Diabetes Self-Management Education (DSME) and Medical Nutrition Therapy (MNT) for Type 2 Diabetes Improves Patient Outcomes: A Retrospective Chart Review

by

Amie Alexander Hardin

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Approved by

Dr. Patricia Z. Marincic, Chair, Associate Professor and Director
Dr. Ramesh B. Jeganathan, Associate Professor
Dr. Jan Kavookjian, Associate Professor

Abstract

Background Diabetes self-management education (DSME) and Medical Nutrition Therapy (MNT) improve patient outcomes; poor reimbursement limits access to care.

Objectives The aim was to develop methodology for tracking patient outcomes subsequent to registered dietitian nutritionist interventions, document outcomes for patients with type 2 diabetes (T2D) attending an American Diabetes Association (ADA)-recognized education program, and obtain outcome data to support reimbursement and public policy initiatives to improve patient access to DSME and MNT.

Design Retrospective chart review.

Participants/setting A random sample of 100 charts was chosen from the electronic medical records of patients with type 2 diabetes completing DSME and individualized MNT, June 2013-June 2014.

Statistical Analysis Mixed model analysis of variance was used to determine differences between means for continuous variables; McNemar tests and Gamma statistic trend analysis were used to assess frequency of patients reaching glycemic targets.

Results Significant weight loss was observed from baseline (94.3±21.1kg) to end of program (91.7±21.2) [-1.6±3.9kg]; $P<0.001$); weight loss in whites (-5.0±8.4kg; $P<0.001$) exceeded that of African Americans (-0.8±9.0kg; ($P>0.05$). Significant hemoglobin A1c reduction was observed from baseline (8.74±2.30%) to end-of-program (6.82±1.37%) [-1.92±2.25%]; $P<0.001$) and retained at one-year (6.90±1.16%; $P<0.001$). Comparatively, 72% of patients reached

hemoglobin A1c targets (≤7.0%) versus 27% at baseline (P=0.008). When stratified by diet alone and diet plus drug therapy, patients exhibited a 1.08±1.20% (P<0.001) and 2.36±2.53% (P<0.001) reduction in hemoglobin A1c respectively. Triglycerides decreased from baseline 181.6±75.5mg/dL (2.0±0.9mmol/L) to 115.8±48.1mg/dL (1.3±0.5mmol/L) (P=0.023). High density lipoprotein increased from 41.4±12.4mg/dL (1.1mmol/L±0.3) to 47.3±12.4mg/dL (1.2±0.3mmol/L) (P=0.007).

Conclusions Retrospective chart review provides an operational model for abstracting existing patient outcome data subsequent to registered dietitian nutritionist interventions. In support of universal reimbursement and patient access to DSME with supplemental individualized MNT, reductions were observed in the key outcome measures of weight, body mass index, hemoglobin A1c, and triglycerides, and increase was observed in HDL, suggesting a potential for reduction in cardiovascular risk from exposure to DSME and MNT.

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List of Abbreviations

T2D	type 2 diabetes
IGT	impaired glucose tolerance
IFG	impaired fasting glucose
ADA	American Diabetes Association
FBG	fasting blood glucose
A1C	glycosylated hemoglobin
ASCVD	atherosclerotic cardiovascular disease
TG	triglyceride
HDL	high density lipoprotein
UKPDS	United Kingdom Prospective Diabetes Study
MNT	medical nutrition therapy
RDN	registered dietitian nutritionist
DSME	diabetes self-management education
DSMT	diabetes self-management training
AADE	American Association of Diabetes Educators
SMBG	self-monitoring blood glucose
NCP	nutrition care process
BMI	body mass index
RCR	retrospective chart review

List of Abbreviations cont.

LDL	low density lipoprotein
TC	total cholesterol
AA	African Americans
OHA	oral hypoglycemic agents
BCBS-AL	Blue Cross Blue Shield - Alabama

Chapter 1

INTRODUCTION

Type 2 diabetes (T2D) is a chronic health condition characterized by metabolic disturbances in insulin use and production. Even before the disease is diagnosed, insulin resistance is present. Insulin resistance occurs when there is a decreased cellular response to insulin causing a delay in the movement of glucose from the bloodstream into the cell for the body to use as energy, therefore causing the cell to "resist" the insulin, which leads to hyperglycemia. To compensate, the pancreas continues to produce insulin, which leads to hyperinsulinemia. Hyperinsulinemia in the presence of hyperglycemia eventually leads to β-cell failure. Diabetes is associated with multiple metabolic derangements leading to comorbid disease and premature death. Diabetes is a chronic progressive disease, warranting aggressive medical and nutritional intervention across the spectrum from disease diagnosis to prevention and treatment of chronic comorbid conditions.

The etiology of T2D is a combination of genetic, environmental, and lifestyle factors. Although there is a genetic component of the disease, there has been no published work to date that identifies the specific gene contributing to the disease. The strongest evidence for the genetic component of the disease is reported in studies of identical twins showing a concordance rate of 50-90% in diagnosis of the disease; this rate is higher than the rates between non-identical twins, siblings or other first-degree relatives.[1] Genetic predisposition cannot account for the rising

incidence of diabetes; environmental and lifestyle factors are the predominant cause of the increase in the prevalence of the disease worldwide.

While the specific effects of environment are unknown, population studies of groups of people who migrate into a different country show a higher prevalence of the disease than people living in their indigenous habitat.[1] The increase in prevalence of disease among migrants reflects the effects of the environment.[1] While obesity is a characteristic associated with T2D, not all obese people will develop the disease. Obesity, in addition to parental diabetes, increases the risk of the disease. Likewise, non-obese individuals whose parents have T2D have a lower risk of developing the disease.

Location of adipose tissue also plays a role in the risk of T2D. Central adiposity can increase the risk of T2D, as well as, heart disease, and dyslipidemia. Sedentary lifestyles and a diet high in fat and calories leading to obesity are known risk factors for the development of T2D.[1] There is a strong interaction between genetic determinants predisposing the population to obesity and diabetes and a plethora of environmental factors, including diet and lifestyle that have contributed to the exacerbation in disease prevalence.

Insulin resistance, the main metabolic effect of T2D begins years before clinical symptoms of diabetes are apparent. This insulin resistance can be identified by higher than normal levels of insulin in the bloodstream; generally, the higher insulin level in the blood correlates to a higher degree of insulin resistance. During this stage of the disease, pancreatic beta cells are able to make up for the resistance by increasing insulin production. Increased insulin production leading to hyperinsulinemia and insulin resistance eventually leads to “burn out” and beta cell failure. The decline in function of the beta cells in turn leads to regulatory metabolic dysfunction causing decreased glucose uptake by peripheral tissues and an increase in

hepatic glucose production resulting in hyperglycemia. Development of both macrovascular and microvascular complications can begin during what can be a long prodrome of disease; patients often present with comorbidities at the time of disease diagnosis. During the prodrome of T2D, disturbances in glucose metabolism are present. During this time, serum blood glucose levels are outside of the normal range, but not yet at the level of diagnosis. In order to emphasize the abnormal glucose levels, CDC and ADA defined impaired fasting glucose (IFG) and impaired glucose tolerance (IGT). [2] Impaired fasting glucose describes abnormal fasting blood glucose values during the fasting state and IGT describes the abnormal blood glucose response after a glucose load.[2] Current diagnostic criteria for IFG, IGT, and diabetes are shown in Table 1.

Table 1. Diagnostic criteria for diabetes

	Normal	IFG/IGT	Diabetes
Fasting blood glucose	< 100 mg/dL	100 -125 mg/dL	≥ 126 mg/dL
Random Blood Glucose	< 140 mg/dL	141 – 199 mg/dL	≥ 200 mg/dL

Adapted from www.diabetes.org (3)

Diabetes affects 29 million Americans, 9.3% of the U.S. population, with 1.4 million new cases diagnosed each year contributing a healthcare burden of $176 billion in direct medical costs and $69 billion in indirect costs (absenteeism, productivity loss, disability, and premature death). In 2010, diabetes was the seventh leading cause of death in the United States. Health disparity is evident in the almost two-fold increase in diagnosis of diabetes in blacks versus whites (9.5% vs 5.8%).[3,4,5] Alabama has one of the highest diabetes rates in the U.S at 12%,[5] which shows an increase in prevalence of 45% in the past ten years. Six Alabama counties make the top ten ranking of counties with the highest disease prevalence in the U.S.[5,6]

Diabetes poses a significant health burden to patients suffering from the disease, as well as, financial burden to the U.S. healthcare system. Direct medical costs are estimated using the healthcare resource cost attributed to people diagnosed with diabetes over and above the healthcare costs of people without diabetes.[7] Direct medical costs of diabetes are associated with common long-term complications such as retinopathy, neuropathy, nephropathy, coronary artery disease, peripheral arterial disease, and stroke. Costs include, but are not limited to, emergency room visits, inpatient hospital stays, physician visits, hospital outpatient visits, and medication prescriptions. The highest costs are associated with inpatient hospital stays and medication prescriptions. Length of hospital stays, regardless of admission reason, are increased in patients with diabetes leading to further increases in healthcare costs.[7]

Notably, diabetes complications are exacerbated by poor glycemic control and prolonged hyperglycemia. The excess blood glucose causes damage to the small and large vessels in the body leading to micro and macrovascular complications respectively. Microvascular complications occur when glucose is diverted from tissues requiring insulin for glucose uptake to those that are non-insulin dependent. Damage to the small vessels within these tissues primarily results in decreased blood flow, which leads to retinopathy, nephropathy, and neuropathy.

In addition, development of retinopathy is related to duration of T2D and glycemic control and is the leading cause of blindness in developed countries. Likewise, forty-four percent of cases of kidney failure are attributed to diabetic nephropathy; treatment consists of long-term dialysis or kidney transplant.[5] Increasing prevalence rates of chronic kidney disease parallel those of obesity and T2D. Neuropathy is a complex constellation of conditions impacting the gastrointestinal tract, central and peripheral nervous systems and contributes significant disability in patients with diabetes.

Macrovascular complications of diabetes occur when excess blood glucose leads to damage of the large blood vessels and largely through exacerbation of the atherosclerotic process of plaque build-up through complex molecular mechanisms involving glycosylation, oxidative stress, and inflammation. Atherosclerotic cardiovascular disease (ASCVD) includes a myriad of conditions such as acute coronary syndrome, myocardial infarction, angina, stroke, and peripheral artery diseases, and is the leading cause of morbidity and mortality in people with diabetes. Common comorbidities of T2D, hypertension and dyslipidemia, further contribute to ASCVD as independent risk factors. Therapeutic interventions and patient education addressing multiple risk factors, such as diabetes, hypertension, and dyslipidemia have been shown to be effective in decreasing morbidity and mortality. Management of hypertension and dyslipidemia is addressed with lifestyle interventions of diet and physical activity, and medications used to lower blood pressure and normalize lipids. The most common form of dyslipidemia in diabetes, elevated triglycerides (TG) and decreased high-density lipoprotein (HDL), can be addressed with lifestyle interventions to decrease triglyceride levels. Studies addressing medication used to treat this common pattern of dyslipidemia associated with T2D have not produced results demonstrating improvement in cardiometabolic outcomes.[8]

The key to diabetes management and prevention of comorbities is glycemic control. The United Kingdom Prospective Diabetes Study (UKPDS), showed that a 1% decrease in A1C level correlated to a 37% decrease in risk for microvascular complications and a 21% decrease in the risk of any endpoint or death related to diabetes.[9] The UKPDS was key to the development of comprehensive, evidence-based diabetes management strategies and education programs aimed at what was termed “tight control” at the time. Results and recommendations are well integrated into the current standards of practice.

