The Efficacy of a Diabetes Self-Management Education and Support Coaching Program for the Ongoing Management of Type 2 Diabetes in North Alabama

by

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Abstract

According to the latest 2020 National Diabetes Statistics Report from the Centers for Disease Control and Prevention, 34.2 million people have diabetes in the United States (10.5% of the population).[1] This number has increased since the 2017.[2] Type 2 diabetes accounts for about 90 to 95 percent of all diagnosed cases of diabetes in adults. Diabetes self-management education and support (DSMES) and medical nutrition therapy (MNT) have been proven to improve patient outcomes. After a diabetes diagnosis, physicians can refer their patients to Registered Dietitians (RD) that provide DSMES regularly. Combining the knowledge of the physician and RD can help patients to reach optimal blood glucose control in order to prevent or minimize complications. However, many patients rely on their physician solely for diabetes education despite referrals for education outside of the physician's office. If they do see a RD, it's only twice a year (every 6 months) due to insurance coverage limits.

Huntsville Hospital provides a special coaching program for employees with diabetes called *Health Matters*. They are provided with DSMES quarterly by a RD, in addition to lab work to track their progress. Using retroactive data collection, we analyzed the health outcomes of the patients in this coaching program, in hopes of this program becoming a standard for managing type 2 diabetes long-term. The data were collected from Huntsville Hospital's electronic medical records via CliniPro electronic health system. One-way analysis of variance was used to calculate the difference between three or more than three group analyses with Tukey post-hoc test. The repeated measures of ANOVA were carried out to determine the significance between different time points of the DSMES program in each group analysis.

Coaching through *Health Matters* led to participants achieving and/or maintaining an A1C near the target of 7%. While there were no significant improvements in health outcomes overall, the ongoing DSMES program significantly improved the A1C in participants with uncontrolled diabetes, A1C >9%. These diabetes management changes could help decrease the risk of complications and improve patients' quality of life. The findings from this research will be used to further explore the effects of DSMES and the importance of more frequent ongoing DSMES.

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List of Abbreviations

T2DM	Type 2 Diabetes Mellitus
DSMES	Diabetes Self-Management Education and Support
A1C	Hemoglobin A1C
RD	Registered Dietitian
CDCES	Certified Diabetes Care and Education Specialists
LDL	Low density Lipoprotein
HDL	High density Lipoprotein
ADA	American Diabetes Association
ADCES	Association of Diabetes Care & Education Specialists
AND	Academy of Nutrition and Dietetics
PCP	Primary Care Physician
DSME	Diabetes Self-Management Education
CMS	Centers for Medicare & Medicaid Services
DSMT	Diabetes Self-Management Training
AADE	American Association of Diabetes Educators
CBDCE	Certification Board for Diabetes Care and Education
SOAP	Subjective, Objective, Assessment, Plan
GEE	Generalized Estimated Equation
ANOVA	Analysis of Variance
SEM	Standard Error of Mean

Chapter 1

Introduction

According to the latest 2020 National Diabetes Statistics Report from the Centers for Disease Control and Prevention, 34.2 million people have diabetes in the United States (10.5% of the population).[1] This number has increased since the 2017 National Diabetes Statistics Report that reported 30.3 million people with diabetes in the United States (9.4% of the population).[2] Diabetes is a chronic disease that requires making a multitude of daily self-management decisions and performing complex care activities. Diabetes self-management education and support (DSMES) provides patients with diabetes the foundation and education to help incorporate and navigate treatment decisions and activities into their lives and has been shown to improve health outcomes.[3,4,5] Studies have found that DSMES is associated with improved diabetes knowledge and self-care behaviors, lower hemoglobin A1C (A1C) levels, lower self-reported weight, improved quality of life, healthy coping, and reduced health care costs.[6,7,8] DSMES is "the ongoing process of facilitating the knowledge, skills, and ability necessary for diabetes self-care, as well as activities that assist a person in implementing and sustaining the behaviors needed to manage his or her condition on an ongoing basis, beyond or outside of formal self-management training." [9] The American Diabetes Association defines Diabetes Self-Management Education (DSME) as the process of facilitating the knowledge, skill, and ability necessary for diabetes self-care, and Diabetes self-management support (DSMS) refers to the support that is required for implementing and sustaining coping skills and behaviors needed to self-manage on an ongoing basis.[3] DSMS services can address the patient's health beliefs, cultural needs, current knowledge, physical limitations, emotional concerns, family support, financial status, medical history, health literacy, numeracy, and other factors that influence or

create barriers for each person's ability to meet the challenges of diabetes self-management.[3] However, to ensure DSMES is available to every person affected by diabetes, prediabetes, or other cardiometabolic conditions, it is essential that health systems, payers, providers and the diabetes care team work together to reduce barriers and improve access. Traditionally, DSMES services provided information to people with diabetes in a didactic manner and setting.[10] However, DSMES services are developing empowerment models that enable people with diabetes to self-manage their diabetes more effectively. [11]

Statement of the Problem

The ongoing management of type 2 diabetes is complex and burdensome. Healthcare professionals are aware of the importance of providing initial education when type 2 diabetes is diagnosed, but what about beyond that first year? During the first year after diagnosis, patients can be provided 10 hours of education as a "once in a lifetime" coverage.[12] If the "once in a lifetime" coverage is completed, the patients may receive yearly follow-ups. However, many are unaware or skip appointments unless they have issues, and others go years without DSMES beyond their doctor unless complications arise. There is no structure for ongoing management beyond the four critical times to provide and modify DSMES: 1) at diagnosis, 2) annually and/or when not meeting treatment targets, 3) when complicating factors develop, and 4) when transitions in life and care occur.[13]

There are specific objectives of DSMES, including teaching the basics of type 2 diabetes, determining and counting carbohydrates, maintaining a healthy body weight, exercising regularly, and monitoring and controlling blood glucose levels. Registered Dietitian Nutritionists (RDNs) and Certified Diabetes Care and Education Specialists (CDCES) can work with patients individually to discuss ways to incorporate all these factors in daily life. They can give patients

practical tools to use when planning daily meals and incorporating all diabetes management tasks into their daily lives, if given access to the health professionals. While there is evidence that diabetes self-management education and support (DSMES) is effective, it is only effective if patients have access to the service.[13]

Purpose of the Study

Health Matters is a DSMES program provided by Huntsville Hospital in Huntsville, AL to provide diabetes education and support to hospital employees and their families. The purpose of this study is to evaluate the efficacy of health outcomes of an ongoing DSMES coaching program in a small group of hospital employees with type 2 diabetes.

Objectives

1. Evaluate the effectiveness of health outcomes among employees in the *Health Matters* DSMES program.
2. Evaluate the effectiveness of the *Health Matters* DSMES program among subgroups.
3. Determine differences in health outcomes among *Health Matters* participants.

Hypotheses

Hypothesis 1: The *Health Matters* program will have a positive impact on health-related outcomes (A1C, weight, Body Mass Index [BMI], Blood pressure [BP], Low density lipoprotein [LDL], high density lipoprotein [HDL] and Triglycerides) within the 2 years evaluated.
Hypothesis 2: There will be no difference in health-related outcomes among *Health Matters* participants at the end of the 2 years between gender, race, marital status, and insulin treatment

Significance of the Study

Health Matters is being proposed as an ideal DSMES program model for long-term management of type 2 diabetes and can be tailored to meet the needs of groups and subgroups. Through regular follow-ups with the CDCES and frequent monitoring, the DSMES team can

track diabetes and cardiovascular labs to identify any changes before complications occur. This individualized DSMES coaching style provides patients with the tools, education, motivation, and support to make changes in the patients' management plan sooner rather than later. These diabetes management changes could help decrease the risk of diabetes complications and improve patients' quality of life. The more frequent and deliberate access to DSMES, as seen in *Health Matters,* has great potential to assist in reducing complications, empowering patients, and promoting self-efficacy.

Chapter 2: Literature Review

Introduction to Type 2 Diabetes

Type 2 diabetes mellitus (T2DM) is a chronic health condition characterized by metabolic disturbances in insulin use and production, disrupting glucose homeostasis. Insulin resistance is present before the diabetes develops and 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.[14] A fundamental mechanism for the maintenance of glucose homeostasis is the rapid action of insulin to stimulate glucose uptake and metabolism in peripheral tissues. Skeletal muscle is the primary site of glucose disposal in the insulin-stimulated state.[15] The ability of insulin to increase glucose transport in skeletal muscle is stimulated by the translocation of glucose transporter 4 (Glut4), the major insulin regulated glucose transporter, from intracellular vesicles to the plasma membrane and transverse tubules.[16] Resistance to the actions of insulin in skeletal muscle can lead to obesity and complicates poorly controlled diabetes. [15–17]

To compensate for insulin resistance, 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.

Complications and Mortality of Uncontrolled Diabetes

Risks of diabetes complications can be reduced by controlling blood glucose, blood pressure (BP), cholesterol levels and body weight, but accomplishing this can be challenging.

There are several barriers to achieving these optimal health outcomes in these southern states i.e., cultural food preferences, finances, education, time, and efficacy to complete diabetes self-management behaviors. [18] However, the demands of diet modification, physical activity, medication adherence, and self-monitoring of blood glucose levels are influenced by socioeconomic, cultural, and psychosocial factors such as lack of social support, self-efficacy and coping skills. [19,20]

Diabetes complications are exacerbated by poor glycemic control and prolonged hyperglycemia. Microvascular complications occur when the excess 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[21]. In addition, development of diabetic retinopathy is the leading cause of blindness in developed countries. Likewise, many cases of kidney failure are attributed to diabetic nephropathy; treatment consists of long-term dialysis or kidney transplant. Increasing prevalence rates of chronic kidney disease parallel those of obesity and T2DM. Neuropathy is a complex constellation of conditions impacting the gastrointestinal tract and central and peripheral nervous systems and contributes to significant disability in patients with diabetes. Furthermore, during the recent SARS-CoV-2 coronavirus (COVID-19) pandemic, T2DM patients experienced severe challenges. T2DM predisposes to a severe course of the disease and doubles the COVID-19 mortality risk due to pulmonary and cardiac involvement. In addition, diabetes patients often suffer from comorbidities which further worsen clinical outcomes.[22]

With increasing interests in aging-related diseases and mental health, diabetes-related cognitive impairment is also a possible complication of diabetes. [23,24] The prevalence of diabetes and Alzheimer's disease is getting higher. [25,26] A chronic exposure to hyperglycemia can

deteriorate cognitive function and other aspects of mental health. Recent reports have demonstrated that hyperglycemia is closely related to the development of cognitive impairment and dementia, suggesting that there may be a cause-effect relationship between hyperglycemia and dementia. Hyperglycemia increases amyloid beta accumulation on brain lesions, exacerbates oxidative stress, neuroinflammation, and mitochondrial dysfunction, impairs neuronal integrity, and causes neurodegeneration [27,28]

Type 2 Diabetes in Alabama

Approximately 550,149 people in Alabama, or 14.1% of the adult population, have diagnosed diabetes (3rd highest in the U.S). An additional 119,000 people in Alabama have diabetes but don't know it, greatly increasing their health risk. [29] There are 1,316,000 people in Alabama, 34.6% of the adult population, who have prediabetes with blood glucose levels that are higher than normal but not yet high enough to be diagnosed as diabetes. Every year an estimated 34,668 adults in Alabama are diagnosed with diabetes. Diagnosed diabetes costs an estimated $5.9 billion in Alabama each year. [1,30]

The southern United States includes counties in close proximity with an estimated prevalence of diagnosed diabetes ≥11.0% and are considered part of the "diabetes belt". [30,31] Many of the counties in southern states like Mississippi, Georgia, Tennessee, and Alabama are included in the diabetes belt. The serious complications of type 2 diabetes include heart disease, stroke, amputation, end-stage kidney disease, blindness—and death. In addition to Alabama being in the top 5 highest prevalence of diabetes, Alabama has a high prevalence of all nutrition/lifestyle related conditions, like heart disease, stroke, obesity, and kidney disease. However, only 40% of the counties in Alabama have accredited DSMES programs. [32]

In Chester et. al, a random sample of 40 charts was chosen from the electronic medical records of patients with type 2 diabetes completing DSMES and an individualized MNT session with a Registered Dietitian in North Alabama.[33] Data were extracted from a retrospective chart review on hemoglobin A1C levels before and after appointments with the Registered Dietitian in the family practice clinic from September 2015-November 2015. Analyses were used to assess frequency of patients decreasing their hemoglobin A1C levels, which reveals improved glycemic control. A paired sample t test was performed, and results revealed that post DSMES and MNT Hemoglobin A1C values (M = 6.84%, SD ± 1.0) were significantly lower than the pre DSMES and MNT Hemoglobin A1C values (M = 7.17%, SD ± 1.3), t (40) = 2.89, p < 006.

Alabama has some of the highest prevalence of diabetes, stroke and heart disease mortality in the United States. [29,34,35] These lifestyle and nutrition related diseases are specifically widespread in the 25 counties in Alabama's Black Belt region, named for its dark soil and agricultural history.[36] All Black Belt Counties are among the top half of counties in the state for the percentage of residents living below the poverty line.[37,38] African Americans comprise 30% - 80% of the population in some areas and more than 30% of African Americans over the age of 50 have diagnosed diabetes.[18] [18]. Non-Hispanic blacks are twice as likely as non-Hispanic whites to die from diabetes. [39] In rural areas like the Alabama Black Belt, barriers to achieving optimal health outcomes are particularly daunting, including the mistrust of the health care system among African Americans in this area and there are fewer than half as many primary care physicians per 10,000 population as the US average. [36,38] Low-cost diabetes education programs that can overcome these barriers are urgently needed.

Delivery and Design of MNT and DSMES

The evidence shows MNT and DSMES for diabetes is effective for improving glycemic

control, lipid profiles, weight loss, blood pressure, need for medication, and decreased risk of onset and progression to diabetes-related comorbidities.[40] The American Diabetes Association recommends that people with diabetes receive individualized MNT , preferably by a registered dietitian/nutritionist familiar with the components of medical nutrition therapy in diabetes, to achieve treatment goals (Figure 1). The National Standards for Diabetes Self-Management and Support require providers delivering DSME services in accredited or recognized locations to meet 10 standards, and the standards are highly recommended for programs that are not accredited or recognized (Figure 2). 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[41]. Current clinical practice guidelines recommend that all people with diabetes participate in DSMES programs and activities to achieve and maintain glycemic control for the management of T2DM. Reported A1C reductions after MNT are similar or greater than what would be expected with treatment with currently available pharmacologic treatments for diabetes.[42] The documented decreases in A1C observed in these studies for patients with type 2 diabetes are −0.5 to −2%. [43,44, 45, 46, 47]

While there is evidence to support the benefits of DSMES, only about half of all people with diabetes receive diabetes education and even fewer see a registered dietitian/nutritionist according to US national data.[48] One study of people with diabetes (over 18,000 patients in Philadelphia) revealed that only 9.1% had at least one nutrition visit within a 9-year period of time. [49] The joint position statement from the American Diabetes Association (ADA), Association of Diabetes Care & Education Specialists (ADCES), and the Academy of Nutrition and Dietetics (AND) includes an evidence-based diabetes education algorithm that defines four

Figure 1. 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 measurable 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)

Figure 2. Nutrition Therapy Recommendations for Diabetes Management

Effectiveness of nutrition therapy

- 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.

Energy balance

- 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.

Eating patterns and macronutrient distribution

- 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.

Protein

- 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.

Dietary fat

- 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.

Micronutrients and herbal 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.

Alcohol

- 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.

Sodium

- 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 American Diabetes Association Standard for Care

critical times for delivery of DSMES for people with type 2 diabetes: at diagnosis, during the annual assessment, when a person with diabetes has new complicating factors, and upon transitions in care.[3] Often times, the referral starts and ends with the initial DSMES, and many don't attend that first session.[50] While initial DSMES is necessary, it is not sufficient for sustaining a lifetime of diabetes self-management, initial improvements in outcomes have been shown to diminish 6 months after conclusion of the intervention.[7]

Mehta et al. conducted an online survey of primary care physicians (PCPs) linked with DSMES referral data from electronic medical records of patients treated by each surveyed physician.[51] Physicians reported that they recommend diet and lifestyle coaching to nearly all their patients with diabetes (96% of patients), but only referred 67% of their newly diagnosed patients to DSMES services. Almost all physicians (n=290, 97%) reported their treatment approaches for patients newly diagnosed with diabetes vary by severity level (those with an A1C less than 9% were referred to DSMES services less than half of the time compared with those with A1C greater than 9%). Diet and lifestyle coaching was provided to all patients with type 2 diabetes irrespective of their severity level, whereas a statistically significant increase in rates of referral to DSMES was observed with an increase in diabetes severity (range: 45%–82%, p value <0.05). Despite severity level, all patients with diabetes should receive DSMES as a form of

early and ongoing intervention.

In 2014, Williams et al. conducted a community-based randomized controlled trial evaluating a culturally tailored community-based group diabetes self-management education (DSME) program among rural African Americans.[52] The participants' A1C levels decreased, although not significantly, from post-intervention and 3-month follow-up: 8.0% to 7.6%, $t(23) = 1.23$, $P = .22$, and decreased further at 12 months (7.4%). Their BMI levels did significantly decrease for participants over the first 3 months from 38.5 at baseline to 38.0 ($P = .03$). It decreased further to 37.4 at month 12, although not significantly. In terms of daily self-management actions, level of exercise increased significantly post intervention to 3-month follow-up: 2.12 to 3.10 ($P = .007$). Although there was a drop between 3 and 12 months, the final value was still consistently higher than at baseline. There were also significant increases in knowledge about diabetes at 3 months, 0.6 to 0.7 ($P = .001$) and another increase 12-months post intervention, 0.8 ($P = .001$). A similar improvement was seen in participants' attention to foot care: 4.2 to 4.9 ($P = .013$) at 3 months post intervention and 5.7 ($P = .001$) at 12-month follow-up.

DSMES curriculum provides the DSMES team with guidance, effective teaching strategies, and methods for evaluating learning outcomes and includes all aspects of diabetes self-management and support.[53,54,55] DSMES delivery should be innovative, patient-centered and integrate topics across content areas rather than creating silos of content that limit informed and wise decision making. The delivery of curriculum content must also be based on continuing assessment of need, preferences, and evaluation of outcomes; practical problem solving and self-advocacy approaches; collaborative care, including family and peer support; addressing

psychosocial issues, behavior change, diabetes devices, and strategies to sustain self-management efforts. [56–58]

Obesity and Weight Management for Treatment

Strong evidence exists that obesity management is highly beneficial in the treatment of type 2 diabetes.[53,59,60] Achieving and maintaining ≥5% weight loss is recommended for people with type 2 diabetes who are overweight or obese. The modest weight loss and behavior changes improve glycemic control and reduce the need for glucose-lowering medications.More intensive dietary energy restriction can substantially reduce A1C and fasting glucose and promote sustained diabetes remission through at least 2 years. The ADA Standards of Medical Care states that metabolic surgery strongly improves glycemic control and often leads to remission of diabetes, improved quality of life, improved cardiovascular outcomes, and reduced mortality. Food and lifestyle habits are personal and interventions should be patient centered. Healthcare professionals should evaluate systemic, structural, and socioeconomic factors that may impact dietary patterns and food choices, such as food insecurity and hunger, access to healthful food options, cultural circumstances, and social determinants of health.

Kelley et al. found that calorie restriction had an important regulatory effect on the metabolism of patients with obesity and non-insulin dependent type 2 diabetes independent of weight loss.[60] Intensive lifestyle interventions should include a high frequency of counseling (≥16 sessions in 6 months) and focus on dietary changes, physical activity, and behavioral strategies to achieve a 500–750 kcal/day energy deficit. There are several dietary approaches to control hyperglycemia in type 2 diabetes patients, but carbohydrate portion control is the typical diet taught by the ADA, registered dietitians (RD) and diabetes self-management education and support (DSMES) facilities (Figure 4).[41] The ADA also recommends a variety of eating patterns

that are acceptable for the management of type 2 diabetes and pre-diabetes, including Mediterranean, dietary approaches to stop hypertension (DASH), and plant-based diets.[41,61] Reducing calories and monitoring carbohydrate intake are the leading medical nutrition therapy concepts for type 2 diabetes.[40,42]

Glycemic Targets for Diabetes Management

Research shows that DSMES can improve hemoglobin A1C levels and have a positive effect on other clinical, psychosocial, and behavioral aspects of diabetes, like reducing the development of diabetes-related complications, increasing quality of life and fostering healthy coping strategies to manage diabetes-related distress.[62] The prevalence of diagnosed diabetes is projected to increase in the U.S. from 34.2 million (9.1% of the total population) in 2020, to 39.7 million (13%) in 2030, and to 60.6 million (17%) in 2060.[63] Despite advancements in medication and technology treatment modalities, there is a lack of improvement in reaching clinical target goals since 2005.[64]

Hemoglobin A1C or glycosylated hemoglobin (A1C) is the most common measurement used to assess glycemic control. The A1C is used in clinical trials demonstrating the benefits of improved glycemic control. Glucose present in the blood attaches to the hemoglobin protein in red blood cells, and increased glucose levels will reflect on the surface of the hemoglobin protein, thereby rendering a higher A1C level.[65] The A1C test shows an average of the blood glucose level over the past 90 days and represents a percentage that can be used to diagnose and manage diabetes.[66] According to the American Diabetes Association, a person has a normal blood glucose level with an A1C below 5.7%. [41] People diagnosed with prediabetes, who are at risk for developing type 2 diabetes have an A1C between 5.7% and 6.4%, and are diagnosed with diabetes with an A1C above 6.5%. Though A1C has proven to be very helpful in diagnosing

diabetes and assessing diabetes management, this measure alone is not appropriate to help guide therapy decisions.

According to the 2017 National Standards for Diabetes Self-Management Education and Support, engagement in DSMES services lowers A1C by at least 0.6%, as much as many diabetes medications, with no side effects.[9] Greater A1C reductions have been associated with more than 10 hours of DSMES services. An A1C goal for many nonpregnant adults of <7% (53 mmol/mol) without significant hypoglycemia is appropriate. [67] The American Diabetes Association (ADA) recommends lowering hemoglobin A1C levels to < 7%, controlling blood pressure to < 130/80 mmHg, and controlling LDL cholesterol to < 100 mg/dl (< 70 mg/dl for those with a diagnosed cardiovascular disease) to reduce the risk of microvascular and cardiovascular complications.[41]

Pharmacotherapy in conjunction with lifestyle changes are recommended to help patients with diabetes achieve glycemic control. The 2016 Consensus Statement from the American Association of Clinical Endocrinologists (AACE) recommends lifestyle therapy as a first line treatment in T2DM and emphasizes the need for continued lifestyle modification even in the presence of pharmacotherapy. The AACE publishes a comprehensive type 2 diabetes management algorithm to assist providers in achieving glycemic control in their patients with T2DM [68]. The 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 comorbidities of T2DM, including heart disease and hypertension.

Underutilization and Barriers to DSMES

There are many reasons why DSMES is underutilized. There are a limited number of programs in the state relative to diabetes burden, limited access to DSMES locations, no or limited insurance coverage or coverage not promoted well, limited provider referrals to DSMES programs due to lack of knowledge of current clinical skills for managing diabetes, DSMES programs or burdensome referral process, low participation rates, and poor cultural tailoring of DSMES programs.[69] Although ADA-recognized and ADCES-accredited DSMES services are offered in 56% of counties across the United States, 62% of rural counties do not have DSMES services. [70] Delivery of medical nutrition therapy (MNT) by a registered dietitian is also associated with a decrease of about 0.5%–2% in A1C in people with type 2 diabetes.[71-72] Ideally, a primary care physician should have a registered dietitian or a diabetes education facility that he or she refers the patients for diabetes education.

The 2017 Standards of Medical Care in Diabetes recommends that each person with diabetes should be actively engaged in education, self-management, and treatment planning with his or her health care team, including the collaborative development of an individualized eating plan.[41] All individuals with diabetes should receive individualized MNT from a registered dietitian.[41] Often, DSME begins and ends with the primary care physician. Patients with diabetes generally visit their primary care physician (PCP)/other qualified healthcare professional two to four times per year, where the average appointment lasts 15–20 min and addresses four or more health conditions. [73] This equates to the person with diabetes (PWD) spending less than 1% of their life with their healthcare professionals.[73] However, the knowledge and support of a health care team is crucial for diabetes management.

Medicare Part B (Medical Insurance) covers outpatient diabetes self-management training (DSMT) when a patient has been diagnosed with diabetes. Medicare may cover up to 10 hours of initial DSMT – 1 hour of individual training and 9 hours of group training. The Centers for

Medicare & Medicaid Services (CMS) provides reimbursement for Medicare beneficiaries for DSMT provided by DSMES facilities.[74] Becoming familiar with the Medicare and insurance company DSMT reimbursement guidelines can help increase a DSMES service's financial sustainability and access to the community.[12] In the United States, less than 5% of Medicare beneficiaries with diabetes and 6.8% of privately insured people with diagnosed diabetes have used DSMES services.[13]

Promoting access to DSMES services requires identifying and addressing population barriers and health inequities, and informing referring physicians.[63] The 2017 AADE practice survey of over 4,696 diabetes educators reported that only 23% of participants in diabetes education services completed 75% or more of the program.[75] Underutilization of services can be due to the patients lack of understanding or knowledge of the benefits; cultural factors; a desire to keep their diagnosis private due to perceived stigma and shame; lack of family support; and perceptions that the program did not meet their needs and is not relevant for their life. Referring physicians and facilities are the gatekeepers to DSMES services covered by insurance, and should also be informed of local services. Referring providers may not emphasize the value and benefits of initial and ongoing DSMES.[76–79] Referrals may also be limited by unconscious or implicit bias of providers, which perpetuates health care disparities and leads to therapeutic inertia. The provider may too quickly judge an individual's potential to benefit from DSMES [80] and may incorrectly assume the person's willingness/ability to participate. To address these barriers, providers can meet with those currently providing DSMES services in their area to better understand the benefits, access, and referral processes and to develop collaborative interdisciplinary partnerships.

There are many other barriers to participating in DSMES, including logistical factors such as cost, timing, transportation, and medical status, socioeconomic factors, cultural factors, scheduling conflicts, health insurance gaps, and a lack of encouragement from healthcare

professionals.[5,81,82] It is imperative to implement and support processes that streamline referral practices throughout the system in order to reduce barriers. Once this major barrier is overcome, the diabetic education and care specialist can be an invaluable resource in addressing other barriers. DSMES services will be increasingly difficult to access if this doesn't happen, especially in rural and underserved areas.

Low DSMES utilization numbers are seen even in areas where cost is less of a barrier because of national health insurance. Analysis of National Health Service data in the U.K. revealed that only 8% of those referred to formal diabetes education, an annually reviewed standard of care, attended. Other national organizations are working to identify and utilize resources that address all barriers including those related to health systems, health care providers, participants, and the environment.[13]

Health system or programmatic barriers include lack of administrative leadership support, limited numbers of diabetes care and education specialists, geographic location, referral to DSMES services not effectively embedded in the health system service structure, limited resources for marketing, and limited or low reimbursement rates.[13,83] Some of the barriers with Medicare include the following: hours allowed in the first year the benefit is used and subsequent years are predefined and not based on individual needs; a referral is required and must be made by the primary provider managing the patient's diabetes; there is a requirement of diabetes diagnosis using methods other than A1C; and costly copays and deductibles may apply.[12] A person cannot have Medicare DSMES and MNT visits either face to face or through telehealth on the same day, thus requiring separate days to receive both of these valuable services and possibly delaying questions, attendance, education, and support.[74] Creative and innovative solutions include offering a variety of DSMES options that meet individual needs within a

population such as telehealth formats, affordable coaching programs, online resources, mobile DSMES services, discussion groups, and maximizing community resources related to supporting healthy behaviors.

Chapter 3: Methodology

IRB Approval

Prior to collecting retrospective data for *Health Matters*, an expedited research protocol review form for protocol number #19-314 EX 1907 was submitted and approved by the Auburn University Institutional Review Board for Research Involving Human Subjects (IRB) and Huntsville Hospital Institutional Review Committee (Appendix III and IV).

Study Design and Participants

Using retrospective secondary data collection, we analyzed the effects of the diabetes self-management education employee coaching program in North Alabama and Southern Tennessee. The data were collected for 256 participants from Huntsville Hospital's electronic medical records via CliniPro and Cerner's electronic health system. Participant ages ranged from 22 – 78 years old, mean age of 58. The data were collected from patients with type 2 diabetes who received diabetes coaching through *Health Matters* in the diabetes control center from January 2015 - May 2019. It included age, race, gender, marital status, weight, height, BMI, blood pressure, LDL, HDL, triglycerides, A1C, insulin, medications, and total cholesterol.

The research objectives include how DSMES quarterly coaching affects cardiovascular health and glycemic control via A1C and weight; and how DSMES quarterly coaching differs between races, ages, A1C groups and prescribed medications. The short-term and long-term efficacy of frequent DSMES coaching is evaluated by quarterly health outcome measures of weight, Hemoglobin A1C, BMI: baseline, 3 months, 6 months, 9 months, 12 months, 2 years). Exclusion criteria included: (1) Type 1 diabetes, (2) pregnant, (3) missing more than 1 datapoint. While there were 786 *Health Matters* participants during 2015- 2019, only 256 participants consistently attended DSMES coaching and completed quarterly lab work.

Program Overview

Health Matters is an individualized diabetes management program for Huntsville Hospital employees in Huntsville, AL. The program is free for participants and participants are terminated from the program if the ongoing mandatory requirements are not completed (Appendix I). Mandatory requirements include attending a kick-off meeting, remaining a Huntsville Hospital employee on hospital insurance, completing Diabetes Education courses through Diabetes University and the Diabetes Control Center (Appendix II), completing initial labs, health/fitness assessments, committing to exercising at least 8 x per month, following Physician's orders regarding diabetes, having diabetes and cardiovascular labs drawn (no cost) at a Huntsville Hospital lab every 3 months, and attending quarterly care manager and group meetings. The program benefits include free diabetes medications, lancets, and test strips through the employee pharmacy; free Wellness Center membership; free diabetes education and quarterly support through care managers from Huntsville Hospital's HealthWorks, Diabetes Control Center, and Wellness Centers. Diabetes University assigns a care manager (CDCES, Registered Nurses, RDNs, or clinical exercise physiologist) to provide the quarterly individual care manager meeting to monitor and support patients.

Program Description

Once the initial assessment and diabetes education classes are completed, the long-term maintenance phase begins, and participants are assigned a care manager with whom they meet for quarterly DSMES follow ups that will continue for the duration of their employment at the hospital (Figure 3). Care managers are trained to provide DSMES through their departments at Huntsville Hospital (i.e., the diabetes control center, employee health department or the wellness centers). Many of the care managers have the CDCES certification for experienced health

professionals, previously referred to as Certified Diabetes Educator (CDE). The CDCES program is a practice-based certification by the Certification Board for Diabetes Care and Education (CBDCE) for experienced health professionals who provide diabetes care and education in the United States or its territories. [84]

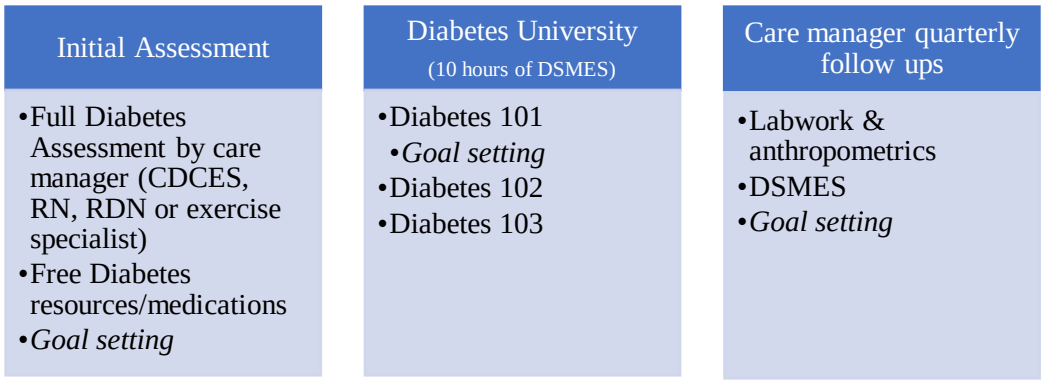

Figure 3. *Health Matters* Program Overview

The ongoing support and monitoring of weight, labs and management skills is the foundation of the Health Matters program to help control type 2 diabetes. The coaching style provided by the diabetes care managers provides more structure and individualized education and skills management to help make diabetes management changes before they lead to complications. All these benefits and resources could help reduce several of the barriers to type 2 diabetes management and reduce the long-term complications of diabetes.

During the quarterly coaching sessions, care managers weigh and measure blood pressure of their participants and discuss changes in diabetes and cardiovascular lab results. The AADE7 (now the ADCES7) education material and guidelines used to assist with self-management include healthy coping, healthy eating, being active, taking medication, monitoring, reducing risk, and problem solving. [85(p7)] The Care managers chart the information gathered in the patient

sessions via a SOAP (Subjective, Objective, Assessment, Plan) note format in the CliniPro electronic medical records system. Care managers ask a series of questions and review any changes that have occurred since the previous session and prompt the need for discussion, education, or intervention:

Subjective

DM Education history:

- Have you completed the series of required classes?
- Do you feel you are managing your diabetes?
    - What makes managing your diabetes difficult?
- What part of your diabetes management is most difficult?

Patient Medical History:

- Have you seen your physician for illness or injury since your last care manager visit? If so, why?
- Have you been seen in the emergency room for any diabetes related problem since your last care manager visit? If so, how many ER visits and why were you seen?
- Have you had admissions to the hospital for any diabetes related problem since your last care manager visit? If so, how many and why were you admitted?
- Have you missed any days of work or school due to surgery, illness, or injury since your last care manager visit? If so, how many and why?
- How often do you check your feet?

Social History:

- Do you live alone?
    - With whom do you live?

- Do you smoke? If so, how many packs a day?
    - Are you trying to stop smoking?
    - What method(s) are you using to stop smoking?
- Do you drink alcohol? If so, how often?
    - How many drinks do you consume per occasion?
- Has your shift changed recently?
    - What shift do you work?
    - What part of the day do you work?
- Is your job stressful?

Exercise:

- Do you exercise regularly?
    - What type(s) of physical exercise activity do you do?
    - Duration of activity?
    - How often?
- Do you experience any problems with exercise?
    - What types of problems?
- What are your barriers to regular exercise? (Lack of time, financial reasons, physical problems, dislikes exercise, no barriers to exercise)

Diet History:

- What time/what do you usually eat for Breakfast?
- What time/what do you usually eat for a morning snack?
- What time/what do you usually eat for Lunch?
- What time/what do you usually eat for afternoon snack?

- What time/what do you usually eat for Dinner/Supper?
- What time/what do you usually eat for a bedtime snack?
- What types of beverages do you usually consume?

Hypertension:

- Do you have a family history of high cholesterol?
- Do you have a family history of coronary artery disease?
- How often do you consume high fat foods like butter, whole milk, cream, fatty meats or fried food?
- Are you monitoring your sodium intake on a daily basis?
- Are you monitoring your caffeine intake on a daily basis?
- How much caffeine do you consume in a daily?

<u>Objective</u>

New Diagnosis:

- Do you have any new diagnoses since your last care manager visit?
- Have there been any changes or additions to your medications? If so, list them

Medications/Vitamins:

- Do you take your medications as directed by your physician?
    - What is the reason for not taking your medications as prescribed by your physician?
- Do you take any vitamins, minerals and/or herbal supplements?
    - What type(s)?

Vital signs:

- Systolic Blood Pressure/Diastolic Blood Pressure

- Height (in)
- Weight (lb.)
- Body Mass Index (BMI)
- Comments

Review Immunizations:

- Flu vaccine (last 12 month)
- Pneumonia vaccine

Assessment

Diabetes Care Plan:

- Type of DM
- Number of blood glucose readings/day and meter type
- DM Control type (Diet, Exercise, Insulin, Medication)
- Blood glucose goals

Plan

Set New Goals

- Goal
    - Date set
    - Confidence rating (0: Not confident, 3: Somewhat Confident, 5: Confident)
- Objective
- Action steps to accomplish goal
- Link to Risk Factors
    - Depression
    - Diabetes

    - Hypertension
    - Lipids
    - Physical Activity
    - Smoking
    - Weight
- Disease Category (Asthma, Cardiovascular Disease, Diabetes, General Fitness, Neurological, Obesity, Perinatal, Pulmonary Disease, Renal, Wound Care)
- AADE 7 Self Care Behaviors Education Material
    - Healthy coping
    - Healthy eating
    - Being active
    - Taking medication
    - Monitoring
    - Reducing risk
    - Problem solving

Outcome Measures

Demographic information was collected for age, sex, race, marital status, and comorbid disease (Table 1). Prescription medication use for diabetes was documented at baseline and included oral hypoglycemic agents, insulin, and other injectables (Table 1). Key outcomes measures via the hospital laboratories included anthropometrics (weight and BMI); glycemic control (A1C); serum lipids (total cholesterol, LDL, HDL, and triglycerides); and BP (Table 2 and 3). Anthropometric data were available at baseline (at least 2 years following diagnosis) and quarterly DSMES for 2 years. Participants were grouped into categories in order to analyze any

difference between groups: A1C target (<7%) and poor control (> 9%); BMI groups (Non-obese, Obese Class 1, Obese Class 2, Obese Class 3); race (African American and White); marital status (Single/unmarried and married); insulin and non-insulin use.

