if the differences between the associations of diabetes self-management as measured by the DSMQ versus SDSCA, HgbA1c were statistically significant. The comparison yielded z -scores of 10.10 for type 1 and 3.39 for type 2 diabetes, indicated significantly stronger associations between the DSMQ self-management scores HgbA1c compared to those of the SDSCA for both type 1 and 2 diabetes (both $p < 0.001$). All correlations with HgbA1c were significantly stronger with the DSMQ than those obtained with the SDSCA (Schmitt et al., 2016).

The SED is a self-administered questionnaire that was developed and tested specifically for patients with diabetes by the self-management resource center (SMRC). It is used to assess patients' perceived diabetes self-efficacy. The tool is an 8-item scale with an internal consistency reliability of 0.828 that can be administered before and after DSME interventions to demonstrate behavioral changes among patient after program participation and it is a widely used for diabetes-specific self-efficacy measurement

(Allen et al., 2018). The tool measures patients' perceived self-efficacy related to those aspects of diabetes management addressed in the DSMQ sub-scales. The SED is available in English and Spanish versions at no cost and requires no permission for its use in studies (Allen et al., 2018).

The SED tool is used to assess diabetic patients' health behaviors and confidence in their daily ability to self-manage their diabetes in terms of blood sugar monitoring, dietary adherence, medication compliance, physical activity and contact with healthcare providers under the general self-efficacy, medical self-efficacy and diabetes specific self-efficacy scales (Allen et al., 2018). The survey answers range from 1 to 10. The circled number on the scale is the score for each item. If two consecutive numbers are circled, the lower number is coded as lower self-efficacy. A higher number indicates higher self-efficacy. If the numbers are not consecutive, the item remains unscored. The score for the scale is the mean of the eight items. If more than two items are missing, the scale is not scored. The higher the number, the higher self-efficacy (Allen et al., 2018).

Validity

Patients' medical records are considered rich sources of data for investigations that involve prospective and retrospective clinical studies in which available data in the medical records are utilized (Gregory & Radovinsky, 2012). However, researchers must employ strategic approaches to data collection efforts by implementing rigorous methodologies (Gregory & Radovinsky, 2012). In clinical nursing research, to produce high-quality accurate data and results, a strategic approach is needed when chart reviews are conducted (Gregory & Radovinsky, 2012).

Before initiating any data collection effort from EHR systems, a consistent review process guideline and protocol for data extraction must be in place (Gregory &

Radovinsky, 2012). The research questions must describe the situations, the relationships between, and/or comparisons of the variable of interest (Vassar & Holzmann, 2013). Based on the review of valid references that included prior articles, reports, standards and guidelines of international institutions such as the CDC and the ADA, clinical data in participants EHRs are considered accurate patient-monitoring and progress data (Vassar & Holzmann, 2013).

Retrospective review of pre-recorded, patient-centered data are often employed to answer research questions (Vassar & Holzmann, 2013). The use of the GCU-issued DPI project master code and the validated DSMQ Schmitt et al. (2016) and SED questionnaires Allen (2017), ensured that valid data was systematically collected and coded for analysis with the SPSS version 25 data analysis software. Pre-intervention retrospective review of participants' charts, and collection of previous recorded FBS results that met the clinical criteria set in the questions asked in the project (i.e., FBS levels above 100mg/dl) and collection of post-intervention FBS results directly from participants, ensured validity of the FBS results.

Reliability

This project involved previously documented clinical data in patients' health records and primary data from patient questionnaires. Three strategies that ensured the reliability of data included the initial definition of the project's limitations. Next, was the use of the GCU-issued DPI project master code (see Appendix E) for the gathering of participants' demographic and the clinical data (i.e., FBS results) from EHRs to ensure accurate data extraction and numerical coding of primary data from the DSMQ (see Appendix B) and SED tools (see Appendix C). Finally, the use of a trained, familiar clinic staff, directly under the supervision of the project investigator (PI) to assist with

record review and collection of pre-intervention FBS results from participants' EHRs, collection of post-intervention FBS results and verification of data by both the PI and the trained clinic staff to ensure accurate data collection and entry in the project master code.

Data Collection Procedures

After Institutional Review Board (IRB) approval was obtained, the PI met with an identified familiar clinic staff prior to the initiation of the project, for forty-five minutes instructions and orientation conference to ensure a proper understanding of the project, its purpose, the methodology and design, the independent and dependent variables of interest, the project terms and terminology such as FBS and DSME. All relevant documents including the DSMQ and SED questionnaires, Health Insurance Portability and Accountability Act (HIPAA) authorization form, confidentiality agreement form, informed consent form, the recruitment script and the master code were made available to the staff. The purpose and use of the project master code and the reason for the numerical coding of questionnaire answers for analysis, the importance of accurate data collection and coding, and the deadline for the project were stressed.

Clinic staff members collectively provided a list of 19 potential participants from the project site's EHR system and helped to distribute the project information and recruitment scripts to the identified patients. Patients who were interested in learning more about the study were referred and advised to contact the PI directly with any questions using the contact information provided on the recruitment script. The clinic staff helped to enroll and provide participants with the informed consent, the HIPAA authorization and confidentiality agreement forms and obtained participants' signatures. The defined independent variable for the project was a nurse-led DSME measured by a total of 10 hours of contact, comprised of a weekly one hour, forty-five minutes to two

hours class over a period of six weeks. The defined dependent variables of interest were glycemic control measured by FBS of 100md/dl or lower and patient reported diabetes self-efficacy measured by numerically coded questionnaire answers.

Prior to the interventional phase of the six-week project and the first nurse-led DSME class, participants' demographic data that included age, medical record numbers (MRN) and previous documented clinical data (i.e., FBS levels) were collected from the EHRs and paper files and were recorded in the DPI project master code (Appendix E). To obtain needed, relevant diabetes knowledge, self-care behaviors and skills, and perceived self-efficacy primary data absent from the EHRs, the DSMQ (Appendix B) and SED (Appendix C) questionnaires were administered, and the answers were collected for numerical coding. These pre-intervention clinical and primary data served as the baseline data for the project.

On the last day of the nurse-led DSME program, before the class began, FBS levels were collected directly from patients, or were checked at the clinic using patients' own glucose monitors or the clinic's and were documented in the DPI master code as the post-intervention clinical data. Post-intervention DSMQ and SED questionnaires were administered after the class and the answers were collected for numerical coding. The clinical and primary data collected on the last day of the program, served as the post-intervention and comparison data that showed the effects of nurse-led DSME.

Data Analysis Procedures

Quantitative research analysis is number driven and involves calculation of number of occurrences such as survey results, to classify and organize features into groups for computation and organization of statistical models to explain observations (Rouse, 2014). When data sets are large, researchers represent them with single values

that describe the middle (median) or average (mean) values of the whole data sets. In statistics the single values are referred to as the central tendencies, and the mean, median and mode are the ways the central tendencies are described (Rouse, 2014).

Data analysis for this project was done with the SPSS version 25 data analysis software using a paired sample t-test; SPSS default (p -value < 0.05) was deemed statistically significant. To prepare the collected raw data, demographic data was limited to the last three digits of participants' medical record numbers and age, to remove identifiers and maintain anonymity. Documented pre and post-intervention FBS values in the DPI master code were entered in SPSS and labeled separately as pre and post-DSME variables and the numerically coded primary data from answers in the different scales of the DSMQ and score-scales of the SED questionnaires were entered and labeled separately by subscales as pre and post-intervention variables in SPSS for quantitative analysis and comparison.

The defined dependent variable for the first clinical question was FBS levels. Numerical pre and post-intervention FBS levels were collected and used to create clinical datasets that were labeled as pre-intervention FBS in mg/dl and post-intervention FBS in mg/dl, data were analyzed and compared to establish statistical significance and differences between pre-intervention values and post-intervention values, the findings provided the answer to the first clinical question (see Tables 3 and 4 below).

The defined dependent variable for the second clinical question was participants' reported diabetes self-efficacy. To answer the second clinical question, the 16-item DMSQ questionnaire related to diabetes health behaviors and the corresponding eight-item self-efficacy SED questionnaires were administered before and after the nurse-led DSME program. Participants' answers in the questionnaires were numerically coded and

used to create pre and post-intervention datasets for the four subscales of the DSMQ and the SED score scales.

