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Diabetes Self-Management Education and Support: Understanding Knowledge and the Impact

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DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT: UNDERSTANDING KNOWLEDGE AND THE IMPACT

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ABSTRACT

Diabetes has reached epidemic proportions in the United States. To address this, many organizations employ diabetes self-management education and support (DSMES) programs to aid in managing the impact of increasing prevalence. The purpose of this dissertation is to examine the impact of two Upstate South Carolina DSMES programs on several process and outcome measures for adults with diabetes, while also identifying current primary care provider DSMES knowledge and perceptions in an Upstate South Carolina health system.

This dissertation found inconclusive results of the impact of DSMES on PCP utilization, retinal exam screening, nephropathy attention, HDL, LDL, TC, and TG. DSME was found to reduce A1C and BMI over time. Additionally, providers were found to be lacking knowledge of the appropriate times to refer individuals to DSMES. Providers sought bilateral, closed-loop communication from DSMES team.

In general, further studies should determine if these results hold with a larger sample size. Additionally, primary care providers should be further educated on how, when, and whom to refer to the service. While national DSMES programs should aim to further incorporate primary care providers in the program.

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CHAPTER ONE

INTRODUCTION

Overview

In the United States in 2018, there were 34.1 million adult Americans with diabetes, yielding a national prevalence rate of 13%.[1] Of the 34.1 million adults with diabetes, it is estimated that 7.3 million of them are unaware they have this condition.[1] These crude estimates show that approximately 1 in 5 adults are unaware they have diabetes.[2] Over the past 20 years, the national diabetes prevalence rate has doubled.[3,4]

The national trend for this chronic condition holds for South Carolina. South Carolina had the 8th highest diabetes prevalence in the nation in 2018.[5] In 2018, an estimated 531,143 South Carolina adults (13.3%) had diabetes compared to 205,236 adults (7.1%) in 2000.[4] In 18-years, the prevalence of diabetes in the state has doubled.

While South Carolina does not have the highest prevalence of diabetes in the nation, this chronic condition has been rising throughout counties in the state. Presently, only values for self-reported diabetes diagnosis are available for county-level data in South Carolina via the Center for Disease Control and Prevention's (CDC) Behavioral Risk Factor and Surveillance System (BRFSS). In 2017, the self-reported diabetes diagnosis prevalence for adults 20 years old or older in Greenville County was 10.9% compared to 8.9% in 2008.[4,6] This percentage is likely an underestimation of the actual prevalence of people living with diabetes in Greenville County given 20% of adults are unaware they have diabetes.

With the diabetes prevalence in Greenville County mirroring South Carolina and the rest of the nation, understanding the extent of the impact of diabetes and how Diabetes Self-Management Education and Support (DSMES) can address the impact of diabetes is imperative. From 2014 to 2016, there was a 12.68% increase in ED visits with diabetes listed as a diagnosis in the United States.[1,7] Of the 16 million ED visits in 2016, 59% were considered to be treated and released.[1] For the 59% treated and discharged, DSMES could provide these individuals with the necessary information and confidence to mitigate the problem before it escalates to the point of needing emergency attention.

In South Carolina, the total healthcare expenditure related to diabetes in 2017 was estimated to be $4.3 billion in direct costs and another $1.6 billion in indirect costs, totaling $5.9 billion for the state.[8] Annual expenditure for individuals with diabetes is approximately 2.3 times higher than for someone without this disease.[8] With prevalence on the rise, health care expenditures related to diabetes are expected to continue increasing.

Given the burden of diabetes, many organizations have taken steps to implement DSMES programs. DSMES, composed of Diabetes Self-Management Education (DSME) and Diabetes Self-Management Support (DSMS), is a process that provides initial and ongoing education and support to facilitate individuals with diabetes in learning or maintaining the knowledge and skills necessary to manage their condition. [9–12] This critical service teaches skills such as informed decision-making and problem-solving

while incorporating individual experiences/situations, goals, and current needs to assist the person with diabetes to obtain optimal self-management. [9–12] DSME is known as "the active, on-going process of facilitating the knowledge, skill, and ability necessary for diabetes self-care," while DSMS "refers to the support that is required for implementing and sustaining coping skills and behaviors needed to self-manage on an on-going basis." [13] Research has shown that DSMES is associated with improved diabetes knowledge and self-care behaviors, quality of life, lower A1C, reduced hospitalizations, and health care costs. [9–12] Despite the known benefits, DSME utilization has been consistently low. Within the first year of diabetes diagnosis, less than 5% of Medicare beneficiaries and 6.8% of privately insured individuals receive this service. [9,14] For individuals under or uninsured, utilization is likely even lower.

Problem Statement

While DSME is considered the gold standard for developing and ongoing education of crucial diabetes self-management behaviors, this service is not easily accessible due to barriers such as lack of awareness, geographical access, financial costs, and other social determinants of health. Despite the known benefits of DSME for diabetes management, utilization of this service remains low for the population.

Another more easily accessible option for individuals is diabetes self-management support. The two services are complimentary but seek to provide different education and support for individuals on their diabetes journey. While DSMS options are more widely

accessible with fewer barriers, barriers still exist for many individuals, resulting in their inability to obtain this service.

This creates three distinct groups for analysis, individuals who obtain DSME, individuals who obtain DSMS, and individuals who have not received either service. The goal is to examine how process measures, such as primary care utilization, nephropathy attention, and retinal exam, and outcome measures, such as BMI, A1C, LDL, HDL, total cholesterol, and triglycerides, differ for the three groups to understand better if there are significant practical and statistical differences. In addition, to better understand low utilization of DSME, a preliminary assessment of primary care provider knowledge of the service will be explored.

Dissertation Aims

The purpose of this dissertation is to examine the impact of two Upstate South Carolina DSMES programs on several process and outcomes measures for adults with diabetes while also identifying current primary care provider DSMES knowledge and perceptions in an Upstate South Carolina health system. This dissertation will have two empirical studies (Aim 1 and Aim 2) with a complimentary mixed methods study design (Aim 3).

This dissertation serves to:

- Describe the impact of an upstate South Carolina ADA-Accredited DSME program and a community-based DSMS program on three diabetes management

process measures: retinal exam, nephropathy attention, and primary care service utilization. (Aim 1)

- Describe the impact of an upstate South Carolina ADA-Accredited DSME program and a community-based DSMS program on six diabetes management outcome measures: A1C, body mass index (BMI), triglycerides, low-density lipoprotein (LDL), high-density lipoprotein (HDL), total cholesterol. (Aim 2)
- Identify primary care providers' knowledge and perceptions of DSMES in one South Carolina health system. (Aim 3)

Dissertation Organization

This dissertation is organized into seven chapters. This chapter and chapter 2 provide the introduction and background to diabetes, DSMES, and diabetes management. Chapter three outlines the methodology employed for each study. Chapters four, five, and six explore each of the respective studies. Lastly, chapter 7 will provide the overarching conclusions found in this dissertation from each of the studies.

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CHAPTER TWO

BACKGROUND AND LITERATURE REVIEW

Diabetes is a complex, chronic condition where the body's blood glucose level is too high due to insulin inefficiency or lack of insulin production. There are two paths to become diagnosed with diabetes. The first path is the clinical manifestation of hyperglycemia with a random plasma glucose test of ≥ 200mg/dL. [1–4] The other path involves two abnormal test results from a sample or two separate samples. [1–4] The tests used for this diagnosis are fasting plasma glucose (FPG), oral glucose tolerance test (OGTT), and A1C. [1–4] A FPG ≥ 126 mg/dL after an individual fasted for at least 8 hours is considered diabetes. [1–4] In an OGTT, 2-hour plasma glucose (2-h PG) is collected after an individual consumes 75g of anhydrous glucose dissolved in water. [1–4] A 2-h PG ≥ 200mg/dL during an OGTT is considered diabetes. [1–4] The last test is an A1C, where A1C ≥ 6.5% is considered diabetes. [1–6] Once someone is diagnosed with diabetes and receiving care from their provider, the journey of glycemic control and management begins.

As stated in chapter 1, the prevalence of diabetes in the United States is drastically increasing. Simultaneously as the prevalence of diabetes has increased, healthcare expenditure surrounding this disease has risen. National healthcare expenditures associated with diabetes management for diagnosed and undiagnosed diabetes totaled almost $359 billion in 2017. [7] This equated to an annual burden of

$13,240 and $4,250 for diagnosed and undiagnosed diabetes, respectively. [7] The excess diabetes-associated medical costs per person increased from $8,417 in 2012 to $9,601 (in 2017 dollars).[8]

Screening and Management of Diabetes

To further understand the impact of the increasing burden on diabetes on individuals and the health system, a discussion of the complexity of diabetes management is crucial. This disease has micro and macrovascular complications, such as retinopathy, neuropathy, heart attack, stroke, kidney failure, and others. [8,9] While the criteria for providing a diabetes diagnosis is standardized, initial screening for this condition in asymptomatic adults is inconsistent, and clinical guidelines vary. In general, a cost-effectiveness study found that diabetes screening every three years beginning at age 45 is very cost-effective compared to no screening. [10] The ADA supports the screening of asymptomatic adults starting at age 45, but earlier screening is recommended if individuals present with risk factors. [4] Screening of adults can include the use of the ADA Risk Test or bloodwork, as discussed above. [11]

Once a person is diagnosed with diabetes, disease management begins. Depending on the type of diabetes, medical management will differ. If an individual is diagnosed with type 1 diabetes, insulin will be a necessary aspect of management. For individuals with type 2 diabetes, initial management is dependent on individual factors. Management for T2DM may include medications, such as GLP-1 RAs, DPP-4 inhibitors, SGLT2

inhibitors, lifestyle modifications, or a combination of medication and lifestyle modification. [12] Regardless of medication management decisions between the patient and provider, screening for complications is a necessary component of diabetes management. Retinal exam, nephropathy screening, BMI, A1C, and lipid panels are some of the crucial aspects of management.

Recommendations for Diabetes Self-Management: Key Factors to Assess and Control

A retinal exam, also referred to as a dilated eye exam or dilated retinal exam, is when an individual has their pupil dilated so the ophthalmologist or optometrist, can examine the optic nerve, more specifically, the retina. [13] Sometimes, primary care providers will do this process and share the images of the retina with an ophthalmologist or optometrist. This retinal exam is screening for diabetic retinopathy. Diabetic retinopathy is a microvascular complication where the retina has been specifically altered. [14] Developing diabetic retinopathy has various risk factors, such as duration of diabetes, hypertension, and genetic factors, but the most commonly known risk factor is hyperglycemia. [14] The high glucose levels block the blood vessels going to the eye causing it to leak or bleed. [14,15] Retinal exams are recommended to occur within five years of disease onset for type 1 diabetes and at disease diagnosis for type 2 diabetes. [16] For individuals with diabetes, the ADA Standards of Care in Diabetes – 2021 recommends screening every 1 – 2 years if there is no evidence of retinopathy present at the last exam and glycemia is well-managed. [14,16] If glycemia is not well-managed, retinal

exams will need to be conducted at least annually, but likely more frequently, depending on the rate of disease progression. [16]

Nephropathy attention and nephropathy screening are the terms used to indicate screening for chronic kidney disease. [16,17] Chronic kidney disease attributed to diabetes is called diabetic kidney disease, but many practitioners use these two terms interchangeably. [16–19] Common names for this condition are diabetic kidney disease, DKD, chronic kidney disease, CKD, kidney disease of diabetes, or diabetic nephropathy. [16,17,17,19,20] Diabetic kidney disease is when the kidneys are damaged and cannot filter to remove waste as efficiently. [19–21] A method to diagnose this condition is by the presence of albuminuria (protein) in the urine. [16,21] Tests to determine kidney function via urine are urinary albumin-to-creatinine ratio (uACR) and urine albumin. [28,32] Another method utilized to test kidney function is a blood test. Blood tests to determine kidney function via a blood sample are glomerular filtration rate (GFR), serum creatinine, or blood urea nitrogen (BUN). [16,20–23] Estimated GFR (eGFR) can be calculated from serum creatinine with other body measures. [16,21–23] Another test that requires both a blood and urine sample is creatinine clearance. [21,23] Guideline-appropriate screening for CKD involves eGFR and uACR. [16] Nephropathy attention is recommended at least once annually for people with type 2 diabetes and people with type 1 diabetes with a duration of 5 years or more. [16–20] Nephropathy screening may be required more frequently than once annually, depending on the lab values of these tests. [16,19]

A1C is also commonly called hemoglobin A1C, HbA1c, glycated hemoglobin, or glycosylated hemoglobin. [1,5] A1C is an average measure of an individual's blood glucose level over the last two to three months. [2,3,5,6] A1C testing is considered part of routine diabetes management. [2,5,24] Recall, an A1C≥6.5% is when an individual is diagnosed with diabetes. For the majority of non-pregnant adults, the optimal A1C goal is <7.0%. [24] For adults with a shorter life expectancy or complicating factors, a less strict goal of A1C<8.0% may be used. [24] While these are the targets for glycemic management for adults, very poor control is often defined as having A1C>9.0%. [25] For individuals meeting their treatment goals and considered to have stable glycemia, the ADA Standards of Medical Care for Diabetes (SOC) recommends that glycemic status be assessed at least twice annually. [24] For individuals who are not meeting their treatment goals or their therapy has recently been modified, ADA SOC recommends that glycemic status be assessed at least quarterly and as needed. [24] These are the minimum standards for management. The frequency of testing should depend on the clinician's judgment, the current treatment regimen, and the overall clinical situation. [24]

To understand the importance of glycemic control, in 2016, there were 16 million ED visits for adults where diabetes was listed as a diagnosis. [8] Of the 16 million ED visits in 2016, 235,000 were for hypoglycemia, and 224,000 were for a hyperglycemic crisis. [8] These two potential occurrences within daily diabetes management accounted for 2.87% of the ED visits. Hypoglycemia is a condition where the blood glucose level is lower than normal. [24,26,27] There are various levels of severity for hypoglycemia that have different

symptoms and require different treatment. [24] For the individuals that were there for hypoglycemia, 71.0% were treated and released. [8] This equates to 166,850 visits or 1.04% of the total ED visits in 2016. Hypoglycemia is considered the major limiting factor for the glycemic management of diabetes. [24] This factor is mainly preventable if the person knows how to identify the symptoms and treat accordingly. Symptoms may include shakiness, sweating, chills, dizziness, weakness, confusion, and in severe cases, seizures or loss of consciousness.[24,26,27]

Body mass index, also referred to as BMI, is a measure of body fat on an individual based on height and weight. While BMI is not a direct measure of body fat, studies have found it moderately correlated with direct measurements. [28] The two common ways to calculate BMI are using kilograms (kg) and meters (m):

$$weight\ in\ kg \Big/ [height\ in\ m]^2$$

or pounds (lb.) and inches (in):

$$\left(weight\ in\ lb \Big/ [height\ in\ in]^2\right) \times 703$$ [28].

As BMI increases, this states the individual has a higher amount of body fat. Increased BMI is a common risk factor for developing diabetes. [1,4,28,29] BMI is a value that should be assessed at every patient contact. [18] It is recommended that overweight or obese individuals lose weight to aid in managing type 2 diabetes. [30]

Lastly, a common acronym that is discussed with people with diabetes is the ABCs of diabetes. The ABCs of diabetes stand for: A – A1C, B – Blood pressure, and C – Cholesterol. As stated above, for most individuals, their doctors recommend an A1C < 7.0%. [31,32] This will vary by individual, but all individuals are recommended to speak to their doctor about their specific goal. [31,32] For blood pressure, it is recommended to be less than 120mmHg / 80mmHg, but it can vary, similar to A1C, individuals are recommended to speak to their doctor about their specific goal. [32] For the C in ABC, cholesterol, the four measures checked in a lipid panel are total cholesterol (TC), low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides (TG). Lipid management is a crucial aspect of diabetes management. Each component of the lipid panel measures different aspects of the overall cardiovascular health of the individual. The lipid panel measures the good and bad cholesterol, or fat, in the blood. [33,34]

LDL, also called LDL-C, is commonly referred to as bad cholesterol for its critical role in the development of atherosclerosis, which is the narrowing of arteries through fatty buildup. [35] In general, the ADA recommends that an individual's have an LDL < 100 mg/dL. [32,36] This level is selected given that individuals with diabetes are considered at high risk for atherosclerotic cardiovascular disease (ASCVD). However, this recommended level may vary depending on ASCVD risk factors, such as obesity, acute coronary syndrome, hypertension, smoking, low HDL, family history, and diabetes management. [37,38] Diabetes-specific ASCVD risk factors include long diabetes duration, retinopathy, neuropathy, low eGFR, or albuminuria. [39] The American Association of

Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) recommend that very high-risk individuals (i.e., diabetes with at least one ASCVD risk factor) have an LDL-C < 70 mg/dL. [38] For individuals at extreme risk (i.e., diabetes with two or more ASCVD risk factors), AACE and ACE recommend they have an LDL-C < 55 mg/dL. However, individuals are not expected to obtain these levels through lifestyle modification alone. Statin therapy is a crucial aspect of lipid management.

Given the high risk for ASCVD that people with diabetes have due to their disease, a common way to reduce this risk is the addition of statin medications to disease management. Statins are a class of lipid-lowering medications that aim to reduce an individual's LDL-C. [36,38–40] Examples of these medications include brand names such as Lipitor, Crestor, and Zocor. [41] For individuals less than 40 years old with diabetes and no ASCVD risk factors, statin therapy is not presently recommended. [38] However, if these individuals have at least one ASCVD risk factor, statin therapy is recommended to be initiated. [38,39] Once an individual turns 40, regardless of the presence of ASCVD risk factors, AACE, ACE, American College of Cardiology (ACC), and ADA all recommend beginning statin therapy. [38,39] The management may vary from moderate-intensity to high intensity or could include the addition of non-statin medications depending on an individual's life stage or if treatment goals are not being achieved. Once statin management is initiated or modified for an individual, it is recommended that lipids be assessed four to twelve weeks after and annually to verify that treatment goals are being met. [36,42]

HDL, also called HDL-C, is commonly referred to as good cholesterol because of its protective effect against ASCVD by bringing the LDL to the liver to be processed. The ADA recommends that women have an HDL > 50mg/dL and men have an HDL > 40mg/dL. [36,42] When an individual begins statin therapy to decrease their LDL, a secondary factor found is a marginal increase in HDL level. [36,40,41,43] These increases have been found to be unrelated to the decline in LDL. [41,43] However, physical activity has been shown to increase HDL levels for individuals. [36,42,43] The HDL level can play a role in the determination of the intensity of statin management initiated. [39] With the statin-induced increase in an individual's HDL, literature shows that regardless of medication intensity, there is a correlated reduction in triglycerides levels. [41,43]

Another component of the lipid panel is triglycerides. Triglycerides store the excess energy in your body from your diet and are the most common type of fat. The ADA recommends that an individual's TG < 150mg/dL. [32,36,42] While statin therapy has been shown to aid in the reduction of TG levels, lifestyle modifications, such as diet and physical activity, have been proven to be highly effective in decreasing the level. [36,42] When the TG levels go above 150mg/dL, the individual has a condition called hypertriglyceridemia. [42,44]

Hypertriglyceridemia is a condition where an individual's TG level is above 150mg/dL. [36,42,44] As with other conditions, hypertriglyceridemia has varying levels. Mild

hypertriglyceridemia is defined as a TG level of 150mg/dL - 175mg/dL, moderate is 175mg/dL - 499mg/dL, while severe is ≥ 500mg/dL. [42,44] For individuals with mild or moderate hypertriglyceridemia, ADA, ACC, American Heart Association (AHA), and the Endocrine Society recommend lifestyle modifications, such as losing weight, reducing alcohol consumption, increasing physical activity, and limiting saturated fat intake. [36,39,42,45] If an individual has severe hypertriglyceridemia, pharmacological intervention may be necessary, but a reduction in dietary saturated fat is recommended to prevent pancreatitis. [36,39,42,45] Statin therapy may also be added for individuals with hypertriglyceridemia due to its secondary effect of reducing TG levels. [36,39,42,45]

Lastly, total cholesterol is the sum of LDL and HDL. Presently, ADA and AHA recommend that individuals with diabetes have a TC level < 200mg/dL. [32] In the 2018 AHA and ACC Task Force guideline report suggested a stricter goal of <150mg/dL, with the idea that 100 is attributed to the LDL at maximum. [39] In general, clinicians often pay more attention to the actual LDL and HDL values rather than this composite score when making clinical decisions. Overall, similarly to A1C and blood pressure, lipid panel value goals may vary by individual, so it is recommended that individuals consult with their provider to determine their specific goals.[32,36,42]

Understanding Diabetes Self-Management Education and Support

Diabetes self-management education and support (DSMES) programs are available to individuals with diabetes to aid in developing or maintaining the knowledge,

skills, decision-making, and skills necessary for the self-management of diabetes. [46–48] However, social determinants of health have played a critical role in lowering the utilization of these types of programs. Diabetes self-management education (DSME) is known as "the active, on-going process of facilitating the knowledge, skill, and ability necessary for diabetes self-care." [49] Diabetes self-management support (DSMS) "refers to the support that is required for implementing and sustaining coping skills and behaviors needed to self-manage on an on-going basis." [49] DSMES is the combination of these two necessary components that allow services, programs, or departments to address the variety of individual factors, such as health beliefs, health literacy, social support, that impact an individual's ability to self-manage their condition. [46–49]

Formal diabetes self-management education, DSME, is recommended at four key points: 1.) at diagnosis, 2.) annually and/or when the individual is not meeting treatment target goals, 3.) when complicating factors arise, and 4.) when transitions in care or life occur. [46–48,50] DSME is one-on-one, individualized care with a Certified Diabetes Care and Education Specialist (CDCES) or Board Certified in Advanced Diabetes Management (BC-ADM). [46–48,50] Some education may be delivered in group settings though. This service is billed through insurance, making this a substantial barrier to service uptake. [46–48,50] The number of hours covered by insurance varies by insurance plan. Many individuals lack insurance, [48,50–52] cannot afford the associated cost, [46,48,50,53] do not have the time, [46,48,50,52] and many other obstacles to obtaining DSME.

Impact of DSME on Process Measures

Effect of DSME on Primary Care Utilization

Obtaining DSME can be beneficial for patients in various aspects of patient care and diabetes management. Several process measures of interest are primary care utilization, retinal exams, and nephropathy attention. Primary care utilization is a process measure that can be impacted by an individual obtaining DSME. A randomized controlled trial evaluating a telephonic support DSME versus standard DSME found a higher number of federally qualified health center (FQHC) visits from the intervention group than the standard DSME group. [54] Similarly, A cross-sectional study using BRFSS data in South Carolina found that DSME attendance had an impact on having an annual primary care provider (PCP) visit. [55] Lastly, an observational study for individuals in a certain health system found that the intervention resulted in an increase in PCP usage. [56] This increased contact with PCPs allows for more collaboration and potentially better management of their condition.

Effect of DSME on Retinal Exam Screening

Another process measure is obtaining a retinal exam. Utilization of DSME had mixed effects on obtaining an individual's retinal exam. However, it is important to note, a systematic review of the cost-effectiveness of ADA recommendations found telemedicine for diabetic retinopathy screening to be cost-saving. [10] Two RCTs were conducted that examined the impact of DSME on obtaining an annual retinal exam. The first randomized controlled trial discussed above that evaluates a telephonic support

DSME versus standard DSME found no significant difference in obtaining a retinal exam. [54] In contrast, the 1-year telecare DSME RCT found that 42.4% more individuals in the treatment group reported receiving a retinal exam during the twelve months than those in the control group. [57] Similarly, a nested, case-control study found that individuals who received DSME were 1.5 times more likely to improve in their diabetes bundle measure (blood pressure, nephropathy screening, retinal exam, LDL, & A1C). [58] A feasibility study found that during the 9-month study period 67.7% of the population obtained a retinal exam. [59] Other researchers utilized BRFSS to examine the impact of DSME on obtaining an annual retinal exam. A study using South Carolina BRFSS data found that DSME attendance and other factors, such as age, educational attainment, and insurance status, had a significant impact on receiving an annual retinal exam. [55] Conversely, the Florida BRFSS cross-sectional study found that DSME attendance or the number of hours had no impact on obtaining an annual retinal exam, but insurance status and age impacted the likelihood of obtaining an annual retinal exam. [60] Overall, the literature showed a significant impact of DSME on the likelihood of individuals obtaining a retinal exam.

Effect of DSME on Nephropathy Attention

Another critical screening assessment that is a necessary component of diabetes management is nephropathy screening. Several studies found they could positively impact nephropathy screening or levels. The Microalbuminuria Education Medication and Optimization (MEMO) randomized control trial found that an intensive, structured

DSME could provide improved uACR and eGFR at 3 and 4 years, respectively. [61] Another RCT found that the treatment and control group both has significant within-group declines in creatinine. [62] However, a telecare DSME 1-year randomized control trial found that the telemedicine DSME did not show significant improvements in uACR. [57]

Other interventional studies found promising results for the impact of DSME on nephropathy screening and outcomes. A collaborative chronic care management model found significant improvements in eGFR values over 12 months, but no significant changes in microalbumin or BUN levels. [63] A nested case-control study found that those individuals who obtained DSME were 1.5 times more likely to obtain nephropathy screening as measured as part of their diabetes bundle. [58] One study found that 73.2% of participants had their microalbumin assessed by 9 months. [59] Another DSME intervention found that uACR was trending downward and towards significance. [64]

A systematic review of the cost-effectiveness of ADA recommendations found that multi-component interventions targeting comorbidities of diabetes along with angiotensin-converting enzyme (ACE) inhibitors/angiotensin II receptor blocker (ARB) medications to prevent CKD in individuals with albuminuria are cost-saving measures for people with diabetes. [10] It should be noted, presently guideline-concordant screening for CKD by PCPs is alarmingly low in the nation with 19.6% - 51.6% of individuals obtaining screening consistent with ADA recommendations. [65,66]

Impact of DSME on Clinical Measures

Effect of DSME on A1C

A commonly known aspect of DSME is its ability to aid in the reduction of A1C. The ADA SOC Chapter 5 dives into the improvement of health outcomes by outlining the benefits of DSME.[48] The literature discussed in this section shows the various randomized control trials, quasi-experimental studies, cross-sectional studies, and systematic reviews done boasting the positive impact of DSME in reducing A1C from 0.5% up to 2.1%, but not all programs showed reductions in A1C. This section will discuss the articles evaluating the impact of DSME on A1C that did and did not show reductions.

Numerous randomized control trials (RCT) have been conducted to determine the efficacy of various DSME programs on A1C reductions. A systematic review and meta-analysis for DMSE RCTs for T2DM patients across the globe found that 85% of the studies had a reduction in A1C with a standardized mean difference of -0.604%. [67] A community-based pharmacist-led DSME RCT found that the intervention group had a 1.03% A1C reduction at post-intervention. [68] Some of the RCTs employed nutritional education components as part of the DSME provided. A 3-arm RCT found that individuals with an A1C from 7-10% participating in nutritional education on carb counting or plate method as part of DSME could significantly reduce A1C (-0.86% & -0.76%, respectively) compared to the control group. [69] Another RCT found significant

within-group reductions in A1C at the three-month follow-up point, with the mindful eating intervention showing a greater A1C reduction (-0.83%) than smart choices DSME-based education (-0.67%). [70] Similarly, an RCT conducted in local food banks found that individuals fully engaged in the intervention had an A1C 0.64% lower at follow-up. [71]

Another area commonly studied to determine DSME effectiveness is telehealth. One RCT evaluating a telephonic support DSME vs. standard DSME found significant A1C improvements for both arms (I= -1.7% & C= -1.4%). [54] Similarly, a small sample mHealth application RCT found the intervention group had a 0.3% decline in A1C. [72] Another small sample RCT evaluating a DSME calendar application found the application significantly lowered A1C by 1.10% compared to a control group. [73] A digital health coaching 3-arm RCT did not find significant differences between the arms, but when the samples were pooled together, the population did have a -0.793% A1C reduction. [74] Lastly, in South Carolina, a telecare DSME 1-year RCT found the telemedicine DSME provided significant improvements in A1C (-1.2%), where A1C continued to stay lower in the intervention group at 24mths.[57]

A RCT comparing two DSMS models after DSME found that the peer-led intervention had a 0.7% A1C reduction post-DSME refresher compared to -0.5% for the community health worker (CHW) DSMS group, where the peer-led A1C reduction was sustained at 18 months from baseline (-0.6%).[75] Another RCT found that both the DSME-managed and PCP-managed groups had significant A1C reductions (-0.98% and -

0.68%, respectively). [76] This RCT tested DSMS delivered by various providers after DSME, where all groups had significant A1C reductions ranging from 0.73% to 1.01%, with peer and usual care groups boasting the largest reductions. [77] This RCT of DSME followed by a DSMS social support group found that after DSME, individuals had a significant improvement in their A1C levels but it was not sustained with the social support group DSMS follow-up. [78] The Microalbuminuria Education Medication and Optimization RCT found that an intensive, structured DSME could provide a long-term impact on A1C (-0.4%). [61] Conversely, a culturally-tailored DSME RCT found that individuals in the intervention group had a 1.5% A1C reduction at ten months.[79] Similarly, a community-based, 15-month, small RCT found the group that received diabetes group education had a 1.2% decrease in A1C compared to increases in the control group.[80] While that study showed significant reductions in the group education DSME, another study did not boast those results. This DSME study found that individual education results in a greater A1C reduction (-0.51%) than group education (-0.27%) with usual care having a 0.24% reduction. [81] An RCT comparing standard DSME to motivational interviewing DSME that sought to aid in addressing diabetes-related emotional distress found the motivational interviewing DSME had a smaller A1C reduction of 0.41% compared to 0.58% at 6 months for the standard DSME group. [82]Lastly, a group-based DSME RCT found a significant within-group A1C reduction of 0.9% for individuals with an A1C>7.7%, while the control group boasted a 0.3% increase in A1C.[62]

Rather than employing RCTs to examine the effects of various DSME interventions, other researchers conducted quasi-experimental designs. Two studies focused on the impact of nutritional DSME on A1C. A pilot study in food banks providing access to fruits and vegetables found that individuals with A1C > 7.5% at baseline had a 0.48% reduction, with all individuals having a mean 0.15% reduction in A1C. [83] Another intervention comparing diabetes consultations and DSME interventions delivered via telehealth found significant A1C reductions of 2.1% and 1.5% with diabetes consultation and DSME interventions, respectively [84]. This study found that embedding a CDCES in primary care practices with a standardized treatment intensification protocol led to a 1.1% A1C reduction. [85] While an insurer-based DSME found a 1.1% A1C reduction at 12 months. [86]

Other DSME interventions focused on community-based interventions. A community health worker-led DSME program in the community found the average A1C went from 8.7 to 7.4% at the one-year post-program follow-up. [87] Another community-based DSME intervention found a significant 0.55% reduction in A1C. [88] While a different community-based DSME study found the DSME group to have better 3-year A1C outcomes with a mean difference of -1.1% in their A1C compared to the control group. [89] A longitudinal, prospective cohort design study supplying DSME to home-based individuals via telehealth found that this care model had a significant A1C reduction of 1.6% over the year-long study. [63]

Another approach for many researchers to evaluate the impact of DSME on A1C was delivering a combination of DSME and DSMS. An intervention involving DSME followed by DSMS among T2DM veterans found the largest A1C reduction after completing DSME (-0.64%) with a non-significant post-DSMS A1C decline. [90] However, as the total number of classes increased, the larger the A1C decline for the post-DSME DSMS program. [90] A context-tailored intervention with DSME and DSMS components found that A1C was reduced from 7.7 to 6.9, whereas males showed a significant decline from 7.5% to 6.8%. [91] Other researchers evaluated an intervention testing a treatment of DSME followed by peer-led DSMS compared to an enhanced usual care group of DSME followed by DSMS. This intervention found significant, sustained reductions in A1C for both the treatment and enhanced usual care groups of -0.2%, where individuals with a baseline A1C > 8.0% had reductions of -0.6% for the treatment group and -0.43% for the enhanced usual care control group. [92] Another study found that individuals who attended the novel "speed-dating" DSMS intervention to augment traditional DSMES had significantly greater improvements in A1C compared to traditional DSMES alone (-1.2% vs 0.9%, respectively), with a greater percentage having an A1C<8.0. [93] A retrospective chart review of a DSME then DSMS intervention including healthy cooking classes found that the telehealth delivered DSME portion of their intervention had a 0.88% A1C decline that was maintained during the DSMS component. [94]

Other researchers sought to examine the effectiveness of DSME in marginalized populations, such as low-income individuals or African Americans. A DSME

intervention with community health center patients found a 1.6% A1C reduction within the small sample of fifteen adults. [95] A study assessing the feasibility and effectiveness of delivering telehealth DSME for older adults immediately post-hospitalization found that A1C declined by 1.1%; however, insulin use increased for the small sample of older adults. [96] Another study amongst low-income, minority individuals found that a multisession DSME program reduced A1C by 0.82%. [97] Similarly, a DSME program implemented in an ethnically diverse population in New Zealand had a 0.4% reduction in A1C after three months. [98] A DSME specifically evaluating the effect of DSME on African-American individuals found a significant six-month A1C reduction of 0.7% compared to the standard of care. [99] Lastly, a resilience-based DSME feasibility study for African Americans found that 11% more individuals in the treatment group met the A1C goal of less than 7.0%, showing promise for scaling this intervention. [100]

Some researchers studied the impact of a structured, group-based DSME intervention on A1C and found an A1C reduction of 0.45% at the 6-month follow-up. [64] While another study compared the impact of the addition of motivational interviewing to DSME, finding that the standard DSME had a greater A1C reduction of -0.78% compared to -0.37% for the DSME with motivational interviewing. [101] This quasi-experimental study of the impact of motivational interviewing showed similar results to the RCT examining adding motivational interviewing to DSME.