Comprehensive medical management of diabetes and its comorbidities involves complex regimens that are well articulated in the Standards of Medical Care in Diabetes.[8] However, day-to-day disease management lies with the self-management behaviors of the patient. Multidisciplinary programs offer patients self-management education, training, and support; individualized medical nutrition therapy is typically provided by a registered dietitian nutritionist (RDN). Two acronyms have been used to identify self-management programs: DSME (diabetes self-management education) and DSMT (diabetes self-management training). For the purposes of this review, DSME will be used throughout for consistency. For over 10 years, the standards of practice for management of diabetes have recommended that all patients receive multidisciplinary DSME and MNT, ideally provided by an RDN.[8] Complications of diabetes are four times more likely to develop in people receiving no diabetes education.[10]

The present study includes a review of the most recent literature summarizing the evidence-base to support the provision of DSME and MNT. Despite existing evidence of the efficacy of diabetes education, the Centers for Disease Control (CDC) reports that only an estimated 6.8% of privately insured, newly diagnosed patients with diabetes, participate in DSME.[11] A lack of physician referrals accounts for some but not all of the reported gap in treatment. Notably, universal insurance coverage for these services by both private and public payors is deficient and limits patient access to quality care.[12] While DSME is more frequently covered, patients are often confronted with high co-pays. Limited reimbursement for MNT outside of that designated by Medicare Part B (3 hours of MNT/12 months) warrants attention. Notably, the RDN is not identified as a preferred provider of DSME and MNT by many private payers, which limits both reimbursement and patient access to care.

The Alabama Dietetic Association (ALDA) has approached Blue Cross Blue Shield of Alabama (BCBSAL), the largest health insurance carrier in the state, requesting designation of

preferred provider status in order to gain direct reimbursement for RDNs for provision of DSME and MNT. Despite presentation of data from resources available through the Academy and published studies, Alabama-specific outcome data was requested before further review of the request would occur. The retrospective chart review implemented in this study, given attention to important operational approaches, offers a widely acceptable methodology utilized in healthcare disciplines to collect such data.[13]

The aims of this pilot study were to: 1) develop standardized criteria and an instrument for tracking patient outcomes subsequent to RDN interventions; 2) document anthropometric and biomedical markers of disease outcome for patients with type 2 diabetes (T2D) attending an ADA-recognized diabetes education program; and 3) obtain outcome data to support reimbursement and public policy initiatives to improve patient access to DSME and MNT.

STANDARDS OF PRACTICE FOR DIABETES SELF-MANAGEMENT AND MEDICAL NUTRITION THERAPY

Diabetes Self-Management Education

It has been established that type 2 diabetes (T2D) is managed by lifestyle changes in nutrition and physical activity patterns, and the addition of pharmacotherapy when glycemic targets cannot be met with diet and exercise alone. Lifestyle changes require knowledge in diabetes self-management and motivation to make behavior changes. The behavior changes needed for successful management of T2D are identified by the American Association of Diabetes Educators (AADE) and are commonly known as the AADE 7. The seven behaviors known to impact outcomes of patients with diabetes are healthy eating, being active, monitoring, taking medication, problem solving, reducing risks, and healthy coping.[14] Patient commitment to lifestyle changes is key to achieving glycemic control. Current guidelines stress the importance

of a nutrition care plan with an individualized approach that takes into consideration personal and cultural preferences, health literacy and numeracy, access to healthful foods, willingness and ability to make behavioral changes, and identification of barriers to change. Patient preference, along with goals of glycemic control and weight loss or maintenance, should be considered when developing meal plans with patients.[8] Physical activity is likewise an important component in lifestyle modifications in order to achieve weight loss and maintenance, and glycemic control. Current guidelines recommend a minimum of 150 minutes of moderate-intensity aerobic activity over at least three days a week in addition to resistance training twice as week in the absence of complications.[8]

Pharmacotherapy in patients with diabetes is used in conjunction with lifestyle changes to achieve glycemic control. The 2016 Consensus Statement from the American Association of Clinical Endocrinologists (AACE)[15] recommends lifestyle therapy as a first line treatment in T2D and highlights the need for continued lifestyle modification even in the presence of pharmacotherapy. The glycemic control algorithm presents medication therapy management based on A1C levels at time of diagnosis; mono, dual, and triple therapy are used with A1C levels <9% without symptoms. Once a patient's A1C level exceeds 9% and the patient is experiencing symptoms of diabetes, insulin therapy is added. Many of these drugs, while effective at lowering A1C levels, also aid in reducing the comorbities of T2D, including heart disease and hypertension.[15]

Based on the results of the United Kingdom Prospective Diabetes Study (UKPDS), the ultimate goal of T2D treatment is glycemic control evidenced by A1C levels in addition to daily self-monitoring blood glucose (SMBG). Current glycemic targets for the adult population are A1C < 7%; fasting and pre-prandial glucose 80 – 130 mg/dL; and peak post-prandial glucose <

180 mg/dL. Latitude for individualization is given based on duration of disease, patient age, life expectancy, comorbid conditions and other individual considerations.[8]

Due to the importance of patient diabetes self-management education, the National Standards for Diabetes Self-Management and Support (Table 2) were developed in 1986 and revised in 1995, 2002, 2007 and 2012, and are now revised approximately every five years based on current literature supporting the educational needs of patients. [16,17] Healthcare providers delivering DSME services in accredited or recognized locations are mandated to meet these standards. Locations not accredited or recognized are encouraged to follow these standards as well. Standards provide a foundation for consistent patient management, while allowing individual diabetes education centers flexibility to determine the best ways to provide education and the best educational tools to use based on a needs assessment of their service area and patient population.[8] Current clinical practice guidelines recommend that all people with diabetes participate in DSME programs and engage in diabetes self-management support (DSMS) activities to achieve and maintain glycemic control for the management of T2D.[8] Furthermore, a joint position statement of ADA, AADE, and the Academy of Nutrition and Dietetics (AND) recommends four critical time points when DSME should be offered: 1) at diagnosis; 2) annually for health maintenance and prevention of complications; 3) when new complicating factors occur; and 4) when transitions in care occur.[18]

Medical Nutrition Therapy and the Nutrition Care Process

In addition to DSME, medical nutrition therapy (MNT) provided by a registered dietitian nutritionist (RDN) can further enhance the nutrition education provided to patients with diabetes.[19] In 1994, the term medical nutrition therapy was introduced by the American Dietetic Association.[20] Medical nutrition therapy is defined as the evidence-based application of the

Table 2. National Standards for Diabetes Self-Management Education and Support

Standard 1 – Internal Structure
The provider(s) of DSME will document an organizational structure, mission statement, and goals. For those providers working within a larger organization, that organization will recognize and support quality DSME as an integral component of diabetes care.

Standard 2 – External Input
The provider(s) of DSME will seek ongoing input from external stakeholders and experts in order to promote quality programs.

Standard 3 – Access
The provider(s) of DSME will determine who to serve, how best to deliver diabetes education to that population, and what resources can provide ongoing support for that population.

Standard 4 – Program Coordination
A coordinator will be designated to oversee the DSME program. The coordinator will have oversight responsibility for the planning, implementation, and evaluation of education services.

Standard 5 – Instructional Staff
One or more instructors will provide DSME and, when applicable, DSMS. At least one of the instructors responsible for designing and planning DSME and DSMS will be a registered nurse, registered dietitian, or pharmacist with training and experience pertinent to DSME, or another professional with certification in diabetes care and education, such as a CDE or BC-ADM. Other health workers can contribute to DSME and provide DSMS with appropriate training in diabetes and with supervision and support.

Standard 6 – Curriculum
A written curriculum reflecting current evidence and practice guidelines, with criteria for evaluating outcomes, will serve as the framework for the provision of DSME. The needs of the individual participant will determine which parts of the curriculum will be provided to that individual.

Standard 7 – Individualization
The diabetes self-management, education, and support needs of each participant will be assessed by one or more instructors. The participant and instructor(s) will then together develop an individualized education and support plan focused on behavior change.

Standard 8 – Ongoing Support
The participant and instructor(s) will together develop a personalized follow-up plan for ongoing self-management support. The participant's outcomes and goals and the plan for ongoing self-management support will be communicated to other members of the healthcare team.

Standard 9 – Patient Progress
The provider(s) of DSME and DSMS will monitor whether participants are achieving their personal diabetes self-management goals and other outcome(s) as a way to evaluate the effectiveness of the educational intervention(s), using appropriate measureable techniques.

Standard 10 – Quality Improvement
The provider(s) of DSME will measure the effectiveness of the education and support and look for ways to improve any identified gaps in service or service quality using a systematic review of process and outcome data.

Adapted from Haas et al., 2013. (16)

Nutrition Care Process (NCP), which may include nutrition assessment and reassessment, nutrition diagnosis, nutrition intervention, and nutrition monitoring and evaluation. While MNT was provided prior to 1994, this terminology provides a working definition of the comprehensive services provided by RDNs for the maintenance of health and prevention and treatment of disease.

First developed in 1990, specific MNT guidelines for the management of diabetes based on evidence-based research were developed for use by RDNs when counseling patients with T2D; guidelines were most recently updated in 2016 (Table 3).[8] The focus of the nutrition guidelines is individualization of care provided by the RDN with input from the patient to set short- and long-term goals related to nutrition and glycemic control. For patients managing T2D with lifestyle modification or oral agents, the goal is to develop a plan to achieve modest weight loss or maintenance while achieving glycemic control. The RDN has the unique skill to use the NCP to assess the physical, social, psychosocial, and educational background, as well as the willingness to change of patients in order to develop a nutrition plan for the patient. Patients who are on fixed doses of insulin will benefit from learning basic carbohydrate counting in order to achieve a consistent carbohydrate intake at each meal. Patients who are on multiple daily injections or continuous subcutaneous insulin infusion will benefit from education geared toward advanced carbohydrate counting; in this case insulin is dosed based on the intended intake of carbohydrate at the upcoming meal.

Table 3. Nutrition Therapy Recommendations

- An individualized MNT program, preferably provided by a registered dietitian, is recommended for all people with type 1 or type 2 diabetes.
- For people with type 1 diabetes or those with type 2 diabetes who are prescribed a flexible insulin therapy program, education on how to use carbohydrate counting or estimation to determine mealtime insulin dosing can improve glycemic control.
- For individuals whose daily insulin dosing is fixed, having a consistent pattern of carbohydrate intake with respect to time and amount can result in improved glycemic control and a reduced risk of hypoglycemia.
- A simple and effective approach to glycemia and weight management emphasizing healthy food choices and portion control may be more helpful for those with type 2 diabetes who are not taking insulin, who have limited health literacy or numeracy, and who are elderly and prone to hypoglycemia.
- Because diabetes nutrition therapy can result in cost savings and improved outcomes (e.g., A1C reduction), MNT should be adequately reimbursed by insurance and other payers.
- Modest weight loss achievable by the combination of lifestyle modification and the reduction of energy intake benefits overweight or obese adults with type 2 diabetes and also those at risk for diabetes. Interventional programs to facilitate this process are recommended.
- As there is no single ideal dietary distribution of calories among carbohydrates, fats, and proteins for people with diabetes, macronutrient distribution should be individualized while keeping total calorie and metabolic goals in mind.
- Carbohydrate intake from whole grains, vegetables, fruits, legumes, and dairy products, with an emphasis on foods higher in fiber and lower in glycemic load, should be advised over other sources, especially those containing sugars.
- People with diabetes should avoid sugar-sweetened beverages in order to control weight and reduce their risk for CVD and fatty liver and should minimize the consumption of sucrose-containing foods that have the capacity to displace healthier, more nutrient-dense food choices.
- In individuals with type 2 diabetes, ingested protein appears to increase insulin response without increasing plasma glucose concentrations. Therefore, carbohydrate sources high in protein should not be used to treat or prevent hypoglycemia.
- Whereas data on the ideal total dietary fat content for people with diabetes are inconclusive, an eating plan emphasizing elements of a Mediterranean-style diet rich in monounsaturated fats may improve glucose metabolism and lower CVD risk and can be an effective alternative to a diet low in total fat but relatively high in carbohydrates.
- Eating foods rich in long-chain omega-3 fatty acids, such as fatty fish (EPA and DHA) and nuts and seeds (ALA), is recommended to prevent or treat CVD B; however, evidence does not support a beneficial role for omega-3 dietary supplements.
- There is no clear evidence that dietary supplementation with vitamins, minerals, herbs, or spices can improve diabetes, and there may be safety concerns regarding the long-term use of antioxidant supplements such as vitamins E and C and carotene.
- Adults with diabetes who drink alcohol should do so in moderation (no more than one drink per day for adult women and no more than two drinks per day for adult men).
- Alcohol consumption may place people with diabetes at increased risk for delayed hypoglycemia, especially if taking insulin or insulin secretagogues. Education and awareness regarding the recognition and management of delayed hypoglycemia are warranted.
- As for the general population, people with diabetes should limit sodium consumption to, 2,300 mg/day; further restriction may be indicated for those with both diabetes and hypertension.