The DSMQ subscale were used to generate sum-scores that were used to create separate pre and post-intervention datasets labeled as Glucose Monitoring (GM), Dietary Control (DC), Physical Activity (PA) and Healthcare Use (HU)/Contact with Provider. The SED scale scores for reported diabetes self-efficacy were also used to create pre and post-intervention datasets. For analysis and comparison to establish the differences between pre and post-intervention scores and find the answer to the second question that was asked.

Ethical Considerations

Ethical considerations in quasi-experiments are just as important as they are in true experiments, but quasi-experimental designs have some advantages over true experiments in this aspect (Grand Canyon University, n.d-c). For example, the ethical concerns that are associated with randomized selection of subjects in true experiments have the potential to expose subjects who would otherwise not be exposed to potentially unsafe treatments and the withholding of beneficial treatments to participants in true experiments because of randomization, is never present in quasi-experimental designs as quasi-experiments typically employ established participant groups without randomization (Grand Canyon University, n.d-c).

In this project, pre and post-intervention data were collected from patient health records, with no patient identifiers such as names, dates of birth, social security numbers, addresses or telephone numbers. There were minimal risks to participants, their privacy and confidentiality. IRB approval was sought because the project involves human

subjects and their protected health information (PHI) in accordance with research guidelines stated in the 1979 Belmont Report:

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects (Office for Human Research Protections, 2016).

This project was considered exempt and approved by the GCU IRB (see Appendix A). The HIPAA authorization, informed consent and confidentiality agreement forms were signed by all parties involved in the project before data collection commenced. All parties involved in the project, including the project's Chairperson, the content expert and trained familiar clinic staff were made aware of, and were required to adhere to the specified guidelines for accessing, extraction and coding of data from the project site's EHRs. The guidelines included restricted access to participants' EHR data, numerical coding of answers in questionnaire prior to application in the project and the coding key.

Prior to data collection, safeguards were put place, including the signing of the confidentiality agreement by all individuals involved in the project to ensure proper understanding of the defined rules of ethical use of participants' data. Passworded, restricted access to electronic data. Proper storage of abstracted data in locked cabinets, deletion or destruction of data when no longer needed or after 3 years, in accordance with GCU specific guidelines and policies

Limitations

The limitations of this project were mostly related to the short data collection time frame of six weeks and the small sample size of 10 participants which may not be adequate for an accurate generalization. The size and scope of the single primary care setting and the amount and type of data that could be collected in six weeks, created additional limitations in terms of sustained positive health outcome post-intervention. Due to the time constraints of this project, the efficacy of nurse-led DSME on glycemic control, were referenced as FBS levels rather than the more comprehensive three-monthly HgbA1c levels. Other limitations involved clinic staffing. There were only two full-time nursing staff, two nursing interns, one physician assistant and a single non-clinical staff responsible for the clinic's administrative activities and also help with the project's data collection activities. These unavoidable limitations were however, not expected to affect the results of the project negatively since data related to the variables of interest were straightforward and easily accessible.

Summary

Chapter 3 presented and the described in-depth the quantitative methodology and quasi-experimental designs with more focus on the one-group pre and post-test design, to justify the choice this methodology and design as the most ideal for the project. The data collection instruments used in this project were also considered, their validation processes and application to data collection in prior similar projects and the steps taken to ensure the validity and reliability of the data were addressed. Other areas of focus in this chapter included the project limitations. The data analysis approach in the project, given that data was collected data from sources that included participants' EHR and questionnaires addressed in the in Chapter 4. The need for numerical coding of the primary data and use

of the SPSS version 25 data analysis software to aid the quantification, interpretation and condensing of the huge data output for a concise presentation of the findings of the project were also discussed and presented in the chapter.

Chapter 4: Data Analysis and Results

The purpose of this quantitative, quasi-experimental project was to determine if any, and to what extent a relationship existed between a nurse-led DSME intervention and the lowering of FBS levels to 100mg/dl or below, and reports of improved self-efficacy among patients with poorly controlled T2DM at a primary care clinic in an underserved community in Northwest, Texas. Previous documentations of FBS levels in the participants' health records were used as pre-intervention baseline data that represented the effects of DSME by other HCPs. FBS levels and questionnaire answers collected post-intervention, represented the effects of nurse-led DSME and served as the comparison data for the project. The defined independent variable was 10 contact hours of nurse-led DSME, comprised of a weekly one hour, forty-five minutes to two hours class held over a period of six-weeks. The measured dependent variables were FBS of 100mg/dl or under and patient reported improvements in diabetes self-efficacy.

In this chapter, the effects of a six-week nurse-led DSME program on FBS levels and reported self-efficacy among T2DM patient population were examined. Analysis and comparison of pre and post-intervention data showed the potential effectiveness and superiority of nurse-led DSME in patients' achievement of positive diabetes management goals of sustained glycemic control over conventional care provided by non-nurse HCPs usually comprised of medication therapy, written instructions to lose weight, take medications, diet, exercise, check blood sugar and scheduled follow-up visits with provider. The quantitative methodology and the one group, pre and post-test quasi-experimental design were employed to quantify and analyze pre-intervention clinical data collected from project site's EHR system, the numerically coded pre and post-intervention participants' questionnaire answers related to diabetes specific health

behaviors and perceived self-efficacy, and the clinical data collected after the intervention. Findings from the project were presented as they related to its purpose statement, the variables of interest and the following two questions that guided the project:

Q1: For patients with poorly controlled diabetes, will the implementation of a nurse-led DSME program that provides one hour, forty-five minutes to two hours per class up to a total of 10 hours of contact compared to current diabetes care which includes written instructions by non-nurse health professionals, result in improved FBS of 100mg/dl or below after six weeks?

Q2: For adult patients with poorly controlled T2DM with disease knowledge and self-care deficits, will the implementation of a nurse-led DSME program that provides one hour, forty-five minutes to two hours per class up to a total of 10 hours of contact, compared to current diabetes care which includes written instructions by non-nurse health professionals result in reports of improved self-efficacy after six weeks?

Descriptive Data

Nineteen adult patients with T2DM in a primary care clinic located in an underserved community in Northwest, Texas were identified by clinic staff for the project. Ten patients met the eligibility criteria and were enrolled in the program. The participants were above 18 years of age, English-speaking and able to read and write above the third-grade level and all had confirmed diagnoses of T2DM with poorly controlled blood sugar level and at risk for developing complications (i.e., FBS over 100mg/dl or HgbA1c above 7%) (see Table 1 below).

Table 1

Ten Patients Who Met Age and Clinical Inclusion Criteria

MRN	Age	Pre-DSME FBS in mg/dl
*****040	34	260
*****338	45	157
*****196	64	232
*****320	51	302
*****320	49	167
*****075	67	204
*****663	53	183
*****478	55	160
*****989	63	157
*****222	41	145

Notes. Established adult patients at the project site with fasting blood sugar (FBS) levels above 100mg/dl. All met the defined age and clinical inclusion criteria for participation in the project.

The participants were all established patients at the clinic who visited routinely for follow-up. They* all expressed interest in engaging in the DSME program and committed to completing the program. None reported cognitive impairment or active mental health crises. Patients who had no confirmed diagnoses of T2DM, those with non-T2DM or have well-managed T2DM with FBS at 100mg/dl and below, or HgbA1c below 7% were excluded from the project. Non-English-speaking patients and those unable to read or write above the third-grade level, women who were pregnant or breastfeeding, children and adolescents were also excluded.

Previous documentation of FBS levels in the participants' EHRs were collected and imputed into the DPI master code as the baseline clinical data. A pre-intervention questionnaire was administered using the DSMQ and SED tools, to assess participants diabetes health behaviors and their perceived diabetes self-efficacy, before the initiation of DSME intervention. The questionnaire answers served as the baseline primary data.

Weekly classes led by the PI were held on Tuesday mornings for six weeks, to provide face to face instructions on blood sugar monitoring, healthy eating, medication

compliance, physical activities, weight maintenance, disease symptoms monitoring, and other self-management skills based on the AADE7 education materials. Each class lasted one hour and forty-five minutes to two hours. Strategies for preventing and recognizing complications (i.e., follow up office visits, foot examination and care, vision care, and skin care) were taught by the PI.

