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Impact of Blood Glucose Monitoring Logs in Conjunction with Food Diaries in Lowering HbA1c in Adults Aged 18-89 years with Type 2 Diabetes

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Abstract

Title: Impact of Blood Glucose Monitoring Logs in Conjunction with Food Diaries in Lowering HbA1c in adults aged 18-89 years with Type 2 Diabetes Mellitus

Background: The risk for complications in Type 2 Diabetes Mellitus (T2D) patients has been associated with elevated glycosylated hemoglobin (HbA1c).

Purpose: To integrate Self-Monitoring of Blood Glucose (SMBG) using blood glucose monitoring logs in conjunction with food diaries in the management of T2D with a goal of lowering HbA1c in adults aged 18-89 years with HbA1c > 7.5% over a period of 2 months.

Method: 15 adults aged 18-89 years with HbA1c > 7.5% were enrolled in a primary care clinic setting. Initial HbA1c was checked. Participants were given the *Johns Hopkins Patient Guide to Diabetes – Meal and Glucose Log* to monitor their blood glucose and diet. Biweekly follow-ups were conducted. At the end of the second month, HbA1c was re-checked. Patient data was collected and entered in SPSS software for analysis.

Results: 10 participants out of 15 returned for the second HbA1c test. Descriptive statistics (mean and standard deviation) were used for analysis. The results were categorized into 3 groups; Action 0 (did not monitor, returned for the second test), Action 1 (monitored, returned for the second test), and Action 2 (partially monitored, returned for the second test). Final mean HbA1cs (%) were 10.2 (+14%), 6.9 (-19%), and 7.5 (-2.5%) respectively.

Conclusion: Consistent monitoring of blood glucose and meals showed a reduction in HbA1c. The number of participants was limited mainly due to stress factors related to the current COVID-19 pandemic.

Keywords: type 2 diabetes mellitus, self-monitoring of blood glucose, blood glucose monitoring, hemoglobin A1c, diet, adults, food diaries

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Impact of Blood Glucose Monitoring Logs in Conjunction with Food Diaries in Lowering HbA1c in Adults aged 18-89 years with Type 2 Diabetes.

Type 2 Diabetes Mellitus (T2D) is a chronic condition that is caused by the inability of the body to produce a significant amount of insulin to cover blood glucose. Complications of T2D may include kidney failure, hypertension, blindness, nerve damage, and coronary artery disease (Ampofo & Boateng, 2020). The risk for complications related to T2D is measured using Glycosylated Hemoglobin (HbA1c) which is an indicator of long-term glycemic control over a period of 2-3 months (Sherwani et al., 2016). The lowest level of risk with which HbA1c is associated is the range of 6.5-7.4% and a significant increase in risk is with HbA1c greater than 11% (Anywagu et al., 2019). According to the Center for Disease Control and Prevention (CDC) (2018), 26.9 million people of all ages had a diagnosis of diabetes in 2017 and diabetes was the 7th leading cause of death in the United States (US) in the same year.

The total costs related to diabetes were \$327 billion in the US in 2017 (CDC, 2018). Such statistics prompt studies geared towards finding ways of effectively managing diabetes to prevent related complications. The current medical norm is the prescription of antihyperglycemics to lower HbA1c. Adding Self-Monitoring of Blood Glucose (SMBG) to the ongoing norm of prescribing antihyperglycemics aids in lowering HbA1cs to minimize diabetes complications (Williams et al., 2020). This project aimed to incorporate SMBG using blood glucose logs in conjunction with food diaries in the management of T2D with a goal of lowering HbA1c in adults aged 18-89 years with HbA1c greater than 7.5% over a period of 2 months.

Problem Statement

Patient self-management is an ongoing process that is critical in preventing acute complications as well as reducing the risks of long-term complications (American Diabetes Association [ADA], 2019). Without interventions based on Evidence-Based Practices (EBPs) aimed at reducing the risk of complications, more lives will be lost due to complications of diabetes (Ampofo & Boateng, 2020). The CDC (2018) noted that among the emergency department visits reported in 2016, 16 million had diabetes among adults aged 18 and older with 224,000 visits for hyperglycemic crisis and 235,000 visits for hypoglycemia. The ADA notes hypoglycemia as fasting blood glucose of 70 mg/dL and hyperglycemia as fasting blood glucose greater than 180 mg/dL. These hospital visits are an indicator of the knowledge deficit of blood glucose readings in relation to diet.

Hospitalizations related to diabetes complications were noted to be high in 2016 (CDC, 2018). Out of the 7.8 million hospitalizations due to diabetes, 1.7 million patients had cardiovascular diseases. Among those patients included 438,000 with ischemic heart disease, 313,000 with stroke, and 130,000 with lower-extremity amputations (CDC, 2018). These hospitalization statistics show the implications of uncontrolled T2D. Between 2013 and 2016, out of all patients diagnosed with diabetes, 37.0% had early-stage chronic kidney disease while 24.9% had moderate to severe chronic kidney disease (Saeed et al., 2019). The CDC further noted that diabetes was the leading cause of new cases of blindness among adults aged 18-64 which adds to the detriment of 83,564 death certificates reported in 2017 where diabetes was listed as the underlying cause of death in those patients.

The global prevalence of diabetes in 2017 was 8.8% in adults and was anticipated to increase to 9.9% by 2045 (Standl et al., 2019). This growth translates to 424 million people with

diabetes worldwide in 2017 and is predicted to increase to 628.6 million people worldwide by 2045 (Saeed et al., 2019). Ogurtsova et al. (2019) estimated that there were 415 million people with diabetes aged 20-79, 5.0 million deaths attributed to diabetes, and the total global health expenditure due to diabetes was 673 billion US dollars. Based on such global statistics, multifaceted interventions aimed at effectively controlling diabetes are crucial in order to control this global disease.

Clinical Question

In T2D patients, how does the incorporation of blood glucose monitoring logs in conjunction with food diaries contribute to lowering HbA1c compared to using pharmacotherapy alone in adults aged 18-89 years with HbA1c greater than 7.5% over a period of 2 months?

Project Objectives

The purpose of this project was to find out the impact of continuous monitoring of glucose using blood glucose monitoring logs in conjunction with food diaries in the management of T2D. This project also intended to assess the impact of blood glucose awareness, the impact of diet in relation to glucose as well as factors limiting continuous glucose monitoring.

Review of the Literature

Search Strategy

A literature search was conducted using different databases including PubMed, Cochrane, CINAHL, Embase, JAMA network back file, and Georgia State University (Appendix A). Some databases from associations such as The American Diabetes Association could not be accessed due to restricted access. The search words used included “diabetes type 2”, “self-monitoring blood glucose/blood glucose monitoring”, “hemoglobin A1c”, and “food diaries/diet” and “adults”. The searches were limited to clinical trials, academic journals, meta-analysis, cross-

sectional studies randomized controlled trials, systematic reviews, and longitudinal studies. Only information from within the last five years was selected for review. The inclusion criteria included studies that resulted in an effect on HbA1c regardless of the period studied. Studies that used continuous blood glucose monitoring using automated systems were excluded as these would not be used in the implementation phase of the project.

Search Results

The results of studies obtained from the different databases with limits selected included Cochrane (n=322), CINAHL (n=62), Embase (n=1013), JAMA (n=15), PubMed (n=200), and Georgia State University (n=322) (Appendix A). The results were further narrowed down using the inclusion and exclusion criteria and 25 studies were retained. The studies were mainly randomized control trials with 10 falling into the other categories of cross-sectional, meta-analysis, systematic reviews, longitudinal studies, and expert opinions. Different levels of evidence were identified including level I, II, III, IV, and V.

Review of the Literature: Content

Twelve studies with a common goal of impacting HbA1c were used for this review. The designs used were randomized controlled trials, unrandomized controlled trials, cross-section studies, as well as systematic reviews, and meta-analyses. The sample size of the study participants ranged from 82 to 450. The studies' measurements and results had a shared factor which was their impact on HbA1c. Data from these studies was further categorized into three groups including those related to SMBG and HbA1c, diet and SMBG, as well as the impact of elevated HbA1c.