Instead of conducting an interventional study, many researchers opted to conduct cross-sectional studies, employing research designs, such as retrospective chart reviews and nested case-control studies. An observational study for individuals in one health system found that the DSME intervention resulted in a 0.5% A1C reduction, but the matched control group had a larger A1C reduction of 0.7%. [56] Similarly, a nested case-control study found that individuals who obtained DSME were 1.5 times more likely to improve their diabetes bundle (blood pressure, nephropathy screening, retinal exam, LDL, & A1C) and 2.8 times more likely to have a greater A1C reduction. [58] A cross-sectional study of hospital inpatients found that those without a prior history of DSME had A1Cs 0.86% higher. [102] After a two-year DSMS intervention, this one-year follow-up had no significant A1C reductions during the intervention but found a 0.93% A1C reduction during follow-up. [103] Another study compared two DSME delivery methods and found an A1C of -1.02% for telemedicine and -1.42% for the face-to-face method. [104]

Researchers at various health systems elected to conduct retrospective chart reviews. Researchers at one health system who did a retrospective chart review found that only 53.5% were referred to DSMES, where those who received 1hr assessments and 8hrs or more of full education had similar A1C percentage reductions (14.3% vs. 16%, respectively). [105] Another health system did a retrospective study of DSME and DSMS services at select patient-centered medical homes found that the average A1C reduction was 0.43%. [106] Lastly, one health system conducted two retrospective chart reviews. The first retrospective chart review examined the efficacy of DSME and medical nutrition

therapy on A1C reduction on a small subset of the individuals served by both programs. They found that after DSME and medical nutrition therapy, on average, an individual's A1C reduced by 1.92% after the programs.[107] The researchers conducted a follow-up study examining all patients who obtained DSME and medical nutrition therapy found that A1C reduced by 1.82% after completion of the programs. [108]

Several systematic reviews have been done to understand the impact of DSME on A1C change. These reviews have been done across the globe, and most show a significant reduction in A1C levels. One systematic review of DSME interventions found that 43.5% of studies saw improved A1C values after DSME, with 13% showing a non-significant change. [109] Another systematic review found that individuals assigned DSME in an RCT had significantly greater reductions in A1C, where the absolute reduction in A1C for all studies was 0.57%. [110] A systematic review of DSMEs in mainland China found that 90% of DSMEs significantly impacted glycemic control compared to a control group, whereas the other 10% did not compare between groups. [111] A systematic review of DSME studies in Middle East countries found that 11 showed -1.15% improvement in A1C compared to 0.08% average reduction for the control groups. [112] Lastly, a systematic review of reviews found that A1C reductions ranged from 0.1% to 0.8%, where this was the primary outcome listed in 88% of the studies. [113]

Less than a handful of studies completed a meta-analysis with no systematic review discussed in the article. The first meta-analysis found that nurse-led DSME had

significant intervention group A1C reductions of approximately -0.34%. [114] The other study that only completed a meta-analysis found that DSME case management interventions showed a mean A1C reduction of 0.89%. [115]

Commonly seen in the literature, several studies completed a systematic review and meta-analysis of the impact of DSME interventions of A1C change. A systematic review and meta-analysis of DMSE RCTs for type 2 diabetes patients found that 85% of the studies had a reduction in A1C with a standardized mean difference of -0.604%. [67] The systematic review and meta-analysis of lifestyle, DSME, and DSME + DSMS programs found greater reductions in A1C (mean difference: -0.35%) at the end of behavioral programs. [116] Another systematic review and meta-analysis of DSMES interventions for newly diagnosed T2DM individuals found a significant 12-month A1C reduction of 0.21%. [117] Lastly, a systematic review and meta-analysis of group-based DSME programs found that A1C was reduced by 0.44% at six months, with reductions increasing over time. [118]

While a large number of studies showed promising results in using DSME to aid in the reduction of A1C, not all studies showed those results. A handful of studies found no significant reductions in A1C. A pilot RCT of a diabetes program with clinical navigation showed no change. [119] A feasibility study to understand the potential impact of involving peer support in DSME interventions for South Asian descent found a 0.6% increase in A1C. [120] Another study employed a pre/post study method for a family-adapted DSME

program for Marshallese adults where they found no significant changes in A1C in individuals with diabetes or their participating family members. [121] Other researchers conducted a study of a mobile phone application addition to DSME programs in the low to middle-income counties of Congo, the Philippines, and Cambodia, did not find an increased proportion of individuals with controlled diabetes after the addition to the program of addition. [122] There were two systematic reviews done in marginalized populations. The first is a systematic review of DSME and DSMS RCTs for South Asian individuals found that three of four studies did not result in significant reductions in A1C. [123] Similarly, a systematic review of DSME interventions for Black African / Caribbean and Hispanic / Latin American women with type 2 diabetes found that only three of ten studies reporting A1C change had a decline. [124]

Factors associated with A1C Reductions in DSME Programs

While the discussed DSME studies have shown to be generally efficacious in lowering an individual's A1C, some studies compared different doses to determine if there is a dose-response relationship between DSME and A1C. However, there are discrepancies in the amount of DSME that would be optimal. A systematic review and meta-analysis found that 6-10 sessions of group-based DSME over 6-10 months would yield the best results. [118] Another systematic review and meta-analysis for lifestyle, DSME, and DSME + DSMS programs found DSME with ≥ 27 hours showed the greatest A1C reductions at the end of behavioral programs. [116] While a systematic review found that individuals assigned DSME in an RCT had significantly greater reductions in A1C,

where ≥ 10 contact hours were associated with interventions that had significant A1C reductions. [110] Similarly, another systematic review of DSME interventions for Black African / Caribbean and Hispanic / Latin American women with T2DM found that only of the 13 studies had a short duration (< 6 months) with high intensity (10 or more sessions) led to a positive success rate. [124] In contrast, a retrospective chart review found that those who received one-hour assessments and eight hours or more of complete education had similar A1C percentage reductions. [105] While a different systematic review of DSME in Middle Eastern countries found that few DSME sessions were an important factor in A1C improvement for intervention groups. [112]

Researchers also sought to examine the impact of the intervention setting on the intervention efficacy in A1C reduction. The most common setting assessed was technology-based. Telehealth interventions were found to have A1C reductions ranging from 0.1% to 1.7%. [54,113] A systematic review of reviews, [113] a brief review of literature of particular diabetes guidelines, [125] and a systematic review and meta-analysis [126] found technology-based / telehealth interventions to have stronger effect sizes and improve medication adherence in addition to A1C reductions. An example is a RCT evaluating a telephonic support DSME versus standard DSME where researchers found the telephonic support DSME had a 1.7% A1C reduction compared to a 1.4% reduction for standard DSME. [54] Another example is a 1-year telecare DSME boasting a 1.2% A1C reduction with the reduction persisting in the intervention group at 24 months. [57] Several other studies tested a new care model involving telehealth-delivered DSME, [63] an

implementation study of a person-centered communication tool, [127] a feasibility study post-hospital discharge for older adults, [96] and evaluation of a healthy cooking class with education intermixed. [94]

The next commonly examined setting for DSME interventions is the clinical setting. The clinical setting varies from outpatient hospital sites, hospital-based, clinics, or patient-centered medical homes. Of the DSME studies conducted in or examining this setting, A1C reductions ranged from 0.43% to 1.2%. [80,106] A systematic review of DSME interventions for Black African/Caribbean and Hispanic/Latin American women with T2DM found that hospital-based intervention settings aided in diabetes management for this population. [124] A meta-analysis found that case management showed a mean A1C reduction of 0.89%, where the clinical setting was a predictor of the effect size. [115] A DSME RCT feasibility study of music or music-assisted relaxation therapy conducted in outpatient hospital locations found a significant 0.793% reduction in A1C. [74] Two RCTs took place in medical clinics. The first was a 15-month RCT that found the DSME group had a significant 1.2% decrease in A1C compared to an increase in the control group. [80] The other RCT found that both the DSME-managed group had a greater A1C reduction compared to the PCP-managed group (-0.98% and -0.68%, respectively). [76] Another study examined a multi-session program among low-income minority populations in a community-based, primary care clinic and found that A1C was reduced by 0.82%. [97] Lastly, a retrospective study of DSME and DSMS at select PCMHs found that the greater

number of services provided to individuals resulted in a greater A1C decline, with the average A1C decline for all PCMHs being 0.43%. [106]

The least commonly examined setting for studying the efficacy of DSME in A1C reductions is community-based. Of the two studies conducted in this setting, the A1C reductions from the interventions were 0.55% to 1.10%. [88,89] While these studies took place in the community setting, the type of setting utilized varied by study. A RCT study conducted in a community pharmacy in Iran led by the community pharmacist found that the intervention group had a 1.03% A1C at post-intervention. [68] A marketplace clinic DSME study found the DSME group to have better 3-year outcomes for A1C (Mean difference: -1.10%), where 6-months post-intervention showed a 0.3% A1C reduction. [89] These two studies showed promising results indicating community-based locations for DSME could be efficacious.

Another area studied by researchers is the impact of the DSME intervention delivery method's impact on A1C changes. The common delivery methods assessed were individual versus group-based delivery or in-person versus via another modality. One systematic review found that DSME in Middle East countries found that employing a face-to-face delivery method was an important factor in A1C improvement for intervention groups. [112] Another systematic review and meta-analysis of behavioral interventions found greater reductions in A1C with in-person delivery methods. [116] The same systematic review and meta-analysis of behavioral interventions found the group-

based delivery method to have greater A1C reductions than individual-based methods. [116] This is congruent with another systematic review and meta-analysis that found that group-based DSME interventions reduced A1C with reductions increasing over time. [118] Similarly, a systematic review for Black African/Caribbean and Hispanic/Latin American women with T2DM found that group-based format aid in better diabetes management. [124] Lastly, as discussed above, a 15-month RCT of group-based DSME showed a significant decrease in A1C compared to the control group. [80] Overall, in-person/face-to-face, group-based DSME interventions were found to be the most efficacious delivery methods in the effort to reduce individuals' A1Cs.

Many researchers also examined the impact of the level of training of the facilitator in the role of A1C reduction for DSME interventions. A systematic review for Black African / Caribbean and Hispanic/Latin women with T2DM found dietitian-led interventions to be the most efficacious. [124] However, a systematic review of DSME in Middle Eastern countries found the pharmacist-led interventions to yield the best results. [112] As discussed above, another RCT compared the outcomes of a PCP-managed group versus a group managed by individuals on a DSME-team and found the DSME team-managed had greater A1C reductions than PCP-managed individuals. [76] Similarly, a meta-analysis found that greater A1C reductions were seen by nurse-led interventions than by PCP-led studies. [115] Lastly, a CHW-led DSME program found the average A1C reduced by 1.3% at the one-year follow-up. [87] Overall, these show that various facilitators leading DSME can show promising results in A1C reductions.

Lastly, some studies sought to examine various other potential factors. One systematic review of studies assessing the impact of diabetes distress on T1DM found high distress is related to higher A1C, where A1C improvement and diabetes self-management behaviors are influenced by diabetes distress; DSME was found to reduce diabetes distress. [128] Another systematic review and meta-analysis of DSMES apps impact on medication adherence found a positive interaction between A1C and medication adherence. [126] Similarly, a systematic review of family-supported DSME interventions found positive results for the improvement of A1C values after DSME. [109] A meta-analysis found that nurse-led case management showed an effective strategy in aiding in A1C reduction. [115] This scoping review found that PCP-led and PCP / specialist-led models of care were positively associated with an A1C reduction. [129] A small sample RCT found that those individuals in the intervention group that self-referred showed a greater decline in A1C. [72] Another small sample RCT found that while their DSME calendar application significantly lowered the A1C of the treatment group, they confirmed that insulin use is a positively associated factor in A1C reduction. [73] Lastly, a cross-sectional study of Florida BRFSS adults found that individuals with insurance have a 5.52 times greater odds of obtaining two A1C tests than someone without health insurance. [60]

Effect of DSME on Body Mass Index

Another commonly managed aspect for people with diabetes is BMI. Elevated BMI is correlated with impaired glucose intolerance and the development of diabetes in some individuals. The ADA SOC reviews the health implications of elevated BMI, such as the increased risks for non-alcoholic fatty liver disease and increased insulin resistance, in chapters 4 and 5. [18,48] The literature discussed in this section shows the various randomized control trials, interventional studies, cross-sectional studies, and systematic reviews and meta-analyses completed that boast the positive effect of DSME in reducing BMI from $0.29^{kg}/_{m^2}$ up to $2.59^{kg}/_{m^2}$, but not all studies showed reductions in BMI. One study found that individuals that were classified as overweight/obese were more likely to enroll in DSME. [130] This section will discuss the articles evaluating the impact of DSME on BMI that did and did not show reductions.

Two RCTs showed significant reductions in BMI of $0.2^{kg}/_{m^2}$ and $0.808^{kg}/_{m^2}$. One RCT compared a telephone support DSME vs standard DSM where both groups had significant BMI reductions (I = - $0.2^{kg}/_{m^2}$, C = - $0.4^{kg}/_{m^2}$). [54] A 3-arm RCT evaluating various components of DSME program augmented with music therapy and music assisted relaxation did not find significant differences between the arms, but the reductions ranged from $0.769^{kg}/_{m^2}$ to $0.819^{kg}/_{m^2}$. [74] However, when the groups were pooled together, the population did have a significant BMI $0.808^{kg}/_{m^2}$ reduction. [74]

The quasi-experimental studies found BMI reductions ranging from 0.29$^{kg}/_{m^2}$ to 2.11$^{kg}/_{m^2}$. [89,120] A community-based DSME study in marketplace clinics found the DSME group to have a better 3-year BMI reduction of 2.11$^{kg}/_{m^2}$, while boasting a mean difference of -2.59 $^{kg}/_{m^2}$. [89] Another community-based intervention found that a significant amount of individuals moved from the obese to the overweight category. [97] A peer-support feasibility study, conducted in Vancouver, found a 0.29 $^{kg}/_{m^2}$ BMI reduction at 6 weeks. [120] Other researchers conducted a pilot retrospective chart review from DSME plus MNT found that BMI reduced by 0.6$^{kg}/_{m^2}$ after the DSME portion of the study. [107] A follow-up study to the chart review with a larger sample found that BMI significantly reduced by 1.08$^{kg}/_{m^2}$ after completing DSME and MNT. [108]

Several systematic reviews were conducted. A systematic review examining DSME interventions with family-support integrated into the programs showed that 50% of the studies examining BMI had decreases in BMI. [109] This is similar for another systematic review of DSME interventions in Middle East countries, where 60% of the studies showed BMI reductions. [112] A systematic review and meta-analysis for lifestyle and DSMES programs found a mean difference of -0.51 $^{kg}/_{m^2}$ in BMI at the end of behavioral programs. [116] While another systematic review and meta-analysis for DSMES application impact on medication adherence found BMI to improve as medication adherence improved. [126]

Conversely, the majority of studies did not find significant differences in BMI. A total of thirty studies found non-significant changes in BMI after the DSME portion of the intervention. Ten RCTs found non-significant changes in BMI, where researchers were testing different facilitators and program delivery methods. [57,61,62,72,75,76,78,79,119,131] Eight interventional studies testing different facilitators or examining a particular sub-population showed no significant changes. [68,77,87,88,99,100,121,132] Four quasi-experimental studies testing different delivery methods had non-significant changes in BMI. [91,93,104,122] Three other interventional studies were assessing the impact of DSME on BMI and other measures, where it found BMI to have a non-significant change. [82,95,98] There were two cross-sectional studies that found no significant changes in BMI post-DSME. [130,133] The last three articles showing non-significant changes in BMI were systematic reviews. The first systematic review was also a meta-analysis that showed BMI to not have significantly changed in the 7 studies evaluating it at 6 and 12-months. [118] In the other systematic review, two-thirds of the studies did not show a significant change after completing DSME. [111] In the last systematic review and meta-analysis, the two studies examining BMI did not find significant changes. [117]

Effect of DSME on Low-density Lipoprotein

While A1C and BMI are two of the commonly studied, the lipid panel measures are another aspect. As discussed above, the four measures of a lipid panel are LDL, HDL, TC, and TG. Recall, each component of the lipid panel plays a critical role in the overall

health of individuals with diabetes. LDL is considered the cholesterol that aids in the development of atherosclerosis. [35] The literature discussed in this section shows the various randomized control trials, interventional studies, and systematic reviews and meta-analyses completed that boast the positive effect of DSME in reducing the LDL level from 0.33mg/dL up to 20.42mg/dL, but not all studies showed reductions in the average LDL level. This section will discuss the articles evaluating the impact of DSME on LDL levels that did and did not show reductions.

Several RCTs were conducted, and one of the many outcomes assessed was changes in LDL. Of the RCTs conducted, six showed significant reductions in LDL. The RCT showing the smallest decline of 0.33mg/dL was evaluating an intensive, structured DSME, while the largest decline of 20.42mg/dL was evaluating a DSME calendar application. [61,73] Two telemedicine RCTs showed promising results with one showing a 13.3mg/dL decline and the other finding that self-referred individuals had an 11.4mg/dL decline. [57,72] One of the RCTs found the telephone support DSME intervention and the standard DSME control group had -5.6mg/dL and -5.7mg/dL changes in LDL levels, respectively. [54] The last RCT showing significant declines in the LDL level was a culturally tailored DSME that had an 8.1mg/dL reduction at ten months. [79]

Three quasi-experimental studies found significant improvement in LDL levels. As discussed in other sections, a nested case-control study found individuals who received DSME were 1.5 times more likely to improve their LDL as part of their diabetes

bundle [58] A collaborative chronic care model has a 13.8mg/dL LDL reduction over 12mths. [63] Another study found that those who attended the augmented DSMES program had an average 24.7mg/dL reduction in their LDL level compared to a non-significant reduction for those who attended the standard DSME only. [93]

Lastly, two systematic reviews found significant reductions in LDL after DSME interventions. A systematic review of DSME in Middle East countries found that for the four studies that did pre-post comparisons of LDL, three had significant reductions ranging from 10.5mg/dL to 23.2mg/dL, but the mean difference was non-significant. [112] The other systematic review examined family support integrated with DSME where the two studies evaluating LDL showed significant reductions in the level. [109]

While several studies were able to show significant declines in LDL levels, one study found a significant increase in LDL level for the control group. A RCT of a peer-led, empowerment-based DSME program in an African American population found the control group to have significant increases in LDL levels from baseline at all time points. [131] The control group average LDL increased 5.8mg/dL, 13.6mg/dL, and 14.1mg/dL at 3, 9, and 15 months from baseline, respectively. [131]

Majority of the studies assessing LDL as an outcome did not have significant changes in the level. Twenty-one studies, ranging from randomized control trials to meta-analyses, found non-significant LDL changes. Five RCTs did not find significant changes

in LDL levels. [62,77,78,80,119] Eight quasi-experimental studies examining adapted DSME interventions or specific populations did not show significant changes. [64,88,97,99,100,120,121,134] Three quasi-experimental studies examined different delivery DSME methods found non-significant changes in LDL. [59,84,132] Three retrospective or observational studies did not find changes in LDL levels. [56,106,108] Lastly, three systematic review/meta-analyses did not find significant changes in LDL levels. [112,114,117]

Effect of DSME on High-density Lipoprotein

Another aspect of lipid management is increasing HDL for individuals with diabetes. While statin therapy can play a role in lipid management, many researchers sought to determine if different types of DSME interventions could aid in this goal. The literature in this section will cover RCTs, quasi-experimental, cross-sectional, and systematic reviews and meta-analyses that studied the impact interventions or factors have on HDL. A handful of studies showed significant positive increases, a couple showed declines, and a majority showed no significant changes in HDL after DSME completion. Of the studies showing positive changes, the increases ranged from 1.6mg/dL to 13.3.mg/dL over the study periods. [79,131] For those studies showing significant declines in HDL levels, the declines were 6.34mg/dL and 6.8mg/dL, where the 6.8mg/dL decline was seen in the control group. [73,80] While the remaining sixteen studies examining the impact of DSME on HDL found no significant changes after completion of the DSME portion of the studies. This section will discuss the articles evaluating the impact of DSME on HDL that did and did not show reductions.

Of the studies that showed increases in HDL, two of them were RCTs. The first was an empowerment-based RCT in the African American community and the intervention group had a 5.8mg/dL increase post-3-months of DSME. [131] In this RCT, the intervention group received 12-months of DSMS after DSME while the control group did not, while the treatment group did have a significant HDL increase, the control group also had a significant HDL 13.3 mg/dL increase at 15 months. [131] The other RCT was a culturally tailored DSME where individuals in the intervention group had a 1.6mg/dL HDL increase at 10 months from baseline. [79] Two quasi-experimental studies testing a telehealth network collaborative approach and a resilience-based intervention specifically in African Americans found increases of 2.2mg/dL and 7.02mg/dL, respectively. [63,100]

Initially, Marincic et al. conducted a pilot study of a retrospective chart review of outcomes from DSME+MNT and found that a small subsample had a 5.9mg/dL increase in the average HDL level. [107] After this and other promising results, Marincic et al. did a larger retrospective chart review, wherein the subsample that had lipid panel results, the average HDL level increased by 3mg/dL. [108] Other researchers conducted systematic reviews of DSME interventions to determine if they yielded positive results. A systematic review of family support integrated with DSME for individuals with uncontrolled T2DM found that for the one study that examined HDL, it increased for the treatment group after intervention participation. [109] The other systematic review of DSME programs in Middle East countries found that 50% of the studies showed a statistically significant increase in

HDL with absolute effects being 4.26 and 4.63 between the two studies showing increases. [112]

While the goal is to increase HDL levels for all individuals, two studies had the opposite effect after DSME intervention. The previously discussed small sample RCT of a DSME calendar application had an HDL decline of 6.34mg/dL in the treatment group and a 7.34mg/dL for the control group. [73] Another small RCT that lasted 15 months had no significant change for the intervention group, but the enhanced usual care group had a 6.8mg/dL decline in their HDL level. [80] While HDL levels do fluctuate over time due to various factors, these reductions were not expected by the researchers.

Another alternative that many research teams found is there were no significant changes to individuals' HDL levels after intervention completion. This was found in eighteen studies. Six of the eighteen studies that showed no significant changes were randomized control trials. [54,61,62,75,78,119] Seven of the studies were interventional designs that boasted unique program components, such as culturally-tailored DSME programs, targeted specific marginalized populations like Latino or African Americans, or family-adapted programs. [64,77,84,99,120,121,134] Only one study that showed no significant changes in HDL level employed a retrospective study design. [106] The last four of the eighteen studies that showed no significant changes were a systematic review, meta-analysis, or a combination of the two in specific aspects, such as in the Middle East, nurse-led programs, or group-based programs. [112,114,117,118]

Effect of DSME on Total Cholesterol

Total cholesterol is another aspect of lipid management for individuals with diabetes. The literature in this section will cover several RCTs, interventional, cross-sectional, and systematic reviews and meta-analyses that studied the impact interventions have on TC. Over half of the studies showed significant decreases, but many showed no significant changes in TC after DSME completion. Of the studies showing significant declines, the decreases ranged from 0.32mg/dL to 19.53mg/dL over the study periods. [61,73] While the remaining thirteen studies examining the impact of DSME on TC found no significant changes after completion of the DSME portion of the studies. This section will discuss the articles evaluating the impact of DSME on TC that did and did not show reductions.

Of the studies showing significant improvement in TC levels, eight are randomized control trials. Three of the RCTs tested the impact of telehealth components. The first evaluated an telephonic support DSME vs standard DSME and found a group-by-time interaction between the groups with the control group having a 13.8mg/dL reduction and the treatment group having an 11.0mg/dL reduction in TC. [54] The other RCT tested a DSME calendar application and found a 19.53mg/dL reduction for the treatment group. [73] The third telehealth RCT found the intervention group had an 8.9mg/dL reduction, where those who self-referred in the intervention group boasted a 13.1mg/dL reduction in TC after six months. [72] Two of the RCTs testing tailored DSME

programs found a 0.32mg/dL long-term average reduction and a 7.2mg/dL ten-month average reduction. [61,79] The remaining three RCTs were testing DSMS follow-up methods after a DSME period. The first found a significant decline of 11.38mg/dL in the intention-to-treat analysis for individuals, with 10.7mg/dL as the non-significant reduction for the individuals that completed the DSME portion of the intervention. [78] The second found a 15.5mg/dL reduction in TC after the six-month DSME intervention. [132] While the third found the individuals allocated to the peer support group showed a significant 10.3mg/dL decline in TC compared to the non-significant declines of 7.0mg/dL – 10.8mg/dL range for the other groups during the DSME phase of the intervention. [77]

Another three studies that found significant reductions in TC were quasi-experimental or retrospective study designs. The total cholesterol reductions ranged from 3.98mg/dL to 17mg/dL. A chronic care management model and a culturally-tailored intervention found reductions in TC of 12.8mg/dL and 3.98mg/dL. [63,134] Lastly, a retrospective chart review from DSME + MNT found that in the subsample that had lipid panel results, the TC decreased by 17mg/dL. [108]

Lastly, there are three systematic reviews or meta-analyses that found significant changes in TC levels. The first two are of DSME programs in mainland China and Middle Eastern countries. This systematic review of DSME in mainland China found that eight of nineteen studies had significant declines in TC level. [111] While the systematic

review of Middle Eastern countries DSME had four of five groups having a TC decline with the absolute effect being a 25.37mg/dL decline. [112] This systematic review and meta-analysis of nurse-led DSME found the intervention group to have a 6.75mg/dL decline and the control group to have a 5.52mg/dL decline, with both group changes being significant within-group changes from baseline. [114]

While many studies have shown the benefits that DSME can provide in total cholesterol reduction, not all research studies had that finding. Thirteen studies found that DSME had no significant impact. Two randomized control trials did not find significant changes in TC levels. [62,72] Of quasi-experimental and retrospective studies, six did not show significant changes. [64,84,99,100,106,120] Five systematic reviews and meta-analyses found non-significant changes in TC. [111,112,117,118,126]

Effect of DSME on Triglycerides

The last aspect of lipid management for individuals with diabetes is triglycerides. The literature in this section will cover several RCTs, interventional, cross-sectional, and systematic reviews and meta-analyses that studied the impact interventions have on TG. Approximately half of the studies showed significant decreases, but many showed no significant changes in TG after DSME completion. Of the studies showing significant declines, the decreases ranged from 14.1mg/dL to 65.8mg/dL over the study periods. While the remaining twelve studies examining the impact of DSME on TG found no significant changes after completion of the DSME portion of the studies. This section will

discuss the articles evaluating the impact of DSME on TG that did and did not show reductions.

Of the ten studies showing significant declines in TG levels, three are randomized control trials and three are quasi-experimental. One RCT found a -29.2mg/dL change for the treatment group, while the control group had a -36.6mg/dL change in their average TG level. [54] The other two RCTs found 24.94mg/dL and 14.1mg/dL declines in TG for the intervention groups after the program completions. [73,80] The smallest decrease for a quasi-experimental was a 12.14mg/dL decline for a culturally-tailored intervention for Latino individuals. [134] Another intervention study found TG had 21.25mg/dL and 32.77mg/dL reductions at three and nine months, respectively. [64] The last quasi-experimental study found a reduction of 22.3mg/dL over the twelve-month study period. [63] One study found that attending DSME lead to a higher likelihood of obtaining a lipid profile. [109]

The remaining four studies that found significant reductions in TG levels were retrospective studies and systematic reviews. The pilot retrospective chart review found a 65.8mg/dL reduction over the year period, but the larger retrospective chart review found a 53mg/dL decline in TG over a one-year period. [107,108] Both of the systematic reviews found over 50% of the studies to have a decline in TG for the intervention group. The systematic review of Middle Eastern countries' DSME program found 80% of studies had improvement in triglycerides with an absolute effect of 38.16mg/dL. [112] The other

systematic review of mainland China DSME programs found 11/19 studies had significant declines. [111]

While many studies showed promising results in reducing TG after a DSME intervention, not all studies found decreases. Fourteen studies ranging from RCTs to systematic reviews did not find significant changes in TG levels. Five of the fourteen studies finding no significant changes are RCTs. [61,62,78,79,119] Another four of the studies were quasi-experimental study designs. [84,99,100,106] The last five studies that did not find significant TG changes are systematic reviews and meta-analyses. [109,112,114,117,118]

Summary of the Impact of DSME on Outcomes

Despite these benefits of DSME, utilization has been consistently low. Within the first year of diagnosis, less than 5% of Medicare beneficiaries and 6.8% of privately insured individuals receive this service. [46,51] DSME has been shown to be highly effective in lowering A1C, increasing PCP utilization, and increasing the likelihood of an individual obtaining a retinal exam. The literature above shows mixed results in lipid panel measures and non-significant findings of positive impact on BMI. In general, DSME can be highly effective in helping with the management of diabetes, but the barriers to access and utilization remain.

Diabetes Self-Management Support: Health Extension for Diabetes

To address the variety of barriers, many diabetes education departments employ diabetes support programs. An example of this type of program in South Carolina is the Health Extension for Diabetes program. Health Extension for Diabetes (HED) is a community-based, non-clinical diabetes self-management support program. This ADA Practice-Tested, [135] copyrighted program is four months long and is based on the Association of Diabetes Cares and Education Specialists 7 Self-Care Behaviors (ADCES7). [47,53,136–138] HED was created in collaboration between clinicians, paraprofessionals, and researchers. HED has eight bi-weekly group sessions to deliver core content, with the support group and individual sessions occurring during the in-between weeks. This is a "high-touch" program with standardized components while simultaneously allowing the flexibility to be personalized to participants' goals and needs.

As previously stated, HED has an eight-session curriculum based on the ADCES7. The introductory session acts as an icebreaker, providing an introduction to the program and its components/schedule while having intermixed icebreaker questions. Session 1 covers the concepts of life with diabetes. This session teaches individuals the foundations of diabetes, including topics such as what diabetes is, the general etiology of the disease, common signs/symptoms associated with each type of diabetes, critical components of management for each diabetes type, identifying and treating hypo- and hyperglycemia, and complications of diabetes. Sessions 2 through 7 align the elements of the ADCES7. Session 2 delivers content about ADCES7 skill: Healthy Eating. Healthy

eating teaches an individual how to identify foods that impact blood glucose, plan meals and snacks for an eating plan, and create goals for managing diabetes through healthy eating. Session 3 educates about ADCES7 skill: Being Active. The being active session educates individuals on the importance of physical activity but how it can impact blood sugar while helping individuals understand how to address barriers to becoming physically active.

Session 4 combines two ADCES7 skills: Taking Medications and Monitoring. This session educates individuals on the importance of managing their blood glucose, skills to overcome barriers to checking and managing their blood glucose, and explains the role medication can play in managing diabetes. Session 5 covers ADCES7 skill: Problem-solving. Session 5 assists individuals in identifying situations where managing their diabetes can be challenging, understanding how to overcome barriers during these difficult situations, and learning the importance of social support in their self-management. In Session 5, individuals also learn resource navigation to aid their disease self-management. Session 6 covers ADCES7 skill: Healthy Coping. Healthy coping is a skill necessary for mastery of the other six behaviors. This session teaches individuals how to identify stressors, understand the impact stress has on their bodies, and learn coping strategies to manage their stress. Session 7 covers ADCES7 skill: Reducing Risks. This last session educates individuals on diabetes complications, learn how certain personal care habits can impact their risk of developing complications, and understand the ABCs of diabetes with their target ranges.

The crucial diabetes self-management topics are covered during the core curriculum sessions. Before the COVID-19 pandemic, the weeks between core sessions were solely dedicated to individual follow-up communication. In these follow-up contacts, make-up sessions were scheduled, action plans were discussed, and clients had the opportunity to ask questions and review core content. Methods of contact for follow-up varied by the participant. Options for follow-up include phone call, text, or email.

During COVID-19, the program transitioned to virtual delivery. To decrease the likelihood of attrition during the transition, non-mandatory support group sessions were added between formal core sessions. Support group sessions covered additional resources related to the topic covered in the core session the prior week and provided clients another opportunity to ask questions. For example, in Support Group 6, which occurs after Session 5, the facilitator has review/discussion questions relating to sick day planning, considerations while traveling, and social support. Additionally, the facilitator can use this time to provide answers to "Ask–It Basket" questions, remind of other resources, and go over the prior week's action plan. While the support group sessions occurred in the in-between weeks, individualized follow-up still occurred.

Impact of DSMS on Process Measures

Effect of DSMS on Retinal Screening

DSMS programs can also be beneficial in helping patients make the necessary changes to better manage their condition, including retinal and nephropathy screening. As stated in the *Effect of DSME on Retinal Screening* section above, a systematic review of the ADA recommendations found telemedicine for diabetic retinopathy screening to be cost-saving. [10] Other researchers sought to determine the impact an intervention would have on increasing retinal exams. A practice enhancement program for a behavioral health home found a greater proportion obtaining their retinal exam after program implementation. [139] One study found there was a significant increase in the number of individuals who obtained a retinal exam at 6-months post-intervention, which led to a greater proportion of individuals who had a retinal exam at 11 months post-intervention. [140,141] The diabetes empowerment program for Mexican Americans found that 98.8% of individuals reported having at least one retinal exam in the last year. [142] Another study that was evaluating various DSMS methods found that across all methods 67.7% of individuals had received an eye exam in the last year, with the secure messaging group having the highest percentage at 74%. [59] Overall, these DSMS programs show promising results of the impact DSMS can have on individuals receiving an annual retinal exam.