Prior to the starting last class, post-intervention FBS levels were collected directly from patients or measured at the clinic using patients' own glucose monitors or the clinic's and were documented in the DPI master code and at the ended of the class, the post-intervention questionnaires were administered using the same DSMQ and SED tools and answers were collected for numerical coding and statistical analysis and comparison with the baseline data. The validity and reliability of the data collected were ensured by using the previously tested evidence-based questionnaires (see Appendixes B and C) and the DPI master code (see Appendix J).

Data Analysis Procedures

The collected data comprised of clinical FBS level and numerically coded primary data related to participants' reported diabetes health behaviors and self-efficacy were analyzed with the aid of the SPSS version 25 data analysis software, using a paired sample *t*-test. The mean values of the pre and post-intervention data and the mean differences between the two sets of data for each variable of interest (i.e., FBS levels, and the numerical scores of participants' reported diabetes health behaviors and self-efficacy) were established and compared to answer the two questions asked in the project. A *p* - value < 0.05 was deemed statistically significant.

Clinical data related to FBS levels were collected from patients' EHRs and entered in the SPSS to create datasets labeled pre and post DSME FBS level in mg/dl and

were computed for analysis. Participants' numerically coded questionnaires answers related to diabetes health behaviors and perceived self-efficacy were used to create datasets. The datasets for the four DSMQ subscales included all 16 diabetes health behavior items and were labeled pre and post-DSME Glucose Monitoring (GM), Dietary Control (DC), Physical Activity (PA), Healthcare Use (HU)/Contact with Provider and. Pre and post-intervention sum-scale scores were generated for each of the four subscales. To address the self-efficacy variable, datasets labeled Pre-DSME SED sum-scores and post-DSME SED sum-scores were created using the pre and post-intervention numerically coded eight-item SED questionnaire answers that corresponded with the 16 diabetes health behaviors items of the DSMQ. The data sets were computed for analysis, with p -value set at < 0.05 .

Results

The primary focus of this project was glycemic control, referenced as FBS level and the secondary focus was reported self-efficacy. To establish the effects of a nurse-led DSME on the two variables of interest (i.e., FBS level and reported self-efficacy), clinical and primary data collected before and after a nurse-led DSME intervention data were analyzed and interpreted with the aid of the SPSS version 25 data analysis software and findings were compared with a paired sample t -test to determine if differences in the findings were statistically significant enough to establish a relationship between a nurse-led DSME and lower FBS values and reports of higher levels of diabetes self-efficacy among participants, and answer the questions asked in the project.

Q1: For patients with poorly controlled diabetes, will the implementation of a nurse-led DSME program that provides one hour, forty-five minutes to two hours per class up to a total of 10 hours of contact compared to current diabetes care

which includes written instructions by non-nurse health professionals, result in improved FBS of 100mg/dl or below after six weeks?

Ten patients participated fully and completed the six-week nurse-led DSME program. Significant differences were shown between the baseline and post-intervention FBS levels among all participants (see Table 2 below).

Table 2

Individual Fasting Blood Sugar (FBS) Levels Pre and Post-Nurse-led DSME

Participant's MRN	Pre-DSME FBS Levels	Post-DSME FBS Levels	Difference Levels
*****040	260	240	20
*****338	157	137	20
*****196	232	215	17
*****320	302	289	13
*****320	167	140	27
*****075	204	180	24
*****663	183	165	18
*****478	160	145	15
*****989	157	135	22
*****222	145	118	27

Note. Participants' FBS values before and after a nurse-led DSME and the differences in values are shown.

MRN = medical record number.

The paired-samples *t*-test results showed that mean FBS value differed before nurse-led DSME ($M = 196.7$, $SD = 52.3$). After nurse-led DSME ($M = 176.40$, $SD = 55.1$) at the .05 level of significance ($t = 13.5$, $df = 9$, $n = 10$), $p < .05$, 95% CI for mean difference (16.893 to 23.707). On average FBS value was about 20.3 points lower after participation in nurse-led DSME (see Tables 3 and 4 below).

Table 3

Pre and Post-nurse-led DSME FBS Mean Values

		<i>M</i>	<i>N</i>	<i>STD</i>	<i>SEM</i>
Pair 1	Pre-intervention FBS in mg/dl	196.70	10	52.320	16.545
	Post-intervention FBS in mg/dl	176.40	10	55.120	17.431

Note. Participants' mean FBS levels before and after nurse-led DSME intervention. Average FBS value before intervention was 196.7mg/dl, average FBS value was lowered to 176.4mg/dl after intervention.

Table 4

Mean Difference Between Pre and Post-nurse-led DSME FBS Levels

		Paired Differences					<i>t</i>	df	Sig. (2-tailed)
		<i>M</i>	<i>STD</i>	<i>SEM</i>	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Post-intervention FBS in mg/dl	20.300	4.762	1.506	16.893	23.707	13.480	9	.000

Note. After participation in a nurse-led DSME, average FBS value was lower by about 20.3 points.

The secondary focus of the project was the reported diabetes self-efficacy by participants. To establish the effects of a nurse-led DSME on participants' reported diabetes self-efficacy, diabetes health behaviors that included glucose monitoring, dietary control, physical activity, contact with providers/healthcare use and perceived self-efficacy were assessed. Data collected from participants' answers in the DMSQ (Appendix B) and the SED (Appendix C) questionnaires, were coded numerically to facilitate quantitative analysis, interpretation and comparison of findings in order to find the answer to the second question that was asked in the project.

Q2: For adult patients with poorly controlled T2DM, with disease knowledge and self-care deficits, will the implementation of a nurse-led DSME program that

provides one hour, forty-five minutes to two hours per class up to a total of 10 hours of contact, compared to current diabetes care which includes written instructions by non-nurse health professionals result in reports of improved self-efficacy after six weeks?

For the second variable of interest in the project (i.e., reported diabetes self-efficacy), aspects of diabetes health behaviors (i.e., glucose monitoring, dietary control, physical activity and healthcare us/contact with provider) related to diabetes self-efficacy were assessed using participants' answers in the DSMQ questionnaire. Datasets were created by subscale using the numerically coded answers in the questionnaire and sum-scores were generated for each subscale for analysis (see Appendix B). Overviews of the DSMQ sum-scores per subscale are shown below (see Tables 5 - 12).

For the glucose monitoring subscale, the results of the paired-samples *t*-test showed that mean score differed before nurse-led DSME ($M = 7.0, SD = 3.1$). After nurse-led DSME ($M = 14.1, SD = 1.8$) at the .05 level of significance ($t = 6.28, df = 9, n = 10, p < .000$, 95% CI for mean difference (9.65 to - 4.54). On average the mean difference in glucose monitoring score was - 7.1 after participation in nurse-led DSME (see Tables 5 and 6 below).

Table 5

Mean DSMQ scores - Glucose Monitoring (GM) Pre and Post-Nurse-led DSME

		<i>M</i>	<i>N</i>	<i>STD</i>	<i>SEM</i>
Pair 1	Pre-DSME Glucose Monitoring sum-score	7.00	10	3.127	.989
	Post-DSME Glucose Monitoring sum-score	14.10	10	1.792	.567

Note. Participants' DMSQ mean scores for glucose monitoring before and after participation in nurse-led DSME intervention. A higher mean is shown for glucose monitoring scores after nurse-led DSME intervention.

Table 6

Mean Difference in DSMQ Scores for Glucose Monitoring (GM) Pre and Post-nurse-led DSME

	Paired Differences						<i>t</i>	df	Sig. (2-tailed)
	<i>M</i>	<i>STD</i>	<i>SEM</i>	95% Confidence Interval of the Difference					
				Lower	Upper				
Pair 1 Pre-DSME Glucose Monitoring sum-score	-7.100	3.573	1.130	-9.656	-4.544	-6.284	9	.000	
Post-DSME Glucose Monitoring sum-score									

Note. A mean difference of -7.1 points is shown between participants' pre and post-nurse-led DSME glucose monitoring scores

For dietary control subscale, the paired-samples *t*-test results showed that mean score differed before nurse-led DSME ($M = 4.5$, $SD = 1.17$). After nurse-led DSME ($M = 8.3$, $SD = .823$) at the .05 level of significance ($t = 8.5$, $df = 9$, $n = 10$, $p < .000$, 95% CI for mean difference (- 4.80 to - 2.79). On average the mean difference in dietary control score was - 3.80 after participation in nurse-led DSME (see Tables 7 and 8 below).