Theoretical Framework for *Health Matters*

To maintain self-care behavior at the level needed to effectively reach and sustain diabetes management over time, patients with diabetes benefit from ongoing diabetes self-management support. Ongoing education and support helps patients with diabetes to implement and sustain the ongoing skills, knowledge, coping, and behavioral strategies needed to manage their diabetes daily.[13] All these key points are discussed and applied in patients' DSMES services through the American Association of Diabetes Educator (AADE) 7 Self-Care behaviors, coined the AADE7. The AADE7 (currently Association of Diabetes Care and Education Specialist 7) is an evidence-based framework and outline to provide and document diabetes care and education that can be used in conjunction with the chosen curricula. [53,85]

The DSMES curriculum content provides guidance for the DSMES team through effective teaching strategies and methods for evaluating learning outcomes for all aspects of initial and ongoing diabetes management. The AADE7 used to assist with self-management include healthy coping, healthy eating, being active, taking medication, monitoring, reducing risk, and problem solving. The content of the DSMES curriculum also must be prioritized to meet the patients' current needs and goals at the time of the DSMES service.[13,8,7] Individualized DSMES service requires flexibility and the use of interactive teaching styles that include meaningful discussions to address individual questions and needs while fostering a culture of positivity within the DSMES services. The curriculum content and delivery should be creative, culturally appropriate for the individuals in the target population. and adapted as necessary for

the individuals and groups within the target population. [86,87,88] Furthermore, culturally tailored services have been shown to be effective in improving diabetes care outcomes.[56]

Statistical Methods

The collected patient data were organized and analyzed using IBM statistical package for the social sciences (SPSS) version 25 (IBM, IL, USA). The study data were checked for normality and skewness. Frequency analysis was performed, and a participant percentage table was generated. Repeated measures of analysis of variance (ANOVA) were carried out to determine the overall participants' BMI, weight, A1C, blood pressure parameters, and lipid profile of the longitudinal study. The equality of variances between the repeated measures factor levels refers to the Sphericity, and Mauchly's test measures it is used; the p-value is <0.05, then it violates the sphericity assumption. The test would proceed to different correctional adjustments in this situation, namely Greenhouse-Geisser, Huynh-Feldt, and Lower-Bound. The repeated measures of ANOVA significance value are selected sphericity assumption, or if Sphericity violated and Greenhouse-Geisser test epsilon value is less than 0.750, then Greenhouse-Geisser p-value from the test of within-subject is taken as repeated measures of ANOVA. Greenhouse-Geisser test epsilon value is greater than 0.750, then Huynh-Feldt p-value is selected from the test within-subject effects. Post-hoc test calculated using Bonferroni correction for all the repeated measures of analysis.

Two-tailed t-tests were analyzed to know the difference between gender, race, marital status, and insulin treatment two groups statistical analysis. One-way analysis of variance was used to calculate the difference between three or more than three group analyses with Tukey post-hoc test. The repeated measures of ANOVA were carried out to determine the significance between different time points of the DSMES program in each group analysis. The correlation analysis was

done by linear regression analysis to measure the statistical association between two variables, and scattered plots were plotted with the best fit line. The line graphs and percentage bar graphs were prepared using GraphPad Prism Version 9.2.0 (GraphPad Software, CA, USA).

To address the regression parameters for expected response outcomes from repeated measurement of analysis, a generalized estimated equation (GEE) was used. The effect of the DSMES program at the 3-, 6-, 9-, 12- and 24-months follow-up parameter measurement, including a lipid profile, compared to 0-months, and used as reference. The prospective cofounders adjusted in the model include race and gender.

Chapter 4: Results

Descriptive statistics were used to report the demographic characteristics, comorbidities, and diabetes treatment methods of the study population at baseline. Participants had a mean age of 59.04 ± 0.65 (Table 1). 62.6% had well controlled diabetes at baseline, displayed by the A1C of less than 7%. All participants have completed initial DSMES through Diabetes Unviersity and received quarterly coaching for two years post initial DSMES. A repeated measure of ANOVA was used to analyze the outcome measures of the longitudinal study among the participants at 0 months to 24 months DSMES that would display gradual and long-term changes to overall health (Tables 2 and 3).

During the first year there was an achievement of average A1C of less than 7% (7.13 ± 0.10 at baseline to 6.99 ± 0.09 at 12 months), but after 2 years the average A1C increased to 7.11 ± 0.10. BMI followed a similar pattern with baseline BMI at 34.72 ± 0.47 to 34.53 ± 0.46 at 12 months, then 34.63 ± 0.44 at 24 months. Participants maintained their outcome measures at 24 months and did not see any significant changes at 24 months. All outcome measures slightly improved, except for systolic blood pressure (133.16 ± 1.24 to 133.30 ± 1.07, $p<0.969$), and triglycerides (145.45 ± 6.45 to 151.25 ± 6.82, $p<0.176$), however not significantly. The linear regression in Figure 5 shows that as BMI increased, A1C increased significantly at the 24 month. There is a significantly positive correlation between A1C and weight and A1C and BMI at 24 months. There was also a significantly positive correlation between A1C and blood pressure, but a significantly negative correlation between A1C and HDL (good cholesterol). As A1C goes up, HDL goes down. There was also a significantly positive correlation between A1C and triglycerides at 0 and 12 months, but not at 2 years.

All participants were separated into various groups to evaluate any differences in the

ongoing management of participants. Tables 4 and 5 display the differences in outcome measures between male and female participants. While the average weights of the female participants were significantly lower, but when considering height in the BMIs calculations, there were no significant differences. Women had significantly better A1C levels at baseline, 12 months, and 24 months (6.97 ± 0.12, 6.86 ± 0.1, 6.96 ± 0.12, respectively) than men (7.43 ± 0.18, 7.26 ± 0.15, 7.40 ± 0.16). Male participants had significantly better LDL, and cholesterol at 24 months than women. Women had significantly better HDL and blood pressure than men, but neither gender had significant improvements from baseline to 24 months within their groups.

Tables 6 and 7 display the differences in outcome measures between African American and White participants, excluding other races. While there were no significant differences in average A1C, African Americans had significantly better HDL levels and Triglycerides throughout the 2 years, 53.80 ± 1.56 to 53.87 ± 1.65 vs 45.26 ± 1.09 to 46.27 ± 1.11 and 107.19 ± 5.66 to 109.27 ± 5.71 vs 168.25 ± 9.42 to 173.38 ± 9.84, respectively. Married participants had significantly lower BMI (33.87 ± 0.58 to 33.60 ± 0.54) than single/unmarried participants throughout the 2 years (36.37 ± 0.76 to 36.61 ± 0.75) and LDL 89.62 ± 2.36 to 86.31 ± 2.33 among married participants and 98.14 ± 3.74 to 95.39 ± 3.68 among single/unmarried (Tables 8 and 9).

Tables 10 and 11 display the differences in outcome measures between participants with and without insulin in their treatment plan, and there are significant differences in average A1C levels between them. The non-insulin group had significantly lower A1C levels than the insulin treated group throughout the 2 years (6.71 ± 0.12 and 6.84 ± 0.13 vs 7.52 ± 0.16 to 7.36 ± 0.14, respectively). The glycemic target for diabetes management is a A1C of <7%. In tables 12 through 18, the participants were grouped into participants with A1C levels of <7, 7-9% and

>9% at baseline. The participants with the highest A1C levels at baseline (>9%, n =38) saw significant improvement at 24 months (10.18 ± 0.16 to 8.85 ± 0.29, p<0.001). While many of the other outcome measures of these participants were significantly different than the well-controlled group at baseline, there was only one significant difference in outcome measures after 24 months (average triglycerides were 199.71 ± 29.42 in the >9% A1C groups and 141.85 ± 6.74 in the less than 7% A1C groups and 143.45 ± 11.53 in the 7-9% A1C group, p<0.009). The participants in the A1C >9% saw significant improvements in their A1C levels and saw no significant improvements in other outcome measures at 24 months compared to the well-controlled A1C groups (Tables 12 through 18, Figures 5 and 6).

Tables 19-25 display the differences in outcome measures in participants grouped by BMI groups (non-obese: BMI < 30 kg/m^2, obese class I: 31-34.9 kg/m^2, obese class II: BMI 35-40 kg/m^2 and class III obese: BMI greater than 40 kg/m^2. There were no significant differences among glycemic control among the 4 groups, but average triglycerides and HDL levels were significantly higher in the class III obese group.

Table 1. Population demographics of patients with type 2 diabetes receiving diabetes self-management education and quarterly coaching.

Demographics	Frequency	%
Gender		
Male	83	34.2
Female	160	65.8
Race		
African American	84	34.6
White	151	62.1
Other	8	3.3
A1C group		
A1C ≤ 7	152	62.6
A1C 7 to 9	53	21.8
A1C ≥ 9	38	15.6
Medications		
None	38	15.6
Pills/injectables	205	84.4

Number of medicines		
No medicine	38	15.6
One medicine	130	53.5
Two medicines	62	25.5
Three medicines	13	5.4
Insulin		
Insulin Treated	126	51.9
Non-insulin treated	117	48.1
Comorbidities		
Hypertension	190	78.2
Cardiovascular	31	12.8
Renal Disease	10	4.1
Hyperlipidemia	156	64.2
Treatment style		
No medication/ diet only	38	15.6
Medication only	79	32.5
Insulin Treated	126	51.9
Number of Comorbidities		
0	27	11.1
1	76	31.3
2	116	47.7
3	24	9.9

BMI - Body Mass Index
Other - races include Native Hawaiian, Asian/Pacific Islander and Hispanic
n=243

Table 2. Outcomes measures BMI, weight, blood pressure and A1C for patients with type 2 diabetes receiving diabetes self-management education and quarterly coaching

Parameters	0 Months	3 Months	6 months	9 months	12 months	24 months	p-value
BMI	34.72 ± 0.47	34.63 ± 0.48	34.64 ± 0.47	34.60 ± 0.47	34.53 ± 0.46	34.63 ± 0.44	p<0.786
Weight (lb)	216.02 ± 3.22	215.86 ± 3.26	215.84 ± 3.28	215.43 ± 3.26	215.52 ± 3.26	215.76 ± 3.22	p<0.906
A1C	7.13 ± 0.10	7.03 ± 0.10	7.00 ± 0.09	7.00 ± 0.09	6.99 ± 0.09	7.11 ± 0.10	p<0.152
Systolic BP (mm Hg)	133.16 ± 1.24	133.18 ± 1.09	133.33 ± 1.16	133.69 ± 1.10	132.65 ± 1.16	133.30 ± 1.07	p<0.969
Diastolic BP (mm Hg)	76.14 ± 0.62	76.74 ± 0.68	76.01 ± 0.70	76.85 ± 0.65	76.09 ± 0.60	75.73 ± 0.66	p<0.482

Values are expressed as Mean ± SEM, n=243
BMI - Body Mass Index
A1C - Hemoglobin A_{1c}

Table 3. Outcomes measures total cholesterol, LDL, HDL, and triglycerides for patients with type 2 diabetes receiving diabetes self-management education and quarterly coaching

Parameters	0 Months	12 months	24 months	*p*-value
Total Cholesterol (mg/dl)	169.28 ± 2.42	168.28 ± 2.34	167.99 ± 2.30	p<0.781
LDL (mg/dl)	92.58 ± 2.03	91.26 ± 1.99	89.46 ± 2.00	p<0.204
HDL (mg/dl)	48.52 ± 0.92	49.33 ± 0.99	49.23 ± 0.95	p<0.233
Triglycerides (mg/dl)	145.45 ± 6.45	142.53 ± 5.50	151.25 ± 6.82	p<0.176

Values are expressed as Mean ± SEM, n=243
LDL= Low density Lipoprotein
HDL = High density Lipoprotein

Table 4. Outcomes measures BMI, weight, A1C and blood pressure between male and female patients with type 2 diabetes

Characteristics	Male N = 83	Female N= 160	p-value
BMI			
0 MONTHS	33.51 ± 0.70	35.35 ± 0.60	p<0.061
3 MONTHS	33.52 ± 0.71	35.22 ± 0.62	p<0.091
6 MONTHS	33.64 ± 0.70	35.16 ± 0.62	p<0.127
9 MONTHS	33.68 ± 0.70	35.07 ± 0.61	p<0.160
12 MONTHS	33.78 ± 0.70	34.92 ± 0.59	p<0.240
24 MONTHS	33.78 ± 0.67	35.07 ± 0.58	p<0.169
p-value	p<0.374	p<0.466	
Weight (lb)			
0 MONTHS	235.11 ± 5.84	206.12 ± 3.60	**p<0.001**
3 MONTHS	235.30 ± 5.87	205.78 ± 3.66	**p<0.001**
6 MONTHS	236.01 ± 5.89	205.37 ± 3.69	**p<0.001**
9 MONTHS	236.35 ± 5.84	204.68 ± 3.63	**p<0.001**
12 MONTHS	237.66 ± 5.87	204.04 ± 3.60	**p<0.001**
24 MONTHS	237.28 ± 5.81	204.60 ± 3.56	**p<0.001**
p-value	p<0.164	p<0.351	
A1C (%)			
0 MONTHS	7.43 ± 0.18	6.97 ± 0.12	**p<0.033**
3 MONTHS	7.10 ± 0.14	6.99 ± 0.13	p<0.591
6 MONTHS	7.13 ± 0.15	6.94 ± 0.12	p<0.312
9 MONTHS	7.23 ± 0.15	6.87 ± 0.11	p<0.059
12 MONTHS	7.26 ± 0.15	6.86 ± 0.11	**p<0.030**
24 MONTHS	7.40 ± 0.16	6.96 ± 0.12	**p<0.028**
p-value	p<0.070	p<0.341	
Systolic BP (mm Hg)			
0 MONTHS	136.02 ± 2.21	131.67 ± 1.49	p<0.096
3 MONTHS	134.76 ± 2.00	132.36 ± 1.29	p<0.299
6 MONTHS	137.53 ± 2.10	131.16 ± 1.37	**p<0.009**
9 MONTHS	134.63 ± 1.61	133.21 ± 1.45	p<0.542
12 MONTHS	134.61 ± 1.98	131.63 ± 1.43	p<0.223
24 MONTHS	134.77 ± 1.64	132.54 ± 1.38	p<0.323
p-value	p<0.574	p<0.712	
Diastolic BP (mm Hg)			
0 MONTHS	77.04 ± 0.95	75.68 ± 0.79	p<0.298
3 MONTHS	78.49 ± 1.17	75.84 ± 0.83	p<0.064
6 MONTHS	77.27 ± 1.26	75.36 ± 0.83	p<0.195
9 MONTHS	77.82 ± 1.03	76.35 ± 0.83	p<0.286
12 MONTHS	76.80 ± 0.92	75.72 ± 0.77	p<0.392
24 MONTHS	77.61 ± 1.11	74.75 ± 0.80	**p<0.038**

p-value	p<0.722	p<0.494	

Values are expressed as Mean ± SEM
BMI - Body Mass Index
A1C - Hemoglobin A_{1c}
p values marked with bold reflects significance compared to male participants.
(Column *p* value shows overall repeated measures of ANOVA)

Table 5. Outcomes measures total cholesterol, LDL, HDL, and triglycerides for male and female patients with type 2 diabetes.

Characteristics	Male N = 83	Female N= 160	p-value
Total Cholesterol (mg/dl)			
0 MONTHS	160.48 ± 4.33	173.85 ± 2.86	**p<0.009**
12 MONTHS	160.54 ± 3.97	172.30 ± 2.85	**p<0.017**
24 MONTHS	158.24 ± 3.67	173.05 ± 2.85	**p<0.002**
p-value	p<0.741	p<0.801	
LDL (mg/dl)			
0 MONTHS	84.97 ± 3.52	96.34 ± 2.43	**p<0.008**
12 MONTHS	83.58 ± 3.23	95.06 ± 2.46	**p<0.006**
24 MONTHS	81.35 ± 3.17	93.47 ± 2.50	**p<0.004**
p-value	p<0.426	p<0.409	
HDL (mg/dl)			
0 MONTHS	41.51 ± 1.41	52.16 ± 1.08	**p<0.001**
12 MONTHS	42.06 ± 1.45	53.10 ± 1.19	**p<0.001**
24 MONTHS	41.59 ± 1.47	53.19 ± 1.11	**p<0.001**
p-value	p<0.713	p<0.251	
Triglyceride (mg/dl)			
0 MONTHS	177.51 ± 15.30	128.83 ± 5.35	**p<0.001**
12 MONTHS	177.01 ± 11.60	124.64 ± 5.30	**p<0.001**
24 MONTHS	187.40 ± 16.17	132.49 ± 5.57	**p<0.001**
p-value	p<0.581	p<0.191	

Values are expressed as Mean ± SEM
LDL- Low density Lipoprotein
HDL - High density Lipoprotein
p values marked with bold reflects significance compared to male participants.
(Column *p* value shows overall repeated measures of ANOVA)

Table 6. Outcomes measures BMI, weight, A1C and BP between White American/Caucasian and Black/African American patients with type 2 diabetes

Characteristics	White American/ Caucasian N = 151	Black/ African American N= 84	p-value
BMI			
0 MONTHS	34.57 ± 0.59	35.44 ± 0.78	p<0.377
3 MONTHS	34.49 ± 0.59	35.38 ± 0.84	p<0.380
6 MONTHS	34.40 ± 0.60	35.61 ± 0.81	p<0.226
9 MONTHS	34.40 ± 0.59	35.48 ± 0.79	p<0.273
12 MONTHS	34.38 ± 0.58	35.38 ± 0.78	p<0.300
24 MONTHS	34.42 ± 0.56	35.50 ± 0.77	p<0.251
p-value	p<0.806	p<0.846	
Weight (lb)			
0 MONTHS	219.45 ± 4.09	214.20 ± 5.28	p<0.438
3 MONTHS	219.46 ± 4.12	214.03 ± 5.45	p<0.430
6 MONTHS	219.06 ± 4.18	214.98 ± 5.43	p<0.557
9 MONTHS	219.17 ± 4.14	213.98 ± 5.35	p<0.448
12 MONTHS	219.40 ± 4.16	213.67 ± 5.35	p<0.405
24 MONTHS	219.49 ± 4.10	213.92 ± 5.34	p<0.413
p-value	p<0.966	p<0.763	
A1C (%)			
0 MONTHS	7.15 ± 0.13	7.16 ± 0.18	p<0.933
3 MONTHS	6.99 ± 0.11	7.17 ± 0.19	p<0.396
6 MONTHS	6.97 ± 0.11	7.13 ± 0.17	p<0.424
9 MONTHS	6.98 ± 0.11	7.10 ± 0.16	p<0.527
12 MONTHS	7.04 ± 0.12	6.98 ± 0.15	p<0.758
24 MONTHS	7.08 ± 0.12	7.22 ± 0.17	p<0.494
p-value	p<0.255	p<0.313	
Systolic BP (mm Hg)			
0 MONTHS	132.07 ± 1.58	135.75 ± 2.14	p<0.167
3 MONTHS	132.67 ± 1.44	134.74 ± 1.76	p<0.375
6 MONTHS	132.21 ± 1.43	136.54 ± 2.10	p<0.081
9 MONTHS	132.38 ± 1.31	136.69 ± 2.07	p<0.066
12 MONTHS	131.38 ± 1.46	135.62 ± 2.02	p<0.087
24 MONTHS	133.07 ± 1.32	134.31 ± 1.94	p<0.588
p-value	p<0.885	p<0.822	
Diastolic BP (mm Hg)			
0 MONTHS	75.13 ± 0.77	77.61 ± 1.06	p<0.058
3 MONTHS	76.51 ± 0.88	77.51 ± 1.14	p<0.493
6 MONTHS	74.60 ± 0.85	78.98 ± 1.23	**p<0.003**
9 MONTHS	75.68 ± 0.77	79.07 ± 1.24	**p<0.015**
12 MONTHS	75.20 ± 0.71	77.50 ± 1.11	p<0.070

24 MONTHS	74.90 ± 0.83	77.50 ± 1.11	p<0.062
p-value	p<0.281	p<0.407	

Values are expressed as Mean ± SEM
BMI - Body Mass Index
A1C- Hemoglobin A_{1c}
p values marked with bold reflects significance compared to White American/Caucasian participants.
(Column *p* value shows overall repeated measures of ANOVA)

Table 7. Outcomes measures total cholesterol, LDL, HDL, and Triglycerides between White American/Caucasian and Black/African American patients with type 2 diabetes.

Characteristics	White American/ Caucasian N = 151	Black/ African American N= 84	p-value
Cholesterol (mg/dl)			
0 MONTHS	168.09 ± 3.25	170.44 ± 3.80	p<0.651
12 MONTHS	168.75 ± 3.11	169.05 ± 3.71	p<0.952
24 MONTHS	166.89 ± 2.98	170.37 ± 3.82	p<0.479
p-value	p<0.773	p<0.859	
LDL (mg/dl)			
0 MONTHS	89.90 ± 2.71	96.39 ± 3.14	p<0.132
12 MONTHS	90.14 ± 2.63	94.93 ± 3.15	p<0.257
24 MONTHS	87.18 ± 2.55	95.06 ± 3.41	p<0.065
p-value	p<0.292	p<0.814	
HDL (mg/dl)			
0 MONTHS	45.26 ± 1.09	53.80 ± 1.56	**p<0.001**
12 MONTHS	46.37 ± 1.12	53.80 ± 1.80	**p<0.001**
24 MONTHS	46.27 ± 1.11	53.87 ± 1.65	**p<0.001**
p-value	p<0.111	p<0.997	
Triglyceride (mg/dl)			
0 MONTHS	168.25 ± 9.42	107.19 ± 5.66	**p<0.001**
12 MONTHS	163.82 ± 7.71	108.40 ± 5.86	**p<0.001**
24 MONTHS	173.38 ± 9.84	109.27 ± 5.71	**p<0.001**
p-value	p<0.383	p<0.924	

Values are expressed as Mean ± SEM
LDL- Low density Lipoprotein
HDL - High density Lipoprotein
p values marked with bold reflects significance compared to White American/Caucasian participants.
(Column *p* value shows overall repeated measures of ANOVA)

Table 8. Outcomes measures BMI, weight, A1C and blood pressure between single/unmarried and married patients with type 2 diabetes.

Characteristics	Single/unmarried N = 83	Married N= 160	p-value
BMI			
0 MONTHS	36.37 ± 0.76	33.87 ± 0.58	**p<0.011**
3 MONTHS	36.38 ± 0.80	33.73 ± 0.58	**p<0.008**
6 MONTHS	36.43 ± 0.76	33.72 ± 0.59	**p<0.006**
9 MONTHS	36.40 ± 0.76	33.66 ± 0.58	**p<0.005**
12 MONTHS	36.36 ± 0.74	33.58 ± 0.57	**p<0.004**
24 MONTHS	36.61 ± 0.75	33.60 ± 0.54	**p<0.001**
p-value	p<0.828	p<0.613	
Weight (lb)			
0 MONTHS	218.04 ± 4.79	214.97 ± 4.21	p<0.651
3 MONTHS	218.15 ± 4.77	214.67 ± 4.29	p<0.614
6 MONTHS	218.27 ± 4.76	214.58 ± 4.34	p<0.595
9 MONTHS	217.81 ± 4.70	214.30 ± 4.31	p<0.610
12 MONTHS	218.25 ± 4.78	214.10 ± 4.30	p<0.547
24 MONTHS	219.66 ± 4.85	213.73 ± 4.20	p<0.384
p-value	p<0.630	p<0.720	
A1C (%)			
0 MONTHS	7.17 ± 0.19	7.11 ± 0.12	p<0.775
3 MONTHS	7.08 ± 0.19	7.00 ± 0.11	p<0.708
6 MONTHS	7.10 ± 0.17	6.96 ± 0.11	p<0.473
9 MONTHS	7.02 ± 0.17	6.98 ± 0.11	p<0.855
12 MONTHS	7.03 ± 0.16	6.98 ± 0.11	p<0.769
24 MONTHS	7.25 ± 0.18	7.03 ± 0.11	p<0.270
p-value	p<0.361	p<0.378	
Systolic BP (mm Hg)			
0 MONTHS	136.10 ± 2.22	131.63 ± 1.48	p<0.088
3 MONTHS	134.88 ± 1.87	132.30 ± 1.34	p<0.263
6 MONTHS	133.75 ± 1.74	133.12 ± 1.52	p<0.799
9 MONTHS	136.77 ± 2.03	132.09 ± 1.29	**p<0.044**
12 MONTHS	135.72 ± 2.11	131.06 ± 1.37	p<0.056
24 MONTHS	137.24 ± 1.84	131.26 ± 1.29	**p<0.008**
p-value	p<0.557	p<0.665	
Diastolic BP (mm Hg)			
0 MONTHS	77.05 ± 1.14	75.68 ± 0.73	p<0.291
3 MONTHS	76.71 ± 1.15	76.76 ± 0.85	p<0.971
6 MONTHS	76.58 ± 1.18	75.72 ± 0.86	p<0.559
9 MONTHS	78.20 ± 1.21	76.15 ± 0.76	p<0.135
12 MONTHS	76.87 ± 1.11	75.68 ± 0.70	p<0.346
24 MONTHS	76.61 ± 1.17	75.27 ± 0.79	p<0.331

p-value	p<0.728	p<0.529

Values are expressed as Mean ± SEM
BMI - Body Mass Index
A1C - Hemoglobin A_{1c}
p values marked with bold reflects significance compared to single/unmarried participants
(Column *p* value shows overall repeated measures of ANOVA)

Table 9. Outcomes measures total cholesterol, LDL, HDL, and Triglycerides between single/unmarried and married patients with type 2 diabetes.

Characteristics	Single/unmarried N = 83	Married N= 160	p-value
Total Cholesterol (mg/dl)			
0 MONTHS	171.70 ± 4.44	168.03 ± 2.87	p<0.474
12 MONTHS	172.00 ± 4.17	166.36 ± 2.82	p<0.254
24 MONTHS	171.35 ± 4.21	166.25 ± 2.72	p<0.293
p-value	p<0.977	p<0.709	
LDL (mg/dl)			
0 MONTHS	98.14 ± 3.74	89.62 ± 2.36	**p<0.045**
12 MONTHS	97.10 ± 3.49	88.22 ± 2.40	**p<0.034**
24 MONTHS	95.39 ± 3.68	86.31 ± 2.33	**p<0.031**
p-value	p<0.651	p<0.285	
HDL (mg/dl)			
0 MONTHS	48.86 ± 1.36	48.35 ± 1.20	p<0.794
12 MONTHS	48.39 ± 1.29	49.82 ± 1.34$^{\$}$	p<0.492
24 MONTHS	48.95 ± 1.13	49.37 ± 1.33	p<0.836
p-value	p<0.798	p<0.055	
Triglyceride (mg/dl)			
0 MONTHS	129.24 ± 7.48	153.86 ± 8.95	p<0.070
12 MONTHS	135.00 ± 7.62	146.43 ± 7.36	p<0.326
24 MONTHS	140.73 ± 8.12	156.70 ± 9.45	p<0.268
p-value	p<0.146	p<0.272	

Values are expressed as Mean ± SEM
LDL- Low density Lipoprotein
HDL - High density Lipoprotein
p values marked with bold reflects significance compared to single/unmarried participants.
$^{\$}$Reflects significance taken at the 95% Confidence Interval compared to 0 Months.
(Column *p* value shows overall repeated measures of ANOVA of all outcomes)

Table 10. Outcomes measures BMI, weight, A1C and BP for patients with type 2 diabetes classified based on insulin or no-insulin treatment.

Characteristics	No Insulin N = 117	Insulin N= 126	p-value
BMI			
0 MONTHS	34.21 ± 0.58	35.20 ± 0.72	p<0.292
3 MONTHS	34.11 ± 0.60	35.12 ± 0.73	p<0.291
6 MONTHS	34.19 ± 0.59	35.06 ± 0.73	p<0.359
9 MONTHS	34.07 ± 0.59	35.08 ± 0.71	p<0.282
12 MONTHS	33.90 ± 0.58	35.12 ± 0.70	p<0.183
24 MONTHS	34.43 ± 0.61	34.82 ± 0.65	p<0.662
p-value	p<0.226	p<0.566	
Weight (lb)			
0 MONTHS	211.00 ± 4.08	220.68 ± 4.89	p<0.133
3 MONTHS	211.23 ± 4.09	220.17 ± 4.99	p<0.171
6 MONTHS	211.08 ± 4.09	220.25 ± 5.05	p<0.164
9 MONTHS	210.87 ± 4.11	219.79 ± 4.97	p<0.172
12 MONTHS	209.87 ± 4.08	220.77 ± 5.00	p<0.095
24 MONTHS	212.76 ± 4.23	218.54 ± 4.82	p<0.371
p-value	p<0.253	p<0.372	
A1C (%)			
0 MONTHS	6.71 ± 0.12	7.52 ± 0.16	**p<0.001**
3 MONTHS	6.65 ± 0.11	7.39 ± 0.15	**p<0.001**
6 MONTHS	6.71 ± 0.12	7.28 ± 0.14	**p<0.002**
9 MONTHS	6.70 ± 0.12	7.27 ± 0.13	**p<0.002**
12 MONTHS	6.62 ± 0.11	7.34 ± 0.13	**p<0.001**
24 MONTHS	6.84 ± 0.13	7.36 ± 0.14	**p<0.006**
p-value	p<0.225	p<0.115	
Systolic BP (mm Hg)			
0 MONTHS	129.28 ± 1.64	136.75 ± 1.79	**p<0.002**
3 MONTHS	131.62 ± 1.53	134.63 ± 1.55	p<0.167
6 MONTHS	131.54 ± 1.63	135.00 ± 1.65	p<0.138
9 MONTHS	131.89 ± 1.53	135.37 ± 1.57	p<0.115
12 MONTHS	129.34 ± 1.57	135.72 ± 1.66	**p<0.006**
24 MONTHS	130.02 ± 1.45	136.35 ± 1.52	**p<0.003**
p-value	p<0.311	p<0.773	
Diastolic BP (mm Hg)			
0 MONTHS	75.31 ± 0.90	76.92 ± 0.84	p<0.191
3 MONTHS	76.49 ± 1.00	76.98 ± 0.93	p<0.716
6 MONTHS	76.41 ± 1.00	75.64 ± 0.97	p<0.583
9 MONTHS	77.71 ± 0.99	76.06 ± 0.85	p<0.206
12 MONTHS	76.18 ± 0.82	76.00 ± 0.86	p<0.881
24 MONTHS	75.59 ± 0.94	75.86 ± 0.92	p<0.839

p-value	p<0.163	p<0.579

Values are expressed as Mean ± SEM
BMI - Body Mass Index
A1C - Hemoglobin A_{1c}
p values marked with bold reflects significance compared to no-insulin treated group
(Column *p* value shows overall repeated measures of ANOVA)

Table 11. Outcomes measures total cholesterol, LDL, HDL, and Triglycerides for patients with type 2 diabetes classified based on insulin or non-insulin treatment.

Characteristics	No Insulin N = 117	Insulin N= 126	p-value
Total Cholesterol (mg/dl)			
0 MONTHS	166.82 ± 3.27	171.57 ± 3.55	p<0.328
12 MONTHS	170.07 ± 3.15	166.3.4 ± 3.44	p<0.464
24 MONTHS	170.70 ± 3.02	165.48 ± 3.43	p<0.257
p-value	p<0.338	p<0.053	
LDL (mg/dl)			
0 MONTHS	91.43 ± 2.82	93.69 ± 2.91	p<0.578
12 MONTHS	93.54 ± 2.86	89.08 ± 2.77	p<0.264
24 MONTHS	92.71 ± 2.78	86.35 ± 2.86[$]	p<0.113
p-value	p<0.384	**p<0.015**	
HDL (mg/dl)			
0 MONTHS	48.92 ± 1.37	48.15 ± 1.23	p<0.674
12 MONTHS	49.31 ± 1.37	49.34 ± 1.42	p<0.989
24 MONTHS	49.64 ± 1.40	48.84 ± 1.30	p<0.676
p-value	p<0.569	p<0.298	
Triglyceride (mg/dl)			
0 MONTHS	131.03 ± 6.21	158.85 ± 10.93	**p<0.031**
12 MONTHS	134.00 ± 6.92	150.44 ± 8.41	p<0.136
24 MONTHS	139.62 ± 6.94	162.05 ± 11.41	p<0.100
p-value	p<0.327	p<0.272	

Values are expressed as Mean ± SEM
LDL- Low density Lipoprotein
HDL - High density Lipoprotein
p values marked with bold reflects significance compared to no insulin participants.
[$]Reflects significance taken at the 95% Confidence Interval compared to 0 Months.
(Column *p* value shows overall repeated measures of ANOVA)

Table 12. Outcomes measures BMI and weight for patients with type 2 diabetes classified based on A1C levels.

