Hypoglycemia Management in Primary Care

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Abstract

Diabetes is one of the largest global health emergencies in the 21st Century. Over 30 million individuals have been diagnosed with diabetes, and uncontrolled diabetes can lead to poor patient outcomes. One of the greatest threats to achieving tight glycemic control is hypoglycemia. Hypoglycemia is a common, and potentially preventable complication. This quasi-experimental, single-cohort quality improvement study aimed to improve clinical management of hypoglycemia over three months through time in range monitoring. Time in range monitoring is recommended by the American Diabetes Association to evaluate glycemic control. Study participants were recruited through convenience sampling with the goal of recruting10-15 adults, age 18-70 diagnosed with diabetes from an outpatient endocrinology clinic in Kansas City. Primary outcome measures included improvement in hypoglycemia monitoring, medication adherence, glycosylated hemoglobin, and low-density lipoprotein. Secondary measures were hyperglycemia, weight, and blood pressure. The standard glucose target range for time in range is 70-180 mg/dl. Patients who spend greater than 80% of time in range have fewer complications, fostering improvement in quality of life. The pre-posttest results found a reduction in weight and blood pressure. The time in range goal of 80% showed a 50% improvement. The Summary of Diabetes Self-Care activities served as a valid and reliable tool for assessing diabetes self-care behavior. The study outcomes support the use of time in range monitoring as an effective tool for evaluating hypo- and hyperglycemia management in the outpatient clinic setting.

Keywords: hypoglycemia, continuous glucose monitor (CGM), diabetes management in primary care.

Hypoglycemia Management in Primary Care

Diabetes is a chronic condition that affects millions of individuals both locally and globally (Beck, J et al., 2017; Laranjo et al., 2015; & Reyes et al., 2017). Data from the Centers for Disease Control and Prevention (CDC) showed that individuals diagnosed with diabetes (DM) have quadrupled from 5.5 to 21 million (CDC, 2018). Given the complexity of this chronic disease and associated long-term complications of stroke, heart disease, renal failure, and mortality from uncontrolled diabetes, strict glycemic control is essential. The need to maintain strict glycemic control has led to a reduction in diabetes complications. However, strict glycemic control increases the risk of hypoglycemia among patients with type 1 and type 2 diabetes (Janapala et al., 2019; Jeon et al., 2016 & Samya et al., 2019). Hypoglycemia can be defined by blood glucose level <70 mg/dl, severity of symptoms, or time of day it occurred (Morales & Schneider, 2014; Silbert et al., 2019). These findings show that primary care providers must take caution to avert repeated episodes of hypoglycemia in patients who are elderly, experience poor glycemic control, or have chronic kidney disease.

Background and Significance

Hypoglycemia is a common, potentially preventable consequence of diabetes management, but it remains a challenge for providers in primary care (Morales &Schneider, 2014; Samya et al., 2019; Silbert et al., 2019; Yeoh et al., 2015). Repeated incidence of hypoglycemia can lead to long-term health consequences that have been linked to increased cardiovascular events and mortality (Morales & Schneider, 2014; Samaya et al., 2019). Nurse practitioners in primary care are well positioned to provide early identification, management, and prevention of hypoglycemia (Kreider et al., 2017). To accomplish this goal, providers need to have access to accurate and consistent blood glucose data that obtained from either continuous

glucose monitoring (CGM) or frequent self-monitoring of blood glucose (SMBG). Time in range monitoring is a new guideline recommended by the American Diabetes Association (ADA) for assessing glycemic control (ADA; Gabbay et al., 2020; Ramchandani, 2019). Time in range is defined as the percentage of time an individual's blood glucose remains in the target range of 70-180 mg/dl for 24 hours (Lu et el., 2018: see Appendix A). Data obtained from either CGM or SMBG can easily identify patients at risk for recurrent hypo- or hyperglycemic events, but the advantage for patients with CGM over SMBG is that providers can have access to immediate glucose reading. Having these data can help providers determine appropriate treatment intervention and control for the management of diabetes (Gabbay et al., 2020).

Uncontrolled diabetes can lead to poor patient outcomes and poses a serious financial burden to the U.S. (Unites States) healthcare system (Brunisholz et al., 2014). The economic burden associated with DM management is $245 billion and is projected to reach $622.3 million by 2030, with $176 billion in direct costs, and an additional $69 billion in indirect costs (Cannon et al., 2018; Dress et al., 2016). Indirect costs include missed days from work, inability to work, and unemployment due to chronic disability (Cannon et al., 2018; Dress et al., 2016). Most diabetes healthcare expenditures are inpatient hospital stays, diabetes medications, and supplies (Dress et al., 2016). However, less than 10% of healthcare spending accounts for physician office visits (Dress et al., 2016).

The outpatient cost to manage a hypoglycemic event is estimated at $472 with a mean total cost of $1087 (Morales & Schneider, 2014). A study by Gabbay et al. (2020) concluded that a 40% reduction in hypoglycemic events could decrease healthcare costs by $6.7- $9.7 billion over 10 years. Similarly, the annual national burden to care for a patient diagnosed with diabetes who has hyperglycemia is $10,970 (Morales & Schneider, 2014). Reducing the incidences of

hypo and hyperglycemia has been shown to prevent and delay complication and decrease direct cost (Vigersky & McMahon, 2019).

Local Issues

Missouri is no exception to the major health crises related to diabetes prevalence, complications, mortality, and cost. In Missouri, 15% of adults are diagnosed with DM (Dress et al., 2016). The study took place in the metropolitan area of Kansas City, MO that serves a large African American community. In the Kansas City area, several certified diabetes prevention programs (DPP) are available throughout the Metropolitan area to assist individuals with diabetes management (Dress et al., 2016).

Diversity Considerations

Most patients at the clinic site for the project reside in the geographic location of the clinic, most notably the metropolitan area of Kansas City. Missouri and nationwide, diabetes affects more men than women and more African American and Hispanic than Caucasian (United Health Foundation, 2020). In the state of MO, 13.3% of males and 9.8% of females diagnosed with DM are ages 45-64, and a higher prevalence is seen over age 65 (United Health Foundation, 2020). In Missouri, African Americans account for 14% of the population diagnosed with DM, Hispanic 16.6 %, and Caucasian 10.8% (United Health Foundation, 2020). The rate of individuals affected with DM who have less than a high school education was higher in comparison to individuals who graduated from high school, had some college, or were a college graduate. Individuals with income levels below $2500 were most affected, compared to individuals making over $75,000 annually (United Health Foundation, 2020).

Problem and Inquiry

The mortality rate associated with diabetes is due in part to complications from diabetes. One of the most common complications that poses a challenge in primary care is hypoglycemic management among patients with type 1 and type 2 diabetes. Hypoglycemia management is costly and poses a serious financial burden to our health care system. The high prevalence of diabetes management is estimated at $245 billion annually (Powers et al., 2016). Complications from diabetes increase healthcare costs. The most effective management for addressing this public health priority and decreasing the costly financial burden it poses to healthcare is to improve identification, management, and prevention of hypoglycemia in primary care through TIR monitoring.

Purpose Statement

The primary purpose is to implement TIR monitoring over three months in an outpatient clinic to improve hypoglycemic monitoring, medication adherence, glycosylated hemoglobin (A1c), and low-density lipoprotein (LDL) in adult patients with diabetes. The secondary outcomes include improvement in hyperglycemia, weight, and blood pressure (BP).

Intended Improvement with Purpose

Recurrent episodes of hypoglycemia can lead to long-term disability such as memory impairment and early onset dementia, to seizure, coma, and blindness (Clayton et al., 2013; Morales & Schneider, 2014; Tenzer-Iglesias et al., 2012). With diabetes being the 7th leading cause of death in the U.S (CDC, 2019; Reyes et al., 2017) and the triggers identified above, healthcare providers should work with policymakers to develop guidelines that can improve hypoglycemia management in primary care. Most healthcare expenditures that are spent on diabetes management are spent on inpatient admissions and ED visits, compared to outpatient

physician visits (Clayton et al., 2013; Morales & Schneider, 2014; Reyes et al, 2017). A call for change to diabetes management in primary care could lead to a decrease in healthcare cost.

Facilitators and Barriers

Facilitators are clinic staff, administration, and the endocrinologist. A major facilitator in the management of DM is communication among patients and providers. Potential barriers to the study were time constraints, inability to obtain A1c and LDL every three months, and patient resistance to participate in a DNP study. Other barriers include stress from patients trying to maintain TIR, resistance to frequent BG monitoring before each meal and at bedtime, health literacy, and socioeconomic status. Clinical inertia is a major barrier to the use of CGM. The introduction of new technology into clinical practice requires initiative, awareness of benefit, and effort to integrate use into a potentially busy workflow (Shrivastav et al., 2018). The project leader funded the study through personal financing.

Barriers that might impact sustainability of the study included difficulty changing well-established habits, negative perceptions of a new regimen, and lack of motivation (Laranjo et al., 2015). Factors that can sustain the study are staff readiness to implement a standardized hypoglycemia protocol into daily clinic practice that aligns with recommendations from the ADA. Staff receptiveness to identifying hypoglycemic risk factors, episodes, and severity also increases the sustainability of glycemic management in the primary care clinic. A study by Samya et al. (2019) noted that in 10% of individuals who experience a severe hypoglycemic event, only a fifth report symptoms to their primary care provider.

Review of the Evidence

Inquiry

The study inquiry is, in adults with diabetes, does TIR monitoring improve hypoglycemic management in primary care in three months at an outpatient endocrinology clinic?

Search Strategies

A comprehensive literature search of CINAHL, EBSCOhost, Google Scholar, and PubMed was used to gather relevant information on hypoglycemia management in primary care. Keywords included hypoglycemia, diabetes management in primary care, and TIR. The research results were used to examine interventions aimed at integrating TIR into clinical practice to improve hypoglycemia management in patient with type 1 and type 2 diabetes. The search results support current evidence on the importance of hypoglycemia prevention in primary care. The literature search yielded 337 articles, and 42 were chosen because they reflect findings applicable to the inquiry (see Appendix C). An evidence table was used to rate the level of evidence from high to low (Melynk & Fineout-Overhold, 2019). The level of evidence for the 42 articles included nine-level I systematic review of randomized control trials, one-level II randomized control trial, seven-level III quasi-experimental study, 12-level IV non-experimental study, two-level V descriptive and qualitative, systematic review, and 11-level VII expert opinion (see Appendix D; and Appendix E).

Articles met inclusion criteria if the study included hypoglycemia, hyperglycemia, TIR, CGM, diabetes management in primary care, A1c, and written in English within 10 years. Articles were excluded if they included pediatric patients, gestational diabetes, or not written in English. Four major themes of evidence were derived from the review of literature:

hypoglycemia management in primary care, TIR and A1c, TIR and CGM, and hypoglycemia and antihyperglycemics.

Synthesis of Evidence

Diabetes is one of the largest global health emergencies in the 21st Century (Ansari et al., 2016; Damayanti et al., 2018; Hildebrand, et al., 2019; Mohebi et al., 2018)**.** It is estimated that over 30 million people in the U.S. have been diagnosed with diabetes (Beck. J et al., 2017; CDC, 2019; Reyes et al., 2017). Inadequate treatment of diabetes can lead to serious complications and increase one's risk for mortality in the setting of poor glycemic control and severe hypoglycemia (He et al., 2019; Reyes et al., 2017). After review of the literature on the benefits associated with TIR monitoring on improving diabetes management in primary care, four themes were identified in the synthesis of the evidence.

Hypoglycemia Management in Primary Care

Hypoglycemia management is complex and both patients with type 1 and Type 2 diabetes are affected by low blood glucose. A BG <70 is considered a hypoglycemia alert, <54 clinically significant, and severe hypoglycemia is when an individual requires the assistance of another person (Clayton et al., 2013; Jeon et al., 2016; Samya et al., 2019; Tenzer-Iglesias et al., 2012). A study by Cryer. (2015) showed that 30% to 40% of patients with type 1diabetes experience at least one to three episodes of severe hypoglycemia annually, while those with type 2 diabetes who are taking insulin experience about one-third that number. Similarly, Cryer (2015) showed that the rate of any type of hypoglycemia is 50-fold higher than those of severe hypoglycemia in both types of diabetes. The first symptom of hypoglycemia reported by patients was dizziness followed by diaphoresis, but repeated episodes of hypoglycemia can blunt this effect (Samya et

al., 2019). Additionally, 89.3% of patients who developed hypoglycemia did so because of missed meals (Samya et al., 2019).