Adapted from ADA Clinical Practice Guidelines, 2016. (8)

EFFICACY OF DIABETES SELF-MANAGEMENT AND MEDICAL NUTRITION THERAPY

As noted in a previous section, the first line of management in T2D is lifestyle modification, which requires education on physical activity, nutrition, and behavioral strategies to achieve weight loss or maintenance, and glycemic control.[15] The most recent systematic review explored the evidence and effectiveness of DSME in comparison to usual care or minimal education; the primary outcome measure was reduction in A1C.[21] The studies included in the review were heterogeneous in intensity and mode of delivery, personnel delivering the DSME, and duration of the study. The authors categorized mode of delivery as 1) individual, 2) group, 3) combination of individual and group, or 4) education provided remotely. Provider type was categorized as solo or team. Duration of the studies ranged from less than one month to sixty months with baseline A1C ranging from 6.44% to 11%.

In this review of 118 unique interventions, 86% of the combination interventions obtained more significant A1C reductions than the individual, group, or remote training interventions. In reviewing all DSME intervention taken together, 61.9% reported statistically significant reductions in A1C. When comparing patient outcomes between solo and team providers, 69.6% of team-based programs led to significant reductions in A1C compared to 56.3% of programs administered by solo providers. Collectively, across the studies included in the review, DSME resulted in a mean A1C reduction of 0.74% (SD 0.63).[21] Systematic review of the evidence to specifically support the provision of MNT to patients with diabetes revealed that MNT could reduce A1C 0.5% to 2.6% with the largest reductions coming when patients are first diagnosed.[22] Several studies in this review also reported additional positive outcomes, including reductions in weight, body mass index (BMI), blood pressure, and lipids.

To further explore the evidence base of the efficacy of DSME and MNT, Academic Search Premier databases CINAHL, Health Source: Nursing/Academic Edition, and MEDLINE were used to conduct a thorough review of the present literature. Search terms included medical nutrition therapy, diabetes, diabetes outcomes, and education, with dates of inclusion of 2005 – 2015, to represent the most recent ten years from the initiation of the review. The systematic database search was supplemented with manual searches of citations from relevant systematic reviews and the author's review of the reference lists. Studies were included that provided an intervention of DSME or MNT or both and reported A1C as an outcome. Articles were excluded if patients had type 1 diabetes, included pediatric patients, or if clinical outcome measures of A1C, weight, BMI, or lipids were not reported.

Table 4 summarizes interventions and results in the 24 studies that were identified for review. Sixteen were randomized controlled trials (RCT); two were retrospective chart reviews (RCR); one was convenience sample; one was quasi-experimental; two were prospective; two included one-arm intervention and one was cross-sectional. Thirteen studies reported fasting blood glucose (FBG); 16 reported BMI, weight and low-density lipoprotein (LDL); 13 studies reported high-density lipoprotein (HDL); and 14 studies reported triglycerides (TG). Studies included 6586 participants with a range of 21 to 1395 participants with length of intervention ranging from one day to two years. Interventions varied widely with some provided by a single discipline and others involving a multidisciplinary team and included group and individual education. Outcomes measures were extrapolated for each study parameter of interest to standard measures used in clinical practice in the U.S. to enable the reader to easily assess differences in outcomes. While studies reviewed looked at a variety of outcome measures, the table highlights

glycemic control, weight loss, and changes in serum lipids subsequent to provision of DSME and/or MNT.

Glycemic Control

Glycemic control is the hallmark of management of T2D as prolonged exposure to hyperglycemia is well recognized as the primary causal factor in the pathogenesis of diabetic complications, morbidity, and mortality. Standardization of A1C assays have made A1C the gold standard for assessing long-term glycemic control in patients with diabetes.[49] Therefore, research studies assessing the effectiveness of DSME and MNT use A1C as a primary indicator of glycemic control. A1C is also used in the clinical setting to assess long-term glycemic control in addition to SMBG data to assist practitioners in making adjustments to therapeutic regimens.

The twenty-four reviewed studies reported changes in A1C with a baseline A1C range 5.95% – 10.3%.[23-27,29, 30-32, 34-48] Change in A1C in the intervention groups ranged from -0.19% to -1.7%, while change in the control group ranged from -0.8% to +0.93%. All but two studies[35,37] showed a statistically significant reduction in A1C; significance taken at $P < 0.05$. Lynch and colleagues, set a goal for participants to achieve a 0.5% reduction in A1C over the study period; while the goal was reached, the observed reduction, while clinically significant, did not reach statistical significance.[37] Five studies analyzed patient responses to intervention as measured by baseline A1C levels. [25,35, 40,41,47] Poorly controlled diabetes was identified as A1C > 9% or above the American Diabetes Association target of 7%.[50] Of the studies that analyzed poorly controlled patients, greater A1C reductions were seen in participants with higher levels at baseline.

Current reviews have not provided well-defined interventions to distinguish MNT only versus MNT plus pharmacotherapy. A comprehensive review of the pharmacotherapy literature revealed that drug therapy using oral hypoglycemic agents showed A1C reductions of 1 –

1.25%.[51] Consistent with other reported DSME and MNT outcomes,[21] the literature reviewed within reports A1C reductions of 0.2% to 1.7% from DSME, MNT, or both. However, one study from the current review does provide a clear distinction of patients who are solely treated with MNT alone.[42] A significant reduction in A1C (-0.19%; P=0.01) was observed in these patients.

Studies were heterogeneous in their intensity and duration of intervention, content, mode of delivery, and providers delivering education. Intervention time ranged from one day to two years and visits ranged from one to eighteen. Twelve studies had interventions provided by a RDN only, one study by a pharmacist only, and the remaining interventions were provided by a multidisciplinary team.

In summary, pharmacotherapy can reduce A1C by 1.0 – 1.25%; DSME and MNT have both shown to reduce A1C by - 0.19 to -1.3 and -0.5 to -2.6, respectively. The UKPDS demonstrated that reductions in A1C observed with intensive therapy including intensive pharmacological interventions reduce or delay the onset of diabetes complications. Specifically, for every 1% reduction in A1C there is a 37% reduction in risk for microvascular events; 43% reduction in risk of amputation or death from peripheral vascular disease; 14% reduction in risk of myocardial infarction; 12% reduction in risk of stroke; 16% reduction in risk of heart failure; and a 21% reduction in risk for any diabetes-related end point.[9]

Weight Loss

Weight loss of at least 7% has been shown to delay or prevent the progression from pre-diabetes to T2D.[52] According to Franz in 2010[22], it is not clear if weight loss alone will improve glycemic control in individuals with T2D, but newer guidelines show that modest weight loss of 5% of initial body weight may improve glycemic control and decrease the need for OHAs.[53] There is no one meal plan recommended to achieve this weight loss, but rather an individualized

meal plan developed by the patient and the RDN.[8] Nineteen of the studies reported outcomes of weight, BMI or both.[23-26,28,30-32,34-37,39-41,44,46-48] Baseline weight ranged from 60.25 kg to 102 kg and the change after intervention ranged from -5.1 kg to +1.3 kg. Baseline BMI ranged from 23.82 to 37.1 and the change after intervention ranged from -1.4 to -0.2. Ten studies reported significant weight loss in the intervention groups.[24-26,28,30-31,36,40,46,48] The study with the largest weight loss in the intervention group showed a 7% mean weight loss ($p < 0.5$) in participants in the intervention group and a 4% weight loss ($p > 0.5$) in the control group with sustained weight loss at six months in both the intervention and control groups.[24] Both the intervention and control groups in this study were seen by a RDN with the control group provided one RDN visit and the intervention group provided three visits. This study also had the highest mean A1C at baseline (10.3%) with the largest drop (-1.3%) at the end of study. Andrews et al designed a study with two intervention arms to assess the benefits of exercise added to improved nutrition habits.[25] While weight loss was significant in both arms, greater reductions were seen with a combination of nutrition and exercise -2.4kg ($p<0.0001$) as compared to nutrition alone -1.5 kg ($p< 0.0001$).

Use of insulin can negatively impact weight loss regimens as improved glycemic control, decreased urinary glucose excretion, and anabolism can result in weight gain despite lower calorie intakes. Significant weight gain was reported in one study that assessed the impact of DSME on appropriate insulin use with patients on multiple daily injection therapy; A1C, however significantly improved.[34] With poorly controlled diabetes and initiation of insulin therapy, weight gain is exhibited in response to improvement in glycemic control and is of clinical significance.

Serum Lipids

In addition to glycemic control, lipid levels must be controlled to decrease the risk of ASCVD. Serum lipid goals for patients with diabetes differ between high-risk patients (T2D, but no other risk factor and < 40 years old) and very-high-risk patients (T2D plus ≥ 1 major ASCVD risk or established ASCVD risk). Targets for high-risk patients include LDL of < 100 mg/dL, non-HDL <130 mg/dL, TG < 150 and TC/HDL ratio of < 3.5. Very-high-risk patients LDL targets are < 70 mg/dL, non-HDL < 100 mg/d<, TG < 150, and TC/HDL ratio of <3.0.[15] Targets for HDL levels are > 40 mg/dL for men and > 50 mg/dL for women.[8] Lifestyle modification of weight loss and increased physical activity, along with statin therapy, is recommended for routine use in the treatment of dyslipidemia in people with diabetes. Statin therapy shows positive results in decreasing total cholesterol (TC) and LDL, but has not been as effective in lowering TG or increasing HDL.[8] A high TG/HDL ratio has been identified as an atherogenic lipid profile exhibited in T2D and a strong predictor of heart disease incidence and mortality.[54] Elevated TG/HDL cholesterol is a manifestation of insulin resistance. Sixteen studies reported LDL, with three showing significant reductions: baseline LDL 108.6 to 130 mg/dL with a reduction of -9 to -25 mg/dL.[32,46,48] Thirteen studies reported HDL with two showing significant increases: baseline HDL 43 to 49 mg/dL with an increase of +3 to +5 mg/dL.[41,46] Fourteen reported TG with four showing significant reductions: baseline TG 145 to 357 mg/dL with a decrease of -19 to -153.[24,36,46,47]

CONCLUSION

Effective diabetes self-management education, to include DSME and MNT, has been shown to improve clinical outcomes of A1C, weight, and lipids. Previous systematic reviews have shown significant reductions in A1C, weight, and lipids with evidence from the current

review adding to the evidence base. Studies contributing to the body of evidence are heterogeneous in intensity and mode of delivery, personnel delivering education, and duration of the study. Stratification of patient outcomes to distinguish interventions of MNT only versus MNT plus pharmacotherapy are lacking; therefore, limiting the ability to distinguish reductions in A1C, weight, and lipids resulting from education intervention.

The UKPDS showed that reductions in A1C observed with intensive therapy including intensive pharmacological interventions reduce or delay the onset of diabetes complications. Specifically, for every 1% reduction in A1C there is a 37% reduction in microvascular events; 43% reduction from amputation or death from peripheral vascular disease; 14% reduction in myocardial infarction; 12% reduction in stroke; 16% reduction in heart failure; and a 21% reduction for any diabetes related end point. By reducing the chronic complication of diabetes, the societal burden of healthcare expenditures is therefore reduced.