Effect of DSMS on Nephropathy Attention

Of the studies examining the impact DSMS can have in obtaining nephropathy screening/attention, DSMS was successful in five of the six studies. The MEMO RCT study discussed in a variety of the DSME sections found a significantly improved eGFR at year 4 and an improved UACR at year 3 only, showing the improvements were gradual

and not always maintained. [61] Another RCT with a 3 session DSMS intervention found the treatment group had a significant positive change in their urea and albumin measures. [143] Similarly, a DSMS translation study found that at 6 and 11-months post-program, there was a significant increase in obtaining nephropathy attention. [140,141] A feasibility study found that after the intervention, 73.2% of individuals had received nephropathy screening. [59] However, a study for Mexican Americans found no significant changes in microalbumin levels. [142] Overall, DSMS shows promise in being able to positively impact chronic kidney disease screening rates and values, but further research is needed to confirm.

Impact of DSMS on Clinical Measures

Effect of DSMS on A1C

Another commonly studied area is the impact of DSMS on the A1C level. With the systematic review of the cost-effectiveness of ADA recommendations intensive glycemic management of A1C <7.0% to be cost-effective, the goal would be to obtain this A1C value with the least costly intervention. [10] This section will discuss the randomized control trials, experimental studies, observational studies, along with systematic reviews and meta-analyses that resulted in a change in A1C using DSMS. For interventions showing a significant decline in A1C level, the reduction ranged from 0.15% to 2.2%. [140,144]

Many of the RCT studies sought to examine different DSMS models after the completion of some DSME. For the RCTs testing their DSMS program in this manner, they found A1C reductions ranged from 0.5% to 0.7% in the various arms. [61,75] A pre/post RCT in African Americans found a greater proportion with a 0.5% reduction in A1C in the intervention group. [145] While a CHW-delivered RCT found a 1.0% reduction in A1C at 6 months. [146] Similarly, a secondary analysis of CHW RCT for a Latino population found that adults 55 years old or older had a 1.02 reduction in their A1C. [147]

Other RCTs examined the impact of technological-based interventions, such as text messages or an application. For the RCTs examining the role of technology, the A1C reductions range from 0.4% to 1.28%. [148–150] A feasibility, acceptability, and effect RCT found a 0.57% reduction in A1C. [151] A self-management-oriented RCT for individuals with type 1 diabetes found that the intervention led to a 0.4% reduction in A1C at 6-months. [152] While cluster RCT found that at 3-months the A1C had a -0.29% adjusted mean difference in favor of the DSMS group, where at 6-months A1C had an adjusted mean difference of 0.14% for both groups. [153] Several RCTs found factors correlated to A1C improvement such as program dosage, [154] food security, [155] diabetes social support, [146] problem-solving ability. [151]

Many non-randomized experimental studies of the effect on A1C have been conducted. Many researchers conducted mHealth studies finding reductions ranging from 0.5% to 1.7% [156–159] Other researchers opted to publish studies showing pre to post-

program changes. One study found that the integration of collaborative goal setting into practices allowed for an overall -1.1% change in A1C for individuals with an A1C>7.5% at baseline. [160] Another study showed significantly greater improvements in A1C compared to DSMES along (-1.2% vs -0.9%), with a greater percentage having an A1C<8.0. [93] Pre/post-program changes in A1C ranged from 0.16% to 1.1%. [91,139,161,162] Some researchers reported longer-term outcomes post-program. One translation study found that at 6-months post-program, there was a significant decrease in A1C (-0.15%; -0.93 for A1C>9.0% at baseline. [140] While another study found a (-0.8%) reduction at 6-month follow-up. [163] Another study found that at 11 months an average A1C decrease of 0.447%. [141] While two studies examining changes at 12-months post-program found reductions of 0.93% and 2.2%. [103,144] A dietitian-coached intervention found improvement in A1c (-0.6%) at the 24-month follow-up. [164] Some researchers worked with the Hispanic/Latino and Mexican American populations to determine the efficacy of some interventions. The intervention for Mexican Americans found a 1.1% reduction [142] while the program for Hispanic/Latinos individuals found a 0.6% reduction. [165] One retrospective study of DSME and DSMS at select PCMHs found that the greater number of services provided to individuals resulted in a greater A1C decline, with the average A1C decline for all PCMHs being 0.43%. [106] Lastly, a retrospective study found that insulin initiation mediated the A1C effect by 49.5%, and the intervention was more likely to have a greater impact on individuals who have experienced health literacy problems. [166]

A brief review of literature for particular diabetes guidelines found that mHealth apps had stronger effect sizes for A1C (>0.5% reduction) when clinical involvement from their provider was present. [125] A systematic review of reviews found that on A1C reduction ranged from 0.1% to 0.8%, where this was the primary outcome listed in 88% of the studies. [113] Three systematic reviews and meta-analyses were conducted. The first found for DSMES apps impact on medication adherence found A1C to improve as medication adherence improved. [126] Another for lifestyle and DSMES programs found greater reductions in A1C (MD: -0.35%) at the end of behavioral programs, where most interventions boasting more than 11 contact hours had clinically significant reductions in A1C. [116] The third found that with low-quality evidence, psychological interventions can improve A1C (-0.14%) better than usual care. [167]

While many interventions found significant reductions in A1C levels at various stages post-intervention, not all studies found reductions. An assistance program found that individuals with an A1C>8.5 showed an absolute A1C reduction of 0.9% compared to individuals with A1C<7.0 increasing by 0.6%. [168] Another DSMS intervention found a 0.6% increase in A1C. [120]

While the majority of studies showed positive declines in A1C level after completing a DSMS intervention, not all studies boasted these results. Three randomized controlled trials did not find significant A1C reductions. [78,131,143] Other researchers conducted non-randomized experimental studies. An example is a computer-based

support program that found no significant change after short and long-term follow-up. [169,170] Many of the studies examined the effect of DSMS on A1C after completing the DSME aspect of the intervention. Several studies did not find their DSMS models successful. [90,92,94,132,171,172] Other studies examined their DSMS intervention alone but still found no significant declines in A1C. [59,122,173,174] Lastly, a systematic review of DSME and DSMS RCTs for South Asian individuals found that 3/4 studies did not result in significant reductions in A1C. [123] A systematic review and meta-analysis for RCTs in Africa found inconclusive results for A1C. [175]

Effect of DSMS on Body Mass Index

Similar to the DSME literature, many DSMS studies found reductions in BMI ranging from $0.29^{kg}/_{m^2}$ to $2.4^{kg}/_{m^2}$. [120,144] Of the ten studies finding a decline in BMI level, three of them were RCTs. Two of the RCTs found significant BMI declines of $1.0^{kg}/_{m^2}$ and $0.9^{kg}/_{m^2}$. [131,154] The third RCT was done with African Americans and found non-significant changes in BMI between the two groups, but the intervention group had a greater proportion of individuals with a 5% or greater BMI reduction. [145] For the non-randomized experimental studies, two found reductions in BMI of $0.29^{kg}/_{m^2}$ and $0.6^{kg}/_{m^2}$. [120,164] A pilot study of a virtual intervention found a trend for A1C decline and a significant BMI decline of $0.5^{kg}/_{m^2}$ over the intervention. [172] Another DSMS community-based study found a BMI reduction of $2.4^{kg}/_{m^2}$ at 12-months. [144]

Three systematic reviews and meta-analyses examined BMI change for DSMS interventions. One that examined RCTs in Africa found a mean difference of -0.9$^{kg}/_{m^2}$ for BMI with only one significant change for the 6 studies. [175] Another that examined applications impact on medication adherence found BMI to improve as medication adherence improved. [126] The last systematic review and meta-analysis for lifestyle and DSMES programs found a mean difference of -0.51$^{kg}/_{m^2}$ BMI. [116]

While several studies found significant declines in BMI, the majority of DSMS interventions did not find declines. Of the DSMS studies not finding significant changes in BMI, seven were RCTs, where they varied in the type of primary education delivered to participants or type of lead-facilitator. [61,75,77,78,143,174,176] Several of the studies that did not find declines in BMI involved small samples or short-term follow-ups. [161,163,169] A couple of studies examined certain populations or were done in a different country. [142,173,177] Additionally, several studies that had long-term follow-up did not find significant reductions. [103,132,170] The remaining three studies varied in novel delivery methods. [91,93,122]

Effect of DSMS on Low-density Lipoprotein

One of the major components of lipid management is LDL due to the impact on cardiovascular health. Due to the level of impact lowering LDL can have on diabetes management and overall cardiovascular health, many DSMS programs seek to impact

this aspect of lipid management. In total, nineteen articles discuss LDL changes after DSMS, where twelve show significant reductions. Three of these studies are RCTs, where two found 5.94mg/dL and 15.3mg/dL reductions from baseline. [61,75] The third RCT found that within the treatment group, for those who had suboptimal LDL levels, 75% improved with a median reduction of 25mg/dL. [151] While the majority of the studies found LDL reductions greater than 10mg/dL, three found reductions ranging from 2.3mg/dL to 9.31mg/dL. [139,162,174]

Many of the studies showed reductions in LDL of 10mg/dL or greater. Two of the studies were CHW-led and found reductions of 16.1mg/dL and 10mg/dL. [163,171] Similarly, a nursing intervention in China found a decline of 15.15mg/dL after completion. [177] A study examining the health effects at the one-year follow-up after a 2-year DSMS study found a 15.3mg/dL reduction. [103] The novel "speed dating" intervention found those who attended the DSMS portion of the intervention had an average LDL reduction of 24.7mg/dL. [93]

A plethora of studies found reductions in LDL, but not all studies were successful in reducing this measure. One of those studies was a RCT that did a post-DSME follow-up intervention. This study found an increase of 13.55mg/dL, with an average increase of 7.32mg/dL in the intention-to-treat analysis. [78] The other study that showed a significant increase was a RCT. This RCT had a 12-month DSMS study after the DSME portion of

the study, where the treatment group showed no changes, but the control group had significant increases of approximately 16.0 mg/dL at all three-time points. [131]

While the majority of the studies showed promising declines in LDL, a handful of studies had no significant changes. Of the studies showing no changes, one was dietitian-coached and the other was an intervention specifically for Mexican Americans. [142,164] One study that did not find significant changes was examining different DSMS follow-up methods. [59] Another two intervention studies did not find significant changes. [77,120] The last study that did not find significant results is a retrospective study at PCMHs. [106]

Effect of DSMS on High-density Lipoprotein

Another aspect of lipid management in HDL, where the goal is to increase this level. Three studies found significant changes in HDL level, with one study showing both a significant increase and decrease in HDL. One of the two studies that showed a significant increase in HDL was a RCT where the treatment and control groups both had significant increases of 14.1mg/dL and 131.3mg/dL, respectively. [131] Another study found both increases and decreases in HDL during the DSMS period of the intervention. In this study, the CDCES-led DSMS arm of the study found a 4.0mg/dL increase in HDL from baseline; however, the peer-led group found a 6.5mg/dL from baseline in the average HDL level. [77] The last study found that at the 1-year follow-up after a 2-year intervention, HDL had a 6.6mg/dL decline from baseline. [103]

While a couple of DSMS studies showed positive and negative changes in HDL levels, the majority of the studies showed no changes. Of the nine studies showing non-significant changes, three were RCTs. [61,75,78] Five of the remaining six studies were interventional, where they highlighted interventions that were dietitian or CHW led, longitudinal, or targeting a particular population. [103,120,142,164,171] The last study showing no significant change was a retrospective study at various PCMHs. [106] Overall, the effect of DSMS on raising an individual's HDL level remains mixed so further research should be done in this area to have more conclusive results.

Effect of DSMS on Total Cholesterol

Another aspect of lipid management is TC, as discussed in the DSME section. As discussed in other sections, the MEMO RCT showed promising results, where it showed a 5.94mg/dL reduction in average TC.). [61] Three non-RCT interventional studies found significant results. An intervention for Mexican Americans found a 17mg/dL reduction. [142] For another study, at the 1-year follow-up after a 2-year DSMS intervention, TC had a 26.4mg/dL reduction in the average. [103] The last interventional study was a digital DSMS program where a reduction of 39.5mg/dL was found for individuals with elevated cardiovascular risk at baseline. [156] This systematic review and meta-analysis for diabetes self-management RCTs in Africa found one of three studies measuring TC showing significant results but the meta-analysis showed a significant 2.52mg/dL reduction. [175]

While several studies showed the ability of DSMS to reduce TC, many studies showed no change. Of the studies showing non-significant findings, only one was a RCT. [78] Majority of the studies finding non-significance were quasi-experimental studies. [77,120,132,164,174] A retrospective study also found no significant change in TC level. [106] Conversely, a systematic review and meta-analysis were unable to test TC levels due to high heterogeneity. [126]

Effect of DSMS on Triglycerides

The last aspect of lipid management that DSMS programs typically seek to change is triglycerides. Only eight studies the impact of DSMS on TG changes, where only two studies had significant reductions. This section will discuss the articles evaluating the effect of DSMS on TG that did and did not show reductions.

The two studies showing significant impact on reducing TG level were quasi-experimental. A practice enhancement program for a behavioral health home found a 16.79mg/dL reduction in average TG for the treatment group. [139] Similarly, a CHW motivational interviewing intervention found a 38.73mg/dL reduction. [171] Both of these reductions are important and show the potential for DSMS to be beneficial in TG reduction.

While two studies showed significant reductions in average TG level, the other six studies did not. Of the six studies, two RCTs had DSMS components that did not

show significant declines. [61,78] Three studies were interventional and did not show a decline. [142,164,174] The last study that did not show a significant change is a retrospective analysis. [106]

Summary of the Impact of DSMS on Outcomes

Overall, DSMS has been shown to offer reductions in A1C ranging from 0.15% to 2.2%. [140,144] Similarly, the literature shows that DSMS interventions found reductions in LDL from 4.32mg/dL to 25mg/dL. [151,174] However, further research needs to be done to determine the efficacy of DSMS interventions aiding in positive changes in BMI, HDL, TC, and TG. Only one study reported outcomes showing a DSMS program reduced the need for general outpatient visits in a sample in China. [162] Further research should be done to determine if this holds for other populations.

Non-DSMES Literature for Process and Clinical Measures

As shown in the sections above, the majority of the literature focused on the impact of DSMES interventions on various outcomes. However, not all literature focuses on the impact of a diabetes self-management program. There are several studies examining different factors that might influence the diabetes process and outcome measures. One cross-sectional study found that males were more likely to have the A1C, LDL, and nephropathy screening. [178] This cross-sectional study also found that ambulatory clinics using the registry for patient reminders found their T2DM patients were 6% and 7% more likely than those without reminders to complete recommended lab

tests and receive their retinal exam, respectively. [178] Interestingly, a study of state-mandated insurance coverage of key diabetes self-management behaviors found a 5.8% increase in an individual obtaining their annual foot exam, annual retinal exam, and performing daily glucose self-management. [179] Another cross-sectional study found that LDL was associated with higher complementary health approach use and the group that employed complementary health approaches had a higher LDL mean, a greater proportion with A1C>8.0, a greater proportion with non-adherence to diabetes medications, and a greater proportion of cardiometabolic medications. [180] Similarly, a cross-sectional study of first-generation Korean Americans found that diabetes regimen-related distress was a significant predictor of glycemic control. [181] A population-level evaluation found that the intervention counties had lower screening rates for A1C (4%) and lipid profiles (9%) with no change in retinal screening rates. [182] One large study of health care resource utilization comparison found that patients with diabetes under the care of APRNs or physicians received similar care, but physicians often had more patients to manage. [183] Lastly, a study found that with the integration of a diabetes education team into primary care that individuals with diabetes were more likely to have their diabetes visits and A1Cs done every 6 months but less likely to have their lipid panel or eGFR completed. [184] This section shows there are several factors, such as type of care provider and patient reminders of upcoming appointments, in addition to DSMES programs that influence health outcomes and health behaviors for people with diabetes.

Role of PCP Utilization in Diabetes Self-Management

While many studies examined the impact of DSME or DSMS on PCP utilization for individuals with diabetes, some researchers sought alternative approaches. How PCP utilization is defined varies by study but most commonly is defined as the number of visits by an individual to their PCP. Many researchers conducted cross-sectional, retrospective, or experimental studies with non-DSMES intervention. This section will cover the literature surrounding the role of PCP utilization in diabetes self-management.

For the researchers employing experimental study designs, they show the benefits of PCP utilization and factors associated. An RCT found that those who were using the professional flash glucose monitor had a greater increase in PCP visits and were 1.22 times more likely to visit the PCP in the 6-12 months after sensor application than usual care. [185] Another study examined the 12-month outcomes of a RCT study and found that the group that had a CHW as their PCP had higher utilization, where higher PCP was associated with a greater decrease in A1C. [186] While a telementoring program that connects primary care providers with endocrinologists found an increase in outpatient and emergency department utilization. [187] Similarly, a long-term study found that initiation of insulin as a second-line therapy resulted in an increase in healthcare costs and increased PCP utilization. [188] Lastly, an outreach program found a 3.2% increase in PCP outpatient visits for the cases who participated. [189]

A retrospective study found that for newly diagnosed T2DM, PCP visits peaked in the first year following diagnosis, declined slightly in year 2, then maintained for the

remaining years, where PCP contacts accounted for the largest share of health care contacts. [190] However, a retrospective study found that many newly diagnosed type 2 diabetes individuals did not have a frequently used physician, and those individuals with low income were more likely to use insulin and have a shorter lag time to the initiation. [191] One study found that PCP usage had protective effects (ranging from 0.67 to 0.76) against diabetes-related preventable hospitalizations compared to individuals who did not have any PCP usage. [192] Similarly, a retrospective review of administrative data found that for 85% of the year, individuals with diabetes experience a protective effect from PCP visits, with individuals having fewer complications requiring fewer visits. [193] Another retrospective review found that individuals using the healthcare portal had a rate increase of 0.4/patient visits per year in PCP usage, where users also had a greater reduction in their A1C (-0.13%) compared to nonusers. [194]

A medical records observational study found that diabetes patients for all healthcare use in the lowest class had an average of 4.6 contacts compared to 12.0 contacts for a high use person, which differs from 1.9 diabetes contacts for lowest use and 5.8 for highest use. [195] When individuals with only type 2 diabetes were compared to individuals with T2DM + at least 1 CVD, individuals with only T2DM had a greater number of primary care visits (14.24 vs. 12.48) but fewer primary care-related costs (919 vs. 1055). [196] This cross-sectional study found that approximately 50% of individuals with type 2 diabetes without cardiovascular disease had an average of 1-3 visits to their PCP in a year compared to ~40% with cardiovascular disease. [197] In contrast, a

retrospective review of administrative claims data found that primary care utilization declined during the intervention and did not explain the clinically significant decline in A1C from the intervention. [198]

This cross-sectional study in China found that disease duration, use of diabetes medications, recognition of diabetes complications, and need for PCP services were factors positively associated with visiting their PCP. [199] This study found that greater financial strain, being married, or being on diabetes medications were associated with higher BMI, and where there was a significant positive correlation between patients and family members for the number of times patients saw their health care provider in the last 12 months. [200] This study of American Indians/Alaska Natives with diabetes found that regular PCP usually results in a 177% increased likelihood of having glycemic control, whereas if the distance to the PCP was increased to 10miles likelihood of regular PCP visits decreased by 3.7%. [201] This study found that people with diabetes the use of services varied by SES level, with lower incomes using fewer services in a universal health care system. [202] Similarly, a study found that the frequency of PCP use varied by geographic region, with urban respondents reporting higher use. [203] This study found that physician use varied by ethnicity with South Asians reporting a higher family practice use than others and whites more likely to see ophthalmology/optometry visits than others. [204] This study found that when nurses were placed in practices to help with various diabetes patients management A1C testing increased by 4.4%, and the proportion of patients with A1C<8.0 increased by 8.1%. [205]

Provider Knowledge and Perceptions of DSMES

A facet of understanding why DSME, a program with overall positive well-published results, is underutilized is to understand the first step in obtaining the service. The first step of an individual getting DSME is a provider referral. This leads to the fundamental question of primary care providers' knowledge and perceptions of DSMES.

The majority (~75%) of the studies examining provider knowledge and perceptions of diabetes management were conducted outside of the United States. Of the studies conducted in the U.S., only 60% (n=12) discussed PCP knowledge in some capacity. Of the 12 studies that focused on PCP knowledge of diabetes management and guidelines for practices, 100% of the studies found PCP knowledge lacking. [206–217] The other studies addressed perceived barriers, [218–220] the need for more effective communication, [221] provider perceptions of patients, [222,223] and others. [224,225]

Of the international studies, providers lacked appropriate diabetes management knowledge, [226–255] were not aware of or using current diabetes guidelines, [238,242,252,255–257] and showed a need for more effective communication. [238,241,244,253,258–267] Many studies examined the barriers to effective diabetes management for providers. A study found infrastructure, technical support, pharmaceutical support, and team member provider's interest, knowledge, and skills low in diabetes management, making diabetes management difficult due to various clinic level barriers. [228] Similarly, a qualitative study

found that providers were torn between wanting a patient-provider partnership and advocating for greater patient responsibility while also finding clinic and system factors causing frustration and added burden on providers. [258] Another qualitative study found limited staffing, supply shortages, lack of care continuum, and inadequate infrastructure and process as significant barriers to effective glycemic management for patients. [268] While a cross-sectional study exploring barriers to insulin initiation for physicians found insufficient staffing, patient age, and difficulty providing advice/education as the significant barriers to starting. [237]

More barriers were related to patient support. Another qualitative study found that healthcare providers understand the emotional burden that diabetes can cause but had concerns related to providing that support in a clinic setting. [269] This qualitative study found that providers felt responsible for delivering self-care education to patients but only through information sharing, not behavior change. [241] However, providers reported patient, health care system barriers, and inadequate general training to provide patients with the resources needed. [241]

This exploratory study to understand services in place to help patients with diabetes found an unreliable supply of products, a lack of support for patients at all levels, continuity of care was broken, guidance was lacking, and providers felt ill-prepared with the knowledge necessary to adequate help patients. [243] Another cross-sectional study found a disconnect between physician and patient perceptions of barriers to insulin

transition, where providers were more concerned about injections and patients were more concerned about complications. [260]

Another study of interviews with primary care providers regarding screening guidelines found that providers understood the need for guidelines but noted the lack of feedback opportunities and unclear guidance for patients who screened positive. [230] Several years later, these researchers found that general practitioners understood the importance of oral care in diabetes management but recognized their limited knowledge, time constraints, and lack of referral pathways as barriers to assisting patients with managing their oral health, but would be willing to undergo training, having an assessment tool and patient education materials to help them in management. [245] Similarly, a cross-sectional study found that less than 50% of providers were aware of guidelines, with even fewer having received training on their implementation, but cited various barriers, such as time and resources, in their ability to utilize them in the future. [246]

This study found that the main priorities for newly diagnosed diabetes were teaching the patient how to handle the disease and achieving the A1C target, with most providers recommending education. [249] However, medication recommendations vary significantly in conjunction with many associated barriers at patient and organizational levels, indicating a treatment algorithm could be beneficial. [249] A method to improve

management was the implementation of clinical practice guidelines, but barriers persisted. [270]

Some studies sought to improve the knowledge of providers in diabetes management. An educational intervention found a significant increase in the understanding of the importance of statin therapy, knowledge associated with prescribing, and beliefs about its use for people with diabetes. [271] While an online educational intervention for providers found significant increases in management knowledge (medications, recommendations, etc.) for people with type 2 diabetes. [272] One study found that after undergoing team-based professional development, more patients were referred to diabetes specialists. [273] A survey conducted with primary care providers found that after continuing education, the mean knowledge increased, understanding of practices relating to diabetes management increased, but attitudes on the severity of the disease did not change, likely due to high baseline scores. [274] This mixed-methods study found significant improvement in diabetes knowledge after completing continuing medical education when compared to individuals who did not complete the education. [275] Similarly, web-based training for remote diabetes care providers provided significant increases in the knowledge that persisted at the three-month follow-up. [276] Lastly, a three-day intensive diabetes education intervention found that most diabetes management parameters improved (A1C measurement), but many crucial management parameters for measurement were not improved, showing the continued need for more education. [277]

Other studies sought to understand providers' attitudes toward patients, [278,279] examined knowledge of periodontal disease compared to dentists, [280,281] alternative diabetes screening locations, [282] and understand where providers obtained more knowledge on management. [283,284]

Summary and Implication for Current Studies

This review presented current research for examining diagnostic measures and protocols for diabetes along with disease management approaches and measures of diabetes management successes. Two key diabetes intervention approaches (DSME and DSMS) were presented with other factors impacting diabetes management outcomes. Aims 1 and 2 will compare these two approaches more closely to determine if and how these interventions impact key diabetes management process and outcome measures differently as compared to a control group. Additionally, aim 3 will examine factors related to primary care providers that could influence patient utilization of these self-management services.

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CHAPTER THREE

METHODOLOGY

This dissertation aims to explore the impact of an ADA-accredited DSME program and an ADA Practice-Tested DSMS program on process and outcome measures for adults with diabetes. This dissertation also will explore the primary care provider's knowledge and perceptions of DSMES in one healthcare system in South Carolina.

Specific Aims and Research Questions

AIM 1: To examine the impact of a DSMS and DSME program on diabetes management process measures: retinal exam, nephropathy screening, and primary care service utilization.

- *Question 1:* Do individuals with diabetes who participate in DSMS and DSME programs obtain a retinal exam more often than individuals with diabetes who do not receive these services?
    - *Hypothesis 1:* Individuals in the DSME will be more likely to have obtained a retinal exam after completion of the program than individuals who have obtained DSMS or have not received either service.
- *Question 2:* Do individuals with diabetes who participate in DSMS, and DSME programs obtain nephropathy screening more often than individuals who do not receive these services?
    - *Hypothesis 2:* Individuals in the DSMS will be more likely to have obtained nephropathy screening after completion of the program than individuals who have obtained DSME or have not received either service.

- *Question 3:* Do individuals with diabetes who participate in DSMS and DSME programs have lower primary care service utilization compared to individuals who do not receive these services?
    - *Hypothesis 3:* Individuals in the DSMS or DSME groups will have an increase in primary care service utilization after program completion. Individuals with diabetes who have not obtained either service will have no change in the primary care service utilization.

AIM 2: To examine the impact of a DSMS and DSME program on clinical outcome measures: BMI, A1C, LDL, HDL, total cholesterol, and triglycerides.

- *Question 1:* Do individuals with diabetes who participate in DSMS and DSME programs have BMI lower BMI than individuals with diabetes who do not receive these services?
    - *Hypothesis 1:* Individuals in the DSMS group will have a larger BMI reduction than individuals in the DSME group or someone who had not had either program.
- *Question 2:* Do individuals with diabetes who participate in DSMS and DSME programs have a lower A1C than individuals with diabetes who do not receive these services?
    - *Hypothesis 2:* Individuals in the DSME group will have a larger A1C reduction than individuals in the DSMS group or someone who had not had either program. Individuals in the DSMS group will have a larger

A1C reduction than individuals with diabetes who have not had either program, but a smaller reduction than the DSME group. Individuals with diabetes who have not received either program will have no change in their A1C.

- *Question 3:* Do individuals with diabetes who participate in DSMS and DSME programs have a lower LDL than individuals with diabetes who do not receive these services?
    - *Hypothesis 3:* Individuals in the DSMS group will have a larger LDL reduction than individuals in the DSME group or someone who had not had either program. Individuals in the DSME group will have a larger LDL reduction than individuals with diabetes who have not had either program, but smaller reduction than the DSMS group. Individuals with diabetes who have not received either program will have no change in their LDL.
- *Question 4:* Do individuals with diabetes who participate in DSMS and DSME programs have a lower HDL than individuals with diabetes who do not receive these services?
    - *Hypothesis 4:* Individuals in the DSME group will have a larger HDL increase than individuals in the DSMS group or someone who had not had either program. Individuals in the DSMS group will have a larger HDL increase than individuals who have not had either program, but smaller

increase than the DSME group. Individuals who have not received either program will have no change in their HDL.

- *Question 5:* Do individuals with diabetes who participate in DSMS and DSME programs have a lower total cholesterol than individuals with diabetes who do not receive these services?
    - *Hypothesis 5:* Individuals in the DSME group will have a larger total cholesterol reduction than individuals in the DSMS group or someone who had not had either program. Individuals in the DSMS group will have a larger total cholesterol reduction than individuals with diabetes who have not had either program, but smaller increase than the DSME group. Individuals with diabetes who have not received either program will have no change in their total cholesterol.
- *Question 6:* Do individuals with diabetes who participate in DSMS and DSME programs have lower prevalence of hypertriglyceridemia than individuals who do not receive these services?
    - *Hypothesis 6:* There will be a lower prevalence of hypertriglyceridemia for individuals in the DSME group than individuals in the DSMS group or someone who had not had either program. Individuals in the DSMS group will have lower prevalence of hypertriglyceridemia than individuals with diabetes who have not had either program, but higher prevalence than the DSME group. Individuals with diabetes who have not received either program will have the highest prevalence of hypertriglyceridemia.

AIM 3: Describe primary care providers' knowledge and perceptions of DSMES in one health care system in South Carolina.

- *Question 1:* What are primary care providers' knowledge and perceptions of DSMES in one health care system in South Carolina?
    - *Hypothesis 1:* Majority (>50%) of sampled primary care providers in the health care system in South Carolina will have limited self-reported awareness and limited knowledge of DSMES, as measured by ADA-recommended referral timepoints and explanation of what DSMES entails.

Overall Research Design

This dissertation features two retrospective, quantitative studies, and one convergent mixed-methods study design. Aim 1 and aim 2 will feature the quantitative designs, and aim 3 will have the mixed-methods study design.

Quantitative Research Design

Aim 1 and Aim 2 of this dissertation will employ three groups, retrospective, cohort study design. The aims of the quantitative studies are to understand the impact of a DSMS and DSME program on process and outcome measures. The years studied for these two aims are 2017 – 2021. The individuals examined individuals that participated in DSMS or DSME from March 1, 2018, to December 31, 2020.

Table 1 provides a brief description of the intervention length, pre-program measure length, post-program length, and overall examination period for the three groups studied in aim 1 and aim 2. Recall that these will be measured at the individual level and will vary.

Table 1: Three Group, Retrospective Cohorts: Groups and Examination Descriptions

Group 1: DSMS: Health Extension for Diabetes	**Group 2:** DSME: Prisma Health – Upstate Diabetes Self-Management Program	**Group 3:** Neither DSMS nor DSME
• *Intervention length:* From date of registration to date of last session • *Pre-measures length:* One year prior to date of individual registration • *Post-measures length:* One year post the date of the last session • *Examination period:* Approximately 28 months; Will vary by the individual due to varying intervention lengths	• *Intervention length:* From date of first billed session date of last billed session in one calendar year • *Pre-measures length:* One year prior to date of first billed session • *Post-measures length:* One year post the date of the last billed session • *Examination period:* Approximately 28 months; Will vary by the individual due to varying intervention lengths	• *Intervention length:* Not applicable • *Pre-measures length:* One year prior to date of the first referral to DSME • *Post-measures length:* One year post the first referral date to DSME • *Examination period:* Approximately 24 months

For the DSMS program, the intervention length is from the date of program registration to the date of the last program session. As discussed in chapter 2, HED is a four-month intervention. The intervention length will vary by the individual due to different

registration dates, the different number of sessions attended, and different dates of the last session due to make-up sessions. The pre-program measures period is one year prior to the registration date. The post-program measures length is one year after the date of the last program session. The total examination period for individuals is approximately 28 months, where this will vary slightly by the individual due to the varying intervention lengths.

For the DSME program, the intervention length is from the date of the first billed session to the date of the last billed session during one calendar year. The length of DSME and the amount of DSME (number of hours) varies by patient. The number of hours will be determined by the number of hours listed as billable in the electronic health record. The pre-program measures period is one year prior to the first billed session. The post-program measures length is one year after the date of the last billed session. The total examination period for individuals is approximately 28 months, where this will vary slightly by the individual due to the varying intervention lengths.

For neither DSMS nor DSME, the intervention length is not applicable due to individuals not receiving an intervention. The pre-measures period will be one year prior to the date of the first referral to DSME. The post-measures length will be one year after the date of the first referral to DSME. The examination period will be approximately 24 months.

Table 2 shows various components of the methodology associated with aim 1 of this dissertation.