Characteristics	A1C ≤7	A1C 7 to 9	A1C ≥9	p-value
BMI – All participants				
0 MONTHS	34.32 ± 0.59	35.21 ± 1.02	35.66 ± 1.14	p<0.513
3 MONTHS	34.19 ± 0.61	35.31 ± 1.05	35.48 ± 1.10	p<0.478
6 MONTHS	34.32 ± 0.61	35.07 ± 0.99	35.34 ± 1.11	p<0.669
9 MONTHS	34.27 ± 0.60	34.95 ± 1.00	35.40 ± 1.10	p<0.644
12 MONTHS	34.18 ± 0.59	34.75 ± 0.97	35.62 ± 1.13	p<0.525
24 MONTHS	34.18 ± 0.56	35.13 ± 1.01	35.72 ± 1.07	p<0.397
p-value	p<0.854	p<0.394	p<0.690	
	N = 152	N= 53	N= 38	
BMI – EA participants				
0 MONTHS	34.38 ± 0.78	35.04 ± 1.31	34.66 ± 1.23	p<0.903
3 MONTHS	34.38 ± 0.80	34.84 ± 1.25	34.44 ± 1.21	p<0.954
6 MONTHS	34.35 ± 0.81	34.67 ± 1.22	34.24 ± 1.24	p<0.969
9 MONTHS	34.42 ± 0.81	34.42 ± 1.20	34.30 ± 1.23	p<0.997
12 MONTHS	34.36 ± 0.79	34.35 ± 1.14	34.48 ± 1.22	p<0.997
24 MONTHS	34.20 ± 0.74	34.93 ± 1.21	34.53 ± 1.17	p<0.870
p-value	p<0.876	p<0.364	p<0.750	
	N = 91	N= 33	N= 27	
BMI – AA participants				
0 MONTHS	34.69 ± 0.93	36.03 ± 1.64	38.11 ± 2.48	p<0.325
3 MONTHS	34.38 ± 1.02	36.68 ± 1.92	38.05 ± 2.27	p<0.256
6 MONTHS	34.89 ± 1.00	36.27 ± 1.73	38.05 ± 2.18	p<0.396
9 MONTHS	34.64 ± 0.96	36.37 ± 1.78	38.09 ± 2.19	p<0.300
12 MONTHS	34.52 ± 0.91	36.05 ± 1.75	38.43 ± 2.42	p<0.229
24 MONTHS	34.68 ± 0.89	36.03 ± 1.85	38.63 ± 2.18	p<0.222
p-value	p<0.673	p<0.533	p<0.731	
	N = 54	N= 19	N= 11	
BMI – Male participants				
0 MONTHS	33.83 ± 1.04	33.22 ± 1.41	33.11 ± 1.16	p<0.892
3 MONTHS	33.80 ± 1.07	33.40 ± 1.48	32.97 ± 1.04	p<0.896
6 MONTHS	34.03 ± 1.05	33.36 ± 1.46	33.06 ± 1.10	p<0.844
9 MONTHS	34.20 ± 1.07	33.12 ± 1.42	33.14 ± 1.06	p<0.757
12 MONTHS	34.20 ± 1.05	33.40 ± 1.44	33.26 ± 1.08	p<0.829
24 MONTHS	34.23 ± 1.04	33.54 ± 1.39	32.99 ± 0.87	p<0.759
p-value	p<0.260	p<0.637	p<0.932	
	N = 43	N= 22	N= 18	
BMI – Female participants				
0 MONTHS	34.51 ± 0.72	36.63 ± 1.38	37.96 ± 1.77	p<0.104
3 MONTHS	34.34 ± 0.74	36.67 ± 1.43	37.75 ± 1.75	p<0.106
6 MONTHS	34.44 ± 0.75	36.28 ± 1.32	37.40 ± 1.76	p<0.201

9 MONTHS	34.30 ± 0.73	36.24 ± 1.35	37.43 ± 1.76	p<0.158
12 MONTHS	34.18 ± 0.71	35.70 ± 1.30	37.75 ± 1.82	p<0.120
24 MONTHS	34.16 ± 0.66	36.26 ± 1.41	38.17 ± 1.73	**p<0.045**
p-value	p<0.676	p<0.306	p<0.465	
	N = 109	N= 31	N= 20	
BMI –Single/Unmarried				
0 MONTHS	35.67 ± 0.89	38.06 ± 1.68	37.02 ± 2.39	p<0.435
3 MONTHS	35.45 ± 0.94	39.12 ± 1.90	36.59 ± 2.25	p<0.198
6 MONTHS	35.75 ± 0.91	38.48 ± 1.71	36.52 ± 2.15	p<0.370
9 MONTHS	35.69 ± 0.88	38.62 ± 1.82	36.37 ± 2.23	p<0.317
12 MONTHS	35.72 ± 0.89	38.17 ± 1.60	36.60 ± 2.31	p<0.433
24 MONTHS	35.71 ± 0.88	39.09 ± 1.84	37.03 ± 2.00	p<0.201
p-value	p<0.850	**p<0.044**	p<0.635	
	N=53	N=17	N=13	
BMI – Married				
0 MONTHS	33.59 ± 0.77	33.86 ± 1.22	34.95 ± 1.23	p<0.713
3 MONTHS	33.51 ± 0.79	33.51 ± 1.17	34.91 ± 1.22	p<0.687
6 MONTHS	33.56 ± 0.80	33.46 ± 1.14	34.73 ± 1.28	p<0.762
9 MONTHS	33.51 ± 0.79	33.21 ± 1.09	34.90 ± 1.22	p<0.644
12 MONTHS	33.36 ± 0.75	33.13 ± 1.13	35.11 ± 1.26	p<0.503
24 MONTHS	33.36 ± 0.70	33.26 ± 1.10	35.03 ± 1.27	p<0.518
p-value	p<0.782	p<0.362	p<0.839	
	N=99	N=36	N=25	
BMI – No-insulin treated				
0 MONTHS	33.86 ± 0.68	34.75 ± 1.16	37.23 ± 2.50	p<0.360
3 MONTHS	33.72 ± 0.70	35.03 ± 1.20	36.50 ± 2.67	p<0.436
6 MONTHS	33.93 ± 0.70	34.45 ± 1.03	36.81 ± 2.95	p<0.512
9 MONTHS	33.88 ± 0.70	34.04 ± 1.06	36.70 ± 3.12	p<0.538
12 MONTHS	33.75 ± 0.67	33.48 ± 1.18	36.93 ± 2.95	p<0.419
24 MONTHS	34.26 ± 0.71	34.43 ± 1.15	36.57 ± 3.27	p<0.674
p-value	p<0.253	p<0.126	p<0.947	
	N = 90	N= 20	N= 7	
BMI –Insulin treated				
0 MONTHS	34.98 ± 1.06	35.49 ± 1.49	35.30 ± 1.29	p<0.955
3 MONTHS	34.86 ± 1.10	35.48 ± 1.54	35.25 ± 1.23	p<0.936
6 MONTHS	34.89 ± 1.11	35.45 ± 1.48	35.01 ± 1.20	p<0.951
9 MONTHS	34.85 ± 1.08	35.50 ± 1.47	35.11 ± 1.17	p<0.932
12 MONTHS	34.80 ± 1.05	35.51 ± 1.38	35.33 ± 1.24	p<0.904
24 MONTHS	34.07 ± 0.90	35.56 ± 1.48	35.52 ± 1.12	p<0.524
p-value	p<0.316	p<0.993	p<0.630	
	N = 62	N= 33	N= 31	
Weight (lb) – All participants				
0 MONTHS	211.62 ± 4.02	221.95 ± 7.57	225.35 ± 7.16	p<0.200
3 MONTHS	211.49 ± 4.05	222.44 ± 7.85	224.17 ± 7.06	p<0.220

6 MONTHS	211.73 ± 4.14	221.84 ± 7.74	223.89 ± 7.03	p<0.267
9 MONTHS	211.75 ± 4.12	220.31 ± 7.58	223.76 ± 6.99	p<0.316
12 MONTHS	211.19 ± 4.11	220.03 ± 7.58	226.54 ± 7.09	p<0.192
24 MONTHS	211.44 ± 4.07	221.60 ± 7.58	224.88 ± 6.74	p<0.214
p-value	p<0.944	p<0.825	p<0.459	
	N = 152	N= 53	N= 38	
Weight (lb) – EA participants				
0 MONTHS	216.06 ± 5.36	224.40 ± 9.48	224.79 ± 8.12	p<0.598
3 MONTHS	216.47 ± 5.38	224.62 ± 9.73	223.21 ± 8.07	p<0.671
6 MONTHS	216.25 ± 5.54	223.71 ± 9.54	222.82 ± 8.19	p<0.712
9 MONTHS	217.18 ± 5.56	221.98 ± 9.17	222.44 ± 8.10	p<0.841
12 MONTHS	216.79 ± 5.61	221.86 ± 9.04	225.15 ± 8.13	p<0.723
24 MONTHS	216.09 ± 5.51	224.68 ± 9.15	224.61 ± 7.63	p<0.597
p-value	p<0.867	p<0.455	p<0.606	
	N = 91	N= 33	N= 27	
Weight (lb) – AA participants				
0 MONTHS	208.97 ± 6.14	221.83 ± 12.84	226.72 ± 15.27	p<0.403
3 MONTHS	208.36 ± 6.34	222.93 ± 13.55	226.52 ± 14.87	p<0.375
6 MONTHS	209.89 ± 6.39	222.79 ± 13.52	226.51 ± 14.27	p<0.450
9 MONTHS	208.45 ± 6.24	222.16 ± 13.37	226.98 ± 14.31	p<0.375
12 MONTHS	207.66 ± 6.05	221.33 ± 13.76	229.96 ± 14.84	p<0.292
24 MONTHS	209.25 ± 6.18	220.49 ± 13.57	225.55 ± 14.47	p<0.489
p-value	p<0.660	p<0.662	p<0.364	
	N = 54	N= 19	N= 11	
Weight (lb) – Male participants				
0 MONTHS	235.84 ± 8.08	236.58 ± 13.63	231.57 ± 9.64	p<0.950
3 MONTHS	236.14 ± 8.02	237.81 ± 14.16	230.22 ± 9.10	p<0.898
6 MONTHS	237.43 ± 8.16	237.53 ± 14.09	230.77 ± 8.77	p<0.898
9 MONTHS	238.75 ± 8.26	235.78 ± 13.61	231.32 ± 8.62	p<0.885
12 MONTHS	239.33 ± 8.29	237.55 ± 13.66	233.81 ± 8.89	p<0.936
24 MONTHS	239.33 ± 8.44	237.89 ± 13.31	231.67 ± 7.85	p<0.876
p-value	p<0.146	p<0.692	p<0.695	
	N = 43	N= 22	N= 18	
Weight (lb) – Female participants				
0 MONTHS	202.07 ± 4.29	211.56 ± 8.29	219.75 ± 10.55	p<0.213
3 MONTHS	201.77 ± 4.36	211.53 ± 8.56	218.72 ± 10.70	p<0.241
6 MONTHS	201.60 ± 4.45	210.71 ± 8.30	217.69 ± 10.81	p<0.287
9 MONTHS	201.10 ± 4.36	209.33 ± 8.27	216.95 ± 10.77	p<0.303
12 MONTHS	200.09 ± 4.29	207.60 ± 8.07	220.01 ± 10.85	p<0.177
24 MONTHS	200.44 ± 4.18	210.04 ± 8.45	218.80 ± 10.70	p<0.186
p-value	p<0.554	p<0.396	p<0.585	
	N = 109	N= 31	N= 20	
Weight (lb) – Single/Unmarried				
0 MONTHS	214.60 ± 6.02	226.48 ± 9.97	221.06 ± 13.26	p<0.604

3 MONTHS	214.58 ± 5.99	229.25 ± 10.48	218.22 ± 12.33	p<0.486
6 MONTHS	215.11 ± 6.11	228.62 ± 10.25	217.61 ± 11.41	p<0.540
9 MONTHS	214.75 ± 6.00	228.21 ± 10.01	216.64 ± 11.84	p<0.533
12 MONTHS	215.08 ± 6.25	226.94 ± 9.33	219.82 ± 12.03	p<0.620
24 MONTHS	215.59 ± 6.35	230.79 ± 9.91	221.73 ± 11.05	p<0.464
p-value	p<0.884	p<0.110	p<0.472	
	N=53	N=17	N=13	
Weight (lb) –Married				
0 MONTHS	210.03 ± 5.27	219.81 ± 10.17	227.58 ± 8.59	p<0.281
3 MONTHS	209.84 ± 5.34	219.22 ± 10.49	227.26 ± 8.73	p<0.306
6 MONTHS	209.93 ± 5.46	218.64 ± 10.37	227.15 ± 8.98	p<0.332
9 MONTHS	210.14 ± 5.47	216.58 ± 10.14	227.46 ± 8.75	p<0.352
12 MONTHS	209.11 ± 5.37	216.77 ± 10.29	230.04 ± 8.88	p<0.216
24 MONTHS	209.22 ± 5.26	217.26 ± 10.13	226.52 ± 8.63	p<0.316
p-value	p<0.859	p<0.411	p<0.458	
	N=99	N=36	N=25	
Weight (lb) – No-insulin treated				
0 MONTHS	207.48 ± 4.75	217.53 ± 8.36	237.50 ± 16.56	p<0.171
3 MONTHS	208.07 ± 4.79	217.38 ± 8.28	234.27 ± 16.46	p<0.255
6 MONTHS	208.26 ± 4.84	215.40 ± 7.66	235.10 ± 16.86	p<0.272
9 MONTHS	208.49 ± 4.85	212.44 ± 7.75	237.02 ± 17.46	p<0.261
12 MONTHS	207.62 ± 4.80	209.89 ± 7.83	238.69 ± 16.58	p<0.201
24 MONTHS	210.43 ± 5.00	214.88 ± 7.80	236.74 ± 18.87	p<0.336
p-value	p<0.224	p<0.184	p<0.783	
Weight (lb) – Insulin treated				
0 MONTHS	217.63 ± 7.01	224.62 ± 11.12	222.61 ± 7.98	p<0.821
3 MONTHS	216.47 ± 7.08	225.50 ± 11.63	221.89 ± 7.89	p<0.744
6 MONTHS	216.78 ± 7.31	225.75 ± 11.57	221.35 ± 7.79	p<0.761
9 MONTHS	216.48 ± 7.26	225.08 ± 11.24	220.76 ± 7.65	p<0.772
12 MONTHS	216.37 ± 7.29	226.18 ± 11.17	223.80 ± 7.89	p<0.681
24 MONTHS	212.92 ± 6.90	225.67 ± 11.25	222.20 ± 7.17	p<0.504
p-value	p<0.281	p<0.821	p<0.586	

Values are expressed as Mean ± SEM
BMI - Body Mass Index
A1C - Hemoglobin A_{1c}
(*p* value shows overall repeated measures of ANOVA of all outcomes)

Table 13. Outcomes measures A1C for patients with type 2 diabetes classified based on A1C levels.

Characteristics	A1C ≤7	A1C 7 to 9	A1C ≥9	p-value
A1C (%) – All participants				
0 MONTHS	6.15 ± 0.04	7.76 ± 0.06*	10.18 ± 0.16*	**p<0.001**
3 MONTHS	6.20 ± 0.04	7.68 ± 0.11*	9.44 ± 0.29*	**p<0.001**
6 MONTHS	6.29 ± 0.06$	7.55 ± 0.13*	9.12 ± 0.28*$	**p<0.001**
9 MONTHS	6.29 ± 0.06$	7.62 ± 0.14*	8.95 ± 0.27*$	**p<0.001**
12 MONTHS	6.30 ± 0.06$	7.74 ± 0.16*	8.71 ± 0.28*$	**p<0.001**
24 MONTHS	6.46 ± 0.08$	7.70 ± 0.15*	8.85 ± 0.29*$	**p<0.001**
p-value	**p<0.001**	p<0.606	**p<0.001**	
	N = 152	N= 53	N= 38	
A1C (%) – EA participants				
0 MONTHS	6.10 ± 0.06	7.73 ± 0.08*	9.97 ± 0.17*	**p<0.001**
3 MONTHS	6.17 ± 0.06	7.63 ± 0.12*	8.96 ± 0.29*	**p<0.001**
6 MONTHS	6.28 ± 0.09	7.50 ± 0.14*	8.66 ± 0.29*$	**p<0.001**
9 MONTHS	6.29 ± 0.08	7.56 ± 0.20*	8.58 ± 0.30*$	**p<0.001**
12 MONTHS	6.31 ± 0.09	7.85 ± 0.22*	8.52 ± 0.31*$	**p<0.001**
24 MONTHS	6.42 ± 0.11	7.70 ± 0.19*	8.55 ± 0.36*$	**p<0.001**
p-value	**p<0.005**	p<0.464	**p<0.001**	
	N = 91	N= 33	N= 27	
A1C (%) – AA participants				
0 MONTHS	6.21 ± 0.06	7.83 ± 0.11*	10.68 ± 0.34*	**p<0.001**
3 MONTHS	6.25 ± 0.06	7.76 ± 0.22*	10.63 ± 0.56*	**p<0.001**
6 MONTHS	6.31 ± 0.06	7.65 ± 0.25*	10.25 ± 0.52*	**p<0.001**
9 MONTHS	6.31 ± 0.07	7.75 ± 0.21*	9.85 ± 0.52*	**p<0.001**
12 MONTHS	6.30 ± 0.08	7.63 ± 0.22*	9.18 ± 0.57*	**p<0.001**
24 MONTHS	6.55 ± 0.15	7.74 ± 0.25*	9.59 ± 0.44*	**p<0.001**
p-value	**p<0.026**	p<0.866	p<0.111	
	N = 54	N= 19	N= 11	
A1C (%) – Male participants				
0 MONTHS	6.17 ± 0.09	7.77 ± 0.11*	10.03 ± 0.24*	**p<0.001**
3 MONTHS	6.30 ± 0.10	7.60 ± 0.16*	8.42 ± 0.32*$	**p<0.001**
6 MONTHS	6.41 ± 0.15	7.64 ± 0.22*	8.26 ± 0.33*$	**p<0.001**
9 MONTHS	6.46 ± 0.12	7.66 ± 0.21*	8.56 ± 0.41*	**p<0.001**
12 MONTHS	6.51 ± 0.12$	7.73 ± 0.21*	8.50 ± 0.8*	**p<0.001**
24 MONTHS	6.79 ± 0.18$	7.71 ± 0.24*	8.45 ± 0.44*	**p<0.001**
p-value	**p<0.002**	p<0.905	**p<0.001**	
	N = 43	N= 22	N= 18	
A1C (%) – Female participants				
0 MONTHS	6.14 ± 0.05	7.75 ± 0.08*	10.31 ± 0.23*	**p<0.001**
3 MONTHS	6.17 ± 0.05	7.73 ± 0.15*	10.36 ± 0.35*	**p<0.001**
6 MONTHS	6.24 ± 0.06	7.49 ± 0.15*	9.90 ± 0.36*	**p<0.001**

9 MONTHS	6.23 ± 0.06	7.59 ± 0.20*	9.30 ± 0.36*	**p<0.001**
12 MONTHS	6.22 ± 0.07	7.75 ± 0.23*	8.91 ± 0.40*$	**p<0.001**
24 MONTHS	6.33 ± 0.09	7.70 ± 0.19*	9.21 ± 0.38*	**p<0.001**
p-value	**p<0.047**	p<0.605	**p<0.002**	
	N = 109	N= 31	N= 20	
A1C (%) – Single/Unmarried				
0 MONTHS	6.14 ± 0.07	7.77 ± 0.11*	10.56 ± 0.29*	**p<0.001**
3 MONTHS	6.15 ± 0.07	7.91 ± 0.25*	9.78 ± 0.57*	**p<0.001**
6 MONTHS	6.30 ± 0.10	7.64 ± 0.25*	9.63 ± 0.47*	**p<0.001**
9 MONTHS	6.22 ± 0.08	7.90 ± 0.32*	9.15 ± 0.49*	**p<0.001**
12 MONTHS	6.26 ± 0.10	8.22 ± 0.36*	8.61 ± 0.48*$	**p<0.001**
24 MONTHS	6.56 ± 0.17	7.88 ± 0.27*	9.26 ± 0.54*	**p<0.001**
p-value	**p<0.007**	p<0.481	**p<0.019**	
	N=53	N=17	N=13	
A1C (%) –Married				
0 MONTHS	6.15 ± 0.06	7.75 ± 0.08*	9.98 ± 0.19*	**p<0.001**
3 MONTHS	6.23 ± 0.06	7.57 ± 0.11*	9.26 ± 0.32*	**p<0.001**
6 MONTHS	6.28 ± 0.07	7.51 ± 0.14*	8.86 ± 0.34*$	**p<0.001**
9 MONTHS	6.33 ± 0.07$	7.49 ± 0.15*	8.84 ± 0.33*	**p<0.001**
12 MONTHS	6.33 ± 0.08$	7.52 ± 0.16*	8.77 ± 0.34*$	**p<0.001**
24 MONTHS	6.41 ± 0.09$	7.62 ± 0.18*	8.64 ± 0.34*$	**p<0.001**
p-value	**p<0.012**	p<0.465	**p<0.002**	
	N=99	N=36	N=25	
A1C (%) – No-insulin treated				
0 MONTHS	6.18 ± 0.05	7.72 ± 0.12*	10.64 ± 0.49*	**p<0.001**
3 MONTHS	6.22 ± 0.06	7.67 ± 0.13*	9.26 ± 0.95*	**p<0.001**
6 MONTHS	6.32 ± 0.07	7.58 ± 0.23*	9.20 ± 1.05*	**p<0.001**
9 MONTHS	6.31 ± 0.08	7.59 ± 0.25*	9.20 ± 1.05*	**p<0.001**
12 MONTHS	6.29 ± 0.07	7.35 ± 0.26*	8.81 ± 1.09*	**p<0.001**
24 MONTHS	6.51 ± 0.12$	7.62 ± 0.29*	8.82 ± 0.89*	**p<0.001**
p-value	**p<0.006**	p<0.620	p<0.234	
	N=90	N=20	N=7	
A1C (%) –Insulin treated				
0 MONTHS	6.10 ± 0.07	7.78 ± 0.07*	10.07 ± 0.17*	**p<0.001**
3 MONTHS	6.18 ± 0.07	7.68 ± 0.16*	9.48 ± 0.29*	**p<0.001**
6 MONTHS	6.24 ± 0.09	7.53 ± 0.15*	9.10 ± 0.26*$	**p<0.001**
9 MONTHS	6.26 ± 0.08	7.64 ± 0.18*	8.89 ± 0.25*$	**p<0.001**
12 MONTHS	6.32 ± 0.10	7.98 ± 0.20*	8.69 ± 0.25*$	**p<0.001**
24 MONTHS	6.40 ± 0.11	7.76 ± 0.16*	8.85 ± 0.30*$	**p<0.001**
p-value	**p<0.021**	p<0.143	**p<0.001**	
	N=62	N=33	N=31	

Values are expressed as Mean ± SEM
BMI - Body Mass Index
A1C - Hemoglobin A_{1c}

*Reflects significance taken at the 95% Confidence Interval compared to A1C ≤7 participants.
[$]Reflects significance compared to 0 Months by repeated measure of ANOVA.
(*p* value shows overall repeated measures of ANOVA of all outcomes)

Table 14. Outcomes measures BP for patients with type 2 diabetes classified based on A1C levels.

Characteristics	A1C ≤7	A1C 7 to 9	A1C ≥9	p-value
Systolic BP (mm Hg) – All participants				
0 MONTHS	130.05 ± 1.31	134.96 ± 2.44	143.08 ± 4.54*	**p<0.001**
3 MONTHS	131.71 ± 1.30	135.55 ± 2.45	135.76 ± 3.12	p<0.220
6 MONTHS	131.55 ± 1.43	136.60 ± 2.36	135.89 ± 3.39	p<0.139
9 MONTHS	133.13 ± 1.37	134.32 ± 2.69	135.08 ± 2.44	p<0.786
12 MONTHS	129.80 ± 1.38	136.81 ± 2.56*	138.26 ± 3.16*	**p<0.006**
24 MONTHS	132.01 ± 1.27	133.66 ± 2.47	137.97 ± 2.97	p<0.140
p-value	p<0.137	p<0.736	p<0.138	
	N = 152	N= 53	N= 38	
Systolic BP (mm Hg) – EA participants				
0 MONTHS	128.44 ± 1.68	133.55 ± 3.19	142.52 ± 5.10*	**p<0.003**
3 MONTHS	130.24 ± 1.70	136.03 ± 3.10	136.74 ± 4.03	p<0.113
6 MONTHS	129.22 ± 1.65	136.88 ± 2.92	136.56 ± 4.26	**p<0.035**
9 MONTHS	131.23 ± 1.65	133.58 ± 3.17	134.78 ± 2.84	p<0.539
12 MONTHS	127.69 ± 1.68	136.09 ± 3.36*	138.04 ± 3.79*	**p<0.007**
24 MONTHS	131.46 ± 1.67	133.58 ± 2.79	137.89 ± 3.24	p<0.190
p-value	p<0.175	p<0.735	p<0.366	
	N = 91	N= 33	N= 27	
Systolic BP (mm Hg) – AA participants				
0 MONTHS	133.41 ± 2.26	137.37 ± 4.00	144.45 ± 9.90	p<0.219
3 MONTHS	134.85 ± 2.14	135.21 ± 4.28	133.36 ± 4.45	p<0.953
6 MONTHS	136.94 ± 2.71	136.68 ± 4.28	134.27 ± 5.52	p<0.917
9 MONTHS	137.17 ± 2.50	135.84 ± 5.21	135.82 ± 4.95	p<0.955
12 MONTHS	133.76 ± 2.53	139.05 ± 4.07	138.82 ± 6.00	p<0.472
24 MONTHS	133.59 ± 2.08	134.11 ± 4.98	138.18 ± 6.79	p<0.741
p-value	p<0.412	p<0.895	p<0.551	
	N = 54	N= 19	N= 11	
Systolic BP (mm Hg) – Male participants				
0 MONTHS	131.07 ± 2.31	134.41 ± 3.52	149.83 ± 6.58*	**p<0.003**
3 MONTHS	130.33 ± 2.44	138.59 ± 4.17	140.67 ± 4.68	p<0.066
6 MONTHS	134.28 ± 2.59	141.45 ± 4.03	140.50 ± 5.53	p<0.274
9 MONTHS	132.93 ± 2.06	135.86 ± 3.49	137.17 ± 3.68	p<0.536
12 MONTHS	130.67 ± 2.45	140.05 ± 4.02	137.39 ± 4.74	p<0.105
24 MONTHS	134.42 ± 2.02	133.36 ± 2.91	137.33 ± 4.73	p<0.692
p-value	p<0.381	p<0.165	**p<0.038**	

	N = 43	N= 22	N= 18	
Systolic BP (mm Hg) – Female participants				
0 MONTHS	129.64 ± 1.59	135.35 ± 3.38	137.00 ± 6.12	p<0.131
3 MONTHS	132.26 ± 1.54	133.39 ± 2.95	131.35 ± 4.03	p<0.904
6 MONTHS	130.48 ± 1.71	133.16 ± 2.75	131.75 ± 3.98	p<0.740
9 MONTHS	133.20 ± 1.73	133.23 ± 3.91	133.20 ± 3.27	p<1.000
12 MONTHS	129.45 ± 1.67	134.52 ± 3.32	139.05 ± 4.33	p<0.056
24 MONTHS	131.06 ± 1.58	133.87 ± 3.72	138.55 ± 3.83	p<0.190
p-value	p<0.145	p<0.979	p<0.316	
	N = 109	N= 31	N= 20	
Systolic BP (mm Hg) – Single/Unmarried				
0 MONTHS	132.21 ± 2.23	139.82 ± 4.81	147.08 ± 8.31*	**p<0.039**
3 MONTHS	132.04 ± 2.28	142.41 ± 3.51	136.62 ± 5.57	p<0.085
6 MONTHS	131.96 ± 2.28	138.24 ± 3.23	135.15 ± 4.41	p<0.350
9 MONTHS	136.94 ± 2.52	136.71 ± 5.60	136.15 ± 3.51	p<0.991
12 MONTHS	131.79 ± 2.70	141.76 ± 4.10	143.85 ± 4.70	p<0.043
24 MONTHS	134.83 ± 2.21	141.06 ± 5.26	142.08 ± 2.94	p<0.220
p-value	p<0.177	p<0.799	p<0.273	
	N=53	N=17	N=13	
Systolic BP (mm Hg) –Married				
0 MONTHS	128.89 ± 1.62	132.67 ± 2.75	141.00 ± 5.47*	**p<0.014**
3 MONTHS	131.54 ± 1.59	132.31 ± 3.08	135.32 ± 3.83	p<0.611
6 MONTHS	131.33 ± 1.83	135.83 ± 3.15	136.28 ± 4.67	p<0.328
9 MONTHS	131.08 ± 1.58	133.19 ± 2.99	134.52 ± 3.27	p<0.578
12 MONTHS	128.73 ± 1.55	134.47 ± 3.20	135.36 ± 4.08	p<0.092
24 MONTHS	130.49 ± 1.53	130.17 ± 2.50	135.84 ± 4.23	p<0.308
p-value	p<0.349	p<0.434	p<0.564	
	N=99	N=36	N=25	
Systolic BP (mm Hg) – No-insulin treated				
0 MONTHS	128.64 ± 1.83	130.10 ± 2.79	135.14 ± 12.46	p<0.636
3 MONTHS	131.53 ± 1.74	130.95 ± 3.21	134.57 ± 9.18	p<0.881
6 MONTHS	130.83 ± 1.94	132.25 ± 3.06	138.57 ± 6.81	p<0.529
9 MONTHS	131.74 ± 1.76	132.15 ± 3.75	133.00 ± 5.99	p<0.979
12 MONTHS	127.68 ± 1.77	134.35 ± 3.55	136.43 ± 7.71	p<0.148
24 MONTHS	130.84 ± 1.70	124.40 ± 2.23	135.43 ± 7.47	p<0.160
p-value	p<0.134	p<0.093	p<0.979	
	N=90	N=20	N=7	
Systolic BP (mm Hg) – Insulin treated				
0 MONTHS	132.08 ± 1.80	137.91 ± 3.47	144.87 ± 4.86*	**p<0.013**
3 MONTHS	131.97 ± 1.97	138.33 ± 3.36	136.03 ± 3.30	p<0.206
6 MONTHS	132.60 ± 2.09	139.24 ± 3.26	135.29 ± 3.89	p<0.250
9 MONTHS	135.13 ± 2.15	135.64 ± 3.70	135.55 ± 2.71	p<0.989
12 MONTHS	132.87 ± 2.16	138.30 ± 3.52	138.68 ± 3.52	p<0.238
24 MONTHS	133.69 ± 1.88	139.27 ± 3.39	138.55 ± 3.28	p<0.226

p-value	p<0.680	p<0.880	p<0.098	
	N=62	N=33	N=31	
Diastolic BP (mm Hg) – All participants				
0 MONTHS	75.58 ± 0.82	75.68 ± 1.13	79.05 ± 1.45	p<0.126
3 MONTHS	76.79 ± 0.89	76.26 ± 1.28	77.24 ± 1.79	p<0.908
6 MONTHS	75.53 ± 0.88	77.34 ± 1.47	76.11 ± 1.81	p<0.578
9 MONTHS	77.07 ± 0.83	76.06 ± 1.46	77.08 ± 1.51	p<0.814
12 MONTHS	75.82 ± 0.75	76.06 ± 1.28	77.18 ± 1.54	p<0.722
24 MONTHS	75.64 ± 0.84	75.83 ± 1.45	75.92 ± 1.49	p<0.986
p-value	p<0.280	p<0.846	p<0.499	
	N = 152	N= 53	N= 38	
Diastolic BP (mm Hg) – EA participants				
0 MONTHS	74.21 ± 1.03	75.58 ± 1.53	77.67 ± 1.71	p<0.241
3 MONTHS	76.35 ± 1.20	76.73 ± 1.60	76.78 ± 2.14	p<0.976
6 MONTHS	73.52 ± 0.98	77.15 ± 2.02	75.15 ± 2.28	p<0.218
9 MONTHS	75.24 ± 0.97	76.06 ± 1.79	76.67± 1.81	p<0.764
12 MONTHS	74.26 ± 0.90	76.45 ± 1.63	76.81 ± 1.67	p<0.271
24 MONTHS	74.53 ± 1.08	76.55 ± 1.93	74.15 ± 1.71	p<0.571
p-value	p<0.167	p<0.960	p<0.558	
	N = 91	N= 33	N= 27	
Diastolic BP (mm Hg) – AA participants				
0 MONTHS	77.39 ± 1.42	75.42 ± 1.71	82.45 ± 2.58	p<0.157
3 MONTHS	78.24 ± 1.44	74.95 ± 2.21	78.36 ± 3.42	p<0.483
6 MONTHS	79.59 ± 1.66	77.53 ± 2.21	78.45 ± 2.84	p<0.782
9 MONTHS	80.56 ± 1.58	75.42 ± 2.61	78.09 ± 2.84	p<0.230
12 MONTHS	78.17 ± 1.38	75.26 ± 2.23	78.09 ± 3.48	p<0.558
24 MONTHS	77.89 ± 1.42	74.79 ± 2.33	80.27 ± 2.68	p<0.331
p-value	p<0.222	p<0.763	p<0.618	
	N = 54	N= 19	N= 11	
Diastolic BP (mm Hg) – Male participants				
0 MONTHS	76.40 ± 1.45	76.55 ± 1.64	79.17 ± 1.87	p<0.507
3 MONTHS	77.84 ± 1.63	79.09 ± 2.28	79.33 ± 2.64	p<0.846
6 MONTHS	75.05 ± 1.59	81.91 ± 2.43	76.89 ± 3.06	p<0.072
9 MONTHS	77.23 ± 1.24	79.95 ± 2.27	76.61 ± 2.50	p<0.453
12 MONTHS	75.84 ± 1.15	78.14 ± 1.77	77.44 ± 2.42	p<0.544
24 MONTHS	77.42 ± 1.53	79.00 ± 2.29	76.39 ± 2.32	p<0.711
p-value	p<0.505	p<0.177	p<0.774	
	N = 43	N= 22	N= 18	
Diastolic BP (mm Hg) – Female participants				
0 MONTHS	75.26 ± 0.99	75.06 ± 1.56	78.95 ± 2.23	p<0.297
3 MONTHS	76.38 ± 1.06	74.26 ± 1.39	75.35 ± 2.42	p<0.598
6 MONTHS	75.72 ± 1.06	74.10 ± 1.63	75.40 ± 2.13	p<0.752
9 MONTHS	77.01 ± 1.06	73.29 ± 1.77	77.50 ± 1.83	p<0.195
12 MONTHS	75.82 ± 0.95	74.58 ± 1.77	76.95 ± 2.00	p<0.688

24 MONTHS	74.94 ± 1.01	73.58 ± 1.80	75.50 ± 1.98	p<0.759
p-value	p<0.342	p<0.921	p<0.513	
	N = 109	N= 31	N= 20	
Diastolic BP (mm Hg) – Single/Unmarried				
0 MONTHS	76.34 ± 1.54	76.76 ± 2.05	80.31 ± 2.50	p<0.466
3 MONTHS	76.75 ± 1.53	75.47 ± 1.48	78.15 ± 3.46	p<0.788
6 MONTHS	76.83 ± 1.58	74.18 ± 2.15	78.69 ± 2.73	p<0.507
9 MONTHS	79.38 ± 1.59	75.47 ± 2.53	77.00 ± 2.68	p<0.414
12 MONTHS	76.74 ± 1.37	76.74 ± 1.37	76.24 ± 2.70	p<0.859
24 MONTHS	76.64 ± 1.55	75.29 ± 2.69	78.23 ± 2.16	p<0.761
p-value	p<0.328	p<0.938	p<0.924	
	N=53	N=17	N=13	
Diastolic BP (mm Hg) –Married				
0 MONTHS	75.17 ± 0.95	75.17 ± 1.37	78.40 ± 1.81	p<0.272
3 MONTHS	76.81 ± 1.10	76.64 ± 1.76	76.76 ± 2.09	p<0.997
6 MONTHS	74.83 ± 1.05	78.83 ± 1.88	74.76 ± 2.35	p<0.152
9 MONTHS	75.84 ± 0.94	76.33 ± 1.81	77.12 ± 1.86	p<0.833
12 MONTHS	75.33 ± 0.89	75.97 ± 1.42	76.64 ± 1.85	p<0.785
24 MONTHS	75.11 ± 1.00	76.08 ± 1.75	74.72 ± 1.96	p<0.845
p-value	p<0.454	p<0.266	p<0.469	
	N=99	N=36	N=25	
Diastolic BP (mm Hg) – No-insulin treated				
0 MONTHS	75.00 ± 1.07	74.85 ± 1.65	80.57 ± 3.90	p<0.343
3 MONTHS	76.19 ± 1.18	75.40 ± 1.72	83.43 ± 4.81	p<0.207
6 MONTHS	75.23 ± 1.16	78.05 ± 1.72	86.86 ± 3.80	p<0.016
9 MONTHS	77.00 ± 1.14	78.30 ± 2.15	85.14 ± 4.38	p<0.150
12 MONTHS	75.37 ± 0.94	78.05 ± 1.69	81.29 ± 4.24	p<0.139
24 MONTHS	75.26 ± 1.07	74.65 ± 2.04	82.57 ± 4.37	p<0.166
p-value	p<0.426	p<0.190	p<0.660	
	N=90	N=20	N=7	
Diastolic BP (mm Hg) –Insulin treated				
0 MONTHS	76.42 ± 1.27	76.18 ± 1.53	78.71 ± 1.57	p<0.474
3 MONTHS	77.66 ± 1.36	76.79 ± 1.78	75.84 ± 1.86	p<0.727
6 MONTHS	75.95 ± 1.35	76.91 ± 2.14	73.68 ± 1.80	p<0.477
9 MONTHS	77.18 ± 1.20	74.70 ± 1.94	75.26 ± 1.41	p<0.423
12 MONTHS	76.48 ± 1.25	74.85 ± 1.77	76.26 ± 1.61	p<0.727
24 MONTHS	76.21 ± 1.37	76.55 ± 1.99	74.42 ± 1.45	p<0.668
p-value	p<0.801	p<0.658	p<0.109	
	N=62	N=33	N=31	

Values are expressed as Mean ± SEM

BMI - Body Mass Index

A1C - Hemoglobin A_{1c}

*Reflects significance taken at the 95% Confidence Interval compared to A1C ≤7 participants.

(*p* value shows overall repeated measures of ANOVA of all outcomes)

Table 15. Outcomes measures total cholesterol, and Triglycerides for patients with type 2 diabetes classified based on A1C levels.