Significant risk of hypoglycemia will require providers to change management approach and employ less stringent BG strategies on patients at increased risk for recurrent episodes. The ADA recommends that strict glycemic control should be avoided in the elderly population (Tenzer-Iglesias et al., 2012). To minimize the risk of hypoglycemic complications from seizure, coma, or life-long neurocognitive impairment, providers should individualize treatment regimens (Clayton et al., 2013; Morales & Schneider, 2014; Samya et al., 2019). Most patients who experience one or more episodes of hypoglycemia live in fear of future glycemic episodes (Samya et al., 2019). Such fear complicates the management of hypoglycemia among patients and their providers as patients are reluctant to report hypoglycemic events for fear of retribution of losing driving privileges (Samya et al., 2019; Silbert et al., 2019). The primary care provider has a duty to maintain patient safety, and although the loss of driving privileges may prevent patients from reporting hypoglycemic events, hypoglycemia is dangerous and can occur while a patient is driving or operating machinery.

Hypoglycemia management poses a significant burden to our healthcare system from the increased use of emergency services, hospitalization, and outpatient management. The current literature review estimated that 245 thousand ED visits were due to hypoglycemia (Silbert et al., 2014). A study by Silbert et al. (2014) found that between 2007 and 2009 that insulin and oral glucose-lowering medication resulted in nearly 10.7% to 14% of emergent hospitalization for patients over 65. Providers in primary care should work collectively with patients to avoid use of emergent hospitalizations as this increase’s healthcare costs. The financial impact of hypoglycemic management places significant burden on our healthcare system (Silbert et al.,

2014; Morales & Schneider, 2014; Samya et al., 2019). A study by Morales and Schneider (2014) concluded that healthcare finances were impacted by lost productivity from work and was estimated at $15.26 to $93.47 for each episode. This calculation represents 8.3 to 15.9 hours of lost work per month with monthly out of pocket costs for test strips and lancets at $17.23. It may take half a day to one day to return to normal functioning, but such impact does not account for the lifelong financial cost in curd by patients for treatment associated with permanent neurologic damage from hypoglycemia (Jeon et al., 2016). The first step in preventing hypoglycemia in primary care is the identification of modifiable risk factors (Rodriguez-Gutierrez et al., 2020). All patients at risk for hypoglycemia should be screened for risk factors such as prior episodes of hypoglycemia, duration of insulin therapy, length of time as a diabetic, alcohol abuse, socioeconomic status, food insecurity, and health literacy (Clay et al.,2013). Early identification of risk factors and symptom management can improve hypoglycemia management and a patient's quality of life (QOL).

Time in Range and A1c

The effectiveness of diabetes education on improving glycemic control, medication adherence, A1c, LDL, and healthcare costs have been well established by numerous clinical trials (Brunisholz et al., 2014; Mikhael et al., 2020; Zheng et al., 2019). The hemoglobin A1c is an endocrine test that gives an indirect average on the blood glucose concentration over a prior three months (see Appendix A). Although A1c remains the gold standard for determining glycemic control, providers in primary should follow current ADA guidelines for the use of TIR monitoring. Time in range monitoring was validated as an outcome measure for effectively assessing direct glycemic control (Gabbay et al., 2020). A strong correlation between A1c and

TIR exits that may permit transition to TIR as a preferred metric for determining risk of diabetes complications in assessing glycemic control (Vigersky & McMahon, 2019).

Multiple systematic reviews documented that A1c results might not be a reliable indicator of glycemic control and the results can be influenced by several conditions that affect the survival of red blood cells including anemia, sickle cell disease, smoking, ethnicity, and chronic kidney disease (Gabbay et al., 2020; Beck, R et al., 2019; Lanspa et al., 2019; Mayeda et al., 2019; Ramchandani, 2019; Vigersky & McMahon, 2019). A study by Pamungkas et al. (2017) concluded that an A1c level greater than 7% is stilled considered uncontrolled diabetes but lowering of A1c < 6.0 might contribute to hypoglycemia in certain populations (Pamungkas et al., 2017). Having 80% TIR correlates to an A1c of 7% and for every 10% change in TIR, there is a 0.5%-0.8% change in A1c level (Gabbay et al., 2020). When one considers that a 1% decline in A1c correlated to a15% reduction in cardiovascular risk, then this small change can translate to clinically significant risk reduction for patients (Brunisholz et al., 2014).

Time-in-range monitoring offers patients and providers real-time and accurate BG readings to improve hypoglycemic management in primary care. Based on TIR monitoring, hypoglycemic is expressed as a blood glucose <70 and hyperglycemia as >180. Time spent within the target range of 70- 180 mg/dl was strongly supported by evidence as promoting better diabetes management. According to Ramchandani. (2019), a critical aspect of TIR is that it gives patients the opportunity to improve diabetes management as it provides target results that are understandable and actionable. Based on a retrospective study by Gabbay et al. (2020), the set standard target range for TIR is 70-180 mg/dl, something an A1c level is unable to show, but knowing both A1c and TIR is valuable for optimal diabetes management. Study results from

Gabbay et al. (2020) and Ramchandani (2019) showed that timing is essential, and patients who spend 80% of their TIR can see a 40% reduction in hypoglycemic events.

Time in Range and Continuous Glucose Monitoring

Data for TIR monitoring should be obtained from CGM as it allows providers to have access to immediate glucose readings. The ADA, in June 2019, gave its first recommendation for TIR monitoring (Ramchandani, 2019). Several studies have concluded that CGM is the best approach to identifying a patient's current glycemic control (Beck.R, et al., 2019; Lanspa et al., 2019; Mayeda et al., 2019; Ramchandani, 2019; Vigersky & McMahon, 2019). The main benefit of CGM is seen in high-risk patients with recurrent or severe hypoglycemia, hypoglycemia unawareness, and nocturnal hypoglycemia (Gabbay et al., 2020). Conversely, although SMBG provides a single point in time blood glucose reading and does not allow for real-time CGM, it is still widely used and recommended as a valuable component of patient self-care practice. Self-monitoring of blood glucose has helped patients since the 1990s assess their response to therapy and allow for assessment of glycemic targets (Jeon et al., 2016).

Continuous glucose monitoring allows for direct and accurate presentation of a patient's blood glucose in real time compared to an average A1c taken over three months (Jeon et al., 2018; Shrivastav et al., 2018). Data from CGM and SMBG can aid in the identification and management of hypoglycemia in primary care. Both tools can be used to guide treatment action concerning changes in diet, exercise, and appropriate use of antihyperglycemic medications (Jeon 2016). A study by Yeoh et al. (2015) found that impaired awareness occurs in 1/3 of patients with type 1 diabetes, thus placing them at a six-fold risk for severe hypoglycemia. Continuous glucose monitoring has effectively detected hypoglycemia in patients with type 1 and type 2 diabetes (Shrivastav et al, 2018). A CGM should be considered for patients at

increased risk for nocturnal hypoglycemia as it would be beneficial to alert the patient. However, despite the benefits of CGM in hypoglycemic management, its use is limited secondary to cost.

Hypoglycemia and Antihyperglycemics

Patients taking oral agents, insulin therapy, or both face an increased risk of hypoglycemia (Samya et al., 2019). Drug-induced hypoglycemia poses a major risk for patients and providers attempting to achieve strict glycemic control. Strict glycemic control has led to a threefold increase risk of hypoglycemia and providers should take caution when selecting these medications (Samya et al., 2019). Current studies concluded that hypoglycemic events occur frequently in patients receiving either insulin or a sulfonylurea, but more frequently in 90% of patients treated with a combination of insulin or sulfonylurea (Cryer, 2015; Jeon et al.,2016: Samya et al., 2019). Other studies also showed that the incidences of severe hypoglycemia were consistently higher among patients on insulin therapy compared to treatment with oral medications alone (Jeon et al., 2016, Silbert et al., 2019).

A cross-sectional study by Silbert et al. (2019) found that iatrogenic hypoglycemia is one of the most common adverse drug events requiring emergency department visits or hospitalizations. Silbert at al. (2019) reported data from the CDC that showed more than 245,000 ED visits for hypoglycemia in 2014. Severe hypoglycemia is serious and can lead to permanent cognitive impairment in both young and older adults. Older adults with cognitive impairment secondary to hypoglycemia are at increased risk for dementia (Morales & Schneider, 2014; Tenzer-Iglesias et al., 2012; Clayton et al., 2013). Apart from cognitive impairment, patients who experience hypoglycemic complications are also at risk for increased morbidity and mortality. It is estimated that 4%-10% of deaths from type 1 diabetes was associated with hypoglycemic

events (Morales & Schneider, 2014). Morales and Schneider. (2014) also concluded that the mortality rate among patients reporting severe hypoglycemia was 19.5%, compared with 9% for those without severe hypoglycemia, and this risk remains substantial for four years following a severe hypoglycemic episode. Tenzer-Iglesias et al. (2012) found that the annual cost of hypoglycemia associated with the use of insulin was estimated at $620 to $1500.

Evidence Summary and Discussion

The management of diabetes is life-long and requires ongoing lifestyle changes. The total estimated cost to treat diabetes is expected to rise from $245 billion to $327 billion (ADA, 2020). Preventing hypoglycemia is a priority in primary care management. Efforts to prevent hypoglycemia depend on the providers' ability to recognize at-risk patients and identify potential precipitating and contributing factors (Rodriguez-Gutierrez et al., 2020). Simple lifestyle changes such as diet, increased physical activity, and regular glucose monitoring can prevent and delay the onset of complications from diabetes (Powers et al., 2016; Weller et al., 2017). While some practice guideline recommends raising the glycemic target for a patient at higher risk for hypoglycemia; Silbert et al. (2019) emphasized that this strategy alone might not be sufficient. He believed that a more effective approach is to de-escalate treatment regimens for those being over treated, especially older adults and patient with adverse kidney disease and dementia. Due to the multiple mobility and life expectancy of these patient, they face increased risk of hypoglycemic events and are less likely to benefit from intensive glycemic control.

The de-escalation of glucose lowering therapy, simplification of treatment regimens, and preferential use of medication that has lower rates for hyperglycemia may essentially help to decrease the risk of hypoglycemia among these patients (Silbert et al., 2019). To reduce the risk of hypoglycemia, effective patient self-management is essential. Diabetes care should be patient-

centered and include a multidisciplinary approach. Collaboration among patients and providers is vital to developing an acceptable individualized treatment plan. There should be clear communication and effective collaboration among the patient and the health care team. Communication should include progression towards set goals and the use of appropriate interventions (Powers et al., 2016). The plan should include education on hypoglycemic awareness and treatment recommendations to reduce the incidence of hypoglycemic episodes.

Gaps

The literature results show insufficient time available for primary care providers to develop strategies to identify patients at risk for hypoglycemia (Rodriguez-Gutierrez et al., 2020). Patients taking hypoglycemia-prone mediations were screened for hypoglycemia in primary care 38.2% of the time and 69.2% of the time during an endocrinologist encounter (Rodriguez-Gutierrez et al., 2020). Providers in primary care de-escalate treatment by 30.4% compared to an endocrinologist at 46% (Rodriguez-Gutierrez et al 2020). Screening for hypoglycemia was less prevalent during primary care than care provided by an endocrinologist (Rodriguez-Gutierrez et al., 2020). According to Rodriguez-Gutierrez et al. (2020), this is due to a lack of specific diabetes training among primary care providers compared to an endocrinologist.

Successful management of diabetes is highly dependent on the patient’s intention to change, but literature shows there are gaps in assessing a patient's readiness and motivation to change (Karimy et al., 2018; Powers et al., 2016). Treatment plans for patients with diabetes fail to consider the patient's physiological, behavioral, psychological, cultural, and social-environmental realities (Strychar et al., 2012). Given the demands of a busy primary care

practice, it is often difficult for providers to address these issues due to time constraints during office visits.