Despite existing evidence, CDC reports that an estimated 6.8% of privately insured, newly diagnosed patients participate in DSME. Access to the services of DSME and MNT are limited by inconsistent insurance coverage and lack of physician referral. This study provides the Alabama specific patient outcome data requested by BCBS-AL in order for RDNs to be considered preferred providers. By obtaining preferred provider status for RDNs, more patients would have access to these services. Due to the lack of evidence delineating the outcomes associated with MNT only versus MNT versus pharmacotherapy, this study aims to show that MNT, dependent of pharmacotherapy, produces positive patient outcomes.

Table 4. Characteristics and results of eligible studies assessing efficacy of DSME and MNT

Author, year of publication,country	Participants	Design	Intervention	Results – Glycemic control	Results – Weight/BMI	Results – Lipids
Adachi and colleagues, 2013, Japan [23]	N =193 HbA1c ≥6.5%	RCT	***Intervention*** 4 sessions with a RDN/6 months (increase vegetable intake at breakfast and decrease energy intake at dinner.) ***Control*** 1 session RDN	HgbA1c ***Intervention*** – Baseline 7.6, Change -0.7 (p = 0.004) ***Control*** - Baseline 7.3, Change -0.2 FBG (p > 0.05)	BMI (p >0.05)	LDL (p >0.05) HDL (p >0.05) TG (p >0.05)
Al-Shookri and colleagues, 2012, Oman [24]	N = 170 T2D w/o chronic complications	RCT	***Intervention*** Practice guidelines nutrition care; 3 visits with RDN within 4-8 weeks ***Control*** 1 hour RDN visit	HgbA1c ***Intervention*** Baseline 10.3 Change -1.3 at 3 months; -0.8 at 6 months (p <0.001; <0.01) ***Control*** Baseline 10.2 Change -0.8 at 3 months; -0.4 at 6 months (p > 0.05) FBG ***Intervention*** Baseline 223 Change -36 at 3 months; -23 at 6 months (p <0.001; <0.01) ***Control*** - Baseline 218 Change -16 at 3 months; -4 at 6 months (p > 0.05)	BMI ***Intervention*** Baseline 27.6 Change -1.3 at 3 months; -1.4 at 6 months (p <0.05 at 3 months) ***Control*** Baseline 28.4 Change -1 at 3 and 6 months (p > 0.05) Weight (kg) ***Intervention*** Baseline 73.3 Change -4.6 at 3 months; -5.1 at 6 months (p < 0.5 at both intervals) ***Control*** - Baseline 72.2, Change -2.5 at 3 months; -2.6 at 6 months (p > 0.05)	LDL (p>0.05) HDL (p>0.05) TG ***Intervention*** Baseline 145 Change -22 at 3 months; -19 at 6 months (p < 0.05 at both points) ***Control*** Baseline 159 Change -19 at 3 months; -17 at 6 months (p < 0.05 3 vs 6 months)
Andrews and colleagues, 2011, United Kingdom [25]	N = 593 T2D with A1C <10% and no chronic complications	RCT	***Intervention 1*** Intensive diet 5 RDN and 8 RN visits over 12 months ***Intervention 2*** Intensive diet plus activity – As above plus 30+ minutes PA 5 days/week ***Control*** Diet and physical activity advice twice during 12 months	HgbA1c ***Intervention 1*** – Baseline 6.64 , Change – 0.09 p = 0.005 ***Intervention 2*** – Baseline 6.69, Change -0.04 p = 0.027 P value reflects significance between intervention and control	BMI ***Intervention 1*** – Baseline 31.5, Change – 0.6 p < 0.0001 ***Intervention 2*** – Baseline 31.6, Change - 0.9 p < 0.0001 Weight ***Intervention 1*** – Baseline 90.2 , Change – 1.5 p < 0.0001 ***Intervention 2*** Baseline 91.1, Change – 2.4 p < 0.0001 P value reflects significance between intervention and control	LDL (p > 0.05) HDL (p > 0.05) TG (p > 0.05)

Author, year of publication, country	Participants	Design	Intervention	Results – Glycemic control	Results – Weight/BMI	Results – Lipids
Battista and colleagues, 2012, Canada [26]	N = 101 T2D and HbgA1c >= 7%, OR type 1 DM with at least 1 CV risk factor.	RCT	***Intervention*** Quarterly RDN visits plus monthly phone call for 24 months **Control** Received CDA guidelines on nutrition and activity from primary care physician.	HgbA1c ***Intervention*** Baseline 7.9 Change -0.6 (p = 0.04) FBG ***Intervention*** Baseline 155 Change -13 (p > 0.05)	BMI ***Intervention*** – Baseline 32 Change -0.3 (p = 0.009) Weight (kg) ***Intervention*** Baseline 92 Change -0.7 (p = 0.004)	LDL (p > 0.05) HDL (p > 0.05) TG (p > 0.05)
Beverly and colleagues, 2013, US [27]	N =134 T2D who had previously received at least three hours of DSME	RCT	***Intervention*** Conversation Map – 4, 1-hr sessions taught by RN CDE or RDN CDE. ***Control*** 2, 2-hr classes focusing on dyslipidemia and HTN taught by RN and RDN.	HgbA1c ***Intervention*** Baseline 8.5 Change - 0.4 at 3 months (p=0.004); 6 and 12 months (p >0.05)	Nothing to report	Nothing to report
Bradley and colleagues, 2013, US [28]	N = 1395 Overweight or obese	Retrospective case-control.	***Intervention*** Up to 6 RDN visits ***Control*** No MNT	Nothing to report	BMI ***Intervention*** Baseline 33.4 Change -1.1 p <0.001 ***Control*** Baseline 33.9 Change -0.4 p = 0.004 Weight ***Intervention*** Baseline 94 Change -3.1 p <0.001 ***Control*** Baseline 94.6 Change -1.4 p <0.001	Nothing to report
Bray and colleagues, 2005, US [29]	N = 160 T2D, plus one complication	Convenience sample from two primary care practices in rural NC.	***Intervention*** Four, 2-hr group classes over 6 months taught by an interdisciplinary team. ***Control*** No class	HgbA1c ***Intervention*** Baseline 8.2 Change -1.1 p <0.0001	Nothing to report	Nothing to report
Cheyette and colleagues, 2007, United Kingdom [30]	N = 49 T2D on insulin therapy for > 1 year.	RCT	***Intervention*** Eight, 1 ½ hour group education sessions provided by multidisciplinary team ***Control*** 1 RDN visit	HgbA1c ***Intervention*** Baseline 8.4 Change -0.9 (p < 0.01) ***Control*** - Baseline 8.4, Change -0.3 (p <0.05)	Weight ***Intervention*** Baseline 97.2 Change -2.2 (p <0.01)	

Author, year of publication, country	Participants	Design	Intervention	Results – Glycemic control	Results – Weight/BMI	Results – Lipids
Coppell and colleagues, 2010, New Zealand [31]	N = 93 T2D and HbA1c >7% plus 2 comorbidities	RCT	***Intervention*** 7 RDN visits - Intensive, individualized dietary advice ***Control*** No MNT	HgbA1c ***Intervention*** Baseline 8.9 Change -0.5 (p = 0.007) FBG (p>0.05)	BMI ***Intervention*** Baseline 35.1 Change -0.8 (p=0.026) Weight ***Intervention*** Baseline 98.4 Change -2.1 (p=0.032)	LDL (p > 0.05) HDL (p > 0.05) TG (p > 0.05)
Davis and colleagues, 2010, US [32]	N = 165 T2D with A1C >7% w/o chronic complications	RCT	***Intervention*** 13 telehealth sessions with RDN and RN CDE ***Control*** 1, 20 minute session with LPN	HgbA1c ***Intervention*** Baseline 9.3 Change -1.1 six months; -1.2 twelve months (p = 0.003; 0.004)	BMI ***Intervention*** Baseline 37.1 Change -0.3 six months; -0.2 twelve months (p = 0.07; >0.05)	LDL ***Intervention*** Baseline 108.6 Change -6.3 six months; -13.3 twelve months (p = 0.5; 0.02)
Fokkens and colleagues, 2010, Holland [33]	N = 795	Quasi-experimental study	***Intervention*** Individualized education provided by RDN and RN ***Control*** No individual education	HgbA1c (p >0.05)	BMI (p >0.05)	LDL (p >0.05) HDL (p >0.05)
Hermanns and colleagues, 2012, Germany [34]	N = 186	RCT	***Intervention*** 10 lessons; 90 minutes each. Self-management, empowerment approach. ***Control*** Active comparator group. Provided established education program focused on DM and HTN.	HgbA1c ***Intervention*** – Baseline 8.5, Change -0.6 p<0.001 ***Control*** - Baseline 8.2, Change -0.4 p = 0.003	Weight ***Intervention*** Baseline 95.2 Change +1.3 p = 0.018	LDL (p >0.5) TG (p >0.5)
Huang and colleagues, 2010, Taiwan [35]	N=154	RCT	***Intervention*** DSME and MNT by RD every 3 months for 12 month ***Control*** Routine care from primary care clinic	HgbA1c in whole group (p > 0.05) HgbA1c in poorly controlled patients (>=7%) Change -0.7 (p = 0.034) FBG ***Intervention*** – Baseline 147 , Change -6.8 p = 0.026 ***Control*** - Baseline 160, Change +12.7	BMI (p > 0.05)	LDL (p > 0.05) HDL (p > 0.05) TG (p > 0.05)

Author, year of publication, country	Participants	Design	Intervention	Results – Glycemic control	Results – Weight/BMI	Results – Lipids
Lemon and colleagues, 2004, US [36]	N = 244	Prospective, non-controlled descriptive study	***Intervention*** RD providing diabetes nutrition education/counseling per facility protocol over 6 months. Average of 2 visits, range 1-6. ***No Control***	HgbA1c ***Intervention*** – Baseline 8.7, Change -1.4 at 3 months; -1.7 at 6 months p <0.0001 at both times FBG ***Intervention*** – Baseline 205, Change -52 at 3 months; - 56 at 6 months p <0.0001 at both times	BMI ***Intervention*** – Baseline 34.6, Change -0.78 at 3 months; -0.94 at 6 months p <0.0001 at both times Weight ***Intervention*** – Baseline 102 Change -2.4 at 3 months; -2.8 at 6 months P < 0.0001 at both times	LDL (p> 0.05) HDL (p> 0.05) TG ***Intervention*** – Baseline 357, Change -274 at 3 months; -153 at 6 months p < 0.01, 0.05; respectively
Lynch and colleagues, 2014, US [37]	N = 61	RCT	***Intervention*** 18 group sessions led by RD and weekly phone calls by peer ***Control*** 2, 3-hr group sessions taught by community health worker	HgbA1c (p > 0.05)	Weight (p > 0.05)	Nothing to report
Martins and colleagues, 2014, Brazil [38]	N = 21	Cross-sectional study	***Intervention*** 1, 4 hour carb counting class ***No Control***	HgbA1c ***Intervention*** – Baseline 8.42, Change -0.76 p < 0.005	Nothing to report	Nothing to report
Miller and colleagues, 2014, US [39]	N = 24 DM2 6 months or longer; A1C >=7% and 1 of following: SBP>=130, LDL >=100, BMI>=30.	One-arm interrupted time series design, quasi-experimental research design.	***Intervention*** 5 sessions of group MNT and MI intervention ***No Control***	HgbA1c ***Intervention*** – Baseline 9.7, Change -0.9 p = 0.029	BMI (p > 0.05)	Nothing to report
Molsted and colleagues, 2011, Denmark [40]	N = 702 Participants had DM2 >=12 months	Intervention, but not RCT. Patients on waiting list served as control.	***Intervention*** 7, 7 hour group sessions taught by interdisciplinary team (RN, RD, physiotherapists, PCP). ***Control*** Waiting list for classes.	HgbA1c ***Intervention*** – Baseline 7.34, Change - 0.46 p < 0.001 ***Control*** p > 0.05	Weight ***Intervention*** – Baseline 90.0, Change -3.8 p < 0.001	Lipid improvements contributed to medication changes