Table 7

Mean DSMQ Scores for Dietary Control (DC)

		<i>M</i>	<i>N</i>	<i>STD</i>	<i>SEM</i>
Pair 1	Pre-DSME DC sum-score	4.5000	10	1.17851	.37268
	Post-DSME DC sum-score	8.30	10	.823	.260

Note. Average participants' DMSQ scores for dietary control before and after participation in nurse-led DSME intervention. A higher mean of 8.30 is shown for dietary control scores after nurse-led DSME intervention compared to 4.5 before intervention.

Table 8

Mean Difference Between Pre and Post-Nurse-led DSMQ Scores for Dietary Control (DC)

		Paired Differences			95% Confidence Interval of the Difference		<i>t</i>	df	Sig. (2-tailed)
		<i>M</i>	<i>STD</i>	<i>SEM</i>	Lower	Upper			
Pair 1	Pre-DSME DC sum-score	-3.80000	1.39841	.44222	-4.80036	-2.79964	-8.593	9	.000
	Post-DSME DC Sum-score								

Note. Average difference of -3.8 points is shown between participants' scores before and after participating in nurse-led DSME DMSQ dietary control scores.

For physical activity subscale, the paired samples *t*-test results showed that mean score differed before nurse-led DSME ($M = 1.7$, $SD = 1.2$). After nurse-led DSME ($M = 6.2$, $SD = 1.5$) at the .05 level of significance ($t = -8.6$, $df = 9$, $n = 10$, $p < .000$, 95% CI for mean difference (- 5.6 to - 3.3). On average the mean difference in physical activity score was - 4.500 after participation in nurse-led DSME (see Tables 9 and 10).

Table 9

Mean DSMQ Scores for Physical Activity (PA)

		<i>M</i>	<i>N</i>	<i>STD</i>	<i>SEM</i>
Pair 1	Pre-DSME PA sum-score	1.70	10	1.160	.367
	Post-DSME PA sum-score	6.20	10	1.476	.467

Note. The average DMSQ scores for physical activity before and after participation in nurse-led DSME intervention. A higher mean of 6.2 is shown for dietary control scores after intervention compared to average score of 1.7 before intervention.

Table 10

Mean Difference Between Pre and Post-Nurse-led DMSQ Scores for Physical Activity (PA)

		Paired Differences					<i>t</i>	df	Sig. (2-tailed)
		<i>M</i>	<i>STD</i>	<i>SEM</i>	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Pre-DSME PA sum-score	-4.500	1.650	.522	-5.680	-3.320	-8.625	9	.000
	Post-DSME PA sum-core								

Note. Average difference of - 4.5 is shown between participants' scores for physical activity before and after participating in nurse-led DSME.

For contact with provider/healthcare use subscale, the paired samples *t*-test results showed that mean score differed before nurse-led DSME ($M = 3.90$, $SD = 2.18$). After nurse-led DSME ($M = 5.40$, $SD = 1.2$) at the .05 level of significance ($t = -3.0$, $df = 9$, $n = 10$, $p < .015$, 95% CI for mean difference (-2.6 to -.369). On average the mean difference in contact with provider/ healthcare use score was -1.500 after participation in nurse-led DSME (see Tables 11 and 12).

Table 11

Mean DSMQ Scores for Healthcare Use (HU)/Contact with Provider

		<i>M</i>	<i>N</i>	<i>STD</i>	<i>SEM</i>
Pair 1	Pre-DSME HU sum-score	3.90	10	2.183	.690
	Post-DSME HU sum-score	5.40	10	1.265	.400

Note. Average scores for healthcare use/contact with provider before and after participation in a nurse-led DSME intervention. A higher average score was shown after nurse-led DSME intervention.

Table 12

Mean Difference Between Pre and Post-Nurse-led DSMQ Scores for Healthcare Use (HU)/Contact with Provider

		Paired Differences					<i>t</i>	df	Sig. (2-tailed)
		<i>M</i>	<i>STD</i>	<i>SEM</i>	95% Confidence Interval of the Difference				
Pair					Lower	Upper			
1	Pre-DSME HU sum-score	-1.500	1.581	.500	-2.631	-.369	-3.000	9	.015
	Post-DSME HU sum-score								

Note. Average difference of - 1.5 points was shown between participants' physical activity scores before and after participating in a nurse-led DSME.

To assess and establish changes and improvements in participants' reported diabetes self-efficacy, the SED (Appendix C) Likert scale was used to measure the extent to which participants were confident of their ability to manage their blood sugar levels, adhere to healthy dietary choices and medications, increase their levels of physical activity and reduce risks of complications through contact with provider (i.e., follow up office visits). Data collected from the scored answers in the SED before and after intervention, were analyzed and compared. The paired samples *t*-test results for reported diabetes self-efficacy showed that mean score differed before nurse-led DSME ($M =$

42.5, $SD = 14.3$). After nurse-led DSME ($M = 70.7$, $SD = 5.5$) at the .05 level of significance ($t = -9.0$, $df = 9$, $n = 10$, $p < .000$, 95% CI for mean difference (-35.2 to -21.1). On average the mean difference in reported diabetes self-efficacy score was -28.2 after participation in nurse-led DSME (see Tables 13 and 14) below.

Table 13

Mean DSMQ Scores for Healthcare Use (HU)/Contact with Provider

		<i>M</i>	<i>N</i>	<i>STD</i>	<i>SEM</i>
Pair 1	Pre-DSME SED sum-score	42.47	10	14.268	4.512
	Post-DSME SED sum-score	70.70	10	6.533	2.066

Note. Average self-efficacy (SED) scores before and after nurse-led DSME intervention.

Table 14

Mean Difference Pre and Post-Nurse-Led DSME for Self-Efficacy for Diabetes (SED) Scale Scores

		Paired Differences					<i>t</i>	<i>df</i>	Sig. (2-tailed)
		<i>M</i>	<i>STD</i>	<i>SEM</i>	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Pre-DSME SED sum-score	-28.230	9.834	3.110	-35.265	-21.195	-9.078	9	.000
	Post-DSME SED Sum-score								

Note. Average difference of -28.3 was shown between participants' scores for diabetes self-efficacy before and after nurse-led DSME.

Summary

In this quantitative, pre and post-test quasi-experimental project, the relationship between a nurse-led DSME and lower FBS of 100mg/dl or below and reports of improved diabetes self-efficacy among T2DM patients with poorly controlled blood

sugar in primary care clinic was examined. Before and after the nurse-led DSME intervention, clinical data comprised of FBS levels and primary data comprised of answers in questionnaires related to participants' diabetes health behaviors and perceived diabetes self-efficacy were collected, analyzed and compared to determine if participants' FBS levels were lower and if participants reported improved diabetes self-efficacy after the intervention.

The two set of data were analyzed and compared using the SPSS data analysis software and a paired sample *t*-test to establish and compare the differences between the two sets of data related to the variables of interest. Data output showed there were significant differences between the pre-intervention and the post-intervention scores. Overall, a comparison of the pre and post-DSME intervention clinical data indicated better post-DSME clinical values with an average of 20.3 points reduction in FBS levels. Data analysis showed that all participants had decreases of at least 13 points up to 27 points in their FBS levels after participation in the nurse-led DSME intervention. Post-DSME questionnaires showed increases in patient-reported self-efficacy at an average of at least 28.23 points. Also, noteworthy is the fact that, the sum-cores for all four subscales of the DSMQ and the scores of SED scales for all participants showed statistically significant improvements after nurse-led DSME participation.

Based on data analysis, the first clinical question was not answered because none of the participants reached the target FBS goals of 100mg/dl or below. However, post-intervention data indicate better glycemic control among all participants with statistically significant lower values and an average reduction in FBS levels of at least 20.3 points. For the second question that was asked in the project, data output and data analysis showed increases in participant's reported diabetes self-efficacy with post-intervention

average score of 70.7 points compared to pre-intervention average score of 42.5 points. The average difference between pre and post-intervention scores was 28.2 points. These were results were significant enough for a conclusion that the second question was answered. The implications of the findings of this project, the conclusions that were reached after data analysis and the recommendations for future studies related to the effectiveness of nurse-led DSME programs for the T2DM patient were presented in Chapter 5.