Characteristics	A1C ≤7	A1C 7 to 9	A1C ≥9	p-value
Total Cholesterol (mg/dl) – All participants				
0 MONTHS	167.82 ± 2.87	164.02 ± 4.79	182.50 ± 7.77	p<0.051
12 MONTHS	166.56 ± 2.88	163.83 ± 4.25	181.39 ± 7.25	**p<0.048**
24 MONTHS	167.93 ± 2.82	162.55 ± 5.01	175.84 ± 6.22	p<0.218
p-value	p<0.818	p<0.921	p<0.459	
	N = 152	N= 53	N= 38	
Total Cholesterol (mg/dl) – EA participants				
0 MONTHS	165.08 ± 3.69	163.64 ± 6.58	183.67 ± 10.22	p<0.079
12 MONTHS	167.44 ± 3.83	163.06 ± 5.57	180.11 ± 9.35	p<0.200
24 MONTHS	167.87 ± 3.72	159.15 ± 5.82	173.07 ± 8.33	p<0.316
p-value	p<0.655	p<0.600	p<0.344	
	N = 91	N= 33	N= 27	
Total Cholesterol (mg/dl) – AA participants				
0 MONTHS	170.83 ± 4.96	164.00 ± 7.09	179.64 ± 10.20	p<0.496
12 MONTHS	166.80 ± 4.73	166.47 ± 6.88	184.55 ± 10.64	p<0.271
24 MONTHS	169.11 ± 4.69	166.84 ± 9.65	182.64 ± 6.74	p<0.452
p-value	p<0.481	p<0.893	p<0.855	
	N = 54	N= 19	N= 11	
Total Cholesterol (mg/dl) – Male participants				
0 MONTHS	152.63 ± 4.73	157.68 ± 7.59	181.94 ± 12.74*	**p<0.028**
12 MONTHS	154.07 ± 4.73	159.32 ± 4.88	177.50 ± 12.62	p<0.067
24 MONTHS	155.91 ± 4.88	154.86 ± 5.38	167.94 ± 10.37	p<0.344
p-value	p<0.756	p<0.674	p<0.379	
	N = 43	N= 22	N= 18	
Total Cholesterol (mg/dl) – Female participants				
0 MONTHS	173.69 ± 3.38	168.52 ± 6.14	183.00 ± 9.61	p<0.378
12 MONTHS	171.49 ± 3.45	167.03 ± 6.39	184.90 ± 8.07	p<0.208
24 MONTHS	172.67 ± 3.34	168.00 ± 7.59	182.95 ± 7.14	p<0.348
p-value	p<0.745	p<0.959	p<0.942	
	N = 109	N= 31	N= 20	
Total Cholesterol (mg/dl) – Single/Unmarried				
0 MONTHS	167.85 ± 5.02	168.88 ± 8.34	191.08 ± 16.08	p<0.171
12 MONTHS	168.89 ± 4.73	166.24 ± 8.24	192.23 ± 14.24	p<0.108
24 MONTHS	169.09 ± 5.33	167.24 ± 8.79	185.92 ± 10.78	p<0.328
p-value	p<0.950	p<0.879	p<0.804	
	N=53	N=17	N=13	
Total Cholesterol (mg/dl) – Married				
0 MONTHS	167.80 ± 3.50	161.72 ± 5.89	178.04 ± 8.47	p<0.226
12 MONTHS	165.31 ± 3.64	162.69 ± 4.97	175.76 ± 8.17	p<0.335
24 MONTHS	167.30 ± 3.28	160.33 ± 6.15	170.60 ± 7.56	p<0.462

p-value	p<0.654	p<0.904	p<0.583	
	N=99	N=36	N=25	
Total Cholesterol (mg/dl) – No-insulin treated				
0 MONTHS	168.71 ± 3.71	160.85 ± 7.70	159.57 ± 16.43	p<0.576
12 MONTHS	169.54 ± 3.72	167.45 ± 5.93	184.29 ± 14.89	p<0.511
24 MONTHS	172.47 ± 3.61	161.25 ± 5.82	175.00 ± 10.01	p<0.361
p-value	p<0.655	p<0.593	p<0.281	
	N=90	N=20	N=7	
Total Cholesterol (mg/dl) – Insulin treated				
0 MONTHS	166.52 ± 4.55	165.94 ± 6.18	187.68 ± 8.61*	**p<0.033**
12 MONTHS	162.23 ± 4.53	161.64 ± 5.83	180.74 ± 8.34	p<0.063
24 MONTHS	161.34 ± 4.42	163.33 ± 7.30	176.03 ± 7.35	p<0.208
p-value	p<0.336	p<0.644	p<0.173	
	N=62	N=33	N=31	
Triglyceride (mg/dl) – All participants				
0 MONTHS	128.69 ± 5.83	155.06 ± 11.77	199.11 ± 28.37*	**p<0.001**
12 MONTHS	129.75 ± 5.96	143.51 ± 11.25	192.26 ± 18.84*	**p<0.001**
24 MONTHS	141.85 ± 6.74$	143.45 ± 11.53	199.71 ± 29.42*	**p<0.009**
p-value	**p<0.004**	p<0.436	p<0.892	
	N = 152	N= 53	N= 38	
Triglyceride (mg/dl) – EA participants				
0 MONTHS	147.46 ± 8.32	173.45 ± 16.13	231.93 ± 38.07*	**p<0.003**
12 MONTHS	149.70 ± 8.63	158.09 ± 15.58	218.41 ± 23.33*	**p<0.003**
24 MONTHS	165.99 ± 9.53$	155.12 ± 15.18	220.59 ± 40.11	p<0.073
p-value	**p<0.008**	p<0.335	p<0.832	
	N = 91	N= 33	N= 27	
Triglyceride (mg/dl) – AA participants				
0 MONTHS	99.89 ± 6.70	121.37 ± 14.65	118.55 ± 11.20	p<0.224
12 MONTHS	100.33 ± 5.98	119.95 ± 14.67	128.09 ± 21.94	p<0.168
24 MONTHS	100.61 ± 6.25	111.21 ± 11.76	148.45 ± 20.77*	**p<0.020**
p-value	p<0.986	p<0.709	p<0.303	
	N = 54	N= 19	N= 11	
Triglyceride (mg/dl) – Male participants				
0 MONTHS	158.42 ± 13.66	152.50 ± 18.32	253.67 ± 56.20*	**p<0.030**
12 MONTHS	161.30 ± 13.86	168.82 ± 21.50	224.56 ± 31.41	p<0.093
24 MONTHS	180.14 ± 16.11	145.59 ± 16.81	255.83 ± 58.74	p<0.054
p-value	p<0.092	p<0.374	p<0.690	
	N = 43	N= 22	N= 18	
Triglyceride (mg/dl) – Female participants				
0 MONTHS	116.96 ± 5.75	156.87 ± 15.61*	150.00 ± 12.90	**p<0.004**
12 MONTHS	117.30 ± 5.89	125.55 ± 10.93	163.20 ± 20.61*	**p<0.018**
24 MONTHS	126.74 ± 6.43	141.94 ± 15.93	149.20 ± 11.90	p<0.301
p-value	**p<0.048**	p<0.052	p<0.491	
	N = 109	N= 31	N= 20	
Triglyceride (mg/dl) – Single/Unmarried				

0 MONTHS	111.21 ± 7.07	165.47 ± 22.73*	155.38 ± 18.71	**p<0.004**
12 MONTHS	123.89 ± 8.23	138.47 ± 14.78	175.77 ± 27.76*	**p<0.051**
24 MONTHS	129.53 ± 8.94$	151.76 ± 22.06	172.00 ± 21.93	p<0.141
p-value	**p<0.012**	p<0.256	p<0.443	
	N=53	N=17	N=13	
Triglyceride (mg/dl) – Married				
0 MONTHS	138.05 ± 7.98	150.14 ± 13.76	221.84 ± 41.62*	**p<0.004**
12 MONTHS	132.89 ± 8.03	145.89 ± 15.13	200.84 ± 24.94*	**p<0.004**
24 MONTHS	148.44 ± 9.14$$	139.53 ± 13.58	214.12 ± 43.34*	**p<0.029**
p-value	**p<0.027**	p<0.723	p<0.738	
	N=99	N=36	N=25	
Triglyceride (mg/dl) – No-insulin treated				
0 MONTHS	124.83 ± 6.57	155.50 ± 15.97	140.71 ± 39.04	p<0.169
12 MONTHS	128.42 ± 7.63	157.75 ± 19.56	137.86 ± 23.86	p<0.284
24 MONTHS	135.50 ± 7.74	157.00 ± 19.70	142.86 ± 20.76	p<0.511
p-value	p<0.136	p<0.994	p<0.988	
	N=90	N=20	N=7	
Triglyceride (mg/dl) – Insulin treated				
0 MONTHS	134.29 ± 10.67	154.79 ± 16.43	212.29 ± 33.41*	**p<0.014**
12 MONTHS	131.68 ± 9.59	134.88 ± 13.65	204.55 ± 21.99*	**p<0.001**
24 MONTHS	151.06 ± 12.11$$	135.24 ± 14.21	212.55 ± 35.49**	**p<0.033**
p-value	**p<0.022**	p<0.103	p<0.882	
	N=62	N=33	N=31	

Values are expressed as Mean ± SEM
LDL- Low density Lipoprotein
HDL - High density Lipoprotein
*Reflects significance taken at the 95% Confidence Interval compared to A1C ≤7 participants by One way ANOVA.
$Reflects significance $p<0.05$ levels compared to 0 Months and $$ compared to 12 Months by repeated measure of ANOVA.
(*p* value shows overall repeated measures of ANOVA of all outcomes)

Table 16. Outcomes measures LDL and HDL for patients with type 2 diabetes classified based on A1C levels.

Characteristics	A1C ≤7	A1C 7 to 9	A1C ≥9	p-value
LDL (mg/dl) – All participants				
0 MONTHS	92.13 ± 2.50	87.92 ± 3.50	99.71 ± 6.33	p<0.135
12 MONTHS	90.76 ± 2.53	87.60 ± 3.69	100.62 ± 5.92	p<0.159
24 MONTHS	89.71 ± 2.56	83.62 ± 3.76	96.26 ± 5.46	p<0.132
p-value	p<0.559	p<0.328	p<0.642	
	N = 152	N= 53	N= 38	
LDL (mg/dl) – EA participants				
0 MONTHS	88.75 ± 3.28	85.21 ± 4.65	100.16 ± 8.83	p<0.200

12 MONTHS	90.23 ± 3.41	84.94 ± 4.46	96.92 ± 7.67	p<0.378
24 MONTHS	87.66 ± 3.37	80.03 ± 3.67	94.88 ± 7.44	p<0.189
p-value	p<0.621	p<0.328	p<0.771	
	N = 91	N= 33	N= 27	
LDL (mg/dl) – AA participants				
0 MONTHS	96.20 ± 4.11	92.53 ± 5.47	104.00 ± 9.13	p<0.578
12 MONTHS	92.83 ± 4.03	94.00 ± 6.50	106.82 ± 7.70	p<0.342
24 MONTHS	95.33 ± 4.21	90.26 ± 8.27	102.00 ± 7.33	p<0.613
p-value	p<0.538	p<0.808	p<0.753	
	N = 54	N= 19	N= 11	
LDL (mg/dl) – Male participants				
0 MONTHS	80.44 ± 4.29	84.50 ± 5.88	97.25 ± 10.62	p<0.191
12 MONTHS	79.52 ± 4.21	82.77 ± 3.80	96.13 ± 10.69	p<0.156
24 MONTHS	79.54 ± 4.64	80.64 ± 4.02	87.00 ± 8.75	p<0.666
p-value	p<0.963	p<0.645	p<0.298	
	N = 43	N= 22	N= 18	
LDL (mg/dl) – Female participants				
0 MONTHS	96.52 ± 2.94	90.35 ± 4.32	104.60 ± 8.67	p<0.271
12 MONTHS	94.75 ± 3.02	91.03 ± 5.68	102.95 ± 6.35	p<0.407
24 MONTHS	93.53 ± 2.98	85.74 ± 5.79	105.10 ± 6.93	p<0.102
p-value	p<0.548	p<0.410	p<0.920	
	N = 109	N= 31	N= 20	
LDL (mg/dl) – Single/Unmarried				
0 MONTHS	95.72 ± 4.43	93.59 ± 6.17	114.00 ± 13.06	p<0.184
12 MONTHS	95.79 ± 4.23	94.76 ± 6.90	106.17 ± 11.49	p<0.562
24 MONTHS	94.40 ± 4.86	89.88 ± 5.81	106.62 ± 10.01	p<0.380
p-value	p<0.932	p<0.509	p<0.807	
	N=53	N=17	N=13	
LDL (mg/dl) – Married				
0 MONTHS	90.16 ± 3.02	85.25 ± 4.23	94.17 ± 7.20	p<0.506
12 MONTHS	87.66 ± 3.13	84.22 ± 4.30	96.83 ± 6.53	p<0.279
24 MONTHS	87.14 ± 2.91	80.67 ± 4.78	91.65 ± 6.60	p<0.335
p-value	p<0.494	p<0.533	p<0.773	
	N=99	N=36	N=25	
LDL (mg/dl) – No-Insulin treated				
0 MONTHS	92.49 ± 3.31	87.85 ± 5.99	88.00 ± 11.92	p<0.793
12 MONTHS	93.00 ± 3.37	90.15 ± 5.53	110.14 ± 12.14	p<0.321
24 MONTHS	93.94 ± 3.39	84.70 ± 4.66	99.71 ± 8.51	p<0.381
p-value	p<0.869	p<0.598	p<0.166	
	N=90	N=20	N=7	
LDL (mg/dl) – Insulin treated				
0 MONTHS	91.58 ± 3.83	87.97 ± 4.36	104.55 ± 7.74	p<0.099
12 MONTHS	86.85 ± 3.79	86.06 ± 4.94	97.50 ± 6.57	p<0.254
24 MONTHS	83.35 ± 3.76	82.97 ± 5.39	96.41 ± 6.70	p<0.145
p-value	p<0.090	p<0.459	p<0.375	

	N=62	N=33	N=31	
HDL (mg/dl) – All participants				
0 MONTHS	50.94 ± 1.27	44.92 ± 1.49*	43.87 ± 1.65*	**p<0.003**
12 MONTHS	50.85 ± 1.35	47.55 ± 1.70$	45.74 ± 2.14	p<0.118
24 MONTHS	50.89 ± 1.31	48.08 ± 1.69$	44.18 ± 1.88*	**p<0.036**
p-value	p<0.989	**p<0.008**	p<0.263	
	N = 152	N= 53	N= 38	
HDL (mg/dl) – EA participants				
0 MONTHS	47.26 ± 1.60	43.55 ± 1.75	40.63 ± 1.50	p<0.053
12 MONTHS	47.37 ± 1.60	46.55 ± 2.08$	42.78 ± 1.96	p<0.316
24 MONTHS	47.45 ± 1.59	47.45 ± 2.02$	40.85 ± 1.70	p<0.075
p-value	p<0.972	**p<0.003**	p<0.155	
	N = 91	N= 33	N= 27	
HDL (mg/dl) – AA participants				
0 MONTHS	56.56 ± 2.01	47.11 ± 2.81*	51.82 ± 3.41	**p<0.038**
12 MONTHS	55.83 ± 2.35	48.47 ± 3.00	53.00 ± 5.15	p<0.245
24 MONTHS	55.74 ± 2.13	49.42 ± 3.20	52.36 ± 4.18	p<0.279
p-value	p<0.786	p<0.453	p<0.848	
	N = 54	N= 19	N= 11	
HDL (mg/dl) – Male participants				
0 MONTHS	42.14 ± 2.33	42.41 ± 2.43	38.89 ± 1.64	p<0.623
12 MONTHS	42.05 ± 2.29	42.77 ± 2.77	41.22 ± 2.10	p<0.936
24 MONTHS	40.88 ± 2.30	45.00 ± 2.83	39.11 ± 1.90	p<0.344
p-value	p<0.402	p<0.122	p<0.230	
	N = 43	N= 22	N= 18	
HDL (mg/dl) – Female participants				
0 MONTHS	54.41 ± 1.38	46.71 ± 1.84*	48.35 ± 2.39	**p<0.008**
12 MONTHS	54.32 ± 1.53	50.94 ± 1.95$	49.80 ± 3.39	p<0.317
24 MONTHS	54.83 ± 1.42	50.26 ± 2.02	48.75 ± 2.80	p<0.088
p-value	p<0.805	**p<0.018**	p<0.642	
	N = 109	N= 31	N= 20	
HDL (mg/dl) – Single/Unmarried				
0 MONTHS	51.75 ± 1.82	42.06 ± 1.69*	45.92 ± 2.89	**p<0.011**
12 MONTHS	50.38 ± 1.76	43.76 ± 1.61	46.31 ± 3.05	p<0.101
24 MONTHS	50.91 ± 1.51	46.00 ± 1.47	44.85 ± 2.78	p<0.066
p-value	p<0.503	**p<0.039**	p<0.823	
	N=53	N=17	N=13	
HDL (mg/dl) – Married				
0 MONTHS	50.51 ± 1.69	46.28 ± 2.02	42.80 ± 2.02	**p<0.049**
12 MONTHS	51.10 ± 1.85	49.33 ± 2.33$	45.44 ± 2.87	p<0.325
24 MONTHS	50.88 ± 1.84	49.06 ± 2.38	43.84 ± 2.50	p<0.172
p-value	p<0.758	p<0.057	p<0.165	
	N=99	N=36	N=25	
HDL (mg/dl) – No-insulin treated				
0 MONTHS	50.89 ± 1.66	41.95 ± 1.81*	43.57 ± 4.05	**p<0.030**

12 MONTHS	50.34 ± 1.66	45.70 ± 2.27[$]	46.43 ± 4.39	p<0.391
24 MONTHS	50.88 ± 1.71	45.15 ± 2.24	46.57 ± 4.02	p<0.268
p-value	p<0.713	**p<0.053**	p<0.388	
	N=90	N=20	N=7	
HDL (mg/dl) – Insulin treated				
0 MONTHS	51.02 ± 1.98	46.73 ± 2.08	43.94 ± 1.84*	**p<0.050**
12 MONTHS	51.58 ± 2.27	48.67 ± 2.36	45.58 ± 2.46	p<0.223
24 MONTHS	50.90 ± 2.04	49.85 ± 2.32	43.65 ± 2.14	p<0.070
p-value	p<0.831	p<0.079	p<0.325	
	N=62	N=33	N=31	

Values are expressed as Mean ± SEM

LDL- Low density Lipoprotein

HDL - High density Lipoprotein

*Reflects significance taken at the 95% Confidence Interval compared to A1C ≤7 Participants by One way ANOVA.

[$] Reflects significance $p<0.05$ levels compared to 0 Months by repeated measure of ANOVA. (*p* value shows overall repeated measures of ANOVA of all outcomes)

Table 17. Changes in the BMI, weight, blood pressure measurement and A1C from baseline to 3-,6-,9-,12- or 24-months of follow-up within three A1C groups.

Characteristics	A1C ≤7	A1C 7 to 9	A1C ≥9
BMI			
3 MONTHS	-0.145 (0.076)*	0.270 (0.098)*	0.013 (0.017)
6 MONTHS	-0.101 (0.054)	-0.006 (0.092)	0.032 (0.027)
9 MONTHS	-0.086 (0.058)	-0.124 (0.139)	0.016 (0.035)
12 MONTHS	-0.012 (0.066)	0.155 (0.173)	0.044 (0.031)
24 MONTHS	0.081 (0.0764)	0.426 (0.209)*	0.036 (0.045)
Weight (lb)			
3 MONTHS	-0.137 (0.067)*	0.150 (0.065)*	0.011 (0.015)
6 MONTHS	-0.112 (0.060)	0.056 (0.086)	0.016 (0.025)
9 MONTHS	-0.111 (0.050)*	0.009 (0.133)	0.017 (0.033)
12 MONTHS	-0.019 (0.068)	0.198 (0.153)	0.053 (0.029)
24 MONTHS	-0.030 (0.079)	0.369 (0.188)*	0.059 (0.035)
A1C (%)			
3 MONTHS	-0.242 (0.091)*	0.222 (0.314)	-0.032 (0.056)
6 MONTHS	-0.289 (0.138)*	-0168 (0.455)	-0.135 (0.095)
9 MONTHS	-0.376 (0.117)*	-0.135 (0.462)	-0.232 (0.113)*
12 MONTHS	-0.371 (0.135)*	-0.490 (0.408)	-0.297 (0.107)*
24 MONTHS	-0.248 (0.244)	-0.571 (0.513)	-0.048 (0.126)
Systolic BP (mm Hg)			
3 MONTHS	0.207 (0.154)	0.118 (0.254)	-0.287 (0.074)*
6 MONTHS	0.266 (0.168)	0.670 (0.305)*	-0.138 (0.081)
9 MONTHS	0.306 (0.132)	-0.513 (0.284)	-0.422 (0.089)*
12 MONTHS	0.104 (0.124)	0.437 (0.346)	-0.308 (0.077)*
24 MONTHS	0.037 (0.151)	0.850 (0.367)*	0.054 (0.095)

Diastolic BP (mm Hg)			
3 MONTHS	-0.270 (0.215)	-0.138 (0.308)	-0.041 (0.075)
6 MONTHS	-0.079 (0.196)	0.059 (0.323)	0.050 (0.087)
9 MONTHS	-0.055 (0.193)	-0.970 (0.291)*	-0.112 (0.080)
12 MONTHS	-0.303 (0.152)*	-0.537 (0.299)	-0.152 (0.067)*
24 MONTHS	-0.316 (0.205)	0.194 (0.296)	-0.010 (0.072)

Results from the Generalized Estimated Equation adjusted for gender and race with respect to base line parameters that is compared to 0 Months to 3, 6, 9, 12 and 24 Months. Values are expressed as β coefficient (SE) within each group compared to baseline levels. *Reflects significance taken at the $p<0.05$ levels compared to 0 months.
BMI - Body Mass Index; A1C - Hemoglobin A_{1c}; BP – Blood pressure

Table 18. Changes in the total cholesterol, LDL, HDL, and Triglycerides from baseline to 12- or 24-months of follow-up within three A1C groups.

	A1C ≤7	A1C 7 to 9	A1C ≥9
Cholesterol			
12 MONTHS	0.199 (0.173)	-0.952 (0.450)*	-0.146 (0.124)
24 MONTHS	0.370 (0.234)	-0.862 (0.470)	-0.184 (0.101)
LDL			
12 MONTHS	-0.328 (0.353)	-0.348 (0.790)	-0.083 (0.180)
24 MONTHS	-0.357 (0.432)	-0.020 (0.845)	-0.005 (0.162)
HDL			
12 MONTHS	0.504 (0.210)*	-0.992 (0.336)*	0.101 (0.110)
24 MONTHS	0.248 (0.215)	-0.824 (0.420)*	0.253 (0.083)*
Triglyceride			
12 MONTHS	0.149 (0.596)	-1.776 (1.249)	-0.615 (0.240)*
24 MONTHS	1.376 (0.690)*	-3.006 (0.961)*	-0.587 (0.171)*

Results from the Generalized Estimated Equation adjusted for gender and race with respect to base line parameters that is compared to 0 Months to 12 and 24 Months. Values are expressed as β coefficient (SE) within each group compared to baseline levels. *Reflects significance taken at the $p<0.05$ levels compared to 0 months.
LDL- Low density Lipoprotein; HDL - High density Lipoprotein

Table 19. Outcomes measures BMI and weight for patients with type 2 diabetes in four obese groups

Characteristics	Non-Obese	Class I Obese	Class II Obese	Class III Obese	p-value
BMI – All Participants					
0 MONTHS	26.84 ± 0.28	32.69 ± 0.17*	37.00 ± 0.18*	45.76 ± 0.74*	**p<0.001**
3 MONTHS	26.79 ± 0.30	32.68 ± 0.22*	36.97 ± 0.26*	45.44 ± 0.91*	**p<0.001**
6 MONTHS	26.82 ± 0.32	32.76 ± 0.24*	36.88 ± 0.32*	45.41 ± 0.83*	**p<0.001**
9 MONTHS	26.85 ± 0.33	32.90 ± 0.24*	36.67 ± 0.34*	45.18 ± 0.83*	**p<0.001**
12 MONTHS	26.98 ± 0.34	32.98 ± 0.25*	36.56 ± 0.32*	44.70 ± 0.87*	**p<0.001**
24 MONTHS	27.34 ± 0.36	33.20 ± 0.31*	36.93 ± 0.35*	43.97 ± 0.87*	**p<0.001**
p-value	p<0.068	p<0.05	p<0.316	p<0.149	
	N = 67	**N= 72**	**N= 54**	**N=50**	
BMI – EA Participants					
0 MONTHS	26.95 ± 0.29	32.76 ± 0.20*	36.85 ± 0.20*	46.16 ± 1.05*	**p<0.001**
3 MONTHS	27.02 ± 0.29	32.69 ± 0.27*	36.62 ± 0.31*	46.00 ± 1.09*	**p<0.001**
6 MONTHS	27.04 ± 0.32	32.63 ± 0.30*	36.34 ± 0.37*	45.91 ± 1.15*	**p<0.001**
9 MONTHS	27.10 ± 0.33	32.76 ± 0.29*	36.32 ± 0.43*	45.63 ± 1.18*	**p<0.001**
12 MONTHS	27.35 ± 0.32	32.85 ± 0.30*	36.43 ± 0.41*	44.87 ± 1.32*	**p<0.001**
24 MONTHS	27.53 ± 0.39	32.99 ± 0.36*	36.80 ± 0.45*	44.19 ± 1.19*	**p<0.001**
p-value	p<0.191	p<0.510	p<0.356	p<0.257	
	N = 43	**N= 46**	**N= 33**	**N=29**	
BMI – AA Participants					
0 MONTHS	27.08 ± 0.68	32.49 ± 0.30*	37.34 ± 0.32*	45.19 ± 1.08*	**p<0.001**
3 MONTHS	26.72 ± 0.79	32.56 ± 0.40*	37.59 ± 0.47*	44.94 ± 1.63*	**p<0.001**
6 MONTHS	26.82 ± 0.80	32.91 ± 0.41*	37.85 ± 0.54*	45.12 ± 1.20*	**p<0.001**
9 MONTHS	26.84 ± 0.84	33.02 ± 0.41*	37.34 ± 0.54*	44.93 ± 1.13*	**p<0.001**
12 MONTHS	26.83 ± 0.86	33.15 ± 0.44*	36.85 ± 0.52*	44.84 ± 1.00*	**p<0.001**
24 MONTHS	27.42 ± 0.86	33.51 ± 0.58*	37.22 ± 0.60*	43.94 ± 1.34*	**p<0.001**
p-value	p<0.255	p<0.065	p<0.126	p<0.631	
	N = 19	**N= 25**	**N= 20**	**N=20**	
BMI – Male Participants					
0 MONTHS	27.10 ± 0.39	32.79 ± 0.25*	36.51 ± 0.31*	44.33 ± 1.13*	**p<0.001**
3 MONTHS	27.31 ± 0.40	32.68 ± 0.34*	36.22 ± 0.55*	44.45 ± 1.33*	**p<0.001**
6 MONTHS	27.46 ± 0.40	33.03 ± 0.35*	36.14 ± 0.66*	44.28 ± 1.38*	**p<0.001**
9 MONTHS	27.63 ± 0.43	33.00 ± 0.36*	36.21 ± 0.83*	44.21 ± 1.44*	**p<0.001**
12 MONTHS	27.90 ± 0.44	33.15 ± 0.39*	35.95 ± 0.76*	44.23 ± 1.50*	**p<0.001**
24 MONTHS	28.39 ± 0.48	32.82 ± 0.44*	36.09 ± 0.60*	43.78 ± 1.54*	**p<0.001**
p-value	**p<0.004**	p<0.377	p<0.794	p<0.710	
	N=27	**N=28**	**N=14**	**N=14**	
BMI – Female Participants					
0 MONTHS	26.66 ± 0.39	32.62 ± 0.22*	37.17 ± 0.21*	46.31 ± 0.93*	**p<0.001**
3 MONTHS	26.44 ± 0.42	32.68 ± 0.30*	37.23 ± 0.29*	45.83 ± 1.16*	**p<0.001**
6 MONTHS	26.39 ± 0.45	32.59 ± 0.33*	37.14 ± 0.35*	45.86 ± 1.02*	**p<0.001**

9 MONTHS	26.33 ± 0.45	32.83 ± 0.31*	36.83 ± 0.36*	45.56 ± 1.02*	**p<0.001**
12 MONTHS	26.35 ± 0.46	32.87 ± 0.32*	36.77 ± 0.34*	44.89 ± 1.07*	**p<0.001**
24 MONTHS	26.63 ± 0.48	33.44 ± 0.41*	37.23 ± 0.42*	44.04 ± 1.07*	**p<0.001**
p-value	p<0.527	**p<0.020**	p<0.301	p<0.199	
	N=40	**N=44**	**N=40**	**N=36**	
BMI – Single/Unmarried Participants					
0 MONTHS	27.18 ± 0.49	33.24 ± 0.30*	37.21 ± 0.28*	45.50 ± 1.02*	**p<0.001**
3 MONTHS	27.19 ± 0.54	33.60 ± 0.37*	37.28 ± 0.41*	45.10 ± 1.57*	**p<0.001**
6 MONTHS	27.61 ± 0.51	33.45 ± 0.43*	37.19 ± 0.44*	45.22 ± 1.17*	**p<0.001**
9 MONTHS	27.52 ± 0.50	33.64 ± 0.45*	36.84 ± 0.46*	45.40 ± 1.10*	**p<0.001**
12 MONTHS	27.42 ± 0.48	33.58 ± 0.56*	36.93 ± 0.43*	45.29 ± 0.91*	**p<0.001**
24 MONTHS	27.96 ± 0.50	34.08 ± 0.61*	37.37 ± 0.46*	44.82 ± 1.30*	**p<0.001**
p-value	p<0.828	p<0.149	p<0.423	p<0.886	
	N=16	**N=21**	**N=25**	**N=21**	
BMI – Married Participants					
0 MONTHS	26.73 ± 0.33	32.46 ± 0.19*	36.82 ± 0.22*	45.94 ± 1.06*	**p<0.001**
3 MONTHS	26.67 ± 0.36	32.30 ± 0.26*	36.70 ± 0.33*	45.69 ± 1.11*	**p<0.001**
6 MONTHS	26.58 ± 0.38	32.48 ± 0.28*	36.62 ± 0.45*	45.55 ± 1.17*	**p<0.001**
9 MONTHS	26.65 ± 0.40	32.59 ± 0.27*	36.52 ± 0.49*	45.02 ± 1.21*	**p<0.001**
12 MONTHS	26.84 ± 0.41	32.73 ± 0.26*	36.24 ± 0.46*	44.28 ± 1.35*	**p<0.001**
24 MONTHS	27.14 ± 0.44	32.84 ± 0.34*	36.56 ± 0.52*	43.34 ± 1.18*	**p<0.001**
p-value	p<0.153	p<0.189	p<0.584	p<0.099	
	N=51	**N=51**	**N=29**	**N=29**	
BMI – No-insulin treated					
0 MONTHS	27.12 ± 0.40	32.70 ± 0.23*	36.96 ± 0.28*	43.88 ± 0.73*	**p<0.001**
3 MONTHS	27.08 ± 0.39	32.74 ± 0.32*	36.95 ± 0.37*	43.35 ± 1.22*	**p<0.001**
6 MONTHS	27.19 ± 0.43	32.78 ± 0.30*	36.63 ± 0.43*	43.95 ± 0.91*	**p<0.001**
9 MONTHS	27.31 ± 0.45	32.62 ± 0.32*	36.21 ± 0.43*	43.90 ± 1.04*	**p<0.001**
12 MONTHS	27.36 ± 0.49	32.66 ± 0.32*	36.25 ± 0.39*	42.77 ± 1.28*	**p<0.001**
24 MONTHS	27.81 ± 0.50	32.71 ± 0.40*	37.19 ± 0.48*[$$]	43.70 ± 1.29*	**p<0.001**
p-value	p<0.102	p<0.917	**p<0.021**	p<0.620	
	N=33	**N=35**	**N=27**	**N=22**	
BMI –Insulin treated					
0 MONTHS	26.57 ± 0.39	32.67 ± 0.25*	37.04 ± 0.22*	47.23 ± 1.13*	**p<0.001**
3 MONTHS	26.51 ± 0.45	32.62 ± 0.31*	36.99 ± 0.37*	47.08 ± 1.25*	**p<0.001**
6 MONTHS	26.47 ± 0.46	32.74 ± 0.37*	37.14 ± 0.47*	46.56 ± 1.27*	**p<0.001**
9 MONTHS	26.41 ± 0.47	33.16 ± 0.35*	37.12 ± 0.51*	46.18 ± 1.22*	**p<0.001**
12 MONTHS	26.60 ± 0.46	33.27 ± 0.37*	36.86 ± 0.50*	46.22 ± 1.11*	**p<0.001**
24 MONTHS	26.89 ± 0.50	33.66 ± 0.45*	36.68 ± 0.51*	44.17 ± 1.21*	**p<0.001**
p-value	p<0.488	**p<0.004**	p<0.667	p<0.091	
	N=34	**N=37**	**N=27**	**N=28**	
Weight (lb) – All participants					
0 MONTHS	167.80 ± 3.12	206.63 ± 3.54*	228.27 ± 3.57*	280.93 ± 5.85*	**p<0.001**
3 MONTHS	167.69 ± 3.28	206.66 ± 3.56*	227.51 ± 3.54*	281.08 ± 6.18*	**p<0.001**

6 MONTHS	167.82 ± 3.34	207.25 ± 3.72*	227.20 ± 3.82*	280.29 ± 6.32*	**p<0.001**
9 MONTHS	168.14 ± 3.42	208.14 ± 3.67*	225.88 ± 3.99*	278.32 ± 6.37*	**p<0.001**
12 MONTHS	168.64 ± 3.52	208.86 ± 3.79 *	226.16 ± 3.83*	276.44 ± 6.82*	**p<0.001**
24 MONTHS	170.41 ± 3.61	208.69 ± 3.77*	228.01 ± 3.76*	273.48 ± 7.10*	**p<0.001**
p-value	p<0.183	p<0.085	p<0.358	p<0.142	
Weight (lb) – EA participants					
0 MONTHS	173.84 ± 3.91	210.83 ± 4.53*	230.51 ± 4.51*	288.15 ± 8.15*	**p<0.001**
3 MONTHS	174.60 ± 4.05	210.62 ± 4.51*	228.65 ± 4.47*	289.53 ± 8.36*	**p<0.001**
6 MONTHS	174.77 ± 4.13	210.30 ± 4.83*	227.74 ± 5.11*	288.74 ± 8.50*	**p<0.001**
9 MONTHS	175.53 ± 4.17	211.24 ± 4.68*	227.36 ± 5.42*	287.14 ± 8.61*	**p<0.001**
12 MONTHS	176.62 ± 4.26	212.34 ± 4.92*	229.13 ± 5.25*	282.93 ± 9.82*	**p<0.001**
24 MONTHS	177.22 ± 4.53	212.12 ± 4.93*	230.63 ± 4.95*	281.20 ± 9.50*	**p<0.001**
p-value	p<0.255	p<0.451	p<0.355	p<0.261	
Weight (lb) – AA participants					
0 MONTHS	161.29 ± 4.95	199.13 ± 5.67*	226.24 ± 5.97*	271.26 ± 8.31*	**p<0.001**
3 MONTHS	159.12 ± 5.48	199.43 ± 5.88*	227.04 ± 6.07*	271.44 ± 8.90*	**p<0.001**
6 MONTHS	159.62 ± 5.53	201.79 ± 5.94*	227.76 ± 5.93*	271.30 ± 9.09*	**p<0.001**
9 MONTHS	159.71 ± 5.70	202.36 ± 6.12*	225.07 ± 5.94*	268.95 ± 8.97*	**p<0.001**
12 MONTHS	159.01 ± 5.87	202.81 ± 6.02*	222.86 ± 5.47*	270.00 ± 8.90*	**p<0.001**
24 MONTHS	162.62 ± 6.08	202.85 ± 5.90*	225.22 ± 5.92*	265.21 ± 10.73*	**p<0.001**
p-value	p<0.296	p<0.042	p<0.141	p<0.496	
Weight (lb) – Male participants					
0 MONTHS	187.56 ± 3.67	229.43 ± 5.31*	257.21 ± 5.63*	316.08 ± 13.95*	**p<0.001**
3 MONTHS	189.49 ± 3.80	228.64 ± 5.28*	253.95 ± 5.80*	318.31 ± 14.49*	**p<0.001**
6 MONTHS	190.48 ± 3.66	230.01 ± 5.54*	254.80 ± 6.63*	317.05 ± 15.11*	**p<0.001**
9 MONTHS	191.63 ± 3.90	230.18 ± 5.32*	254.11 ± 7.29*	317.18 ± 14.73*	**p<0.001**
12 MONTHS	193.73 ± 4.09	231.40 ± 5.77*	254.89 ± 6.60*	317.66 ± 15.38*	**p<0.001**
24 MONTHS	195.76 ± 4.16	229.05 ± 5.97*	254.94 ± 6.85*	316.14 ± 15.29*	**p<0.001**
p-value	**p<0.010**	p<0.527	p<0.785	p<0.875	
Weight (lb) – Female participants					
0 MONTHS	154.46 ± 3.18	192.12 ± 3.16*	218.14 ± 3.08*	267.26 ± 4.40*	**p<0.001**
3 MONTHS	152.98 ± 3.20	192.67 ± 3.38*	218.26 ± 3.27*	266.60 ± 4.75*	**p<0.001**
6 MONTHS	152.52 ± 3.26	192.76 ± 3.54*	217.54 ± 3.53*	265.99 ± 4.89*	**p<0.001**
9 MONTHS	152.29 ± 3.21	194.11 ± 3.66*	216.00 ± 3.66*	263.21 ± 4.93*	**p<0.001**
12 MONTHS	151.71 ± 3.04	194.52 ± 3.63*	216.10 ± 3.44*	260.41 ± 5.49*	**p<0.001**
24 MONTHS	153.30 ± 3.24	195.73 ± 3.76*	218.59 ± 3.42*	256.89 ± 6.02*	**p<0.001**
p-value	p<0.380	**p<0.043**	p<0.304	p<0.134	
Weight (lb) – Single/Unmarried participants					
0 MONTHS	170.49 ± 6.62	198.67 ± 5.54*	222.44 ± 4.82*	268.40 ± 7.10*	**p<0.001**
3 MONTHS	170.37 ± 6.61	201.29 ± 5.94*	221.71 ± 4.82*	167.19 ± 7.33*	**p<0.001**
6 MONTHS	172.41 ± 6.19	200.77 ± 6.32*	221.62 ± 5.05*	266.72 ± 7.42*	**p<0.001**
9 MONTHS	171.87 ± 6.15	201.87 ± 6.43*	220.03 ± 4.93*	266.10 ± 7.14*	**p<0.001**
12 MONTHS	170.97 ± 5.69	201.70 ± 7.08*	221.23 ± 5.01*	267.29 ± 6.83*	**p<0.001**
24 MONTHS	174.66 ± 5.71	204.45 ± 7.36*	223.51 ± 4.92*	264.60 ± 9.10*	**p<0.001**

p-value	p<0.630	p<0.113	p<0.419	p<0.794	
Weight (lb) – Married participants					
0 MONTHS	166.95 ± 3.56	209.90 ± 4.40*	233.29 ± 5.07*	290.00 ± 8.38*	**p<0.001**
3 MONTHS	166.85 ± 3.81	208.87 ± 4.39*	232.52 ± 5.02*	291.14 ± 8.88*	**p<0.001**
6 MONTHS	166.38 ± 3.94	209.92 ± 4.54*	232.01 ± 5.56*	290.11 ± 9.16*	**p<0.001**
9 MONTHS	166.98 ± 4.07	210.72 ± 4.45*	230.92 ± 6.02*	287.18 ± 9.46*	**p<0.001**
12 MONTHS	167.91 ± 4.28	211.81 ± 4.47*	230.41 ± 5.64*	283.07 ± 10.61*	**p<0.001**
24 MONTHS	169.08 ± 4.40	210.43 ± 4.40*	231.90 ± 5.56*	279.91 ± 10.29*	**p<0.001**
p-value	p<0.340	p<0.201	p<0.635	p<0.072	
Weight (lb) – No-insulin treated					
0 MONTHS	167.04 ± 4.34	201.87 ± 4.97*	229.73 ± 5.12*	268.46 ± 4.41*	**p<0.001**
3 MONTHS	167.62 ± 4.51	202.31 ± 5.00*	229.15 ± 5.11*	268.84 ± 4.66*	**p<0.001**
6 MONTHS	168.07 ± 4.70	202.52 ± 5.06*	227.81 ± 5.10*	268.70 ± 4.83*	**p<0.001**
9 MONTHS	168.81 ± 4.98	202.52 ± 5.12*	225.76 ± 5.10*	268.99 ± 5.31*	**p<0.001**
12 MONTHS	168.92 ± 5.14	202.95 ± 5.27*	226.03 ± 4.75*	262.45 ± 7.25*	**p<0.001**
24 MONTHS	170.98 ± 5.32	202.54 ± 5.44*	231.43 ± 5.04*	268.80 ± 6.66*	**p<0.001**
p-value	p<0.221	p<0.900	p<0.051	p<0.531	
Weight (lb) – Insulin treated					
0 MONTHS	168.54 ± 4.53	211.13 ± 4.98*	226.81 ± 5.04*	290.73 ± 9.54*	**p<0.001**
3 MONTHS	167.76 ± 4.83	210.78 ± 5.04*	225.88 ± 4.99*	290.70 ± 10.13*	**p<0.001**
6 MONTHS	167.57 ± 4.81	211.72 ± 5.38*	226.59 ± 5.79*	289.40 ± 10.41*	**p<0.001**
9 MONTHS	167.50 ± 4.77	213.45 ± 5.18*	225.99 ± 6.25*	285.66 ± 10.48*	**p<0.001**
12 MONTHS	168.36 ± 4.88	214.45 ± 5.34*	226.28 ± 6.11*	287.44 ± 10.42*	**p<0.001**
24 MONTHS	169.86 ± 4.97	214.50 ± 5.12*	224.60 ± 5.60*	277.16 ± 11.63*	**p<0.001**
p-value	p<0.571	**p<0.048**	p<0.769	p<0.053	