Author, year of publication, country	Participants	Design	Intervention	Results – Glycemic control	Results – Weight/BMI	Results – Lipids
Molsted cont.				FBG ***Intervention*** – Baseline 157, Change -17 p = 0.001		
Nisak and colleagues, 2013, Malaysia [41]	N = 114	Prospective, single-group, pre-post design.	***Intervention*** 3 MNT visits over 12 weeks ***No Control***	HgbA1c ***Intervention*** – Baseline 7.6, Change -0.4 p <0.001 FBG ***Intervention*** – Baseline 129, Change +6 p < 0.05	BMI (p> 0.05) Weight (p> 0.05)	LDL (p> 0.05) TG (p> 0.05) HDL ***Intervention*** – Baseline 43, Change +3 p < 0.05
Parker and colleagues, 2014, US [42]	N = 76	RCT	***Intervention*** 5 MNT visits over 12 weeks	HgbA1c ***Intervention*** – Baseline 5.99, Change -0.19 p = 0.01 ***Control*** - Baseline 5.95, Change +0.05 FBG (p > 0.05)	Nothing to report	LDL (p > 0.05) HDL (p > 0.05) TG (p > 0.05)
Rock and colleagues, 2014, US [43]	N = 227	RCT	***Intervention*** Commercial weight loss program with two study arms -low fat (LF) or low carb (LC) for 12 months ***Control*** 2, 1 hr MNT visits with RDN with monthly phone/email contact	HgbA1c ***Intervention LF*** – p > 0.05 ***Intervention LC*** – Baseline 7.3, Change -1.1 at 6 months; -0.7 at 12 months p < 0.05 at both times when compared to LF group ***Control*** - Baseline 7.4, Change -0.2 at 6 months; +0.1 at 12 months p < 0.01 at both times compared to aggregate weight loss groups FPG ***Intervention LF*** – p > 0.05 ***Intervention LC*** – Baseline 146. Change -21 at 6 months; - 13 at 12 months. p < 0.05 at 6 months; > 0.5 at 12 months ***Control*** - Baseline 145, +3 at 6 months; + 14 at 12 months p < 0.01 at 6 months; < 0.05 at 12 months compared to aggregate weight loss groups	BMI p < 0.001 at 6 and 12 months compared aggregate weight loss groups to control Weight p < 0.001 at 6 months; p = 0.005 at 12 months compared to aggregate weight loss groups	LDL p > 0.05 HDL p < 0.01 at 12 months compared to aggregate weight loss groups to control TG p < 0.01 at 6 and 12 months compared to aggregate weight loss groups to control.

Author, year of publication, country	Participants	Design	Intervention	Results – Glycemic control	Results – Weight/BMI	Results – Lipids
Ryan and colleagues, 2013, US [44]	N = 100	One arm, intervention	***Intervention*** 4, 3 hour class over 4 weeks taught by RDN and RN ***No Control***	HgbA1c ***Intervention*** – Baseline 8.38, Change -0.82 p = 0.007	BMI (p > 0.05) Weight (p > 0.05)	LDL (p > 0.05)
Sperl-Hillen and colleagues, 2013, US [45]	N = 623	RCT	***Intervention*** Individual Care (IC) – 3, 1 hr RDN/RN/CDE visits over 3 months Group Care (GC) – 4, 2 hr	HgbA1c ***Intervention IC***– Baseline 8.11 Change -0.51 at 6 months; 0.35 at 12	Nothing to report	Nothing to report
Author, year of publication, country	**Participants**	**Design**	**Intervention**	**Results – Glycemic control**	**Results – Weight/BMI**	**Results – Lipids**
Sperl-Hillen cont.			classes by RDN/RN/CDE over 2 weeks. ***Control*** No education, but not limited in being referred for education by primary care provider	months p < 0.001 at both times ***Intervention GC***– Baseline 8.07 Change -0.26 at 6 months; 0.31 at 12 months p < 0.001 at both times ***Control*** - Baseline 8.09 Change - 0.27 at 6 months; 0.42 at 12 months p = 0.004, < 0.001; respectively		
Trento and colleagues, 2010, Italy [46]	N = 815 Non-insulin treated, >=1 yr known diabetes	RCT	***Intervention*** 7, 1 hr group sessions over two years, then repeated ***Control*** Individual visits based on local clinic practice	HgbA1c ***Intervention*** – Baseline 7.75, Change -0.53 p < 0.001 ***Control*** - Baseline 7.81, Change +0.93 p < 0.001 FBG ***Intervention*** – Baseline 168, Change -13 p < 0.001 ***Control*** p > 0.05	BMI ***Intervention*** – Baseline 30.62, Change -0.59 p < 0.001 ***Control*** - Baseline 29.34, Change +0.65 p <0.01 Weight ***Intervention*** – Baseline 81.44, Change -1.57 p < 0.001 ***Control*** - Baseline 78.22, Change +1.96 p < 0.001	LDL ***Intervention*** – Baseline 130 Change -25 p < 0.001 ***Control*** p > 0.05 HDL ***Intervention*** – Baseline 49, Change +5 p < 0.001 ***Control*** p > 0.05 TG ***Intervention*** – Baseline 163, Change -33 p < 0.001 ***Control*** p > 0.05
Yoder and colleagues, 2012, US[47]	N = 98 Participants were part of an employee sponsored program	RCR	***Intervention*** Monthly visits for 6 months, then every 1-6 months based on need, provided by pharmacist. Referred to RDN if MNT needed.	HgbA1c ***Intervention*** – Baseline 7.8, Change -0.7 p < 0.01	BMI (p > 0.05) Weight (p > 0.05)	LDL (p > 0.05) HDL ***Intervention*** – Baseline 47, Change -2 p = 0.05

Author, year of publication, country	Participants	Design	Intervention	Results – Glycemic control	Results – Weight/BMI	Results – Lipids
Yoder cont.			***No Control***			TG ***Intervention*** – Baseline 160, Change -25 p = 0.02
Yuan and colleagues, 2014, Hong Kong [48]	N = 88	RCT	***Intervention*** 8, 2 hr classes by RDN ***Control*** Standard advice on MNT	HgbA1c ***Intervention*** – Baseline 6.97, Change -0.2 p = 0.039 ***Control*** p > 0.05 FBG (p > 0.05)	BMI ***Intervention*** – Baseline 23.82, Change -0.57 p < 0.001 ***Control*** - Baseline 25.42, Change -0.39 p = 0.019 Weight ***Intervention*** – Baseline 60.25, Change -1.19 p < 0.001 ***Control*** p > 0.05	LDL ***Intervention*** – Baseline 109, Change -9 p = 0.005 ***Control*** - Baseline 113, Change -11 p < 0.001 HDL(p > 0.05) TG (p > 0.05)

*All values were converted to mg/dL for comparison purposes.

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Chapter 2

Diabetes Self-management Education and Medical Nutrition Therapy improve Patient Outcomes: A Pilot Study Documenting the Efficacy of Registered Dietitian Nutritionist Interventions through Retrospective Chart Review

Background

According to the Centers for Disease Control and Prevention (CDC), 29.1 million Americans (9.3%) have diabetes, which results in $176 billion in medical costs and an additional $69 billion in indirect costs (disability, productivity loss, and premature death).[1] The American Diabetes Association (ADA) Standards of Medical Care in Diabetes present a framework for evidence-based disease management.[2] The hallmark of diabetes management is the provision of diabetes self-management education (DSME) and support, including preferential referral to a registered dietitian (RDN) for individualized medical nutrition therapy (MNT).[2-6] Effective self-management education has been shown to improve clinical outcomes, behaviors, quality of life, and result in cost savings (Evidence Level B).[2, 7-21] MNT, one of the most challenging components for patients,[2] has an established evidence-base demonstrating improved glycemic outcomes,[22-31] reduction in hospital admissions and cost savings.[32] Complications are fourfold more likely to develop in people receiving no diabetes education.[13] Despite the evidence, CDC report that an estimated 6.8% of privately insured, newly diagnosed patients with diabetes participate in DSME.[33] Lack of physician referral accounts for some,[6] but not all of the reported gap in treatment.

Medicare Part B sets a standard of coverage for DSME (10 hours/12 months) and MNT (3 hours/12 months) as separate benefits for newly diagnosed patients.[6] In order to be eligible for reimbursement, DSME programs must be ADA-recognized or American Association of Diabetes Educators (AADE)-accredited.[5] While DSME is interdisciplinary, the RDN is the only Medicare-credentialed provider of MNT.[6,33] Medicaid coverage for both DSME and MNT varies by state. Universal coverage for diabetes education by private insurers is inconsistent. While DSME is more frequently covered, patients are often confronted with high co-pays.[34] MNT coverage by third-party payers warrants attention. These discrepancies impede diabetes education programs and RDNs working in private practice to bill for services and subsequently limit patient access to ADA-recommended standard care.

Current and emerging health care models place a greater emphasis on patient outcomes in order to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policy makers make informed health decisions.[34,36] The retrospective chart review (RCR), given attention to important operational approaches, offers a widely acceptable methodology utilized in healthcare disciplines to collect such data.[37] The RCR allows for extraction of existing data of current practices and affords time-sensitive and cost-effective dissemination of outcomes to stakeholders including providers, payers, and health policy leaders.

The Alabama Dietetic Association (ALDA) has approached Blue Cross Blue Shield of Alabama (BCBSAL), the largest health insurance carrier in the state, requesting designation of preferred provider status in order to gain direct reimbursement for RDNs for provision of DSME and MNT. Despite presentation of data from resources available through the Academy and published studies, Alabama-specific outcome data was requested before further review of the

request would occur. The aims of this pilot study were to develop standardized criteria and an instrument for tracking patient outcomes subsequent to RDN interventions, document anthropometric and biomedical markers of disease outcome for patients with type 2 diabetes (T2D) attending an ADA-recognized diabetes education program, and obtain outcome data to support reimbursement and public policy initiatives to improve patient access to DSME and MNT.

METHODS

Study Design

This retrospective chart review was designed to develop a tool (Appendix 1) to abstract existing information from medical records regarding patient outcomes subsequent to RDN interventions, the methodology having broader implications for future study to delineate the benefits of MNT. The data abstraction form was developed with input from RDNs employed at four regional ADA-recognized diabetes education centers in Alabama. A comprehensive review of 10 charts was conducted at the pilot site to determine time required for data collection, availability of data on dependent variables, and the potential frequency of missing data.[37] To establish interrater reliability, two researchers, one familiar with the patient records at the site and one novice, independently abstracted information from three electronic medical records (EMRs) and completed data entry for all demographic and outcome variables (264 observations) (Cohen's kappa = 1). Given the high interrater reliability, no further duplication was performed. The protocol was approved under Expedited Review by the Institutional Review Boards of Auburn University and East Alabama Medical Center.

Population and Intervention

The population included adult patients diagnosed with T2D completing the comprehensive ADA-recognized program at an outpatient clinic located in eastern Alabama; the program includes both DSME with group nutrition education and individualized RDN-provided MNT. Charts of patients beginning the program between June 2013 and June 2014 and completing all scheduled visits were identified as eligible for review; patients in the employee program and with chronic kidney disease on dialysis were excluded from the study. A randomized sample of 100 medical records were queried; after exclusions 88 charts were included in the analysis. A suitable control group was not identified; each patient served as his or her own control.