Limitations

Diabetes management is complex and demanding. Individual behavior change remains a challenge for many patients with diabetes (Zheng et al., 2019). Disparities in diabetes risk show that minority populations are more likely to be affected by diabetes (Gucciardi et al., 2013). Racial and ethnic minorities disproportionately face barriers to diabetes related changes including a safe place for physical activity, diabetes education, and self-management resources (Gucciardi et al., 2013; Healthy People 2020, 2018). Minority groups constitute 25% of all adults with diabetes in the United States (CDC, 2019). African Americans, Hispanic/Latino Americans, and Asian Americans are at greater risk for developing diabetes (Gucciardi et al., 2013; Healthy People 2020, 2018, Hildebrand et al., 2020). The dynamic nature of adding literacy-sensitive material to diabetes management programs may improve knowledge, self-efficacy, and A1c outcomes for people with low health literacy.

Theory

The theory of planned behavior (TPB) is the primary theoretical framework used for the evidence-based study. The TPB is supported by empirical evidence and is widely used for predicting past and present intentions for behavior change (Ajzen 2011; Armitage et al., 2010). The TIR monitoring for identifying strict glycemic control for this study aligned with the main concepts of TPB: intention, attitude, subjective norms, and perceived behavior control (Damayanti et al., 2018; see Appendix F). The intervention aimed to decrease the incidences of hypoglycemia and assess the patient's ability to perform diabetes self-care activities with regards

to attitude and perceived behavioral control. The conceptual framework, rationale for use, and application to the TPB were used to analyze the effectiveness of TIR and the SDSCA.

The main reason for the popularity of the TPB is the predictive validity compared to other models on health-related behaviors. The leading concept of the TPB model is intention (Armitage al., 2010). A patient's intentional behavior towards participation in a new concept of diabetes management will predict a patient's past or present intentions to adherence to blood glucose monitoring, medication use, diet, and physical activity. With diabetes being a lifelong chronic disease that requires individuals to make frequent lifestyle changes, the success of these changes depends on behavior change that can be assessed using the theory of planned behavior. A study by Damayanti et al. (2018) concluded that education level and intention together influence the self-management of patients with diabetes, which supports all constructs of the TPB. The TPB can help providers improve diabetes management among patients with diabetes.

Methods

IRB and Site Approval

The study took place at an endocrinology clinic in Kansas City, and the primary institutional review board (IRB) was the University of Missouri Kansas City (UMKC). The study aimed to improve hypoglycemic management in primary care, and the study was determined to be Non-Human Subject Research, quality improvement (see Appendix N).

Ethical Issues

Ethical considerations for all participants include race, age, and gender. Adult participants who met inclusion criteria for the study were informed of the purpose and process of the study. Participants signed an informational letter acknowledging their willingness to participate (see Appendix O). The autonomy of each patient was upheld during the study period.

Patient privacy and confidentiality were maintained under the Health Insurance Portability and Accountability Act (HIPAA) privacy rules and the patient privacy policy at the clinical site. Participants were informed that their participation is strictly voluntary and that they have the right to terminate their commitment at any time during the study without any negative consequences. Although there are significant ethnic disparities among patients diagnosed with diabetes, the project leader anticipates the study intervention can be transferable to any ethnic group.

Funding

The study focussed on the management of hypoglycemia in primary care. The study was funded through personal financing of the project leader and included the cost to cover supplies, recruitment flyers, and participant stipend (See Appendix B).

Settings and Participants

The site for the proposed evidence-based study was an outpatient endocrinology clinic located in the Metropolitan area of Kansas City. Adult patients age 18-70 diagnosed with type 1 and type 2 diabetes were recruited through convenience sampling with a projected sample size of 10-15. The project leader assumed that staff at the endocrinology clinic are familiar with managing patients with diabetes and the importance of implementing the use of TIR to improve glycemic control. Participants met inclusion criteria if they are an adult, diagnosed with diabetes, have an A1c level between 8 and 14, and an LDL level over 100. Participants were excluded if they are pediatric, pregnant, or do not speak English. The interventions were aimed at patients improving their self-care behavior towards successful hypoglycemic management.

Evidence-Based Intervention

The evidence-based intervention used TIR monitoring to evaluate glycemic control. Time in range monitoring is defined as a new metric that measures the amount of time a patient's blood glucose is in the target range of 70-180mg/dl (see Appendix A). This self-management study sought to evaluate TIR monitoring on improving hypoglycemia, medication compliance, hyperglycemia, A1c, LDL, BP, and weight in patients with diabetes. The intervention consisted of written and verbal communication of content, review of glucose diary, medical chart, medication use, and clinical parameters (see Appendix I). Clinical parameter included A1c, LDL, weight, and blood pressure (see Appendix A). The intervention included increasing the use of TIR monitoring in the clinic. The intervention consisted of an initial 8-minute clinic visit. After the initial visit, weekly phone calls were completed by the project leader.

Recruitment

Participants were recruited from an endocrinology clinic. Participants diagnosed with type 1 and type 2 diabetes were recruited through convenience sampling, starting in September 2020. Recruitment flyers were placed in each patient's intake room (see Appendix J).

Assessment and Intervention Protocol

Implementation of the study began October 2020 and included the completion of a baseline questionnaire using the Summary of Diabetes Self-Care Activities assessment (SDSCA) tool (see Appendix H). The Summary of Diabetes Self-Care Activities is a brief self-reported questionnaire that assesses behaviors such as diet, exercise, blood glucose testing, foot care, and smoking (Mohebi et al., 2018; see Appendix A). Baseline demographics obtained were age, gender, and race. During the initial 8-minute visit, the project leader provided written and verbal

education to patients on the importance of TIR monitoring, taking medications as prescribed, following the recommended diet, and reporting hypoglycemic events.

Participants were given a glucose log to record their blood glucose. Participants who did not have a CGM were asked to obtain BG before each meal and at bedtime. Participants recorded their weight and BP biweekly, medication administration daily, and blood glucose four times daily on the provided data spreadsheet. If medications were missed, patients would provide a reason code as indicated on the spreadsheet. Compliance with antihyperglycemics was assessed, and reminders were provided initially and during follow up phone calls. The project leader discussed risk factors and episodes of hypoglycemia. Clinical parameters and the glucose diary were reviewed at the initial visit (see Appendix I).

The project leader monitored TIR data with attention to episodes of hypo- and hyperglycemia. Clinical parameters were tracked over three months. There were weekly follow-up phone calls by the project leader to assess compliance, answer questions, and provide encouragement to participants. The project leader reviewed the patient's electronic medical records (EMR) for clinical parameters before the initial visit to determine the need for further testing of A1c and LDL. Baseline clinical parameters were recorded, and trends were monitored during the study.

Current literature from the ADA supports the use of TIR for patients with diabetes. A step-by-step hypoglycemia action plan and a wallet-size version were provided to participants to enhance hypoglycemic awareness. Goal setting was revised with each participant at the initial visit. Specific goals included education on the identification of symptoms and risk factors for hypoglycemia, 30 minutes of physical activity at least three times a week, consuming 60grams or less of carbohydrate per meal, monitoring blood glucose, and taking prescribed medication. Goal

range for A1c, LDL, and blood pressure were discussed along with frequency to be obtained. Clinical parameters were assessed as indicated with follow-up revision at 12 weeks. The project leader completed a pretest and posttest data collection at 12 weeks (see Appendix I).

Change Process and EBP Model

The project leader utilized Kotter and Cohen's Model of Change. The model was chosen because it offers an easy-to-use step-by-step process for implementing change in many health care organizations (Kotter & Cohen, 2014). Kotter and Cohen's eight-step process for change aligns well with TIR monitoring and the self-care behavior of patients in managing their diabetes. Kotter and Cohen’s change model can be used to empower individuals to change their behaviors. Self-care practices among patients with diabetes are core components of diabetes care and require a high level of individual responsibility (Kamradt et al., 2014). Consistent self-care behaviors have been shown to improve patient outcomes and reduced long-term complications of hypo and hyperglycemia.

For an evidence-based practice model, the ACE Star Model of Knowledge Transformation was utilized for this study. The model uses a systematic approach for change at the individual and organizational levels (Stevens, 2013). The ACE star model focuses on knowledge transformation using the following five stages of action: knowledge discovery, evidence summary, translation into practice recommendations, integration into practice, and evaluation of outcomes (Stevens, 2013). Based on the literature review, the ACE Star Model and Kotter and Cohen's model for change have shown that the use of TIR monitoring can be successfully implemented and sustained in the outpatient clinic if providers and clinic staff are willing to accept the change. Regardless of the setting, clear communication and effective

collaboration among the healthcare team is essential to ensuring goals are clear, progress towards goals is being made, and appropriate interventions are being used (Powers et al., 2016).

Study Design

To support the inquiry of TIR monitoring in patients with diabetes, a quasi-experimental, single-cohort design with pretest-posttest was used to evaluate improvements in patient outcomes. The study identified the benefits of specific interventions, including TIR monitoring on improving hypoglycemic episodes, medication adherence, A1c, and LDL.

Validity

The study utilized the Summary of Diabetes Self-Care Activities. The SDSCA is one of the most valid, reliable, and widely used tools for assessing diabetes self-management (Kamradt et al., 2014). Potential threats to internal validity included selection bias, pre and posttest questionnaire, and attrition. Internal validity of the study was enhanced with the use of the SDSCA questionnaire. The potential threats to external validity include a small sample size, clinic setting, and timing that might not allow for similar findings beyond the study population. The study intervention can be transferred and achieved in similar outpatient clinics if the facility is willing to adopt and follow ADA recommendations for the use of TIR.

Outcomes and Measurement Instruments

The ADA allows for the adaptation of TIR monitoring for use in diabetes patients in any clinic setting. One of the major outcome measures for managing hypoglycemia in primary care is prevention. Prevention of hypoglycemia starts with the early identification of symptoms and risk factors that predispose patients to hypoglycemia. Early treatment of hypoglycemic events could contribute to improvement in hypoglycemia management. The primary outcome measures for the

study included improvement in identifying episodes of hypoglycemia, medication adherence, A1c <7.0, and LDL <100 over three months (see Appendix G).

Secondary outcome measures included hyperglycemia, weight, and BP <130/80.

Summary of Diabetes Self-Care Activities

The study utilized the SDSCA measurement tool (see Appendix G). The SDSCA is easy to use and is supported by current literature as a valid questionnaire (Kamradt et al., 2014). The reliability of the SDSCA questionnaire was measured using pre-test-posttest. The SDSCA is a questionnaire used to assess five variables of diabetes self-care activities: diet, blood glucose testing, foot care, and smoking status and is measured using the number of days per week on a scale of 0-7 excepts for question 11. Permission was obtained for use from the author (Tolbert et al., 2000). The SDSCA can be used in conjunction with the TPB to predict self-care behaviors among patients with diabetes. The SDSCA tool should take 3-5 minutes to complete on paper.

Quality of Data

The SDSCA tool is frequently used by researchers to evaluate a patient's intention to participate in diabetes self-care management. Participants were asked to complete the SDSCA questionnaires pre- and post-intervention. An a priori power analysis, using G* Power with an alpha of .05, power of .8, medium effect of 0.5, and Wilcoxon Signed-rank test, calculated a sample size of 28 participants (Faul et al., 2007).

Analysis

Descriptive statistics was used to analyze the effects of the educational intervention on patient outcomes in a single-group with a small sample size. The SDSCA generated total scores based on the number of items on each questionnaire (see Appendix L). The self-administered survey was given to each participant to acquire baseline self-care behaviors.

Results

Setting and Participants

The evidence-based project was implemented from September 2020 through April 2021 at an outpatient endocrinology clinic in Kansas City. A total of 16 participants enrolled in the study, but only four participants completed the study. The study included three females and one male, ranging in age from 40-60 years old. Each was a high school graduate who met inclusion criteria for diabetes management in the study.

Intervention Course, actual

Participants were recruited through convenience sampling. Due to the COVID 19 pandemic, the time frame for the study was adjusted from six month to three months in duration. Each participant was approached separately for their consent to participate in the self-management study. All study participants gave their consent to participate and completed the preintervention SDSCA survey. In consideration of time constraints in the clinic, participants were asked to complete their survey at home. The initial clinic visit lasted 8 minutes. Participants were given a folder containing the SDSCA survey and blood glucose, weight, and blood pressure logs. Additionally, they were given a wallet sized hypoglycemia treatment card that displayed a step-by-step action plan that was reviewed with each participant. The website for the step-by-step action plan was also made available to the participants. Participants were directed to monitor their blood glucose before each meal and at bedtime, check weight and blood pressure biweekly, and take their prescribed medications.