Values are expressed as Mean ± SEM
BMI - Body Mass Index
A1C - Hemoglobin A_{1c}
*Reflects significance taken at the 95% Confidence Interval compared to non-obese participants.
$^{\$\$}$Reflects significance taken at the 95% Confidence Interval compared to 12 Months.
(Column *p* value shows overall repeated measures of ANOVA)

Table 20. Outcomes measures BMI and A1C for patients with type 2 diabetes in four BMI groups

Characteristics	Non-Obese	Class I Obese	Class II Obese	Class III Obese	p-value
A1C – All Participants					
0 MONTHS	6.81 ± 0.18	7.23 ± 0.19	7.22 ± 0.21	7.31 ± 0.25	p<0.279
3 MONTHS	6.72 ± 0.14	7.01 ± 0.18	7.11 ± 0.20	7.40 ± 0.25	p<0.108
6 MONTHS	6.73 ± 0.14	6.99 ± 0.16	6.98 ± 0.19	7.42 ± 0.25*	p<0.079
9 MONTHS	6.75 ± 0.14	7.03 ± 0.16	7.03 ± 0.19	7.25 ± 0.25	p<0.288
12 MONTHS	6.76 ± 0.15	7.08 ± 0.16	7.00 ± 0.20	7.18 ± 0.22	p<0.403
24 MONTHS	6.84 ± 0.15	7.13 ± 0.17	7.24 ± 0.21	7.28 ± 0.25	p<0.354

p-value	p<0.647	p<0.391	p<0.181	p<0.647	
	N = 67	**N= 72**	**N= 54**	**N=50**	
A1C – EA Participants					
0 MONTHS	6.90 ± 0.24	7.20 ± 0.24	7.51 ± 0.29	7.01 ± 0.29	p<0.402
3 MONTHS	6.75 ± 0.18	6.90 ± 0.21	7.32 ± 0.27	7.13 ± 0.27	p<0.299
6 MONTHS	6.79 ± 0.19	6.85 ± 0.16	7.15 ± 0.26	7.22 ± 0.31	p<0.450
9 MONTHS	6.79 ± 0.18	6.85 ± 0.17	7.25 ± 0.27	7.14 ± 0.33	p<0.422
12 MONTHS	6.89 ± 0.20	6.90 ± 0.16	7.22 ± 0.29	7.29 ± 0.33	p<0.518
24 MONTHS	6.91 ± 0.21	6.90 ± 0.17	7.62 ± 0.31	7.01 ± 0.31	p<0.133
p-value	p<0.629	p<0.194	p<0.156	p<0.686	
	N = 43	**N= 46**	**N= 33**	**N=29**	
A1C – AA Participants					
0 MONTHS	6.66 ± 0.34	7.35 ± 0.31	6.80 ± 0.29	7.79 ± 0.44	p<0.107
3 MONTHS	6.71 ± 0.30	7.25 ± 0.35	6.80 ± 0.30	7.87 ± 0.48	p<0.129
6 MONTHS	6.67 ± 0.28	7.26 ± 0.36	6.74 ± 0.24	7.79 ± 0.43	p<0.092
9 MONTHS	6.75 ± 0.27	7.36 ± 0.34	6.71 ± 0.22	7.49 ± 0.41	p<0.214
12 MONTHS	6.59 ± 0.25	7.42 ± 0.35	6.69 ± 0.22	7.10 ± 0.29	p<0.159
24 MONTHS	6.79 ± 0.23	7.56 ± 0.34	6.69 ± 0.21	7.75 ± 0.43	p<0.054
p-value	p<0.566	p<0.675	p<0.784	p<0.089	
	N = 19	**N= 25**	**N= 20**	**N=20**	
A1C – Male Participants					
0 MONTHS	7.09 ± 0.34	7.78 ± 0.30	8.01 ± 0.48	6.81 ± 0.34	p<0.119
3 MONTHS	6.85 ± 0.21	7.11 ± 0.20	7.66 ± 0.45	7.01 ± 0.32	p<0.260
6 MONTHS	6.90 ± 0.24	7.22 ± 0.23	7.25 ± 0.37	7.30 ± 0.44	p<0.736
9 MONTHS	6.99 ± 0.21	7.44 ± 0.24	7.45 ± 0.50	7.09 ± 0.43	p<0.593
12 MONTHS	7.07 ± 0.26	7.41 ± 0.22	7.40 ± 0.45	7.20 ± 0.36	p<0.786
24 MONTHS	7.21 ± 0.30	7.49 ± 0.23	7.84 ± 0.52	7.14 ± 0.38	p<0.549
p-value	p<0.438	p<0.075	p<0.307	p<0.438	
	N=27	**N=28**	**N=14**	**N=14**	
A1C – Female Participants					
0 MONTHS	6.62 ± 0.19	6.89 ± 0.23	6.94 ± 0.22	7.50 ± 0.31	p<0.083
3 MONTHS	6.63 ± 0.19	6.94 ± 0.26	6.91 ± 0.22	7.54 ± 0.33	p<0.094
6 MONTHS	6.62 ± 0.17	6.85 ± 0.22	6.89 ± 0.21	7.47 ± 0.31	p<0.078
9 MONTHS	6.59 ± 0.18	6.77 ± 0.20	6.89 ± 0.18	7.31 ± 0.31	p<0.143
12 MONTHS	6.56 ± 0.16	6.87 ± 0.22	6.86 ± 0.22	7.17 ± 0.28	p<0.317
24 MONTHS	6.60 ± 0.14	6.90 ± 0.22	7.04 ± 0.21	7.33 ± 0.32	p<0.175
p-value	p<0.887	p<0.764	p<0.551	p<0.461	
	N=40	**N=44**	**N=40**	**N=36**	
A1C – Single/Unmarried Participants					
0 MONTHS	6.98 ± 0.52	6.99 ± 0.26	7.19 ± 0.32	7.48 ± 0.44	p<0.777
3 MONTHS	6.69 ± 0.32	6.86 ± 0.29	7.08 ± 0.32	7.60 ± 0.49	p<0.365
6 MONTHS	6.66 ± 0.30	6.92 ± 0.25	7.12 ± 0.31	7.59 ± 0.45	p<0.312
9 MONTHS	6.74 ± 0.34	7.04 ± 0.27	6.95 ± 0.24	7.29 ± 0.47	p<0.752
12 MONTHS	6.75 ± 0.34	7.05 ± 0.23	7.04 ± 0.31	7.22 ± 0.41	p<0.829

24 MONTHS	6.58 ± 0.21	7.51 ± 0.40	7.27 ± 0.31	7.49 ± 0.45	p<0.313
p-value	p<0.361	p<0.121	p<0.501	p<0.796	
	N=16	**N=21**	**N=25**	**N=21**	
A1C – Married Participants					
0 MONTHS	6.75 ± 0.17	7.34 ± 0.24	7.24 ± 0.29	7.19 ± 0.29	p<0.247
3 MONTHS	6.73 ± 0.16	7.07 ± 0.22	7.13 ± 0.26	7.25 ± 0.26	p<0.356
6 MONTHS	6.75 ± 0.16	7.02 ± 0.21	6.87 ± 0.22	7.30 ± 0.29	p<0.353
9 MONTHS	6.75 ± 0.15	7.03 ± 0.20	7.10 ± 0.28	7.21 ± 0.28	p<0.443
12 MONTHS	6.77 ± 0.16	7.09 ± 0.21	6.96 ± 0.26	7.14 ± 0.25	p<0.567
24 MONTHS	6.93 ± 0.19	6.97 ± 0.17	7.22 ± 0.29	7.12 ± 0.30	p<0.784
p-value	p<0.342	p<0.251	p<0.228	p<0.857	
	N=51	**N=51**	**N=29**	**N=29**	
A1C – No-insulin treated					
0 MONTHS	6.32 ± 0.14	6.96 ± 0.28	6.95 ± 0.22	6.59 ± 0.28	p<0.134
3 MONTHS	6.32 ± 0.14	6.74 ± 0.22	6.81 ± 0.22	6.79 ± 0.29	p<0.295
6 MONTHS	6.37 ± 0.12	6.94 ± 0.27	6.73 ± 0.19	6.82 ± 0.33	p<0.278
9 MONTHS	6.40 ± 0.13	6.88 ± 0.24	6.84 ± 0.26	6.70 ± 0.32	p<0.428
12 MONTHS	6.39 ± 0.14	6.81 ± 0.25	6.66 ± 0.24	6.63 ± 0.28	p<0.552
24 MONTHS	6.55 ± 0.20	6.99 ± 0.25	7.01 ± 0.27	6.79 ± 0.33	p<0.530
p-value	p<0.359	p<0.620	p<0.205	p<0.689	
	N=33	**N=35**	**N=27**	**N=22**	
A1C – Insulin treated					
0 MONTHS	7.28 ± 0.31	7.49 ± 0.26	7.49 ± 0.36	7.88 ± 0.35	p<0.619
3 MONTHS	7.11 ± 0.23	7.26 ± 0.28	7.40 ± 0.33	7.87 ± 0.37	p<0.322
6 MONTHS	7.08 ± 0.24	7.04 ± 0.20	7.24 ± 0.32	7.89 ± 0.34	p<0.111
9 MONTHS	7.08 ± 0.23	7.17 ± 0.21	7.22 ± 0.26	7.68 ± 0.36	p<0.408
12 MONTHS	7.13 ± 0.24	7.33 ± 0.21	7.33 ± 0.31	7.61 ± 0.32	p<0.658
24 MONTHS	7.12 ± 0.22	7.26 ± 0.22	7.48 ± 0.32	7.66 ± 0.35	p<0.529
p-value	p<0.580	p<0.203	p<0.463	p<0.694	
	N=34	**N=37**	**N=27**	**N=28**	

Values are expressed as Mean ± SEM

A1C - Hemoglobin A_{1c}

*Reflects significance taken at the 95% Confidence Interval compared to non-obese participants.

(Column *p* value shows overall repeated measures of ANOVA)

Table 21. Outcomes measures BMI and systolic and diastolic pressure for patients with type 2 diabetes

Characteristics	Non-Obese	Class I Obese	Class II Obese	Class III Obese	p-value
Systolic BP (mm Hg) – All Participants					
0 MONTHS	129.33 ± 2.12	132.58 ± 2.17	133.09 ± 2.54	139.18 ± 3.20*	p<0.055
3 MONTHS	128.57 ± 2.21	134.94 ± 2.08	134.59 ± 2.18	135.30 ± 2.08	p<0.076
6 MONTHS	130.75 ± 2.29	132.82 ± 2.29	135.89 ± 2.56	134.78 ± 2.02	p<0.424

9 MONTHS	128.06 ± 2.15	133.54 ± 2.13	137.12 ± 2.25*	137.68 ± 1.97*	**p<0.006**
12 MONTHS	127.12 ± 1.97	134.46 ± 2.43	133.67 ± 2.36	136.36 ± 2.29*	**p<0.025**
24 MONTHS	130.18 ± 2.00	134.15 ± 2.04	132.46 ± 2.17	137.16 ± 2.31*	p<0.147
p-value	p<0.530	p<0.822	p<0.286	p<0.616	
	N = 67	**N= 72**	**N= 54**	**N=50**	
Systolic BP (mm Hg) – EA Participants					
0 MONTHS	128.77 ± 2.93	135.09 ± 2.93	129.52 ± 2.83	135.10 ± 4.03	p<0.304
3 MONTHS	127.60 ± 3.00	136.52 ± 2.64	131.76 ± 2.60	135.10 ± 2.90	p<0.093
6 MONTHS	128.77 ± 2.85	133.41 ± 2.91	133.03 ± 2.91	134.45 ± 2.26	p<0.493
9 MONTHS	126.49 ± 2.76	134.17 ± 2.18	133.18 ± 2.45	137.34 ± 2.82*	**p<0.025**
12 MONTHS	126.93 ± 2.70	133.57 ± 2.95	132.67 ± 2.64	133.03 ± 3.24	p<0.292
24 MONTHS	130.28 ± 2.62	136.04 ± 2.42	133.30 ± 2.84	132.24 ± 2.57	p<0.407
p-value	p<0.759	p<0.735	p<0.708	p<0.697	
	N = 43	**N= 46**	**N= 33**	**N=29**	
Systolic BP (mm Hg) – AA Participants					
0 MONTHS	130.74 ± 3.46	127.60 ± 3.00	140.40 ± 4.50	146.05 ± 5.17**	**p<0.005**
3 MONTHS	131.79 ± 3.65	131.60 ± 3.49	139.35 ± 3.90	136.85 ± 2.82	p<0.371
6 MONTHS	136.37 ± 4.66	132.64 ± 3.81	142.00 ± 4.58	136.10 ± 3.83	p<0.455
9 MONTHS	129.84 ± 4.14	133.08 ± 4.68	144.95 ± 3.93	139.45 ± 2.48	**p<0.052**
12 MONTHS	126.84 ± 3.10	136.84 ± 4.40	135.95 ± 4.66	142.10 ± 2.82*	p<0.075
24 MONTHS	129.11 ± 3.88	131.80 ± 3.66	132.45 ± 3.35	144.25 ± 3.98*	**p<0.032**
p-value	p<0.220	p<0.171	**p<0.043**	p<0.224	
	N = 19	**N= 25**	**N= 20**	**N=20**	
Systolic BP (mm Hg) – Male Participants					
0 MONTHS	130.70 ± 3.44	138.64 ± 3.94	132.07 ± 5.10	145.00 ± 5.80	p<0.126
3 MONTHS	128.70 ± 3.76	138.21 ± 3.79	131.93 ± 3.28	142.36 ± 3.57	p<0.078
6 MONTHS	132.74 ± 3.85	140.07 ± 3.68	139.71 ± 4.85	139.50 ± 4.72	p<0.477
9 MONTHS	126.26 ± 2.77	136.57 ± 2.78*	138.86 ± 3.00*	142.64 ± 3.02*	**p<0.001**
12 MONTHS	126.41 ± 2.91	139.71 ± 3.76*	134.50 ± 4.38	140.36 ± 4.38	**p<0.023**
24 MONTHS	134.26 ± 2.81	134.61 ± 3.27	132.07 ± 3.45	138.79 ± 3.40	p<0.688
p-value	p<0.100	p<0.574	p<0.216	p<0.808	
	N=27	**N=28**	**N=14**	**N=14**	
Systolic BP (mm Hg) – Female Participants					
0 MONTHS	128.40 ± 2.72	128.73 ± 2.38	133.45 ± 2.96	136.92 ± 3.82	p<0.141
3 MONTHS	128.48 ± 2.74	132.86 ± 2.39	135.53 ± 2.72	132.56 ± 2.40	p<0.284
6 MONTHS	129.40 ± 2.84	128.20 ± 2.74	134.55 ± 3.01	132.94 ± 2.10	p<0.308
9 MONTHS	129.28 ± 3.08	131.61 ± 3.00	136.60 ± 2.87	135.75 ± 2.42	p<0.238
12 MONTHS	127.60 ± 2.68	131.11 ± 3.10	133.38 ± 2.82	134.81 ± 2.68	p<0.322
24 MONTHS	127.43 ± 2.71	133.86 ± 2.64	132.60 ± 2.70	136.53 ± 2.95	p<0.135
p-value	p<0.970	p<0.141	p<0.653	p<0.697	
	N=40	**N=44**	**N=40**	**N=36**	
Systolic BP (mm Hg) – Single/Unmarried Participants					
0 MONTHS	133.94 ± 4.71	132.38 ± 3.61	137.00 ± 3.79	140.38 ± 5.61	p<0.603
3 MONTHS	133.88 ± 5.23	133.86 ± 2.86	137.68 ± 3.71	133.33 ± 3.58	p<0.813

6 MONTHS	131.56 ± 3.34	129.81 ± 3.37	139.68 ± 3.58	132.29 ± 3.19	p<0.154
9 MONTHS	135.38 ± 5.23	132.62 ± 4.55	140.68 ± 3.73	137.33 ± 2.98	p<0.522
12 MONTHS	130.69 ± 5.23	138.71 ± 4.72	136.16 ± 3.84	136.05 ± 3.46	p<0.662
24 MONTHS	133.38 ± 5.09	140.67 ± 3.50	137.08 ± 2.95	136.95 ± 3.81	p<0.639
p-value	p<0.557	**p<0.017**	p<0.719	p<0.539	
	N=16	**N=21**	**N=25**	**N=21**	
Systolic BP (mm Hg) – Married Participants					
0 MONTHS	127.88 ± 2.35	132.67 ± 2.71	129.72 ± 3.35	138.31 ± 3.83	p<0.103
3 MONTHS	126.90 ± 2.38	135.39 ± 2.71*	131.93 ± 2.47	136.72 ± 2.49	**p<0.030**
6 MONTHS	130.49 ± 2.83	134.06 ± 2.92	132.62 ± 3.57	136.59 ± 2.61	p<0.570
9 MONTHS	125.76 ± 2.23	133.92 ± 2.39*	134.17 ± 2.62	137.93 ± 2.71*	**p<0.005**
12 MONTHS	126.00 ± 2.01	132.71 ± 2.82	131.52 ± 2.89	136.59 ± 3.11*	**p<0.048**
24 MONTHS	129.18 ± 2.11	131.47 ± 2.42	128.48 ± 3.00	137.31 ± 2.94	p<0.126
p-value	p<0.261	p<0.656	p<0.456	p<0.989	
	N=51	**N=51**	**N=29**	**N=29**	
Systolic BP (mm Hg) – No-insulin treated					
0 MONTHS	126.97 ± 3.39	128.69 ± 2.51	128.67 ± 3.27	134.45 ± 4.37	p<0.482
3 MONTHS	125.97 ± 3.25	135.43 ± 2.86	133.07 ± 2.63	132.23 ± 3.12	p<0.114
6 MONTHS	126.39 ± 3.40	130.43 ± 2.61	135.67 ± 3.66	135.95 ± 3.15	p<0.120
9 MONTHS	125.30 ± 2.87	132.11 ± 2.55	136.52 ± 3.52*	135.73 ± 3.05	**p<0.034**
12 MONTHS	124.73 ± 2.94	129.49 ± 2.79	129.96 ± 3.08	135.27 ± 3.86	p<0.160
24 MONTHS	124.67 ± 3.05	132.37 ± 2.28	127.07 ± 2.52	137.91 ± 3.34*	**p<0.009**
p-value	p<0.958	p<0.156	**p<0.020**	p<0.808	
	N=33	**N=35**	**N=27**	**N=22**	
Systolic BP (mm Hg) – Insulin treated					
0 MONTHS	131.62 ± 2.57	136.27 ± 3.43	137.52 ± 3.75	142.89 ± 4.52	p<0.179
3 MONTHS	131.09 ± 3.00	134.49 ± 3.05	136.11 ± 3.51	137.71 ± 2.74	p<0.479
6 MONTHS	134.97 ± 2.95	135.08 ± 3.71	136.11 ± 3.64	133.86 ± 2.68	p<0.977
9 MONTHS	130.74 ± 3.16	134.89 ± 3.39	137.85 ± 2.87	139.21 ± 2.59	p<0.236
12 MONTHS	129.44 ± 2.61	139.16 ± 3.79	137.37 ± 3.48	137.21 ± 2.80	p<0.135
24 MONTHS	135.53 ± 2.30	135.84 ± 3.34	137.85 ± 3.27	136.57 ± 3.24	p<0.956
p-value	p<0.278	p<0.633	p<0.983	p<0.287	
	N=34	**N=37**	**N=27**	**N=28**	
Diastolic BP (mm Hg) – All participants					
0 MONTHS	74.81 ± 1.20	76.28 ± 0.96	76.26 ± 1.28	77.62 ± 1.61	p<0.476
3 MONTHS	74.93 ± 1.39	77.75 ± 1.25	76.91 ± 1.32	77.56 ± 1.48	p<0.404
6 MONTHS	74.91 ± 1.30	74.81 ± 1.22	78.48 ± 1.53	76.56 ± 1.58	p<0.212
9 MONTHS	74.27 ± 1.32	76.22 ± 1.14	79.67 ± 1.35*	78.18 ± 1.36	**p<0.021**
12 MONTHS	73.18 ± 1.12	76.38 ± 1.09	76.69 ± 1.25	78.92 ± 1.22*	**p<0.008**
24 MONTHS	73.18 ± 1.25	75.61 ± 1.22	77.41 ± 1.27	77.50 ± 1.49	p<0.067
p-value	p<0.414	p<0.310	p<0.115	p<0.733	
Diastolic BP (mm Hg) – EA participants					
0 MONTHS	73.05 ± 1.52	76.89 ± 1.19	75.06 ± 1.49	75.48 ± 2.15	p<0.299
3 MONTHS	73.70 ± 1.82	79.37 ± 1.69	75.58 ± 1.41	77.21 ± 1.91	p<0.090

6 MONTHS	72.81 ± 1.65	75.11 ± 1.63	75.42 ± 1.54	75.52 ± 1.95	p<0.616
9 MONTHS	71.67 ± 1.47	76.98 ± 1.37*	77.76 ± 1.41*	77.17 ± 1.75	**p<0.011**
12 MONTHS	71.93 ± 1.38	76.28 ± 1.19	75.85 ± 1.47	77.59 ± 1.64*	**p<0.028**
24 MONTHS	71.49 ± 1.50	76.04 ± 1.53	76.94 ± 1.73	75.83 ± 1.84	p<0.071
p-value	p<0.599	p<0.190	p<0.633	p<0.782	
Diastolic BP (mm Hg) – AA participants					
0 MONTHS	77.42 ± 2.14	75.00 ± 1.68	78.55 ± 2.37	80.10 ± 2.40	p<0.353
3 MONTHS	77.84 ± 2.50	75.08 ± 1.69	79.40 ± 2.65	78.35 ± 2.48	p<0.549
6 MONTHS	79.68 ± 2.12	74.84 ± 1.80	84.15 ± 2.85**	78.30 ± 2.77	**p<0.048**
9 MONTHS	79.05 ± 2.85	75.24 ± 2.07	83.00 ± 2.68	79.95 ± 2.27	p<0.147
12 MONTHS	74.37 ± 2.23	76.72 ± 2.28	78.45 ± 2.33	80.50 ± 1.88	p<0.281
24 MONTHS	77.53 ± 2.47	75.36 ± 2.05	78.35 ± 1.94	79.30 ± 2.51	p<0.608
p-value	p<0.228	p<0.942	**p<0.020**	p<0.906	
Diastolic BP (mm Hg) – Male participants					
0 MONTHS	75.96 ± 1.87	77.29 ± 1.59	78.07 ± 1.98	77.57 ± 2.42	p<0.881
3 MONTHS	76.30 ± 2.27	80.18 ± 2.03	77.14 ± 1.86	80.71 ± 3.07	p<0.454
6 MONTHS	75.37 ± 2.19	78.43 ± 2.14	79.43 ± 2.47	76.43 ± 3.83	p<0.669
9 MONTHS	74.04 ± 1.78	79.36 ± 1.76	82.50 ± 2.24*	77.36 ± 2.31	**p<0.031**
12 MONTHS	73.56 ± 1.76	77.96 ± 1.27	77.79 ± 2.19	79.71 ± 2.36	p<0.087
24 MONTHS	74.56 ± 1.96	78.11 ± 1.94	80.64 ± 2.61	79.50 ± 2.50	p<0.233
p-value	p<0.643	p<0.732	p<0.430	p<0.497	
Diastolic BP (mm Hg) – Female participants					
0 MONTHS	74.03 ± 1.57	75.64 ± 1.20	75.63 ± 1.58	77.64 ± 2.05	p<0.485
3 MONTHS	74.00 ± 1.77	76.20 ± 1.55	76.83 ± 1.67	76.33 ± 1.65	p<0.635
6 MONTHS	74.60 ± 1.62	72.50 ± 1.38	78.15 ± 1.89	76.61 ± 1.65	p<0.076
9 MONTHS	74.43 ± 1.86	74.23 ± 1.42	78.68 ± 1.62	78.50 ± 1.68	p<0.086
12 MONTHS	72.93 ± 1.47	75.36 ± 1.59	76.30 ± 1.52	78.61 ± 1.45	p<0.081
24 MONTHS	72.25 ± 1.62	74.02 ± 1.53	76.28 ± 1.43	76.72 ± 1.83	p<0.181
p-value	p<0.561	p<0.178	p<0.311	p<0.691	
Diastolic BP (mm Hg) – Single/Unmarried participants					
0 MONTHS	76.19 ± 2.54	75.05 ± 1.71	76.96 ± 1.89	79.81 ± 2.94	p<0.503
3 MONTHS	75.63 ± 3.13	74.62 ± 1.89	78.88 ± 2.17	77.05 ± 2.21	p<0.557
6 MONTHS	75.81 ± 2.64	70.81 ± 1.74	81.04 ± 2.38**	77.62 ± 2.13	**p<0.011**
9 MONTHS	78.81 ± 3.00	72.67 ± 2.24	81.88 ± 2.23**	78.90 ± 2.07	**p<0.040**
12 MONTHS	73.44 ± 2.46	77.05 ± 2.41	77.00 ± 2.01	79.14 ± 2.08	p<0.413
24 MONTHS	74.44 ± 3.09	75.67 ± 2.23	77.72 ± 1.77	77.90 ± 2.64	p<0.711
p-value	p<0.728	p<0.076	**p<0.048**	p<0.810	
Diastolic BP (mm Hg) – Married participants					
0 MONTHS	74.37 ± 1.37	76.78 ± 1.16	75.66 ± 1.76	76.03 ± 1.77	p<0.615
3 MONTHS	74.71 ± 1.56	79.04 ± 1.55	75.21 ± 1.56	77.93 ± 2.01	p<0.161
6 MONTHS	74.63 ± 1.51	76.45 ± 1.52	76.28 ± 1.92	75.79 ± 2.27	p<0.848
9 MONTHS	72.84 ± 1.41	77.69 ± 1.28*	77.76 ± 1.56	77.66 ± 1.84	**p<0.030**
12 MONTHS	73.10 ± 1.27	76.10 ± 1.20	76.41 ± 1.60	78.76 ± 1.51*	**p<0.039**
24 MONTHS	72.78 ± 1.33	75.59 ± 1.47	77.14 ± 1.85	77.21 ± 1.76	p<0.149

p-value	p<0.438	p<0.262	p<0.774	p<0.609	
Diastolic BP (mm Hg) – No-insulin treated					
0 MONTHS	74.24 ± 1.76	74.89 ± 1.38	77.19 ± 1.90	75.27 ± 2.52	p<0.699
3 MONTHS	73.64 ± 1.75	78.83 ± 1.96	77.81 ± 1.96	75.41 ± 2.32	p<0.207
6 MONTHS	73.97 ± 1.67	74.63 ± 1.42	80.81 ± 2.42	77.50 ± 2.63	p<0.059
9 MONTHS	74.85 ± 2.08	76.83 ± 1.56	81.48 ± 2.07	78.77 ± 2.20	p<0.105
12 MONTHS	73.91 ± 1.44	74.37 ± 1.43	78.70 ± 1.65	79.36 ± 2.05	**p<0.033**
24 MONTHS	71.30 ± 1.60	75.26 ± 1.63	79.19 ± 1.70*	78.14 ± 2.52	**p<0.012**
p-value	p<0.264	p<0.159	p<0.142	p<0.406	
Diastolic BP (mm Hg) – Insulin treated					
0 MONTHS	75.35 ± 1.65	77.59 ± 1.32	75.33 ± 1.73	79.46 ± 2.06	p<0.267
3 MONTHS	76.18 ± 2.16	76.73 ± 1.57	76.00 ± 1.78	79.25 ± 1.88	p<0.624
6 MONTHS	75.82 ± 2.00	74.97 ± 1.99	76.15 ± 1.81	75.82 ± 1.95	p<0.976
9 MONTHS	73.71 ± 1.65	75.65 ± 1.67	77.85 ± 1.69	77.71 ± 1.75	p<0.273
12 MONTHS	72.47 ± 1.72	78.27 ± 1.59*	74.67 ± 1.84	78.57 ± 1.51	**p<0.026**
24 MONTHS	75.00 ± 1.88	75.95 ± 1.82	75.63 ± 1.86	77.00 ± 1.82	p<0.901
p-value	p<0.292	p<0.360	p<0.724	p<0.403	

Values are expressed as Mean ± SEM
BP – Blood pressure.
*Reflects significance taken at the 95% Confidence Interval compared to non-obese participants;
** compared to obese class I participants.
(Column *p* value shows overall repeated measures of ANOVA)

Table 22. Outcomes measures BMI and total cholesterol, and Triglycerides for patients with type 2 diabetes

Characteristics	Non-Obese	Class I Obese	Class II Obese	Class III Obese	p-value
Total Cholesterol (mg/dl) – All participants					
0 MONTHS	167.40 ± 4.23	170.69 ± 4.52	161.85 ± 5.48	177.80 ± 5.28	p<0.179
12 MONTHS	159.03 ± 3.63	174.99 ± 4.25*	162.96 ± 5.84	176.78 ± 4.94*	**p<0.013**
24 MONTHS	165.33 ± 4.32	171.04 ± 4.28	158.89 ± 5.00	177.00 ± 4.65	p<0.055
p-value	p<0.077	p<0.375	p<0.655	p<0.948	
Total Cholesterol (mg/dl) – EA participants					
0 MONTHS	165.12 ± 5.64	174.13 ± 6.14	158.94 ± 7.07	173.31 ± 7.42	p<0.320
12 MONTHS	158.09 ± 4.72	179.07 ± 5.63*	164.48 ± 7.80	173.03 ± 6.83	p<0.057
24 MONTHS	162.67 ± 5.63	173.76 ± 5.45	154.33 ± 5.57	176.55 ± 6.87	**p<0.042**
p-value	p<0.381	p<0.438	p<0.252	p<0.753	
Total Cholesterol (mg/dl) – AA participants					
0 MONTHS	170.16 ± 7.17	164.60 ± 6.42	165.60 ± 9.21	182.85 ± 7.55	p<0.308
12 MONTHS	163.26 ± 6.58	170.00 ± 5.94	159.70 ± 9.32	182.70 ± 7.37	p<0.149
24 MONTHS	170.89 ± 7.50	167.96 ± 7.00	165.55 ± 9.85	177.70 ± 6.18	p<0.718
p-value	p<0.324	p<0.517	p<0.602	p<0.570	
Total Cholesterol (mg/dl) – Male participants					
0 MONTHS	159.41 ± 7.04	162.43 ± 8.69	152.36 ± 8.43	166.79 ± 10.77	p<0.798

12 MONTHS	148.89 ± 5.59	173.00 ± 7.63	155.29 ± 8.04	163.36 ± 10.71	p<0.087
24 MONTHS	151.37 ± 5.59	165.39 ± 6.69	147.14 ± 7.23	168.26 ± 10.58	p<0.155
p-value	p<0.246	p<0.180	p<0.609	p<0.788	
Total Cholesterol (mg/dl) – Female participants					
0 MONTHS	172.80 ± 5.16	175.95 ± 4.83	165.18 ± 6.77	182.08 ± 5.97	p<0.226
12 MONTHS	165.88 ± 4.50	176.25 ± 5.04	165.65 ± 7.37	182.00 ± 5.30	p<0.124
24 MONTHS	174.75 ± 5.77	174.64 ± 5.56	163.00 ± 6.17	180.39 ± 4.96	p<0.190
p-value	p<0.131	p<0.918	p<0.864	p<0.887	
Total Cholesterol (mg/dl) – Single/Unmarried participants					
0 MONTHS	170.31 ± 10.11	178.90 ± 9.58	163.44 ± 9.39	175.38 ± 6.04	p<0.602
12 MONTHS	166.63 ± 8.45	182.14 ± 8.32	163.72 ± 9.40	175.81 ± 5.82	p<0.364
24 MONTHS	170.31 ± 10.70	176.19 ± 9.29	166.20 ± 8.73	173.43 ± 4.94	p<0.841
p-value	p<0.844	p<0.609	p<0.880	p<0.882	
Total Cholesterol (mg/dl) – Married participants					
0 MONTHS	166.49 ± 4.62	167.31 ± 5.00	160.48 ± 6.38	179.55 ± 8.06	p<0.234
12 MONTHS	156.65 ± 3.95	172.04 ± 4.92	162.31 ± 7.42	177.48 ± 7.49*	**p<0.039**
24 MONTHS	163.76 ± 4.63	168.92 ± 4.72	152.59 ± 5.36	179.59 ± 7.21**	**p<0.022**
p-value	p<0.082	p<0.514	p<0.195	p<0.895	
Total Cholesterol (mg/dl) – No-insulin treated					
0 MONTHS	163.82 ± 6.24	169.51 ± 5.65	158.30 ± 5.96	177.50 ± 8.88	p<0.263
12 MONTHS	161.67 ± 5.33	172.71 ± 5.26	167.04 ± 7.00	182.18 ± 8.25	p<0.157
24 MONTHS	169.52 ± 6.46	170.11 ± 4.99	169.22 ± 6.20	175.23 ± 7.00	p<0.914
p-value	p<0.306	p<0.775	p<0.213	p<0.538	
Total Cholesterol (mg/dl) –Insulin treated					
0 MONTHS	170.88 ± 5.77	171.81 ± 7.05	165.41 ± 9.28	178.04 ± 6.49	p<0.711
12 MONTHS	156.47 ± 4.97	177.14 ± 6.66	158.89 ± 9.43	172.54 ± 5.99	p<0.076
24 MONTHS	161.26 ± 5.78	171.92 ± 6.93	148.56 ± 7.43$^{\$}$	178.39 ± 6.31	**p<0.018**
p-value	**p<0.032**	p<0.465	**p<0.025**	p<0.364	
Triglyceride (mg/dl) – All participants					
0 MONTHS	122.64 ± 9.57	163.11 ± 16.49	138.46 ± 10.60	158. 14 ± 10.39	p<0.081
12 MONTHS	110.43 ± 8.14	158.79 ± 10.50*	145.48 ± 13.09	158.92 ± 11.65*	**p<0.003**
24 MONTHS	122.87 ± 8.47	177.81 ± 17.36*	153.26 ± 12.94	148.46 ± 10.92	**p<0.024**
p-value	p<0.184	p<0.216	p<0.181	p<0.503	
Triglyceride (mg/dl) – EA participants					
0 MONTHS	130.09 ± 14.05	200.41 ± 23.60*	161.15 ± 14.86	181.86 ± 13.52	**p<0.031**
12 MONTHS	119.21 ± 11.71	184.93 ± 13.50*	176.73 ± 18.80*	181.79 ± 16.77*	**p<0.003**
24 MONTHS	127.49 ± 9.45	211.83 ± 25.06*	178.79 ± 18.38	174.28 ± 16.28	**p<0.011**
p-value	p<0.524	p<0.274	p<0.257	p<0.819	
Triglyceride (mg/dl) – AA participants					
0 MONTHS	107.26 ± 10.06	94.60 ± 9.67	102.50 ± 10.87	127.55 ± 14.08	p<0.195
12 MONTHS	94.37 ± 9.29	110.48 ± 12.65	98.55 ± 9.24	129.00 ± 13.28	p<0.175
24 MONTHS	97.21 ± 12.01	113.88 ± 11.78	114.65 ± 13.17	109.60 ± 8.12	p<0.709
p-value	p<0.335	p<0.134	p<0.208	p<0.226	

Triglyceride (mg/dl) – Male participants					
0 MONTHS	150.11 ± 20.58	208.54 ± 35.90	167.00 ± 29.59	178.79 ± 24.89	p<0.480
12 MONTHS	134.41 ± 16.44	204.89 ± 18.29	196.00 ± 40.34	184.43 ± 23.42	p<0.074
24 MONTHS	131.30 ± 12.52	235.75 ± 37.98	197.50 ± 37.60	188.79 ± 30.61	p<0.069
p-value	p<0.387	p<0.422	p<0.342	p<0.846	
Triglyceride (mg/dl) – Female participants					
0 MONTHS	104.10 ± 6.88	134.20 ± 13.04	128.48 ± 9.71	150.11 ± 10.67*	**p<0.025**
12 MONTHS	94.25 ± 7.02	129.45 ± 10.61	127.80 ± 9.67	149.00 ± 13.22*	**p<0.003**
24 MONTHS	117.18 ± 11.43$$	140.93 ± 12.50	137.78 ± 10.88	133.33 ± 8.48	p<0.434
p-value	**p<0.027**	p<0.326	p<0.294	p<0.265	
Triglyceride (mg/dl) – Single/Unmarried participants					
0 MONTHS	104.44 ± 10.02	143.43 ± 20.74	126.68 ± 12.25	137.00 ± 13.00	p<0.348
12 MONTHS	120.31 ± 12.88	155.43 ± 19.24	121.20 ± 12.26	142.19 ± 14.74	p<0.293
24 MONTHS	131.81 ± 11.45	161.76 ± 23.96	138.76 ± 13.77	128.86 ± 10.82	p<0.485
p-value	p<0.068	p<0.348	p<0.186	p<0.573	
Triglyceride (mg/dl) – Married participants					
0 MONTHS	128.35 ± 12.11	171.22 ± 21.68	148.62 ± 16.65	173.45 ± 14.78	p<0.194
12 MONTHS	107.33 ± 9.92	160.18 ± 12.64*	166.41 ± 21.42*	171.03 ± 16.88*	**p<0.003**
24 MONTHS	120.06 ± 10.55	184.41 ± 22.50*	165.75 ± 20.92	163.34 ± 16.77	**p<0.049**
p-value	p<0.083	p<0.274	p<0.259	p<0.748	
Triglyceride (mg/dl) – No-Insulin treated					
0 MONTHS	115.88 ± 9.76	148.00 ± 13.41	106.15 ± 9.84	157.27 ± 14.03**	**p<0.010**
12 MONTHS	114.00 ± 11.12	152.60 ± 14.37	118.19 ± 13.12	153.82 ± 15.56	p<0.062
24 MONTHS	132.85 ± 13.02	159.03 ± 13.77	120.26 ± 11.86	142.64 ± 16.40	p<0.218
p-value	p<0.156	p<0.660	p<0.216	p<0.565	
Triglyceride (mg/dl) – Insulin treated					
0 MONTHS	129.21 ± 16.39	177.41 ± 29.52	170.78 ± 16.77	158.82 ± 15.15	p<0.382
12 MONTHS	106.97 ± 11.99	164.65 ± 15.37*	172.78 ± 21.66*	162.93 ± 17.06	**p<0.016**
24 MONTHS	113.18 ± 10.82	195.57 ± 31.12*	186.26 ± 21.40	153.75 ± 14.83	**p<0.034**
p-value	p<0.127	p<0.257	p<0.460	p<0.759	

Values are expressed as Mean ± SEM

*Reflects significance taken at the 95% Confidence Interval compared to non-obese participants,

**compared to Class II obese group.

$Reflects significance taken at the 95% Confidence Interval compared to 0 months.

$$Reflects significance taken at the 95% Confidence Interval compared to 12 months.