The comprehensive diabetes education program is offered in compliance with the National Standards for Diabetes Self-Management Education and Support*,* these standards serve as the framework for the ADA Education Recognition requirements.[6,38] Core content areas included diabetes disease process; treatment options, incorporating nutritional management and physical activity into lifestyle; using medications safely and for maximum therapeutic effectiveness; monitoring blood glucose and other parameters, and interpreting and using the results for self-management decision making; preventing, detecting, and treating acute and chronic complications; developing personal strategies to address psychosocial issues and concerns; and developing personal strategies to promote health and behavior change.[6] The DSME portion of the program was provided in a series, one initial individual assessment and three, 2.5- hour group classes offered by a multidisciplinary team (total 8.5 hours); RDNs provided the nutritional management components of DSME. Following the DSME series, patients were instructed to maintain a 2-week food and self-monitoring blood glucose (SMBG)

diary and were scheduled for an individual 1-hour MNT consultation with the RDN; a 30-minute follow-up was scheduled after two to three months (total 1.5 hours). Individualized MNT included review of food and SMBG diaries to assess trends in hyperglycemia and knowledge deficits in carbohydrate counting; patients were educated on heart healthy eating, eating out, and eating on a budget. Individual goal-setting was facilitated by the RDN and included incorporating nutritional management and physical activity into lifestyle to promote health and behavior change. The length of the program was approximately 4 months.

Outcome Measures

Demographic information was queried for age, sex, race; length of diagnosis and comorbid disease; smoking and alcohol use; learning barriers; and primary insurance. Prescription medication use for diabetes and common comorbid disease was documented at baseline and follow-up and included oral hypoglycemic agents (OHA), insulin, other injectables, blood pressure medications, and statins. Key outcomes measures include: anthropometrics (weight and BMI); glycemic control (HbA1c, SMBG means, and frequency of hypoglycemia); serum lipids (total cholesterol, LDL, HDL, and triglycerides); blood pressure; and number of hospitalizations. Anthropometric data were available at baseline, following DSME, after MNT (end-of-program), and at one-year. HbA1c was available at baseline, end-of-program, and at one-year. To further discriminate the additional benefit of MNT, SMBG averages were classified by quintiles in mg/dL (<100, 100-150, 150-200, 200-250 and > 250) and queried at baseline, after DSME, and after MNT. Given that most newly diagnosed patients did not have SMBG data at baseline, baseline HbA1c was used to extrapolate average blood glucose values and place subjects in the corresponding quintile.[39] Patients were grouped into categories of HbA1c targets ($\leq$ 7%) and corresponding SMBG targets ($\leq$ 150 mg/dl)[2] and those with poor control, HbA1c $\geq$

9%[40] and approximate corresponding SMBG means of ≥ 200 mg/dl.[39] Blood pressure was taken at all visits; baseline and follow-up lipids were available in a small subset of the sample population. Primary care providers were contacted to obtain missing data where feasible.

Statistical Analysis

Descriptive statistics were used to present the demographic characteristics of the population and to classify patients at baseline, end of program, and 1-year follow-up with regard to glycemic targets. A mixed-model ANOVA was used to compare changes in continuous variables, anthropometric measures ,and HbA1c, across the treatment period and at 1 year. This methodology accounts for missing data inherent in the RCR. To assess the impact of MNT subsequent to DSME on glycemic control, trend analysis using the Gamma Statistic was performed to determine the significance of the frequency and movement between SMBG quintiles across the treatment period. McNemar's test was performed to assess relative frequencies of patients reaching glycemic targets and at risk. Anthropometric measures and HbA1c were stratified by sex, race, and length of diagnosis to address potential confounders and effect modifiers. In order to further discriminate the benefits of MNT, HbA1c was stratified by diet alone and diet plus drug therapy. Paired T-tests were used to determine significance of changes from baseline to end-of-program for serum lipids and in weight and HbA1c by sex, race, and length of diagnosis. Significance testing was conducted at the 95% confidence interval (alpha = 0.05). Given that this study is a pilot for a multisite outpatient study and the employee diabetes education program, a power study was conducted. The minimum number of subjects to achieve 80% power was 12, 52, and 56 for HbA1c, weight, and BMI respectively.

RESULTS

Demographic characteristics of the study sample are presented in Table 5. The mean age was 60 years (range = 29 to 81 years). For those patients with insurance coverage for DSME; 84% received services administered by BCBS (BCBS-AL and Medicare). The diabetes education program is administered such that both DSME and MNT are reimbursed for Medicare beneficiaries; there is no state coverage for DSME or MNT for adult Medicaid patients with a diagnosis of T2D in Alabama. Medicaid beneficiaries and uninsured patients participate in a scholarship program awarded by the medical center. Approximately 60% of the sample had a recent diagnosis of T2D within the preceding year. More than 90% of the sample had at least one diagnosed comorbid condition; hypertension, dyslipidemia, and obesity were most common.

Table 6 provides a summary of patient outcomes across dependent variables of BMI, weight, and HbA1c. Baseline BMI ranged from 19.0 to 50.8 kg/m^2. There was a statistically significant reduction in BMI and weight from baseline after DSME. Additional weight loss was observed following MNT (end of program), but did not reach significance over and above that observed with DSME alone. Weights were available for a small subset of the population at 1 year, although lower than any interval of the study; were highly variable; and did not reflect significant additional loss over end of program. When stratified by race, only whites exhibited statistically significant weight loss. Newly diagnosed patients (< 1 year) exhibited weight loss of 5.4 ± 9.0 kg ($P<0.001$) across the treatment period as compared to patients with diagnosed disease of longer duration 0.9 ± 7.8 kg ($P > 0.05$).

Significant reduction in HbA1c was observed following DSME and MNT; reductions were maintained at 1-year follow-up (Table 2). Notably, 27% of the patient population had an HbA1c at the target of ≤ 7.0% at baseline as compared to 72% of patients reaching target

following DSME and MNT (P = 0.008). Conversely, 33% of patients exhibited baseline HbA1c ≥ 9% compared to < 5% (P = 0.01) and 4% (P = 0.009) at end of program and at 1-year follow-up, respectively. When stratified by race, both whites and AAs exhibited significant reductions in HbA1c. Baseline HbA1c was higher in AAs as compared to whites (P < 0.001); AAs exhibited greater reduction in HbA1c (P < 0.001). In addition, length of diagnosis impacted HbA1c outcomes; patients with a diagnosis of < 1 year responded better to treatment compared to those with diagnosed disease of 1 to 5 years (P < 0.001), 6 to 10 years (P = 0.002), and more than 10 years (P < 0.001), although all groups exhibited significant reductions in HbA1c at the P < 0.001 level.

Two strategies were employed to discriminate the benefits of MNT and nutritional management of T2D. Figure 1, discriminates HbA1c outcomes based on disease managed by diet alone and diet plus drug therapy. To further discriminate DSME outcomes and the added benefits realized with the addition of individualized MNT, self-monitoring blood glucose (SMBG) data were used; distinct from HbA1c, SMBG data were available at the approximate mid-point of the 4-month treatment period. Additional gains were achieved in glycemic control following one-hour of individualized MNT beyond those observed with DSME alone, but did not reach statistical significance (Figure 2). Data regarding frequency of hypoglycemia was incomplete.

Baseline and follow-up lipids were available from a small subset of the sample (n = 9). Serum triglycerides (TG) decreased from baseline of 181.6 ± 75.5mg/dL (2.0 ± 0.9mmol/L) to 115.8 ± 48.1mg/dL (1.3 ± 0.5mmol/L) (P = 0.023). HDL increased from 41.4 ± 12.4mg/dL (1.1mmol/L ± 0.3) to 47.3 ± 12.4mg/dL (1.2 ± 0.3mmol/L) (P=0.007).

There were no apparent trends in blood pressure across the treatment period and information regarding new prescriptions or changes, if any, to the antihypertensive regimen was

incomplete; full statistical analysis was deferred. Data regarding hospitalizations was not fully accessible from records queried; the diabetes center services patients who may seek hospitalization at a number of other regional hospitals.

DISCUSSION

Retrospective research utilizes data that has originally been collected for reasons other than research.[41] Consistent with best practices and methodologic considerations outlined for use by medical disciplines,[37] the present study identified key outcome measures to answer specific research questions. Identified strengths of the RCR in the pilot setting included the relative ease of conducting the study and documentation of positive patient outcomes subsequent to RDN interventions that are practical and achievable for the patient in daily life. The RCR has multiple applications for future research within the profession. One of the advantages is the relatively inexpensive means of accessing existing data[42] and multiple applications for clinical research.[43] The RCR can serve as a time-sensitive, cost-effective means for RDNs in practice to obtain outcome data from current programs and interventions in a variety of settings and disease conditions. Data obtained can support facility-specific assessments of services and more broadly the expansion of a needed repository of information to further demonstrate the efficacy of MNT, specifically RDN-provided interventions, in the management of diabetes and other chronic disease.

The present RCR adds to the evidence base by documenting outcomes from patients participating specifically in a comprehensive ADA-recognized program. ADA-recognition requires compliance with 10 identified standards: internal structure, external input, access, program coordination, instructional staff, curriculum, individualization, ongoing support, patient progress, and quality improvement.[38] Systematic review and meta-analysis has been used to

summarize the evidence from RCTs and observational studies with regard to efficacy of DSME and MNT.[7,16,25,30,41] Direct comparative analysis between studies is challenging given the heterogeneity of what constitutes DSME across studies; breadth, duration and intensity of the interventions; use of individual providers or multidisciplinary teams; and whether the RDN is the provider of the nutrition education component.[5,10-13,15,21,26,44] Exploring outcomes specifically in ADA-recognized programs, with interdisciplinary DSME with integrated nutrition education and adjunct individualized RDN-administered MNT provides a means to assess outcomes that are administered according to the current standard of practice. The methodology tested through this RCR lays a foundation for a multisite study currently underway, and holds the potential to gather national data from ADA and AADE comprehensive programs in support of better referral, reimbursement, and access to these needed services.

The majority of patients presenting with T2D are overweight or obese; prevalence of obesity in the states with the top ten highest rates of diabetes varies from 28.8% to 35.6% of the adult population.[45] The paradox of weight management in T2D is that improved glycemic control and insulin therapy can result in weight gain. Weight-loss outcomes secondary to MNT interventions are mixed. In a recent systematic review and meta-analysis of RCTs exploring lifestyle interventions for overweight and obese patients with T2D, 17 study groups reported weight loss of < 5% with no significant benefit to HbA1c, lipids, or blood pressure.[30] Two study groups, the Mediterranean-style diet and the Look AHEAD (Action for Health in Diabetes) trial, reported weight loss of > 5% at 12 months and subsequent HbA1c reductions of 1.2% and 0.6%, respectively. RDNs provided the nutrition counseling in both of these trials. The overall conclusion emphasized that a weight loss of > 5% appeared to be necessary for beneficial effects on HbA1c, lipids, and blood pressure. Both statistically and clinically significant weight loss was

observed in Whites in the present study and reached ADA target recommendations of 5-7%.[46] Additional reduction after MNT and at 1-year follow-up for all participants suggests added benefit of individualized RDN-provided MNT over that observed with DSME alone.