Chapter 5: Summary, Conclusions, and Recommendations

Diabetes is a complex and severe disease condition that results in higher rates of morbidity, disabling complications, diminished QOL, tremendous increases in healthcare spending and higher rates of mortality. Its daily management and the management of its complications can be challenging (Powers et al., 2016). Due to these challenges, patients who suffer from diabetes must familiarize themselves with different and necessary complicated self-management activities for their survival and optimum quality of life, such as frequent monitoring of blood glucose levels, administration of glucose-lowering medications like injections of insulin and the early recognition of complications and knowledge of actions they must take when complications occur (Powers et al., 2016). Healthcare providers and organizations must ensure the delivery of quality care by utilizing all available resources to address difficulties associated with access to DSME and seek out resources to meet the vital healthcare needs of adults with T2DM (Powers et al., 2016).

DSME programs with ongoing supports provide learning and self-management skills acquisition opportunities that are vital for sustaining improvements gained by patients from partaking in diabetes education at the time of diagnosis from (Powers et al., 2016). DSME programs enable successful and sustained patient engagement in self-care behaviors relevant to glycemic control, including healthy eating, increased physical activities, regular blood sugar monitoring, medication compliance, and follow-up checkups (Chrvala et al., 2015). Different healthcare team members including nurses, pharmacists, physicians and dieticians provide disease management education to patients with well-documented diabetes management successes (Azami et al., 2018).

Evidence that support the beneficial effects of DSME delivered by registered nurses is accumulating but remains limited (Azami et al., 2018). This quantitative, pre and post-test quasi experimental project, presented an opportunity for an in-depth look at the effectiveness and benefits of a nurse-led DSME program, compared to DSME by other HCPS on the FBS levels and reported diabetes self-efficacy of T2DM patients in a small primary care clinic located in an underserved community in Northwest, Texas. This project is important because its findings differentiate and provide added support for nurse-led diabetes education as a distinct contribution by nurses to healthcare and diabetes care. The findings provide additional evidence that can potentially compel more investigations in support and validation of nurse-led DSME as a fundamental element of diabetes care that defines nursing excellence in healthcare delivery.

Additionally, the findings of this project add to the growing body of knowledge surrounding nurse-led DSME, to support potential proposals for routine inclusion of nurse-led DSME programs in all diabetes care settings for more productive diabetes management regimes for sustained glycemic control and prevention of complications (Powers et al., 2016). Lastly, in support of the unique expertise and experiences that nurses bring to the current multidisciplinary healthcare workforce, the findings from this project could provide support for potential policy changes to make DSME training and certification mandatory elements of nursing curricular.

Summary of the Project

Chapter 1 of this practice improvement project presented the positive effects of DSME, introduced and addressed nurse-led DSME and presented its potential beneficial effects on blood sugar control and reported diabetes self-efficacy among adult patients with uncontrolled T2DM. The following were the underpinning clinical questions for this

project:

Q1: For patients with poorly controlled diabetes, will the implementation of a nurse-led DSME program that provides one hour, forty-five minutes to two hours per class up to a total of 10 hours of contact compared to current diabetes care which includes written instructions by non-nurse health professionals, result in improved FBS of 100mg/dl or below after six weeks?

Q2: For adult patients with poorly controlled T2DM, with disease knowledge and self-care deficits, will the implementation of a nurse-led DSME program that provides one hour, forty-five minutes to two hours per class up to a total of 10 hours of contact, compared to current diabetes care which includes written instructions by non-nurse health professionals result in reports of improved self-efficacy after six weeks?

The purpose of this quantitative, quasi-experimental project was to determine if any, and to what extent a relationship existed between a nurse-led DSME intervention and the lowering of FBS levels to 100mg/dl or below, and reports of improved self-efficacy among patients with poorly controlled T2DM at a primary care clinic located in an underserved community in Northwest, Texas. In the background of the project, detailed history of diabetes and its management over the years was presented to stress the importance of DSME; against that historical backdrop, the particular importance and benefits of nurse-led DSME was defined, addressed and supported by research articles.

Chapter 2 presented a synthesis of 50 DSME related research articles of existing knowledge. The related theoretical basis for the application of the findings of this project to practice, to close gaps in diabetes care that were defined in the problem and purpose statements of Chapter 1 were presented. The selected literature articles for the project

were classified under two themes and two subthemes as follows: (1) Efficacy of DSME on metabolic markers. The two subthemes were as followed: (a) Effects of DSME on blood sugar level. (b) Effects of DSME on body weight/BMI measurements and BP readings. (2) Effects of DSME on patient care outcomes and health behaviors. The subthemes were as followed: (a) Effects of DSME on self-efficacy and patient satisfaction. (b) Effectiveness of nurse-led DSME Vs non-nurse-led DSME on patient care outcomes. Each subtheme was supported by three prior studies that were specific to the two outcome variables defined FBS levels and reported self-efficacy and the two clinical questions asked.

Chapter 3 introduced and justified the quantitative methodology and the one-group pre and post-test design employed in the project. The quantitative methodology and one group pre and post-test quasi-experimental design ensured consistency in the data collection and data analysis processes. The design required only a single group of participants with a single disease condition, who were exposed to the same pre and post-intervention assessments (Allen, 2017). Weekly classes were held with participants and conducted by the PI at the project site. All seven focus spheres of diabetes self-care recommended by the AADE, that included healthy eating, physical activities, problem-solving, monitoring, taking medications, risks reduction and coping skills were addressed (AADE, 2018). The DSME educational materials and class activities were described in detail in this chapter and the data collection tools and processes, the validity and reliability of the tools and the sources of data were also presented.

Chapter 4 presented the results of the project that showed the effects of a six-week nurse-led DSME program on participants' FBS levels and reported health behaviors and self-efficacy. Statistical data analysis, interpretation and comparison processes were

performed using SPSS version 25 data analysis software and a paired sample *t*-test; results were presented in tables to show the differences between pre and post-intervention data and how the two clinical questions were answered and in Chapter 5, inferences were made, and the conclusions that were reached based on data analysis results were presented. The efficacy and weight of nurse-led DSME project in patient's achievement of desired diabetes management goal of sustained glycemic control over conventional diabetes care provided by other HCPs were determined based on statistically significant differences between the pre and post-nurse-led DSME results. Future professional, practice and theoretical implications of the findings of the project were discussed, and recommendations were made for future studies relevant to the effectiveness of nurse-led DSME programs in the care of the adult diabetic patient.

Summary of Findings and Conclusion

Before and after the nurse-led DSME intervention, FBS levels and entered in the master code data. Primary data related to participants' diabetes health behaviors and perceived diabetes self-efficacy were collected and numerically coded for quantitative analysis. At the end of the intervention, data analysis and comparison were performed with the aid of the SPSS version 25 data analysis software, using a paired sample *t*-test to establish a relationship between the independent variable defined as nurse-led DSME and the two dependent variables of interest defined as FBS levels and patient reported diabetes self-efficacy. The following were the two clinical questions that were asked and answered in this project:

Q1: For patients with poorly controlled diabetes, will the implementation of a nurse-led DSME program that provides one hour, forty-five minutes to two hours per class up to a total of 10 hours of contact compared to current diabetes care

which includes written instructions by non-nurse health professionals, result in improved FBS of 100mg/dl or below after six weeks?

Q2: For adult patients with poorly controlled T2DM, with disease knowledge and self-care deficits, will the implementation of a nurse-led DSME program that provides one hour, forty-five minutes to two hours per class up to a total of 10 hours of contact, compared to current diabetes care which includes written instructions by non-nurse health professionals result in reports of improved self-efficacy after six weeks?

None of the participants in the project reached the defined goal of FBS level of 100mg/dl. The data was however, encouraging, as there were significant differences between values of the data collected before and after the intervention. A comparison of the clinical data indicated better post-intervention clinical values with an average of 20.3 points reduction in FBS levels. Data analysis showed 100% of the participants had decreases of at least 13 points up to 27 points in their FBS after participation in the nurse-led DSME intervention. Post-intervention questionnaire answers showed increases in participants' reported self-efficacy with an average of at least 28.23 points. It should be noted that the sum-scores for all four subscales of the DSMQ, and the SED scale scores for all participants showed statistically significant improvements after nurse-led DSME participation. Based on these positive outcome data, a conclusion can be reached that the nurse-led DSME intervention resulted in enhanced glycemic control and higher levels of participants' reported self-efficacy.