Initially, each participant received weekly phone calls to answer questions and support self-care management of their diabetes. The frequency of phone calls was adjusted based on the return of phone calls when messages were left, and until the participants returned the call. The

step-by-step action plan web site could be assessed using any personal electronic items such as a smart phone, tablet, or computer. Following completion of the study, arrangements were made for folder pickup of the participants recorded information, and each participant was asked to complete the postintervention SDSCA survey. A major component of the interventions was the use of the SDSCA survey pre- and post-intervention. The survey help determined self-care activities. All surveys and forms completed by the participants were in hand-written format, kept confidential, and void of identifiers. The data analysis was conducted by the project leader.

Outcome Data

At study completion, the data was analyzed using descriptive statistic. The major outcome variables for the study were TIR, SDSCA, BP, weight, LDL and A1c (see Appendix L)**.** The survey consisted of six variables that were pertinent to diabetes management. The two major outcomes for the study were TIR and SDSCA. Time in range monitoring was used to evaluate glycemic control. Blood glucose trends were evaluated for both hypo and hyperglycemia. Participant were expected to have their blood glucose levels fall within the set target range of 70-180mg/dl in 24hrs, as this would depict actual glycemic control over the average A1c results taken over three months.

Time in Range, Hypoglycemia

The data analysis for TIR showed improvement from pre to post intervention. Data results showed a 50% improvement in post BG within the target range of 70-180mg/dl. Three of the four participants showed 100% participation in monitoring their blood glucose as directed. The descriptive data for both blood pressure and weight also showed postintervention blood pressure improvement among three of the four participants ranging from 3-6mmhg. Post

intervention data for weight also showed improvement in three out of the four participants ranging from 2-5lbs.

In preintervention data, one of the four participants recorded over 29 episodes of significant hypoglycemic episodes. With TIR monitoring and working with the endocrinologist at the clinic, the participant's postintervention data showed less than 15 hypoglycemic episodes. This participant had an A1c score of 10. The other three participants recorded stable but elevated BG over 180mg/dl with an average pre A1c of 8.7. Participants with lower A1c scores had higher but consistent BG readings over the target range of 180mg/dl.

Summary of Diabetes Self-Care Activities

The SDSCA data showed improvement in self-care activities for blood glucose monitoring from pre to post intervention. The SDSCA post intervention showed three of the four participants consistently monitored their BG as directed. Due to the shortened time frame of the study, post intervention data for A1c and LDL levels were not obtained.

Discussion

Success

The study results showed multiple successes for this single cohort pre- posttest study. All four participants completed the intervention which showed small but noticeable changes in blood pressure, weight, blood glucose monitoring, and medication adherence that could be investigated in larger research studies. The findings showed 100% adherence in medication compliance. Other major components of the study were seen with the SDSCA data results and the impact on evaluating self-care activities among patients with diabetes. Glycemic control can best be achieved with TR monitoring as it allows for direct and real time monitoring of BG. These

findings support the use of TR as an essential tool for assessing true glycemic control. Given the small sample size, the validity of the finding is threatened.

There were no post data to evaluate a trend in LDL and A1c, but the pre-data was valuable and showed the importance of TIR over A1c in predicting glycemic control. The trend in the data analysis showed that some participants who had lower blood glucose level shad higher A1c scores and conversely. This confirms that an A1c score is not a true representation of glycemic control. With additional time for the study, it would have been valuable to obtain the post A1c for a comparison to the pre A1c. The data was threatened as these labs are normally obtained every six months or annually, and the study lasted three months. Study participants were unfamiliar with TIR, but most had used a blood glucose diary or log in the past and knew how to utilize one to monitor trends in their blood glucose.

Study Strengths

The study site administration, endocrinologist, and medical assistant were engaged and resourceful throughout the planning and implementation phase of the study. The medical assistant would greet the patient and then inquire about their willingness to participate in the study. Once acceptance to participate in the study was agreed upon, time was provided to visit with each participant prior to them seeing the endocrinologist. Participants who showed interest were introduced to the project leader who then provided a brief narrative of the study expectations and time-line. As soon as participation was acknowledged, informed consent was obtained. Each signed consent was then given to the administrative staff to upload into the participants electronic health record (EHR). The medical assistant was knowledgeable and had experience caring for patients with diabetes. Support for participation was also encouraged by the endocrinologist. Flow of the study was successful in terms of response to participates, but

only four of the 16 participants recruited completed the study over three months. Post intervention visits were completed on December 31st.

The most challenging aspect of the study intervention was development of the step-by-step hypoglycemia wallet size card. Determining the size, color, and essential content was challenging. Since three of the four participants did not experience severe hypoglycemic events, it was difficult to determine if they found this helpful. Time to conduct the study over funding was most important, and funding was done through personal financing.

Results Compared to Evidence in the Literature

Results from the evidence-based study support current literature on the importance of TIR. In 2019, the ADA published its first recommendation for the use of TIR monitoring in the management of diabetes. The recommendation was designed to be used by clinicians to guide and interpret data in routine diabetes care (Ramchandani, 2019.) A study conducted at Shanghai University shows that TIR is the preferred way of measuring glycemic control as it provides useful information not captured by an A1c score (Lu et al., 2018). The Brazillian Diabetes Society is seeking to demand a request that would make TIR monitoring a national practice (Gabbay et al., 2020). This expectation is evident in this current study of nurse-led intervention. Other studies also concluded that research evidence supports the use and effectiveness of TIR monitoring (Gabbay et al, 2020; Janapala et al., 2019; Ramchandani, 2019) on improving hypoglycemia, A1c, and medication adherence. The current study results showed meaningful use for TIR monitoring.

Limitations

Internal and External Validity Effects

Both internal and external validity limitations played an important role throughout planning and implement in the study. Limitations associated with internal validity include use of a single-cohort study and lack of a control group. The use of convenience sampling warrants the possibility of selection biases. Selection bias was possible during participants self-selection and project leader involvement in planning, implementation, and interaction with study participants. Limitations to external validity included a small sample size. Implementing the study at a single clinic site also affected the external validity of the study. Although continuous glucose monitoring is important to the management of diabetes, clinical inertia creates a major barrier for use in the primary care settings. But participants were not limited to using only CGM devices. The intervention would work well in the outpatient clinic setting.

Internal validity for the study was supported using valid and reliable tools such as the SDSCA questionnaire. External validity was supported through inclusion and exclusion criteria. The study intervention is realistic for implementation in a primary clinic setting and the intervention can be transferred, although the evidence-based is limited, indicating a need for further research.

Sustainability of Effects and Plans to Maintain Effects

The sustainability of the study intervention is realistic and can be accomplished by clinic staff and healthcare providers who are willing to use TIR monitoring to assess glycemic control. Barriers that might pose a challenge for sustainability include difficulty changing well-established habits and lack of motivation. Sustaining the intervention could require continuous

support for TIR in primary care. Additional research is needed to strengthen this evidence-based intervention among patients with chronic and debilitating health conditions.

Efforts to Minimize the Study Limitations.

Study limitations were minimized with the use of convenience sampling and diversity recruitment. All efforts were made to recruit a large sample size posting flyers in the patient's intake room. All participants were given a folder detailing the study requirements and length of time for study completion. A step-by-step hypoglycemic wallet card with action plan was reviewed with each participant. Phone calls were provided to participants to answer study related questions and provide reassurance.

Interpretation

Expected and Actual Outcomes

Expected outcomes for the study included full participation with twice monthly blood pressure and weight monitoring. The postintervention data showed less than expected results due to time constraints or possible lack of resources such as a scale at home or blood pressure machine. The study showed significant improvement in self-care behaviors for blood glucose monitoring. Of the four participants, only one participant did not check their blood glucose routinely. The study showed the importance of completing other studies for each areas of self-care behaviors using the SDSCA. The small sample size, the qualitative improvement approach based on improvement as one clinic, and a sample of four patients does not allow for generalization of the findings, but a more extended study period may have been more advantageous.

Intervention Effectiveness

The study supports the use of the intervention for glycemic management in primary care clinic and other specialty clinic that treat patients with diabetes. The intervention can be duplicated in any primary care setting. The project leader's prior knowledge and experience with diabetes management were strengths. Participants who fully completed the study did so to improve their knowledge on the newest trends in diabetes management. Time in range monitoring is a new concept that they were willing to embrace, and the results towards self-care behaviors were evident in the pre and post SDSCA survey.

Intervention Revision

Lack of return phone calls and packet resulted in limited data for analysis and will require revision and further research studies. Having a larger sample size would have enhanced the study results, but there were other variables to this pilot study that warrants revision. These include not being a provider of that clinic, having limited access to the electronic health record, and not being able to follow up on clinical metrics beyond the recruitment process. If a participant visited the endocrinology during the implementation phase of the study, the ability to obtain clinical metrics was limited. Additional time was needed with participants to fully review the study timeline and answer questions. Written communication should have highly emphasized specific criteria for protection of identity, including specific understanding that the study is strictly voluntary and that they can stop at any time without consequences. Highlights these criteria initially might have eased fear and anxiety and increase study participation. There was limited time to review the entire packet provided to each participant and how to use the step-by-step hypoglycemia wallet care when they experienced a hypoglycemic episode. Revision to the intervention can be made in further studies and quality improvement initiates.

Expected and Actual Impact to Health Systems, Cost, and Policy

The study estimated cost was $400, but due to the smaller than expected sample size, the actual cost to fund the intervention was $60.81. The self-management intervention was personally funded by the project leader. The cost for the study covered educational materials, printing and laminating of wallet cards, and participants stipends. Overall, the study showed a decrease in direct and indirect costs towards the management of diabetes. The study is favorable to provide for cost-saving measures that could lead to the economic sustainability of the intervention. Study results showed improvement in medication compliance. Compliance can lead to a decrease in diabetes complications and, subsequently, healthcare costs. Self-care behaviors for blood glucose monitoring improved post intervention, as evidenced by the SDSCA postintervention results. Outcomes from the pilot study can be used to improve diabetes care in the primary care setting. The data results showed support for continued diabetes management that could lead to changes in standard of care practice in primary care clinics locally.

Conclusion

Practical Usefulness of Intervention

Hypoglycemia is prevalent among patients with diabetes. This quality improvement study shows that time in range monitoring superseded A1c in determining glycemic control. Setting a target BG range can improve glycemic control and subsequently patient outcomes. Individuals can also use the SDSCA tool as a guide to enhancing diabetes self-care activities. On average, about 10% of patients develop severe episodes of hypoglycemia (Samya et al., 2019). The results indicate that hypoglycemia management in primary care is essential. All patients diagnosed with diabetes should be asked about hypoglycemic symptoms or events during each visit and should receive education on symptoms management. Healthcare providers must identify patient barriers

to self-care behavior and work with patients to develop specific and realistic patient-centered action plans. A specific and realistic plan that is individualized can decrease complications and healthcare costs associated with recurrent ER visits or inpatient admissions.

Further Study of Intervention

Setting a target range for TIR is essential for this self-management study. The study focuses on improving the utilization of TIR monitoring in the outpatient clinic beyond the three-month intervention. The process can be sustained if further evidence- based research can be done to enhance its validity and accepted use of the recommended guidelines already in place by the ADA. With only three years since the ADA recommendation, there is strong support for the use of TIR on a global scale. A study by Ramchandani. (2019) showed that recommendations for TIR are being used nationwide by clinicians to guide and interpret diabetes management. The Brazilian Diabetes Society is also seeking to demand that TIR become a national practice (Gabbay et al., 2020). Since there are less published articles on TIR, additional research is needed to test reliability and validity for sustained use in primary care practice.

Dissemination

The impact of diabetes on multiple areas of a person's life requires the individual to make frequent and ongoing self-care adjustments (Sherifali et al., 2018; Mikhael et al., 2020). This pilot study shows there are numerous opportunities towards improving self-care behaviors and nurse practitioners are trained to lead change and advance the health of patients with chronic disease processes. Dissemination plans for this pilot study include a poster presentation at the AMNP (Association of Missouri Nurse Practitioners) in October 2020, and a manuscript submission to *The Journal of Nurse Practitioners* in May 2021. The study will also be uploaded to the UMKC DNP study repository.