(Column *p* value shows overall repeated measures of ANOVA)

Table 23. Outcomes measures total LDL, and HDL for patients with type 2 diabetes

Characteristics	Non-Obese	Class I Obese	Class II Obese	Class III Obese	p-value
LDL (mg/dl) – All participants					
0 MONTHS	88.76 ± 3.71	92.27 ± 3.65	90.74 ± 4.60	100.18 ± 4.42	p<0.256
12 MONTHS	81.71 ± 3.22	94.44 ± 3.58	91.75 ± 5.00	98.86 ± 4.11*	**p<0.016**

24 MONTHS	84.15 ± 3.62	89.38 ± 3.63	86.81 ± 4.72	99.67 ± 4.04*	p<0.052
p-value	p<0.081	p<0.084	p<0.447	p<0.987	
LDL (mg/dl) – EA participants					
0 MONTHS	88.74 ± 4.76	92.16 ± 4.96	84.91 ± 6.24	93.71 ± 6.23	p<0.713
12 MONTHS	83.33 ± 4.37	96.31 ± 4.62	87.90 ± 6.97	92.79 ± 5.48	p<0.269
24 MONTHS	85.67 ± 4.90	88.44 ± 4.32$^{\$}$	77.65 ± 5.31	98.00 ± 5.94	p<0.086
p-value	p<0.446	**p<0.026**	p<0.175	p<0.695	
LDL (mg/dl) – AA participants					
0 MONTHS	86.58 ± 7.04	92.28 ± 5.40	100.20 ± 6.64	107.05 ± 5.76	p<0.115
12 MONTHS	80.74 ± 5.24	93.28 ± 5.53	97.20 ± 7.24	108.20 ± 6.09*	**p<0.026**
24 MONTHS	83.63 ± 6.02	92.64 ± 6.67	100.90 ± 8.31	103.10 ± 5.38	p<0.194
p-value	p<0.356	p<0.971	p<0.846	p<0.590	
LDL (mg/dl) – Male participants					
0 MONTHS	83.81 ± 5.48	83.37 ± 6.70	85.31 ± 7.74	90.31 ± 9.98	p<0.925
12 MONTHS	77.27 ± 4.93	86.74 ± 5.69	85.50 ± 8.34	87.57 ± 9.05	p<0.600
24 MONTHS	78.67 ± 4.98	80.19 ± 5.40	79.83 ± 8.31	90.77 ± 9.28	p<0.627
p-value	p<0.401	p<0.096	p<0.586	p<0.995	
LDL (mg/dl) – Female participants					
0 MONTHS	91.98 ± 4.97	97.73 ± 4.07	92.50 ± 5.57	103.75 ± 4.77	p<0.309
12 MONTHS	84.60 ± 4.22	99.16 ± 4.51	93.63 ± 6.02	103.25 ± 4.36*	**p<0.048**
24 MONTHS	87.85 ± 5.01	95.02 ± 4.68	88.90 ± 5.62	102.89 ± 4.33	p<0.144
p-value	p<0.177	p<0.497	p<0.612	p<0.975	
LDL (mg/dl) – Single/Unmarried participants					
0 MONTHS	93.38 ± 9.31	104.57 ± 7.50	94.04 ± 7.80	100.24 ± 5.42	p<0.688
12 MONTHS	86.69 ± 8.39	103.35 ± 6.40	95.80 ± 7.59	100.62 ± 5.12	p<0.426
24 MONTHS	90.19 ± 9.79	96.81 ± 7.06	95.24 ± 8.06	98.10 ± 4.54	p<0.909
p-value	p<0.625	p<0.236	p<0.963	p<0.874	
LDL (mg/dl) – Married participants					
0 MONTHS	87.28 ± 3.93	87.10 ± 3.95	87.79 ± 5.30	100.14 ± 6.67	p<0.226
12 MONTHS	80.12 ± 3.33	90.94 ± 4.25	88.00 ± 6.64	97.59 ± 6.10	p<0.074
24 MONTHS	82.25 ± 3.66	86.26 ± 4.19	79.00 ± 4.87	100.86 ± 6.27*	**p<0.020**
p-value	p<0.127	p<0.279	p<0.165	p<0.955	
LDL (mg/dl) – No-insulin treated					
0 MONTHS	85.64 ± 5.44	92.89 ± 4.82	91.41 ± 5.77	97.82 ± 7.11	p<0.531
12 MONTHS	82.55 ± 4.98	95.11 ± 4.61	97.07 ± 6.52	103.18 ± 7.07	p<0.078
24 MONTHS	86.58 ± 5.58	90.46 ± 4.51	98.22 ± 6.45	98.73 ± 5.84	p<0.344
p-value	p<0.630	p<0.481	p<0.441	p<0.620	
LDL (mg/dl) – Insulin treated					
0 MONTHS	91.88 ± 5.09	91.67 ± 5.54	90.04 ± 7.32	102.11 ± 5.60	p<0.493
12 MONTHS	80.88 ± 4.16	93.78 ± 5.52	86.00 ± 7.63	95.46 ± 4.81	p<0.197
24 MONTHS	81.79 ± 4.69	88.33 ± 5.73	74.48 ± 6.13$^{\$}$	100.44 ± 5.68**	**p<0.019**
p-value	**p<0.029**	p<0.164	**p<0.018**	p<0.617	
HDL (mg/dl) – All participants					
0 MONTHS	54.24 ± 2.04	46.43 ± 1.71*	46.07 ± 1.53*	46.52 ± 1.60*	**p<0.002**

12 MONTHS	56.66 ± 2.28	47.75 ± 1.87*	45.52 ± 1.34*	45.90 ± 1.58*	**p<0.001**
24 MONTHS	55.18 ± 2.31	46.47 ± 1.68*	46.30 ± 1.42*	48.38 ± 1.59	**p<0.001**
p-value	p<0.121	p<0.142	p<0.748	p<0.073	
HDL (mg/dl) – EA participants					
0 MONTHS	50.28 ± 2.48	42.87 ± 1.93*	43.21 ± 1.77	43.97 ± 1.95	**p<0.033**
12 MONTHS	52.70 ± 2.68	43.73 ± 1.80*	44.30 ± 1.80*	43.52 ± 1.95*	**p<0.005**
24 MONTHS	51.56 ± 2.59	43.17 ± 1.81*	44.73 ± 2.04	45.10 ± 1.93	**p<0.023**
p-value	p<0.147	p<0.632	p<0.451	p<0.473	
HDL (mg/dl) – AA participants					
0 MONTHS	62.68 ± 3.61	53.40 ± 2.98	49.45 ± 2.40*	50.20 ± 2.69*	**p<0.012**
12 MONTHS	64.68 ± 4.22	55.44 ± 3.83	46.55 ± 1.82*	48.65 ± 2.57*	**p<0.002**
24 MONTHS	62.63 ± 4.77	53.16 ± 3.13	47.70 ± 1.30*	52.60 ± 2.53	**p<0.017**
p-value	p<0.729	p<0.195	p<0.323	p<0.113	
HDL (mg/dl) – Male participants					
0 MONTHS	45.19 ± 2.79	39.71 ± 2.49	37.14 ± 1.95	42.36 ± 3.22	p<0.218
12 MONTHS	47.37 ± 3.28	40.64 ± 2.18	37.36 ± 1.58	39.36 ± 2.88	p<0.068
24 MONTHS	46.48 ± 3.29	39.86 ± 2.43	37.07 ± 1.96	40.14 ± 2.27	p<0.119
p-value	p<0.321	p<0.700	p<0.980	p<0.249	
HDL (mg/dl) – Female participants					
0 MONTHS	60.35 ± 2.42	50.70 ± 2.08*	49.20 ± 1.70*	48.14 ± 1.80*	**p<0.001**
12 MONTHS	62.93 ± 2.71	52.27 ± 2.51*	48.38 ± 1.48*	48.44 ± 1.73*	**p<0.001**
24 MONTHS	61.05 ± 2.84	50.68 ± 2.06*	49.53 ± 1.48*	51.58 ± 1.78*	**p<0.001**
p-value	p<0.310	p<0.188	p<0.672	**p<0.019**	
HDL (mg/dl) – Single/Unmarried participants					
0 MONTHS	56.56 ± 4.04	45.62 ± 2.16*	47.60 ± 2.24	47.71 ± 2.43	**p<0.042**
12 MONTHS	57.00 ± 3.75	44.76 ± 2.33*	46.68 ± 1.91*	47.48 ± 2.12	**p<0.008**
24 MONTHS	53.50 ± 3.41	46.14 ± 1.94	47.92 ± 1.78	49.52 ± 2.11	p<0.171
p-value	p<0.452	p<0.529	p<0.702	p<0.417	
HDL (mg/dl) – Married participants					
0 MONTHS	53.51 ± 2.37	46.76 ± 2.25	44.76 ± 2.10	45.66 ± 2.15	**p<0.028**
12 MONTHS	56.55 ± 2.77$	48.98 ± 2.45	44.52 ± 1.87*	44.76 ± 2.25*	**p<0.003**
24 MONTHS	55.71 ± 2.85	46.61 ± 2.25*$$	44.90 ± 2.14*	47.55 ± 2.30	**p<0.010**
p-value	**p<0.041**	**p<0.018**	p<0.951	p<0.162	
HDL (mg/dl) – No-insulin treated					
0 MONTHS	55.15 ± 3.23	46.26 ± 2.33	45.41 ± 2.17*	48.14 ± 2.52	**p<0.034**
12 MONTHS	56.30 ± 3.42	46.39 ± 2.07*	45.85 ± 1.85*	47.73 ± 2.63	**p<0.013**
24 MONTHS	56.42 ± 3.50	45.66 ± 2.06*	47.56 ± 2.15	48.36 ± 2.59	**p<0.019**
p-value	p<0.661	p<0.741	p<0.292	p<0.905	
HDL (mg/dl) – Insulin treated					
s 0 MONTHS	53.35 ± 2.55	46.59 ± 2.52	46.74 ± 2.19	45.25 ± 2.08	p<0.075
12 MONTHS	57.00 ± 3.07	49.03 ± 3.07	45.19 ± 1.96*	44.46 ± 1.92*	**p<0.005**
24 MONTHS	53.97 ± 3.06	47.24 ± 2.65	45.04 ± 1.85	48.39 ± 2.04	p<0.089
p-value	p<0.096	p<0.082	p<0.446	**p<0.039**	

Values are expressed as Mean ± SEM

*Reflects significance taken at the 95% Confidence Interval compared to non-obese participants; **compared to obese class II participants.
$Reflects significance taken at the 95% Confidence Interval compared to 0 months; $$compared to 12 months.
(Column *p* value shows overall repeated measures of ANOVA)

Table 24. Changes in the BMI, weight, blood pressure measurement and A1C from baseline to 3-,6-,9-,12- or 24-months of follow-up within four obese groups.

Characteristics	Non-Obese	Class I Obese	Class II Obese	Class III Obese
BMI				
3 MONTHS	-0.037 (0.173)	-0.010 (0.060)	-0.003 (0.690)	-0.317 (0.106)*
6 MONTHS	-0.043 (0.189)	-0.028 (0.069)	0.201 (0.096)*	-0.192 (0.075)*
9 MONTHS	-0.164 (0.200)	-0.009 (0.088)	0.298 (0.151)*	-0.282 (0.096)*
12 MONTHS	-0.114 (0.198)	0.183 (0.115)	-0.067 (0.128)	-0.181 (0.141)
24 MONTHS	0.100 (0.203)	0.344 (0.169)*	-0.149 (0.131)	0.058 (0.197)
Weight (lb)				
3 MONTHS	-0.069 (0.167)	-0.010 (0.053)	-0.039 (0.065)	-0.232 (0.059)*
6 MONTHS	-0.012 (0.184)	0.041 (0.064)	0.269 (0.092)*	-0.238 (0.074)*
9 MONTHS	-0.022 (0.204)	0.090 (0.065)	0.290 (0.125)*	-0.223 (0.079)*
12 MONTHS	-0.152 (0.185)	0.247 (0.093)*	-0.104 (0.115)	-0.124 (0.114)
24 MONTHS	0.062 (0.760)	0.312 (0.134)*	-0.141 (0.121)	-0.069 (0.150)
A1C (%)				
3 MONTHS	-0.168 (0.291)	-0.441 (0.384)	0.776 (0.291)*	-0.101 (0.316)
6 MONTHS	-0.213 (0.300)	-1.185 (0.520)*	2.678 (0.312)*	0.220 (0.582)
9 MONTHS	-0.140 (0.281)	-1.004 (0.432)*	2.371 (0.456)*	0.258 (0.509)
12 MONTHS	-0.151 (0.254)	-1.076 (0.400)*	2.488 (0.496)*	0.451 (0.526)
24 MONTHS	-0.331 (0.302)	-0.728 (0.664)	3.097 (0.573)*	0.839 (0.382)*
Systolic BP (mm Hg)				
3 MONTHS	0.209 (0.237)	0.077 (0.345)	2.838 (0.263)*	0.456 (0.453)
6 MONTHS	0.456 (0.287)	0.629 (0.396)	4.422 (0.294)*	0.425 (0.434)
9 MONTHS	0.393 (0.284)	0.291 (0.399)	-1.955 (0.236)*	0.154 (0.484)
12 MONTHS	-0.176 (0.306)	0.467 (0.324)	0.427 (0.193)*	-0.543 (0.550)
24 MONTHS	-0.168 (0.274)	0.620 (0.141)	0.707 (0.265)*	0.317 (0.459)
Diastolic BP (mm Hg)				
3 MONTHS	-0.007 (0.316)	-0.015 (0.395)	1.511 (0.313)*	0.368 (0.215)
6 MONTHS	0.600 (0.253)*	0.062 (0.453)	1.221 (0.340)*	0.403 (0.300)
9 MONTHS	0.288 (0.294)	-0.214 (0.427)	-1.432 (0.290)*	0.332 (0.197)
12 MONTHS	-0.671 (0.276)*	-0.389 (0.208)	-1.489 (0.200)*	0.088 (0.260)
24 MONTHS	-0.448 (0.306)	0.130 (0.299)	0.217 (0.304)	-0.175 (0.308)

Results from the Generalized Estimated Equation adjusted for gender and race with respect to base line parameters that is compared to 0 Months and 3, 6, 9, 12 and 24 Months. Values are expressed

as β coefficient (SE) within each group compared to baseline levels. *Reflects significance taken at the p<0.05 levels compared to 0 months.
BMI - Body Mass Index; A1C - Hemoglobin A_{1c}; BP – Blood pressure

Table 25. Changes in the total cholesterol, LDL, HDL, and Triglycerides from baseline to 12- or 24-months of follow-up within four obese groups.

Characteristics	Non-Obese	Class I Obese	Class II Obese	Class III Obese
Total Cholesterol				
12 MONTHS	-0.478 (0.424)	-0.569 (0.428)	-2.204 (0.480)*	0.555 (0.368)
24 MONTHS	-0.102 (0.361)	0.001 (0.393)	2.036 (0.380)*	0.371 (0.396)
LDL				
12 MONTHS	-1.023 (0.683)	0.443 (0.891)	-3.200 (0.798)*	-0.704 (0.780)
24 MONTHS	0.008 (0.611)	-0.165 (1.010)	4.201 (0.643)*	-0.469 (0.620)
HDL				
12 MONTHS	0.295 (0.333)	0.231 (0.442)	0.105 (0.353)	0.487 (0.352)
24 MONTHS	0.458 (0.294)	-0.380 (0.367)	1.242 (0.572)*	0.530 (0.418)
Triglycerides				
12 MONTHS	-1.432 (0.883)	-2.971 (1.404)*	-2.238 (0.881)*	2.737 (0.926)*
24 MONTHS	-1.995 (0.919)*	-0.197 (0.844)	-3.259 (1.197)*	2.520 (0.876)*

Results from the Generalized Estimated Equation adjusted for gender and race with respect to base line parameters that is compared to 0 Months to 12 and 24 Months. Values are expressed as β coefficient (SE) within each group compared to baseline levels. *Reflects significance taken at the p<0.05 levels compared to 0 months.
LDL- Low density Lipoprotein; HDL - High density Lipoprotein

Chapter 5: Discussion and Conclusion

This study evaluated the overall diabetes and health related outcomes for all participants as well as specific groups. Particpants were separated by various characteristics to analyze the differences among them. DSMES programs should be tailored to the audience for groups and individualized for patients to achieve optimal results. Grouping participants by gender, race, marital status and obesity gives us possible insight to which groups are achieving better outcomes, which could be due to the tailoring of the program. If specific groups of people have significantly different results, it could reveal possible bias or cultural insensitivity, or natural progession of diabetes.

The retrospective chart review adds to the evidence base by documenting outcomes from patients participating specifically in a comprehensive DSMES program. While ADA-recognition requires compliance with 10 identified standards, due to a variety of different program structures and healthcare providers, there can be variations in services. Several studies summarize the evidence and efficacy of DSME and MNT[89–91]. 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 [1,8,44,68,92,93].

Exploring outcomes specifically in ADA-recognized programs, with interdisciplinary DSMES and individualized RDN-administered MNT provides a means to assess outcomes that are administered according to the current standards of practice. The methodology tested through this retrospective chart review sparks the need for the *Health Matters* program to continue to track health outcomes, but also to include more innovative and consistent methods of tracking outcomes. Evaluating long-term DSMES programs is crucial to continue to support better

referral systems, reimbursement, structure/frequency of sessions and access to these needed services.

DSMES and MNT insurance billing, physician referral, and patient identification training should be conducted yearly and provided by the DSMES providing facilities and the ADA and ADCES to establish rapport and partnership between referring providers and DSMES programs. Interdisciplinary treatment and communication could assist in eliminating barriers to access. The training will establish and maintain relationships between the local physician's offices, health centers, hospitals and the facilities providing DSMES. Communication between the referring provider, patient, and DSMES team is essential for the promotion and utilization of DSMES services. In Krall et al, the local diabetes educators were introduced as team members of the primary care practices, while still being employed by their hospitals[94]. They were approved to collaborate with community primary care clinics in identifying patients, notifying them and assisting with scheduling DSMES appointments. Compared to the usual care group with diabetes educators being outside providers, a higher percentage of patients in the intervention practices were referred to DSMES (18.4% vs 13.4%; $P < .0001$), and of those referred, a higher percentage of patients in the intervention practice participated in DSMES (34.9% vs 26.1%; $P = .02$). This interdisciplinary team's theory with consistent interaction between diabetes educators and primary care clinics is ideal for effective referral process and access to DSMES.

Poor cultural tailoring of DSMES is another unfortunate barrier, especially when diabetes affects minorities disproportionately. Non-Hispanic blacks are twice as likely as non-Hispanic whites to die from diabetes; 60 percent more likely than non-Hispanic white adults to be diagnosed with diabetes by a physician; and 3.2 times more likely to be diagnosed with end stage renal disease as compared to non-Hispanic whites.[39] In 2017, non-Hispanic blacks were 2.3 times

more likely to be hospitalized for lower limb amputations as compared to non-Hispanic whites. The mean percent increase of individuals with diabetes from 2005 to 2050 was projected to be 174% for men and 220% for women, with a disproportionate number of minorities having the fastest growth: 481% among Hispanics, 208% among Blacks and 113% among Whites[95]. The higher prevalence of diabetes among Blacks and Hispanics opens up the conversation of cultural differences among people with diabetes and how it affects diabetes self-management. Kulkarni et al. concluded that it was crucial to ask about each patient's specific food habits to have any hope of providing culturally appropriate interventions or education for modifying eating patterns to prevent and treat T2DM. T2DM requires nutrition intervention and skill in the cultural aspects of working with these clients[96]. Goff et al. concluded that the provision of culturally sensitive DSMES is a challenging area of practice for practitioners, but they recognize the need for more training and resources to support them in developing cultural competence[97]. This training could be provided virtually by providers from various cultural backgrounds to make sure that DSMES providers are equipped with cultural competence and sensitivity.

Different cultures present different barriers specific to culture and family dynamics. In a study about the perceptions of barriers to diabetes management from the perspectives of Hispanic immigrant patients and family members, the family members/significant others claimed that they could provide support, but they lack the knowledge to do so[98]. Participants described the emotional suffering resulting from diabetes as depression and feeling isolated from their family members during mealtime since they were unable to eat the same things. Lack of self-control was identified as a barrier to diabetes self-management in a study conducted with urban African American Adults with T2DM[99]. Participants specifically noted that it was difficult to follow dietary recommendations when food was present in a social context, like holiday

celebrations or family gatherings. Another study conducted with Haitian and African Americans with type 2 diabetes concluded that when developing strategies to manage these minority groups, diabetes healthcare providers should consider cultural background, coping abilities, and socio-demographic factors when providing guidance and education[100].

There are many barriers to DSMES, but for every barrier there is a facilitator or enabler. Healthcare professionals should assess the patient's living situation, cultural background, and barriers so the best plan for intervention can be implemented. Promoting DSMES as a profession and a service for patients with type 2 diabetes will spread the word that this service is available. If more providers from various backgrounds and cultures participate, this also helps bridge the gap in culturally sensitive DSMES. With improved access to DSMES through virtual education, increased administrative assistance and training for referrals and billing, interdisciplinary teams in primary care clinics, and increased numbers of providers and DSMES facilities, this could help to improve participation in DSMES.

Health Matters was able to help participants get closer to achieving and/or maintaining an A1C near the target of 7%. While there were no significant improvements in health outcomes overall, the ongoing DSMES program significantly improved the A1C in participants with uncontrolled diabetes, A1C >9%. This population is at risk for complications, but the risk decreases with the decrease in A1C.

There were also few significant differences among groups, which is encouraging that the DSMES program can be successful for all. Participants with various BMIs can still achieve glycemic targets despite their weight. There were no significant differences in hemoglobin A1C

when we separated the participants into obesity groups and compared them to the nonobese groups.

Limitations

There were several limitations to this study, including a small sample size, lack of a control group and the use of secondary data. Future studies should track participants who chose not to participate in the program to compare outcomes. Health Matters Participants are all employees of the hospital, so that creates a level of bias and financial resources that are not available to all patients with T2DM. The majority of the participants were white (62.1%) and female (65.8%). Health Matters only has one male care manager and one care manager of color. Diversity in DSMES providers could assist in rapport and tailoring DSMES to participants' lifestyles. This study also didn't include methods to assess possible confounding factors like self-efficacy, behavioral changes, and adherence to medications.

Conclusion

Understanding the outcome differences among groups can help to identify and address areas for improvement or more success in tailoring DSMES services to patients. While DSMES is only one part of the diabetes management plan, DSMES providers are in contact with the patient and monitoring their results more than most health care providers. DSMES providers have an opportunity to make great change. The structure of the *Health Matters* program would help eliminate several of the barriers to DSMES. The consistent support and education quarterly could help eliminate these barriers and help patients with T2DM gain access to individualized DSMES, and a team that is trained to make changes in the patients' management plan sooner rather than later. These diabetes management changes could help decrease the risk of complications and improve patients' quality of life.

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Sign up for your diabetes management program

FREE diabetes meds & supplies

FREE Wellness Center membership

Online and one-on-one education

FREE quarterly labwork

Health Matters is a **FREE** disease management program for employees that have been diagnosed with type 1 or type 2 diabetes or pre-diabetes and are insured by Huntsville Hospital.

OPEN ENROLLMENT
JULY 20 - AUGUST 28

Registration forms are available on the Pulse page and at the HealthWorks 2.0 office.

Health Matters

Your employee disease management program

Huntsville Hospital Health*Matters* Diabetes Management Application

Name _____Employee ID#_____
Phone_____Email_____
Date of Birth _____Physician _____Phys phone_____
Cigna Group No._____ Member ID_____

Health History: ____Type 1 Diabetes ____Type 2 Diabetes ____Pre-Diabetes
____Insulin Resistance ____ High Blood Pressure ____High Cholesterol
____Polycystic Ovarian Syndrome
Other_____

_____

Program Benefits:

- ✓ **Free** diabetes medications, lancets, and test strips through **Employee Pharmacy**
- ✓ **Free** 12-month **Wellness Center** membership
- ✓ **Free** diabetes education and support through Huntsville Hospital's **Health***Works*, **Diabetes Control Center**, and **Wellness Centers**

Mandatory **Requirements:**

***Please initial if you agree:**

- ✓ **Attend kick-off meeting** *_____
- ✓ **Huntsville Hospital employee on hospital insurance** *_____
- ✓ **Complete Diabetes Education courses** *_____
- ✓ **Complete initial labs, health/fitness assessments** *_____
- ✓ **Commit to exercising at least 8 x per month** *_____
- ✓ **Follow your Physician's orders regarding your diabetes** *_____
- ✓ **Have labs drawn (no cost) at a HH lab every 3 months** *_____
- ✓ **Attend quarterly care manager and group meetings** *_____

Please complete the following chart (may attach additional sheet if needed):

Drug	Dose	How taken (orally etc.)	How Often

IMPORTANT: Return this completed application ***in person*** **to HealthWorks**, Blackwell Medical Towers Suite 10. The **Physician Approval Form**, downloadable from Pulse, must be completed by your primary care physician. *(BOTH forms must be completed and the information returned to HealthWorks to be eligible for benefits.)* **Questions? Call 256-265-6288.**

HealthMatters

Your employee disease management program

Program Benefits

- ***Free*** **diabetes medications, glucose meter, lancets, and test strips through Employee Pharmacy**
- ***Free*** **diabetes education and support through Corporate Wellness, Health*Works* department, the Diabetes Control Center, and HH Wellness Centers**
- **Free Lab Work through Huntsville Hospital Lab**

  Labs must be done the month prior to care manager visits
- **Free Diabetes Grocery Store Tours and Healthy Cooking Demos**

Program Requirements:

- **Huntsville Hospital Employee on HH Insurance**
- **Huntsville Utility Employee on Insurance**
- ***Complete Initial Labs**
- ***Have labs drawn (at no cost) by any HH lab every 3 months**
- ***Attend quarterly care manager meetings**
- **Commit to exercising at least 8 x per month and documenting your exercise. This will be shared with your care manager at each visit.**

  (Take advantage of your *Free* Wellness Center membership)
- *** Attend end of the year meeting**
- **Follow your physician's orders regarding your diabetes management**

****Failure to adhere will result in termination from the HealthMatters Disease Management Program.***

HEALTH*MATTERS* ~ RETURNING MEMBER CALENDAR 2017-2018

August
- Care Manager Visit
- Exercise

September
- Exercise

October
- A1C lab
- Exercise
- * Grocery Store Tour (TBD)

November
- Care manager visit
- Exercise

December
- Exercise
- * Healthy Cooking Demo and Q&A

January
- A1C lab
- Exercise

February
- Care manager visit
- Exercise

March
- Exercise

April
- A1C lab
- Exercise
- * *Special Exercise Class* (TBD)

May
- Care manager visit
- Exercise

June
- End of year *Nutrition-Exercise-Medication Review* Class
- Exercise

July
- 12 Month Fasting Labs
- Exercise

August
- Care manager visit
- Exercise

*Optional, but highly encouraged

Address:	420 Lowell Drive, Suite 500
City, State, and Zip Code	Huntsville, AL 35801

Facsimile Cover Sheet

Date:	# of pages including cover sheet: 2
To:	From: Diabetes Control Center Staff
	Dept: Diabetes Control Center
Phone #:	Dept Phone #: 256-265-3069
Fax #:	Dept Fax #: 256-265-3073

The Diabetes Control Center would like to help your patients and staff with the scheduling process.

The referral form attached is what we will need signed by the physician in order to give your patients specialized care for Diabetes.

Please have your referral specialist call the number located at the top of the referral form or the patient may call to schedule, if appropriate. Then please fax this referral to us at 256-265-3073.

The patient will then be scheduled for an INITIAL ASSESSMENT. At this initial assessment we will schedule our classes, Diabetes University. Our team of certified diabetes educators including nurses and dietitians will provide your patients with the knowledge and tools needed to help manage diabetes and to help prevent complications.

Please call 256-265-3069 if you have any questions. Thank you for your ongoing support of our program.

CONFIDENTIALITY NOTE: The information contained in this facsimile message is legally privileged and confidential information intended only for the use of the individual or entity named above. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying this telecopy is strictly prohibited.

If you have received this fax in error, please complete the below information and fax this form (along with your fax coversheet) to the HH Health System Privacy and Security Officer at 256.265.4477 Thank you.

Please check the one box below that describes what you did with the document(s) you received.

- ☐ **The document(s) was shredded. No copies made or kept.**
- ☐ **The document(s) was not shredded, but was destroyed so that it would be impossible for someone to piece the document back together. No copies were made or kept.**
- ☐ **The original document(s) was returned to the above address. No copies were made or kept**

How many pages of documents you unintentionally received_____

Thank you for your assistance in this matter!

HealthWorks 2.0

HealthMatters Physician Approval and Medical Clearance

Patient Name: | DOB:

Medical Clearance for Exercise

For the HealthMatters program, your patient will be required to participate in an exercise program at Huntsville Hospital's Wellness Center. Your patient has completed a readiness questionnaire which has highlighted the need for a medical clearance. By completing this form, you are not assuming responsibility for our program. If however, you know of any reason why your patient should not undertake a basic assessment of fitness, please indicate the reasons below.

☐ No medical restrictions to exercise ☐ Refer patient to physician before engaging in exercise program

☐ Restrictions of the following: _____

Diagnosis

☐ 250.00 Type 2 ☐ 250.01 Type 1 ☐ 250.02 Type 2, uncontrolled ☐ 250.03 Type 1, uncontrolled

☐ Other _____

Is the patient treated with insulin? ☐ Yes ☐ No Using an insulin pump? ☐ Yes ☐ No

Is the patient treated with oral agents? ☐ Yes ☐ No

Comments_____

☐ Diet order _____

Dispense as Written

Test Strips: ☐ 50 strips ☐ 100 strips ☐ Other amount _____

Glucose Meter: **X** Meter as specified by HealthMatters

Frequency of Monitoring Ordered

☐ Daily ☐ 2 times a day ☐ 3 times a day ☐ 4 times a day ☐ Other _____

Documentation

Co morbidities: ☐ Hypertension ☐ Peripheral vascular disease ☐ Neuropathy ☐ Visual impairment

☐ Dyslipidemia ☐ ESRD ☐ Other _____

Complicating/aggravating circumstances: ☐ Hospitalization: Last date admitted: _____

☐ Other_____

Physician's signature: _____ Date: _____ Time:_____

Physician's name (printed): _____ Phone #: _____

Address: _____ Fax #: _____

City: _____ State: _____ Zip: _____

The HH Healthy System Lab will fax your patient's **Health*Matters* free lab results to your office every 3 months. **

****Please return this form to your patient or fax to Health*Works* at (256) 265-6278****

DIABETES UNIVERSITY

According to the American Diabetes Association, diabetes education is associated with lower average blood glucose and improved quality of life.

DIABETES 101: What You Need to Know

This introductory class focuses on diabetes self-care including food groups, meal planning and timing, target blood glucose levels, sick days, symptoms and treatments of hypoglycemia, and the positive effects of exercise on blood glucose. This is a four-hour class.

Please bring to class:

- Glucose meter
- A list of current medicines and any medical procedures since your initial appointment on _____.
  (date)

You are scheduled for Diabetes 101 on

_____
(date)

_____
(time)

DIABETES 102: Taking Steps to Stay Healthy

This class will build upon the basic principles learned in Diabetes 101. You will learn how to understand lab results, read food labels, use sugar alternatives and care for your feet. This is a two-hour class.

Please bring to class:

- Meal Time Glucose Worksheet (green sheet) from Diabetes 101
- Exercise and Behavior Goals (blue sheet) from Diabetes 101

You are scheduled for Diabetes 102 on

_____
(date)

_____
(time)

DIABETES 103: Trouble Shooting and Keeping a Positive Outlook

This class will help prepare you for the unexpected situations that can interfere with your diabetes control. You will learn strategies for dealing with issues such as illness, disasters, travel, social activities and family situations. You will develop a plan for healthy coping. This is a two-hour class.

Please bring to class:

- Exercise and Behavior Goals (blue sheet) fro Diabetes 102

You are scheduled for Diabetes 103 on

_____
(date)

_____
(time)

If needed, individual follow-up appointments (30-60 minutes) can be scheduled.

420 Lowell Drive, Suite 500
(256) 265-3069 | fax: (256) 265-3073

HUNTSVILLE HOSPITAL
DIABETES CONTROL CENTER

HUNTSVILLE HOSPITAL

Name: _____

Date: _____

Diabetes 101 Class

Goal 1: Set an Exercise goal that you will begin today!
I plan to:

How long?

How often/what days?

Goal 2: Set another goal of your choice to start today!
I plan to:

How often/what days?

Diabetes 102 Class

Date: _____

Goal 1: Were you successful with your Exercise Goal?

☐ Always ☐ Most of the time ☐ ½ the time ☐ Seldom ☐ Never

If you answered ½ the time or less, what was/were the reason(s)?

☐ lack of time

☐ don't like the activity

☐ physical problem such as pain or injury

☐ weather related problems

Goal 2: Were you successful with this Goal?

☐ Always ☐ Most of the time ☐ ½ the time ☐ Seldom ☐ Never

If you answered ½ the time or less, what was/were the reason(s)?

Set a new goal that you will begin today!

I plan to:

How often/what days?

Diabetes 103 Class

Date: _____

Goal 1: Were you successful with the Goal set in Diabetes 102 class?

☐ Always ☐ Most of the time ☐ ½ the time ☐ Seldom ☐ Never

If you answered ½ the time or less, what was/were the reason(s)?

MEMO

To: IRB Admin, Office of Research Compliance

From: Brittannie Chester, PhD Student in Nutrition

Department of Nutrition, Dietetics and Hospitality Management

Protocol: #19-314- The Effects of Diabetes Self-Management Education and Support in North Alabama: Comparing Education Structures

Date: July 25, 2019

Subject: IRB Revisions

Auburn IRB Admin,

I have attached the application revisions.

1. In item 4 of the application form, describe the PI's relationship with Huntsville Hospital. If the PI is an employee of the hospital, that must be described in item 4.
    a. The Principal Investigator is a former full-time employee and current PRN, seasonal/as needed Registered Dietitian with Huntsville Hospital. Chart access has been granted to the principal investigator by the Huntsville Hospital Institutional Review Committee for this research.

2. In item 4 of the application form, provide the timeframe of the data collection (for example, what years of data will be reviewed).
    a. The data will be collected from January 2015 – May 2019

3. If a data collection form, will be used, submit a copy.
    a. No official data collection form will be used, the data will be recorded in a blank excel spreadsheet.

Auburn University Human Research Protection Program

EXEMPTION REVIEW APPLICATION

For information or help completing this form, contact: **The OFFICE OF RESEARCH COMPLIANCE,**
Location: 115 Ramsay Hall **Phone:** 334-844-5966 **Email:** IRBAdmin@auburn.edu

Submit completed application and supporting material as one attachment to irbsubmit@auburn.edu.

1. PROJECT IDENTIFICATION **Date** 07/08/2019

a. Project Title The Effects of Diabetes Self-Management Education and Support in North Alabama: Comparing Education Structures

b. Principal Investigator Brittannie Chester Degree(s) BS Biology, MS Nutrition

Rank/Title Graduate Assistant Department/School Nutrition, Dietetics & Hospitality Mgmt

Phone Number (256) 361-7333 AU Email bzc0052@tigermail.auburn.edu

Faculty Principal Investigator (required if PI is a student) Geetha Thangiah

Title Associate Professor Department/School Nutrition, Dietetics

Phone Number (334) 844 7418 AU Email thangge@auburn.edu

Dept Head Dr. Martin O'Neill Department/School Nutrition, Dietetics & Hospitality Mgmt

Phone Number (334) 844 3264 AU Email oneilm1@auburn.edu

c. Project Personnel (other than PI) - Identify all individuals who will be involved with the conduct of the research and include their role on the project. Role may include design, recruitment, consent process, data collection, data analysis, and reporting). Attach a table if needed for additional personnel.