SMBG in Relation to HbA1c

Williams et al. (2020) conducted a 12-month randomized controlled trial to assess the impact of structured SMBG on glycemic variability in non-insulin treated T2D patients. Participants undertook structured SMBG over a period of 12 months with HbA1c recorded at the baseline and at 3-months follow-up. This study included manipulation of the independent variable, presence of a control group, and study participants were randomly assigned to the intervention. A baseline HbA1c of 7.5-13.0% was obtained prior to initiating the study. Results indicated significant improvements in each of the measurements used for blood glucose control at 12 months compared to 3 months.

Cutrizzolà et al. (2020) also conducted a study to evaluate the association between HbA1c, and time spent in Target Range (TIR), using the Diabetes Management System (DMS), over a period of 2 months, and 2 weeks. A randomized control trial of 197 patients with Type 1 diabetes (T1D) and T2D insulin-treated patients was conducted. Point in range (PIR) and TIR were calculated at 2-month and 2-week time ranges using available HbA1c measurements. By comparing metrics measured over 2 months and 2 weeks, there was significantly higher 2-month points below range (PBR) compared to the 2-week PBR in T1D. There was also a significantly higher 2-month Glycemic Variability (GV) compared to 2-week GV in subjects with T2D. This study verified that a change can occur in HbA1c in a period of 2 months through the measurement of PIR and TIR using data from glucose monitoring devices.

Zhou et al. (2016) conducted a study to evaluate the effectiveness of glucose monitoring using a smartphone-based diabetes management application called Welltang. Individuals aged 18-74 years were randomly recruited from an outpatient department of endocrinology and HbA1c, blood glucose, blood pressure, and low-density lipoprotein were all measured. The

control group included individuals who were not using the Welltang application. In this study, patient care was analyzed using independent t-test and they found out that there was an average decrease in HbA1c by 1.95% in the intervention group and 0.79% decrease in the control group. It was concluded that self-monitoring of glucose using Welltang application achieved significant improvement in HbA1c and blood glucose.

Zhang et al. (2020) found out that there was an increased standard deviation in blood glucose assessed by SMBG associated with β -cell dysfunction in Chinese patients with T2D. This study aimed to find out if glycemic variability could be determined by SMBG and β -cell function among Chinese patients with T2D. The study obtained data about the β -cell function of the pancreas from participants' SMBG records., This study emphasized the importance of keeping glucose logs for reference to reflect the β -cell function.

Frías-Ordoñez & Pérez-Gualdrón (2019) also conducted a narrative literature review on the role of SMBG as a control tool in different management contexts for T2D using different databases such as PubMed, Embase, Cochrane, Medline, and ScienceDirect. The authors found evidence that showed that using SMBG in patients with T2D is beneficial and has a positive impact on non-insulin users in terms of achieving better glycemic control. This study found that the provision of the necessary diabetes supplies for monitoring blood glucose in non-insulin-treated T2D patients was linked to a decrease in the HbA1c levels after 3 and 6 months.

Another study which was intended to explore the feasibility and impact of implementing SMBG in patients with T2D in rural Rwanda districts also emphasized the importance of SMBG (Ng'ang'a et al., 2020). The study was an open randomized controlled trial where 82 participants were enrolled to explore the feasibility and impact of implementing SMBG. The exclusion criteria for this study included having a diagnosis of Type 1 diabetes, chronic kidney disease,

gestational diabetes, inability to read and write, and having no access to a reliable guardian who can sufficiently use logbooks. Measurement, which was based on HbA1c, fidelity to SMBG, perceived usefulness, facilitators, and barriers, showed a 1.2% change in HbA1c among the intervention group. The participants in the control group had a 0.2% change in their HbA1c. This change in the intervention group denoted a positive impact of SMBG on HbA1c.

To examine whether SMBG could be more effective with or without telecare support, a study was conducted to analyze the impact of structured SMBG on glycemic control in T2D patients with or without telecare support (Parsons et al., 2019). This was a randomized controlled trial which enrolled 446 patients divided into a control group and an intervention group with one (intervention group) having telecare support in addition to SMBG while the other (control group) did not have telecare support. At the end of the 12 months period, the results showed a decrease in HbA1c in all groups even though the group with added telecare support had a more decrease. The mean HbA1c in all groups was lower by 3.3 mmol/mol indicating that with or without telecare support, SMBG using blood glucose logs contributed to lowering HbA1c in those patients.

Diet in Relation to Blood Glucose

Russell et al. (2016) conducted a comprehensive review which summarized results from human dietary interventions exploring the impact of dietary components on blood glucose levels in T2D patients. This review measured macronutrients such as carbohydrate, fat, protein, micronutrient minerals and vitamins, non-nutrient phytochemicals as well as additional foods such as low-calorie sweeteners. The results of this review indicated that dietary components had a significant effect on blood glucose modulation. The results also indicated that interventions

such as physical activity along with diabetic dietary regimens were recommended to regulate blood glucose levels in order to achieve effective control of T2D.

Another study focused on diet was conducted to evaluate the efficacy of a low carbohydrate diet on T2D management (Meng et al., 2017). This was a systematic review and meta-analysis of randomized controlled trial literature review on 9 studies with a total of 734 diabetes patients using measurements of HbA1c, triglycerides concentration, and high-density lipoproteins (HDL). An intervention and control group were created with one group having a low carbohydrate diet while the other group did not have a low carbohydrate diet. The results indicated that a low carbohydrate diet had a positive effect on HbA1c levels. Meta-analysis showed that HbA1c levels and triglycerides were markedly decreased in the low carbohydrate diet group compared with the control group.

McAndrew et al. (2015) also conducted a study which was intended to find the association between SMBG and diet among minority patients with diabetes. This study was a cross-sectional study which enrolled 104 minority patients living with diabetes in Harlem, New York. The measures for this study included fat intake, fruit, and vegetable consumption. The study found that there was a significant interaction between the frequency of SMBG and change in one's diet in response to the patients' awareness of their total fat intake. Greater frequency of SMBG was associated with lower fat intake but fruit and vegetable consumptions. Individuals who frequently monitored their blood glucose ended up lowering the fat intake in the diet. This study highlighted that those patients were more aware of their dietary intake when they monitored their blood glucose regularly.

Impact of Elevated HbA1c

Anynwagu et al. (2019) conducted a study which was aimed at investigating the relationship between HbA1c and cardiovascular morbidity as well as the cause of mortality among older insulin-treated patients. This study enrolled 4589 adults aged 65 years and older with T2D on insulin. The participants were categorized into 8 groups based on their HbA1cs levels ranging from less than 6.5% to greater than 11.5% associated with the risk for complications over a period of 5 years. The results showed that the lowest risk was seen in the HbA1c range of 6.5-7.4% and a markedly increase in risk with HbA1c greater than 11%.

In light of the role of HbA1c in the management of T2D, a review of several studies was conducted on the significance of the HbA1c test in the diagnosis and prognosis of diabetic patients (Sherwani et al., 2016). HbA1c was noted to be a vital indicator for long-term glycemic control with the capability to mirror the cumulative glycemic history of the preceding two to three months. This study further noted that HbA1c not only shows a consistent measure of chronic hyperglycemia but also compares well with the risk of diabetes complications. High levels of HbA1c were associated with amplified risks for recurrence of atrial tachyarrhythmia in T2D as well as stroke due to its relation to increased triglyceride levels. This review added that a slight increase of 1% in HbA1c concentration was linked to the risk of increased morbidity and mortality.

Conceptual Framework: Key Concepts

ADKAR Model

The ADKAR model, which was developed by Jeff Haitt, is a goal-oriented model that guides individual and organizational change (Haitt, 2006). The ADKAR model outlines the outcomes that are needed to achieve change effectively. The outcomes include the following:

Awareness, Desire, Knowledge, Ability, and Reinforcement (ADKAR). The ADKAR streamlines the steps below needed for efficient change to occur which helps to ease the change process.