HbA1c is the hallmark of glycemic control. A 1% reduction in HbA1c results in risk reduction of morbidity and mortality associated with comorbid disease: 21% for deaths related to diabetes (P<0.0001), 14% for myocardial infarction (P<0.0001), and 37% for microvascular complications (P<0.0001).[47] A recent meta-analysis exploring the impact of group based DSME alone (21 studies with 2833 participants) revealed a 0.44% (P = 0.0006) and 0.46% (P = 0.0005) reduction in HbA1c at six-months and one-year respectively.[10] The most recent systematic review of the DSME literature included studies specifically addressing the efficacy of DSME against usual care or minimal education; inclusion criteria included studies that specified components of DSME with goals to improve knowledge, skills, and abilities to perform self-management activities; results were more favorable with HbA1c reductions of 0.74%.[16]

Effectiveness of MNT with DSME with integrated nutrition modules provided by an RDN, with or without supplemental individualized MNT, and standalone MNT has been reported to result in significant reductions in HbA1c ranging from 0.7% - 1.9%; usual care showed reductions of < 0.2%.[25] Comparatively, individualized RDN-administered MNT, based on RCTs, meta-analysis, and systematic review accounts for statistically significant HbA1c reductions of 0.9-1.9.[22,25,28,31] Total time and number of nutrition visits has been associated with improved patient outcomes.[13,32]

There is much variability within the studies reviewed which include, but are not limited to, years diagnosed, baseline HbA1c, and use and documentation of pharmacotherapy as an adjuvant to MNT. The latter poses significant error to overall outcomes if diet alone is not

discriminated from combined diet and drug therapy. The present study clearly discriminated HbA1c outcomes for patients managed by diet alone and those receiving diet and drug therapy. While both groups exhibited significant reductions in HbA1c, consistent with other reported DSME and MNT outcomes, patients receiving combination therapy had higher baseline HbA1c and exhibited greater reductions in HbA1c.[16] HbA1c reductions of 0.5% to 1.5% are reported for oral hypoglycemic alone.[2]

A target HbA1c level < 7% is the widely accepted goal for most patients with diabetes.[2] HbA1c > 9% is associated with increased risk of comorbidities.[40] Greater response to treatment, in both weight loss and reduction in HbA1c in the present study, was observed with newly diagnosed patients; baseline HbA1c was higher in our population than many studies reviewed within.[23,26-27,29,44,48-49] With regard to SMBG data extracted across the intervention period in the present study, trend analysis revealed a positive significant trend across the treatment model; the greatest benefit of individualized MNT was evinced in patients with highest SMBG levels subsequent to DSME. It has recently been argued that patients with HbA1c > 9% benefit the most from DSME based on a greater reduction in HbA1c, and that treatment at lower HbA1c could occur later.[16] This seems counterintuitive given the effectiveness of the established evidence base supporting the Diabetes Prevention Program.[50] Delaying DSME and MNT for treatment of this progressive disease may further exacerbate metabolic derangements, increase prevalence of comorbidities, and subsequently have deleterious effects on patient outcomes increasing healthcare costs.

Diabetic dyslipidemia is a known risk factor for cardiovascular disease; hyperglycemia is associated with elevation in serum lipids, particularly TGs.[13,47] Reduction in serum lipids, particularly triglycerides, has been reported in multiple studies.[15,22,25,29] Metabolic derangements

associated with hyperglycemia and hyperinsulinemia with T2D favors fatty acid synthesis and inhibits lipolysis resulting in this effect. While others have reported reductions in total cholesterol,[13,15,22,29,47] this was not a finding of the present study. Statins along with diet and exercise are recommended for elevations in total and LDL cholesterol,[2] but have limited effects on TGs and HDL. A high TG/HDL ratio, has been identified as atherogenic and strong predictor of heart disease incidence and mortality in patients with T2D.[51] Elevated TG/HDL cholesterol is a manifestation of insulin resistance. Our results demonstrate a significant reduction in the TG/HDL ratio; TG/HDL ratio of < 2.0 is considered favorable, CVD risk increases when TG/HDL ratio exceeds 4.0. Both weight loss and improved glycemic control improve lipid outcomes.

Despite the evidence for DSME and MNT for T2D, the Joint Position Statement of the American Diabetes Association and the Academy of Nutrition and Dietetics identifies several factors resulting in underutilization of these services; current reimbursement models and requirement for physician referral are noted as key barriers.[5] Patients managed by diet alone who receive no DSME or MNT are essentially not receiving treatment for T2D. The present study provided a means to extract outcome data in support of the request from BCBS-Alabama in a timely and cost-effective manner. Educating employers, insurers, and primary care providers of the benefits and availability of effective RDN-provided services in local healthcare systems, as evidenced in the present study, could increase reimbursement, referral and ultimately patient access to care. In the present climate of outcome driven research and cost-to-benefit analysis, such data obtained using RCR from individual programs to multisite and national studies can inform health policy decisions and position the RDN in current and emerging healthcare models for the treatment and prevention or chronic disease.

Limitations and Future Directions

The RCR has the limitation that not all information is available for all patients. Mixed model ANOVA utilized within provides a means of accounting for missing data. Because the pilot study is a relatively small sample and was conducted in Alabama, results might not be applicable to other states. Alabama has one of the highest rates of obesity and diabetes. Notably our sample population is higher in AA than the US as a whole; health disparity is evinced in higher baseline HbA1c in our AA population. Preliminary findings regarding differences in outcomes between whites and AAs completing the program requires further study. A multicenter study is in progress to demonstrate the reproducibility of the outcomes across other comprehensive ADA-recognized education programs.

CONCLUSIONS

This RCR of 88 patients who received DSME with integrated nutrition education and RDN-provided individualized MNT through an ADA-recognized education program reports positive outcomes for all endpoints (weight, BMI, HbA1c, and lipids) that are consistent with or exceed those previously described in observational studies and RCTs that can be achieved in the real-life setting. Significant reductions in HbA1c were observed for both patient managed by diet alone and diet plus drug therapy and were sustained at 1 year. Reduction in HbA1c is associated with a decrease in chronic comorbid disease and hospital admissions and ultimately reductions in healthcare costs. Given national figures and high rates of obesity, diabetes, kidney disease, and other chronic comorbid conditions,[1] these results demonstrate a critical role of the RDN; specifically, the importance of the RDN as a member of the multidisciplinary team providing DSME and the preferred provider of patient-centered individualized MNT to support both improved health outcomes and cost reduction. The methodology described in this retrospective

chart review provides an operational model for abstracting existing data in a cost-effective and time-sensitive manner to delineate patient outcomes subsequent to provision of individualized MNT by the RDN. Use of this methodology is encouraged to provide documentation of quality indicators of RDN interventions in diverse healthcare settings and for the treatment of other chronic disease (e.g., obesity, dyslipidemia, and eating disorders). In addition, RDNs in clinical practice are encouraged to partner with research institutions to take advantage of resources to support outcome-based research. Outcome data, which enhances the repository of information documenting the efficacy of RDN interventions from the local to national level, can serve as testimony to healthcare administrators, private and public payers, and public policy leaders to support reimbursement and further identify the role of the RDN in current and emerging healthcare models.

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Table 5. Population Demographics of Patients with T2D receiving DSME and MNT

N = 88	Frequency	%
Sex		
Female	52	59.1
Male	36	41.9
Race (Ethnicity)		
African American	31	35.2
White (non-Hispanic)	56	63.6
Asian	1	1.1
Years Diagnosed		
< 1 year	52	59.8
1 - 5 years	9	10.3
6 - 10 years	9	10.3
> 10 years	17	19.5
Barriers		
Physical	2	2.3
Hearing	10	11.9
Vision	5	6.0
Low Literacy	4	4.8
Language	0	0
Diabetes Medications		
None	31	35.2
OHA	43	48.9
Injectable	4	4.5
Insulin	14	15.9
OHA + Injectable	4	4.5
OHA + insulin	7	8.0
Injectable + insulin	2	2.3

N = 88	Frequency	%
Comorbidities		
Amputations	0	0
CVD	6	6.8
CVA	9	10.2
Depression	14	15.9
Dyslipidemia	51	58
Hypertension	65	73.9
Kidney Disease	3	3.4
Neuropathy	16	18.2
Non-healing Wounds	0	0
Retinopathy	17	19.3
Obesity	49	57.6
OSA	14	15.9
Number of Comorbidities		
None	8	9.1
One	16	18.2
Two	38	43.2
Three	10	11.4
Four	9	10.2
Five	5	5.7
Six	2	2.3
Insurance		
BCBS/other	35	39.8
Medicare	40	45.5
Medicaid/none	13	14.8

OHA – oral hypoglycemic agent
CVD – cardiovascular disease
CVA – cerebral vascular accident
OSA – obstructive sleep apnea
BCBS – Blue Cross Blue Shield

Table 6. Outcomes Measures BMI, Weight, and A1C in Patients with T2D receiving DSME and MNT							
Outcome N = 88	Baseline (n)	DSME (n)	P-value	MNT (end of program) (n)	P-value	1-year (n)	P-value
Body Mass Index							
BMI kg/m^2	32.9 ± 6.9 (84)	32.3 ± 6.8 (84)	P < 0.001[1]	31.8 ± 6.8 (84)	P < 0.001[1] P> 0.05[2]	30.7 ± 5.7 (33)	P> 0.05[1] P> 0.05[2] P> 0.05[3]
White BMI kg/m^2	33.5 ± 6.5 (55)	-	-	32.2 ± 6.9 (54)	P < 0.001[1]	-	-
AA BMI kg/m^2	32.7 7.3 (28)	-	-	31.6 6.3 (30)	P> 0.05[1]	-	-
Weight							
Weight (kg)	94.3 ± 21.0 (84)	92.6 ± 20.9 (84)	P < 0.001[1]	91.7 ± 21.2 (84)	P < 0.001[1] P> 0.05[2]	88.6 ± 17.0 (33)	P> 0.05[1] P> 0.05[2] P> 0.05[3]
Weight Change (from baseline)	-	-1.3 ± 2.9 (81)	P < 0.001[1]	-1.6 ± 3.9 (84)	P < 0.001[1]	-1.3 ± 5.8 (33)	P> 0.05[1]
White Weight (kg)	97.0 ± 20.9 (55)	-	-	93.9 ± 22.1 (54)	P < 0.001[1]	-	-
Weight Change (from baseline)	-	-	-	-5.0 ± 8.4 (54)	P < 0.001[1]	-	-
AA Weight (kg)	90.3 ± 20.7 (28)	-	-	88.9 ± 19.0 (30	P> 0.05[1]	-	-
Mean Weight Change	-	-	-	-0.8 ± 9.0 (30)	P> 0.05[1]		

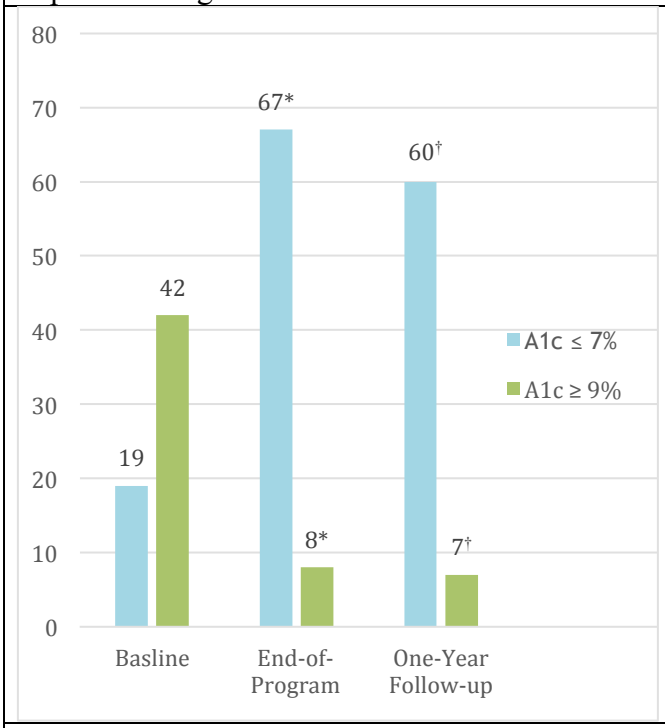
BMI – Body Mass Index; T2D – type 2 diabetes; DSME – diabetes self-management education; MNT – Medical Nutrition Therapy; AA – African American

Table 6. Outcomes Measures BMI, Weight, and A1C in Patients with T2D receiving DSME and MNT cont.							
Outcome N = 88	Baseline (n)	DSME (n)	P-value	MNT (end of program) (n)	P-value	1-year (n)	P-value
Glycemic Control – A1C							
A1C%	8.74 ± 2.30 (88)	-	-	6.82 ± 1.37 (88)	$P < 0.001^1$	6.9 ± 1.16 (49)	$P < 0.001^1$
Change in A1C (from baseline)	-	-	-	-1.92 ± 2.25 (88)	$P < 0.001^1$	-1.33 ± 1.67 (49)	$P < 0.001^1$
Diet Alone							
A1C%	7.3 ± 1.22 (17)	-	-	6.22 ± 0.46 (17)	$P < 0.001^1$	6.35 ± 0.52 (13)	$P < 0.001^1$
Change in A1C (from baseline)	-	-	-	-1.08 ± 1.2 (17)	$P < 0.001^1$	-0.98 ± 0.26 (13)	$P < 0.001^1$
Diet plus Pharmacotherapy							
A1C%	9.32 ± 2.47 (52)	-	-	6.96 ± 1.63 (52)	$P < 0.001^1$	7.05 ± 1.3 (28)	$P < 0.001^1$
Change in A1C (from baseline)					$P < 0.001^1$		$P < 0.001^1$
White							
A1C%	8.10 ± 1.78 (56)	-	-	6.59 ± 1.04 (56)	$P < 0.001^1$	6.67 ± 0.75 (38)	$P < 0.001^1$
Change in A1C (from baseline)	-	-	-	1.51 ± 1.67 (56)	$P < 0.001^1$	-1.26 ± 1.81 (38)	$P < 0.001^1$
AA							
A1C%	9.82 ± 2.73 (31)	-	-	7.18 ± 1.76 (31)	$P < 0.001^1$	7.62 ± 1.92 (10)	
Change in A1C (from baseline)				-2.64 ± 2.94 (31)	$P < 0.001^1$	-1.49 ± 1.11 (10)	

[1]Reflects significance over baseline [2]Reflects significance over weight two DSME [3]Reflects significance over end-of-program

Significance taken at the 95% confidence interval $P < 0.05$)

Figure 1. HbA1c outcomes following DSME with integrated nutrition education and individualized MNT in patients diagnosed with T2D.