Impact to Healthcare

Primary care providers can play their part by providing early identification, assessment, and management of hypoglycemia. Early identification and prevention of hypoglycemia can reduce healthcare costs associated with ED visits and hospitalization. The total estimated cost to treat diabetes is expected to rise from $245 billion to $327 billion (ADA, 2020). To improve the impact of rising healthcare costs, primary care clinics should incorporate quality improvement strategies into their daily practice. Quality improvement strategies should be aimed at acknowledging the benefits of TIR in the outpatient clinic setting. Patients who use TIR to manage their DM have shown greater glycemic control, improved dietary habits, lower A1c, LDL, and enhanced medication adherence. Clear communication and effective collaboration among the healthcare teams are essential to ensure clear goals, foster progress toward goals, and provide appropriate interventions (Powers et al., 2016).

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Appendix A
Terms Defined

A1c: glycosylated hemoglobin A1c is an endocrine test that gives the average blood glucose concentration over a three-month period and is frequently used to assess glycemic control (Pamungkas et al., 2017).

Clinical Parameters: refers to clinical parameters such as A1c, LDL, weight, and BP.

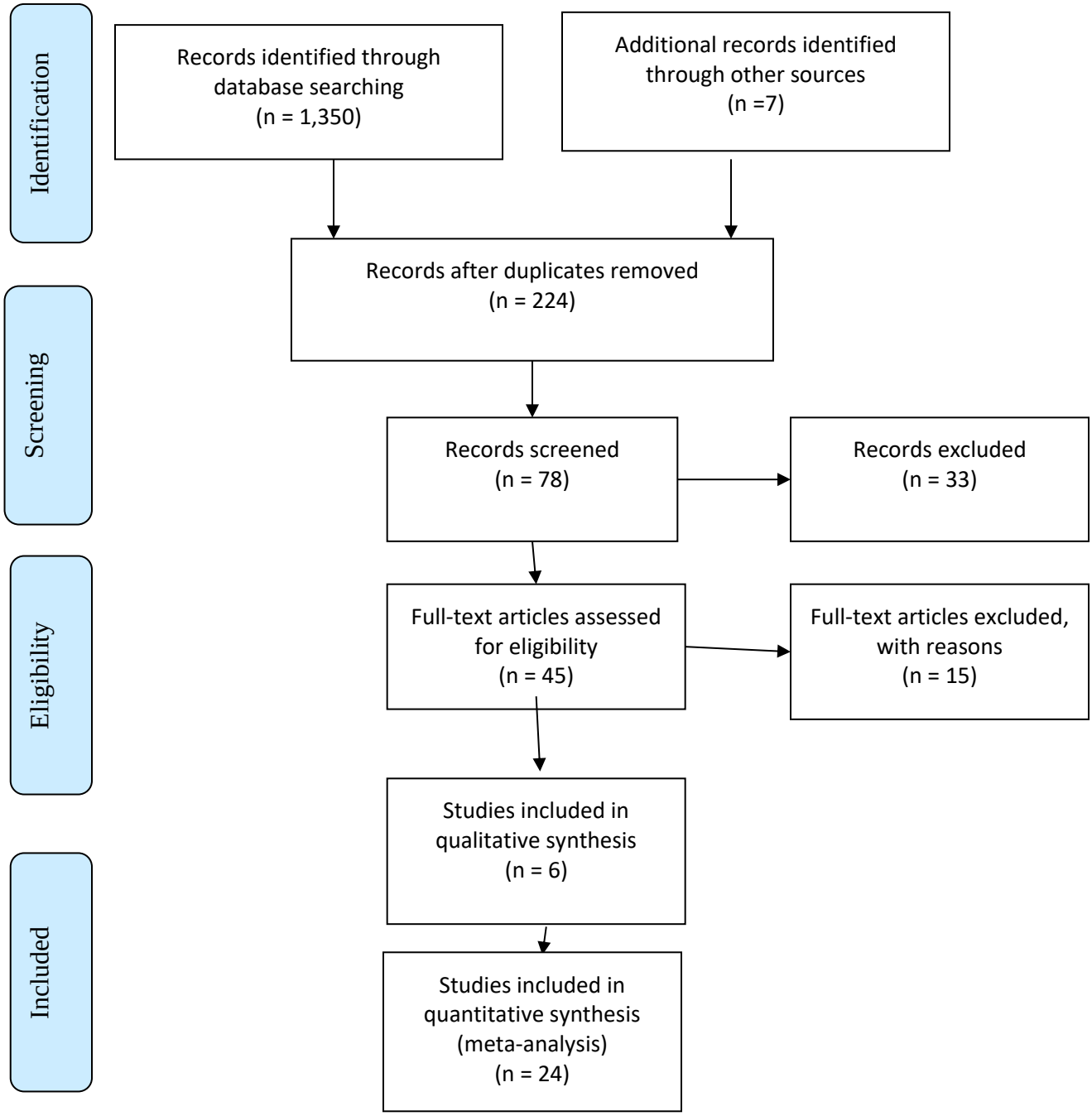
LDL: low density lipoprotein- is a clinical metric that is used to assess cardiovascular risk.

SDSCA: the summary of diabetes self-care activities is a brief self-reported questionnaire that assesses behaviors such as diet, exercise, blood glucose testing, foot care, and smoking (Mohebi et al., 2018).

Time in Range: the percentage of time a person spends with their in a target range, normally 70-180mg/dl (Lu et el., 2018).

Appendix C

PRISMA



Appendix D-**Synthesis of Evidence**

First author, Year, Title, Journal	**Purpose**	**Research Design, Evidence Level & Variables**	**Sample & Sampling, Setting**	**Measures & Reliability (if reported)**	**Results & Analysis Used**	**Limitations & Usefulness**
Andrade (2020). Time and range: a new parameter to evaluate blood glucose control in patients with diabetes	To evaluate the use of TIR on improving clinical outcome measures	LOE VII Expert opinion Race	Brazil	The international consensus in time in rage validates its use	TIR was validated as an outcome measures that evaluate glycemic control such as blood glucose an A1C.	Most of the subjects were white and Non-Hispanic. results might be inaccurate for Non-Caucasian To use TIR evaluation in clinical practice nationwide to improve glycemic control

Ansari (2016). A quantitative research on self-management of type 2 diabetes in middle-age population of rural area of Pakistan	To explore the association between illness and cultural beliefs, family and provider support, self-management behaviors Intervention Illness, cultural believe, family and providers Outcome Will this influence self-management	LOE III Quantitative design Sampling method (Interviews o patient from 3 rural dm centers. Analysis (self-administered question. Statistical analysis using STATA	200 randomly selected patient from the Medical center of rural area in and Pakistan and	Self-administered questionnaire then than	To improve DSME approach in rural population sample sized powered at 80% with Alpha, significance level =5% 0r 0.05 Standardized difference of 0.38, power 0.8, alpha =0.05 chi-square, t test, logistic regression Improve DSME approach. SDSCA, BIPQ, RSSM, DFSC.	
Ajzen (2011). Material plan behavior: reactions and reflections	To predict behaviors based on intentions	LOE III				Additional predictors should be proposed and added with caution and only after careful deliberation and empirical exploration
Armitage (2010).test of a brief theory of planned behavior-based intervention to promote adolescent safe sex intervention	To change attitude, subjective norm, and perceived behavioral control regarding safe sex behavior	LOE I A 2x2 Randomized control design Variables: Attitude, subjective norm, perceived behavioral control	288 participant, 16-18 years old. University half Sheffield, United Kingdom	Pre-and post-test. Webb, and Sheeran's meta-analysis, Gpower from Faul, Buchner, and Erdfelder,	Intervention designed to change subjective norms might ultimately be effective in changing behavior	How participant was part- or full-time student and does not reflect the same age group in general. Study might not

		Independent variable- condition Dependent variable- age and pretest theory have planned behavior measures		and Lang. Cronbach's Alpha. Semantic differential scale		allow for generalization . Small effect size. Intervention based on the theory of planned behavior can successfully change safe sex intention
Beck (2017). 2017 National Standards for diabetes self-management and support	The standards define timely, evidence-based, quality DSME services that meet CMS diabetes self-management education	LOE VII	Expert opinions	Self-care inventory. SDSCA. EHR.	Quality improvements can improve DM outcomes	
Beck.R (2019). Validation of time in range as an outcome measure for diabetes clinical trial	To evaluate the Association of time and range with the Development our progression of retinopathy and development of microalbumin	LOE III Cohort study	1440 Participants . National Institute of diabetes and digestive and kidney disease central database repository and the Biostatistics center at George Washington University	Glycemic data, A1C Seven-point glucose sample measure every three months	T IR is strongly associated with the risk of microvascular complication and should be an acceptable endpoint for clinical trial.	There is limited ability to assess glycemic their ability using Seven-point testing. testing is only done during the daytime TIR of 70 to 80 has a strong Association with the risk of development or progression of retinopathy and microalbuminuria

Brunisholz (2014). Diabetes self-management education improves quality of care and clinical outcomes determined by a diabetes bundle measure. Journal of Multidisciplinary Healthcare.	Determine the impact of DSME in improving quality of care and clinical outcomes using a diabetes bundle measure	LOE III Retrospective Case-control Independent variable (case & cohort DSME group. Intervention was diabetes bundle. Outcomes (improvement in clinical outcomes).	1920 adults (18-75 yrs.) 384 case-1536 control (1:4 ratio), Accredited ADA Outpatient clinic.	IH diabetes bundle. Data systems, physician expert panel. P<0.05-statistically significant	Statistical analysis: *t*-test, multivariate models, graphs. DSME is 1.5 times effective at reducing A1C, LDL and BP within 6 months when offered at an accredited ADA facility.	Large percentage of Caucasian female. Registry did not distinguish between type 1 or II DM, might include both.
Cannon (2018). Burden of illness in type 2 diabetes mellitus	To evaluate the burden of diabetes management	LOE VII	Expert opinion		Type 2 diabetes imposes a considerable burden on both the individual and society	Treatment strategy for type 2 diabetes should consider the effect of treatment on health-related quality of life
Clayton (2013). Hyperglycemia	The importance of early recognition and prevention of hypoglycemia	LOE VII Expert opinion	Expert opinion	Being able to identify risk factors for hypoglycemia, prior episode, current low A1C less than 6.0%, food insecurity, low health literacy, low socioeconomic status	Goal of treatment for hyperglycemia is to detect and treat no BG promptly using intervention That provides the fastest rise in BG to a safe level and to eliminate the risk of injury and to relieve symptoms quickly	provider should Institute hypoglycemia protocols within their hospital or outpatient clinic
Cryer (2015). Minimizing	To evaluate the effects of hyperglycemi	LOE VII	Peer Review	The risk of hyperglyce	Hyperglycemia increases	Minimizing hypoglycemia by

hyperglycemia in diabetes	a caused by oral or insulin regimen			mia is modifiable	the risk of morbidity and mortality	acknowledging the problem, consider the risk factor and applying principle of intensive glycemic therapy. Selecting appropriate individualized glycemic goals and providing structured patient education
Damayanti (2018). Theory of planned behavior implementation on the factors affecting self-care management in type 2 diabetes mellitus patients.	Analyze the factors affecting self-care management in patients with type 2 DM using TPB	Level I RCT Independent variables (Intervention) were intention, attitude, subjective norms, self-efficacy, and education level. Dependent (outcome): self-care management in type 2 DM	126 participants from 7 Community health canter	Collected by questionnaire. Analyzed by path analysis. SDSCA questionnaire	Self-care management was positively and directly influenced by education and strong intention. Frequency and percentage Bivariate analysis,	Low education level among participants
Dress (2016). Reducing the burden of diabetes mellitus in the state of Missouri: a call to action	To reduce the burden of diabetes in the state of Missouri	LOE VII	Expert opinion	Each patient diagnosed diabetes should have an individualized treatment plan to prevent risk of complication based on evidence-based guidelines	Diabetes care is costly. CDC certified DPP program year long, intensive behavior modification program	Providers can reduce the burden of diabetis by screening, diagnosing, treating DM, and engaging with health Department, the public an elected official on health policy and promotion of neighborhoods and communities that support

						health in general
Gucciardi (2013). A systematic literature review of diabetes self-management education features to improve diabetes education in women of Black African/Caribbean and Hispanic/Latin American ethnicity	Identify DSME features to improve diabetes for women with T2DM	LOE- II RCT. Hospital and group-based interventions, dietician interventionist. Outcome: groups were effectiveness in improving A1c.	13 studies analyzed (10 random, 3 cohort), Urban hospital	Hospital and group-based interventions. Posttest outcome data, face to face, telephone, written literature, audio visual	Different DSME intervention may influence self-management outcomes for women. hospital based was more successful across outcomes	Lack of gender base analysis. Small number of studies. Study population had different cultural values, experiences, and beliefs. Study pop, intervention, and measurement limited efforts to conduct a meta-analysis
He (2017). Diabetes self-management education reduces risk of all-cause mortality in type 2 diabetes patients: A systematic review and meta-analysis	To elucidate the impact of DSME on all-cause mortality risk of type 2 diabetes	LOE I Systematic review and meta-analysis DSME is the independent variable and dependent variable is the reducing the risk of mortality	42Randomized trials of 13,017 participants	Cochrane Collaboration tool was used to assess the risk of bias	DMSE reduces the risk of mortality among patients with type 2 diabetes. P5% CI's, Q test. statistical analysis using Review management P value <0.05 was statistically significant	Did not assess impact on DMSE on complications. Not generalized to all type 2 diabetes. Cost-effectiveness of DSME had not be well evaluated