Awareness

Awareness is the first step of change noted to represent the person's understanding of why change is made, its importance, and the risk involved if old practices are continued (Haite, 2006). Awareness campaigns identify the problems with the existing practice and highlight solutions to these problems if the change occurs. Building awareness is catalyzed by how it is going to benefit the individual or organization. Haite (2016) noted that it is important for the change advocator to be able to answer questions about why change is necessary and highlight the implications of the failure to make the required change. He added that the nature of change and how it is going to align with the vision for the organization as well as its impact on the community is important to highlight during this process. It helps to encourage individuals involved to recognize the positives of the change in relation to the goals of the organization. Barriers to awareness were noted to include the individual's view of the current state, how someone perceives problems, the credibility of the sender, misinformation going around, and contestability of reasons for change. Addressing these barriers is necessary before moving on to the next step of the creation of desire. The groundwork of this step is accomplished when individuals can make personal choices about change based on the information provided (Shaw, 2017).

Desire

Desire involves the individual or organization's willingness to support and be involved in the change (Haite, 2006). This element of the model is influenced by personal choice and

individual situations, determined by how effective awareness was in the first step of the model. Since there is limited control on individual perceptions about change, this element poses a challenge in this process. It is important to appreciate the factors which may inspire individuals' participation in change including what the change is, and its impact on them will help to contribute to individual perceptions positively (Kachian & Haghani, 2018). Haitt (2006) added that the view of "what's in it for me?" determines if this change is an opportunity or a threat to an individual's wellbeing and ultimately influences their desire. Tailoring awareness to meet the organization or individual goals will contribute to the accomplishment of this element. The total satisfaction of this element will lead to the next element of knowledge.

Knowledge

This is an element of the model which represents having the needed information, training, and education necessary to know how to change (Haitt, 2006). Processes, skills, systems, and tools are incorporated into this element in order to effect change (Shaw, 2017). Knowledge will be affected by the capacity to learn, availability of resources for reference, current knowledge level, and access to needed information. Resources available may include equipment for use, availability of subject matter experts, books, and materials. Being mindful of the relevance of avoiding giving large amounts of new information is important as this can lead to resistance (Shaw, 2017). Anderson & Zimmerman (2018) noted that a gradual release of information materials may be the best practice in some settings where individuals are more open to smaller pieces of information at a time, as this would encourage accommodation and ease in obtaining this knowledge. Access to the required information should be available as it will facilitate learning and bridge knowledge gaps which may hinder implementation.

Ability

This element of the model represents the recognition of change involving turning knowledge into action (Shaw, 2017). Ability involves the implementation of change based on the knowledge acquired and focuses on people being able to do their roles differently with the integration of change. Change champions should be onsite to facilitate implementation and intervene in any situation causing interruptions hindering change (Haitt, 2006). Shaw added that this strategy promotes smooth transitions and reduces stress levels among individuals being affected by the change. Being able to implement change successfully requires that all stakeholders are able to interpret change the same way in order to put the learned practices into action.

Reinforcement

This element in the model is characterized by factors that sustain change (Haitt, 2006). These factors include both internal and external factors. The internal factors include personal satisfaction with their achievement, while external factors include recognition and rewards. Assessing individual understanding of the change is important at this level as this may promote or impede change. Knowing if the changes are meeting intended goals is crucial in order to confirm the success or failure of the change. The focus should be on finding out why issues are present than continuing to implement change during this stage (Shaw, 2017). Haitt emphasized that if the change has not been successful, then going back to the awareness stage should be considered.

Application of ADKAR model

The ADKAR model was used in change management in the screening of postpartum patients who were at a high risk for developing pelvic floor disorders at Andrew's Women's Hospital in Fort Worth, Texas which serves women of all ages for evaluation and treatment of

pelvic floor disorders (Anderson & Zimmerman, 2018). They invited a new Pelvic Medicine Center nurse practitioner and physical therapist to meet their staff and discussed post-childbirth pelvic floor disorders and current treatment options. This was intended to promote awareness according to the ADKAR model. To instill desire, they emphasized how the change would benefit their patients through improving health outcomes and quality of life. Knowledge was increased through providing staff education using journal articles related to the subject. Ability was executed through the development of a risk factor screening tool specific to their patient population. Reinforcement was done through the creation of tools to screen for understanding of the change. ADKAR model was very instrumental in the success of the change at that hospital.

In a study to investigate the readiness of using nursing Kardex, the ADKAR model was used to implement the change (Kachian & Haghani, 2018). The results obtained showed that more than half of the nurses got enough readiness to use the nursing process Kardex based on the ADKAR model. It was added that the use of this model was convenient and easy to use as it was straightforward. This model was not only used to measure individual readiness but was also influential in identifying weaknesses and strengths in the implementation process.

Furthermore, a study which was intended to assess the effectiveness of Khodro's software infrastructure showed that using the ADKAR model helped increase domestic and foreign sales (Ghalandari & Beigi, 2015). This study noted however that not all ADKAR model elements had the same effect on change management such as the element of ability. Awareness was noted to have the highest effect in this change process.

Clinical Question in Relation to the Model

In T2D patients, how does the incorporation of blood glucose monitoring logs in conjunction with food diaries contribute to lowering HbA1c compared to using pharmacotherapy

alone in adults aged 18-89 years with HbA1c > 7.5% over a period of 2 months? Since this question involves changing what is currently existing in order to incorporate an intervention based on EBP which would improve the quality of life of patients, using the ADKAR model helped to facilitate this process.

Awareness was created through the provision of data on statistics relating to T2D including indicators of risk for complications, morbidity, and mortality, practices being put into place to effectively control diabetes based on EBP, as well as what is desirable to be incorporated into this setting for better glucose control in order to improve patients' quality of life. T2D is one of the most challenging health conditions noted and its prevalence has been predicted to increase to approximately 550 million people affected globally by 2030. (Frías-Ordoñez & Pérez-Gualdrón, 2019). The risk for complications has also been noted to be higher in HbA1cs greater than 11%, thus the need to have well-controlled glucose levels is crucial to prevent complications (Anyanwagu et al., 2019). The use of blood glucose logs helps in therapy modulation, leads to lesser incidences of depression, creates a better sense of awareness of the disease state among diabetes patients, and the overall feeling of more empowerment in the control of the disease occurs (Chitra et al., 2017). This engagement provided opportunities to assess individuals' comprehension of the current situation. Barriers to this awareness such as an individual's existing view of the situation as well as misinformation going around as noted in the ADKAR model were mitigated through the provision of information from reputable sources such as the CDC and EBP studies. This helped to eliminate possible doubts and uncertainties hindering awareness.

Desire was achieved through aligning the changes with the individual's goal of good quality of health. Knowing that individual contributions to this change can help to reduce the

national costs incurred such as the \$327 billion in 2017 relating to the management of diabetic complications, helped to inspire the desire to implement change (CDC, 2018). The Diabetes Self-Management Education and Support (DSMES) program is one of the initiatives which was launched by the CDC to prevent costly complications from diabetes and is being adopted in many states. Having such information available helps to contribute to the individual's desire to be a part of this change. The level of awareness, individual motivation, and perceived likely victories or losses helped to influence their desire.

The *knowledge* phase, which involves the state of possessing the necessary information needed through training and education to facilitate change was crucial. Participants were equipped with knowledge regarding how to monitor and record their blood glucose and meals on the logs provided. Having knowledge about the complications of uncontrolled glucose and how self-monitoring of blood glucose and diet can help improve this, helped the successful implementation.

The *ability* element, which is the implementation phase involving providing patients with blood glucose monitoring and diet logs with a goal of reducing their HbA1c to minimize the risk of complications comes after the knowledge element. It was necessary to be available to answer any questions and provide the needed guidance for the effectiveness of this change. Recognizing that sometimes individuals may lack the capability for making the required change was important thus the possibility of training or reframing directions was necessary to effect change (Shaw, 2017). Participants were contacted every 2-4 weeks to check on the progress of the intervention.