Table 2: Study 1 Methodology Information

Study 1: Exploration of DSMES programs on diabetes management process measures
Study Design: Retrospective 3-cohort design
Data Source: Self-reported demographic information from the GHA grant and patient electronic medical records
Primary Aim: Examine the impact of a DSMS and DSME program on individuals obtaining a retinal exam, nephropathy screening, and primary care service utilization.
Inclusion Criteria: • *DSMS:* Individuals must have graduated HED by December 31, 2020. Individuals also must use a health system that uses EPIC. • *DSME:* Individuals must have obtained DSME from the Prisma Health – Upstate Diabetes Self-Management Program between March 1, 2018, to December 31, 2020. Individuals' primary language must be English. • *Neither DSMS nor DSME:* Individuals who have not been enrolled in HED or obtained DSME from Prisma Health – Upstate Diabetes Self-Management Program after January 1, 2017. Their primary care provider must be using EPIC EHR for the duration of the study period. Individuals must have been provided a referral for DSME but did not enroll.
Exclusion Criteria: • *DSMS:* Individuals who have not graduated the intervention, have died, or formally disenrolled will not be included. • *DSME:* Individuals whose primary language is not English or died during the study period will not be included. • *Neither DSMS nor DSME:* Individuals who died during the study period. Individuals whose primary care provider changed to a non-EPIC EHR primary care provider during the study period. Individuals who did not receive a referral to DSME at Prisma Health – Upstate Diabetes Self-Management Program.
Outcomes: • Frequency of retinal exam

• Frequency of nephropathy screening • Primary care service utilization
Primary Predictors: • DSMS program participation • DSME program participation • No program participation
Covariates: Covariates necessary depend on the particular research questions. All models adjust for age, race, sex, and intervention length. For the retinal exam model, average frequency of retinal exams in year prior to program start will be utilized. For the nephropathy screening model, average frequency of nephropathy screenings in year prior to program start will be utilized. For the primary care service utilization, average primary care service utilization in the year prior to program start will be utilized.
Statistical Analysis: • Descriptive statistics of cohorts on demographic variables, including number of sessions/hours of DSMS or DSME • Chi-square test to determine if there are differences between DSMS cohort, DSME cohort, and no DSMES program cohort at pre-program, post-program, and post-program plus intervention length. • Generalized Linear Mixed Model (GLMM) for each outcome in year after program completion • GLMM for each outcome from start of program • Sensitivity analysis: based on results of chi-square, propensity score matching on unbalanced variables. Once PS matched groups created, repeat the two GLMM models with each outcome.

Table 3 shows the various components of the methodology for Aim 2 of this dissertation. This study design will be the same as aim 1.

The intervention length, pre-program measures, post-program measures, and examination period are measured the same as aim 1 shown in Table 1. The number of times the respective outcome was obtained prior to program start, during the program, and after

program completion will be utilized to determine if guideline concordant care, as defined by ADA, is being achieved.

Table 3: Study 2 Methodology Information

Study 2: Exploration of DSMES programs on diabetes management outcome measures
Study Design: Retrospective, 3-cohort design
Data Source: Self-reported demographic information from the GHA grant and patient electronic medical records
Primary Aim: Examine the impact of a DSMS and DSME program on individuals BMI, A1C, LDL, HDL, total cholesterol, and triglycerides.
Inclusion Criteria: • *DSMS:* Individuals must have graduated HED by December 31, 2020. Individuals also must use a health system that uses EPIC. • *DSME:* Individuals must have obtained DSME from the Prisma Health – Upstate Diabetes Self-Management Program between March 1, 2018, to December 31, 2020. Individuals' primary language must be English. • *Neither DSMS nor DSME:* Individuals who have not been enrolled in HED or obtained DSME from Prisma Health – Upstate Diabetes Self-Management Program after January 1, 2017. Individuals' primary care provider must be using EPIC EHR for the duration of the study period. Individuals must have been provided a referral for DSME but did not enroll.
Exclusion Criteria: • *DSMS:* Individuals who have not graduated the intervention, have died, or formally disenrolled will not be included. • *DSME:* Individuals whose primary language is not English or died during the study period will not be included. • *Neither DSMS nor DSME:* Individuals who died during the study period. Individuals whose primary care provider changed to a non-EPIC EHR primary care provider during the study period.
Outcomes: • BMI • A1C

• LDL • HDL • Total cholesterol • Triglycerides
Primary Predictors: • DSMS program participation • DSME program participation • No program participation
Covariates: Covariates necessary depend on the particular research questions. All models will have age, race, sex, and intervention length. In each of the models, the average value for each of the outcomes prior to starting the programs will be included. The number of times that value was obtained will be included. For HDL and LDL, a binary indicator of if the individual is on statin therapy will be included. For triglycerides, a binary indicator of if the individual has hypertriglyceridemia will be included.
Statistical Analysis: • Descriptive statistics of cohorts on demographic variables, including number of sessions / hours of DSMS or DSME • Chi-square test to determine if there are differences between DSMS cohort, DSME cohort, and no DSMES program cohort at pre-program, post-program, and post-program plus intervention length. • Generalized Linear Mixed Model (GLMM) for each outcome in year after program completion • GLMM for each outcome from the start of program • Sensitivity analysis: based on results of chi-square, propensity score matching on unbalanced variables. Once PS matched groups created, repeat the two GLMM models with each outcome.

The hypotheses for BMI and A1C are based on findings from the literature discussed in Chapter 2. Recall from Chapter 2, the current literature showed larger reductions in BMI for individuals participating in DSMS than the reductions seen in studies that employed DSME. Similarly, larger A1C reductions were seen from studies employing a DSME intervention than those with DSMS.

Mixed-Methods Research Design

Aim 3 of this dissertation will employ convergent mixed methods with parallel databases study design.[1] This study will take place in one health system in South Carolina whose coverage spans over half of the state. The quantitative survey will be pilot tested via a small group of clinicians, delivered to all eligible PCPs, followed by a semi-structured interview with selected providers who have completed the survey.

Sampling and Theoretical Framework

Purposive sampling that combines criteria-based, convenience, and snowball sampling methods will be employed to obtain this population. In order for the provider to be included in this study, they must be a primary care provider in the one health system (Prisma Health) in the Family Medicine or Internal Medicine departments and are actively managing non-pregnant adults with diabetes (type 1 or type 2). This can include DOs, MDs, APRNs, or PAs working in a primary care setting.

The questionnaire and interview guide were grounded in the Theoretical Domains Framework (TDF) (Table 1). TDF is a theoretical framework created in collaboration between implementation and behavioral scientists that sought to create a comprehensive, theory-informed framework for researchers to guide them in identifying behavioral determinants. It should be noted, TDF is not a theory as it does not propose testable relationships between variables/elements. [2,3] This theoretical framework is composed of

14 domains with 84 constructs. The 14 domains are: 1) knowledge; 2) skills; 3) social/professional role and identity; 4) beliefs about capabilities; 5) optimism; 6) beliefs about consequences; 7) reinforcement; 8) intentions; 9) goals; 10) memory, attention, and decision processes; 11) environmental context and resources; 12) social influences; 13) emotion; and 14) behavioral regulation. [2,4]

Four of the 14 domains utilized in this study: knowledge, skills, beliefs about consequences, and beliefs about capabilities. Five of the 84 constructs will be employed in this study: procedural knowledge (knowledge domain), ability (skills domain), outcome expectancies (beliefs about consequences domain), beliefs (beliefs about consequences domain), and self-efficacy (beliefs about capabilities domain).

Survey Development and Study Procedures

Prior to sending the survey to all eligible providers in the health system, the questionnaire will be pilot tested via a small group of 4 – 7 providers. The providers will be individuals that meet the inclusion criteria for this study. After the providers have completed the pretest, informal semi-structured interviews will be held to discuss the survey flow, question order, verbiage, clarity, and overall survey suggestions. [5,6] These semi-structured interviews will last approximately 30 minutes. The participating providers will receive no compensation for their time.

Upon completion of the pilot testing phase, the next step will be to send the questionnaire to the health system providers via email. An initial email will be sent to all included providers to inform them of the study and include a link to the survey. One week after the first email is sent, a reminder email will be sent to the providers who have yet to respond. Another reminder email will be sent two weeks after the first reminder email. On the morning of the last day that the survey will be open, one last reminder email will be sent to inform them the survey will be closing that day. This will result in a total of 3 reminders at the following time points post initial email: 1 week, 3 weeks, and the day of closure. The survey window will be closed five weeks after the initial email to provide ample time for a response while eliminating the potential for an extraneous response.

For the survey, a sample size calculation has been completed for the 372 providers in the two departments at both locations of the organization, 95% confidence interval with a 5% margin of error yields a needed sample size of 190 responses. This would result in a response rate of 51.1%. If a margin of error of 6% is utilized, 156 responses would be needed, which resulting in a response rate of 41.9%. While there is no methodology stating the optimal response rate, a response rate above 50% is often considered excellent. The a priori goal of a 35% response rate will be utilized given this is considered a good response rate.

After a provider completes the survey, they will fall into one of two groups: have referred a patient or have not referred a patient to DSMES. The interview sample size is 18 – 22

providers, where there are 9 – 11 providers that self-identify as either having referred a patient or have not referred a patient to DSMES. This sample size was selected based on the use of semi-structured interviews with a narrow aim, moderate specificity of experiences, applied theory, and cross-case analysis. [7] The interviews are anticipated to last 20 – 40 minutes.

Analysis

After all survey responses are collected, if the response rate is below 80, an analysis of nonresponse will be employed to check for nonresponse bias. [8] Descriptive statistics and hypothesis testing will be conducted.

Once the interview data has been collected, a thematic analysis approach will be conducted using inductive and deductive coding. This approach will allow for the key constructs to be explored while allowing for other themes to emerge. [1] The quantitative analysis will be conducted prior to the qualitative analysis to allow for the merging of these parallel databases.

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CHAPTER FOUR

STUDY 1

EXAMINATION OF THE IMPACT OF DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT ON DIABETES MANAGEMENT PROCESS MEASURES

Abstract

Background: Diabetes has reached epidemic proportions in the United States. To address this, many organizations employ diabetes self-management education and support programs to aid in managing the impact of increasing prevalence.

Objective: The aim of this study is to describe the impact of an Upstate South Carolina ADA-accredited DSME program and community-based ADA Practice-tested DSMS program on three diabetes management process measures: retinal exams, nephropathy screening, and primary care service utilization.

Study Design: A 3-cohort, retrospective study design was employed to assess these outcomes. Given the unbalanced nature of the baseline demographics, three-group propensity score matching was conducted. For PCP utilization, a GLMM Poisson regression was conducted. For the retinal exam process measure, logistic regression was done. Lastly, for nephropathy screening, a GLMM logistic regression was completed.

Results: After propensity score matching the three groups, the groups remained unbalanced on age, hypertension, and dyslipidemia. These variables were controlled for in models. Intervention, race, age, sex, time, and other factors were found to not be significant predictors of PCP usage, retinal exam screening, or nephropathy attention.

Conclusion: This study found that DSME and DSMS did not significantly impact primary care utilization, retinal screenings, or nephropathy attention. Given the small sample and multiple limitations, these findings are inconclusive. Future studies should explore these findings with a larger sample size.

Introduction

In the United States, diabetes has reached epidemic proportions, with over 34 million adults, or 13.0% of the population, affected by this disease, where this prevalence rate has doubled over the past two decades. [1–3] Similarly, in South Carolina in 2018, approximately 531,143 South Carolina adults (13.3%) had diabetes compared to 205,236 adults (7.1%) in 2000. [3]

To address this growing burden, frequently recommended services are diabetes self-management education and support programs. Diabetes self-management education and support (DSMES) programs are composed of two programs, diabetes self-management education (DSME) and diabetes self-management support (DSMS), available to individuals with diabetes to aid in developing or maintaining the knowledge, skills, decision-making, and skills necessary for the self-management of diabetes. [4–6] DSME is known as "the active, on-going process of facilitating the knowledge, skill, and ability necessary for diabetes self-care," [7] while DSMS "refers to the support that is required for implementing and sustaining coping skills and behaviors needed to self-manage on an on-going basis." [7]

Obtaining DSMES can be beneficial for patients in various aspects of patient care and diabetes management. Several process measures of interest are primary care provider (PCP) utilization, retinal exams, and nephropathy attention. These three aspects are all critical aspects of managing an individual's diabetes. Literature has found DSME

beneficial in improving primary care utilization, but there is a limited to no literature of the impact of DSMS on PCP usage. A randomized controlled trial (RCT) and observational study both found that DSME attendance created an increase in PCP usage. [8,9] Similarly, a cross-sectional study in South Carolina found that DSME attendance had an impact on having an annual primary care provider (PCP) visit. [10] This increased contact with PCPs allows for more collaboration and potentially better management of their condition.

Another aspect of diabetes management is obtaining a retinal exam. A retinal exam is when an individual has their pupil dilated so the ophthalmologist or optometrist can examine the optic nerve, more specifically, the retina. [11] Utilization of DSME had mixed effects on obtaining an individual's retinal exam. One RCT found no significant difference in obtaining a retinal exam, while another found that more individuals in the DSME arm had received their retinal exam. [8,12] The same South Carolina study discussed above also found that DSME attendance had no impact on obtaining an annual retinal exam; rather, insurance status and age impacted the likelihood of obtaining an annual retinal exam. [13] DSMS programs show promising results of the impact they can have on annual retinal exams. After undergoing various DSMS interventions, the results showed that after the intervention, a significant portion of participants had obtained their annual retinal exam. [14–18]

Lastly, DSME and DSMS literature show the potential benefit of these interventions in aiding nephropathy screening. Nephropathy attention is the screening for chronic kidney disease (CKD). [19,20] The landmark Microalbuminuria Education Medication and Optimization (MEMO) randomized control trial found that an intensive, structured DSME could provide improved uACR and eGFR at 3 and 4 years, respectively. [21] Other interventional DSME studies found better nephropathy measures. [18,22] Similarly, a nested case-control study found that those individuals who obtained DSME were 1.5 times more likely to obtain nephropathy screening as measured as part of their bundle of diabetes self-management. [23] In the literature examining the impact of DSMS in obtaining nephropathy screening/attention, DSMS was successful in the majority of the studies. Several interventional studies found that the DSMS treatment group had a significant positive change in their nephropathy screening/values. [15,16,24] A feasibility study found that after the DSMS intervention, 73.2% of individuals had received nephropathy screening. [18] Overall, DSME and DSMS show promise in being able to positively impact chronic kidney disease screening rates and values, but further research is needed to confirm. It should be noted that presently guideline-concordant screening for CKD by PCPs is alarmingly low in the nation, with 19.6% - 51.6% of individuals obtaining screening consistent with American Diabetes Association (ADA) recommendations. [25,26]

In general, the literature shows promising results in DSME and DSMS improving retinal and nephropathy screening rates along with PCP utilization. The aim of this study is to describe the impact of an Upstate South Carolina ADA-accredited DSME program

and community-based ADA Practice-tested DSMS program on three diabetes management process measures: retinal exams, nephropathy screening, and primary care service utilization. It is hypothesized that those individuals participating in the interventions will have higher screening rates that are more consistent with the standard of care and higher primary care usage than those individuals who did not receive the services.

Methods

Data Management and Ethical Considerations

A three-cohort retrospective study design was employed to test the hypothesis. Cohorts were defined by intervention enrollment with sampling discussed below. Data were obtained from the longitudinal study entitled CU Healthy Greenville County: Integrated Services for Diabetes Prevention and Management and from Prisma Health-Upstate EPIC health records. The study team was not deidentified to the data for the HED individuals. Informed consent was provided by these individuals in the approved IRB protocol at Prisma Health-Upstate. For the DSME and control group, data were obtained via EPIC health record, and the study team was deidentified to these individuals. Prisma Health-Upstate IRB determined that the study is considered exempt from IRB approval.

Health Extension for Diabetes (DSMS) Intervention

Health Extension for Diabetes (HED) is a community-based, non-clinical diabetes self-management support program. HED is a four-month long, ADA Practice-Tested, [27] copyrighted support program based on the Association of Diabetes Cares and Education Specialists 7 Self-Care Behaviors (ADCES7). [5,28–31] HED was created in collaboration between clinicians, paraprofessionals, and researchers. HED has eight bi-weekly group sessions to deliver core content, with the support group and individual sessions occurring during the in-between weeks.

HED was designed to be delivered via paraprofessionals, with one session delivered by a Certified Diabetes Care and Education Specialist (CDCES) with a health system affiliation. The Health Extension Agents (HEAs) that lead the intervention have been trained in ADCES Prevention 101 and Diabetes Community Care Coordinator, formerly known as Paraprofessional level 2. These HEAs are based at Clemson Cooperative Extension. This is a "high-touch" program with a standardized core curriculum but the flexibility to be personalized to individuals' goals and needs. This is a free service for all individuals.

Diabetes Self-Management Education (DSME) Intervention

As stated above, DSME is " the ongoing process of facilitating the knowledge, skill, and ability necessary for diabetes self-care" [7] through "incorporat[ing] the needs, goals, and life experiences of the person…and is guided by evidence-based research" [7] where "the overall objectives of DSME are to support informed decision making, self-care

behaviors, problem-solving, and active collaboration with the health care team and to improve clinical outcomes, health status, and quality of life." DSME is commonly one-on-one, individualized care with a Certified Diabetes Care and Education Specialist (CDCES) or Board Certified in Advanced Diabetes Management (BC-ADM). [4–6,32] Some education may be delivered in group settings. DSME is recommended at four key points: 1.) at diagnosis, 2.) annually and/or when the individual is not meeting treatment target goals, 3.) when complicating factors arise, and 4.) when transitions in care or life occur. [4–6,32] This service is billed through insurance, which often is a barrier to service uptake. [4–6,32]

Sampling

To be included in the DSMS sample, individuals must have graduated HED by December 31, 2020. Individuals also must use a health system that uses EPIC. For the DSME program, individuals must have obtained DSME from the Prisma Health – Upstate Diabetes Self-Management Program between March 1, 2018, to December 31, 2020. Individuals' primary language must be English. The control sample included individuals who have been provided a referral for DSME but did not enroll. These individuals have not been enrolled in HED or obtained DSME from Prisma Health – Upstate Diabetes Self-Management Program between January 1, 2017, to December 31, 2021.

Individuals were excluded from the DSMS sample if they had not graduated from the intervention, died during the study period, or were formally disenrolled. For the DSME sample, individuals who died during the study period were excluded. Lastly, for the

control sample, the following individuals were excluded from the sample: individuals who died during the study period, individuals whose primary care provider changed to a non-EPIC EHR primary care provider during the study period, and individuals who did not receive a referral to DSME at the Prisma Health – Upstate Diabetes Self-Management Program. For all three groups, individuals who have a history of diagnosed stroke or hypertriglyceridemia were dropped from the sample.

Outcome Variables and their Operational Definitions

PCP Utilization

Primary care utilization is the number of times that an individual visits their primary care provider. A visit is defined as a virtual or in-person touchpoint between the provider and the patient. The number of visits was calculated on a monthly basis. Baseline PCP utilization is defined as the number of visits in the one month prior to starting the DSME or DSMS intervention. For the control group, baseline PCP utilization was set to one for the first PCP visit.

Retinal Exam

Retinal exams are recommended to occur within five years of the onset of type 1 diabetes and at disease diagnosis for type 2 diabetes. [19] For individuals with diabetes, the ADA Standards of Care in Diabetes – 2021 recommends screening every 1 – 2 years if there is no evidence of retinopathy present at the last exam and glycemia is well-managed. [19,33] If glycemia is not well-managed, retinal exams will need to be conducted at least annually,

but likely more frequently, depending on the rate of disease progression. [19] For this study, retinal exams will be examined annually.

Given retinal exams being conducted at least annually, this measure is examined once every 12 months. A baseline retinal exam is defined as having had a retinal exam during the one year before the end of the intervention. The retinal exam was assessed from the end date of the intervention to one-year post-intervention for people in DSME or DSMS.

Nephropathy attention

Chronic kidney disease is when the kidneys are damaged and cannot filter to remove waste as efficiently. [34–36] Tests to determine kidney function are urinary albumin-to-creatinine ratio (uACR), urine albumin, glomerular filtration rate (GFR), serum creatinine, or blood urea nitrogen (BUN). [19,35–38]. [28,32] Estimated GFR (eGFR) can be calculated from serum creatinine with other body measures. [19,36–38] Guideline-appropriate screening for CKD involves eGFR and uACR. [19] Nephropathy attention is recommended at least once annually for people with type 2 diabetes and people with type 1 diabetes with a duration of 5 years or more. [19,20,34,35,39] Nephropathy screening may be required more frequently than once annually, depending on the lab values of these tests. [19,34]

Nephropathy attention is defined in this study as the patient obtaining their eGFR screening at least every six months. The variable is examined via a six-month window. The value of eGFR is not examined but rather a binary indicator of screening being

conducted (1=yes, 0=no). Baseline nephropathy screening is defined as having an eGFR done within the prior six months from the intervention end date for DSME and DSMS groups. Baseline nephropathy screening is defined as the date of the first eGFR for the control individual.

Statistical Analysis

Prior to descriptive statistics being conducted, the data was cleaned. Individuals with unknown diabetes type or a diabetes type other than type 1 or type 2 were removed. For example, individuals with latent autoimmune diabetes in adults were removed from the sample. Additionally, individuals with a history of stroke or hypertriglyceridemia were removed due to the small number of individuals with these conditions (Figure 1). This was done consistently across the three groups. Additionally, given that the majority of the HED sample was unknown for the comorbid conditions (dyslipidemia, retinopathy, etc.), the no and unknown categories were merged. Lastly, race and ethnicity variables were merged into one variable.

Descriptive statistics were conducted. Standardized differences were utilized to assess differences between groups. [40] Propensity score matching was conducted to attempt to reduce the confounding effects of observational data. [41] To maximize group sample sizes while optimizing covariate balance, the common-referent approach to matching was employed. [42,43] This approach allows for one group to be the common connecter between the groups while selecting a matching pair individual from each of the other groups that

share a similar propensity score. [42,43] For the three groups, a 1:2 HED to control and a 3:1 HED to DSME nearest neighbor caliper matching was conducted. [44] The caliper width was set to 0.2 times the standard deviation of the propensity score for the respective treatment groups. [42,43]. The variables used in the model are age, race/ethnicity, sex, diabetes type, history of coronary artery disease, history of chronic kidney disease, history of dyslipidemia, history of hypertension, and history of retinopathy.

For each measure, a different statistical analysis was conducted. For primary care utilization, a generalized linear mixed effects model (GLMM) Poisson regression was completed because the outcome is a count variable and met model assumptions. This model controlled for age, race, sex, statin usage, hypertension, dyslipidemia, and baseline PCP utilization. For retinal exams, a logistic regression controlling for age, race, sex, statin usage, hypertension, and dyslipidemia was done due to the outcome variable being binary. Lastly, for nephropathy attention, a GLMM logistic regression with a categorical time effect was conducted due to the outcome being binary and multiple time measured over the study period. This model controlled for age, race, hypertension, dyslipidemia, and baseline nephropathy screening. Statistical significance was set at $p<0.05$. All analyses were conducted using SAS software, Version 9.4 of the SAS System for Windows (SAS Institute, Cary, NC, USA).

Results

Description of the study sample

Descriptive characteristics of the study sample prior to propensity score matching is shown in Table 1. HED consisted of 168 individuals with an average age of 67.0 (11.3) and a BMI of 34.4 (7.23). The majority (72.6%) of the sample was female, with 97.0% of individuals having type 2 diabetes and 78% with a history of hypertension. There was a relatively even balance between Black/African American (48.2%) and White (47.6%) individuals.

The DSME sample had 1376 people with an average age of 57.9 (15.4) and a BMI value of 34.4 (8.21). Slightly over half (56.1%) of the sample was female, with the majority having type 2 diabetes (87.9%) and a history of hypertension (93.8%). Over half (67.1%) of the sample was white, with 26.8% reporting as Black/African American.

The control sample had 348 individuals with an average age of 57.0 (14.2) and a BMI of 35.1 (15.1). The group was relatively evenly divided between males (48.6%) and females (51.4%). The majority of the sample had been diagnosed with type 2 diabetes (89.9%) and had a history of hypertension (98.3%).

Description of the propensity score matched sample

The descriptive characteristics of individuals in the sample are shown in table 2. After matching the unbalanced variables, age, hypertension, and dyslipidemia remained unbalanced, with standardized differences greater than 0.25.

For HED, the post-matched sample consisted of 84 individuals with an average age of 61.7 (10.3) and a BMI value of 36.1 (7.67). Over half (65.5%) were female, with 95.2% having type 2 diabetes. The majority (61.9%) of the sample was white, 33.3% Black/African American, and 4.76% was other/unknown. The majority of the sample did not report/was unknown if they had a history of coronary artery disease, chronic kidney disease, dyslipidemia, or retinopathy. Conversely, 88.1% had a history of hypertension.

For the DSME group, the post-matched sample consisted of 112 individuals with an average age of 58.4 (13.1) and a BMI of 34.2 (7.69). Slightly over half (58.9%) of the sample was female, with the majority (71.4%) being white. Ninety-six percent of individuals had type 2 diabetes. The majority of the sample did not have a history of coronary artery disease, chronic kidney disease, or retinopathy. Over half (58.0%) had no history of dyslipidemia, but 82.1% had a history of hypertension.

For the control group, the post-matched sample consisted of 125 individuals with an average age of 62.4 (11.9) and a BMI of 35.5 (8.90). Over half of the sample (62.4%) was female, with 72.98% being white. Similar to HED and DSME, the control group has 95.2% with type 2 diabetes. The majority of the sample did not have a history of coronary artery disease, chronic kidney disease, or retinopathy. Additionally, the majority (96.8%) had a history of hypertension, and 43.2% had a history of dyslipidemia.

Table 3 shows the number of individuals with at least one observation for each of the outcome measures.

PCP Utilization

The results of the GLMM Poisson regression are shown in Table 4. No variables were found significant in the model. There was no difference between the groups as compared to the control group for their PCP utilization (B_{DSMS}= -0.2035, p_{DSMS} = 0.305; B_{DSME}= -0.2829, p_{DSME}= 0.244). When looking at the impact of time on PCP usage in the one-year post-intervention, time was found to be non-significant (B=-0.0049; p-value =0.257). Similarly, a history of hypertension or dyslipidemia were found to have a non-significant impact on PCP utilization (B_{htn}= -0.126, p_{htn} = 0.632; B_{dys}= -0.009, p_{dys}= 0.917). Additionally, an individual's age was found to not be a significant predictor of PCP utilization (B= -0.005, p = 0.207). Race and sex were also found to be non-predictors of PCP utilization (B_{Black}= 0.0912, p_{Black} = 0.369; $B_{Other/Unknown}$ = 0.1887, $p_{Other/Unknown}$= 0.439; B_{Male}= -0.0393, p_{Male} = 0.673). Lastly, the impact of time by the group was examined to determine if the utilization rate changed over time by the group. This interaction was found to non-significant (B_{DSMS}= -0.126, p_{DSMS} = 0.632; B_{DSME}= -0.009, p_{DSME}= 0.917).

Retinal Exam

The results of the logistic regression are shown in Table 5. Similar to the results of PCP utilization, none of the variables were found to be significant in the model. There was no

difference in the log odds of the interventions being a predictor of individuals obtaining their retinal exam (B_{DSMS}= -4.9768, p_{DSMS} = 0.958; B_{DSME}= -5.3391, p_{DSME}= 0.955). Time was also found to not be a significant predictor of receiving a retinal exam (B = -0.3948; p-value =0.960).

Nephropathy Attention

The results of the GLMM logistic regression with a categorical time effect are shown in Table 6. There was no difference in the log odds of the intervention having an impact on receiving nephropathy attention (B_{DSMS}= -8.8383, p_{DSMS} = 0.286; B_{DSME}= -6.1016, p_{DSME}= 0.462). Time was also found to have no significant impact on obtaining nephropathy screening (B_{6mths}= 0.9967, p_{6mths} = 0.939; B_{12mths}= 0.750, p_{12mths}= 0.950). Similar to retinal exam screening, an individual's age and having a history of hypertension or dyslipidemia were not predictors of having a retinal exam conducted (B_{age}= 0.0211, p_{age} = 0.292; B_{htn}= 0.2079, p_{htn}= 0.751; B_{dys}= 0.1652, p_{dys} = 0.654). Lastly, the interaction between the impact of the group over time was found to be non-significant for both groups at all time points.

Discussion

This study sought to examine the impact of DSMS and DSME interventions on critical diabetes management process measures. It was hypothesized that those individuals participating in the interventions would have higher screening rates that are more consistent with the standard of care and higher primary care usage than those individuals

who did not receive the services. Utilizing an individual's primary care provider and obtaining the necessary screening measures for other complex conditions is an imperative aspect of diabetes management. This study found that DSME and DSMS did not have a significant impact on PCP utilization, retinal exam screening, or nephropathy screening.

While this study did not find PCP utilization to significantly change after DSME or DSMS intervention completion, the current results for the impact on utilization are mixed. The current literature on the impact of DSME on PCP usage shows limited but promising results. [9,10] Similarly, there is limited information about the impact of DSMS on usage. It is interesting that this study's results differ from the findings of a cross-sectional study conducted in South Carolina that found an impact of DSME on PCP usage. [10] This could be due to the population examined, given this study was conducted in one region of the state, and the cross-sectional study was conducted statewide. While this study did not find these interventions played a significant role in changing PCP utilization, it does show the need for continued research on this topic area.

Similarly, the literature surrounding the impact of DSME on obtaining retinal exams is positive, and the DSMS literature shows promising results of the impact. [8,12,14,17] The results of this study found that the interventions did not play a significant role in changing the odds of an individual obtaining their annual screening. Whether someone receives screening is due to a multitude of factors. [10,13] Future research should seek to include factors like these in the models to determine if these results hold true.

Lastly, participation in DSME and DSMS was inconclusive regarding the impact on nephropathy screening for individuals. Other studies in the current literature for DSME and DSMS found a positive impact for individuals obtaining nephropathy screening. [15,16,18,21,22,24] This could be due to the limited sample size and only examining eGFR. Given that studies recently found that many patients were not receiving ADA guideline-concordant care with nephropathy screening, future studies should examine if these interventions can aid in obtaining appropriate care. [25,26]

Limitations

While this study has many strengths, there are limitations to consider. The first is the small sample size for the cohorts after propensity score matching, particularly in the HED group. This results in the study being underpowered and vulnerable to a Type II error. Additionally, not all matched individuals had the measures (Table 3). This left the analyzed groups much smaller than the matched populations. For example, only 46 HED, 34 DSME, and 37 control group individuals had PCP utilization data during the study period. Future studies should seek to have a larger sample size to determine if these results remain true. Additionally, future studies should determine if setting the one month before the study period as the baseline for the control group for PCP utilization would have an impact on the outcomes.

Another limitation is that PCP is defined as only visits with the person defined at their primary care practitioner in EPIC. This definition limits the observations to only visits with one provider for the individual. Often patients do not utilize one individual for their primary care. Often patients are unable to meet with their primary provider on short notice and work with another provider in the office. Future studies should examine all internal medicine or family medicine practitioner visits as part of primary care usage. Additionally, future studies should also consider that not all patients utilize a family medicine or internal medicine provider as their primary care provider. Other disciplines, such as obstetrics/gynecologists and geriatricians, are commonly used for that role. Another future study should look at all provider visits and consider the changes in utilization for the individual's diabetes management needed.

Another limitation is that it is likely that not all retinal exams are recorded in an individual’s electronic health record. Often retinal exams are conducted by an optometrist or ophthalmologist, with the results not transferred back to be placed into the respective patient’s health record. Future studies should address seek to find complete retinal exam data either through a prospective study collecting this outcome or via a retrospective analysis working with an individual’s health record and local optometrists/ophthalmologists.

The next limitation is that nephropathy attention is only measured by eGFR. To determine true, guideline-concordant care, uACR and eGFR should be assessed.

Additionally, these measures and their testing time points should vary by individual as determined by their lab value. Future studies should consider the optimal time points to assess uACR and eGFR for each individual. Potentially conducting a prospective study to track individuals obtaining these measures could be beneficial. Similar to this limitation, the nephropathy attention only determined if the participant obtained the screening; it did not determine if the person had CKD. CKD was also not controlled for in the model; thus, some individuals may be tested more frequently due to being diagnosed with CKD. Future studies should control for CKD diagnosis and should consider the value of the test when examining the screening.

Another limitation is that the data was obtained from one health record at one health system. Individuals in this study may utilize multiple health systems, given the numerous healthcare organizations in the Upstate region of South Carolina. Individuals may have utilized primary care services at another organization or completed the screenings without the results being reported back to Prisma Health-Upstate. Future studies should seek to determine if there is data from individuals at multiple health organizations to ensure a comprehensive examination of the individual.

Conclusions

DSME and DSMS are critical interventions in helping address the impact diabetes has on an individual's daily life. While this study did not show the impact of DSME and DSMS on PCP utilization, retinal exam, and nephropathy screening when compared to a control

population, this does not mean the interventions do not aid in other diabetes management measures. Future research should seek to have a larger sample size to determine if these findings hold true.