Hilderbrand (2020). Effects of diabetes self-management education on glycemic control and Latino adults with type 2 diabetes: A systematic review and meta-analysis.	To evaluate the effectiveness of DSME in reducing A1c levels in Latinos with T2DM	LOE I Systematic review and meta-analysis The effect on DSME on A1C level. Culturally tailored program can improve patient outcome	18 Systematic review studies Of Latino participants	Eggers regression PRISMA guidelines	Culturally tailored DSME intervention significantly reduces A1c in Latinos with T2DM Providers must allow patient opportunity to engage in programs to improve health outcomes Flow diagram	Need comprehensive care that reinforces behavior changes that improve glycemic control for participants. includes unbiased sample of relevant studies
Janapala (2019). Continuous glucose monitoring versus self-monitoring of blood glucose and type 2 diabetes mellitus: A systematic review with meta-analysis	Two evaluate if there is supporting evidence suggesting that CGM is more effective that than SMBG in type 2 diabetes	LOE I systematic review with meta-analysis		Systematic review and meta-analysis Prisma flow diagram		Cast of CGM. CGM is helpful in the management of hypoglycemia
Jeon (2016). Risk factors for severe hyperglycemia requiring medical assistance and neurological sequel impatient with diabetes	To Identify risk factors associated with severe hyperglycemia requiring medical assistant and the resulting neurologic sequelae in patients with diabetes	LOE III A case-control study Variable: demographics. Medications, BP, previous hypoglycemia	129 patients with diabetes, single tertiary hospital, Control group with non-severe hypoglycemia who visited the outpatient clinic during	Modified ranking scale	Absents of-SMBG and previous severe hyperglycemia word a risk factor for severe hyperglycemia requiring medical assistance Multivariate analysis	Selection bias, may not be generalized to all patients with DM. Providers should increase efforts to educate patients on the importance of performing SMBG for

			same period			prevention of hyperglycemia
Kamradt (2014). Assessing self-management in patients with diabetes mellitus type 2 in Germany: validation of a German version of the summary of diabetes self that care activities measure SDSCA-G	To translate the SDSCA into German and examine its psychometric properties	LOE IV Cross sectional Random	315 patients with diabetes. In 20 primary care practices located in Germany.	Cronbach's Alpha Questionnaires Exploratory factor analysis confirmatory factor analysis, convergent construct validity	The German version of SDSC demonstrated acceptable psychometric properties regarding reliability and validity for use in Germany	Limited to patient with type 2 diabetes lack of gold standard comparison. No retest was performed due to cross sectional study design. The revised German version of the SD SCA is reliable invalid in assessing self-management. It is a relatively short and easy tool which can be used in a busy clinic setting to collect appropriate data

Karimy (2018) The association between attitude, self-efficacy, and social support and adherence to diabetes self-care behavior.	To investigate association of self-efficacy, attitude & social support with adherence to diabetes self-care behavior	LOE IV Cross-sectional Intervention: Diabetes self-care behavior. Outcome: impact of attitude, Self-efficacy & social support on self-care - care behaviors	420 participants in a diabetic clinic in Iran.	Questionnaires	Higher self-care scores equal better self-efficacy, social support, and attitude towards self-care. ANOA, *t*-test up, SPSS, multiple regression	Data might be subject to recall bias. Causal relationship cannot be determined
Lanspa (2019). Percentage of time in range 70-139 mg/dl is associated with reduced mortality among critically ill patients receiving IV insulin infusion	Examine the relationship between T IR and mortality	LOE III Retrospective study	ICU patients. Intermountain Healthcare electronic medical record was used to perform a retrospective cohort analysis of all patient's Medical record	Charlson comorbidity index. Acute Physiology score. Mann Whitney U test, small type variable logistic regression	TIR was independently associated mortality in critically I will patients particularly those with good antecedent glucose control	Study with occupational Which reduces inferences. Conclusion should be considered hypothesis generating. Generalizability of the study is limited maybe use of retrospective analysis. TIR 70 to 130 they strongly associated with increased survival
Laranjo (2015) Facilitators, barriers, and expectations in the self-management of type 2 diabetes qualitative study from Portugal	Facilitators, barriers, and expectations in the self-management of type 2 diabetes- a qualitative study from Portugal	LOE V Descriptive qualitative design using convenience sampling	3 focus groups were conducted in June 2013 and lasted 45- and 60-min. Outpatient clinic	NVivo 7	Open coding of transcripts. 3 themes identified: diet, physical exercise, and glycemic control.	Low number of participants and sessions. Bias with focus location same at patient place of usual care.
Lu (2018). Association of time in range, as assessed by continuous glucose monitoring, with diabetic	To investigate the Association between the time in range assessed by CGM and	LOE IV retrospective Cross-sectional study	3362 patients with T2DM Shanghai Jiao Tong University	multinomial logistic regression. ANOVA	TIR assessed by CGM is associated with diabetic retinopathy in type 2 diabetes	cross sectional study could not examine cause and effect relationship between TIR in the development

retinopathy in type 2 diabetes	diabetic retinopathy					of Dr. TIR might not reflect the historical glycemic control of participant. TIR is an intuitive metric of glycemic control for both patient and clinician Word
Mayeda (2020). Glucose time in range in peripheral neuropathy in type 2 diabetes mellitus in chronic kidney disease	This study hypothesizes that glucose time in range measured by CGM is associated with DPN symptoms among participant with type 2 diabetes mellitus and moderate to severe CKD	LOE IV prospective observational cohort study design	105 with T2DM.	Linear regression. A2 tail P value was taken as evidence of statistical significance	Symptoms of diabetic peripheral neuropathy (DNP) were common among participant with long-standing type 2 diabetes in CKD. Lower TIR in higher GM I was associated wait DPN	Small sample size and cross-sectional observational study design, unable to assess the relationship between CKD are glycemia in DPN. Small amount of GCM data may not be accurate to reflect long term glycemic pattern
Mikheal (2020). Effectiveness of diabetes self-management educational programs for type 2 diabetes mellitus patients in Middle East conference: A systematic review	To determine the effectiveness & factors affecting the success of DSME programs in T2DM patients	LOE I A systematic review Interventions Effectiveness of DSME on clinical outcome for patients with T2DM Outcomes DSME is highly effective in improving A1c, Lipid, BP	12 Studies chose for review for patients living in middle east countries	Cochrane bias tool.	DSME programs are highly effective in improving glycemic control lipid profile and BMI and BP.	Small number of studies Inaccurate two generalization. Poor quality and high risk of bias.

Mohebi (2018). Relationship between perceived social support is self-care behavior in type two diabetics: cross sectional study	Assess relationship between social support and self-care of pt with T2DM.	LOE IV Cross-sectional Social support and selfcare-behavior Social support and self-care behavior improve glycemic control	325 participants	P <0.05 SDSCA. MSPSS.	SPSS. one-way ANOVA. Glycemic control improves with positive self-care behaviors	Participants were already enrolled in a DSME 1program. Limited sample size. use of self-reported questionnaire
Morales (2014). Hypoglycemia	To valuate strategies for improving hypoglycemic management	LOV VII	Expert opinion	ADA standard of less than 70 is an alert value for hyperglycemia	Provider should pay close attention to hyperglycemia when managing patient with diabetes Selecting or modifying therapy to reduce hyperglycemia can minimize hyperglycemic risk	Ongoing health care reform efforts will result in more emphasis on reducing side effects of diabetes treatment
Pamungkas (2017). A systematic review: family support integrated with diabetes self-management among uncontrolled type II diabetes mellitus patients	To review and describe the impact of diabetes manages self-management education that involved the member on patient outcome	LOE I Systematic review and meta-analysis Glycemic control in the past 3 months	22 intervention studies were identified	PRIMSA Hand-tracking	Significant improvement in clinical outcomes such as A1c, blood pressure, lipid profile, and BMI	Methods, setting strategies, population and outcomes made it difficult to compare effect size.
Powers (2016) Diabetes self-management education and support in type two diabetes: a joint statement	To improve the patient experience of care & education, to improve health of	LOV VII Expert opinions	Expert opinion	Tables, charts, algorithm	All individuals with diabetes should receive DSME at	A patient centered approach to DSME at diagnosis provides the foundation for

of the American diabetes association, the American Association of diabetes educators, in the economy of nutrition and dietetics	individuals and populations, and to reduce diabetes associated healthcare costs				diagnosis and as needed thereafter	current and future needs
Ramchandani (2019). 88 timing range guidelines: what they are, they are important and how this affect diabetes educators	To evaluate the ADA time in range guideline	LOE VII	Expert panel	TIR should be individualized	6/2019, ADA recommender TIR target for CGM.	T IR informs A1C and is easier metrics to use to make adjustment to diabetes medication and lifestyle intervention. T IR provides valuable information that a A1C does not
Reyes (2017). Factors influencing diabetes self-management among medically underserved the shanties with type 2 diabetes	Explore barriers and facilitators for DSME	LOE V Descriptive qualitative study	44 participants from 4 mid-western community health center Focus group with common developed themes	Open ended questions	Effective diabetes management is essential to achieve optimal glycemic control and decrease morbidity and mortality Audio-taped	Study is consistent with previous results. Small sample size due to limited participation from pts with lack of transportation. 60% or participants were female
Rodriguez-Gutierrez (2020) Documentation of hyperglycemia assessment among adults with diabetes during clinical encounters in primary care in	To examine the number of diabetis focus clinical encounters in primary care in endocrinology practices where the evaluation for hyperglycemi	LOE III retrospective cohort study	283 Adults participant with diabetes seen in the Mail clinic primary care in endocrinology practices	HER Charleston Comorbidity index	Unpaired students T test, man with Whitney U test, logistic regression analysis	Data limited to HER, patient hypoglycemic event was not routinely captured by CGM or SMBG. Important for provider to identify

endocrinology practices	a is documented identify by clinician in the action stated					patient at risk for hypoglycemia and to initiate appropriate treatment regimen
Samya (2019). Prevalence of hyperglycemia among patients with type 2 diabetes mellitus in a rural Health Center in South India	To evaluate the self-reported prevalence of hyperglycemia among patients with type 2 diabetes	LOE IV cross sectional study Variables- age, sex common type of family, occupation, treatment taken, A1C, duration of diabetes	390 participants with type 2 diabetes mellitus, Hey rural help and training center In India people right now	descriptive statistics, child square odds ratio. AP value of less than .05 was considered statistically significant. SPSS.	First reported symptoms have hyperglycemia with business. Most common etiology factor was missing a meal. Female all right increase risk for hypoglycemia	Limited resource for measuring blood glucose in rural setting with low economic status. Accuracy of self-reported hyperglycemia may be affected by the patient recall especially if the event is mild Urgent need for primary care physician to inquire about hypoglycemic symptoms to all diabetic patient at each visit. Educate patient about symptoms of hyperglycemia and the importance of reporting such symptoms
Sherifali (2018). Self-management education and support.	DSME improves glycemic control, self-efficacy, and self-care behaviors	LOE VII Expert opinion			Evidence supports the benefit of DSME	