This project contributes to the advancement of the science of nursing in particular and healthcare in general. Findings from this project adds to existing knowledge of nurse-led DSME and builds supports for existing evidence that, in comparison to conventional

diabetes care, lifestyle modification that stem from knowledge gained from participation in nurse-led DSME programs, can reduce risks factors for diabetes in entire populations; help patients with inadequate baseline FBS and diabetes self-efficacy, achieve optimum FBS levels and enhanced diabetes self-efficacy.

Implications

Nurses are academically equipped and are highly knowledgeable in disease management, often playing central roles in the devising, delivery and supervision of structured interventional programs that are focused on health preservation, health improvement and the achievement of the self-management objectives of patients diagnosed with chronic diseases like diabetes (Powers et al., 2016). Nurses possess the unique ability to connect with patients in ways other HCPs are not able. DSME, requires a collaborative participation of patients and care providers and nurses are trained to approach healthcare delivery in holistic ways, that engender trust and collaborative responses from patients as well as other healthcare colleagues (Massimi et al., 2017). Nurses have more impact and opportunities to organize and direct quality improvement projects and able to employ evidence-based and evidence-focused chronic disease on management approaches to improve patients care outcomes in concert with other healthcare specialties (Massimi et al., 2017)

Nurse experts in diabetic management, and those who implement DSME are afforded opportunities to apply for and possibly obtain federal government grants to facilitate healthcare policies that enhance diabetic care outcomes (Peros, 2016). Nurse-led DSME programs could impact groups of patients and facilitate maximum utilization of available healthcare and communal resources (Peros, 2016). This nurse-led DSME project provided an opportunity to execute an evidence based-intervention with potentials

for enhanced patient care outcomes and the positive influencing of healthcare and nursing policies.

Theoretical implications.

This project was built on the theory of planned behavior (TPB) by Ajzen (1988) and Orem's theory of self-care and self-care deficit (1959; 2001). The two clinical questions that guided this project were directed at the effects of a nurse-led DSME on FBS levels and reported diabetes self-efficacy. To successfully implement the nurse-led DSME and answer the questions, the TPB provided the theoretical basis for assessment of participants' diabetes health behaviors and their perceived diabetes self-efficacy before and after the program. The TPB has been effectively utilized to predict and explain different health behaviors and objectives such as tobacco use, alcohol consumption, usage of healthcare services, breastfeeding, and drug use (LaMorte, 2018). These assessments provided useful insights into participant's diabetes health behaviors and helped to determine and target the behaviors that needed modification, post-intervention, evaluation of participants' gains and impact of the intervention for sustained outcomes.

The findings of this project further validate the TPB and Orem's theories as appropriate implementation theories for nurse-led interventional projects that improve nursing practices and positively influence health outcomes for patients with chronic diseases such as T2DM, for enhanced QOL. Orem's nursing theories revolve around the promotion of self-reliance and the active involvement of patients in their own care. These theories have been used by providers before to guide, identify, plan and implement DSME for higher levels of patient participation in self-care that have resulted in positive changes in health statuses and health behaviors (Oliveiral et al., 2016). The application of Orem's theories in this project helped to strengthen the credibility of the findings that

could be attributed to the nurse led DSME intervention. All participants were fully engaged in and completed the program.

Although, the findings of the project are positive and encouraging, some areas of weakness include the cope and size of the clinic, the sample size of 10 participants which may not be an adequate representation of the general population of T2DM patients, and the short data collection period of six-week that restricted the amount and type of data collected. To lessen these weaknesses, and to reach as credible a conclusion as is possible, the quantitative methodology and the one group pre-test and post-test quasi-experimental design were chosen for the project and the participants' gains shown in the statistically significant outcome data were improvements in clinical values as well as increases in reported diabetes self-efficacy among all ten participants.

Practical implications.

Based on the findings of the project, significant improvement in participants' FBS levels and increases in their reported diabetes self-efficacy were shown after program participation. These findings have important implications for nurse-led DSME in diabetes care. This project was easy to plan and execute in a relatively short period of time and it is replicable because of existing resources as the cost-free assessment tools and standardized teaching materials that required only authors' permissions. The ease with which this program was planned and implemented, indicate that existing resources can be standardized and be used to provide effective and low-cost diabetes education primary care and other healthcare settings

Future implications.

In the literature review, authors reported similar findings in prior nurse-led DSME programs (Azami et al., 2018; Chrvala et al., 2015; Drincic et al., 2016; Jutterströma et

al., 2016; Peros, 2016; Rusdiana et al., 2018). The findings from this project clearly support prior investigation and contribute to the limited but growing evidence in support of the efficacy of nurse-led DSME programs on the glycemic control of T2DM patients.

Although, the full extent of the positive effects of this nurse-led DSME intervention was not fully reflected due to several factors such as the size and scope of the primary care setting, the sample size of 10 participants, the absence of a control group for comparison and the fact that the project drew information from a single community clinic and depended solely on data from the same group of patients. Nonetheless, this project's findings could generate an impetus for future studies of nurse-led DSME and trigger policy changes that could make DSME training and certification a mandatory part of nursing curricular, much like the mandatory basic cardiac life support (BCLS) training/certification. DSME certification for all nurses in all healthcare settings will enable to all practice nurses to ceaselessly deliver substantiated, quality health and self-care education to all T2DM patients and those at risk for developing DM as a routine health services in outpatient or inpatient settings.

Recommendations

DSME is a fundamental aspect of diabetes care that has been shown in several studies to result in enhanced disease knowledge and self-care skills. As diabetes occurrence rates increase, healthcare providers in primary care settings need evidence-based DSME programs that teach patients self-care skills and provide them with needed information for managing their disease (Chrvala et al., 2015).

Recommendations for future projects.

Based on the findings of this project, recommendations for future studies of nurse-led DSME include larger sample sizes that are more representative of the general population. Larger practice settings such as hospitals with larger staffing pool that can spare staff for training to help with data collection, with wider scopes of practice, from which to draw larger sample sizes for more accurate generalization. Longer duration of time (i.e., six months or longer), to allow adequate data collection time and more comprehensive outcome variables such as HgbA1c and LDL cholesterol levels for a more accurately reflection of the effectiveness of nurse-led DSME interventions and the use of randomized control and intervention groups for truly quantitative investigations.

Recommendations for practice.

Nurse-led DSME is differentiated by the nurse's skills of advocacy, communication, resource management and promotion of evidence-based quality and cost-effective interventions that help diabetes patients achieve glycemic control, prevent complications and achieve higher levels of self-efficacy and satisfaction (Chrvala et al., 2015). Findings from this project provide further evidence of the unique expertise and experience that nurses bring to diabetes care. Nurse-led DSME programs are effective across the continuum of care and should be incorporated into diabetes plans of care since these programs are comprehensive and designed to be culturally sensitive and effective for encouraging and facilitating patients' acceptance, participation and adherence to treatment recommendations that result in enhanced patient-centered outcomes and satisfaction (Philis-Tsimikas & Gallo, 2014).

Other practice recommendations include initiatives by healthcare systems and organizations to ensure every nurse in every practice setting is a trained and certified

DSME provider, so that, for all T2DM patients, DSME services is provided unceasingly. Development of collaborative relationships between healthcare systems and nursing departments to provide and ensure access to resources that support nurse-led DSME services. Restructured and standardized DSME curricula that are consistent with the accepted the standards set by the ADA and the AADE. Development and proposals for policy changes that will make training and certification of nurses who are already accomplished in their roles as patient educators to lead DSME programs within healthcare systems and organizations to ensure that the programs meet set national standards and address the needs of patients with T2DM without the need for third party insurance payers' approvals.

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Appendix A

Institutional Review Board (IRB) approval



GRAND CANYON
UNIVERSITY™

3300 West Camelback Road, Phoenix Arizona 85017 602.639.7500 Toll Free 800.800.9776 www.gcu.edu

DATE: February 04, 2019

TO: Consolata Oronsaye
FROM: Grand Canyon University Institutional Review Board

STUDY TITLE: Assessing the Benefits and Effectiveness of Nurse-Led Self-Management Education (DSME) in the Achievement of Diabetes Management Goals Among Adults with Uncontrolled Type2 Diabetes Mellitus

IRB REFERENCE #: IRB-2019-712

SUBMISSION TYPE: Submission Response for Initial Review Submission Packet

ACTION: Determination of Exempt Status

DECISION DATE: February 04, 2019

REVIEW CATEGORY: Category 2

Thank you for your submission of New Project materials for this research study.