Reinforcement which is the last stage was done by assessing the success of the implementation of this intervention. Assessing if all T2D patients are getting these tools needed

to effectively manage diabetes was important at this level. Rewarding success and setting up follow-ups and reiteration was important at this stage for effectiveness. Pointing out why this intervention is not working is crucial as it prompts actions for further investigations into reasons why these barriers exist and possible reiteration of awareness can be considered (Zafar & Naveed, 2015). The fact that this project was carried out during the COVID-19 pandemic impacted its smooth flow in many ways which will be discussed in the *discussion section*.

Methodology

Implementation/Evaluation: Subjects

Participants were randomly selected from the clinic's electronic medical record (EMR). They included 50 randomly selected T2D patients aged 18-89 years irrespective of gender, racial or ethnic group, social-economic background, marital status, or education level whose HbA1c was greater than 7.5% in the last 3 months. The inclusion criteria included adults aged 18-89 years with T2D whose HbA1c was >7.5% in the past 3 months and who had a glucometer at home. The exclusion criteria included individuals with any other type of diabetes other than T2D, individuals with HbA1c <7.5%, those who are already monitoring and recording their glucose and dietary intake, as well as individuals who were unable to read or write.

Implementation/Evaluation: Setting

The practice setting was a primary care clinic located in Decatur, northeast of Downtown Atlanta Georgia. The population at the clinic consists of adults of all ethnic and racial backgrounds, all genders, and different social and economic backgrounds. The clinic has 30 – 50 patient visits scheduled daily with a mix of acute (sinus infections, allergic reactions, insect bites, and mechanical injuries) and chronic conditions (diabetes, hypertension, anemia, hyperlipidemia,

and chronic pain). There are 5 patient rooms with 2 medical providers available daily. There is 1 office manager, 2 medical assistants, 1 administrator, a medical biller, and a lab technician.

Implementation/Evaluation: Instruments/Tools

The *John Hopkins Patient Guide to Diabetes – Meal and Glucose Log* (Appendix D) is a glucose and meal log that was used for this quality improvement project. It has 7 days of the week labeled left to right while glucose and meals are labeled from top to bottom (Johns Hopkins Medicine, 2017). Logs were printed and handed to the participants to record their information. Since the project was going to run for 60 days, 9 pages stapled together were given to each participant. Each day entered had a morning glucose level, breakfast, snack, afternoon glucose level, lunch, snack, evening glucose level, dinner, and then snack. Participants were informed that they did not have to check their glucose level after dinner. The feasibility of this tool is in line with the American Association of College of Nursing (AACN) which urges Doctor of Nursing Practice (DNP) graduates to understand new models of care delivery that are built on current nursing discipline and achievable within the existing structural, cultural, and financial standpoints (AACN, 2006).

To test reliability, SMBG logs were compared with the readings in the glucometer memory in a study which was aimed to find the impact of SMBG log reliability on long term glycemic outcomes where errors in glucose charting were observed in 32.8% of the participants and 42.2% in omission (Selvan et al., 2017). This study found out that participants whose logs were accurate had consistently low HbA1c compared to those who had inaccurate logs. A meta-analysis of randomized controlled trial studies which was intended to find out if SMBG was effective in improving glycemic control in T2D without insulin treatment found that SMBG moderated HbA1c levels better than the control in all subgroups analyses (Zhu et al, 2016).

SMBG improved HbA1c levels in both 6- and 12-months follow-ups in patients with T2D who were not using insulin.

Implementation/Evaluation: Intervention & Data Collection

The Implementation of this project was initiated after Georgia State University Institutional Review Board (IRB) approval (Appendix E) was granted on June 4th, 2021. Implementation began on June 7th, 2021, and data collection was completed on September 30th, 2021. The patients who met the inclusion criteria were contacted via telephone to inform them about the project. They were invited to the primary care clinic for detailed information about the project behind a closed door where they were given the consent forms (Appendix F). Patients were informed of the total estimated time for the entire project which included 3 minutes for preparation and finger pricking at home, 1 minute to record the result, and 2 minutes to record the meal. The total time was 5 minutes. They were informed that this was to be done 3 times a day which would equal 15 minutes each day. Since the entire project was 60 days, this would equal 900 minutes. Checking for HbA1c in the lab was expected to take 3 minutes each time. Total estimated patient time commitment: 906 minutes (15.1 hours).

The patients who agreed to participate signed the consent form and were invited to the lab for HbA1c checking. The participants were handed the John Hopkins meal and diet log with instructions about how to use it. Participants were notified of being contacted monthly to check on the progress of glucose and diet monitoring. Shaw (2017) noted that recognizing that sometimes individuals may lack the capability for making the required change is important thus the possibility for training or reframing of directions will be necessary to effect change. During the interaction with the participants to check their progress, emphasis was made on the need to keep monitoring. They were also urged to reach out with any concerns. At the end of the 2

months, each participant was contacted to return to the clinic with the completed logs for HbA1c testing. These logs were collected, and data was stored in password-protected computers and key-locked cabinets. A coding sheet was used to de-identify patients. Code 001 was used for the first patient and the next in a numeric sequence.

Components of Analysis and Statistical Tests

Data was entered into IBM Statistical Package for the Social Sciences (SPSS) with the guidance of a statistician at Georgia State University. SPSS is a statistics software package used for interactive statistical analysis (IBM, 2021). This quality improvement study was analyzed using descriptive statistics. Percentages were derived from the increase or decrease in HbA1c results divided by the original HbA1c test result, multiplied by 100. The mean and standard deviation were used for the analysis of the HbA1c test results. Other statistical tests were not appropriate for the analysis of these results because the sample was too small to make an inference about the entire population.

Results

The intended sample size was 50 participants, 15 enrolled, and 10 participants were able to return the SMBG and diet logs and take the second HbA1c test. The demographics (Table 1) of the participants who completed the study were 60% women and 40% men. The age range of the participants was 40-65 years. Seventy percent were African Americans, 20% white, and 10% identified as Hispanic. No other races/ethnic groups were identified among the participants. The participants were divided into 3 groups according to the degree of SMBG and diet log completion. Participants who fully completed the SMBG and diet logs were labeled as *Action 1*. Participants who completed 3-4 pages out of the 9 pages of the SMBG and diet logs were labeled as *Action 2*. Participants who did not attempt to complete the SMBG and diet logs at all were

labeled as *Action 0*. The initial HbA1c test was labeled as the *HbA1c test before* and the final HbA1c test at the end of the 2 months was labeled as the *HbA1c test after*. The mean HbA1c in each group is the average HbA1c of the participants. The percentage change was calculated from the difference between the *HbA1c before* the 2-month monitoring period and *HbA1c after* the 2-month monitoring period divided by *HbA1c before* multiplied by 100.

Among the individuals who returned to the clinic for the second HbA1c test (Table 2), 50% had fully completed the SMBG and diet logs (*Action 1*), 20% partially completed the SMBG and diet logs (*Action 2*), and 30% were unable to complete the SMBG and diet logs (*Action 0*). For *Action 0*, the mean *HbA1c before* was 8.9%, and the mean *HbA1c after* was 10.2%. The HbA1c percentage increase for *Action 0* was 14%. For *Action 1*, the mean *HbA1c before* was 8.5%, and the mean *HbA1c after* was 6.9%. The HbA1c percentage decrease for *Action 1* was 19%. For *Action 2*, the mean *HbA1c before* was 7.7%, and the mean *HbA1c after* was 7.5%. The HbA1c percentage decrease for *Action 2* was 2.5%. (Table 2). Comparing the changes in the *HbA1c after* in *Action 0* (Figure 1) to *Action 1* (Figure 2), *HbA1c after* decreased in *Action 1* while it increased in *Action 0*. Comparing the changes in *HbA1c after* in *Action 1* to *Action 2* (Figure 3), a decrease in *HbA1c after* for both groups was noted.