Shrivastav (2018). Type 2 diabetes management in primary care: the role of retrospective, professional continuous glucose monitoring		LOE IV Retrospective study	Expert opinion	According to the CDC primary care visit accounted for 52.3% of all medical office visit in the USA in 2013	CGM technology has created new opportunities to improve glycemic control and reduce the complication of diabetes	Use of CGM in primary care would enable more robust care for patient with diabetis
Silbert (2019). Hyperglycemia among patient with type 2 diabetes: Epidemiology, risk factors and prevention strategies	Review the Epidemiology of hypoglycemia in type 2 diabetes, discuss key risk factors and introduce potential prevention strategies	LOE VII	Expert opinion	Hyperglycemia is most common among older patient multiple comorbidities, patient with long diabetes duration, patient with history of previous hyperglycemia. Clinical decision support tool may help identify at risk patient.	Reliability of self-reported measures of hyperglycemia is contingent on confidence in patient's hyperglycemia awareness and willingness to report the event	Clinical guidelines in quality/ accountability measures need to reflect the importance of hyperglycemia in the management of diabetes

Strychar (2012). Type 2 diabetes self-management: Role of diet self- efficacy	To determine the role of self-efficacy in understanding dietary behaviors and outcomes in type 2 diabetes Intervention Self-efficacy & self-management Outcomes: self-efficacy improves self-management behaviors of patients with type II DM	LOE IV Cross sectional	19	SDSCA	Themes from self-efficacy were used. Self-efficacy was associated with problem solving, social environment support, and self-care behaviors	Absence of detailed clinical assessment on self-reported behavior; absence of a definition of an optimal degree of self-efficacy. Develop standardized diet self-questionnaire.
Tenzer-Iglesias (2012). Managing hyperglycemia in primary care	To evaluate the management of hypoglycemia in primary care	LOE IV				
Weller (2017) Discovering successful strategies for diabetes self-management: A qualitative comparative study	Examine lifestyle of patient in good or poor control to identify strategies for successful management	LOV IV Qualitative	56 semi-structured interviews were among patients in a Family clinic in Texas	Semi-structured interviews and comparative design	Increase glucose monitoring is valuable to diabetes management Themes, medical records	Offering pill boxes and reoffering classes may help improve control

Vigersky (2019). The relationship of hemoglobin A1C to time in renting patient with diabetes	To evaluate the relationship of % TIR to the longstanding metric of overall glycemic control	LOV IV	Recent studies in subjects with type one and type 2 diabetes using CGM as a therapeutic interventio n alone or in combinatio n with insulin pump for review	Linear regression analysis. Pearson's correlation coefficient.	There is good correlation between A1C and % TIR that will permit the transition to % TIR as a preferred metric for determining the outcome of clinical studies, predicting of the risk of diabetes complicatio n, and assessing an individual patient's glycemic control	Only included four studies a patient with type 2 diabetes. 30 based on means from multiple study most of the study subjects were categorize add white are non-Hispanic white
Yeoh (2015). Intervention that restores awareness of hyperglycemia in adults with type one diabetes: a systematic review and meta-analysis	To look at educational, technological , and pharmacolog ical intervention aimed at restoring hyperglycemi a awareness in adult twit type one diabetes	LOE I systematic review and meta-analysis	57 Full text articles	BGAT, CGM.	MED, calc	First systematic review meta-analysis Explorer different intervention available for reversing hypoglycemia unawareness
Zheng (2019). Effects of an outpatient diabetes self-management education on patients with type 2 diabetes in China: A randomized	Develop and evaluate the effects of a DSME program in the outpatient setting	LOE I Single blinded RCT, Intervention: Questionnaire, vs regular vs DSME. Nutrition and exercise guidance. Outcomes:	60 patients with type II DM randomly chosen to achieve a 1:1 ratio	Questionnai re, Regular and intervention al Education. Likert 0-7. Cronbach alpha 0.913, t-test 0.774 ($p<0.01$)	Descriptive statistics: SPSS. t-test. $P<0.05$. Short term use of DSME for outpatient can improve	Small sample, limited intervention pattern, lack of statistical analysis, and short observation period.

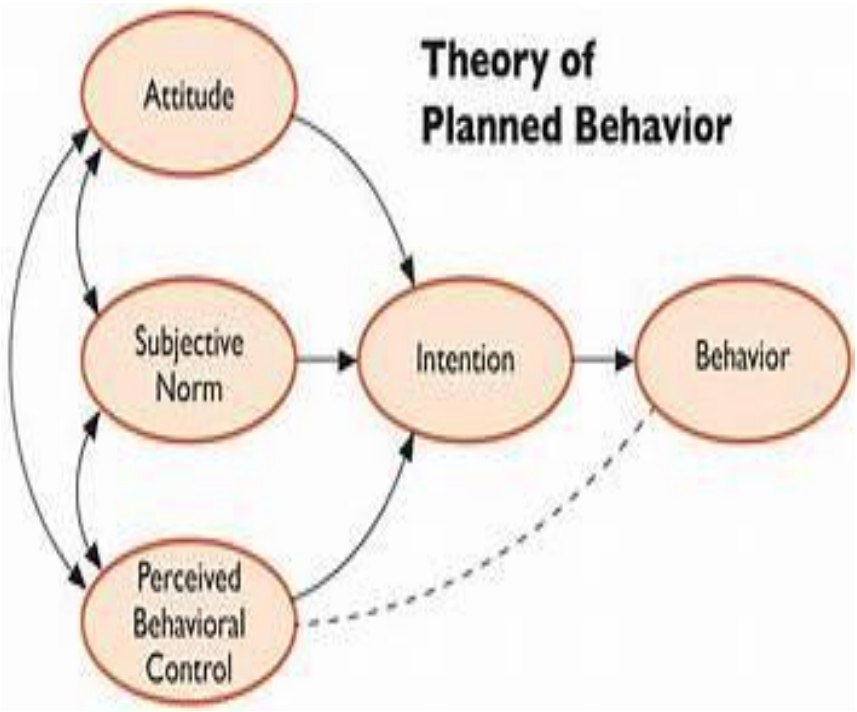
controlled trial. Journal of Diabetes Research		Higher participation=better compliance/self-care behaviors			self-management and glycemic control	

Appendix E **Evidence Grid**

Evidence Themes	**Hypoglycemia management in primary care**	**Hypoglycemia and antihyperglycemic**	**TIR and A1c**	**TIR and CGM**
Articles				
Andrade,2020	X	X	X	X
Ansari, 2016	X			
Ajzen, 2011	X			
Armitage, 2010	X			
Beck.J, 2017			X	
Beck. R, 2019			X	X
Brunisholz, 2014			X	
Cannon,2018	X			
Clayton, 2013	X	X		
Cryer, 2015	X	X		
Damayanti, 2018	X			
Dress, 2016	X			
Gucciardi,2013	X		X	
He, 2017	X			
Hildebrand,2019			X	
Janapala, 2019			X	X
Jeon, 2016	X	X		X
Kamradt, 2014	X			
Karimy, 2018	X			
Lanspa, 2019			X	X
Laranjo, 2015	X			
Lu, 2018			X	
Mayeda,2019			X	X
Mikhael, 2020			X	
Mohebi, 2018	X			
Morales, 2014	X	X		
Pamungkas, 2017			X	
Powers, 2016			X	
Ramchandani, 2019			X	X
Reyes,2017	X		X	
Rodriguez-Gutierrez, 2020	X	X		
Samya, 2019	X	X		
Sherifali, 2018			X	
Shrivasta,208				X
Silbert, 2019	X	X		
Stevens, 2013				
Strychar, 2012	X			
Tenzer-Iglesias, 2012	X	X		
Weller, 2017	X		X	
Vigersky, 2019			X	X
Yeoh, 2015	X			
Zheng,2019	X			

Appendix F

Theory of Planned Behavior (TPB) Diagram



Appendix N-**IRB Approval Letter**

UMKC **Institutional Review Board**
University of Missouri-Kansas City

5319 Rockhill Road
Kansas City, MO 64110
816-235-5927
umkcirb@umkc.edu

Dear Lyla Jo Lindholm,

A member of the UMKC Research Compliance Office screened your QI Questionnaire to project #2024941-QI entitled "Hypoglycemia Management in Primary Care" and made the following determination:

QI Determination: **The project has been determined to be a quality improvement activity not requiring IRB review.**

If you have any questions regarding this determination, please feel free to contact our office at 816-235-5927, umkcirb@umkc.edu, or by replying to this notification.

Note Regarding Publications: It is appropriate to disseminate and replicate QI/program evaluation successes, including sharing the information external to an organization. This may include presentations and publications. The mere intent to publish the findings does not require IRB review as long as the publication does not refer to the activity as research.

Thank you,
UMKC Institutional Review Board

Appendix O- **IRB Approved Informational Letter**

I_____ agree to take part in this nursing research study and gives permission to Kamaria Harris DNP, FNP-C (on behalf of Saint Joseph Endocrinology Clinic) to access my medical records. Information obtained from your medical records will be used as pertaining to the research study and all information will be kept confidential as provided by law.

If you have any questions, please call 816-941-222

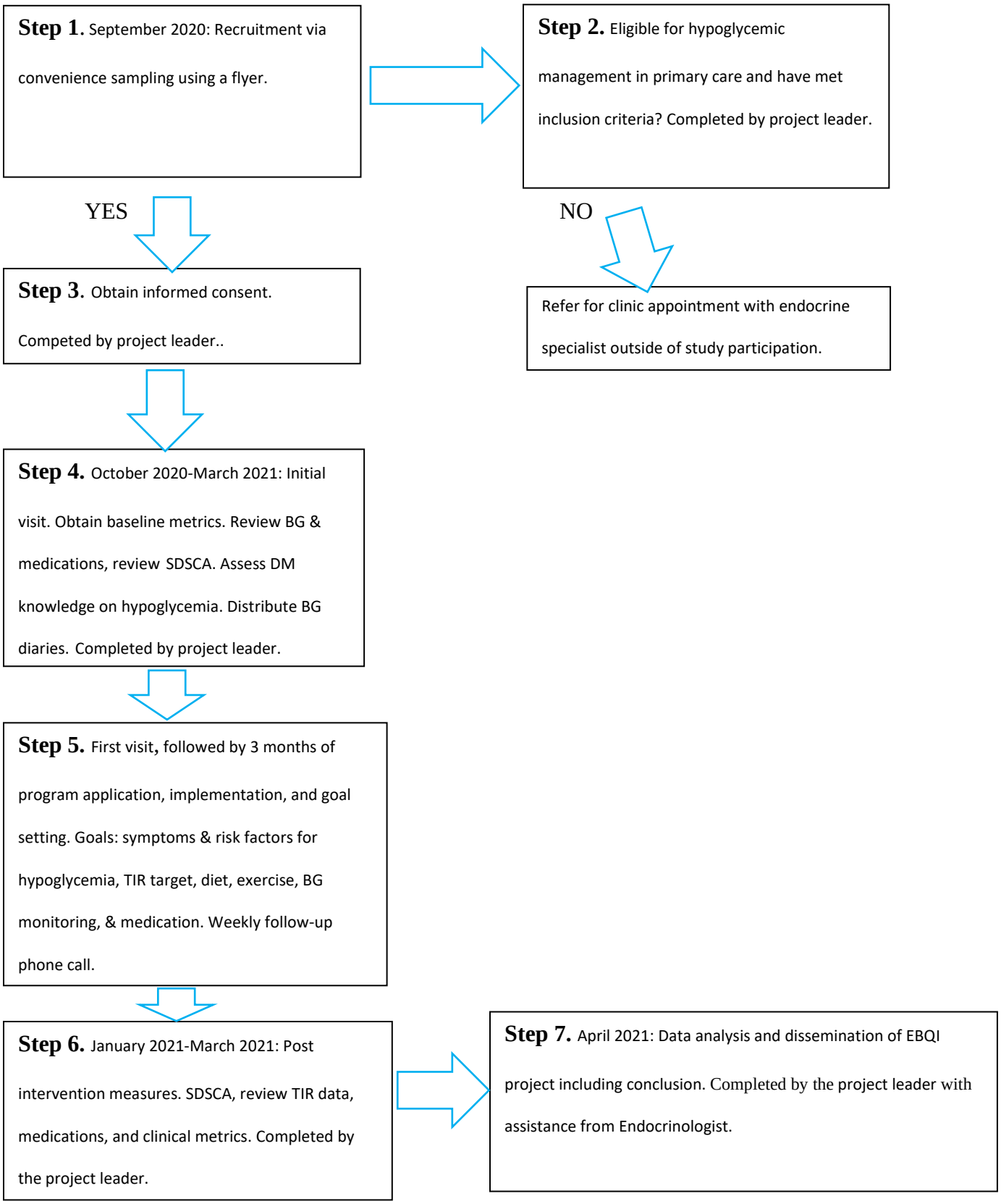
Appendix B

Budget Table

Item	**Item Description**	**Quantity**	**Unit Cost**	**Anticipated Cost**
Print materials	Recruitment flyers, SDSCA and DIABQ questionnaires, consent form	25	$ 3.97 per ream x3	$ 11.91
Equipment	2 Pocket folders Computer	1 pack of 25 1	$ 8.90 per pack $0-Provided by facility	Total cost $8.90
Miscellaneous	Blood glucose diary. Gift cards for participants	15 4	$0 will use printable version $40- Wal-Mart gift card	$0 Per project leader funding
Student Time	Project leader Salary Kamaria Harris, DNP student, MSN, FNP-c	600 hrs.	15 hrs./per week	$0- project leader completed outside of normal work hours
Total				$60.81

Appendix I

Intervention Flow Diagram



Appendix J

Intervention Materials

Recruitment Flyer

WANT TO LEARN MORE ABOUT HYPOGLYCEMIA?