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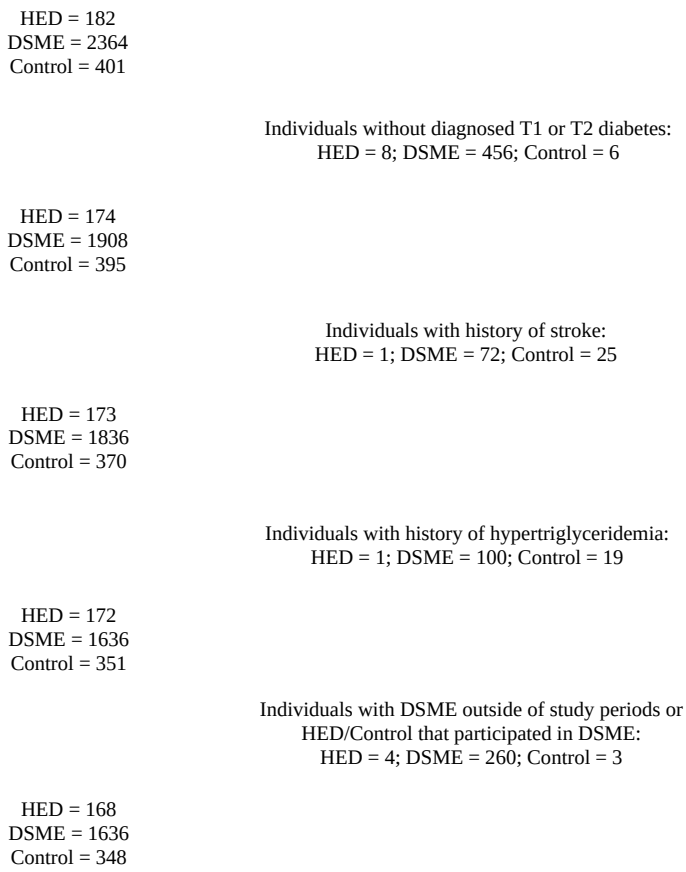
Figures and Tables

Figure 1: Diagram of Individuals removed from the sample



T1=Type 1 diabetes; T2=Type 2 diabetes; HED=Health Extension for Diabetes; DSME=Diabetes Self-management Education

Table 1: Descriptive Characteristics before Propensity Score Matching

	HED (1) (N=168)	DSME (2) (N=1376)	Control (3) (N=348)	SMD 1v2	SMD 1v3	SMD 2v3
	mean (SD)	*mean (SD)*	*mean (SD)*			
Age (years)	67.0 (11.3)	57.9 (15.4)	57.0 (14.2)	-0.672	-0.776	-0.058
BMI (kg/m^2)	34.4 (7.23)	34.4 (8.21)	35.1 (15.1)	-0.031	-0.029	0.0005
	N (%)	*N (%)*	*N (%)*			
Sex				0.3501	0.4472	0.0937
Male	46 (27.4)	604 (43.9)	169 (48.6)			
Female	122 (72.6)	772 (56.1)	179 (51.4)			
Race/Ethnicity				0.4446	0.3385	0.1253
Black/African American	81 (48.2)	369 (26.8)	111 (31.9)			
White	80 (47.6)	923 (67.1)	212 (60.9)			
Other/Unknown	7 (4.17)	84 (6.10)	25 (7.18)			
Diabetes Type				0.3519	0.2899	-0.066
1	5 (2.98)	167 (12.1)	35 (10.1)			
2	163 (97.0)	1209 (87.9)	313 (89.9)			
History of CAD*				0.5231	0.6367	0.1173
No	162 (96.4)	1103 (80.2)	262 (75.3)			
Yes	6 (3.57)	273 (19.8)	86 (24.7)			
History of CKD*				0.3573	0.3812	0.0267
No	165 (98.2)	1237 (89.9)	310 (89.1)			
Yes	3 (1.79)	139 (10.1)	38 (10.9)			
History of Dyslipidemia*				1.157	1.214	0.0418
No	143 (85.1)	498 (36.2)	119 (34.2)			
Yes	25 (14.9)	878 (63.8)	229 (65.8)			
History of Hypertension				0.4648	0.6609	0.2329
No	37 (22.0)	86 (6.25)	6 (1.72)			
Yes	131 (78.0)	1290 (93.8)	342 (98.3)			
History of Retinopathy*				0.3351	0.2988	-0.039
No	163 (97.0)	1217 (88.4)	312 (89.7)			
Yes	5 (2.98)	159 (11.6)	36 (10.3)			

* For the HED cohort, No and unknown responses were merged.
SMD=Standardized mean difference; HED=Health Extension for Diabetes; DSME=Diabetes Self-Management Education; BMI=Body mass index; CAD=Coronary artery disease; CKD=Chronic kidney disease.

Table 2: Descriptive Characteristics after Propensity Score Matching

	HED (1) (N=84)	DSME (2) (N=112)	Control (3) (N=125)	SMD 1v2	SMD 1v3	SMD 2v3
	Mean (SD)	*Mean (SD)*	*Mean (SD)*			
Age (years)	61.7 (10.3)	58.4 (13.1)	62.4 (11.9)	-0.273	0.0630	0.3136
BMI (kg/m^2)	36.1 (7.67)	35.2 (7.69)	35.5 (8.90)	-0.110	-0.111	0.0037
	N (%)	*N (%)*	*N (%)*			
Sex				0.1353	0.0641	-0.071
Male	29 (34.5)	46 (41.1)	47 (37.6)			
Female	55 (65.5)	66 (58.9)	78 (62.4)			
Race/Ethnicity				0.1919	0.2391	0.0618
Black/African American	28 (33.3)	28 (25.0)	30 (24.0)			
White	52 (61.9)	80 (71.4)	91 (72.8)			
Other/Unknown	4 (4.76)	4 (3.57)	4 (3.20)			
Diabetes Type				-0.060	0.0018	0.1001
1	4 (4.76)	4 (3.57)	6 (4.80)			
2	80 (95.2)	108 (96.4)	119 (95.2)			
History of CAD*				0.1255	0.1657	0.0405
No	78 (92.9)	100 (89.3)	110 (88.0)			
Yes	6 (7.14)	12 (10.7)	15 (12.0)			
History of CKD*				0.0000	0.1211	0.0614
No	81 (96.4)	108 (96.4)	119 (95.2)			
Yes	3 (3.57)	4 (3.57)	6 (4.80)			
History of Dyslipidemia*				0.2831	0.4732	0.0250
No	60 (71.4)	65 (58.0)	71 (56.8)			
Yes	24 (28.6)	47 (42.0)	54 (43.2)			
History of Hypertension				-0.168	0.3086	0.4918
No	10 (11.9)	20 (17.9)	4 (3.20)			
Yes	74 (88.1)	92 (82.1)	121 (96.8)			
History of Retinopathy*				0.0272	0.0714	0.0443
No	80 (95.2)	106 (94.6)	117 (93.6)			
Yes	4 (4.76)	6 (5.36)	8 (6.40)			

* For the HED cohort, No and unknown responses were merged.
SMD=Standardized mean difference; HED=Health Extension for Diabetes; DSME=Diabetes Self-Management Education; BMI=Body mass index; CAD=Coronary artery disease; CKD=Chronic kidney disease.

Table 3: Number of Individuals with at least one observation at each time point

	DSMS	**DSME**	**Control**
PCP Utilization (number of visits	*46 different individuals*	*34 different individuals*	*37 different individuals*
Baseline	13	11	37
1 month	10	14	15
2 months	16	9	10
3 months	18	8	13
4 months	13	11	9
5 months	13	2	7
6 months	20	6	12
7 months	14	4	12
8 months	14	4	7
9 months	19	4	13
10 months	14	2	8
11 months	13	6	12
12 months	22	6	13
Retinal Exam	*41 different individuals*	*32 different individuals*	*51 different individuals*
Baseline	19	11	51
12 months	33	21	7
Nephropathy Attention	*53 different individuals*	*65 different individuals*	*108 different individuals*
Baseline	33	56	108
6 months	53	55	58
12 months	51	53	49

Table 4: Results of Regression Analysis for PCP Utilization

Variable	*Estimate (Std. Err.)*	*p-value*
Intercept	0.7377 (0.379)	0.054
Time	-0.0177 (0.020)	0.379
Intervention Group		
DSMS	-0.2035 (0.198)	0.305
DSME	-0.2829 (0.243)	0.244
Control	Ref.	Ref.
Age	-0.0049 (0.004)	0.257
Race		
Black	0.0912 (0.101)	0.369
Other/Unknown	0.1887 (0.243)	0.439
White	Ref.	Ref.
Sex		
Male	-0.0393 (0.093)	0.673
Female	Ref.	Ref.
Statin		
Yes	-0.0161 (0.110)	0.884
No	Ref.	Ref.
Hypertension		
Yes	-0.1123 (0.286)	0.695
No	Ref.	Ref.
Dyslipidemia		
Yes	0.0060 (0.094)	0.949
No	Ref.	Ref.
Group by Time Interaction		
DSMS by Time	0.0336 (0.026)	0.196
DSME by Time	0.0160 (0.036)	0.655
Control by time	Ref.	Ref.

DSMS=Diabetes Self-Management Support (i.e., HED); DSME=Diabetes Self-Management Education

Table 5: Results of Regression Analysis for Retinal Exam Screening

Variable	*Estimate (Std. Err.)*	*p-value*
Intercept	4.4858 (94.718)	0.962
Time	-0.3948 (7.893)	0.960
Intervention Group		
DSMS	-4.9768 (94.713)	0.958
DSME	-5.3391 (94.779)	0.955
Control	Ref.	Ref.
Age	0.0036 (0.016)	0.825
Race		
Black	0.2289 (0.612)	0.708
Other/Unknown	-0.2594 (1.112)	0.816
White	Ref.	Ref.
Sex		
Male	0.0058 (0.179)	0.974
Female	Ref.	Ref.
Statin Use		
Yes	0.0843 (0.196)	0.667
No	Ref.	Ref.
Hypertension		
Yes	0.0239 (0.288)	0.934
No	Ref.	Ref.
Dyslipidemia		
Yes	0.0738 (0.179)	0.681
No	Ref.	Ref.
Group by Time Interaction		
DSMS by Time	0.5260 (7.893)	0.947
DSME by Time	0.5033 (7.893)	0.949
Control by time	Ref.	Ref.

DSMS=Diabetes Self-Management Support (i.e., HED); DSME=Diabetes Self-Management Education

Table 6: Results of Regression Analysis for Nephropathy Attention

Variable	*Estimate (Std. Err.)*	*p-value*
Intercept	8.5150 (8.368)	0.310
Time		
6 months	0.9567 (12.392)	0.939
12 months	0.750 (11.946)	0.950
Intervention Group		
DSMS	-8.8383 (8.286)	0.286
DSME	-6.1016 (8.288)	0.462
Control	Ref.	Ref.
Age	0.0211 (0.020)	0.292
Race		
Black	0.4690 (0.458)	0.306
Other/Unknown	-1.6541 (1.497)	0.269
White	Ref.	Ref.
Hypertension		
Yes	0.2079 (0.655)	0.751
No	Ref.	Ref.
Dyslipidemia		
Yes	0.1652 (0.419)	0.694
No	Ref.	Ref.
DSMS by Time Interaction		
DSMS at 6 months	-0.6934 (12.401)	0.955
DSME at 12 months	-0.4007 (11.955)	0.973
DSME by Time Interaction		
DSMS at 6 months	-4.4187 (12.763)	0.722
DSME at 12 months	-5.5714 (11.962)	0.642

DSMS=Diabetes Self-Management Support (i.e., HED); DSME=Diabetes Self-Management Education

CHAPTER FIVE

STUDY 2

EXAMINATION OF THE IMPACT OF DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT ON DIABETES MANAGEMENT CLINICAL OUTCOME MEASURES

Abstract

Background: Diabetes is a chronic condition whose prevalence has doubled in the last two decades. To address this growing burden, many organizations employ diabetes self-management education and support programs to aid in addressing the increasing prevalence.

Objective: The aim of this study is to describe the impact of an upstate South Carolina ADA-accredited DSME program and an upstate South Carolina ADA practice-tested, community-based DSMS program on six diabetes management outcomes measures (A1C, BMI, LDL, HDL, TC, and TG) as compared to individuals who did not receive either intervention.

Study Design: This was a 3-cohort retrospective study design. The three cohorts were propensity score matched. Linear mixed effects models controlling age, BMI, race/ethnicity, sex, statin usage, history of hypertension, and history of dyslipidemia were conducted.

Results: As time progressed, there was a significant difference in A1C between groups ($B_{DSMS\ at\ 3mths}$=-0.6913, p-value=0.355; $B_{DSME\ at\ 3mths}$=-2.7217, p-value=0.002). Similar to A1C, DSME had significant reductions in BMI at 6 months (B=-0.9305, p-value=0.006), 9 months (B=-0.8426, p-value=0.026), and 12 months (B=-0.8689, p-value=0.024).

Black/African American race was found to be a significant predictor of BMI (B=2.1422, p-value=0.049), LDL (B=14.3752, p-value=0.040), HDL (B=6.2356, p-value=0.009), and triglycerides (B=-76.4897, p-value=0.001). Statin usage had a non-significant impact on all lipid panel measures. DSME and DSMS had no other significant changes over time for the lipid panel measures.

Conclusion: This study supports that DSME is a highly beneficial tool for lowering A1C. Similar to the literature, this study found non-significant changes in lipid panel measures over time for DSMS and DSME interventions when compared to a control group. Interestingly, statin usage was found to be a non-significant predictor for all four lipid panel measures. Future studies should seek to determine if these results hold with a larger, more generalizable sample.

Introduction

Diabetes is a chronic condition that has reached epidemic proportions in the United States. In 2018, over 34 million adults, or 13.0% of the population, are affected by this disease, with the diabetes prevalence rate having doubled over the past 20 years. [1,2] South Carolina's prevalence rate mimics the rapidly increasing national prevalence rate. In South Carolina in 2018, over 531,000 (13.3%) adults had diabetes compared to approximately 205,000 adults (7.1%) in 2000. [2]

To address this increasing burden in the U.S. and aid in the self-management of this chronic condition, the American Diabetes Association (ADA) recommends the utilization of diabetes self-management education and support (DSMES). DSMES is comprised of two complementary parts: diabetes self-management education (DSME) and diabetes self-management support (DSMS). Diabetes self-management education (DSME) is known as "the active, on-going process of facilitating the knowledge, skill, and ability necessary for diabetes self-care" [3] while diabetes self-management support (DSMS) "refers to the support that is required for implementing and sustaining coping skills and behaviors needed to self-manage on an on-going basis." [3] The combination of these two components allows organizations, programs, or departments to address the plethora of individual factors that impact an individual's ability to self-manage their diabetes. [3–6]

While DSMES is a common modality to aid in addressing the burden of diabetes, there are several measures that have been used consistently to evaluate the success of these two intervention approaches in diabetes management. The measures often employed are

changes in hemoglobin A1C (A1C), body mass index (BMI), low-density lipoprotein (LDL), high-density lipoprotein (HDL), total cholesterol (TC), and triglycerides (TG).

The most commonly discussed clinical measure examined to determine how well an individual's diabetes is managed is A1C. A1C is an average measure of an individual's blood glucose level over the last two to three months. [7–10] Extensive research has been conducted on the impact of DSME on A1C and found the intervention to be highly effective in lowering A1C. Studies have shown reductions in DSME of at least 0.6%, with greater education resulting in greater reductions. [11–15] Similarly, many researchers have examined the impact of DSMS on A1C. The majority of DSMS studies found reductions ranging from 0.15% to 2.2%. [16–20]

Another aspect examined to assess the health status of a person with diabetes is BMI. Body mass index (BMI) is a measure of body fat on an individual based on height and weight. While BMI is not a direct measure of body fat, studies have found it moderately correlated with direct measurements. [21] The literature on the impact of DSME and DSMS on BMI shows that majority of studies have non-significant findings. [22–30] Some DSME interventions found reductions ranging from $0.2^{kg}/_{m^2}$ to $2.11^{kg}/_{m^2}$. [31–34] Similarly, some DSMS studies found reductions in BMI ranging from $0.29^{kg}/_{m^2}$ to $2.4^{kg}/_{m^2}$. [17,34–36]

Lipid management is a crucial aspect of diabetes management. LDL, HDL, TC, and TG are the four measures part of a lipid panel. Each component of the lipid panel measures different aspects of the overall cardiovascular health of the individual. The lipid panel measures the good and bad cholesterol, or fat, in the blood. [37,38] Presently, the literature provides mixed results of the efficacy of DSME and DSMS in impacting lipid panel measures. For DSME, the majority of the literature found non-significant reductions in LDL, [39–42] but some DSME programs found reductions ranging from 0.33 mg/dL to 20.42 mg/dL. [22,23,25,43] Presently, the limited literature assessing the impact of DSMS interventions on LDL reductions found changes of -4.32mg/dL to -25mg/dL. [44,45] For HDL, TC, and TG, the literature provides mixed results of the efficacy in positive changes. Similar to LDL, there is limited research on the benefits of DSMS interventions aiding in changes in HDL, TC, and TG.

In general, DSME and DSMS have been shown to be highly effective at reducing A1C, not commonly effective at reducing BMI, and mixed results at impacting an individual's four lipid panel measures. The aim of this study is to describe the impact of an upstate South Carolina ADA-accredited DSME program and an upstate South Carolina ADA practice-tested, community-based DSMS program on six diabetes management outcomes measures (A1C, BMI, LDL, HDL, TC, and TG) as compared to individuals who did not receive either intervention. It is hypothesized that individuals in the DSME and DSMS interventions will have greater changes in the 6 outcome measures than individuals who did not participate in one of those two programs.

Methods

Study Design and Sampling

This is a three-cohort, retrospective study design. The three cohorts are HED/DSMS, DSME, and a control group. The study period goes from March 1, 2017, to December 31, 2021. As stated in chapters 3 and 4, for the DSMS sample, individuals must have graduated HED by December 31, 2020, and also must use a health system that uses EPIC. The DSME individuals must have obtained DSME from the Prisma Health – Upstate Diabetes Self-Management Program between March 1, 2018, to December 31, 2020. The control sample was individuals who have been provided a referral for DSME but did not enroll. These individuals have not been enrolled in HED or obtained DSME from Prisma Health – Upstate Diabetes Self-Management Program between January 1, 2017, to December 31, 2021.

Individuals were excluded from the DSMS sample if they did not graduate from the intervention, died during the study period, or were formally disenrolled. In the DSME sample, individuals who did not complete DSME in English or died during the study period were excluded. For the control sample, individuals who died during the study period, changed to a non-EPIC EHR primary care provider during the study period, or did not receive a referral to DSME at the Prisma Health – Upstate Diabetes Self-Management Program were excluded from the sample.

As stated in Chapter 4, the data was cleaned prior to conducting descriptive statistics. The following individuals were removed from the sample: an unknown diabetes type, diabetes type other than type 1 or type 2, history of diagnosed stroke, or history of hypertriglyceridemia. This was done consistently across all 3 groups (see Chapter 4, Figure 1). Additionally, since the majority of the HED sample was categorized as unknown for the comorbid conditions (dyslipidemia, retinopathy, etc.), the no and unknown categories were merged. Lastly, race and ethnicity variables were merged into one variable. While they are commonly measured separately, they were merged so "White" remained "White", "Black/African American" remained as such, and those listed as any other race or ethnicity became "Other/Unknown."

Health Extension for Diabetes (DSMS) Intervention

Health Extension for Diabetes (HED) is an ADA practice-tested, community-based, non-clinical diabetes self-management support program based on based on the Association of Diabetes Cares and Education Specialists 7 Self-Care Behaviors (ADCES7). [5,46–49] HED is a copyrighted, 4-month-long program with eight bi-weekly group sessions to deliver core content, with the support group and individual sessions occurring during the in-between weeks. HED is delivered via Cooperative Extension Health Extension Agents who are diabetes-educated paraprofessionals, with one session delivered by a Certified Diabetes Care and Education Specialist (CDCES) with a health system affiliation.

Diabetes Self-Management Education (DSME) Intervention

DSME is " the ongoing process of facilitating the knowledge, skill, and ability necessary for diabetes self-care" [3] through "incorporat[ing] the needs, goals, and life experiences of the person…and is guided by evidence-based research." [3] DSME is commonly one-on-one with a Certified Diabetes Care and Education Specialist (CDCES) or Board Certified in Advanced Diabetes Management (BC-ADM), but some education is delivered in a group setting. [4–6,50]. DSME is recommended for people with diabetes at four key points: 1.) at diagnosis, 2.) annually and/or when the individual is not meeting treatment target goals, 3.) when complicating factors arise, and 4.) when transitions in care or life occur. This service can be billed through insurance.

Data Management and Ethical Considerations

As stated in Chapter 4, data were obtained from CU Healthy Greenville County: Integrated Services for Diabetes Prevention and Management and from Prisma Health-Upstate EPIC health records. HED individuals provided informed consent per approved IRB protocol at Prisma Health-Upstate. For the DSME and control group, data were obtained via EPIC health record, and the study team was deidentified to these individuals. Prisma Health-Upstate IRB determined that the study is considered exempt from IRB approval.

Outcome Measure Operational Definitions and Analysis Plan

A1C

For most non-pregnant adults, the optimal A1C goal is <7.0%, and very poor control is commonly defined as having A1C>9.0%. [51] For individuals meeting their treatment goals and considered to have stable glycemia, the ADA Standards of Medical Care for Diabetes (SOC) recommends that glycemic status be assessed at least twice annually. [52] For individuals who are not meeting their treatment goals or whose therapy has recently been modified, ADA SOC recommends that glycemic status be assessed at least quarterly and as needed. [52]

For this study, A1C was assessed in 3-month increments. The baseline value is defined as a measure that occurred within 90 days of the start date of the intervention. For individuals in the control group, the baseline value was set to the first A1C value for that individual.

Body Mass Index (BMI)

The two common ways to calculate BMI are using kilograms (kg) and meters (m):

$$weight\ in\ kg \Big/ [height\ in\ m]^2$$

or pounds (lb.) and inches (in):

$$\left(weight\ in\ lb \Big/ [height\ in\ in]^2\right) \times 703$$ [21].

As BMI increases, this states that the individual has a higher amount of body fat. BMI is a value that should be assessed at every patient contact. [53]

BMI was captured at every in-person appointment with either the individual's PCP or DSME visit. Similar to A1C, BMI was examined in 3-month increments. For individuals in DSME or DSMS, the baseline value was set to the BMI that was within 3 months of the start date of the program. The baseline value for control was defined the same as it was for A1C.

Low-Density Lipoprotein

Low-density lipoprotein (LDL) is commonly referred to as bad cholesterol for its critical role in the development of atherosclerosis, which is the narrowing of arteries through fatty buildup. [54] Generally, the ADA recommends that an individual has an LDL < 100 mg/dL. [55,56] However, this recommended level may vary depending on atherosclerotic cardiovascular disease (ASCVD) risk factors. [57,58] Statin therapy is a crucial aspect of lipid management. Statins are a class of lipid-lowering medications that aim to reduce an individual's LDL. [55,58–60]

For this study, LDL was examined in 6-month increments. The baseline value is defined as a measure that occurred within 90 days of the start date of the intervention. For individuals in the control group, the baseline value was set to the first LDL value for that individual.

High-Density Lipoprotein

High-density lipoprotein (HDL) is often referred to as good cholesterol because of its protective effect against ASCVD by bringing the LDL to the liver to be processed. The ADA recommends that women have an HDL > 50mg/dL and men have an HDL > 40mg/dL. [55,61] When an individual begins statin therapy to decrease their LDL, a secondary factor found is a marginal increase in HDL level. [55,60,62,63] HDL was examined in the same manner as LDL, with the baseline values being determined in the same method.

Total Cholesterol

Lastly, total cholesterol is the sum of LDL and HDL. Presently, ADA and AHA recommend that individuals with diabetes have a TC level < 200mg/dL. [56] In the 2018 American Heart Association and American College of Cardiology Task Force guideline report suggested a stricter goal of <150mg/dL, with the idea that 100 is attributed to the LDL at maximum. [59] TC was examined in the same manner as LDL, with the baseline values being determined in the same method.

Triglycerides

Triglycerides store the excess energy in the body from an individual's diet and are the most common type of fat. The ADA recommends that an individual's TG < 150mg/dL. [55,56,61] While statin therapy has been shown to aid in the reduction of TG levels, lifestyle modifications, such as diet and physical activity, have been proven to be highly effective

in decreasing the level. [55,61] TG was examined in the same manner as LDL, with the baseline values being determined in the same method.

Statistical Analysis

Descriptive statistics were conducted between the three groups, where the standardized difference was employed to determine differences between groups. [64] Propensity score matching on covariates was conducted to reduce the confounding effects of observational data. [65] To maximize group sample sizes while optimizing covariate balance, the common-referent approach to matching was employed. [66,67] For the three groups, a 1:2 HED to control and a 3:1 HED to DSME nearest neighbor caliper matching was conducted. [68] The caliper width was set to 0.2 times the standard deviation of the propensity score for the respective treatment group. [66,67] The variables used in the model are age, race/ethnicity, sex, diabetes type, history of coronary artery disease, history of chronic kidney disease, history of dyslipidemia, history of hypertension, and history of retinopathy.

Five separate random intercept linear mixed effects models (LMM) with categorial time effects were conducted for A1C, BMI, LDL, HDL, and TC. Another random intercept linear mixed model with a piecewise time effect was conducted for TG. Each model controlled for age, race/ethnicity, sex, hypertension, and dyslipidemia. Statin usage was controlled for in the four lipid panel measure models. Type 1 error rate was set at $p<0.05$.

All analyses were conducted using SAS software, Version 9.4 of the SAS System for Windows (SAS Institute, Cary, NC, USA).

Results

Description of the study sample before and after propensity score matching

Descriptive characteristics of the study sample prior to propensity score matching are shown in Table 1. For written description, please see Chapter 4. After matching for the unbalanced variables, the descriptive characteristics of individuals in the sample are shown in table 2. The remaining unbalanced variables are age, hypertension, and dyslipidemia.

Table 3 shows the number of individuals with at least one observation for the various outcome variables at each time point. Table 4 and Figures 1-6 show the average value of the outcome at each time point. Additionally, statin usage is discussed in the four lipid panel analyses. For HED, 38 people report use, 30 individuals for DSME, and 45 individuals for the control group.

A1C

The results of the random intercept LMM with categorical time effect for A1C are shown in table 5. There was a significant baseline difference between the groups, where DSMS was significantly lower than the control group (B=1.6288, p-value=0.006). When looking at the type 3 effects of how the groups differed over time, there was a significant

difference between groups (p-value=0.029). DSME had reductions in A1C at 3 months (B=-2.7217, p-value=0.002), 6 months (B=-1.4067, p-value=0.029), and 12 months (B=-1.6590, p-value=0.026).

BMI

The results of the random intercept LMM with categorical time effect for BMI are shown in table 6. Age, black race, and male sex were found to be significant predictors of BMI change (B_{age}=-0.1839, p-value<0.0001; B_{Black}=2.1422, p-value=0.049; B_{Male}=-2.6486, p-value=0.006). When examining if there is a difference between groups over time, there was found to be a significant difference (p-value=0.0407). DSME was found to have reductions in BMI at 6 months (B=-0.9305, p-value=0.006), 9 months (B=-0.8426, p-value=0.026), and 12 months (B=-0.8689, p-value=0.024).

LDL

The results of the random intercept LMM with categorical time effect for LDL are shown in table 7. Black race was found to be a significant predictor of LDL (B=14.3752, p-value=0.040). When examining how the LDL changed in each intervention group over time, neither DSME nor DSMS had significant changes from baseline as compared to the control group.

HDL

The results of the random intercept LMM with categorical time effect for HDL are shown in table 8. Black race and male sex were found to be significant predictors of HDL change (p_{Black}=0.6.2356; p-value=0.009; p_{male}=-6.0436; p-value=0.004). When examining the type 3 tests for fixed effects, how groups change over time was found to be a non-significant predictor (p-value=0.2788).

TC

The results of the random intercept LMM with categorical time effect for TC are shown in table 9. No variables were found to have a significant impact on change in total cholesterol.

TG

The results of the random intercept LMM with a piecewise time effect for TG are shown in table 10. Black race was found to be a significant predictor for triglycerides (B=-76.4897, p-value=0.001).

Discussion

This study sought to examine the impact of DSMS and DSME interventions in Upstate South Carolina on critical diabetes management clinical measures. Management of an individual's diabetes is commonly measured via A1C and BMI, but lipid panel measures are commonly employed to determine the overall health of the individual and the impact of diabetes on their holistic health. This study found that DSME had a significant

reduction in A1C and BMI but not low-density lipoprotein, total cholesterol, or triglycerides.

The population examined in this study had a high baseline A1C (7.74% for HED, 9.78% for DSME, and 9.35% for control; Figure 1). Recall that for most non-pregnant adults, the optimal A1C goal is <7.0%, but sometimes a less strict goal of A1C<8.0% may be used. [52] Very poor diabetes control is often defined as having A1C>9.0%. [51] This means that the DSME and control groups are considered poorly controlled. This could play a role in the A1C reduction over time seen by the DSME group. Given their high baseline value, they had greater room for improvement than the DSMS group.

Additionally, the BMI for this population is considered Class 2 obesity (37.94 $^{kg}/_{m^2}$ for HED, 35.02 $^{kg}/_{m^2}$ for DSME, and 35.51 $^{kg}/_{m^2}$ for the control; Figure 2). [69] This differs from Table 2 due to the individuals that had BMI data to analyze (71 for HED, 95 for DSME, and 107 for control). Having a BMI this high for these individuals parallels the national average. About 45.8% of people with diabetes have a BMI between 30 and 39.9$^{kg}/_{m^2}$. [70] Given that these BMI values were obtained from DSME or primary care provider visits, these individuals could be needing a higher level of care than others.

The LDL values of these populations are higher than the recommended level of 100mg/dL. [55,56] At baseline, the HED population has an LDL less than the recommended

level (95.63 mg/dL) compared to the DSME (109.40 mg/dL) and control (101.17 mg/dL) groups (Table 4, Figure 3). While the DSME and DSMS groups did not have a significant change at 6 months post-intervention, each had a clinically significant increase of 17.512mg/dL and 14.102mg/dL, respectively. This increase is interesting and should be researched further in future studies to determine if it stays consistent in a larger sample.

Similarly, the HDL had a much lower level than the recommended 45mg/dL for the groups (Figure 4). However, literature shows that individuals with high triglyceride levels commonly have lower HDL levels. [71] The triglyceride levels for individuals in this study are significantly higher than the recommended 150mg/dL (203.8 for HED, 216.6 for DSME, and 237.6 for control groups; Figure 6). Given these levels, many of these individuals likely have undiagnosed hypertriglyceridemia. Hypertriglyceridemia is defined as having a fasting triglyceride level >150mg/dL. [55,61,72] Mild hypertriglyceridemia is defined as a TG level of 150mg/dL - 175mg/dL, moderate is 175mg/dL - 499mg/dL, while severe is ≥ 500mg/dL. [61,72] Future studies should not exclude individuals with diagnosed hypertriglyceridemia at baseline and examine at baseline if more individuals have this condition but are undiagnosed. This could aid in controlling for the condition in future models.

Paralleling TG, total cholesterol was higher than the recommended level of 200mg/dL (217.9 for HED, 234.2 for DSME, and 239.0 for control groups; Figure 5). Interestingly, those with hypertension had a clinically-significant lower TC level than those without

hypertension (-11.2999mg/dL). This could be because statin medications are utilized as antihypertensives, meaning an individual with hypertension could be on a stronger statin medication than someone without hypertension. Future research should determine the type and dosage of the statin medications to be able to better control for the effects of these medications.

Interestingly, statin usage was a non-significant predictor for all lipid panel measures. Traditionally, statin medication is commonly employed to aid in LDL reduction, along with diet and lifestyle modification. [55,58–60] Studies have found statin medication can cause a non-substantial increase in HDL, but this study showed the opposite. [55,60,62,63] Statin medications have also been shown to have small decreases in total cholesterol, due to LDL reductions, and triglyceride levels. [55,61]

Limitations

While this study has many strengths, there are several limitations. The first limitation that should be considered is the small sample size. After matching, each of the groups has smaller sample sizes, and those individuals with measures at each time point are smaller. For example, only 54 HED, 69 DSME, and 90 control individuals had A1C data for analysis. Future studies should obtain a larger, more generalizable sample to determine if these findings hold.

Secondly, this data is only obtained from one geographical region in South Carolina. This region is not representative of the state of South Carolina or the nation. Additionally, the DSME and control groups are from one DSME program. This limits the generalizability of the sample. Future studies should aim to recruit a more diverse sample.

Similarly, there is self-selection bias for those participating in DSME. The control is composed of individuals who have been referred to DSME at this particular program but elected not to participate. This could be due to unmeasured factors that the individuals in the DSME intervention elected to participate in the program, such as patient activation, income level, educational attainment, and insurance status.

Lastly, this study does not control for these values in the years prior to participation in programs. Future studies should attempt to control for prior clinical measure values to determine the role they could have in program participation and future outcomes after the intervention.

Conclusions

This study supports that DSME is a highly beneficial tool for lowering A1C. Given the known benefits of A1C reduction, DSME should continue to be recommended to individuals, regardless of A1C level. Similar to the literature, this study found non-significant changes in lipid panel measures over time for DSMS and DSME interventions when compared to a control group. Interestingly, statin usage was found to be a non-

significant predictor for all four lipid panel measures. However, this population had an unusually high BMI level at baseline, indicating this sample is not representative. Future studies should seek to determine if these results hold with a larger, more generalizable sample.