Grand Canyon University Institutional Review Board has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations. You now have GCU IRB approval to collect data.

If applicable, please use the approved informed consent that is included in your published documents.

We will put a copy of this correspondence on file in our office.

If you have any questions, please contact the IRB office at irb@gcu.edu or 602-639-7804. Please include your study title and reference number in all correspondence with this office.

Dr. Cynthia Bainbridge
Assistant Dean, Research and Dissertations Director, Institutional Review Board College of
Doctoral Studies

Appendix B

Diabetes Self-Management Questionnaire (DSMQ)

The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the last 8 weeks , please specify the extent to which each statement applies to you.	applies to me very much	applies to me to a considerable degree	applies to me to some degree	does not apply to me
1. I check my blood sugar levels with care and attention. <input type="checkbox"/> <i>Blood sugar measurement is not required as a part of my treatment.</i>	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
2. The food I choose to eat makes it easy to achieve optimal blood sugar levels.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
3. I keep all doctors' appointments (appointments with health professionals) recommended for my diabetes treatment.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
4. I take my diabetes medication (e. g. insulin, tablets) as prescribed. <input type="checkbox"/> <i>Diabetes medication / insulin is not required as a part of my treatment.</i>	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
5. Occasionally I eat lots of sweets or other foods rich in carbohydrates.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
6. I record my blood sugar levels regularly (or analyse the value chart with my blood glucose meter). <input type="checkbox"/> <i>Blood sugar measurement is not required as a part of my treatment.</i>	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
7. I tend to avoid diabetes-related doctors' appointments (appointments with health professionals).	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
8. I am regularly physically active to improve my diabetes treatment.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
9. I strictly follow the dietary recommendations given by my doctor or diabetes specialist.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
10. I do not check my blood sugar levels frequently enough to achieve good blood glucose control. <input type="checkbox"/> <i>Blood sugar measurement is not required as a part of my treatment.</i>	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
11. I avoid physical activity, although it could improve my diabetes.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
12. I tend to forget to take or skip my diabetes medication (e. g. insulin, tablets). <input type="checkbox"/> <i>Diabetes medication / insulin is not required as a part of my treatment.</i>	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
13. Sometimes I have real 'food binges' (not triggered by hypoglycaemia).	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0

14. Regarding my diabetes care, I should see my medical practitioner(s) more often.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
15. I am less physically active than would be optimal for my diabetes.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
16. My diabetes self-care is poor.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0

Scoring

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the scale is the mean of the eight items. If more than two items are missing, do not score the scale. Higher number indicates higher self-efficacy.

Characteristics

Tested on 186 subjects with diabetes.

No. of Items	Observed Range	Mean	Standard Deviation	Internal Consistency Reliability	Test-Retest Reliability
8	1-10	6.87	1.76	.828	NA

Source of Psychometric Data

Stanford English Diabetes Self-Management study. Study reported in Lorig K, Ritter PL, Villa FJ, Armas J. Community-Based Peer-Led Diabetes Self-Management: A Randomized Trial. The Diabetes Educator 2009; Jul-Aug;35(4):641-51.

Comments

This 8-item scale was originally developed and tested in Spanish for the Diabetes Self-Management study. For internet studies, we add radio buttons below each number. There is another way that we use to format these items, which takes up less space on a questionnaire, shown also in the PDF document. This scale is available in Spanish.

References

Unpublished.

This scale is free to use without permission

Self-Management Resource Center
 711 Colorado Avenue
 Palo Alto CA 94303
 (650) 242-8040
smrc@selfmanagementresource.com
www.selfmanagementresource.com

Appendix D

Author Permissions: Diabetes Self-Management Questionnaire (DSMQ) and AADE7 Education Materials

AW: Permission to Use Survey/Questionnaire Tool - Consolata Oro... Page 1 of 2

AW: Permission to Use Survey/Questionnaire Tool

Schmitt Andreas <schmitt@diabetes-zentrum.de>

Mon 12/10/2018 2:35 AM

To: Consolata Oronsaye <COronsaye@my.gcu.edu>;

Cc: 'Marla Nieves' <Marla.Nieves@gcu.edu>;

8 attachments (2 MB)

DSMQ English.docx; DSMQ-R English.docx; DSMQ User Information and Scoring Guide.pdf; schmitt_et_al_hqlo-2013_dsmq.pdf; schmitt_et_al_plos-one-2016_assessing_self-management.pdf; schmitt_et_al_jpr2017_depression-related_hyperglycaemia.pdf; schmitt_et_al_jdc-2018_measurement_of_psychological_adjustment_with_the_diabetes_acceptance_scale.pdf; schmitt_et_al_jdc-2018_appendix.docx;

Dear Consolata Oronsaye,

Thank you for your request and your interest in the DSMQ. You have my permission to use the scale for your valuable dissertation research. The suggested condition are agreed upon.

Attached I am sending you the DSMQ (original 16-item version) in English language together with a scoring guide. Please note that we have also developed a revised scale which, however, has not been reported in a paper yet.

I am also sending you some papers of potential interest.

Kind regards,
Andreas Schmitt

Dr. Andreas Schmitt
Clinical Psychologist, Post-doc Researcher

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AW: Permission to Use Survey/Questionnaire Tool - Consolata Oro... Page 2 of 2

Email: schmitt@diabetes-zentrum.de

Von: Consolata Oronsaye [<mailto:COronsaye@my.gcu.edu>]
Gesendet: Sonntag, 9. Dezember 2018 21:30
An: Schmitt Andreas
Cc: Marla Nieves
Betreff: Permission to Use Survey/Questionnaire Tool

Consolata Oronsaye
Grand Canyon University
College of Nursing and Healthcare Professionals
3300 West Camelback Road
Phoenix, AZ 85017

Dear Andrea Schmitt,

I am a doctoral student at the Grand Canyon University (GCU) writing my dissertation titled *Assessing the Benefits and Effectiveness of Nurse-Led Self-Management Education (DSME) in the Achievement of Diabetes Management Goals Among Adults with Uncontrolled Type2 Diabetes Mellitus*, under the direction of my dissertation committee chaired by Dr. Joyce Morrison, who can be reached at (520)-400-3391(Cell) or by email at jmorrison24829@my.gcu.edu.

I would like your permission to use the Diabetes Self-Management Questionnaire (DSMQ) survey/questionnaire instrument in my project. I would also like to use and print your survey under the following conditions:

- I will use the surveys only for my research study and will not sell or use it with any compensated or curriculum development activities.
- I will include the copyright statement on all copies of the instrument.

If these are acceptable terms and conditions, please indicate so by replying to me through e-mail: COronsaye@my.gcu.edu.

Sincerely,

Consolata Oronsaye, RN.

<https://outlook.office.com/owa/?viewmodel=ReadMessageItem&Ite...> 12/29/2018



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Consolata Oronsaye
SIGNATURE
Consolata Oronsaye, RN
PRINTED NAME and TITLE

01, 09, 2019
Date
832 641 1144
Telephone Number/Email consolata@ndtmail.co

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Margaret Maloney
Margaret Maloney, Publications Manager, AADE

01, 11, 19
Date

Appendix F

AADE7 Education Materials



AADE7™ SELF-CARE BEHAVIORS
HEALTHY EATING

If you've just learned that you have diabetes or prediabetes, you probably have a lot of questions about what you can or can't eat. Do you wonder if you can ever have your favorite food again? What happens when you are eating at a restaurant or a friend's house? Do you have to change your meal plan just because you have diabetes?

The answer is **NO**. There is nothing that you can't eat. You don't have to give up your favorite foods or stop eating at restaurants.

But, it is important to know that everything you eat has an effect on your blood sugar. Learning to eat regular meals, controlling the amount you eat, and making healthy food choices can help you manage your diabetes better and prevent other health problems.