PARTICIPANTS NEEDED FOR A NURSING STUDY

Doctoral Nursing Project

The purpose of this study is to determine if Time-in-Range monitoring will improve hypoglycemic management, medication adherence, A1c, and LDL. Participants will receive clinic assessment, blood glucose monitoring, lab review, and education on hypoglycemic management.

UMKC
School of Nursing and Health Studies

Who Should PARTICIPATE?

Adults age 18-75

Experience at least one episode of hypglycemia

Have an A1C score >7, LDL >100, or BP >130/80

Taking medications for diabetes

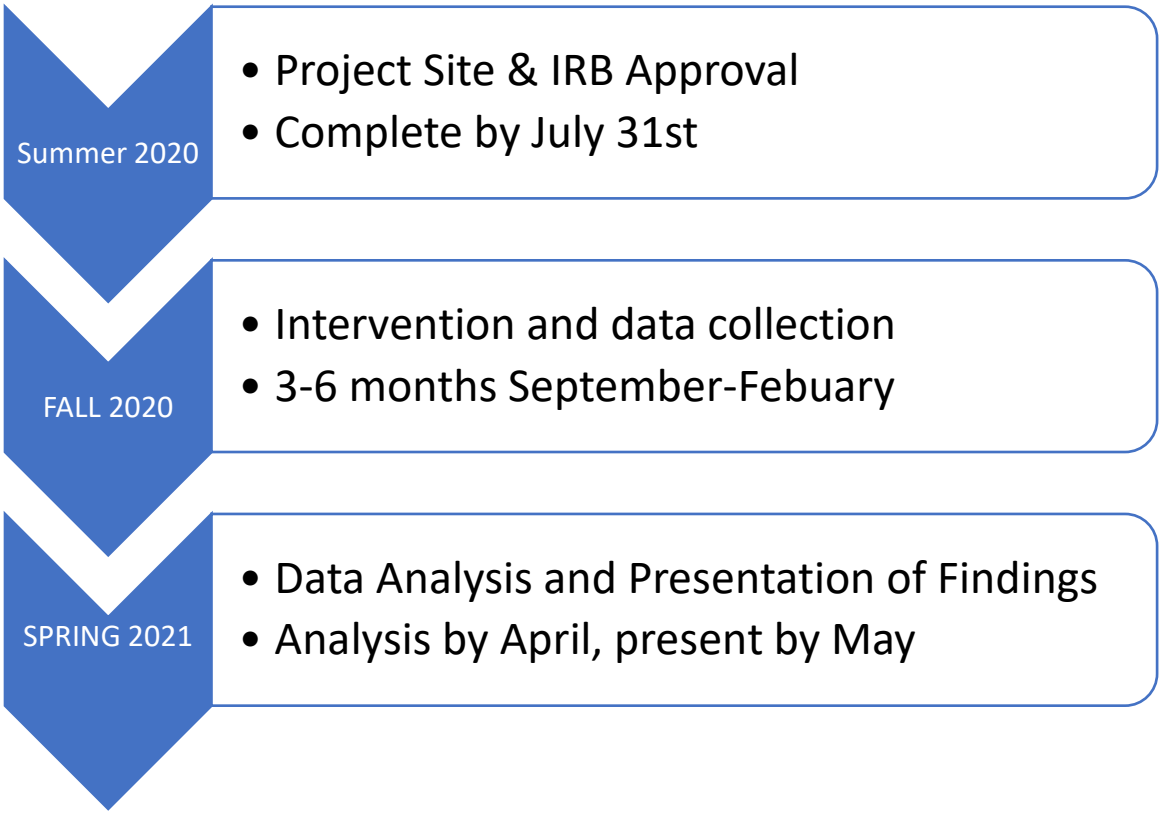
St Joseph Endocrinology

Please call to schedule an appointment or for more information

816-941-2222

Appendix H

Project Timeline Flow Graphic



Appendix G

Logical Flow of Outcomes

	State	Measurement Instrument Name	Tool validity and reliability	Permission Need	Statistical Analysis
Primary Outcome	Hypoglycemia, medication adherence, A1c, and LDL	Physiological measures (Lab draw, chart review) obtain TIR data	SDSCA TIR	Yes. Permission obtained	Descriptive statistics
Secondary Outcome	Hyperglycemia, BP, and weight	BG data and clinical parameters	SDSCA TIR	Yes. Permission obtained	Descriptive statistics
Demographics	Age, gender, race	Not applicable	Not applicable	Not Applicable	Self-administered survey/questionnaire
Participant Completion of the Measurement Tool (Procedure): Participants will complete the above questionnaires prior to start of study.					

The SDSCA Questionnaire

The **SDSCA** (summary of self-care activities) is a self- reporting questionnaire that ask about your daily diabetes self-care activities during the past 7 days. The results of this questionnaire will be used as a guide by your healthcare provider to formulate a personalized plan of care for your diabetes management.

Permission obtained for use in this study

Summary of Diabetes Self-Care Activities Questionnaire

The questions below ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

Diet

	Number of Days
1. How many of the last SEVEN DAYS have you followed a healthful eating plan?	□0□1□2□3□4□5□6□7
2. On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?	□0□1□2□3□4□5□6□7
3. On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?	□0□1□2□3□4□5□6□7
4. On how many of the last SEVEN DAYS did you eat high-fat foods, such as red meat or full-fat dairy products?	□0□1□2□3□4□5□6 □7

Physical Activity

5. On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? *(Total minutes of continuous activity, including walking).*	□0□1□2□3□4□5□6□7
6. On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?	□0□1□2□3□4□5□6□7

Blood Sugar Testing

	Number of Days
7. On how many of the last SEVEN DAYS did you test your blood sugar?	□0□1□2□3□4□5□6□7
8. On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health-care provider?	□0□1□2□3□4□5□6□7

Foot Care

9. On how many of the last SEVEN DAYS did you check your feet?	□0□1□2□3□4□5□6□7
10. On how many of the last SEVEN DAYS did you inspect the inside of your shoes?	□0□1□2□3□4□5□6□7

Smoking

11. Have you smoked a cigarette, even a puff, in the past SEVEN DAYS?	□0 No □1 Yes ≡

11a. How many cigarettes did you smoke on an average day?

Number of cigarettes: _____

Scoring Instructions for the Summary of Diabetes Self-Care Activities

Scores are calculated for each of the five regimen areas assessed by the SDSCA: Diet, Exercise, Blood-Glucose Testing, Foot Care, and Smoking Status.

Step 1
For items 1–10, use the number of days per week on a scale of 0–7. Note that this response scale will not allow for direct comparison with the percentages provided in Table 1.

Step 2: Scoring Scales

General Diet = Mean number of days for items 1 and 2.

Specific Diet = Mean number of days for items 3 and 4, reversing item 4 (0=7, 1=6, 2=5, 3=4, 4=3, 5=2, 6=1, 7=0). Given the low inter-item correlations for this scale, using the individual items is recommended.

Exercise = Mean number of days for items 5 and 6.

Blood-Glucose Testing = Mean number of days for items 7 and 8.

Foot Care = Mean number of days for items 9 and 10.

Smoking Status = Item 11 (0 = nonsmoker, 1 = smoker) and number of cigarettes smoked per day.

Scoring for Additional Items

Recommended Regimen = Items 1A–4A and items 12A–14A, no scoring required.

Diet = Use total number of days for item 5A.

Medications = Use item 6A *OR* 7A AND 8A. Use total number of days for item 6A; use mean number of days if both 7A and 8A are applicable.

Foot Care = Mean number of days for items 9A–11A, after reversing 10A and including items 9 and 10 from the brief version.

https://www.healthline.com/health/diabetes/hypoglycemic-action-plan

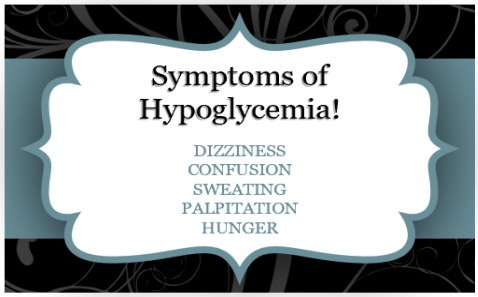
Step-by-Step Hypoglycemic Action Plan

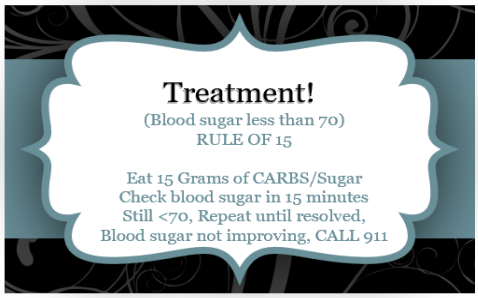
For people with diabetes, managing your blood glucose level goes beyond just making sure it isn't too high. It can also be dangerous when your blood sugar gets too low.

Low blood sugar is known as hypoglycemia. It occurs when the glucose level in your blood falls below normal. Usually, below normal means 70 milligrams per deciliter (mg/dL) or less.

Low blood sugar can happen if you take medications for diabetes that increase insulin levels in your body. If you don't treat it right away, hypoglycemia can lead to a range of serious symptoms. This includes mental confusion, seizures, brain damage, coma, and even death in rare cases.

If you're taking insulin to treat your diabetes, it is essential to have an action plan for managing a potential hypoglycemic episode.





Appendix L

Statistical Analysis Table

Demographic Data (N=4)

Gender	
Male	1
Female	2
Age	
N	4
Mean	23.5
Range	40-65
Ethnicity	
African America	2
Caucasian	2

Summary of Diabetes Self-Care Activities (4)

Participants	Gen Diet	Gen Diet	Specific Diet	Specific Diet	Exercise	Exercise	BG Testing	BG Testing	Foot Care	Foot Care	Smoking Status
	Pre/Post	Change	Pre/post	Change	Pre/Post	Change	Pre/Post	Change	Pre/Post	Change	(1) Yes/ (2) No
1	6/4, 6/4	-2,-2	6/2, 3/5	-4,+2	0/3, 1/3	+3,+2	7/7, 7/7	0,0	4/7,4/7	+3,+3	0,0
2	0/0, 0/3	0, +3	0/0, 0/7	0, +7	7/0, 7/0	-7,-7	7/7, 7/7	0,0	0/0, 0/0	0,0	0,0
3	4/4, 3/3	0,0	4/3, 3/3	-1,1	5/5, 3/1	0, -1	5/3, 1/3	-2,+2	5/0, 5/0	-5,-5	0,0
4	6/6, 6/6	0,0	7/1, 5/1	-6,-4	5/3, 4/3	-2,-1	7/7, 7/7	0,0	3/3, 4/3	0, -1	1,1

∗ Number of participants with pre- and post-intervention data

** Descriptive statistics was used to calculate the results of this pretest-posttest design with a small sample size. The SDSCA tool shows the total calculated scores pre- and postintervention of the five variables related to the questionnaire items (diet, exercise, blood glucose testing, foot care, and smoking status).

Faculty DNP Project Proposal Letter

UMKC School of Nursing and Health Studies

June 28, 2020

UMKC DNP Student, Kamaria Harris

Congratulations. The UMKC Doctor of Nursing Practice (DNP) faculty has approved your DNP project proposal, *Hypoglycemia Management in Primary Care*

You may proceed with IRB application or quality improvement approval.

Sincerely,

Lyla Lindholm, DNP, RN, ACNS-BC
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MSN-DNP Program Coordinator
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