The results from this study suggested that individuals who completed all 9 pages of the SMBG and diet logs had a significant decrease (19%) in their HbA1c after the 2 months monitoring period. Individuals who partially completed the SMBG and diet logs had a slight (2.5%) decrease in the HbA1c compared to those who completed the SMBG and diet logs. These results also indicated that the individuals who did not complete the SMBG and diet logs at all had had an increase (14%) in their HbA1c. The participants reported the inability to complete the

logs to be related to barriers such as the loss of health insurance, lack of diabetes supplies, and general stress factors related to the COVID-19 pandemic.

Discussion

The purpose of this project was to determine the impact of blood glucose monitoring logs in conjunction with food diaries in lowering HbA1c in adults aged 18-89 years with T2D. The findings from this project suggest that individuals who continuously monitored and recorded their blood glucose and meals daily had an improvement in their diabetes as evidenced by a decrease in their HbA1c (Figure 1). The project answered the clinical question; In T2D patients, how does the incorporation of blood glucose monitoring logs in conjunction with food diaries contribute to lowering HbA1c compared to using pharmacotherapy alone in adults aged 18-89 with HbA1c greater than 7.5% over a period of 2 months? For this project, participants who had HbA1c greater than 7.5% were contacted. Fifty patients were found in the clinic's EMR who met the inclusion criteria. Several subjects were not able to be contacted by telephone secondary to either their telephones being disconnected or failure to answer. Only 30 patients were able to be reached by telephone about the project. Fifteen patients declined to be a part of the project while the rest of the 15 patients were agreeable to participating in the project and were present to sign the informed consents, get the HbA1c testing, and receive the logs. A complication noted during the biweekly telephone calls to participants was requesting to no longer participate in the project or not answering their telephones.

Participants who indicated not to be included in the project anymore were excluded. Participants who were not answering their telephone calls after several attempts were excluded as well. Participants who declined to return for the second HbA1c testing were also removed from the project. Ten participants returned to the clinic for the second HbA1c test. Three

participants did not complete the logs at all but returned for the second HbA1c test. Two participants partially completed the logs while 5 participants fully completed the logs and returned for the second HbA1c test. The logs were collected when the participants returned to the clinic for the second test. Patients who were not able to complete the project attributed their concerns to the general impact of the COVID-19 pandemic. The concerns were related to job losses and lack of health insurance coverage, lack of proper functioning glucometers, the stress of losing loved ones, fear of daily finger-pricking, and having to record every meal taken every day.

These results are consistent with a study that was intended to examine whether SMBG could be more effective with or without telecare support where individuals who received telecare support during the enrollment period had a more decrease in HbA1c compared to others (Parsons et al., 2019). In this project, barriers were identified and addressed for individuals who responded to biweekly - monthly telephone calls, and thus were able to have better glucose outcomes. Some of the barriers included running out of diabetic supplies leading to the inability to continue monitoring their glucose. The medical providers were contacted for refills of the participants' diabetic supplies such as lancets and glucose strips which helped the participants to continue monitoring their glucose and diet.

The findings of this project were also consistent with the narrative literature review which was conducted on the role of SMBG as a control tool in diabetes management. This review found that having the necessary diabetes supplies for monitoring blood glucose was linked to a decrease in HbA1c levels (Frías-Ordoñez & Pérez-Gualdrón, 2019). Individuals who failed to get refills on their diabetic supplies or had faulty glucose meters during this project implementation were not able to continue monitoring their glucose and diet. Although the

medical providers were contacted for refills, participants who did not have insurance coverage reported an inability to cover the cost of these diabetic supplies.

A change in HbA1c was noted in individuals who returned to the clinic for the second HbA1c test after 2 months. The change in HbA1c is consistent with the findings from a study that found that HbA1c was a vital indicator for long-term glycemic control with the capability to mirror the cumulative glycemic history of the preceding 2-3 months (Sherwani et al., 2016). *Action 0* had an increase in HbA1c by 14%, *Action 1* had a decrease in HbA1c by 19%, and *Action 2* had a decrease in HbA1c by 2.5%. All the second HbA1c tests indicated an increase or decrease in HbA1c compared to the initial HbA1c test. This project was carried out over a period of 2 months and a change in HbA1c was noted which is consistent with the research findings regarding HbA1c glycemic history.

An unexpected finding in this project was that individuals who completed the logs to their entirety had an overall change in their health such as losing weight and an improvement in their cholesterol levels. Also, during the enrollment period, some patients reported that they had never heard of some of the complications of diabetes such as kidney disease, and how diabetes was related to dialysis (CDC, 2018). Some patients were also unaware of the implications of high HbA1c numbers. The other unexpected finding was the anxiety around finger pricking among some individuals who declined to be a part of the study which explains why individuals fail to monitor their daily glucose.

Limitations

The major obstacle that limited this project was the effect of the ongoing COVID-19 pandemic. This pandemic affected the number of patients who showed up for their scheduled appointments. Some participants reported that they could not come to the clinic in person due to

the COVID-19 pandemic. The failure to keep their scheduled appointments was related to participants being COVID-19 positive or being afraid of contracting the virus at the clinic. There was the inability to refill supplies by some participants who lost their health insurance coverage during the pandemic. Other participants reported not having enough money to pay out-of-pocket for their diabetic supplies as well as a lack of reliable transportation. Although there was a decrease in HbA1c in those patients who monitored and recorded their glucose and meals, the 60-day time limit could have been extended to 90 days for a greater change in HbA1c. Another limitation was related to the lack of a reliable validating tool for what the patients had recorded on the logs. Some glucose numbers were recorded as low in relation to meals taken on a particular day which could not be validated. Regardless of these limitations, the results indicated that the use of blood glucose logs along with food dairies helped to lower HbA1c. Those individuals who did not monitor had an increase in the HbA1c due to stress factors related to the pandemic as noted.

Practice Implications

SMBG continues to be important in improving glucose control and medical outcomes in patients with T2D (Sherwani et al., 2016). The results of this project can be used to strengthen the benefits of providing these logs to diabetic patients during an office visit. Using these logs aids in providing accurate feedback not only to the patients on how their dietary behaviors affect immediate glucose control but also teaching points for medical providers when they are presented during a visit. SMBG and diet logs teach T2D patients to use objective measures of glucose levels rather than symptoms to guide the management of their condition (McAndrew et al., 2015).

Awareness of blood glucose numbers which is created from continuous monitoring decreases hypo and hyperglycemic events in those individuals who are aware of their numbers. Participants from this project reported the ability to relate blood glucose numbers to the meals they had taken on a particular day. Since medical costs related to hypo and hyperglycemic events increased from \$8,417 to \$9,601 per person between 2012 – 2017, such awareness can help lower those costs (CDC,2018).

The effectiveness of this intervention corresponds with the benefits of having continuous monitoring devices such as the Freestyle Libre. Individuals with these monitoring systems are alerted every time their glucose is out of range (Blum, 2018). The continuous monitoring devices would eliminate the anxiety related to finger pricking. A study that investigated the relationship between SMBG and diet showed that those who monitored their glucose lowered fat intake in their diet. The diet change was a response to being aware of dietary intake due to SMBG which helped to decrease their HbA1c (McAndrew et al., 2015). Some participants who completed the logs had an overall weight reduction and lower cholesterol levels which is an indicator of the effectiveness of SMBG and diet.

Sherwani et al., (2016) noted that a reduction in one's HbA1c lowers the risk of complications in T2D. Therefore, participants who had a reduction in their HbA1cs after implementing this intervention lowered their risk of complications. A rise of 1% in HbA1c concentration in diabetic patients is linked to about a 30% rise in all-cause mortality and a 40% increase in mortality related to cardiovascular complications. Individuals who did not monitor and had an increase in the HbA1c increased their chances of complications related to uncontrolled diabetes.