Some skills are more complex, but your diabetes educator or dietitian can help you learn about:

- Counting carbohydrates

Word Wall

CARBOHYDRATE (AKA "CARBS"):
One of the three main types of nutrients found in food. Bread, pasta, rice, fruits, vegetables (especially starchy vegetables such as potatoes, corn, peas, dried beans), milk, and sweets are all carbs. Don't forget that carbohydrates can be found in beverages, too.

PORTION:
How much of a food you eat

MEAL PLAN:
A guide for healthy eating developed



AADE7™ SELF-CARE BEHAVIORS
BEING ACTIVE

Being active is not just about losing weight. It has many health benefits like lowering cholesterol, improving blood pressure, lowering stress and anxiety, and improving your mood. If you have diabetes, physical activity can also help keep your blood sugar levels closer to normal and help you keep your diabetes in control.

It can be difficult to find the time or the motivation to start an exercise program. Everyone's physical abilities and schedules are different; choose the best ways to fit physical activity into your daily life—whether it's walking to work, doing chair exercises or working out at the gym.

The important thing to remember is to choose activities that you enjoy doing and to set goals that are realistic.

Your healthcare provider can help you design an activity plan that works for you.

Word Wall

EXERCISE (OR PHYSICAL ACTIVITY):
Activities that get your body moving and help you stay healthy

CARDIO:
Exercise that raises your heart rate

RESISTANCE TRAINING:
Activities that help you build muscle and strength



AADE7™ SELF-CARE BEHAVIORS
MONITORING

Checking your blood sugar levels regularly gives you vital information about your diabetes control. Monitoring helps you know when your blood sugar levels are on target. It helps you make food and activity adjustments so that your body can perform at its best. It takes some time and experience to figure out how your daily activities and actions affect your blood sugar.

Your diabetes educator can help you learn:

- How to use a blood sugar (glucose) meter.
- When to check your blood sugar and what the numbers mean.
- What to do when your numbers are out of your target range.
- How to record your blood sugar results.

Checking your blood sugar is an important part of diabetes self-care, but monitoring your overall health includes a lot of other things too, especially when you have diabetes. You and your healthcare team will also need to monitor your:

- Long-term blood sugar control—A1C, eAG
- Cardiovascular health—blood pressure, weight, cholesterol levels
- Kidney health—urine and blood testing
- Eye health—dilated eye exams
- Foot health—foot exams and sensory testing

DID YOU KNOW?
The American Diabetes Association recommends an A1C target below 7% (an eAG of 154 mg/dl); the American Association of Clinical Endocrinologists recommends less than 6.5% (an eAG of 140 mg/dl).

Word Wall

METER:
A small device that is used to check blood sugar levels

LANCET:
A small needle used to get a blood sample

A1C:
A test that measures your average blood sugar levels during the past 2-3 months

ESTIMATED AVERAGE GLUCOSE (eAG):
The number of the A1C test changed into mg/dl like the blood sugar levels shown on your glucose meter

QUICK TIPS



AADE7™ SELF-CARE BEHAVIORS
TAKING MEDICATION

There are several types of medications that are often recommended for people with diabetes. Insulin, pills that lower your blood sugar, blood pressure medication, cholesterol-lowering medication, or a number of others may work together to help you lower your blood sugar levels, reduce your risk of complications and help you feel better.

Your medications come with specific instructions for use—and they can affect your body differently depending on when and how you take them. It may take a while to figure out which medicines work best with your body. So it's important for you to pay attention to how you feel and how your body reacts to each new medicine or treatment. It's up to you to tell your pharmacist, doctor, nurse practitioner, or diabetes educator if you've noticed any side effects.

It's important to know the names, doses and instructions for the medications you're taking, as well as the reasons they are recommended for you.

Word Wall

INSULIN:
A hormone that helps the body use glucose (sugar) for energy

SIDE EFFECT:
An effect that a drug has on your body that it is not intended (i.e. diarrhea, nausea, headache)



AADE7™ SELF-CARE BEHAVIORS REDUCING RISKS

Having diabetes puts you at a higher risk for developing other health problems. However, if you understand the risks, you can take steps now to lower your chance of diabetes-related complications.

Talk to your diabetes educator and healthcare provider about potential health issues such as kidney damage, nerve damage and vision loss. They can explain why complications happen and how they can be avoided.

But don't rely on your healthcare team to identify areas of concern—you need to play an active role in reducing your risk. Make an effort to learn about complications and consistently track your overall health. You can reduce your risks for several complications by taking these precautions:

- » Don't smoke.
- » Schedule regular medical checkups and medical tests.
- » See an ophthalmologist (eye doctor) at least once a year.
- » Keep your feet dry and clean. Look out for redness or sores, and report these to your healthcare team as soon as you find them. If you have trouble seeing the bottom of your feet, ask a family member or friend to help you.
- » Be sensitive to your body—recognize when you aren't feeling well, and contact your care team if you need help identifying the problem.

DID YOU KNOW?

Lowering your cholesterol can decrease your risk for stroke, heart attack or other circulation problems.

Word Wall

BLOOD PRESSURE:

The amount of pressure that is applied to your arteries when blood is pumped through your body.

CHOLESTEROL:

A waxy substance that is in your blood that exists in two types: LDL ("bad") and HDL ("good").

COMPLICATION:

Another health problem that can happen when you have diabetes.

HYPERTENSION:

When your blood pressure is higher than 140/90.

QUICK TIPS



AADE7™ SELF-CARE BEHAVIORS HEALTHY COPING

Diabetes can affect you physically and emotionally. Living with it every day can make you feel discouraged, stressed or even depressed. It is natural to have mixed feelings about your diabetes management and experience highs and lows. The important thing is to recognize these emotions as normal. Take steps to reduce the negative impact they could have on your self-care.

The way you deal with your emotional lows is called "coping." There are lots of ways to cope with the ups and downs in your life—and not all of them are good for your health (smoking, overeating, not finding time for activity, or avoiding people and social situations).

However, there are healthy coping methods that you can use to get you through tough times (faith-based activities, exercise, meditation, enjoyable hobbies, joining a support group).

Having a support network is key to healthy coping. Be sure to develop and nurture partnerships in your personal life with your spouse, loved ones and friends. Go to group educational sessions where you can meet and relate to other people going through the same experiences. Build healthy relationships—and remember that you're not alone.

Sometimes, emotional lows can be lengthy and have a more serious impact on your life, health, and relationships. This can be a sign of depression. Tell your diabetes educator if you:

- » Don't have interest or find pleasure in your activities.
- » Avoid discussing your diabetes with family and friends.
- » Sleep most of the day.
- » Don't see the benefit in taking care of yourself.
- » Feel like diabetes is conquering you.
- » Feel like you can't take care of yourself.



Did You Know?

Physical activity can influence your mood. If you are sad, anxious, stressed or upset, go for a walk, stand up and stretch, or take a bicycle ride. Exercise actually increases the chemicals in your brain that help make you feel good!

TRUE OR FALSE?

Nobody wants to hear about your problems. When you are feeling down, you should keep it to yourself.

FALSE. You need to talk about your emotions with friends, family, or your healthcare provider. Sometimes just talking about a problem will help you solve it, and loved ones can help you gain perspective.

QUICK TIPS

Recognize the power of positive thinking. When you are feeling down, think about your successes and feel good about the progress you've made toward a goal—even if it's just a little bit. Find time to do something pleasurable every day.



AADE7™ SELF-CARE BEHAVIORS PROBLEM SOLVING

What do you do when you have a problem like low blood sugar (hypoglycemia)? Do you know what caused it? How can you help reduce the risk of it happening in the future? Learn more at DiabetesEducator.org/hypo.

Everyone encounters problems with their diabetes control; you can't plan for every situation you may face. However, there are some problem-solving skills that can help you prepare for the unexpected—and make a plan for dealing with similar problems in the future.

Some of the most important problem-solving skills for diabetes self-care are learning how to recognize and react to high and low blood sugar levels, and learning how to manage on days when you are sick.

Your diabetes educator can help you develop the skills to identify situations that could upset your diabetes control.

DID YOU KNOW?

Skipping meals and snacks, taking too much diabetes medication, engaging in physical activity and drinking too much alcohol can all cause you to experience low blood sugar problems.

Word Wall

HYPOGLYCEMIA:

Low blood sugar

HYPERGLYCEMIA:

High blood sugar

GOAL SETTING:

Choosing a specific task or activity that you want to achieve and making a plan to get there