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Tables and Figures

Table 1: Descriptive Characteristics before Propensity Score Matching

	HED (1) (N=168)	DSME (2) (N=1376)	Control (3) (N=348)	SMD 1v2	SMD 1v3	SMD 2v3
	Mean (SD)	*Mean (SD)*	*Mean (SD)*			
Age (years)	67.0 (11.3)	57.9 (15.4)	57.0 (14.2)	-0.672	-0.776	-0.058
BMI (kg/m^2)	34.4 (7.23)	34.4 (8.21)	35.1 (15.1)	-0.031	-0.029	0.0005
	N (%)	*N (%)*	*N (%)*			
Sex				0.3501	0.4472	0.0937
Male	46 (27.4)	604 (43.9)	169 (48.6)			
Female	122 (72.6)	772 (56.1)	179 (51.4)			
Race/Ethnicity				0.4446	0.3385	0.1253
Black/African American	81 (48.2)	369 (26.8)	111 (31.9)			
White	80 (47.6)	923 (67.1)	212 (60.9)			
Other/Unknown	7 (4.17)	84 (6.10)	25 (7.18)			
Diabetes Type				0.3519	0.2899	-0.066
1	5 (2.98)	167 (12.1)	35 (10.1)			
2	163 (97.0)	1209 (87.9)	313 (89.9)			
History of CAD*				0.5231	0.6367	0.1173
No	162 (96.4)	1103 (80.2)	262 (75.3)			
Yes	6 (3.57)	273 (19.8)	86 (24.7)			
History of CKD*				0.3573	0.3812	0.0267
No	165 (98.2)	1237 (89.9)	310 (89.1)			
Yes	3 (1.79)	139 (10.1)	38 (10.9)			
History of Dyslipidemia*				1.157	1.214	0.0418
No	143 (85.1)	498 (36.2)	119 (34.2)			
Yes	25 (14.9)	878 (63.8)	229 (65.8)			
History of Hypertension				0.4648	0.6609	0.2329
No	37 (22.0)	86 (6.25)	6 (1.72)			
Yes	131 (78.0)	1290 (93.8)	342 (98.3)			
History of Retinopathy*				0.3351	0.2988	-0.039
No	163 (97.0)	1217 (88.4)	312 (89.7)			
Yes	5 (2.98)	159 (11.6)	36 (10.3)			

* For the HED cohort, No and unknown responses were merged. SMD=Standardized mean difference; HED=Health Extension for Diabetes; DSME=Diabetes Self-Management Education; BMI=Body mass index; CAD=Coronary artery disease; CKD=Chronic kidney disease.

Table 2: Descriptive Characteristics after Propensity Score Matching

	HED (1) (N=84)	DSME (2) (N=112)	Control (3) (N=125)	SMD 1v2	SMD 1v3	SMD 2v3
Age	61.7 (10.3)	58.4 (13.1)	62.4 (11.9)	-0.273	0.0630	0.3136
BMI	36.1 (7.67)	35.2 (7.69)	35.5 (8.90)	-0.110	-0.111	0.0037
Sex				0.1353	0.0641	-0.071
Male	29 (34.5)	46 (41.1)	47 (37.6)			
Female	55 (65.5)	66 (58.9)	78 (62.4)			
Race/Ethnicity				0.1919	0.2391	0.0618
Black/African American	28 (33.3)	28 (25.0)	30 (24.0)			
White	52 (61.9)	80 (71.4)	91 (72.8)			
Other/Unknown	4 (4.76)	4 (3.57)	4 (3.20)			
Diabetes Type				-0.060	0.0018	0.1001
1	4 (4.76)	4 (3.57)	6 (4.80)			
2	80 (95.2)	108 (96.4)	119 (95.2)			
History of CAD*				0.1255	0.1657	0.0405
No	78 (92.9)	100 (89.3)	110 (88.0)			
Yes	6 (7.14)	12 (10.7)	15 (12.0)			
History of CKD*				0.0000	0.1211	0.0614
No	81 (96.4)	108 (96.4)	119 (95.2)			
Yes	3 (3.57)	4 (3.57)	6 (4.80)			
History of Dyslipidemia*				0.2831	0.4732	0.0250
No	60 (71.4)	65 (58.0)	71 (56.8)			
Yes	24 (28.6)	47 (42.0)	54 (43.2)			
History of Hypertension				-0.168	0.3086	0.4918
No	10 (11.9)	20 (17.9)	4 (3.20)			
Yes	74 (88.1)	92 (82.1)	121 (96.8)			
History of Retinopathy*				0.0272	0.0714	0.0443
No	80 (95.2)	106 (94.6)	117 (93.6)			
Yes	4 (4.76)	6 (5.36)	8 (6.40)			

* For the HED cohort, No and unknown responses were merged. SMD=Standardized mean difference; HED=Health Extension for Diabetes; DSME=Diabetes Self-Management Education; BMI=Body mass index; CAD=Coronary artery disease; CKD=Chronic kidney disease.

Table 3: Number of Individuals with at least one Observation for an Outcome

	DSMS	**DSME**	**Control**
A1C	*54 different individuals*	*69 different individuals*	*90 different individuals*
Baseline	20	60	90
3 months	26	17	11
6 months	26	17	28
9 months	23	10	13
12 months	28	12	22
BMI	*71 different individuals*	*95 different individuals*	*107 different individuals*
Baseline	51	89	106
6 months	54	38	61
12 months	0	25	55
LDL	*48 different individuals*	*56 different individuals*	*63 different individuals*
Baseline	17	47	63
6 months	31	15	10
12 months	27	13	15
HDL	*50 different individuals*	*59 different individuals*	*65 different individuals*
Baseline	16	49	65
6 months	32	17	11
12 months	30	14	19
TC	*49 different individuals*	*58 different individuals*	*66 different individuals*
Baseline	15	48	66
6 months	31	16	10
12 months	30	14	17
TG	*49 different individuals*	*59 different individuals*	*68 different individuals*
Baseline	16	50	68
6 months	32	16	12
12 months	26	14	17

BMI=Body mass index; LDL=Low-density lipoprotein; HDL=High-density lipoprotein; TC=Total Cholesterol; TG=Triglycerides

Table 4: Average Value of Outcome at Each Timepoint

	DSMS	**DSME**	**Control**
A1C (%)			
Baseline	7.74	9.78	9.35
3 months	7.39	6.82	8.82
6 months	7.28	7.24	8.70
9 months	7.27	7.33	8.54
12 months	7.53	7.09	8.75
BMI (kg/m^2)			
Baseline	37.94	35.02	35.51
6 months	37.56	32.85	35.97
12 months	-	36.21	38.49
LDL (mg/dL)			
Baseline	95.63	109.40	101.17
6 months	82.24	102.61	87.3
12 months	82.74	86.25	91.47
HDL (mg/dL)			
Baseline	45.89	40.88	43.17
6 months	45.35	42.57	42
12 months	41.41	37.53	40.77
TC (mg/dL)			
Baseline	162.19	182.04	187.92
6 months	159.28	178.05	172.40
12 months	156.44	155.59	181.20
TG (mg/dL)			
Baseline	139.47	178.38	198.15
6 months	156.08	171.55	174.53
12 months	128.43	180.24	197.45

BMI=Body mass index; LDL=Low-density lipoprotein; HDL=High-density lipoprotein; TC=Total Cholesterol; TG=Triglycerides

Table 5: Results of Regression Analysis for A1C

Variable	*Estimate (Std. Err.)*	*p-value*
Intercept	10.0920 (1.299)	**<0.0001**
Time		
Baseline	Ref.	Ref.
3 months	0.4411 (0.545)	0.419
6 months	-0.6480 (0.328)	**0.050**
9 months	-1.2471 (0.469)	**0.009**
12 months	-0.6137 (0.361)	0.091
Intervention Group		
DSMS	-1.6488 (0.484)	**0.006**
DSME	0.3572 (0.388)	0.377
Control	Ref.	Ref.
Age	-0.0014 (0.014)	0.919
BMI	-0.0258 (0.019)	0.199
Race		
Black	0.6277 (0.363)	0.111
Other/Unknown	1.1212 (1.168)	0.358
White	Ref.	Ref.
Sex		
Male	-0.0466 (0.317)	0.886
Female	Ref.	Ref.
Hypertension		
Yes	-0.0040 (0.601)	0.995
No	Ref.	Ref.
Dyslipidemia		
Yes	-0.4465 (0.309)	0.176
No	Ref.	Ref.
DSMS by Time Interaction		
DSMS at Baseline	Ref.	Ref.
DSMS at 3 months	-0.6913 (0.716)	0.355
DSMS at 6 months	0.5248 (0.565)	0.373
DSMS at 9 months	1.0909 (0.663)	0.128
DSMS at 12 months	0.5886 (0.570)	0.324
DSME by Time Interaction		
DSME at Baseline	Ref.	Ref.
DSME at 3 months	-2.7217 (0.697)	**0.002**
DSME at 6 months	-1.4067 (0.562)	**0.029**
DSME at 9 months	-0.6393 (0.727)	0.398
DSME at 12 months	-1.6590 (0.645)	**0.026**

*Results with p-value<0.05 are bolded.
DSMS=Diabetes Self-Management Support (i.e., HED); DSME=Diabetes Self-Management Education

Table 6: Results of Regression Analysis for BMI

Variable	*Estimate (Std. Err.)*	*p-value*
Intercept	47.1508 (2.763)	**<0.0001**
Time		
Baseline	Ref.	Ref.
3 months	-0.1207 (0.205)	0.556
6 months	0.1660 (0.216)	0.443
9 months	0.3819 (0.222)	0.086
12 months	0.7499 (0.227)	**0.001**
Intervention Group		
DSMS	0.5562 (1.189)	0.640
DSME	-1.047 (1.095)	0.339
Control	Ref.	Ref.
Age	-0.1839 (0.0408)	**<0.0001**
Race		
Black	2.1422 (1.087)	**0.049**
Other/Unknown	-0.895 (2.604)	0.942
White	Ref.	Ref.
Sex		
Male	-2.6486 (0.962)	**0.006**
Female	Ref.	Ref.
Hypertension		
Yes	0.7809 (1.688)	0.644
No	Ref.	Ref.
Dyslipidemia		
Yes	-0.9026 (0.975)	0.355
No	Ref.	Ref.
DSMS by Time Interaction		
DSMS at Baseline	Ref.	Ref.
DSMS at 3 months	0.3037 (0.330)	0.358
DSMS at 6 months	0.0003 (0.332)	0.999
DSMS at 9 months	-0.2364 (0.339)	0.485
DSMS at 12 months	No obs.	No obs.
DSME by Time Interaction		
DSME at Baseline	Ref.	Ref.
DSME at 3 months	-0.4120 (0.294)	0.162
DSME at 6 months	-0.9305 (0.338)	**0.006**
DSME at 9 months	-0.8426 (0.379)	**0.026**
DSME at 12 months	-0.8689 (0.384)	**0.024**

*Results with p-value<0.05 are bolded.

DSMS=Diabetes Self-Management Support (i.e., HED); DSME=Diabetes Self-Management Education

Table 7: Results of Regression Analysis for LDL

Variable	*Estimate (Std. Err.)*	*p-value*
Intercept	131.86 (25.289)	**<0.0001**
Time		
Baseline	Ref.	Ref.
6 months	-27.9354 (9.763)	**0.006**
12 months	-8.141 (7.540)	0.284
Intervention Group		
DSMS	-7.0415 (8.772)	0.431
DSME	6.0568 (6.985)	0.395
Control	Ref.	Ref.
Age	-0.5498 (0.276)	0.060
BMI	0.1826 (0.373)	0.630
Race		
Black	14.3752 (6.553)	**0.040**
Other/Unknown	3.545 (24.118)	0.885
White	Ref.	Ref.
Sex		
Male	4.2147 (5.813)	0.477
Female	Ref.	Ref.
Hypertension		
Yes	-13.6520 (11.539)	0.251
No	Ref.	Ref.
Dyslipidemia		
Yes	7.9142 (5.766)	0.185
No	Ref.	Ref.
Statin Use		
Yes	0.7698 (6.589)	0.908
No	Ref.	Ref.
DSMS by Time Interaction		
DSMS at Baseline	Ref.	Ref.
DSMS at 6 months	17.512 (12.376)	0.173
DSMS at 12 months	-1.6544 (10.879)	0.881
DSME by Time Interaction		
DSME at Baseline	Ref.	Ref.
DSME at 6 months	14.1016 (12.932)	0.289
DSME at 12 months	-0.6975 (11.407)	0.952

*Results with p-value<0.05 are bolded.

DSMS=Diabetes Self-Management Support (i.e., HED); DSME=Diabetes Self-Management Education

Table 8: Results of Regression Analysis for HDL

Variable	*Estimate (Std. Err.)*	*p-value*
Intercept	60.8445 (8.319)	**<0.0001**
Time		
Baseline	Ref.	Ref.
6 months	-3.5046 (1.976)	0.080
12 months	-0.729 (1.432)	0.612
Intervention Group		
DSMS	0.3742 (2.595)	0.887
DSME	-2.5750 (2.264)	0.267
Control	Ref.	Ref.
Age	0.0725 (0.091)	0.434
BMI	-0.4131 (0.122)	**0.003**
Race		
Black	6.2356 (2.176)	**0.009**
Other/Unknown	-0.6906 (8.314)	0.935
White	Ref.	Ref.
Sex		
Male	-6.0436 (1.894)	**0.004**
Female	Ref.	Ref.
Hypertension		
Yes	-2.2588 (3.772)	0.509
No	Ref.	Ref.
Dyslipidemia		
Yes	-1.4650 (1.870)	0.441
No	Ref.	Ref.
Statin Use		
Yes	-3.590 (2.100)	0.101
No	Ref.	Ref.
DSMS by Time Interaction		
DSMS at Baseline	Ref.	Ref.
DSMS at 6 months	3.7220 (2.588)	0.164
DSMS at 12 months	0.3073 (2.215)	0.891
DSME by Time Interaction		
DSME at Baseline	Ref.	Ref.
DSME at 6 months	6.0217 (2.663)	**0.034**
DSME at 12 months	2.2170 (2.331)	0.351

*Results with p-value<0.05 are bolded.
DSMS=Diabetes Self-Management Support (i.e., HED); DSME=Diabetes Self-Management Education

Table 9: Results of Regression Analysis for TC

Variable	*Estimate (Std. Err.)*	*p-value*
Intercept	221.37 (32.081)	<0.0001
Time		
Baseline	Ref.	Ref.
6 months	-14.4918 (12.745)	0.260
12 months	-3.2656 (9.160)	0.723
Intervention Group		
DSMS	-14.8841 (11.967)	0.227
DSME	-2.918 (9.225)	0.755
Control	Ref.	Ref.
Age	-0.7019 (0.350)	0.058
BMI	0.2757 (0.473)	0.566
Race		
Black	2.7079 (8.408)	0.750
Other/Unknown	3.3977 (30.846)	0.913
White	Ref.	Ref.
Sex		
Male	-1.5140 (7.325)	0.838
Female	Ref.	Ref.
Hypertension		
Yes	-11.2999 (14.615)	0.448
No	Ref.	Ref.
Dyslipidemia		
Yes	10.9847 (7.279)	0.146
No	Ref.	Ref.
Statin Use		
Yes	2.8037 (8.208)	0.736
No	Ref.	Ref.
DSMS by Time Interaction		
DSMS at Baseline	Ref.	Ref.
DSMS at 6 months	0.8089 (16.348)	0.961
DSMS at 12 months	-6.6964 (13.860)	0.634
DSME by Time Interaction		
DSME at Baseline	Ref.	Ref.
DSME at 6 months	-0.2223 (16.448)	0.989
DSME at 12 months	-10.8221 (14.236)	0.455

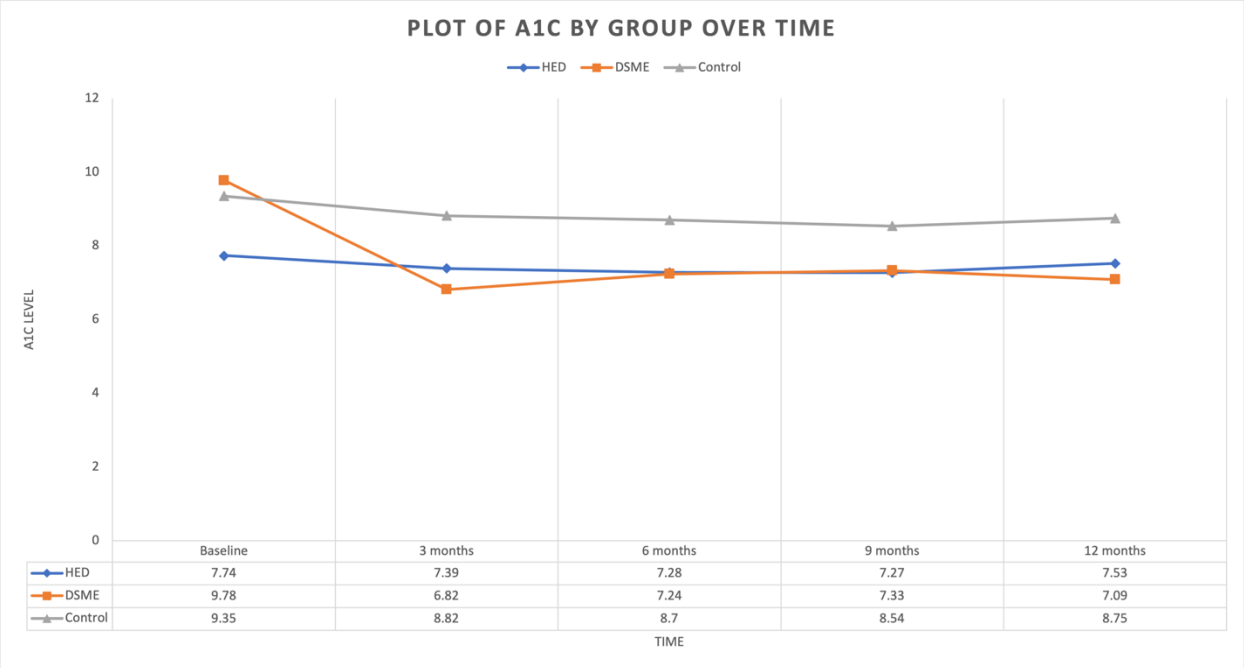
*Results with p-value<0.05 are bolded.
DSMS=Diabetes Self-Management Support (i.e., HED); DSME=Diabetes Self-Management Education

Table 10: Results of Regression Analysis for TG

Variable	*Estimate (Std. Err.)*	*p-value*
Intercept	136.40 (77.192)	**<0.0001**
Time 1 (baseline to 6 months)	-3.6518 (3.973)	0.362
Time 2 (6 months to 12 months)	9.0944 (7.873)	0.256
Intervention Group		
DSMS	-29.2607 (26.677)	0.280
DSME	-13.973 (20.861)	0.507
Control	Ref.	Ref.
Age	-0.6101 (0.8504)	0.478
BMI	1.6981 (1.134)	0.143
Race		
Black	-76.4897 (20.022)	**0.001**
Other/Unknown	26.8281 (76.448)	0.728
White	Ref.	Ref.
Sex		
Male	7.6263 (17.630)	0.668
Female	Ref.	Ref.
Hypertension		
Yes	21.6351 (35.694)	0.548
No	Ref.	Ref.
Dyslipidemia		
Yes	-3.1766 (17.372)	0.856
No	Ref.	Ref.
Statin Use		
Yes	38.5627 (19.621)	0.057
No	Ref.	Ref.
Group by Time 1 Interaction		
DSMS by time 1	0.9162 (5.353)	0.865
DSME by time 1	-0.2809 (5.403)	0.959
Control by time 1	Ref.	Ref.
Group by Time 2 Interaction		
DSMS by time 2	-7.1284 (9.600)	0.463
DSME by time 2	-3.9250 (10.487)	0.710
Control by time 2	Ref.	Ref.

*Results with p-value<0.05 are bolded.
DSMS=Diabetes Self-Management Support (i.e., HED); DSME=Diabetes Self-Management Education

Figure 1: Line Chart of A1C by Group over time



	Baseline	3 months	6 months	9 months	12 months
HED	7.74	7.39	7.28	7.27	7.53
DSME	9.78	6.82	7.24	7.33	7.09
Control	9.35	8.82	8.7	8.54	8.75

Figure 2: Line Chart of BMI by Group over time

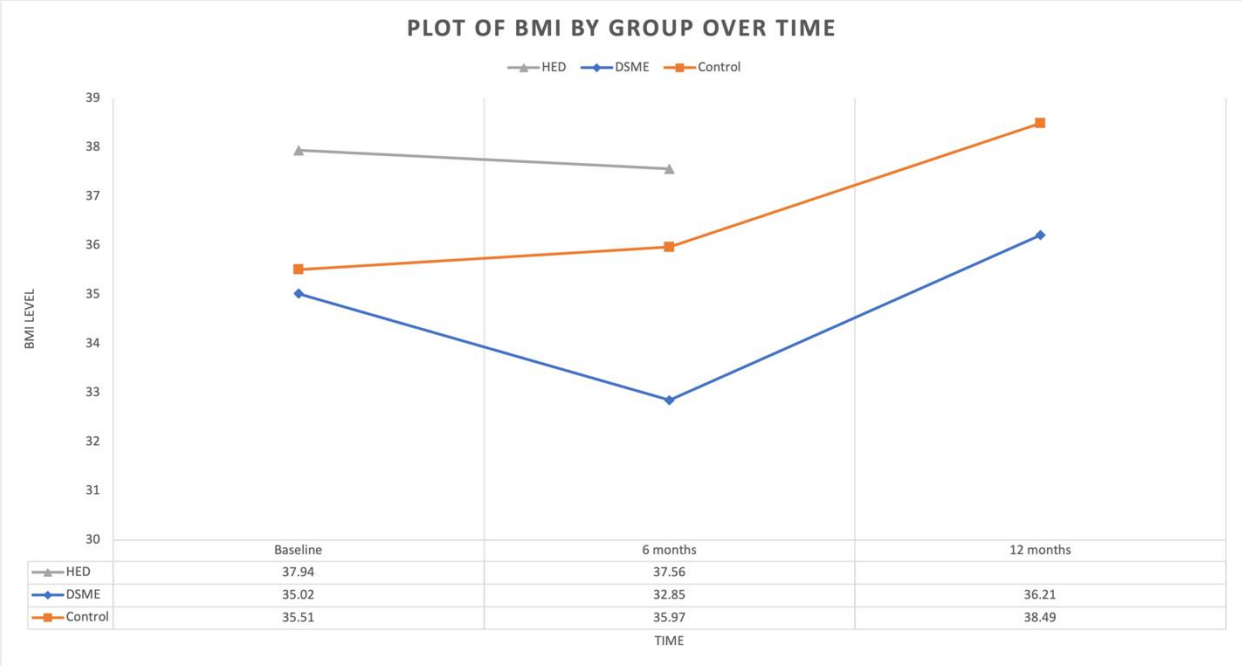


Figure 3: Line Chart of LDL by Group over time

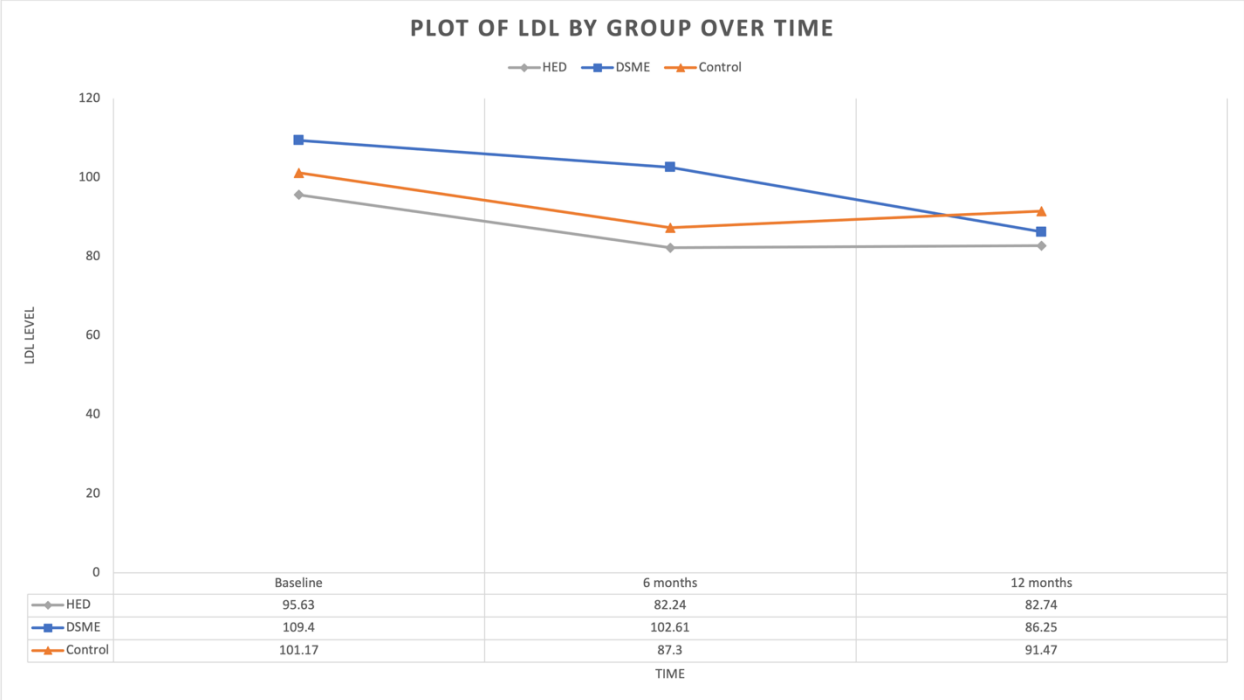


Figure 4: Line Chart of HDL by Group over time

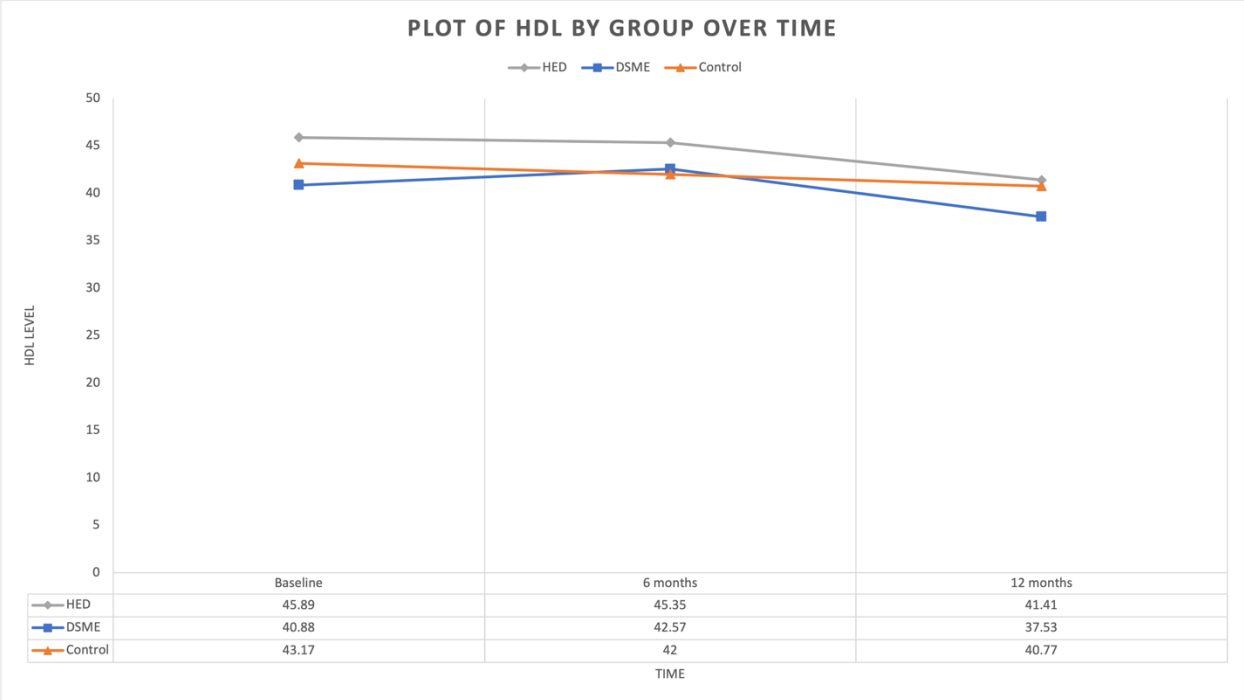


Figure 5: Line Chart of TC by Group over time

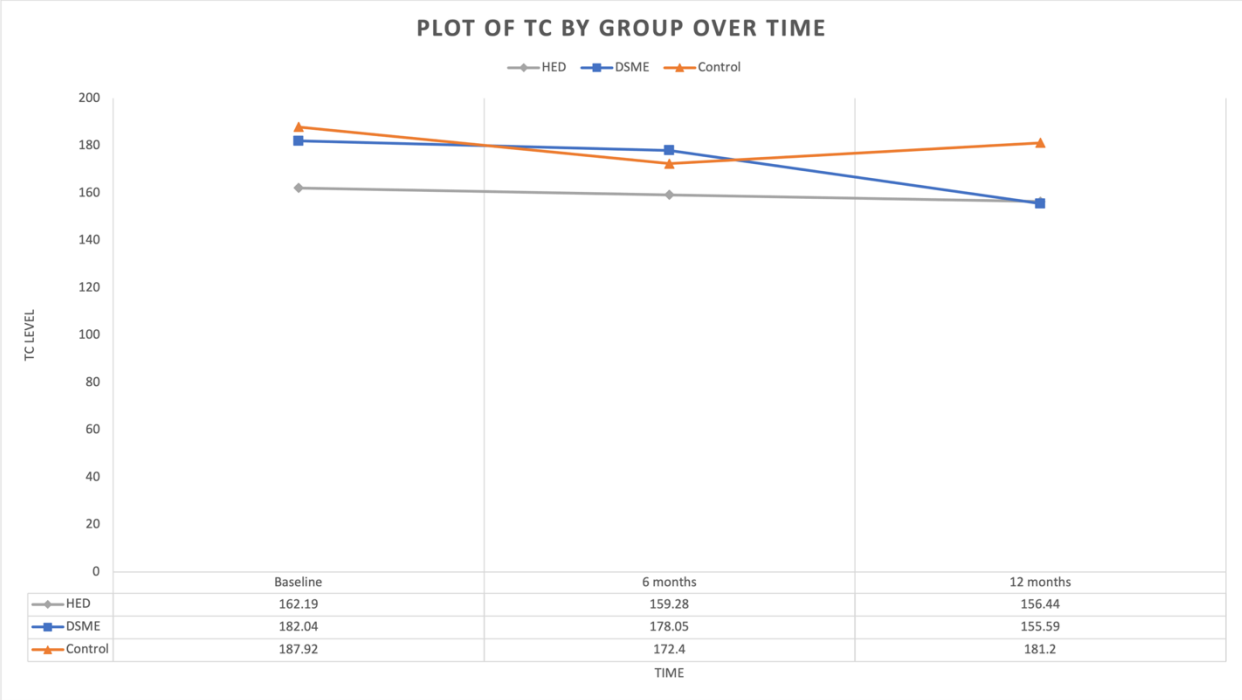
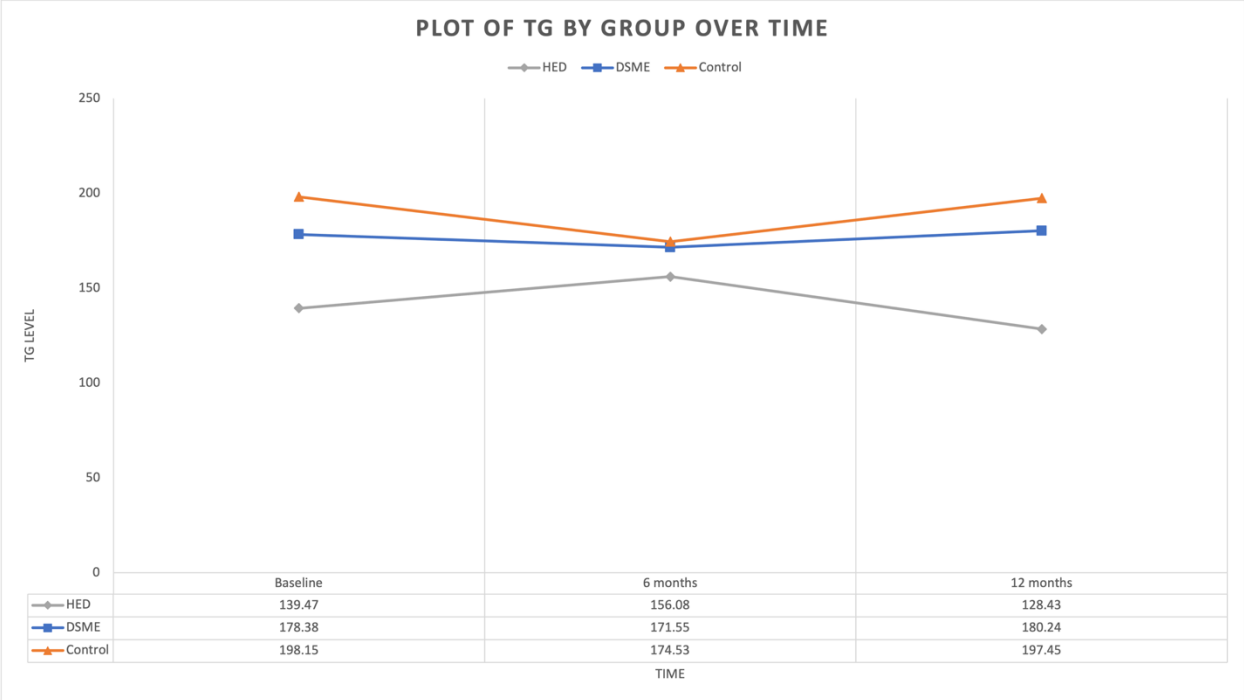


Figure 6: Line Chart of TG by Group over time



CHAPTER SIX

STUDY 3

UNDERSTANDING PRIMARY CARE PROVIDER'S KNOWLEDGE AND PERCEPTIONS OF DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT

Abstract

Objective: The American Diabetes Association Standards of Care recommends that individuals with diabetes receive self-management education, but the utilization of these services remains low. The majority of the current research examines patient-level barriers to the service. This study explores primary care providers' knowledge and perceptions of diabetes self-management education and support (DSMES).