American Association of College of Nursing (AACN) (2006) noted that Doctor of Nursing Program (DNP) graduates need to master balancing productivity with the quality of care. Delivery approaches which are in line with the current and future needs of different patient groups based on scientific findings in nursing are also encouraged by AACN. Through a provider's role in the community, nurse practitioners are exposed to the daily circumstances which people face that affect their health. Using the leadership platform as medical providers, these patients are able to listen to health advice provided to them. However, due to the limited time spent with them during a regular clinical visit, different aspects of their lives that affect their care are left out. Incorporating an approach that would address issues that are left out during an office visit while still meeting productivity will be very fundamental to providing a better quality of patient care. The incorporation of SMBG and food diaries in the management of T2D is a feasible intervention which translates into the DNP graduates' abilities to understand new models of care delivery that are built on current nursing discipline and achievable within the existing structural, and financial standpoints.

Conclusion

T2D continues to be a global disease that is affecting individuals of all age groups which can be controlled through lifestyle modifications. The results from this project showed that consistent monitoring of blood glucose and meals showed a reduction in HbA1c. Bi-weekly to monthly follow-ups were very beneficial to this project as some barriers were addressed during interactions. Factors as noted that limited this project were related to lack of diabetic supplies and the stress factors of the ongoing COVID-19 pandemic. A larger sample is however

recommended for future related projects with a longer time frame in an environment that has practices in place to accommodate the current COVID-19 pandemic restrictions.

References

- American Association of College of Nursing (AACN). (2006). *The essentials of doctoral education for advanced nursing practice*.
<https://www.aacnnursing.org/Portals/42/Publications/DNPEssentials.pdf>
- American Diabetes Association (ADA). (2019). Standards of medical care in diabetes—2019. *Diabetes Care*, 42(Supplement 1): S1-S2. <https://doi.org/10.2337/dc19-Sint01>
- Ampofo, A. G., & Boateng, E. B. (2020). Beyond 2020: Modelling obesity and diabetes prevalence. *Diabetes Research and Clinical Practice*, 167.
<https://doi.org/10.1016/j.diabres.2020.1083627>
- Anderson, K. & Zimmerman, G. (2018). Change management: Using the ADKAR model of success. <https://www.synovaassociates.com/wp-content/uploads/2018/12/Change-Management-Anderson.pdf>
- Anywagu, U., Mamza, J., Donnelly, R., & Idris, I. (2019). Relationship between HbA1c and all-cause mortality in older patients with insulin-treated type 2 diabetes: Results of a large UK Cohort Study. *Age and Ageing*, 48(2), 235–240. <https://doi.org/10.1093/ageing/afy178>
- Blum A. (2018). Freestyle Libre glucose monitoring system. *Clinical diabetes: A publication of the American Diabetes Association*, 36(2), 203–204.
<https://doi.org/10.2337/cd17-0130>
- Center for Disease Control and Prevention (CDC). (2018). National diabetes statistics report 2020: Estimates of diabetes and its burden in the United States.
<https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.
- Chitra, S., Deep, D., Sujoy G., & Subhankar C. (2017). Impact of self-monitoring of blood

glucose log reliability on long-term glycemic outcomes in children with type 1 diabetes.

Indian Journal of Endocrinology and Metabolism, 21(3), 382–386.

https://doi.org/10.4103/ijem.IJEM_342_16

Cutruzzolà, A., Irace, C. Parise, M., Fiorentino, R., Tripodi, P, Ungaro, S., Babinsky, V., & Gnasso, A. (2020). Time spent in the target range assessed by self-monitoring blood glucose associates with glycosylated hemoglobin in insulin-treated patients with diabetes. *Nutrition, Metabolism & Cardiovascular Disease*,30, 1800-1805.

<https://doi.org/10.1016/j.numecd.2020.06.009>

Frías-Ordoñez, J. S., & Pérez-Gualdrón, C. E. (2019). Self-monitoring of blood glucose as control tool in the different management contexts for type 2 diabetes mellitus. What is its current role in non-insulin users? *Revista Facultad de Medicina de La Universidad Nacional de Colombia*, 67(3), 293–303. <https://doi.org/10.15446/revfacmed.v67n3.69687>

Ghalandari, P. G. & Beigi, Z. M. (2015). The impact of implementing ADKAR model on Organizational Change Management (OCM) and foreign & domestic sale rates of Iran Khodro Company. *Journal of Social Issues & Humanities*, 2(8).

Haitt, J.M. (2006). *ADKAR: A model for change in business, government and our community*. Prosci Learning Center Publications.

Johns Hopkins Medicine. (2017). *Johns Hopkins nursing evidence-based practice model*. Center for evidence-based practice. https://www.hopkinsmedicine.org/evidence-based-practice/ijhn_2017_ebp.html

Kachian, A., E., S. & Haghani, H., 2018. ADKAR model and nurses' readiness for change.

Journal of Client-Centered Nursing Care, 4(4). <https://doi.org/10.32598/jccnc.4.4.203>

McAndrew, L. M., Horowitz, C. R., Lancaster, K. J., Quigley, K. S., Pogach, L. M., Mora, P. A.,

- & Leventhal, H. (2015). Association between self-monitoring of blood glucose and diet among minority patients with diabetes. *Journal of Diabetes*, 3(2), 147–152.
<https://doi.org/10.1111/j.1753-0407.2011.00114.x>
- Meng, Y., Bai, H., Wang, S., Li, Z., Wang, Q., & Chen, L. (2017). Efficacy of low carbohydrate diet for type 2 diabetes mellitus management: A systematic review and meta-analysis of randomized controlled trials. *Diabetes Research and Clinical Practice*, 131, 124–131. <https://doi.org/10.1016/j.diabres.2017.07.006>
- Ng'ang'a, L., Ngoga, G., Dusabeyezu, S., Hedt-Gauthier, B. L., Ngamije, P., Habiyaremye, M., Harerimana, E., Ndayisaba, G., Rusangwa, C., Niyonsenga, S. P., Bavuma, C. M., Bukhman, G., Adler, A. J., Kateera, F., & Park, P. H. (2020). Implementation of blood glucose self-monitoring among insulin-dependent patients with type 2 diabetes in three rural districts in Rwanda: 6 months open randomized controlled trial. *BMJ Open*, 10(7), 1.
- Ogurtsova, K., da Rocha Fernandes, J. D., Huang, Y., Linnenkamp, U., Guariguata, L., Cho, N. H., Cavan, D., Shaw, J. E., & Makaroff, L. E. (2017). IDF Diabetes Atlas: Global estimates for the prevalence of diabetes for 2015 and 2040. *Diabetes Research and Clinical Practice*, 128, 40–50. <https://doi.org/10.1016/j.diabres.2017.03.024>
- Parsons, S. N., Luzio, S. D., Harvey, J. N., Bain, S. C., Cheung, W. Y., Watkins, A., & Owens, D. R. (2019). Effect of structured self-monitoring of blood glucose, with and without additional telecare support, on overall glycaemic control in non-insulin treated type 2 diabetes: The SMBG Study, a 12-month randomized controlled trial. *Diabetic Medicine*, 36(5), 578–590. <https://doi.org/10.1111/dme.13899>
- Russell, W. R., Baka, A., Björck, I., Delzenne, N., Gao, D., Griffiths, H. R., Hadjilucas, E.,