Personnel Name _____ Degree(s) _____
Rank/Title _____ Department/School _____
Role _____
AU affiliated? ☒ YES ☐ NO If no, name of home institution _____
Plan for IRB approval for non-AU affiliated personnel? _____

Personnel Name _____ Degree(s) _____
Rank/Title _____ Department/School _____
Role _____
AU affiliated? ☐ YES ☐ NO If no, name of home institution _____
Plan for IRB approval for non-AU affiliated personnel? _____

Personnel Name _____ Degree(s) _____
Rank/Title _____ Department/School _____
Role _____
AU affiliated? ☐ YES ☐ NO If no, name of home institution _____
Plan for IRB approval for non-AU affiliated personnel? _____

d. Training - Have all Key Personnel completed CITI human subjects training (including elective modules related to this research) within the last 3 years? ☒ YES ☐ NO

e. Funding Source- Is this project funded by the investigator(s)? ☒ YES ☐ NO
Is this project funded by AU? ☒ YES ☐ NO If YES, identify source Faculty start-up funds
Is this project funded by an external sponsor? ☐ YES ☒ NO If YES, provide the name of the sponsor, type of sponsor (governmental, non-profit, corporate, other), and an identification number for the award.
Name _____ Type _____ Grant # _____

f. List other IRBs associated with this research and submit a copy of their approval and/or protocol.
Huntsville Hospital Institutional Review Committee

The Auburn University Institutional Review Board has approved this Document for use from 07/25/2019 to ----------
Protocol # 19-314 EX 1907

2. Mark the category or categories below that describe the proposed research:

☐ 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices. The research is not likely to adversely impact students' opportunity to learn or assessment of educators providing instruction. 104(d)(1)

☐ 2. Research only includes interactions involving educational tests, surveys, interviews, public observation if at least ONE of the following criteria. (The research includes data collection only; may include visual or auditory recording; may NOT include intervention and only includes interactions). **Mark the applicable sub-category below (i, ii, or iii).** 104(d)(2)

☐ (i) Recorded information cannot readily identify the participant (directly or indirectly/linked); **OR**

- surveys and interviews: no children;
- educational tests or observation of public behavior: can only include children when investigators do not participate in activities being observed.

☐ (ii) Any disclosures of responses outside would not reasonably place participant at risk; **OR**

☐ (iii) Information is recorded with identifiers or code linked to identifiers and IRB conducts limited review; no children. **Requires limited review by the IRB.***

☐ 3. Research involving Benign Behavioral Interventions (BBI)** through verbal, written responses (including data entry or audiovisual recording) from adult subjects who prospectively agree and ONE of the following criteria is met. (This research does not include children and does not include medical interventions) **Mark the applicable sub-category below (I, ii, or iii).** 104(d)(3)(i)

☐ (A) Recorded information cannot readily identify the subject (directly or indirectly/linked); **OR**

☐ (B) Any disclosure of responses outside of the research would not reasonably place subject at risk; **OR**

☐ (C) Information is recorded with identifiers and cannot have deception unless participant prospectively agrees. **Requires limited review by the IRB.***

■ 4. Secondary research for which consent is not required: use of identifiable information or identifiable bio-specimen that have been or will be collected for some other 'primary' or 'initial' activity, if one of the following criteria is met. Allows retrospective and prospective secondary use. **Mark the applicable sub-category below (I, ii, iii, or iv).** 104(d)(4)

☐ (i) Biospecimens or information and must be publically available;

■ (ii) Information recorded so subject cannot readily be identified, directly or indirectly/linked; investigator does not contact subjects and will not re-identify the subjects; **OR**

☐ (iii) Collection and analysis involving investigators use of identifiable health information when use is regulated by HIPAA "health care operations" or "research or "public health activities and purposes" (does not include biospecimens (only PHI and requires federal guidance on how to apply); **OR**

☐ (iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities.

☐ 5. Research and demonstration projects which are supported by a federal agency/department AND designed to study and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs;(iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. (must be posted on a federal web site). 104(d)(5) (must be posted on a federal web site)

☐ 6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. The research does not involve prisoners as participants. 104(d)(6)

New exemption categories 7 and 8: Both categories 7 and 8 require Broad Consent. (Broad consent is a new type of informed consent provided under the Revised Common Rule pertaining to storage, maintenance, and secondary research with identifiable private information or identifiable biospecimens. Secondary research refers to research use of materials that are collected for either research studies distinct from the current secondary research proposal, or for materials that are collected for non-research purposes, such as materials that are left over from routine clinical diagnosis or treatments. Broad consent does not apply to research that collects information or biospecimens from individuals through direct interaction or intervention specifically for the purpose of the research.) **The Auburn University IRB has determined that as currently interpreted, Broad Consent is not feasible at Auburn and these 2 categories WILL NOT BE IMPLEMENTED at this time.**

***Limited IRB review* – the IRB Chairs or designated IRB reviewer reviews the protocol to ensure adequate provisions are in place to protect privacy and confidentiality.**

****Category 3 – Benign Behavioral Interventions (BBI)* must be brief in duration, painless/harmless, not physically invasive, not likely to have a significant adverse lasting impact on participants, and it is unlikely participants will find the interventions offensive or embarrassing.**

3. PROJECT SUMMARY

a. Does the study target any special populations? (Mark all applicable)

Minors (under 19)	☐ YES ■ NO
Pregnant women, fetuses, or any products of conception	☐ YES ■ NO
Prisoners or wards (unless incidental, not allowed for Exempt research)	☐ YES ■ NO
Temporarily or permanently impaired	☐ YES ■ NO

b. Does the research pose more than minimal risk to participants? ☐ YES ■ NO

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 42 CFR 46.102(i)

c. Does the study involve any of the following?

Procedures subject to FDA regulations (drugs, devices, etc.)	☐ YES ■ NO
Use of school records of identifiable students or information from instructors about specific students.	☐ YES ■ NO
Protected health or medical information when there is a direct or Indirect link which could identify the participant.	☐ YES ■ NO
Collection of sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior or alcohol use.	☐ YES ■ NO
Deception of participants	☐ YES ■ NO

4. Briefly describe the proposed research, including purpose, participant population, recruitment process, consent process, research procedures and methodology.

Using retroactive data collection, we would like to analyze the effects of diabetes self management education in North Alabama and Southern Tennessee. The data will be collected from Huntsville Hospital's electronic medical records via Cerner's electronic health system. The principal investigator is a former full time employee and current PRN, seasonal/as needed Registered Dietitian with the hospital. Chart access has been granted to the principal investigator by the Huntsville Hospital Institutional Review Committee for this research. Huntsville Hospital is the second-largest hospital in Alabama. Huntsville Hospital is a 971-bed hospital that serves as the regional referral center for North Alabama and southern Tennessee. The Huntsville Hospital Diabetes Control Center provides diabetes education to the community via inpatient and outpatient education. We would like to collect changes in weight, BMI, Blood glucose, Blood pressure, lipids, and hemoglobin A1C of more than 500 type 2 diabetes patients between the ages of 18-100. The data will be collected from patients with type 2 diabetes who have received diabetes coaching and self-management education and support from the diabetes control center from January 2015 - May 2019 in the outpatient community and the Health matters program provided for hospital employees and their families. Age, race, gender, rural/urban location, weight, height, BMI, Blood pressure, LDL, HDL, Triglycerides, glucose, Hemoglobin A1C, insulin, medications and total cholesterol will be collected and documented in a blank excel spread sheet.

5. Describe how participants/data/specimens will be selected. If applicable, include gender, race, and ethnicity of the participant population.

This population includes women and men with type 2 Diabetes Mellitus between the ages of 18-100 and of all races, mainly African American, Caucasian, and Hispanic. This information will be collected from existing data in the hospital, and the information will be coded. This data will be a limited data set, where the names will only be seen in the hospital during collection, then a code will be given to each patient.

6. **Does the research involve deception? ☐ YES ■ NO If YES, please provide the rationale for deception and describe the debriefing process.**

7. **Describe why none of the research procedures would cause a participant either physical or psychological discomfort or be perceived as discomfort above and beyond what the person would experience in daily life.**

This information will be collected from existing data in the hospital, and the information will be coded. This data will be a limited data set, where the names will only be seen in the hospital during collection, then a code will be given to each patient.

8. **Describe the provisions to maintain confidentiality of data, including collection, transmission, and storage.**

This information will be collected from existing data in the hospital, and the information will be coded. This data will be a limited data set, where the names will only be seen in the hospital during collection, then a code will be given to each patient.

9. **Describe the provisions included in the research to protect the privacy interests of participants (e.g., others will not overhear conversations with potential participants, individuals will not be publicly identified or embarrassed).**

This information will be collected from existing data in the hospital, and the information will be coded. This data will be a limited data set, where the names will only be seen in the hospital during collection, then a code will be given to each patient.

10. **Will the research involve interacting (communication or direct involvement) with participants?** ☐ YES ■ NO **If YES, describe the consent process and information to be presented to subjects. This includes identifying that the activities involve research; that participation is voluntary; describing the procedures to be performed; and the PI name and contact information.**

11. **Additional Information and/or attachments.**

In the space below, provide any additional information you believe may help the IRB review of the proposed research. If attachments are included, list the attachments below. Attachments may include recruitment materials, consent documents, site permissions, IRB approvals from other institutions, etc.

Institutional review committee approval from Huntsville Hospital.

Principal Investigator's Signature _____ **Date** 07/11/2019

If PI is a student,
Faculty Principal Investigator's Signature _____ **Date** 07/11/2019

Department Head's Signature _____ **Date** 07/4/19

HUNTSVILLE HOSPITAL

101 Sivley Road
Huntsville, AL 35801
(256) 265-1000
huntsvillehospital.org

July 1, 2019

Ms. Brittannie Chester
Huntsville Hospital Diabetes Control Center
420 Lowell Drive, Suite 500
Huntsville, AL 35801

RE: Request for Institutional Review Committee Exemption of Study - "The Effects of Diabetes Self-Management Education and Support in North Alabama: Comparing Education Structures"

Dear Ms. Chester:

Thank you for forwarding the Institutional Review Committee Exemption from Review Application to me for your proposed data collection study. Dr. John Cox, Chair of IRC, and I have reviewed your information, and this study qualifies and has been approved for Exemption from IRC review.

Please note: Any proposals or anticipated changes to the project must be submitted to the IRC Coordinator and approved by the IRC Chair prior to implementation. An Exemption from Review Update Form must be submitted on an annual basis if the study remains open. When your project closes, please advise me by letter or email.

Please contact Medical Records, for medical record access and HIPAA compliancy information, if necessary. If you have any questions or I can be of further service, please feel free to call me at (256)265-6990.

Sincerely,

Allison E. Greene, Division Assistant/
Institutional Review Committee Coordinator

cc: John B. Cox, MD, Chair, IRC
Geetha Thangiah, PhD, Auburn University

Re: Chester Diabetes Research project - Exemption Request

From : John Cox <jbcox01@gmail.com> Mon, Jul 01, 2019 06:19 AM
Subject : Re: Chester Diabetes Research project - Exemption Request
To : Allison Greene <allison.e.greene@hhsys.org>

WARNING: This email originated outside of the Huntsville Hospital Health System. **DO NOT CLICK** links or attachments unless you recognize the sender and know the content is safe.
Please forward all suspicious email messages to phishing@hhsys.org.

Yes, I approve.

JBC

On Thu, Jun 27, 2019 at 10:40 AM Allison Greene <allison.e.greene@hhsys.org> wrote:

Dr. Cox:
I have reviewed and this meets criteria for exemption from review. Could you give me a determination?
Thanks, Allison

From: "Brittannie Chester" <brittannie.chester@hhsys.org>
To: "Allison Greene" <allison.e.greene@hhsys.org>
Cc: "Allison Greene" <allison.e.greene@hhsys.org>, "bchester rd" <bchester.rd@gmail.com>, thangge@auburn.edu, bzc0052@tigermail.auburn.edu
Sent: Thursday, June 27, 2019 10:27:11 AM
Subject: Re: Chester Diabetes Research project

Good morning Allison,

I have attached the completed new application for research. Please let me know if there's anything else I need to do for this project to be discussed at the next review committee meeting.

Thanks for all of your help,

Brittannie Chester, MS, RD, LD, CDE
Diabetes Educator
Diabetes Control Center
Huntsville Hospital
420 Lowell Dr., Suite 500
Huntsville, Al. 35801
(256) 265-3179

----- Original Message -----
From: "Allison Greene" <allison.e.greene@hhsys.org>
To: "Brittannie Chester" <brittannie.chester@hhsys.org>
Sent: Wednesday, June 26, 2019 1:45:01 PM
Subject: Re: Research project

----- Original Message -----

From: "Brittannie Chester" <brittannie.chester@hhsys.org>
To: "Allison Greene" <allison.e.greene@hhsys.org>
Sent: Wednesday, June 26, 2019 1:44:03 PM
Subject: Re: Fwd: Research project

Hi Allison!
I'm only seeing the one I completed in this email. Can you send a new email with the new application?
Thanks!
----- Original Message -----
From: Allison Greene <allison.e.greene@hhsys.org>
To: Brittannie Chester <brittannie.chester@hhsys.org>
Sent: Wed, 26 Jun 2019 13:40:18 -0500 (CDT)
Subject: Fwd: Research project

Rec 6/27/19 BG

HUNTSVILLE HOSPITAL – INSTITUTIONAL REVIEW COMMITTEE
PROTOCOL APPLICATION FOR STUDY (FULL/EXPEDITED/EXEMPT) (IRC App. 03/12/19)

SECTION 1: INSTRUCTIONS & CHECKLIST

You are applying for Huntsville Hospital's Institutional Review Committee review of research described in this form. To avoid delay, respond to all items, include all required approvals/documents. To complete the form, click underlined areas and type in your text; double-click checkboxes to check/uncheck. Submit all materials to Huntsville Hospital Institutional Review Committee, Allison E. Greene, IRC Coordinator, 101 Sivley Road, SW, Huntsville, AL 35801 Allison.e.greene@hhsys.org

Huntsville Hospital IRC Checklist: New Study Protocol

All data must be submitted in original hard copy & in electronic format through confidential, unprotected e-mail to the Huntsville Hospital IRC Office or on thumb drive in Word or PDF format only.

- ☐ Completed and signed IRC Application.
- ☐ Phase of Study included on the Application.
- ☐ Significant Risk (SR) device or implant studies must be accompanied by the IDE # and FDA approval letter.
- ☐ Signed Confidential Report of Proprietary/Financial Disclosure of Principal Investigator(s), if applicable.
- ☐ Protocol Summary Letter briefly explaining the protocol in lay terms.
- ☐ Complete Protocol, including date and version number, and any attachments.
- ☐ Informed Consent Form which contains the following elements:
  1. concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
  2. appropriate HIPAA language/HIPAA Addendum. (Language must not "promise" confidentiality but should assure the participant that every effort will be made to protect the information according to HIPAA guidelines.)
  3. inclusion of the following: "I understand that Huntsville Hospital has made no provision of monetary compensation to me in the event of physical injury resulting from the research procedures. Should physical injury occur, medical treatment is available, but treatment is not provided free of charge."
  3. date and/or version number.
  4. no blanks
  5. contact information: (John B. Cox, M.D., Chair, Huntsville Hospital Institutional Review Committee); contact telephone number (256) 265-6990). (If you wish to include the hospital's address, please list as "101 Sivley Road, Huntsville, AL 35801") and Principal Investigator's contact information.
  6. information that addresses Alabama's age of majority of 19 years of age or older.
- ☐ If applicable, copy of the Investigator's Brochure for studies using an investigational new drug or device or the package insert for studies using commercially available drugs in an investigational manner.
- ☐ Fee of $750.00. *(Fee may be waived if nonfunded/compassionate study; note on Application.)*

The Huntsville Hospital Institutional Review Committee meets the second Tuesday of each month, 4:30 p.m. in the Administrative Board Room, Huntsville Hospital at 101 Sivley Road, Huntsville, AL 35801. The Principal Investigator or Co-Investigator is requested to attend the meeting to present a brief overview of the study. Huntsville Hospital IRC Policies and Procedures are found on the intranet Pulse Page or can be obtained from Allison Greene, Division Assistant/IRC Coordinator, at (256)265-6990.

Brittannie Chester, MS, RD, LD, CDE — 06/27/2019

Person submitting request on behalf of Investigator **Date of Submission**

- **Failure to follow the above instructions for submission will delay review of the protocol.**

HH IRC COORDINATOR USE ONLY:

- Date received: 06/27/19
- Items missing/notes: —
- Informed Consent contains all elements: Exempt
- CRC review form completed; Date reviewed by CRC:
- Invoice sent, fee received, deposited, & spreadsheet updated:
- Date protocol submitted to Institutional Review Committee:
- Principal Investigator notified to attend IRC meeting:
- Date approved by IRC and certification and/or stamped Informed Consent issued to PI: HC
- Other action taken by IRC:

Section 1: Research Protocol Title & Category

Title: The Effects of Diabetes Self-Management Education and Support in North Alabama: Comparing Education Structures

Date Submitted to Huntsville Hospital IRC Office: June 26, 2019

Please select one:

☐ Full (Convened) IRC Review Application
☐ Expedited IRC Review Application (must meet criteria for Expedited Review)
☒ Exemption from IRC Review Application (must meet criteria for Exemption from Review)

Signature: Brittannie Chester, MS, RD, LD, CDE

Section 2: Project Personnel

Including the PI, list all key personnel (each individual involved in the design and conduct of this protocol). Complete the tables, as applicable. Use the checkboxes to show each individual's role, whether the individual has financial interests and briefly describe the individual's protocol responsibilities/qualifications to perform responsibilities. **Insert additional rows as needed.**

a. Principal Investigator/Co-Investigtors:

Name and Department	Affiliation	Role	Responsibilities/Qualifications (indicate if this person obtains consent)
Name: Brittannie Chester Department: Huntsville Hospital Diabetes Control Center	Huntsville Hospital - Diabetes Control Center	Principal Investigator	Registered Dietitian and Certified Diabetes Educator/ consent obtained
Name: Click or tap here to enter text. Department: Click or tap here to enter text.	Click or tap here to enter text.	☐Sub-Investigator ☐Other	Click or tap here to enter text.
Name: Click or tap here to enter text. Department: Click or tap here to enter text.	Click or tap here to enter text.	☐Sub-Investigator ☐Other	Click or tap here to enter text.

b. Non-HH Personnel Relying on HH IRC - If you are requesting that the HH IRC serve as the IRC of record for anyone not affiliated with HH, list these individuals below. If N/A ☐

Name and Degree	From Institution with or without own IRC?	Responsibilities/Qualifications (indicate if this person obtains consent)
Name: Geetha Thangiah Degree: PhD Institution: Auburn University Email: thangge@auburn.edu	☒ Has own IRC (submit copy of Exempt designation from site IRC) **-OR-** ☐Does not have own IRC and needs to rely on HH IRC.	Associate Professor Department of Nutrition, Dietetics, and Hospitality Management Consent obtained

***Financial Interest** – for each individual listed above, answer **YES** or **NO** as to whether the individual or an immediate family member has any of the following:

- An ownership interest, stock options, or other equity interest related to the investigator's institutional responsibilities of any value.
- Compensation greater than $5,000 in the previous two years when aggregated for the immediate family
- Proprietary interest including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Board of executive relationship, regardless of compensation.
- Any other Financial Interest.

If the individual or his/her spouse or dependent child has a Financial Interest, a disclosure has to be made to the HH IRC.
Include a Conflict of Interest Form with this submission.

c. Is the principal investigator a student, fellow, or resident?

☐ NO - Continue with Item 2.d.
☒ YES - Complete the following

Supervisor Name	**Dr. Geetha Thangiah**
Title	Associate Professor, Department of Nutrition, Dietetics, and Hospitality Management
Phone	(334) 844 7418
Email	**thangge@auburn.edu**
Signature	G. Geetha

d. Do the investigators listed above include any students using this research for their thesis or dissertation?

☐ NO - Continue with Item 3.
☒ YES - Complete the following

Student Name	**Thesis/Dissertation Title**
Brittannie Chester	**The Effects of Diabetes Self-Management Education and Support in North Alabama: Comparing Education Structures**

Section 3: Funding

a. Is the project funded?

☒ NO - Specify which department will cover the costs of the research (e.g., PI's time and effort) or that the PI will cover these costs personally, then continue with Item 4. **The PI will cover the costs personally**
☐ YES - Continue with Item 3.b.

b. Sponsor/Funding route:	
Title of Grant, Contract, or agreement	Click or tap here to enter text.
PI of Grant, Contract, or Agreement	Click or tap here to enter text.
OSP Number	Click or tap here to enter text.
Sponsor/Funding Route	*(Check and describe all that apply)* ☐ Gov't Agency or Agencies—Agency name(s): **Click or tap here to enter text.** ☐ Department of Defense (DoD): Identify DoD component: **Click or tap here to enter text.** ☐ Department of Energy (DOE) ☐ Department of Justice (DOJ) ☐ Department of Education ☐ NIH Cooperative Group Trial - Group name: **Click or tap here to enter text.** ☐ Private Nonprofit (e.g., Foundation) - Name: **Click or tap here to enter text.** ☐ Industry, investigator-initiated - Name: **Click or tap here to enter text.** ☐ HH Departmental Funds—Specify: **Click or tap here to enter text.**

Section 4: Locations

a. Indicate which sites will provide space, services, facilities, or serve as a source of recruitment or study conduct.

☒ HH Hospital (Includes HH for Women & Children & Madison Hospital)

☒ Other: Huntsville Hospital Diabetes Control Center

☐ None of these

Section 5: Clinical Trial

a. Does this protocol meet the following definition of a clinical trial*?

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

☒ NO

☐ YES - If YES, ensure that all key personnel have current Good Clinical Practices (GCP) training.
If YES, register project on ClinicalTrials.gov & Provide National Clinical Trial (NCT) #: Click or tap here to enter text.

Section 6: Purpose & Background

a. Describe the purpose of your research. Ensure that the purpose describes a research endeavor. If you are conducting Quality Improvement only or some other non-research activity, you will not need to submit.

Using retroactive data collection, we would like to analyze the effects of diabetes education in the diabetes control center. We would like to collect changes in weight, BMI, Blood glucose, Blood pressure, lipids, and hemoglobin A1C of more than 500 patients in North Alabama.

b. Provide any needed background to address why the research is being done or the issue being addressed. Do not describe any methodology or procedures in this section.

Previously, a group of dietitians collected similar data from 100 patients in Huntsville Hospital Diabetes Control Center in a multisite study in 2013. We would like to complete a similar study with more patients and more data. We are interested in the effects of diabetes self-management education and coaching in various forms within Huntsville hospital. We hope that this will lead to improvements in the methods used to provide our patients with the proper education needed to maintain proper control and management of type 2 diabetes.

Marincic, Patricia Z. et al. Diabetes Self-Management Education and Medical Nutrition Therapy: A Multisite Study Documenting the Efficacy of Registered Dietitian Nutritionist Interventions in the Management of Glycemic Control and Diabetic Dyslipidemia through Retrospective Chart Review. Journal of the Academy of Nutrition and Dietetics, Volume 119, Issue 3, 449 - 463

Section 7: Participants

a. Describe each group of participants to be included in your research, including those who will only be represented through collection of secondary data (copy and repeat rows for each participant group type).

Participant Description: **patients with type 2 diabetes who have received diabetes coaching and self-management education and support from Huntsville hospital.**
Age Range of this Participant Group: **18-100**

Participant Description: Click or tap here to enter text.
Age Range of this Participant Group: Click or tap here to enter text.

b. Indicate which, if any, of the special populations listed below will be involved in the protocol. Individual exemption categories below also ask information about populations where there are category-specific applicability. Ensure you are consistent in your description of populations to be included in the project.

☐ Pregnant Women

☐ Neonates/Nonviable Neonates

☐ Minors (<19 years old)

☒Employees or students at institution where research conducted

☐Non-English Speakers (provide a copy of all translated documents and the identity and credentials of the person translating them with your submission).

☐Prisoners – if checked, continue with Item 7.b.i:

i. Are prisoners intentionally recruited for this project?

☐YES -prisoners are intentionally recruited for this project – **This project is not eligible for exemption.**

☒NO -this project is aimed at involving a broader subject population that may only incidentally include prisoners.

c. If your project involves any interaction (e.g., emails, surveys, interviews, focus groups, phone calls), observations, or interventions (e.g., training, instruction, benign behavioral intervention), describe all methods used to recruit and screen (if applicable) participants for your research. In your description, include how and when recruitment will occur, who will recruit these participants, and any measures taken to minimize coercion, if applicable.

None, secondary data collection

Section 8: Exemption Categories

Investigators need only complete the sections below that apply to their research. However, be sure to complete sections 9-11 for all projects.

- Category 1: Research conducted in established or commonly accepted educational settings involving normal educational practices.
- Category 2: Research involving educational tests, survey procedures, interview procedures, or observation of public behavior.
- Category 3: Research involving benign behavioral interventions.
- Category 4: Secondary research uses of identifiable private information or identifiable biospecimens.
- Category 5: Research and demonstration projects that are conducted, supported by, or otherwise subject to the approval of a Federal department or agency on public benefit or service programs.
- Category 6: Taste and food quality evaluation and consumer acceptance studies.
- Categories 7 & 8: These are not represented in this application as HH IRC is not adopting them at this time.

1. ☐EXEMPT CATEGORY 1 [§46.104(d)(1)]: Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies and research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.

a. Describe the common educational setting for your project (e.g., specific course/class/curriculum, site of project).

Click or tap here to enter text.

b. Briefly describe the normal educational practice to be evaluated.

Click or tap here to enter text.

c. Indicate whether the normal education practice to be evaluated is being implemented as part of the research or is separate from your research.

☐ The practice is being implemented specifically for this research. If checked, include a copy of all curriculum materials.

☐ The practice is either already-existing or being implemented separate from the research.

d. Will your research involve obtaining and analyzing data from secondary sources including, but not limited to, online educational sources; student records; local, state, or federal datasets?

☐ NO - Skip to Item 8.1.e

☐ YES - Continue to 8.1.d.i

If YES -include documentation of permission to use the data from the source, when applicable. If this documentation does not indicate the data to be received, or if you will be collecting the data from the source yourself, provide a full list of variables to be obtained or a data collection form for each data set.

i. Describe each data set below, including the source of the data and how you have access. Provide specific information, including an IRC protocol number if using secondary research data at HH.

Click or tap here to enter text.

e. Will your research involve any interaction (e.g., e-mails, surveys, interviews, focus groups, phone calls), observations, or interventions (e.g., training, instruction)?

☐ NO -Skip to Item 8.1.f

☐ YES -Continue to Item 8.1.e.i

i. **Describe your research in chronological order to include all data to be collected directly from the participant (what specific data, how), any interactions (emails, surveys, focus groups, phone calls), observations, or interventions (e.g., training, instruction).**

Points to consider:

- **Describe any data requested from participant that they have created (e.g., lesson plans, diaries, journals).**
- **How surveys will be delivered (online survey host vs. pen/paper) and returned.**
- **Whether or not interviews or focus groups will be audio/video recorded and, if so, who will transcribe them.**
- **Include a copy of all data collection instruments or observation forms with your submission.**

Click or tap here to enter text.

f. Family Educational Rights and Privacy Act: Does data to be collected or obtained in Items 8.1.e or 8.1.f include any identifiable study records (e.g., grades, test scores, class assignments, class evaluations) beyond standard directory type data?

☐ NO

☐ YES - Indicate which of the following you will do to ensure FERPA regulations are followed:

☐ Obtain written permission to use this information from the adult (19 and older) student or their parent/guardian, which can be obtained through the consent process described in Item 10. **-OR-**

☐ Obtain and submit a copy of a documented FERPA exception from the educational site's registrar.

g. Provide justification that your project will not adversely impact any student's ability to learn.

Click or tap here to enter text.

h. Provide justification that your research will not adversely impact the assessment of educators who provide instruction.

Click or tap here to enter text.

2. ☐ EXEMPT CATEGORY 2 [§46.104(d)(2)]: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), and at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRC conducts a limited IRC review to make the determination required by §46.111(a)(7).

Note that there are restrictions of Category 2 when research will involve children.

a. Does the research involve children?

☐NO – Skip to 8.2.b.

☐YES - If YES -does research with children involve any of the following:

- Survey procedures
- Interview procedures
- Observation of public behavior when the investigator(s) will participate in the activities being observed

☐NO – proceed to 8.2.b.

☐YES – Exemption 8.2 does not apply to your project. Consider whether other exemptions apply.

b. Does the research include any intervention?

☐No

☐Yes - Exemption 2 does not apply to your project. Consider whether other exemptions apply (specifically Category 3).

c. Exemption category 2 does not allow linkage of other data sources to the information collected through the educational tests, survey procedures, interview procedures, or observations of public behavior. Will your project involve linkage of any other data sources?

☐NO

☐YES - Exemption 2 does not apply to your project. Consider whether other exemptions apply.

d. Describe your research in chronological order to include all data to be collected directly from the participant (what specific data, how), any interactions (emails, surveys, focus groups, phone calls), tests, or observations.

Points to consider:

- **Online survey hosting service and whether you will have access to identifiers such as URLs, IP addresses, or emails of participants**
- **How pen/paper surveys will be returned to the PI**
- **Whether or not interviews or focus groups will be audio/video recorded and, if so, who will transcribe them**
- **Include a copy of all data collection instruments with your submission.**

Click or tap here to enter text.

3. ☐ EXEMPT CATEGORY 3 [§46.104(d)(3)]: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection, and at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRC conducts a limited IRC review to make the determination required by §46.111(a)(7).

a. Does your research involve one or more benign behavioral interventions? (Item 8.3.c. below provides assistance on determining whether an intervention meets the definition of a benign behavioral intervention.)

☐YES

☐NO – Exempt Category 3 does not apply to your project. Consider whether other exemptions apply.

b. Are all research participants adults (aged 19 and older)?

☐YES

☐NO – Exempt Category 3 does not apply.

c. Describe your research methods and procedures in chronological order to include a clear description of the benign behavioral intervention, all data to be collected directly from the participant (what specific data, how), any interactions (emails, surveys, focus groups, phone calls), tests, or observations.

Points to consider:

- **How surveys will be delivered (online survey host vs. pen/paper) and returned**
- **Description of specifically how data are to be collected as Exempt Category 3 only allows for data to be collected are through verbal or written responses (e.g., surveys or interviews, test responses, data entry), observation, or audiovisual recordings. Data cannot be collected via physical procedures such as blood pressure monitoring, EEG, activity trackers (e.g., Fitbit), eye trackers, or blood draws.**
- **Whether or not interviews or focus groups will be audio/video recorded and, if so, who will transcribe them**

Include a copy of all data collection instruments with your submission.

Click or tap here to enter text.

i. What is the maximum amount of time the intervention(s) could take for any single participant? *To qualify for exempt Category 3, the intervention(s) must be brief in duration.*

Click or tap here to enter text.

ii. Is the intervention(s) harmless?

☐YES

☐NO - Exempt Category 3 does not apply.

iii. Is the intervention(s) painless?

☐YES

☐NO - Exempt Category 3 does not apply.

iv. Is the intervention(s) physically invasive?

☐YES - Exempt Category 3 does not apply.

☐NO

v. Is the intervention(s) likely to have a significant adverse lasting impact on the subjects?

☐YES - Exempt Category 3 does not apply.

☐NO

vi. Does the investigator have any reason to think the subjects will find the intervention(s) offensive or embarrassing?

☐YES - Exempt Category 3 does not apply.

☐NO

d. Does the research involve deception or partial disclosure of the purpose or activities involved in the research, including not disclosing the research title?

☐YES - to be eligible for Exempt Category 3, participants must prospectively agree to the deception through an agreement in which they are informed that they will be unaware of or misled regarding the nature or purposes of the research. Describe how you will obtain participants' agreement to the deception in Item 10.

☐NO

e. Is information from subjects recorded through verbal or written responses (including data entry) or audiovisual recording only? (NOTE: data collection via physical procedures such as blood pressure monitoring, activity trackers, eye trackers are not allowed in Exempt Category 3).

☐YES

☐NO - Exempt Category 3 does not apply.

4. ☒ EXEMPT CATEGORY 4 [§46.104(d)(4)]: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. [§46.104(d)(4)]

a. Are the data and/or biospecimens to be evaluated considered private and identifiable?

☐ NO - The data contain no identifying information and cannot be indirectly identified. Exemption 4 does not apply to your project. Consider whether other exemptions apply.

☒ YES

b. Does your research ONLY involve the evaluation of secondary (retrospective or prospective) information or biospecimens for which consent is not required?

☐ NO - some or all of the information or biospecimens will be collected directly from the participant by me or by someone else specifically for my research. Exemption 4 does not apply to your project. Consider whether other exemptions apply.

☒ YES

c. Fully describe the identifiable information and/or identifiable biospecimens to be used on your research, including each source. Provide a list of the variables to be obtained or data collection forms in your application.

Age, race, gender, zip code, weight, height, BMI, Blood pressure, LDL, HDL, Triglycerides, glucose, Hemoglobin A1C, insulin, medications, total cholesterol

5. ☐ EXEMPT CATEGORY 5 [§46.104(d)(5)]: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects. as collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. [§46.104(d)(4)]

a. Does your research ONLY involve research on a public benefit program (e.g., Social Security) conducted by or subject to the approval of the federal government?

☐ NO -Exemption 5 does not apply to your project. Consider whether other exemptions apply.

☐ YES -Provide the publicly accessible Federal website on which this project is listed: Click or tap here to enter text.

6. ☐ EXEMPT CATEGORY 6 [§46.104(d)(6)]: Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

a. Which of the following applies to your project?

☐ Wholesome foods without additives

Describe the foods: Click or tap here to enter text.

☐ Food that contains a food ingredient, agricultural chemical, or environmental contaminant found to be safe.

Describe the food(s), food ingredient(s), agricultural chemical(s), and/or environmental contaminant(s):
Click or tap here to enter text.

Provide information from the Food and Drug Administration, the Environmental Protection Agency, and/or the Food Safety and Inspection Service of the U.S. Department of Agriculture regarding the safety of the items noted above:
Click or tap here to enter text.

☐None of the above - Exemption 6 does not apply to your project. Consider whether other exemptions apply.

Section 9: HIPAA

a. Does your project obtain, review, or make other use of participant's "protected health information" (i.e., information, whether oral or recorded in any form or medium that (a) is created or received by a health care provider and (b) relates to past, present, or future physical or mental health or condition of an individual; or provision of health care; or payment for provision of heath care)?

☐ NO – Skip to Section 10

☒ YES

b. Is the principal investigator requesting that the HH IRC waive patient HIPAA authorization from another institution or entity (e.g., insurance company, collaborating institution)?

☒ NO

☐ YES -If YES, attach copies of the privacy notices from each entity and/or letter from that institution requesting that HH IRC serve as HIPAA Privacy Board, and provide the name of each institution/entity: Click or tap here to enter text.

c. Indicate below which of the entities would be a source for this information, will be the site of active recruitment, and/or will be the site of storage/maintenance of data/biospecimens.

☒ HH (Includes Huntsville Hospital, HH for Women & Children, and Madison Hospital)

☐ None – if NONE, skip to Item 10

d. Indicate any *information systems* that will be the source(s) of information used for the protocol.

☒ A system maintained centrally by HH Hospital .

[e.g., registration, billing, and patient administration; Cerner for meds, Lab, Radiology, UED, Surgery].

NOTE: If a researcher needs information in a specified format or a specified time, the researcher must confirm with the unit who can supply the information/service that the request can be met before writing the information/service into the research protocol. In addition, the researcher must be aware that these services may have a cost attached that should be considered in the research budget.

☐ Another information system on a HH server or an information system. Describe: Click or tap here to enter text.

e. Indicate which of the listed identifiers will be accessed, associated and/or linked with the protected health information (PHI) used for this protocol.

☐ Names

☒ Geographic subdivisions smaller than a state

☐ Elements of dates (except year) related to an individual

☐ Telephone numbers

☐ Fax numbers

☐ Email addresses

☐ Social security numbers

☐ Medical record numbers

☐ Health plan beneficiary numbers

☐ Account numbers

☐ Certificate/license numbers

☐ Vehicle identifiers and serial numbers

☐ Device identifiers and serial numbers

☐ Biometric identifiers

☐ Web universal resource locators (URLs)

☐ Internet protocol address numbers

☐ Full-face photographic images

☐ Any other unique identifying number - Describe: Click or tap here to enter text.

NOTE: Codes are not identifying as long as the researcher cannot link the data to an individual

☐ None - If None, skip to Item 10

f. Choose one plan to describe your use of the personal health information:

☒ The data collected meet the specifications for a "limited data set" (LDS)
If the LDS will leave the covered entity or will be received from another covered entity you will need a Data Use Agreement.

☐ Research staff will obtain authorization from each participant to use the information Include the stand-alone HIPAA Authorization form.

☐ PI requests to waive authorization to use the information. Attach a Waiver of HIPAA Authorization form.