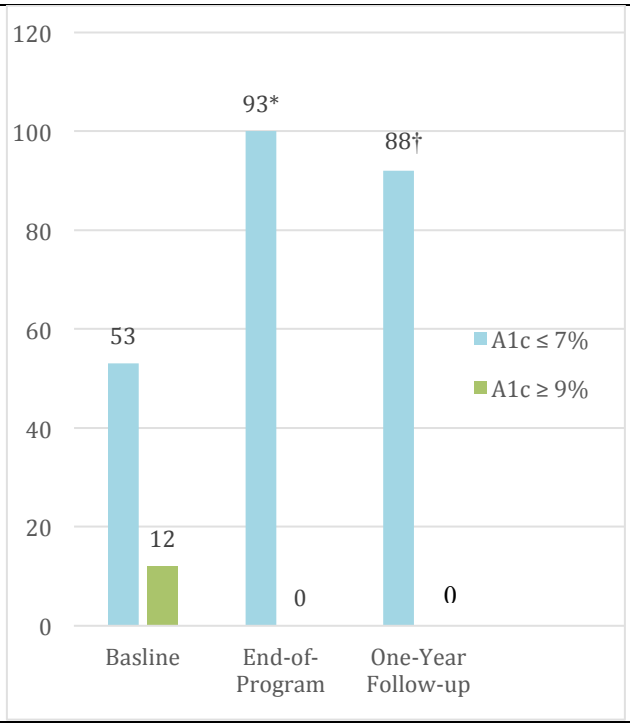


Figure 1a. Diet plus Drug Therapy
Relative frequency of patients reaching HbA1c targets (A1c ≤ 7%) and at risk (A1c ≥ 9%) with T2D managed by diet plus drug therapy (oral agents, insulin, and other injectables).

McNemar test exact (significance taken at $P < 0.05$)
* Denotes significant decrease in patients at risk (A1c ≥ 9%) ($P < 0.001$) and significant increase in patients meeting targets (A1c ≤ 7%) ($P < 0.001$).
† Denotes maintenance of treatment effect at 1-year as compared to end-of-program ($P < 0.05$).

Figure 1b. Diet Alone
Relative frequency of patients reaching HbA1c targets (A1c ≤ 7%) and at risk (A1c ≥ 9%) with T2D managed by diet alone.

McNemar test exact (significance taken at $P < 0.05$)
* Denotes significant increase in patients meeting targets (A1c ≤ 7%) ($P = 0.001$).
† Denotes maintenance of treatment effect at 1-year as compared to end-of-program ($P = 0.016$).

End-of-Program reflects changes from baseline and includes DSME with integrated nutrition education and RDN-provided individualized MNT administered over approximately 4 months.

RDN –registred dietitian nutritionist
DSME = diabetes self-management education
MNT = medical nutrition therapy

Figure 2.
Discriminating added benefit of RDN-provided individualized MNTsubsequent to DSME with integrated nutrition education by SMBG outcomes in patients diagnosed with T2D.

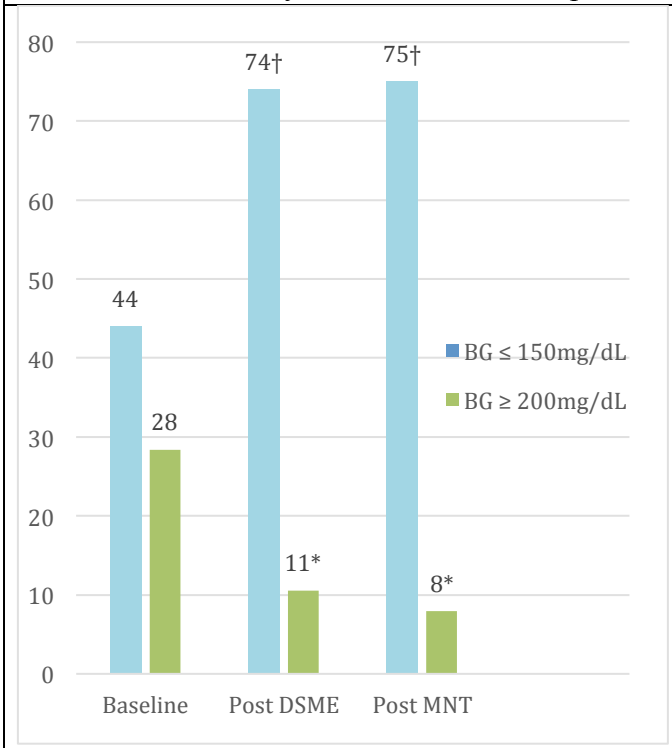


Figure 2a.
Relative frequency of sample population reaching SBGM targets (≤ 150mg/dL) and at risk (≥ 200mg/dL) from baseline, post DSME, and post MNT.

McNemar test exact (significance taken at $P < 0.05$)
* Denotes significant decrease in frequency of Patients at risk (BG ≥200mg/dL) over baseline $P < 0.001$.
† Denotes significant increase in patients reaching glycemic targets (BG ≤ 150mg/dL) over baseline $P < 0.001$.

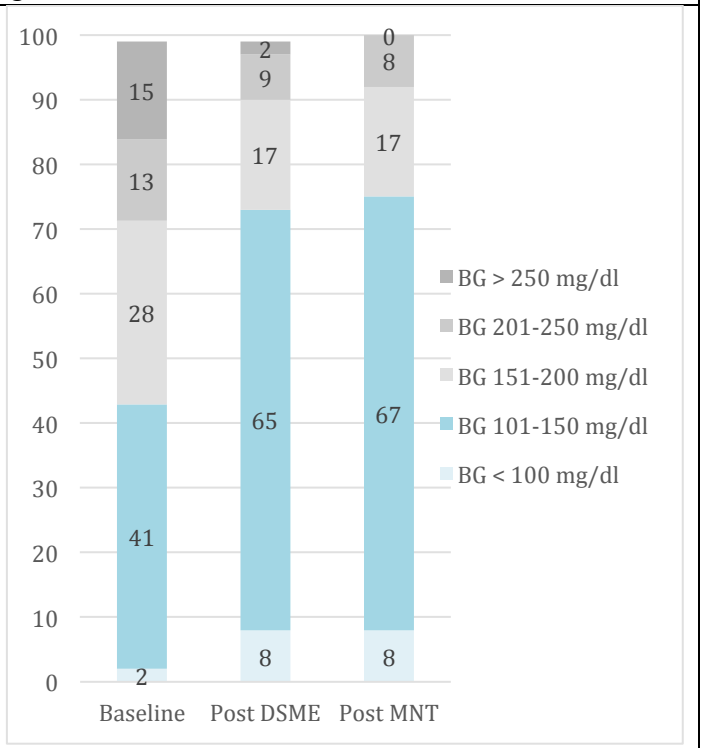


Figure 2b.
Relative frequency of sample population exhibiting improved glycemic control by SMBG quintiles from baseline to end-of-program.

Gamma statistic
(significance on one-tailed test taken at $P < 0.05$)
A significant trend was observed in patients moving from the higher to lower glycemic quintiles between baseline and post DSME ($P < 0.001$); the trend with the addition of RDN-provided individualized MNT did not reach significance ($P > 0.05$).

Post DSME reflects SBGM data taken at the approximate mid-point of the treatment program.
Post MNT reflects SBGM outcomes at End-of-Program from baseline and includes DSME with integrated nutrition education and RDN-provided individualized MNT administered over approximately 4 months.
BG = blood glucose; RDN –registred dietitian nutritionist; DSME = diabetes self-management education; MNT = medical nutrition therapy; SMBG = self-monitoring blood glucose

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Appendix A

Facility:		**Subject Number:**	
Gender: Female Male	**DOB:**	**Age (yrs) at beginning of program:**	**How long diagnosed?** <1 year 1-5 yrs 6-10 yrs >10 yrs
Ethnicity: African American American Indian Asian American Hispanic – Latino American White (non-Hispanic	**Primary Insurance:** Medicare Medicaid BCBS – Alabama BCBS - Other Other:_____	**Diabetes Diagnosis: (per referring physician)** Type 1 diabetes Type 2 diabetes BG abnormalities such as IFG, IGT, hyperglycemia, prediabetes	**Co-Morbidities:** ***Please circle all that apply*** CHD, obesity, HTN, dyslipidemia, kidney disease w/o dialysis, neuropathy, CVA, retinopathy, amputations, non-healing wound, depression
Smoker: Yes No If yes: 1-3 day >4/day 2 or more packs/week	**Alcohol Use: Yes No** If yes: Servings per week _____ 1 serving = 12 oz beer, 5 oz wine, or 1.5 oz spirits	**Learning Barriers:** Physical Hearing Vision Low Literacy English as second language	**Notes:**

Data collected by:

_____

_____

Facility:		**Subject Number:**		
Date	**1st visit:**	**F/u visit:**	**F/u visit:**	**F/u visit:**
Intervention	**DSME:** 1:1 or Group RD or Multi-dis **MNT:** 1:1 or Group	**DSME:** 1:1 or Group RD or Multi-dis **MNT:** 1:1 or Group	**DSME:** 1:1 or Group RD or Multi-dis **MNT:** 1:1 or Group	**DSME:** 1:1 or Group RD or Multi-dis **MNT:** 1:1 or Group
Medications: Name/dose	Initial Dosage	Dosage	Dosage	Dosage
OHA		Same More Less	Same More Less	Same More Less
Injectables		Same More Less	Same More Less	Same More Less
Insulin		Same More Less	Same More Less	Same More Less
ACES/ARBS				
Statins				
Ht (in)/Wt (lbs)				
BMI				
BP (mm Hg)				
Total chol(mg/dL)				
LDL (mg/dL)				
HDL (mg/dL)				
TG (mg/dL)				
A1C (%)				
SBGM – Average Mg/dL	<100 100-150 151-200 201-250 > 250	<100 100-150 151-200 201-250 > 250	<100 100-150 151-200 201-250 > 250	<100 100-150 151-200 201-250 > 250
PA in a week	≤50 ≤100 ≤150 ≥150 unknown	≤50 ≤100 ≤150 ≥150 unknown	≤50 ≤100 ≤150 ≥150 unknown	≤50 ≤100 ≤150 ≥150 unknown
# admits past 12 mos for DM		# admits since last visit:	# admits since last visit:	# admits since last visit:
# ER visit in past 12 mos for DM		# ER visits since last visit:	# ER visits since last visit:	# ER visits since last visit:
Frequency of hypoglycemia	Daily 2-3x/week 1-2X/months never	Daily 2-3x/week 1-2X/months never	Daily 2-3x/week 1-2X/months never	Daily 2-3x/week 1-2X/months never