- Juvonen, K., Lahtinen, S., Lansink, M., Loon, L. V., Mykkänen, H., östman, E., Riccardi, G., Vinoy, S., & Weickert, M. O. (2016). Impact of diet composition on blood glucose regulation. *Critical Reviews in Food Science and Nutrition*, 56(4), 541–590.
<https://doi.org/10.1080/10408398.2013.792772>
- Saeedi, P., Petersohn, I., Salpea, P., Malanda, B., Karuranga, S., Unwin, N., Colagiuri, S., Guariguata, L., Motala, A. A., Ogurtsova, K., Shaw, J. E., Bright, D., Williams, R., & IDF Diabetes Atlas Committee (2019). Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045. *Diabetes Research and Clinical Practice*, 157, 107-843. <https://doi.org/10.1016/j.diabres.2019.107843>
- Shaw, L. (2017). Program evaluation of a bundled educational interventional intervention to enhance implementation of professional exchange report. *Doctoral Projects*, 36.
https://scholarworks.gvsu.edu/kcon_doctoralprojects/36/
- Sherwani, S. I., Khan, H. A., Ekhzaimy, A., Masood, A., & Sakharkar, M. K. (2016). Significance of HbA1c test in diagnosis and prognosis of diabetic patients. *Biomarker Insights*, 11, 95–104. <https://doi.org/10.4137/BMI.S38440>
- Standl, E., Khunti, K., Hansen, T. B., & Schnell, O. (2019). The global epidemics of diabetes in the 21st century: Current situation and perspectives. *European Journal of Preventive Cardiology*, 26(2), 7–14. <https://doi.org/10.1177/2047487319881021>
- Williams, D. M., Parsons, S. N., Dunseath, G. J., Stephens, J. W., Luzio, S. D., & Owens, D. R. (2020). The impact of structured self-monitoring of blood glucose on glycemic variability in non-insulin treated type 2 diabetes: The SMBG study, a 12-month randomized controlled trial. *Diabetes & metabolic syndrome. Clinical Research & Reviews*, 14(2), 101–106. <https://doi.org/10.1016/j.dsx.2020.01.006>

Zafar, F., & Naveed, K. (2015). Organizational change and dealing with employees' resistance.

International Journal of Management Excellence, 2(3). 2292-1648.

Zhang, Y., Dai, J., Han, X., Zhao, Y., Zhang, H., Liu, X., Li, W., Ling, H., Zhou, X., & Ying, C.

(2020). Glycemic variability indices determined by self-monitoring of blood glucose are associated with β -cell function in Chinese patients with type 2 diabetes. *Diabetes*

Research and Clinical Practice, 164. <https://doi.org/10.1016/j.diabres.2020.108152>

Zhou, W., Chen, M., Yuan, J., & Sun, Y. (2016). Welltang - A smart phone-based diabetes

management application - improves blood glucose control in Chinese people with

diabetes. *Diabetes Research & Clinical Practice*, 116, 105–110.

<https://doi.org/10.1016/j.diabres.2016.03.018>.

Appendix A

Search Strategy and Results

Data base used	At least 6 key words	Search Terms & Limits	Number of studies:	Type of studies:
CINAHL	Type 2 diabetes, blood glucose logs/self-monitoring blood glucose (SMBG), diet/food diaries, Hemoglobin A1c, adults	<p>Combination: All key words</p> <p>Limits: Academic journals Last 5 years</p> <p>Inclusion/exclusion: HbA1c change/ Automated glucose continuous monitoring</p>	<p>183</p> <p>62</p> <p>63</p>	Most of these studies were systematic reviews and randomized controlled trials
Cochrane. Using Medical terms	Type 2 diabetes, blood glucose logs/self-monitoring blood glucose (SMBG), diet/food diaries, Hemoglobin A1c, adults	<p>Combination: All key words Diabetes glucose self-monitoring</p> <p>Limits: Cochrane reviews Last 5 years</p> <p>Inclusion/exclusion: HbA1c change/ Automated glucose continuous monitoring</p>	<p>0</p> <p>767</p> <p>5</p> <p>322</p>	Only 5 Cochrane systematic reviews were obtained, and the rest were trials
PubMed	Type 2 diabetes, blood glucose logs/self-monitoring blood glucose (SMBG), diet/food diaries, Hemoglobin A1c, adults	<p>Combination: All key words</p> <p>Limits: Clinical trial Meta-analysis Randomized Controlled trial Review Systematic review Last 5 years</p> <p>Inclusion/exclusion: HbA1c change Automated glucose continuous monitoring</p>	<p>1442</p> <p>} 200</p>	All the studies included clinical trials, meta-analysis, random controlled trials, and systematic reviews
Embase	Type 2 diabetes, blood glucose logs/self-monitoring blood glucose (SMBG), diet/food diaries, Hemoglobin A1c, adults	<p>Combination: All key words</p> <p>Limits: controlled study randomized controlled trial cross sectional study systematic review longitudinal study meta-analysis</p>	<p>1523</p> <p>} 1013</p>	These studies included randomized controlled trials, cross sectional studies, systemic reviews, longitudinal studies and meta-analysis.

		<p>Last years</p> <p>Inclusion/exclusion: HbA1c change/ Automated glucose continuous monitoring</p>	620	
JAMA Network backfiles	Type 2 diabetes, blood glucose logs/self-monitoring blood glucose (SMBG), diet/food diaries, Hemoglobin A1c, adults	<p>Combination: All key words</p> <p>Limits: JAMA Research</p> <p>Last 5 years</p> <p>Inclusion/exclusion: HbA1c change/ Automated glucose continuous monitoring</p>	<p>105</p> <p>105</p> <p>15</p>	These included studies from both research and expert options
Georgia State University Library	Type 2 diabetes, blood glucose logs/self-monitoring blood glucose (SMBG), diet/food diaries, Hemoglobin A1c, adults	<p>Combination: All key words</p> <p>Limits: Scholarly journals (Peer reviewed)</p> <p>Last 5 years</p> <p>Inclusion/exclusion: HbA1c change/ Automated glucose continuous monitoring</p>	<p>8,183</p> <p>1726</p> <p>629</p>	This data base provided numerous studies from different data bases including Cochrane, ScienceDirect, Complementary index. The studies largely included expert opinion, case series, cohort studies and randomized control trials

Appendix B

Table 1

Demographic Characteristics

Demographic Characteristics	
Characteristics	
Age (years)	40-65
Male	4(40%)
Female	6(60%)
White	2(20%)
African American	7(70%)
Hispanic	1(10%)

Table 2

Mean and Standard Deviation (SD) of HbA1c for all participants (n=10)

	Action 0 (SD) (n=3)	Action 1 (SD) (n=5)	Action 2 (SD) (n=2)
Mean HbA1c before (%)	8.9 (1.15)	8.5(1.07)	7.7(0.14)
Mean HbA1c after (%)	10.2 (0.45)	6.9 (0.93)	7.5 (0.14)
HbA1c % change	+14	-19	-2.5

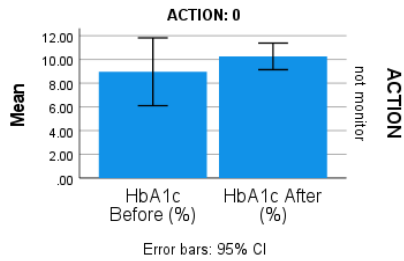
(+) - increase

(-) - decrease

Appendix C

Figure 1:

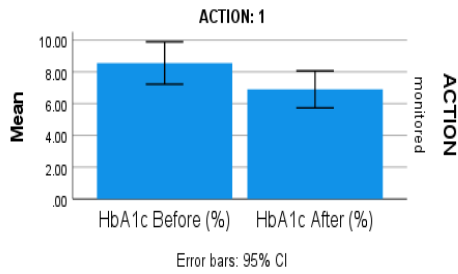
Mean HbA1c for those who did not monitor



Note. Mean HbA1c after was higher in those who did not monitor

Figure 2:

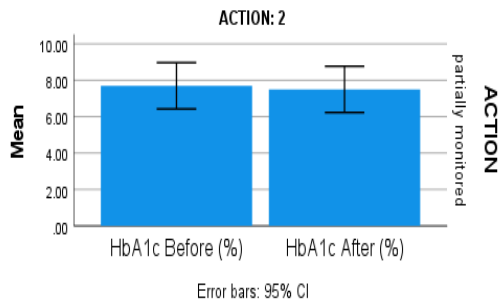
Mean HbA1c for those who monitored



Note. Mean HbA1c after was lower in those who monitored

Figure 3:

Mean HbA1c for those who partially monitored



Note. Mean HbA1c after was lower in those who partially monitored

Appendix D

The John Hopkin Patient Guide to Diabetes–Meal and Glucose Log

The Johns Hopkins Patient Guide to Diabetes - Meal and Glucose Log							
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Glucose							
Breakfast							
Snack							
Glucose							
Lunch							
Snack							
Glucose							
Dinner							
Snack							
Glucose							
Bedtime							

Week of: / /

Copyright: Division of Endocrinology, Diabetes, & Metabolism, The Johns Hopkins University
<https://hopkinsdiabetesinfo.org/>

Appendix E



INSTITUTIONAL REVIEW BOARD

Mail: P.O. Box 3999 In Person: 3rd Floor
 Atlanta, Georgia 30302-3999 58 Edgewood
 Phone: 404/413-3500 FWA: 00000129

June 04, 2021

Principal Investigator: Lisa Cranwell

Key Personnel: Cranwell, Lisa; Hawks, Miranda R; Nakibuuka, Ashar

Study Department: B.F. Lewis School of Nursing

Study Title: Impact of Blood Glucose Monitoring Logs in Conjunction with Food Diaries in Lowering HbA1c in adults with Diabetes Mellitus Type 2 (DMII)

Review Type: Expedited Category 2, 7

IRB Number: H21579

Reference Number: 365098

Approval Date: 06/03/2021

Status Check Due By: 06/02/2024

The Georgia State University Institutional Review Board (IRB) reviewed and approved the above-referenced study in accordance with 45 CFR 46.111. The IRB has reviewed and approved the study and any informed consent forms, recruitment materials, and other research materials that are marked as approved in the application. The approval period is listed above. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the Institution.

It is the Principal Investigator's responsibility to ensure that the IRB's requirements as detailed in the Institutional Review Board Policies and Procedures For Faculty, Staff, and Student Researchers (available at gsu.edu/irb) are observed and to ensure that relevant laws and regulations of any jurisdiction where the research takes place are observed in its conduct.

Federal regulations require researchers to follow specific procedures in a timely manner. For the protection of all concerned, the IRB calls your attention to the following obligations that you have as Principal Investigator of this study.

1. For any changes to the study (except to protect the safety of participants), an Amendment Application must be submitted to the IRB. The Amendment Application must be reviewed and approved before any changes can take place.
2. Any unanticipated problems occurring as a result of participation in this study must be reported immediately to the IRB using the Unanticipated Problem Form.
3. Principal investigators are responsible for ensuring that informed consent is properly documented in accordance with 45 CFR 46.116.
 - The Informed Consent Form (ICF) used must be the one reviewed and approved by the IRB with the approval dates stamped on each page.
4. A Status Check must be submitted three years from the approval date indicated above.
5. When the study is completed, a Study Closure Form must be submitted to the IRB.

All of the above-referenced forms are available online at <http://protocol.gsu.edu>. Please do not hesitate to contact the Office of Research Integrity (404-413-3500) if you have any questions or concerns.

Sincerely,

Ayanna Buckner, IRB Member

Appendix F

Georgia State University Informed Consent

Title: Impact of Blood Glucose Monitoring Logs along with Food Diaries in Lowering HbA1c in adults aged 18-89 years with Diabetes Mellitus Type 2

Principal Investigator: Dr. Lisa Cranwell-Bruce DNP, FNPC

Co-Investigator: Dr. Miranda Hawks PhD, RN, CNL

Student Principal Investigator: Ashar Nakibuuka

Introduction and Key Information

You are invited to take part in a research study. It is up to you to decide if you would like to take part in the study.

The purpose of this study is to find out the impact of blood glucose monitoring logs along with food diaries in lowering HbA1c in adults aged 18 and 89 years with Diabetes Mellitus Type 2.

Your role in the study will last 906 minutes over a period of 60 days.

You will be asked to check and record your blood sugar 3 times a day as well as record all meals taken throughout the day on a glucose and diet log which will be provided to you. Your HbA1c will be checked before beginning the study and at the end of the study.

Participating in this study will not expose you to any more risks than you would experience in a typical day while monitoring your blood sugar.

This study is not designed to benefit you. Overall, we hope to gain information about the importance of monitoring meals and blood sugar in relation to lowering HbA1c. Research studies have shown that a HbA1c of 7.5% and greater increases one's risk for diabetes problems such as blindness, kidney disease, heart failure, and nerve damage.

Purpose

The purpose of the project is to find out the impact of blood glucose monitoring logs along with food diaries in lowering HbA1c in adults aged 18 and older with Diabetes Mellitus Type 2.

HbA1c is a test used to monitor how well you are managing blood sugar levels. You are invited to take part in this project because your most recent HbA1c was found to be greater than 7.5%. A total of 50 people will be invited to take part in this project.

Procedures

If you decide to take part, you will be required to monitor and record your blood sugar and diet every day for 60 days. Your HbA1c will be gotten before the beginning of the project and at the end of the project to measure if there was a change.

- You will be required to have a blood sugar testing machine and testing strips at home for blood sugar testing.

- You will be given a blood sugar and diet log for recording every day.
- You will need to be able to read and record you blood sugar numbers on the log which will be given to you.
- You will need to record your meals on the logs given every day.
- The Student Principal Investigator will contact you via telephone every 2 - 4 weeks to make sure monitoring is being done.
- There will be no cost to you for checking your HbA1c at the beginning and end of the project.

Future Research

Researchers will remove information that may identify you and may use your data for future research. If we do this, we will not ask for any additional consent from you.

Risks

In this project, you will not have any more risks than you would in a normal day of life such as as pain from finger pricking. No injury is expected from this project, but if you believe you have been harmed, contact the research team as soon as possible. Georgia State University and the research team have not set aside funds to compensate for any injury.

Benefits

This project is not intended to benefit you. The goal is to create awareness among diabetes patients in terms of meals taken in relation to blood sugar levels. We hope to gain information about the importance of monitoring meals and blood sugar in relation to lowering HbA1c. Research studies have shown that a HbA1c of 7.5% and greater increases one's risk for diabetes problems such as blindness, kidney disease, heart failure, and nerve damage.

Alternatives

The alternative to taking part in this study is to not take part in the study.

Costs

You will use your own glucose monitor and strips for this study.
The laboratory HbA1c testing will be done at no cost to you.

Voluntary Participation and Withdrawal

You do not have to be in this project. If you decide to be in the project and change your mind, you have the right to drop out at any time. You may skip questions or stop participating at any time. You may refuse to take part in the study or stop at any time. This will not cause you to lose any benefits to which you are otherwise entitled.

Confidentiality

We will keep your records private to the extent allowed by law. The following people and entities will have access to the information you provide:

- Dr. Lisa Cranwell- Bruce (Principal investigator and project chair),
- Dr. Miranda Hawks, (Co-Investigator),
- Ashar [Nakibuuka](#) (Student Principal Investigator)
- GSU Institutional Review Board
- Office for Human Research Protection (OHRP)

We will use the code 001, and your assigned number instead of your name on project records. The information you provide will be securely stored in locked cabinets.

When we present or publish the results of this project, we will not use your name or other information that may identify you.

▲ **Contact Information**

Contact Dr. Lisa Cranwell-Bruce at lcranwellbruce@gsu.edu and Ashar Nakibuuka at 508 371 6265 and anakibuuka1@student.gsu.edu

- If you have questions about the project or your part in it.
- If you have questions, concerns, or complaints about the project.

The IRB at Georgia State University reviews all research which involves human participants. You can contact the IRB if you would like to speak to someone who is not involved directly with the project. You can contact the IRB for questions, concerns, problems, information, or input about your rights as a research participant. Contact the IRB at 404-413-3500 or irb@gsu.edu.

Consent

We will give you a copy of this consent form to keep.

If you are willing to volunteer for this project, please sign below.

Printed Name of Participant	
Signature of Participant	Date
Principal Investigator or Researcher Obtaining Consent	Date