Section 10: Consent

a. If there are interactions with participants, there should generally be a consent process that will disclose the following information:

- Title of Study

- Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
- A statement that the activities involve research
- Purpose of the research and procedures of the research
- A statement that participation is voluntary
- Description of confidentiality of the responses and/or anonymity of the process
- Risks, costs, and payment, if applicable
- Alternatives, if needed (e.g., students not participating may be doing something else while others complete the study)
- Approximate duration of participation
- Contact information for the Principal Investigator, including phone number
- Contact information/language for the HH IRC: If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the HH IRC Office at (256)265-6990. Regular hours for the IRC Office are 8:00 a.m. to 4:30 p.m. CT, Monday through Friday.

b. Will the project involve any interaction (including any written communication) with participants?

☒NO – A consent process is not required for the project.

☐YES – Describe your consent process and attach a copy of the document with your submission (do not use this space to provide the content of your consent) **-OR-** explain why a consent process is not warranted or feasible. Note that projects reviewed under Exempt Category 3 must include participants' prospective agreement to both the intervention and information collection. Click or tap here to enter text.

c. Will the project involve any deception, including incomplete disclosure to participants regarding the nature or purposes of the research?

☒NO - The project will not involve any deception or incomplete disclosure.

☐YES - Describe the deception or incomplete disclosure, including any plans for debriefing participants or if not, why a

debriefing process is not warranted or feasible.

Click or tap here to enter text.

Note that projects that involve deceiving participants regarding the nature or purposes of the research are only allowed under Exempt Category 3 if participants authorize the deception through a prospective agreement to participate that informs participants they will be unaware of or misled regarding the nature or purposes of the research.

Section 11: Privacy & Confidentiality

a. Describe how you will protect the privacy interest of the participants. Include how you will make sure others cannot overhear your conversation with potential participants and that individuals will not be publicly identified or embarrassed.

This research involves secondary data and each individual will be given a code number for identification instead of names, it will be stripped of all identifiers.

b. Describe how you will store research data to maintain confidentiality (both paper records and electronic data), including how access is limited. If data will be stored electronically anywhere other than a server maintained centrally by HH, identify the department and all computer systems used to store protocol-related data.

c. Does your research involve audio or video recording or photographs?

☒ NO

☐ YES – Describe plans for disposal of these materials or justify why they will not be destroyed. If a transcription service is to receive private, identifiable recordings, identify the service and describe the confidentiality agreement in place.

Click or tap here to enter text.

d. Will investigators have any way of ascertaining the identity of the subjects, directly or through identifiers linked to the subjects?

☐No - data to be collected and evaluated are completely anonymous.

☒Yes - Investigators will know or may be able to ascertain the identity of participants

e. Could disclosure of the human subjects' responses outside the research reasonably place the subjects at any risk of harm? That is, could the information in the study place participants at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation?

☒No – the information in the study, if disclosed outside the study, would not place subjects at any risk of harm.

☐YES – the information in the study could place subjects at risk of harm if disclosed outside the study.

f. Will any individual data or biospecimens be shared with anyone outside the research team?

☐ NO

☒ YES – But any data/biospecimens shared will be completely stripped of all identifiers including dates or identifiers created using potentially identifiable pieces of information (e.g., initials).

☐ YES – Individually identifiable data and/or biospecimens will be shared.

If YES to above, describe who will receive the data and or biospecimens, what specifically will be shared, and whether they will be coded or otherwise labeled. Click or tap here to enter text.

FOR HUNTSVILLE HOSPITAL IRC OFFICE USE:

Date Received by HH IRC Office Representative: Click or tap here to enter text. 06/27/19

Meets Exemption from IRC Review Criteria: Click or tap here to enter text. Yes

Meets Expedited Review Criteria: Click or tap here to enter text.

Does Not Meet Expedited Review Criteria; Click or tap here to enter text.

Meets Full (Convened) IRC Review Criteria: Click or tap here to enter text.

Name/Date Approved by HH IRC Chair/Representative/Board: Click or tap here to enter text. Approved 07/01/19

Signature of HH IRC Office Representative: Click or tap here to enter text. Allison E Steele for Dr Cox AES

AADE7™ SELF-CARE BEHAVIORS

HEALTHY EATING

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

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

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

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

- Counting carbohydrates
- Reading food labels
- Measuring the amount of a serving
- Developing a practical meal plan
- Preventing high or low blood sugar
- Setting goals for healthy eating

Pick one or two of these skills and discuss them with your healthcare provider.

DID YOU KNOW?

There are only 3 main types of nutrients in food: carbohydrates, proteins, and fats. A healthy meal will include all three types.

TRUE OR FALSE:

People with diabetes can't have sugar.

FALSE: Sugar is just another carbohydrate and can fit into a meal plan. Sugary foods, however, do not have the same nutrition as grains or vegetables, and can often be high in fat and calories. It's best to limit sugar-containing foods to small portions, and be sure to count the carbohydrates toward the total recommended in your meal plan.

Word Wall

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

PORTION:
How much of a food you eat

MEAL PLAN:
A guide for healthy eating developed with your healthcare provider

HYPOGLYCEMIA:
Low blood sugar

HYPERGLYCEMIA:
High blood sugar

QUICK TIPS

Eat breakfast every day. Breakfast helps begin the calorie-burning process that provides you with energy. Include small snacks between meals as part of your daily intake to help keep your body going.

Space your meals throughout the day. Going too long without eating may result in excessive hunger, which can lead to overeating later on. Try to eat every 4 to 5 hours during waking hours.

Supported by an educational grant from Eli Lilly and Company.

ACTIVITIES

ASK YOURSELF

When I think about healthy eating, I feel: _____ , _____ and _____ . *(Pick 3 words to fill in the blanks)*

What did you eat for dinner last night? _____

Is there anything you could have done to make your meal healthier? _____

For you, what is the hardest part about healthy eating? _____

What is the best part about healthy eating? _____

REMEMBER THAT A HEALTHY MEAL PLAN SHOULD INCLUDE:

- **Complex carbohydrates** such as whole grain bread
- **Fiber,** which is found in beans, whole grains, fruits and vegetables
- **Lean protein,** such as chicken (without skin) or fish
- **Lots of vegetables**—especially the green, leafy ones
- **A limited amount of heart-healthy fats**, such as olive, peanut or canola oil, walnuts, almonds and flax seed

A good first step is to follow the "plate method" of meal planning, which includes a healthy balance of foods and controlled portions.

Visually divide your plate into 4 sections. For lunch or dinner, fill ½ the plate with non-starchy vegetables (such as: greens, green beans, broccoli, cabbage); ¼ should contain meat or other protein (fish, eggs, low-fat cheeses, cottage cheese, beans or legumes); ¼ contains starch (such as a potato or whole grain bread). On the side, include an 8 ounce glass of low fat milk or a small piece of fruit.

PLAN A HEALTHY DINNER THAT YOU WILL ENJOY IN THE SPACE BELOW.

_____

_____

_____

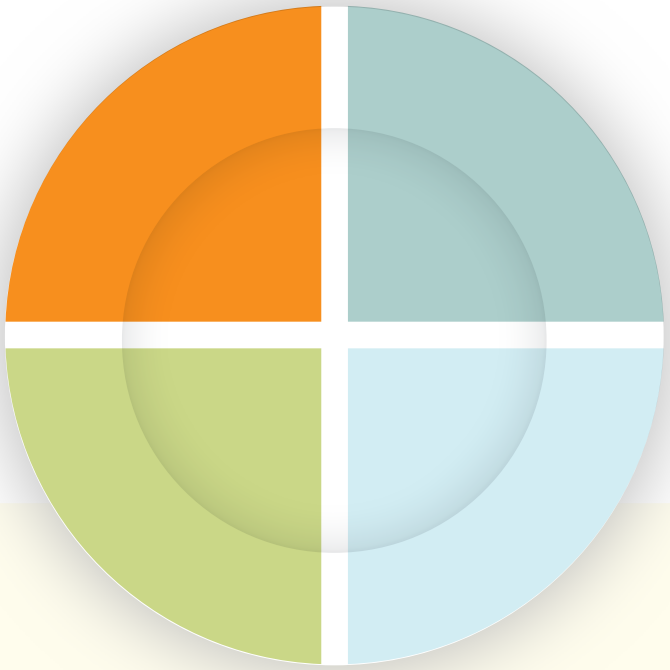
_____

_____

_____

_____

_____



BEING ACTIVE

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

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

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

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

DID YOU KNOW?

Breaking activity into three 10 minute sessions throughout the day is as good as one 30 minute session. This can help you fit exercise into your schedule.

TRUE OR FALSE?

You are not working out hard enough if you can carry on a conversation.

FALSE. You should be able to talk when doing an activity. If you can't, then your body is working too hard and you need to slow your pace.

Word Wall

EXERCISE (OR PHYSICAL ACTIVITY):

Activities that get your body moving and help you stay healthy

CARDIO:

Exercise that raises your heart rate

RESISTANCE TRAINING:

Activities that help you build muscle and strength

QUICK TIPS

Any amount of physical activity is better than none at all. Making physical activity part of your daily lifestyle burns calories even if it's not part of a structured plan.

Even if you are inactive and out of shape now, you can improve your health by moving just a little more. Take small steps to add more movement into your daily lifestyle. In time, you will find that you are stronger and will be able to move even more!

*Check your glucose before and after physical activity to learn how **your** body responds.*

Supported by an educational grant from Eli Lilly and Company.

ACTIVITIES

ASK YOURSELF

What's your all-time favorite activity that gets you moving? _____

What stops you from doing it? *(Circle as many as you want)*

- » Not enough time
- » Too out of shape
- » Too tired
- » Not motivated
- » Can't afford it
- » My _____ hurts too much

What can you do to get started doing this activity or working up to it? _____

_____

Pick some other activities that you enjoy doing:

_____

_____

_____

_____

_____

_____

MAKE A FITT PLAN FOR YOUR PHYSICAL ACTIVITY:

- » **Frequency**—How often will you do this activity? Work up to 5 or more days a week.
- » **Intensity**—How hard should you be working? Remember, you should be able to talk, but not sing during an activity.
- » **Time**—How long will you do it? Be realistic. Start with 5 or 10 minutes, and work up to 30 minutes.
- » **Type of Activity**—What will you be doing? Do something you enjoy!

GET CREATIVE!

- » Partner with a friend to find creative ways to be more physically active.
- » Take your dog for a walk or play fetch at the park.
- » Call a friend to go dancing or put on your favorite song and make the living room your personal dance floor.
- » Find a gym buddy to motivate you to stay active.
- » Take the stairs instead of the elevator.
- » If you eat lunch with a co-worker, ask him/her to join you for a short walk after you eat.

AADE7™ SELF-CARE BEHAVIORS

MONITORING

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

Your diabetes educator can help you learn:

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

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

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

DID YOU KNOW?

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

TRUE OR FALSE?

If you want to see how your body responds to your meal, wait 1-2 hours after eating to check your blood sugar levels.

TRUE. Your blood sugar rises in response to what you've eaten. It takes about 2 hours for the numbers to reflect the full rise.

Word Wall

METER:

A small device that is used to check blood sugar levels

LANCET:

A small needle used to get a blood sample

A1C:

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

ESTIMATED AVERAGE GLUCOSE (eAG):

The number of the A1C test changed into mg/dl like the blood sugar levels shown on your glucose meter

QUICK TIPS

Wash your hands with soap and water and dry them thoroughly before checking your blood sugar. Substances on your skin (like dirt, food, or lotion) can cause inaccurate results.

When traveling, keep your supplies with you. Advise security personnel that you are carrying diabetes supplies.

If you have trouble affording the test strips, call the toll-free number on the back of your meter to see if coupons are available, or ask your diabetes educator about other resources.

Supported by an educational grant from Eli Lilly and Company.

ACTIVITIES

Remember, the way you feel does not always reflect what your blood sugar is doing. The only way you know is to check your numbers!

- Check your blood sugar levels as directed to share with your doctor or diabetes educator.
- Follow a schedule, keep a record of your daily levels, and use the numbers to make decisions about your diabetes care.
- Check your blood sugar levels if you think you're getting sick.

When you check your blood sugar levels:

- Keep a record and bring it to every health appointment.
- Try to identify patterns when your blood sugar goes up or down.

If your numbers aren't at goal, don't get down. This is useful information that can help your healthcare provider match your treatment to your needs.

If you develop a regular schedule and follow it closely, you'll learn how your blood sugar levels affect how you feel. You'll start to recognize unhealthy blood sugar trends before they get out of control.

What is your typical day like, in terms of eating, activity, and diabetes medication? ***(Record it in the space below)***

	Activity	Eating	Medication
6:00 a.m.			
7:00 a.m.			
8:00 a.m.			
9:00 a.m.			
10:00 a.m.			
11:00 a.m.			
12:00 p.m.			
1:00 p.m.			
2:00 p.m.			
3:00 p.m.			
4:00 p.m.			
5:00 p.m.			
6:00 p.m			
7:00 p.m.			
8:00 p.m.			
9:00 p.m.			
10:00 p.m.			

AADE7™ SELF-CARE BEHAVIORS

TAKING MEDICATION

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

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

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

REMEMBER TO:

- **Ask your doctor, nurse practitioner or pharmacist** why this medication was recommended for you.
- **Ask your diabetes educator** to help you fit your medication routine into your daily schedule. Be sure to bring all medications or labels with you when you go to health appointments.
- **Ask a family member** to go with you to an appointment and take notes about any medication instructions. Or, ask someone to remind you to take your medications if you have difficulty remembering to take them.

DID YOU KNOW?

Some over-the-counter products, supplements, or natural remedies can interfere with the effectiveness of your prescribed medicines. Tell your diabetes educator about ANY supplements you are taking so that he/she can make the best recommendations for your care.

TRUE OR FALSE?

When you inject insulin, you need to rotate your injection sites.

TRUE. If you inject insulin in the same spot every time, your tissue can become damaged and won't absorb insulin as well. Be sure to rotate your injection sites between the fattier parts of your upper arm, outer thighs, buttocks, or abdomen.

Word Wall

INSULIN:

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

SIDE EFFECT:

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

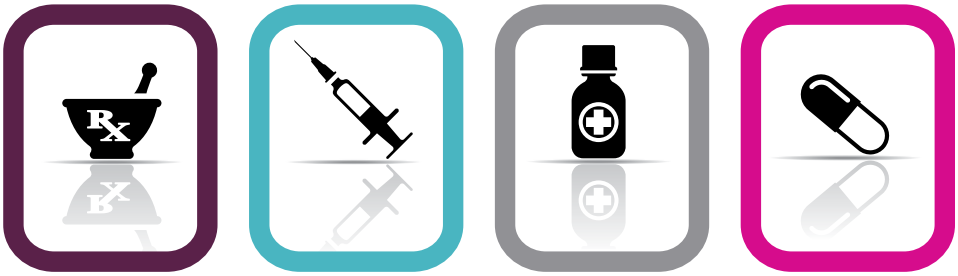
QUICK TIPS

If you often forget to take your medication, try to remind yourself by linking it to a specific activity—like watching the news every night or brushing your teeth—or by setting an alarm on your watch or cell phone.

Take a pen and some paper with you to your healthcare visit and take notes when your provider tells you about your medicine.

Supported by an educational grant from Eli Lilly and Company.

ACTIVITIES



How do you feel about having to take insulin or other medicines?

_____

What is the hardest part about taking your medications?

_____

Name one of your medications.

How much are you supposed to take?

When are you supposed to take it and how often?

Why do you have to take this medication?

What are some of the possible side effects?

What are you supposed to do if you experience side effects?

Anything else you need to know?

What do you do if you forget to take this medication?

**Repeat this exercise for every medication. Be sure to ask your pharmacist or diabetes educator if you do not know the answers.*

AADE7™ SELF-CARE BEHAVIORS

PROBLEM SOLVING

What do you do when you have a problem like low blood sugar (hypoglycemia)? Do you know what caused it? How can you help reduce the risk of it happening in the future?

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

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

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

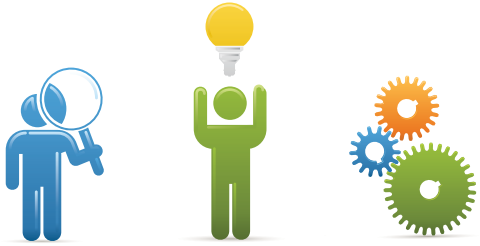
DID YOU KNOW?

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

TRUE OR FALSE?

Nobody has perfect diabetes management.

TRUE. You are not perfect—no one is. There WILL be problems and challenges. The important thing is to learn from each situation—what caused your blood sugar to go above or below target, and what you can do to improve your diabetes self-care.



Word Wall

HYPOGLYCEMIA:

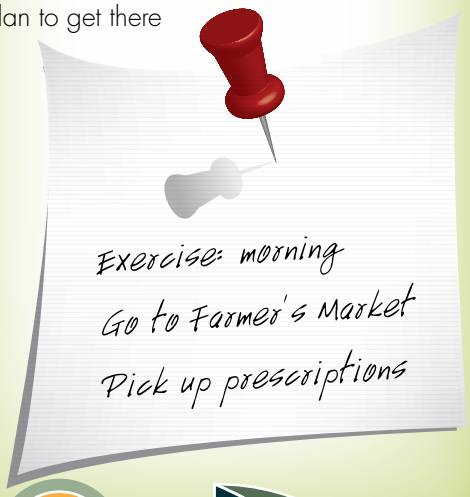
Low blood sugar

HYPERGLYCEMIA:

High blood sugar

GOAL SETTING:

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



QUICK TIPS

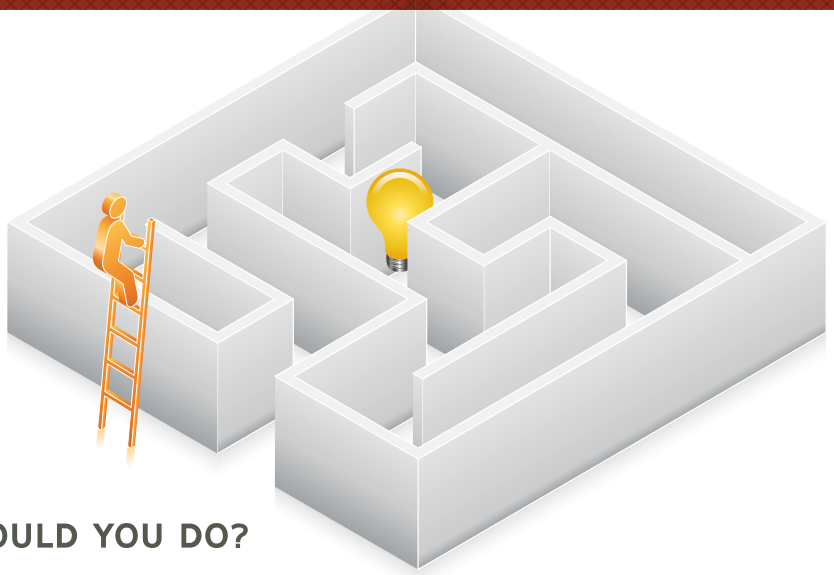
Do not go more than 5 hours without eating during your waking hours.

Limit your alcohol consumption. Learn how it interacts with your medications and how it affects your blood sugar. When you do drink alcoholic beverages, don't drink on an empty stomach.

If you do have a problem with your diabetes control, don't beat yourself up over it—solve it and learn from it! Talk to your healthcare provider—they can help you come up with solutions.

Supported by an educational grant from Eli Lilly and Company.

ACTIVITIES



WHAT WOULD YOU DO?

Think about how the following situations may affect you—and about what steps you could take to maintain proper control of your diabetes in similar situations.

You get the flu and notice that your blood sugar levels are higher than normal. What do you do?

_____

While on vacation, you don't have easy access to a gym or time for exercise. How will you handle this?

_____

You have a hard time finding healthy food choices within your family's cultural or taste preferences. What steps can you take?

_____

Is there something you've been struggling with in your diabetes care? What is it?

_____

Why do you think this is a problem? When does it occur?

_____

Name two things you can do to fix it.

_____

_____

What can you do to prevent it from happening in the future?

_____

AADE7™ SELF-CARE BEHAVIORS

REDUCING RISKS

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

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

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

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

DID YOU KNOW?

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

TRUE OR FALSE?

Controlling your diabetes can help reduce your risk for heart disease.

TRUE. If your blood sugar or blood pressure levels are too high for too long, your blood vessels can become sticky. This makes it easier for blood clots to form…which can lead to a heart attack or stroke.

Word Wall

BLOOD PRESSURE:
The amount of pressure that is applied to your arteries when blood is pumped through your body

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

COMPLICATION:
Another health problem that can happen when you have diabetes

HYPERTENSION:
When your blood pressure is higher than 140/90

QUICK TIPS

Keep a Personal Care Record or a wallet card that lists all of the tests you should be regularly getting and the targets for each.

Sleep apnea affects more than half of people with diabetes and most don't know it. If you snore loudly or feel sluggish and tired during the day, ask your diabetes educator to screen you for sleep apnea.

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ACTIVITIES

THESE ARE SOME OF THE THINGS YOU CAN DO TO STAY HEALTHY AND PREVENT OTHER PROBLEMS.

FOLLOW YOUR HEALTHY EATING PLAN.

Are you proud of the way you ate today? _____

KEEP ACTIVE

What is your favorite outdoor activity? _____

TAKE MEDICATIONS

Did you take your meds today? _____

MONITOR YOUR BLOOD SUGAR

What was your blood sugar number last time you checked? _____

CHECK YOUR FEET

Any pain or sores on your feet? _____

BRUSH AND FLOSS YOUR TEETH

When was your last dentist visit? _____

CHECK YOUR BLOOD PRESSURE

Do you know what your blood pressure is? _____

DON'T SMOKE

What can help you quit? _____

GET AN EYE EXAM (WHICH INCLUDES DILATING YOUR EYES) AT LEAST ONCE A YEAR

Have you had an eye exam this year? _____

RECOMMENDED TESTS	TARGET LEVELS	FREQUENCY
A1C	Less than 7%	Every 3 to 6 months
Blood Pressure	Less than 130/80	Every visit
Lipids HDL (good cholesterol) LDL (bad cholesterol) Triglycerides	 Over 40 (for men); Over 50 (for women) Less than 100 (less than 70 if you have heart disease) Less than 150	At least every year
Eye Exam		Every year
Foot Exam (visual) Foot Exam (with sensory testing)		Every visit to your healthcare provider Every year

AADE7™ SELF-CARE BEHAVIORS

HEALTHY COPING

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

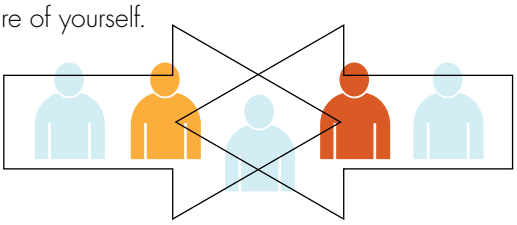
The way you deal with your emotional lows is called "coping." There are lots of ways to cope with the upsets in your life—and not all of them are good for your health (smoking, overeating, not finding time for activity, or avoiding people and social situations).

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

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

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

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



Did You Know?

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

TRUE OR FALSE?

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

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

QUICK TIPS

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

Find time to do something pleasurable every day.

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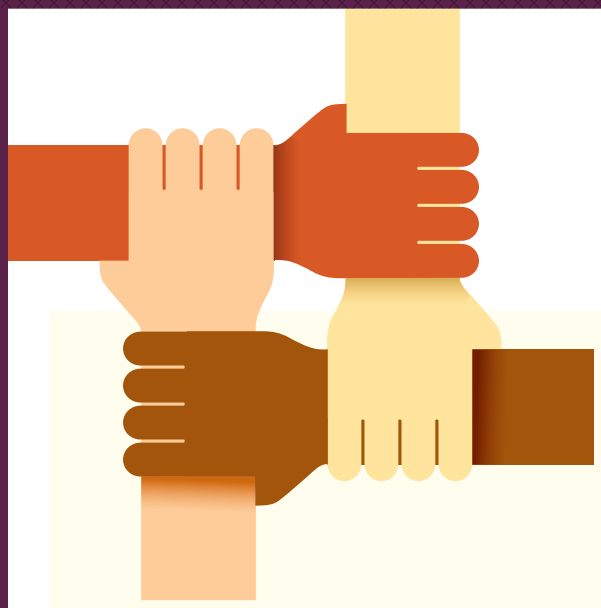
ACTIVITIES



HEALTHY COPING

Name 3 emotions that you feel when you think about your diabetes.			
Who can you talk to when you feel this way?			
Name 3 activities that will help you work through this emotion and feel better.			

What might prevent you from doing these activities?

_____

_____

How can you overcome these obstacles?

_____

_____

Figure 4

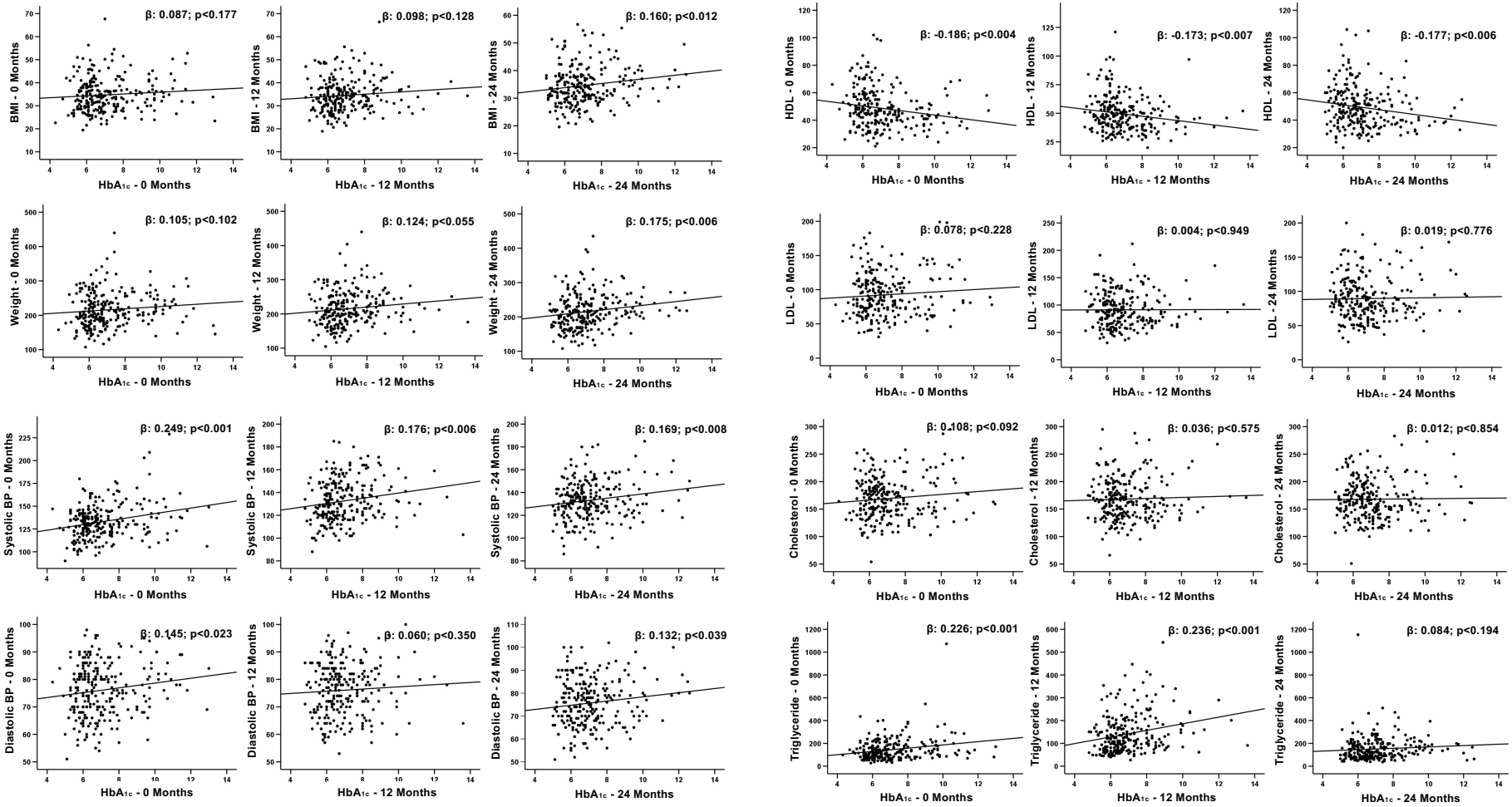

β: 0.087; p<0.177
BMI - 0 Months
HbA1c - 0 Months
β: 0.098; p<0.128
BMI - 12 Months
HbA1c - 12 Months
β: 0.160; p<0.012
BMI - 24 Months
HbA1c - 24 Months
β: -0.186; p<0.004
HDL - 0 Months
HbA1c - 0 Months
β: -0.173; p<0.007
HDL - 12 Months
HbA1c - 12 Months
β: -0.177; p<0.006
HDL - 24 Months
HbA1c - 24 Months
β: 0.105; p<0.102
Weight - 0 Months
HbA1c - 0 Months
β: 0.124; p<0.055
Weight - 12 Months
HbA1c - 12 Months
β: 0.175; p<0.006
Weight - 24 Months
HbA1c - 24 Months
β: 0.078; p<0.228
LDL - 0 Months
HbA1c - 0 Months
β: 0.004; p<0.949
LDL - 12 Months
HbA1c - 12 Months
β: 0.019; p<0.776
LDL - 24 Months
HbA1c - 24 Months
β: 0.249; p<0.001
Systolic BP - 0 Months
HbA1c - 0 Months
β: 0.176; p<0.006
Systolic BP - 12 Months
HbA1c - 12 Months
β: 0.169; p<0.008
Systolic BP - 24 Months
HbA1c - 24 Months
β: 0.108; p<0.092
Cholesterol - 0 Months
HbA1c - 0 Months
β: 0.036; p<0.575
Cholesterol - 12 Months
HbA1c - 12 Months
β: 0.012; p<0.854
Cholesterol - 24 Months
HbA1c - 24 Months
β: 0.145; p<0.023
Diastolic BP - 0 Months
HbA1c - 0 Months
β: 0.060; p<0.350
Diastolic BP - 12 Months
HbA1c - 12 Months
β: 0.132; p<0.039
Diastolic BP - 24 Months
HbA1c - 24 Months
β: 0.226; p<0.001
Triglyceride - 0 Months
HbA1c - 0 Months
β: 0.236; p<0.001
Triglyceride - 12 Months
HbA1c - 12 Months
β: 0.084; p<0.194
Triglyceride - 24 Months
HbA1c - 24 Months

Figure 5

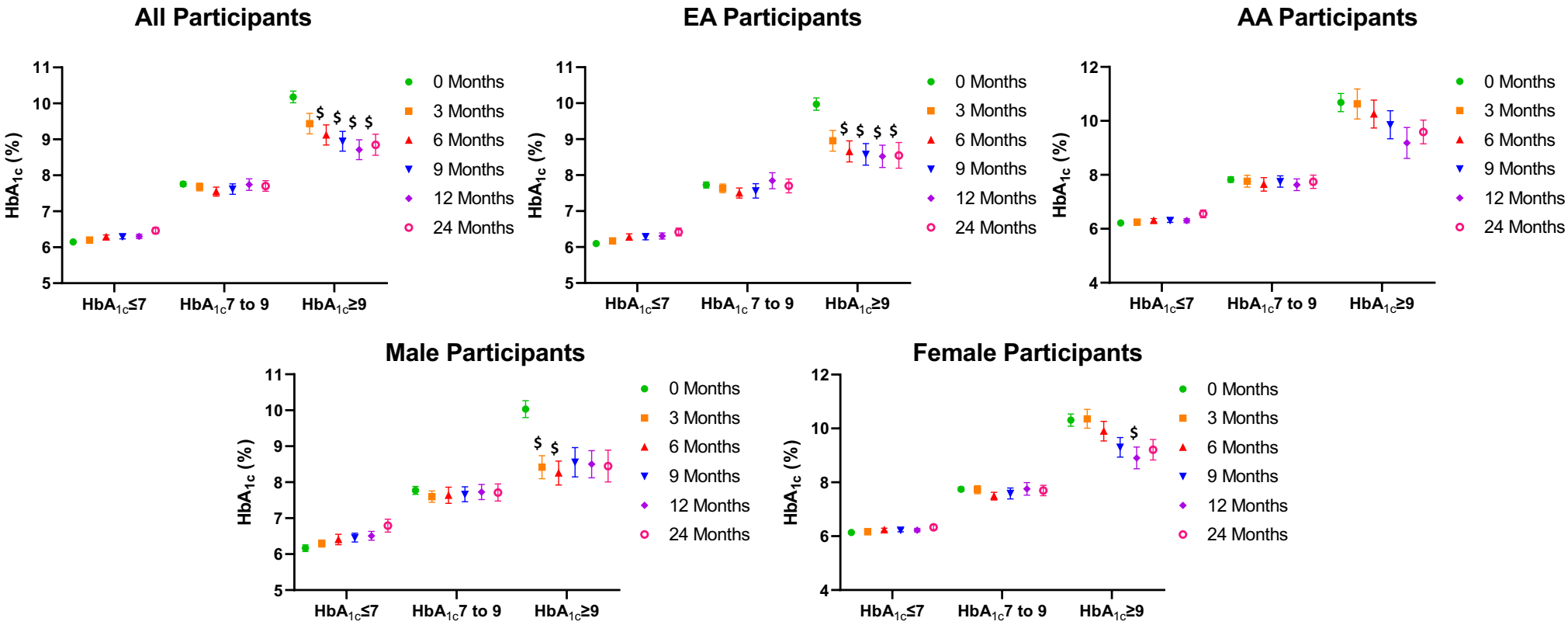

All Participants
EA Participants
AA Participants
Male Participants
Female Participants
HbA1c (%)
HbA1c≤7
HbA1c 7 to 9
HbA1c≥9
0 Months
3 Months
6 Months
9 Months
12 Months
24 Months
$

Figure 6

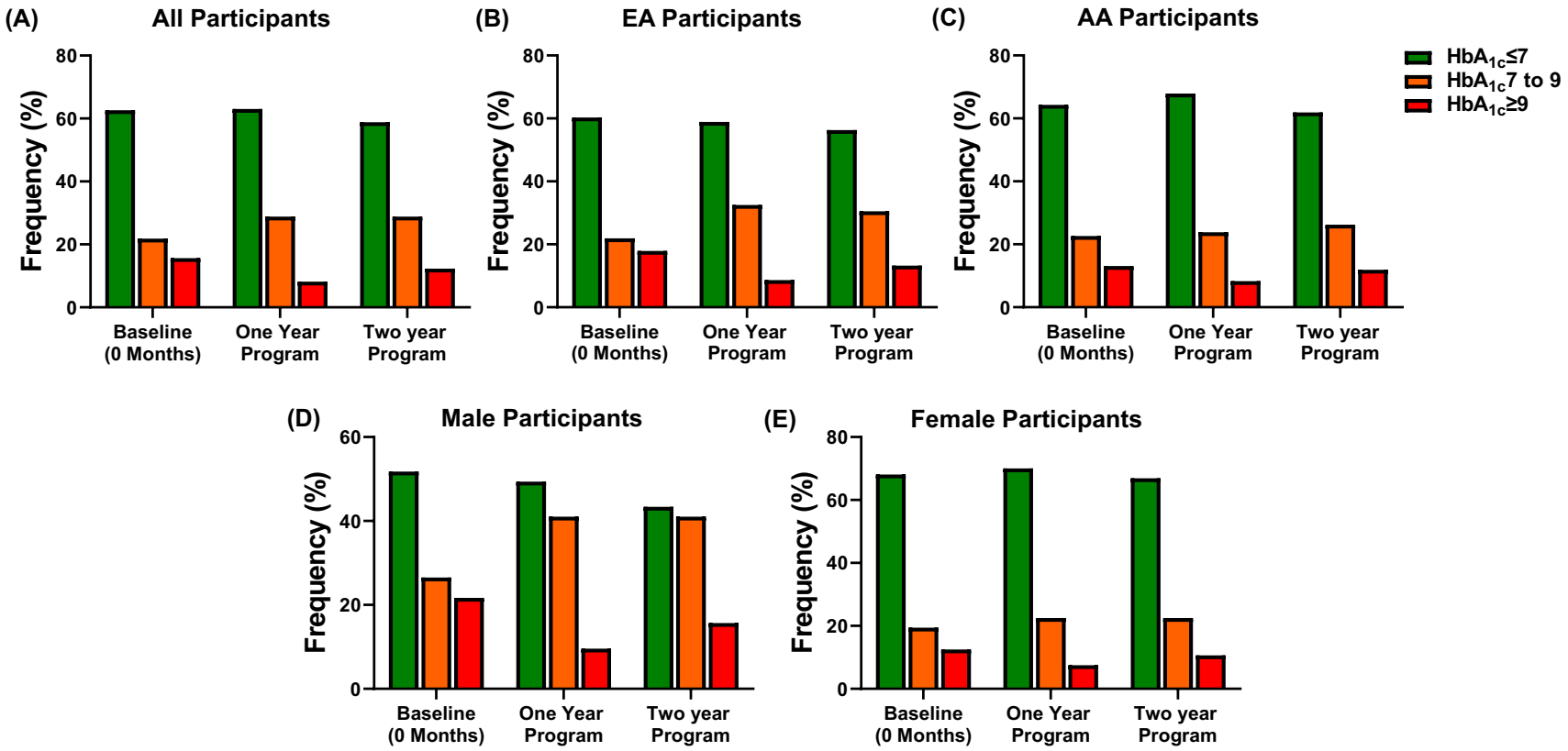

(A)
All Participants
(B)
EA Participants
(C)
AA Participants
Frequency (%)
0
20
40
60
80
Baseline (0 Months)
One Year Program
Two year Program
HbA1c≤7
HbA1c7 to 9
HbA1c≥9
(D)
Male Participants
(E)
Female Participants

Figure 7. American Diabetes Association. Diabetes Healthy plate