Study Design: A convergent mixed methods study design grounded in the Theoretical Domains Framework was conducted with an initial provider survey, followed by a sub-sample of providers participating in a semi-structured interview. Purposive sampling was conducted in one health system in South Carolina. The survey was distributed via REDCap and interviews were recorded and transcribed verbatim. Stata 15 from StataCorp was utilized for quantitative analysis and Atlas.ti v9 was utilized for deductive and inductive thematic analysis for qualitative data.

Results: A total of 372 individuals were contacted, where 140 individuals responded to the survey for a response rate of 37.63%. Of the 140 responses, 128 are from the Upstate region and 12 from the Midland region, with 104 MD/DOs and 36 Advance Practice Providers. The average knowledge score of selecting the correct referral time points was 70.35% with an average awareness of the service at 3.48 out of 5. Five themes emerged from the 17 interviews: procedural knowledge, ability, beliefs, reinforcement, and cultural norms. Providers were found to lack procedural knowledge about a referral but felt confident in their ability to manage diabetes. Beliefs were found to vary by region

and by subtheme. Providers wanted bidirectional communication from the DSMES program and were more likely to refer if they had a cultural norm of referring.

Conclusion: Providers have limited knowledge of the appropriate time to refer to DSMES, but expressed a willingness to refer. They emphasized the importance of providing their patients with appropriate self-management education and support.

Introduction

In 2018 in the United States, there were 34.1 million adult Americans with diabetes, yielding a national prevalence rate of 13%. [1] Of those adults, approximately 1 in 5 are unaware they have diabetes. [2] Over the past 20 years, the national diabetes prevalence rate has doubled. [3,4] The rapidly increasing prevalence rate holds true for South Carolina. In South Carolina in 2018, approximately 531,143 South Carolina adults (13.3%) had diabetes compared to 205,236 adults (7.1%) in 2000. [4]

Given the overwhelming burden of diabetes, many organizations have taken steps to implement diabetes self-management education and support (DSMES) programs. DSMES provides initial and ongoing education and support to facilitate individuals with diabetes to learn or maintain the knowledge and skills necessary to manage their condition. [5–8] Research has shown that DSMES is associated with improved diabetes knowledge and self-care behaviors, quality of life, lower A1C, reduced hospitalizations, and health care costs. [5–8] Despite the known benefits, DSME utilization has been consistently low. Within the first year of diabetes diagnosis, less than 5% of Medicare beneficiaries and 6.8% of privately insured individuals receive this service. [5,9] For individuals under- or uninsured, the utilization is likely even lower. While DSME is considered the gold standard for educating on crucial diabetes self-management behaviors, access to this service is limited due to barriers, such as lack of awareness, geographical access, financial costs, and other social determinants of health. [8]

A health system in the Upstate and Midland regions of South Carolina has robust DSMES programs. This larger health system is the combination of two regional health

systems that merged in the mid-2000s. The DSMES programs are ADA-accredited DSMES programs. This means they follow the ADCES National Standards for DSMES and are able to bill payers for their services. The DSMES in the Upstate region has been established as an ADA-accredited program for over 15 years, and the DSMES program in the Midlands has been accredited for over 20 years. This shows that these DSMES programs are well-established programs in the regions.

The literature on diabetes education and management focuses on clinicians providing diabetes self-management education and support to their patients. However, the majority (~75%) of the studies examining provider knowledge and perceptions of diabetes management were conducted outside of the United States. [10–51] Of the studies conducted in the U.S., only 60% (n=12) discussed PCP knowledge in some capacity, where the primary focus was on diabetes management and guidelines for practices, with 100% of the studies finding PCP knowledge lacking. [52–63] The other studies addressed perceived barriers, [64–66] the need for more effective communication, [67] provider perceptions of patients, [68,69] and others. [70,71]

Additional studies of clinicians providing diabetes self-management education found barriers were related to patient support. A 2019 qualitative study found that providers felt responsible for delivering self-care education to patients but only through information sharing, not behavior change. [25] However, providers reported patient barriers, health care system barriers, and inadequate general diabetes training as barriers to providing patients with the resources needed. [25] Another study of interviews with primary care providers regarding diabetes screening guidelines found that providers understood

the need for guidelines but noted the lack of feedback opportunities and unclear guidance for patients with a positive screen. [14] Similarly, a cross-sectional study found that less than 50% of providers were aware of guidelines, with even fewer having received training on their implementation; the study does cite various barriers, such as time and resources, in providers' ability to utilize screening guidelines in the future. [30]

This paper seeks to describe primary care providers' knowledge referral timing and perceptions of DSMES features and patient impact in one health care system in South Carolina. It is hypothesized that the primary care providers will have limited awareness of DSMES programs and limited knowledge of DSMES ADA-recommended referral time points and program content.

Methodology

Sampling

Providers were sampled from one health system located in the Upstate and Midland regions of South Carolina. Purposive sampling that combines criteria-based, convenience, and snowball sampling methods were employed to obtain this population. In order for the provider to be included, they must have been a PCP (DO, MD, APRN, or PA) in the health system, residing in the Family Medicine or Internal Medicine departments, working in a primary care setting, and actively managing non-pregnant adults with diabetes (type 1 or type 2). The emails for the eligible providers were obtained from the Medical Staff Services Office of the health system. A total of 372 providers met the inclusion criteria and were contacted.

Theoretical framework

The questionnaire and interview guide were grounded in the Theoretical Domains Framework (TDF) (Table 1). TDF is a theoretical framework created in collaboration between implementation and behavioral scientists that sought to create a comprehensive, theory-informed framework for researchers to guide them in identifying behavioral determinants. [72,73] This theoretical framework is composed of 14 domains with 84 constructs. Four of the domains and 5 of the constructs were employed in this study: knowledge domain (procedural knowledge construct), skills domain (ability construct), beliefs about consequences domain (outcome expectancies construct and beliefs construct), and beliefs about capabilities domain (self-efficacy construct) (Table 2).

Survey Development and Study Procedures

For survey development, an initial survey was created based on four constructs in four different domains of the TDF. The survey was pilot tested with four practitioners (Cardiologist, CDCES, Internal Medicine Physician, and Family Medicine Physician) to ascertain if the survey was assessing the desired constructs appropriately. Pilot testing interviews lasting less than 15 minutes each were conducted with the four providers. The survey was modified based on their feedback. Example feedback for the survey was tone/verbiage modifications, the addition of a comment/feedback box, and a question to ascertain when the provider last referred to the service (see Appendix A).

The survey was then disseminated to eligible PCPs in the health system for five weeks with a priori follow-up time points of one week, three weeks, and the day of

survey closure. All internal medicine providers were encouraged to complete the survey by the Chair of their departments. Family Medicine providers were encouraged to complete the survey by a peer. If a provider had a partially completed survey, two follow-up contacts were made to have them complete their survey.

Providers who indicated a willingness to participate in the follow-up interview were contacted first. To ensure adequate balance among geographical regions and referral status, some providers who did not indicate a willingness to participate in an interview were contacted. Interviews were guided by a semi-structured script with seven questions that were designed to discuss knowledge of DSMES, current referral behaviors, and perceptions of DSMES with respect to aiding them or aiding the patient in diabetes management (see Appendix B). Additional questions were asked as needed. All interviews were conducted by the same researcher.

Analysis Plan

Categorical variables are reported as counts and percentages. When assessing the association between correct knowledge of referral time points and confidence in the DSMES program positively impacting patient outcomes, four separate, ordinal logistic regressions were conducted. Values with a p-value<0.05 were considered significant. Data analyses were conducted in Stata 15 from StataCorp.

For the qualitative data, an inductive and deductive thematic analysis was conducted. Deductive codes were created from select constructs of the Theoretical Domains Framework. The analysis was conducted considering the quantitative results of

those interviewed. Preliminary coding of the first four interviews was completed to evaluate and modify the draft codebook. Coding was done by two people, with one person coding all 17 interviews and the other coding half of the interviews. Atlas.ti v9 was utilized for analysis.

Results

Quantitative Results

A total of 372 individuals were invited to participate in the survey, with 314 from the Upstate and 58 from the Midlands. After the 5-week study window, 140 individuals responded, where 128 were from the Upstate, and 12 were from the Midlands. This leads to a total response rate of 37.63%, with a 40.76% response rate for the Upstate and 20.69% for the Midlands. Of the 140 individuals who participated in the study, 88 identified as MD, 16 as DO, 6 as PAs, and 30 as APRNs (Advanced Practice Registered Nurse). Table 3 shows the breakdown of provider type by location.

Providers were asked to "please select the key timepoints a patient should be referred to Diabetes Self-Management Education and Support (check all that apply)." For the potential time points a patient could be referred, only four of the eight were correct. The most commonly selected answer was "at diagnosis," and this was selected by 129 (92.14%) individuals. The least commonly selected correct answer was "when transition in life and care occur" with only 59 (42.14%) of providers selecting this guideline-concordant referral time. The most selected incorrect choice was "A1C>9.0" where 87 (64.14%) choose this time point. The least commonly selected answer was "when a

patient's family member(s) develop diabetes", where only 25 (17.86%) PCPs selected this time point.

Only 2 (1.43%) of the PCPs exclusively selected the four correct ADA time points for referral to the service. Seven of the providers selected 3 of the 4 possible correct time points, and none of the incorrect ones. Five PCPs selected 2 of the 4 correct possible time points, and no incorrect times. While 5 PCPs selected only one of the 4 time points and no incorrect times. All providers selected at least one correct time point. Table 4 shows that 15 (10.71%) providers selected all 8 listed times. Table 2 shows the number of wrong answer choices selected by each level of correct answers.

Additionally, providers were asked if they had ever referred a patient to DSMES while working at the health system. If the provider answered yes, the providers were then asked when the last time was they had referred someone to the service. The majority (76.42%) of the PCPs participating in the survey have referred an individual at some point, with 75.70% of those that have referred a patient to DSMES having done so in the last 6 months.

When examining the percentage correct of the ADA appropriate referral time points by referral status of the provider, there is a relatively even breakdown in the categories of percentage correct for the providers who have referred an individual to DSME. For providers who have referred an individual, 11.21% selected 1 of 4 correct referral times, 30.84% selected 2 of 4 correct referral times, 28.97% selected 3 of 4 correct referral times, and 28.97% selected all four correct referral time points. For those providers who have not referred an individual to DSME, 72.41% selected 3 or 4 of the

correct referral time points on the knowledge assessment. Approximately 17% selected one correct referral time, with the other 10% having selected 2 of 4 correct referral times. For the four providers who were unsure if they had referred anyone to the service, they selected either 3 or 4 of the correct referral time points (Table 5).

Providers were also asked to rate their awareness of DSMES programs on a 1 to 5 scale, where 1 was "not aware," and 5 was "very aware." Table 6 shows the awareness level of DSMES by provider type. Over half (55.71%) of respondents indicated their level of awareness of DSMES to be at a 4 or 5 on a 5-point scale, with 37.14% responding at level 4. Nine (6.43%) individuals rated their awareness level at "1: Not aware." Nineteen (13.57%) providers rated their awareness at level 2, and 34 (24.29%) rated their awareness at level 3.

Additionally, the providers were asked four questions about their confidence in 4 patient outcomes that DSMES could impact. Almost all (96.43%) of providers had a 3 or higher out of 5 in their confidence in DSME assisting their patients in meeting their target A1C goals. Similarly, 97.86% had a 3 or higher in their confidence in DSME helping patients improve their confidence in managing their diabetes, where almost half (47.14%) were at a four. A majority (97.15%) of providers reported a 3 or higher in their confidence that DSME could assist patients in managing their diabetes. Additionally, the majority (97.15%) of providers reported a 3 or higher in their confidence in explaining the role of DSMES in patient care. Tables 7 through 10 show the breakdown of respondent confidence by provider type and confidence level.

The four separate ordinal regressions were conducted to assess the association between the number of correct answers selected for the knowledge of referral times question and the provider's confidence in DSMES questions. None of the regression analysis results showed an association between the percentage correct for the knowledge question and their confidence in DSMES ($p>0.05$). Table 11 shows the results of the ordinal regressions.

Qualitative Results

Seventeen interviews were conducted by providers who completed the survey. For all interviews conducted, the average interview time was 26 minutes, with an average of 24 minutes for the Upstate individuals and 29 minutes for the Midlands providers. The breakdown of interview time and location of providers is shown in Figure 1. To provide context for the providers interviewed, the following are the quantitative results. For all providers who participated in an interview, 1 person selected 3 incorrect answers, 7 people selected one incorrect answer, 6 selected two incorrect answers, and three selected no incorrect answers. On all four confidence questions, the average score was above 4. In contrast, the average awareness level was 3.29 out of 5. When examining if providers felt they had access to the service, eight providers selected yes, six providers selected no, and three providers selected unsure.

For the providers who have referred individuals in the Midlands region (n=7), their average awareness level was 4 [range: 2,5]. For the knowledge of referral times, one person selected 1 correct, one person selected 2 correct, and 4 people selected 3 correct.

The average confidence was above 4 on all four confidence questions. Five providers felt they had adequate access to DSMES, with one person being unsure if they did.

For the providers in the Upstate region (n=10) that have referred individuals, the average awareness level of the service is 4 [range: 2,5]. The average knowledge level was 66.67%, with 2 people scoring 100%, 2 people scoring 75%, and 2 people scoring 25%. The average number of incorrect answers selected was 0.83, with 1 person selecting 2 wrong, 3 people selecting 1 wrong, and 2 people selecting 0 wrong. The providers were split if they felt they felt they had adequate access to the service with 3 providers saying 3 and 3 saying no. For the four confidence questions, the average confidence level was 4.2 or above on all four questions.

In general, the providers who had not referred a patient to DSMES all scored 50% or higher on the knowledge assessment, with over half (60%) selecting 2 incorrect answers to the knowledge question. On all four confidence in DSMES questions, providers selected a 3 or higher, indicating they felt relatively confident in the service or explaining what the service entailed. However, the average awareness level of the service was 1.6 on a 5-point scale. Of the individuals who did not refer to the service, three of them felt they did not have adequate access, while the other two were unsure if they had adequate access. In contrast, four of the five providers expressed having a lack of procedural knowledge on how to refer or get the patient to the service.

Recall, the qualitative data was examined relative to the 5 constructs from the TDF model to assess the extent to which themes emerged relating to these construct areas during the interviews. For each theme, individuals who had referred and those who had

not referred individuals to DSMES were explored. The quantitative results from the survey were considered when analyzing the qualitative data. The themes found are presented below. All quotes under each theme can be found in Table 12.

Theme 1 – Lack of Procedural Knowledge

For the construct of procedural knowledge, the main theme that was found for providers was the lack of this construct. The majority of providers in both regions who have referred a patient to DSMES knew they needed to refer an individual to the service. Only a handful of providers who had referred a patient to the service discussed lacking procedural knowledge for making a referral.

The major aspect of this theme that emerged was providers struggling with the referral process itself. They were unsure how the process worked, how they should document the referral, what information the referral should contain, and had difficulties understanding how this referral differed from another referral type. The Midlands providers lacked knowledge of the appropriate referral timepoint, scoring 25% correct. In contrast, the Upstate provider's knowledge scores were 100%, 100%, and 75%. One Upstate provider struggled with knowing the resources available for their patients. A Midland's region provider who had been with Prisma Health for many years stated,

> *" Uh we just, yeah, it it would be good if we just know how to do the referral. If there's a like, we know who to call to just, who to have our staff call to schedule, a class or what information needs to be sent, which make*

sure we're sent whatever forms we need to fill out to fax over to have them enrolled in the classes and things like that."

Lastly, all four Upstate providers who had not referred an individual to DSMES previously at Prisma Health were found to be lacking procedural knowledge. These providers all lack knowledge of how to make the referral. Each provider asked questions to clarify how to make the referral in Epic. These clinicians often were unaware of what the service entailed, how the service was provided, and the logistics of whom the service was available. The one Midland provider who had not referred a patient understood the process of referring but was unable to refer due to patient-level barriers.

Theme 2 – Ability

Another construct that was assessed during the interview was ability. TDF defines ability as "an ability or proficiency acquired through practice." The theme that was coded for this consult was provider knowledge about diabetes self-management. This code was defined as the provider's personal knowledge about managing diabetes.

The common topics that arose during conversations were lifestyle and diabetes self-management components. For the lifestyle aspects, the two most commonly discussed topics were nutrition and exercise. The providers discussed the need for an appropriate diet and moderate physical activity to help with the individual's diabetes self-management. The other aspect is self-management. This could entail blood glucose checking and monitoring, lifestyle modification, and other aspects necessary to diabetes management. One provider stated, "*I mean, mean mostly um, you know, mostly, we'll talk*

about diet, exercise, checking the sugar, sugar goals, you know, all those types of things."

All providers who have referred patients to DSMES in the Midlands discussed their knowledge of diabetes self-management during the interviews. In contrast, only half of the providers who have referred someone to DSMES in the Upstate discussed their knowledge of diabetes self-management and some of the barriers they face to providing this information to their patients. The providers who had not referred anyone to DSMES in both regions did not discuss their knowledge of DSMES.

Theme 3 - Beliefs

For the construct of beliefs, four key types of beliefs arose: beliefs about service, beliefs about the patient, beliefs about the referral, and beliefs about diabetes self-management (DSM). The beliefs about service broke down into three sub-themes: knowledge of DSMES, DSMES program outcome expectations, and confidence in DSMES. The beliefs about the patient broke down into four primary sub-themes: type of patient referred, type of patient not referred, most benefits, and perceived patient barriers. The beliefs about referral broke down into two sub-themes: provider barriers to referral and changed referral likelihood. The last belief, beliefs about DSM, had one sub-theme emerge: provider barriers to diabetes self-management.

Theme 3.1 – Beliefs about Service

The first subtheme of beliefs about service dives into what the providers know about DSMES. A topic that was frequently discussed is the idea of DSMES providing general diabetes knowledge. One provider described DSMES as *"it seems just to be diabetic education in general, which includes, you know, um usual diabetic teaching."* This includes things like understanding what diabetes is, how it impacts the body, and general self-management techniques. Another topic that emerged among all providers, regardless of referral status, was lifestyle topics, such as diet and exercise. Of the lifestyle behaviors discussed, nutrition was the most common. Providers who had referred in the Midlands and those providers who had not referred patients to the service believed DSMES would include education on medications. This would include things such as the discussion of medications and the importance of medication adherence. Despite these thoughts on what the service entailed, one provider said, *"It's a black box. I would send people there. I would not know exactly what was happening and then they came back a little bit more well-versed in how to manage their diabetes."*

In the Midlands regions, the providers discussed details about how the service is delivered. Approximately half of the providers believed the service was provided in a group setting over several classes. Providers mentioned that it was led by a clinician, such as a pharmacist, dietitian, or diabetes educator. Some discussed that they believed the service explained and stressed the importance of checking and managing an individual's blood glucose level and complications of diabetes to ensure individuals understand the importance of managing their condition. For the providers that had not referred a patient to DSMES, after information on the service was provided, those providers felt this was a

service that all individuals should have access to utilize. Many of these providers viewed this service as a valuable tool, where having more education from different providers is better.

The next sub-theme is outcome expectations. The most common expectations expressed by providers were that DSMES would help with A1C reduction, medication compliance, and knowledge building. For A1C reduction and knowledge building, one provider stated, "*I feel like the people that have gone I've had very good, positive changes in their A1Cs, and they get more knowledge.*" The providers also expected their patients to come back more knowledgeable about diabetes. Some providers specified having patients understand lifestyle management, while others wanted their patients to have more general knowledge about their condition. As for medication compliance, this would entail explaining medications to patients or helping patients understand the importance of taking their medications.

Another common theme that emerged among providers who had referred a patient was the expectation that DSMES would help with confidence building. Providers stated they expected that after participating in the service, their patient's confidence would be improved. Several other outcome expectations were expressed by Midland providers that had referred patients. These expectations were that the service would increase nutrition and self-management skills. For nutrition, providers wanted the service to help with nutrition education and help patients understand the importance of following a regular eating schedule. For self-management skills, they wanted patients to have better self-management knowledge, engage in self-management techniques, and know what they are

supposed to be doing. Additionally, as part of self-management, they are expecting DSMES to stress the importance of checking their blood glucose and keeping a blood glucose log. Another common expectation is that the patients would learn how to better communicate with their provider and be a more active participants in their diabetes care. Other expectations that were expressed by providers were collaboration in patient care from the DSMES staff, helping with sick day planning for the patients, fewer diabetes complications, and having dedicated time for the patients to discuss diabetes.

After the information was provided about the benefits of DSMES to the providers, the majority of the providers who had referred patients previously felt it reaffirmed their current knowledge and was a good refresher, but did not change their current expectations. After providing the information about the benefits of DSMES to the providers who had not referred a patient, the majority of providers reiterated their expectation of an A1C reduction.

The last subtheme of beliefs about the service is confidence in DSMES. Several of the providers who have referred patients in the Upstate stated they felt the service would be helpful for patients to have in their diabetes journey with one provider stating that this is something needed ongoing. After providing the information to the providers, almost all providers expressed positive opinions of the service. The majority stated this was information they already knew but stated that this service is helpful, and the information reinforced the importance of the program. However, a couple of the providers stated they agreed with the statements, but there was no change in their confidence because they already knew the information. For the providers that have not

referred patients to DSMES, this was not a theme that emerged. This could be in part due to their lack of exposure to the service at the system or their lack of knowledge about the service.

Theme 3.2 – Beliefs about Patient

When asked the type of patient that providers would refer to DSMES, the most common answer from providers, regardless of referral status, was individuals with a new diagnosis and individuals who are struggling with their self-management/are uncontrolled. A common answer that arose from Midland providers who had referred a patient to the service is individuals that need a refresher. For some Upstate providers who referred a patient to DSMES indicated that the patient must be willing and/or request to be referred to the service. This connects with the theme of perceived patient barriers where providers do not want to refer individuals who are unwilling to participate in the service. Lastly, for those providers who has not referred a patient, they mentioned individuals who are unable to follow directions from the provider.

After giving information about DSMES, the answers varied on whom providers would refer. The cross-cutting population that providers would consider is patients who are considered well-controlled. In the Midlands, one provider felt all patients should be referred. Several providers felt this information did not influence whom they would refer to the service. Other Midland providers felt those with multiple comorbidities should have access to this service. In the Upstate, the common theme was that most providers would not change the factors considered when referring, but a couple of providers would

send patients to the service sooner than they traditionally would have referred. When discussing the type of patient, they would refer after receiving the information, there were two primary groups of individuals: those who would not change their habits due to already knowing this information and those who would lower the bar or begins referring everyone to the service. Conversely, the majority of the providers who had not referred someone stated they would refer individuals now with the intention to refer all patients to the service.

In contrast, the providers were asked what type of patient they would not refer to the service. The responses for providers who had referred patients before varied by region. Majority of providers in both regions agreed that they would not refer a patient that is considered well controlled. For the providers in the Midlands, there was no common group of individuals that the providers would not refer to the program. Several Midland providers stated they would not refer someone who had previously had the educational service. Another provider stated they would not refer a patient who refused. Of the providers in the Upstate, several noted they would not refer someone who was unwilling or uninterested in the service.

This subtheme was not found for providers who have not referred patients to DSMES. This is in part due to the structure of the interview guide not probing about whom they would not refer because these providers are already not referring individuals. This also could be due to the providers not stating whom they would not refer to the service when asked about the type of patient they would refer.

Another sub-theme was the idea of what patient population would most benefit from the service. When talking about if the impact of DSMES varied by the patient or by disease severity, the majority of providers in the Midlands felt that all patients could benefit from the service. A handful felt that the more severe the patient's disease, the more that individual could benefit and learn from DSMES. The general belief by Upstate providers who had referred and those providers who had not referred, is that it varies by the patient who will most benefit from the service. Some providers felt disease severity played a role but mostly varied by the individual.

The last sub-theme for beliefs about the patient is the provider's perceived patient barriers. The common theme that was across regions and the referral status of providers was the financial burden of DSMES. The providers stated they were hesitant to offer the service to patients if they felt they could not afford it. A common barrier that arose in both regions among providers who had referred a patient to DSMES was that the service is incompatible with the patient's schedule. Some patients may not be able to commit to the time to take the class due to external factors, such as jobs, family life, etc.

Other perceived patient barriers arose and varied by region and referral status. A barrier to referring to the service discussed by Midland providers is if the patient was in denial of having diabetes. One provider expressed,

> *"when in reality, you know, I can talk to I'm blue in the face, I can write a prescription, I can do everything I'm supposed to do. But when the patient walks out the door, I can't control whether they pick up the prescription, I*

can't control what they put in their mouths. I can't control any of their lifestyle, but yet I'm held responsible."

A commonly discussed patient barrier by Upstate providers who had referred a patient is the current knowledge level of the patient. Some patients may have misconceptions while others may feel they already have adequate diabetes knowledge. This connects with the perceived or stated willingness of the patient to attend the program. Some providers may perceive that their patient is unwilling to attend, while other providers may have their patient state they do not wish to attend the DSMES program. For the individuals who expressed they had not referred anyone, two primary reasons for not referring arose: unable to access the service or unaware the service existed. Providers who stated a lack of access to be the primary reason for not referring stated that their patients would not be able to travel outside of their county for the service due to transportation difficulties.

Theme 3.3 – Beliefs about Referral

The first sub-theme of beliefs about referral is provider barriers to referral. When looking at provider barriers to making the referral for the patient to the service, the reasons varied. Several of the providers in both regions that had referred patients to the service discussed the fear of overloading the service. This entailed being nervous about patients being turned away or having to wait for an extended period to participate in the program. As one provider said,

"there's a backlog and it's, there have been occasional glitches and communication between the patient and the hospital's program. So those

are the main things I won't say anything really deterred me from referrals specifically uh. But uh except those types of factors, which kind of slowed the process down and made it a little more difficult."

Another barrier that was commonly discussed was that providers would like to know more about the service. Providers who brought up this concern were also found to be lacking procedural knowledge of referral to the service.

In the Midlands, another barrier to referral is the perceived lack of communication from the diabetes education providers. This connects with the theme of reinforcement and wanting consistent feedback from the DSMES providers. Additionally, another barrier discussed by some providers was an inadequate amount of time during the patient visit to be able to refer an individual. Providers cited wanting more time to be able to talk about the service with patients prior to referring them. For providers in the Upstate region who had referred, some barriers to referral were the Greenville-centric nature of the program and the aspect of having to convince patients to participate.

Another barrier to referral is that several providers felt they had adequate knowledge and confidence in providing diabetes self-management themselves. One provider stated, "*I feel like that my efforts get much more um lead way,*" with another stating, "*I could just deal with this, with kind of similar to what's available*." However, two providers stated that time was the biggest constraint to them providing them knowledge themselves since they only have approximately 15 minutes per patient.

The last sub-theme for beliefs about referral is changed referral likelihood after the information about DSMES was provided to the clinicians partway through the

interview. This sub-theme was found to vary by location and referral status. For the providers in the Midlands who have referred a patient before to DSMES, the responses regarding the change in their referral likelihood fell into two primary categories: no change and more likely to refer. When looking at how these two categories differed, both had varying knowledge levels and awareness levels of the service. Both groups also felt confident in the service.

The Upstate region providers who have referred someone to DSMES predominately felt this information changed their likelihood of referring in the future. They discussed how they would lower their "bar" for referral with the idea of ideally referring all patients to the service. A couple of the providers felt there was no change in their likelihood of referring because they already agreed with this information.

In contrast to the providers who have referred patients, almost all providers who had not referred to the service at Prisma Health felt this information would change their likelihood of referring in the future. They felt that having knowledge about the service and being aware that it existed in the health system impacted their willingness to refer. Only one provider did not change their likelihood to refer to the service, and this was due to patient-level factors.

Theme 3.4 – Beliefs about Diabetes Self-Management

The first sub-theme of beliefs about diabetes self-management is provider barriers to diabetes self-management. When discussing diabetes self-management, a common topic discussed amongst providers who have referred patients to DSMES before is

barriers to providing diabetes self-management education themselves. The two most common barriers discussed are time limitations and competing interests. The most common barrier discussed was the lack of time providers have to address diabetes education and self-management skills with patients. Providers stated that only having 15 minutes or less with patients makes it difficult to be able to discuss self-management techniques accurately and effectively with patients. Having competing interests, such as an additional diagnosis, patient questions, or lab work to discuss takes the limited time they have with patients. These take up the limited time they have with patients and act as an additional barrier to conducting diabetes self-management education with patients.

The providers who have not referred individuals to DSMES, this is not a subtheme that arose in conversation. This could be due to a myriad of factors, such as a focus on referral to the service, a focus on patient-level factors, or a focus on barriers to referral.

Theme 4 – Reinforcement

A theme that emerged in the interviews was the concept of reinforcement. The idea of reinforcement primarily emerged in the desire for bidirectional communication. Many of the providers where this theme arose sought to have meaningful feedback from the diabetes educators and collaboration with them. This ties into the concept of outcome expectations. Some providers explained that in the messages from the diabetes educators, they would like to understand what is being covered with the patients but also some were open to medication recommendations. As one provider stated,

"I would get like contact through the EMR from the, you know, from the DSME. Or I would get faxes from saying, This is what we've done. This is what the needs are, hey, we saw this, and we need this. Um so it may be I haven't had enough patients go through it here to kind of see that process. But I think, on our end, it's nice to get some type of meaningful feedback, not just a form that says they completed it the saying, you know, please consider this or um your patient would benefit from type of thing."

Additionally falling into the reinforcement theme, the providers wanted reinforcement in the idea of being reminded that the service exists. The providers wanted the diabetes educators to spread more knowledge about the service, what the service entails, and coverage for the service. One provider stated, "*I mean...I would like to see the people that offer the education services in the area to be a little bit more proactive in informing the physicians in the community of their services."* Providers stated they often forget the service exists and hoped the educators would be more proactive in sharing and reminding of the service.

When looking at how reinforcement appeared in the interviews, reinforcement was seen in the majority of Midland providers who have referred individuals to DSMES. The theme was seen at varying knowledge levels for these providers. When looking at the providers who have referred patients in the Upstate, this was seen throughout the provider's referral knowledge level. Only one of the providers who had not referred someone from the Upstate and Midlands sought reinforcement from the educators.

Theme 5 – Cultural Norms

Another theme that emerged from the interviews was the role cultural norms played in referring patients to DSMES. The physicians that discussed this concept were providers who have referred individuals in both the Upstate and Midlands. The primary idea that emerged within this theme is patient referral to the DSMES program was standard procedure in their practice. Many of these providers had a diabetes educator in their office, which they stated, made the referral process easier. As one provider stated,

> *"I've already been working here for like six months, if not longer, you know. When I first came into my role, we have a huge office, so I met a ton of people. So even though I met, came up to this floor and saw people having to really absorb it, or know it was an option until you know, I asked a doctor what they would do. And they said, Oh, just refer to diabetes education. So it was like, probably six months or so."*

Some of them stated they had built relationships with the diabetes educators making the referral to the education something that was at the forefront of their minds for people with diabetes. As this same provider stated, "*And I hope I think that it's been helpful that our offices had it in-house, you know that we have a personal relationship with all the doctors. So they they all know it's here. It's a thing within our office. So plenty of patients are referred to to our office."*

Discussion

In this study, primary care providers' understanding, confidence, and expectations of DSMES varied by region and referral status. Recall that the aim of this study was to

understand primary care providers' knowledge and perceptions of DSMES in one healthcare system in South Carolina. The hypothesis of this study, as stated in Chapter 3, was that majority of the sampled primary care providers in the health care system in South Carolina will have limited self-reported awareness and limited knowledge of DSMES, as measured by ADA-recommended referral time points and explanation of what DSMES entails. The goal of the mixed methods approach to this aim was to understand providers' knowledge and perceptions of DSMES via a survey and supplement that survey with semi-structured interviews to provide explanatory information on the factors and components associated with their usage of the service.

Quantitative Findings

When examining the quantitative findings, approximately 92% of providers understood that patients with newly diagnosed diabetes should be referred to DSMES. Conversely, only 42% of primary care providers knew that "when transitions in life and care occur," patients should be referred to the DSMES service. In general, only 2 providers exclusively selected the four correct ADA-recommended referral times, indicating a need for further education on providing guideline-concordant care. However, approximately 76% of the responding PCPs had referred at patient to the DSMES service at some point. This incongruency between the knowledge of the guideline-appropriate referral time points and number of providers who have referred to the service indicates a need for further education. This need for further education providing appropriate referrals is something often studied in the current literature base. [14,15,22,30,36,39,50,53,75,76]

While providers may have low knowledge of appropriate DSMES referral times, the PCPs showed high awareness and confidence in DSMES. Three areas of confidence in DSMES assisting in various aspects of diabetes management were examined, and found that at least 75% of providers felt very confident that DSMES would assist with these components. Interestingly, PCPs had a high level of confidence in their ability to explain the role of DSMES in patient care, which is contradictory to their knowledge of referral time points.

Qualitative Findings

When examining the qualitative findings, a connection between confidence in DSMES, knowledge of DSMES, and outcome expectations for DSMES was found. This makes sense due to these themes falling under the same domain of beliefs about consequences in the Theoretical Domains Framework. Recall that belief about consequences was defined as "the acceptance of the truth, reality or validity about outcomes of a behavior in a given situation." [74] Providers in the Upstate region who had previously referred to DSMES programs had a higher knowledge of the ADA SOC referral time points than providers in the Midlands region who had referred. This is of interest because the Midlands DSMES has been established longer than the Upstate DSMES program. This could be due to geographical factors in the Midlands, such as competing health systems with different requirements, but further research is needed to better understand this difference. Additionally, the referral time points are common knowledge amongst diabetes educators and clinicians working in the diabetes education

space, but based on our findings, seem to be less commonly known for those providers not operating in that space. Steps should be taken in the future to provide primary care providers with the knowledge of when to refer patients to this service.

Another theme that arose connecting to low referral knowledge was the lack of procedural knowledge. Providers, primarily in the Midlands, need more education on how to refer to the service. This includes when to refer but also what the service entails. While the concept of lack of procedural knowledge is not something commonly studied in the literature, the current literature has found that providers are lacking knowledge about procedural steps in managing diabetes. [14,15,22,30,36,39,50,53,75,76] One study showed high knowledge of the guidelines, but the majority of the providers did not put this into practice. [51] This will connect to their confidence in DSMES hopefully further boosting the already high confidence scores from the survey.

The lack of procedural knowledge also did connect with the theme of reinforcement. Providers sought reinforcement through bilateral communication regarding their patients to enhance the concept of collaboration and partnership. An example is that providers often sought information through internet searches of information to help their patients. Additionally, providers wanted to know what resources were available for their patients with diabetes with the hope of a community resource page or the diabetes educators talking more about their services. While procedural knowledge and reinforcement are located in two different domains, these two are connected in that through gaining procedural knowledge on how, when, and whom to

refer to DSMES, the providers would likely receive reinforcement for their actions through closed-loop communication.

Provider barriers to referral were found to be connected to a lack of procedural knowledge and perceived patient barriers. Several providers stated they did not refer a patient to the service due to their perception of patient-level barriers, such as lack of insurance, lack of transportation, financial burden, and potential schedule conflict. Barriers to treatment are a commonly known component in receiving DSMES. [8]

Inductive coding revealed the themes of reinforcement and cultural norms. Interestingly, these are two constructs in the TDF. The reinforcement construct falls into the reinforcement domain, which is defined as "increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus." [77] While cultural norms would be classified as the group norms construct in the social influences domain, where this is defined as "those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviors." [77] Given that the Theoretical Domains Framework is meant to address mediators to behavior change, it is understandable that these two themes would emerge despite not actively trying to measure them.

Strengths and Limitations

While this study is one of the first of its kind to explore provider knowledge and perceptions of DSMES, there are limitations. The first is that this study was only conducted in one health system in South Carolina. These findings are only applicable to

this pilot study population. Another limitation is the low response rate (37.63%) to the survey. Given that the characteristics and reasons of the providers who did not respond are unknown, there is a risk of bias. Future studies should obtain a larger population to determine if these findings continue to hold true.

Implications

When considering the implications of this research study, three primary levels are considered: the provider level, the practice level, and the national DSMES level. At the provider level, the quantitative results showed that PCPs have a lack of knowledge of the appropriate times to refer patients to DSMES. This finding was supported by the qualitative results showing a lack of procedural knowledge of conducting the referral along with which patients should and should not be referred to DSMES. These findings suggest that PCPs working with people with diabetes should be educated on DSMES. The education for providers should contain information on what DSMES entails, what types of patients are appropriate for this service, and when these individuals should be referred to DSMES.

At the practice level, the mixed-methods results show providers' willingness but lack of knowledge to assist patients in obtaining DSMES programs. This indicates that workplace culture is a critical factor in providers engaging in referral behavior. Environments should be created in outpatient healthcare practices to foster referrals to DSMES. This could be done through gamification, placing a CDCES in the practice, or quarterly lunch-and-learns to place DSMES at the forefront of providers’ minds.

Lastly, at the national DSMES level, DSMES sites should explore methods to integrate providers into the service. With providers often feeling the burden of managing a patient and seeking bilateral, closed-loop communication, this presents the opportunity for DSMES to incorporate PCPs further in the DSMES service. Similar to practice-level recommendations, DSMES programs should find a way to ensure referral to these programs becomes a habit for providers. Through creating this referral pipeline, it aids participants in obtaining quality education and support, while reducing the burden on the provider to be the "lone support." Additionally, access to the service is a crucial part of providers referring to the service. This indicates a greater need for DSMES programs in more locations to address the concern over the lack of patient access.

Conclusions

Overall, this study sought to understand primary care providers' knowledge and perceptions of DSMES. This study found that providers lack knowledge about the appropriate referral time points for DSMES, but in general, have a high level of awareness and confidence in the service. This study found that there are some barriers to referral, such as a lack of knowledge of the ADA's four referral time points or perceived patient barriers. Overall, providers in general show a willingness to refer to the service given further education about how to refer, when to refer, and whom to refer.

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Tables and Figures

Table 1: Theoretical Domains Framework

Domain (definition)[a]	**Constructs**
1. Knowledge (An awareness of the existence of something)	Knowledge (including knowledge of condition /scientific rationale) Procedural knowledge Knowledge of task environment
2. Skills (An ability or proficiency acquired through practice)	Skills Skills development Competence Ability Interpersonal skills Practice Skill assessment
3. Social/Professional Role and Identity (A coherent set of behaviors and displayed personal qualities of an individual in a social or work setting)	Professional identity Professional role Social identity Identity Professional boundaries Professional confidence Group identity Leadership Organizational commitment
4. Beliefs about Capabilities (Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use)	Self-confidence Perceived competence Self-efficacy Perceived behavioral control Beliefs Self-esteem Empowerment Professional confidence
5. Optimism (The confidence that things will happen for the best or that desired goals will be attained)	Optimism Pessimism Unrealistic optimism Identity
6. Beliefs about Consequences (Acceptance of the truth, reality, or validity about outcomes of a behavior in a given situation)	Beliefs Outcome expectancies Characteristics of outcome expectancies Anticipated regret

Domain (definition)[a]	Constructs
	Consequents
7. Reinforcement (Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus)	Rewards (proximal / distal, valued / not valued, probable / improbable) Incentives Punishment Consequents Reinforcement Contingencies Sanctions
8. Intentions (A conscious decision to perform a behavior or a resolve to act in a certain way)	Stability of intentions Stages of change model Transtheoretical model and stages of change
9. Goals (Mental representations of outcomes or end states that an individual wants to achieve)	Goals (distal / proximal) Goal priority Goal / target setting Goals (autonomous / controlled) Action planning Implementation intention
10. Memory, Attention and Decision Processes (The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives)	Memory Attention Attention control Decision making Cognitive overload / tiredness
11. Environmental Context and Resources (Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behavior)	Environmental stressors Resources / material resources Organizational culture /climate Salient events / critical incidents Person x environment interaction Barriers and facilitators
12. Social influences (Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviors)	Social pressure Social norms Group conformity Social comparisons Group norms Social support Power Intergroup conflict

Domain (definition)[a]	Constructs
	Alienation Group identity Modelling
13. Emotion (A complex reaction pattern, involving experiential, behavioral, and physiological elements, by which the individual attempts to deal with a personally significant matter or event)	Fear Anxiety Affect Stress Depression Positive / negative affect Burn-out
14. Behavioral Regulation (Anything aimed at managing or changing objectively observed or measured actions)	Self-monitoring Breaking habit Action planning

[a] recreated from Cane et al.

Table 2: Table of Domain/Construct Measured in Study from TDF

Domain (definition)[a]	**Constructs**
1. Knowledge (An awareness of the existence of something)	Procedural knowledge
2. Skills (An ability or proficiency acquired through practice)	Ability
4. Beliefs about Capabilities (Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use)	Self-efficacy
6. Beliefs about Consequences (Acceptance of the truth, reality, or validity about outcomes of a behavior in a given situation)	Beliefs Outcome expectancies

[a] adapted from Cane et al.

Table 3: Breakdown of Provider Type by Location

Location	MD	DO	PA	APRN	Total
Upstate	79	16	5	28	128
Midlands	9	0	1	2	12
Total	88	16	6	30	140

Table 4: Selected DSME Referral Timepoints

% Correct for Referral times	0 incorrect times	1 incorrect time	2 incorrect times	3 incorrect times	4 incorrect times
25%	5	8	4	0	0
50%	5	17	11	3	0
75%	7	19	11	4	2
100%	2	4	17	6	15

Table 5: Assessment of Knowledge Score by Referral Status

	25%	50%	75%	100%	Total
Yes: n(%)	12 (11.21)	33 (30.84)	31 (28.97)	31 (28.97)	107 (100)
No: n(%)	5 (17.24)	3 (10.34)	9 (31.03)	12 (41.38)	29 (100)
Unsure: n(%)	0 (0)	0 (0)	3 (75.00)	1 (25.00)	4 (100)

Table 6: Awareness of DSME by Provider Type

Awareness Level		1: Not Aware	2	3	4	5: Very Aware
Provider Type	MD	3	12	17	38	18
	DO	2	3	2	6	3
	PA	0	1	3	1	1
	APRN	4	3	12	7	4
	TOTAL	9 (6.43%)	19 (13.57%)	34 (24.29%)	52 (37.14%)	26 (18.57%)

Table 7: Provider Confidence in DSME

Assist your patients in meeting their target A1C goals		1: Not Confident	2	3	4	5: Very Confident
Provider Type	MD	1	4	13	41	29
	DO	0	0	3	4	9
	PA	0	0	2	1	3
	APRN	0	0	9	13	8
	TOTAL	1 (0.71%)	4 (2.86%)	27 (19.29%)	59 (42.14%)	49 (35.00%)

Table 8: Provider Confidence in DSME Goal

Help patients improve their confidence in managing their diabetes		1: Not Confident	2	3	4	5: Very Confident
Provider Type	MD	1	2	5	46	34
	DO	0	0	1	5	10
	PA	0	0	1	1	4
	APRN	0	0	6	14	10
	TOTAL	1 (0.71%)	2 (1.43%)	13 (9.29%)	66 (47.14%)	58 (41.43%)

Table 9: Provider Confidence in DSME Goal

Assist in managing a patient's diabetes		1: Not Confident	2	3	4	5: Very Confident
Provider Type	MD	1	2	14	34	37
	DO	0	0	2	5	9
	PA	0	0	0	3	3
	APRN	0	1	6	12	11
	TOTAL	1 (0.71%)	3 (2.14%)	22 (15.71%)	54 (38.57%)	60 (42.86%)

Table 10: Provider Confidence in DSME Goal

Explain the role of DSMES in patient care		1: Not Confident	2	3	4	5: Very Confident
Provider Type	MD	1	3	6	46	32
	DO	0	0	3	4	9
	PA	0	0	2	2	2
	APRN	0	2	8	11	9
	TOTAL	1 (0.71%)	5 (3.57%)	19 (13.57%)	63 (45.00%)	52 (37.14%)

Table 11: Results of Associations between Knowledge Score and Confidence in DSMES

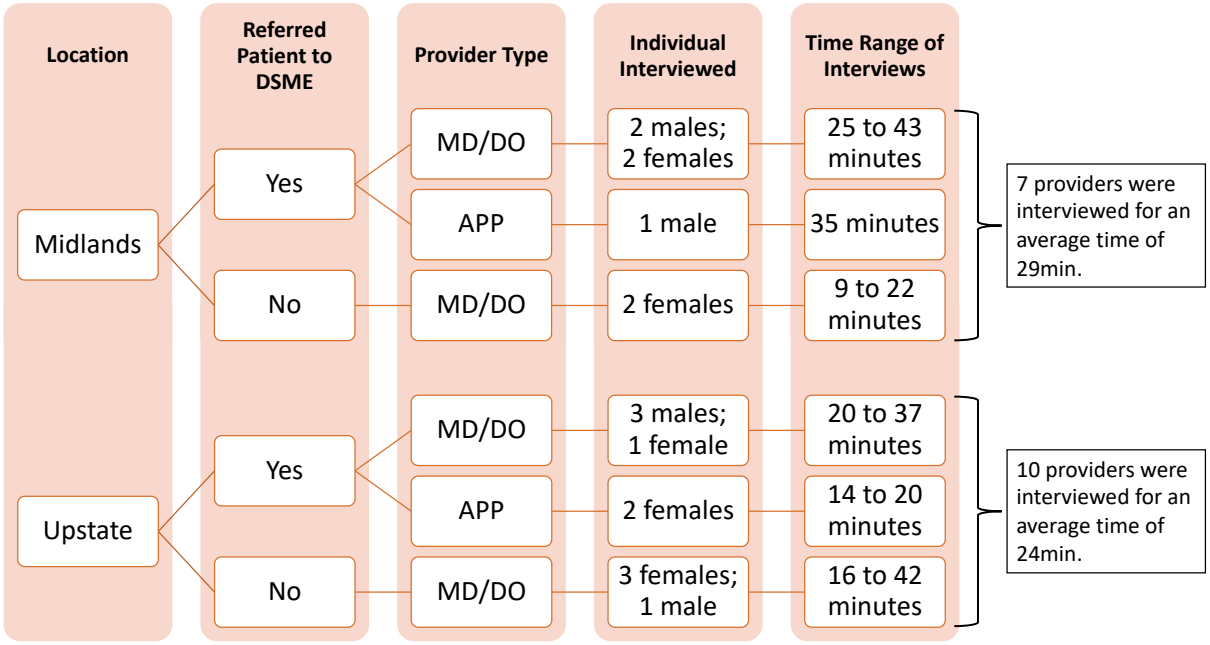
	B [95% CI]	p-value
Assist your patients in meeting their target A1C goals		
1: Not Confident	Ref.	Ref.
2	-0.75 [-4.56, 3.07]	0.701
3	-0.17 [-3.17, 2.83]	0.911
4	-0.32 [-3.27, 2.63]	0.833
5: Very Confident	0.12 [-2.84, 3.08]	0.938
Help patients improve their confidence in managing their diabetes		
1: Not Confident	Ref.	Ref.
2	-0.75 [-5.28, 3.79]	0.747
3	-0.48 [-3.57, 2.62]	0.762
4	-0.22 [-3.16, 2.73[]	0.885
5: Very Confident	0.02 [-2.93, 2.97]	0.991
Assist in managing a patient's diabetes		
1: Not Confident	Ref.	Ref.
2	0.75 [-3.19, 4.69]	0.708
3	-0.25 -3.27, 2.78]	0.873
4	-0.36 [-3.31, 2.60]	0.813
5: Very Confident	0.06 [-2.89, 3.02]	0.966
Explain the role of DSMES in patient care		
1: Not Confident	Ref.	Ref.
2	0.29 [-3.05, 3.62]	0.867
3	-0.34 [-3.38, 2.69]	0.824
4	-0.18 [-3.13, 2.77]	0.904
5: Very Confident	-0.07 [-3.03, 2.89]	0.963

Table 12: Provider Interview Quotes by Theme

Theme	**Sub-theme**	**Quotation**
Procedural Knowledge	Lack of procedural knowledge	*"Uh we just, yeah, it it would be good if we just know how to do the referral. If there's a like, we know who to call to just, who to have our staff call to schedule, a class or what information needs to be sent, which make sure we're sent whatever forms we need to fill out to fax over to have them enrolled in the classes and things like that."*
Ability	Knowledge about diabetes self-management	"*I mean, mean mostly um, you know, mostly, we'll talk about diet, exercise, checking the sugar, sugar goals, you know, all those types of things."*
Beliefs about Service	Provider knowledge of DSMES	*"It's a black box. I would send people there. I would not know exactly what was happening and then they came back a little bit more well-versed in how to manage their diabetes."* *"it seems just to be diabetic education in general, which includes, you know, um usual diabetic teaching."*
	Outcome Expectations	"*I feel like the people that have gone I've had very good, positive changes in their A1Cs and they get more knowledge.*"
Beliefs about Patient	Perceived patient barriers	*"when in reality, you know, I can talk to I'm blue in the face, I can write a prescription, I can do everything I'm supposed to do. But when the patient walks out the door, I can't control whether they pick up the prescription, I can't control what they put in their mouths. I can't control any of their lifestyle, but yet I'm held responsible."*
Beliefs about Referral	Provider barriers to referral	*"there's a backlog and it's, there have been occasional glitches and communication between the patient and the hospital's program. So those are the main things I won't say anything really deterred me from referrals specifically uh. But uh except those types of factors, which kind of slowed the process down and made it a little more difficult."*

Theme	Sub-theme	Quotation
	Confidence in providing diabetes self-management	"*I feel like my efforts get much more um lead way,*" "*I could just deal with this, with kind of similar to what's available*."
Reinforcement		*"I would get like contact through the EMR from the, you know, from the DSME. Or I would get faxes from saying, This is what we've done. This is what the needs are, hey, we saw this, and we need this. Um so it may be I haven't had enough patients go through it here to kind of see that process. But I think, on our end, it's nice to get some type of meaningful feedback, not just a form that says they completed it the saying, you know, please consider this or um your patient would benefit from type of thing."* "*I mean...I would like to see the people that offer the education services in the area to be a little bit more proactive in informing the physicians in the community of their services."*
Cultural Norms		*"I've already been working here for like six months, if not longer, you know. When I first came into my role, we have a huge office, so I met a ton of people. So even though I met, came up to this floor and saw people having to really absorb it, or know it was an option until you know, I asked a doctor what they would do. And they said, Oh, just refer to diabetes education. So it was like, probably six months or so."* "*And I hope I think that it's been helpful that our offices had it in-house, you know that we have a personal relationship with all the doctors. So they they all know it's here. It's a thing within our office. So plenty of patients are referred to to our office."*

Figure 1: Information on Providers Interviewed



CHAPTER SEVEN

CONCLUSIONS

The goal of this dissertation was to describe the impact of diabetes self-management education and support (DSMES) programs on selected diabetes management process and clinical outcome measures while also seeking to understand primary care providers (PCP) knowledge and perceptions of DSMES. **Aim 1** described the impact of an upstate South Carolina ADA-Accredited DSME program and a community-based DSMS program on three diabetes management process measures: retinal exam, nephropathy attention, and primary care service utilization. **Aim 2** described the impact of an upstate South Carolina ADA-Accredited DSME program and a community-based DSMS program on six diabetes management outcome measures: A1C, body mass index (BMI), triglycerides (TG), low-density lipoprotein (LDL), high-density lipoprotein (HDL), total cholesterol (TC). **Aim 3** identified primary care providers' knowledge and perceptions of DSMES in one South Carolina health system.

The studies presented in this dissertation aim to add to our understanding that DSMES programs can assist in addressing the ever-growing diabetes population in the United States, while also identifying and describing the current knowledge and perceptions of DSMES by PCPs. These studies may be useful in informing the further development, implementation, and dissemination of DSMES programs while aiming to address one potential facet of the low utilization of the service. This chapter seeks to summarize the findings from the prior chapters and then conclude by discussing the clinical and public health implications of the work along with future research directions.

Recall that one arm of the study is a community-based diabetes self-management support (DSMS) program called HED. HED is a 4-month long, ADA practice-tested support program. Another arm of the study is diabetes self-management education (DSME). The DSME examined is an ADA-accredited program located in upstate South Carolina. Lastly, the control group is composed of individuals who were referred to the DSME program but elected not to participate for various reasons.

Overview of the Dissertation Findings

Impact of DSMES on Process measures

Chapter 4 explored the impact of DSME and DSMS programs on PCP utilization, retinal screenings, and nephropathy attention as compared to a population that was referred to DSME but elected not to participate. While the literature showed promising results for DSME to have a positive impact on PCP utilization, this study found that participation in DSME and DSMS did not increase usage when compared to a control group. [1–3] Similarly, the literature had positive results on the impact of DSMES programs on people with diabetes obtaining retinal screenings. [1,4,5] However, these results were not confirmed by this study. Similarly, DSME and DSMS interventions were found to be inconclusive predictors of chronic kidney screening.

Impact of DSMES on Clinical measures

Chapter 5 described the impact of DSME and DSMS programs on A1C, BMI, LDL, HDL, TC, and TG. Paralleling the well-documented literature on the impact of DSME on

A1C, in this study, A1C had a significant group-by-time interaction for DSME, with this group boasting a 2.5% reduction at 3 months post-intervention and a 1.54% reduction from baseline at 12 months. [6–10] However, the DSMS intervention did not boast the same significant reductions, but this group had a 1.7% lower starting A1C. Similar to A1C, DSME had significant reductions in BMI at 3, 6, 9, and 12 months after the intervention. Age was found to be a significant predictor of BMI change (p-value < 0.0001). Interestingly, the often longer DSMS intervention did not yield the same reductions in an individual's BMI level.

When examining the four lipid panel measures, statin usage was controlled for due to its known varying impact on lipid levels. [11–14] Interestingly, statin usage was found not to have a significant impact on all lipid panel measures. For the four lipid measures, DSME was found to have a 5.5250-point increase in HDL at 6 months but no other significant impact on other lipid levels. However, it should be noted that LDL, TC, and TG began at higher-than-average levels, indicating the non-generalizability of the sample. Additionally, the weight loss seen in the DSME group could be associated with the increasing HDL level.

Provider Knowledge and Perceptions of DSMES

Chapter 6 identified the knowledge and perceptions of DSMES for primary care providers in one South Carolina health system. Provider's understanding, confidence, and expectations of DSMES varied by region and referral status. A connection between

provider confidence in DSMES, knowledge of DSMES, and outcome expectations for DSMES was found. Lack of procedural knowledge arose as a theme connected to low referral knowledge. Additionally, provider barriers to referral were also found to be connected to a lack of procedural knowledge along with provider-perceived patient barriers. Barriers to treatment are a commonly known component in receiving DSMES. [15] This study found that there are some barriers to referral, such as a lack of knowledge of referral time points or perceived patient barriers. Two additional themes were found through inductive coding: cultural norms and reinforcement. Providers desired to have bidirectional communication about the program and patient results. They were hoping for a community resource page to make access to this knowledge easier. Overall, providers in both geographical region show willingness to refer to the service given further education about how to refer, when to refer, and whom to refer.

Concluding Remarks

Strengths and Limitations

This dissertation has several strengths of information that can contribute to the current knowledge base. For chapter 4, this study continued to find that DSME is beneficial in obtaining chronic kidney screening and should continue to be a method employed by providers to aid their patients with diabetes. The chapter 5 study is one of the few studies of its kind to explore the impact of DSME and DSMS on several diabetes clinical measures. This research currently supports the current literature on the efficacy of DSME in lowering A1C. Additionally, it provides interesting findings that statin usage was a

non-significant predictor of lipid level changes. Lastly, the mixed methods study presented in chapter 6 is one of the first of its kind to explore primary care providers' knowledge and perceptions of DSMES. Currently, the majority of the literature focuses on patient-level factors or provider knowledge about diabetes management.

While this study has several strengths, there are limitations to consider. These limitations are discussed at length in chapters 4, 5, and 6 and will be summarized here.

The first is the small sample size for the cohorts, even after propensity score matching. Additionally, not all matched individuals had the measures. This left the analyzed groups much smaller than the original matched populations. Future studies should seek to have a larger sample size to determine if these results remain true.

Secondly, this data is only obtained from one geographical region in South Carolina. This region is not representative of the state of South Carolina or the nation. Additionally, the DSME and control groups are from one DSME program in South Carolina. This limits the generalizability of the sample. Similarly, there is self-selection bias for those participating in DSME and DSMS programs.

Another limitation is that the data was obtained from one health record at one health system. Individuals in this study may utilize multiple health systems, given the numerous healthcare organizations in the Upstate region of South Carolina. Another limitation is

that PCP is defined as only visits with the person defined at their primary care practitioner in EPIC. This definition limits the observations to only visits with one provider for the individual. Future studies should examine all internal medicine or family medicine practitioner visits as part of primary care usage.

Another limitation is that it is likely that not all retinal exams are recorded in an individual's electronic health record. Often retinal exams are conducted by an optometrist or ophthalmologist, with the results not transferred back to be placed into the respective patient's health record. The next limitation is that nephropathy attention is only measured by eGFR. To determine true, guideline-concordant care, uACR and eGFR should be assessed. Similar to this limitation, the nephropathy attention only determined if the participant obtained the screening; it did not determine if the person had CKD. CKD was also not controlled for in the model; thus, some individuals may be tested more frequently due to being diagnosed with CKD.

A limitation of the mixed methods study is that it was only conducted in one health system in South Carolina, with findings only applying to the pilot study population. Another limitation is the low response rate (37.63%) to the survey. Future studies should obtain a larger population to determine if these findings continue to hold true.

Clinical Implications: Out of Sight, Out of Mind

The findings presented in this dissertation have important clinical implications for managing people with diabetes. While the study did not find significant results in increasing primary care utilization and retinal screening, this does not mean these programs are not effective in aiding in these facets of diabetes management. Given that diabetes requires a multifaceted approach to management, having an interdisciplinary team can aid in diabetes management for the participating individuals.

This study supports the current literature that DSME should continue to be recommended to individuals with diabetes as a way to better manage and lower their A1C. While the DSMS program did not show similar results to the DSME program, the population had a lower A1C value. Commonly, longer interventions are known to aid in the behavior change necessary to impact an individual's BMI value. Interestingly, the DSME program found significant reductions in BMI at the majority of the time points after intervention completion. While the DSMS and DSME programs are not advertised as weight loss programs, changing an individual's health behaviors often results in better lifestyle management.

Lastly, the mixed methods study showed a provider's willingness but lack of knowledge to assist patients in obtaining DSMES programs. It indicated that workplace culture and reinforcement are critical factors in providers engaging in referral behavior. Similarly, access to the service is a crucial part of providers referring to the service. This

indicates a greater need for DSMES programs in more locations to address the concern over the lack of patient access.

When thinking about engagement in DSMES programs, an important aspect to consider is the "out of sight, out of mind concept." Community-based programs, such as the HED/DSMS program, are not commonly referred to by providers. Additionally, the mixed methods study showed that the aspect of cultural norms played a large role in whether a provider referred an individual to DSME or not. DSMES programs should find a way to ensure referral to these programs becomes a habit for providers. By creating this referral pipeline, it aids participants in obtaining quality education and support, while reducing the burden on the provider to be the "lone support."

Diabetes management requires understanding the all-consuming nature of diabetes for the individual, creating an impact on their physical and emotional health. Having a "deeper bench" for diabetes management eases the burden on the provider and patient by spreading the management throughout the healthcare system. Having programs such as HED aids in deepening the bench, but raising awareness is a critical aspect. However, care should be given to ensure the community-based programs continue to provide quality education and provide closed-loop communication back to the provider.

Future studies should measure patient activation, self-efficacy, and other factors that could lead individuals to self-select into participation in these programs. Future

research should also explore if these results hold for other DSME and DSMS programs across the United States and with larger samples. Lastly, future studies should determine if the themes of lack of knowledge, cultural norms, reinforcement, and other themes found in chapter 6 hold for a more generalizable population.

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APPENDICES

Appendix A

Participant Survey

Confidential

Diabetes Self-Management Education and Support: Understanding the Knowledge

Thank you for taking the time to complete this short survey! This survey should take no more than 2 minutes of your time.

Please reach out to Christina Dietz at cjdietz@clemson.edu if you have any questions or concerns.

First, we want to collect some general information about you to help understand who is answering the questionnaire.

Please provide your full name.	_____
What is your email address?	_____
Check which best describes your position:	◯ MD - Doctor of Medicine ◯ DO - Doctor of Osteopathic Medicine ◯ PA - Physician Associate (formerly called Physician Assistant) ◯ APRN - Advanced Practice Registered Nurse ◯ Other
If other, what is your position?	_____
Where is your primary practice location?	◯ Upstate ◯ Midlands

Please note, for this question and the following questions, Diabetes Self-Management Education and Support can be used interchangeably with the terms "diabetes educator" or "diabetes education".

	1 –Not aware	2	3	4	5 –Very Aware
Please rate your awareness of Diabetes Self-Management Education and Support (DSMES) programs.	◯	◯	◯	◯	◯

Do you believe you have adequate access to Diabetes Self-Management Education and Support services for your patients?

- ◯ Yes
- ◯ No
- ◯ Unsure

The following questions will ask you about your knowledge and perceptions regarding Diabetes Self-Management Education and Support programs.

Please select the key timepoints a patient should be referred to Diabetes Self-Management Education and Support (check all that apply):	☐ Annually and/or when not meeting treatment targets ☐ At diagnosis ☐ When A1C > 8.0 ☐ When transitions in life and care occur ☐ When A1C > 9.0 ☐ When complicating factors develop ☐ When a patient's family member(s) develop diabetes ☐ When BMI > 30.0
Have you ever referred a patient to Diabetes Self-Management Education and Support while working at Prisma Health?	◯ Yes ◯ No ◯ Unsure
When is the last time at Prisma Health that you referred a patient to Diabetes Self-Management Education and Support?	◯ Within the last 6 months ◯ Within the last year ◯ Within the last 5 years ◯ Within the last 10 years

On a scale of 1-5, where 5 is very confident and 1 is not confident at all, how confident are you that Diabetes Self-Management Education and Support can:	1: Not confident at all	2	3	4	5: Very Confident
assist your patients in meeting their target A1C goals?	○	○	○	○	○
help patients improve their confidence in managing their diabetes?	○	○	○	○	○
explain the role Diabetes Self-Management Education and Support in patient care?	○	○	○	○	○
assist in managing a patient's diabetes?	○	○	○	○	○

This section provides you with an opportunity to provide comments and feedback. If you have no comments or feedback, please press the next arrow.

If you have any other thoughts or comments about Diabetes Self-Management Education and Support, please write them here. _____

Thank you for taking the time to answer these questions!

Would you be willing to participate in a brief follow-up interview to further discuss your knowledge and perceptions of Diabetes Self-Management Education and Support?	◯ Yes ◯ No ◯ Unsure

Appendix B

PCP Interview

Diabetes Self-Management Education and Support: Primary Care Provider Knowledge and Perceptions

Interview Guide
Semi-structured interviews (20 – 40 minutes)

TDF Domain: Construct

- Knowledge: Procedural Knowledge
  - Questions: 2, 3ab, 4ab, 5a, 6d
- Beliefs about Consequences: Outcome Expectancies
  - Questions: 2bcd, 3, 4, 5, & 6
- Skills: Ability
  - Questions: 2, 3, 5a
- Beliefs about Consequences: Beliefs
  - Questions: 2bcd, 3, 4, 5, & 6

1.) Please tell me about yourself.
   a. Name?
   b. Credentials?
   c. How long have you been practicing in primary care?
   d. Where in the state do you practice?

2.) What do you know about Diabetes Self-Management Education and Support?
   a. Probes What is the service?
   b. What can it provide?
   c. Have you ever referred a patient to DSMES: Yes / No
      i. IF THEY HAVE REFERRED A PATIENT: What patients do you / would you refer? What patients do you not refer? What do you consider when referring? How does that influence your decision?
      ii. IF THEY HAVE NOT REFERRED A PATIENT: What has made you not refer patients? What makes you consider referring a patient to DSMES? What influences your decision?

3.) If applicable, what is your expectation for how Diabetes Self-Management Education and Support can help you manage your patients with diabetes?
   a. Medications?
   b. Clinical outcomes?
   c. IF THEY HAVE REFERRED A PATIENT: Will you tell me about a time you purposely didn't refer a patient who was eligible for DSMS? What contributed to your decision?

d. IF THEY HAVE NOT REFERRED A PATIENT: Will you tell me about what has made you not refer a patient? What contributed to your decision?

4.) If applicable, how do you think Diabetes Self-Management Education and Support can help your patients manage their diabetes?
   a. Skills?
   b. Medication adherence?
   c. Confidence?
   d. Does this vary by patient? By their disease severity?

<u>If in-person, hand this to them on a card. If on zoom show this on screen</u>.

Now I am going to share with you information regarding DSMS:
According to a Joint Statement from the American Diabetes Association, Association of Diabetes Care and Education Specialists, and the Academy of Nutrition and Dietetics:

- ***"DSMES is reported to reduce the onset and/or advancement of diabetes complications, to improve quality of life and lifestyle behaviors such as having a more healthful eating pattern and engaging in regular physical activity, to enhance self-efficacy and empowerment, to increase healthy coping, and to decrease the presence of diabetes-related distress and depression."***
- ***"DSMES improves A_{1c} by as much as 1% in people with type 2 diabetes."***
- ***"DSMES has been shown to be cost-effective by reducing hospital admissions and readmissions, as well as estimated lifetime health care costs related to a lower risk for complications."***

5.) How does this information impact your view of DSMES in supporting you in managing your patients with diabetes?
   a. Does this information impact your likelihood of referring to DSMES?
   b. Does this change t your impressions of how DSMES can impact medication management?
   c. Does this change your impression of how DSMES can impact Clinical outcomes?

6.) How does this information impact your view of DSMES in supporting your patients to manage their diabetes?
   a. Skills?
   b. Medication adherence?
   c. Confidence?
   d. Does this change whom you will refer to this service? What factors will you consider when referring?

7.) Is there any other information you would like to share with me regarding DSMES, your perceptions, or knowledge about these programs?