



Decreasing Glycosylated Hemoglobin with Nutrition, Exercise and Bi-Monthly Telephone Calls in Patients with Type 2 Diabetes Mellitus

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Abstract

Background: Decreasing glycosylated hemoglobin (HbA1c) is a primary diabetes treatment goal. Despite the simplicity of the HbA1c goal, failure to achieve this goal is a major healthcare concern. Healthcare providers fail to adequately educate patients on how to implement behavioral modifications needed for successful goal achievement. Narrowed focused patient encounters, reliance on patient self-education, denial, and delayed follow-up appointments limit a patient's ability to implement required behavioral changes. **Aim:** This study was a quality improvement intervention designed to determine whether a personalized nutrition and exercise plan in conjunction with bi-monthly telephone reinforcement calls improved the HbA1c of patients with type 2 diabetes mellitus. **Setting:** The study was conducted at a community clinic located in the southeastern U.S. that provides care predominantly to the working poor and uninsured patients. **Sample:** Type 2 diabetic patients (n = 40) with a baseline HbA1c > 7%. **Intervention:** A nurse practitioner; certified diabetic educator and an exercise physiologist developed an individualized action plan with each participant. Baseline HbA1c values were documented and participants were scheduled for three education sessions as well as telephone calls twice monthly for three months followed by a repeat HbA1c. **Results:** Pretest and posttest HbA1c data were analyzed using the Wilcoxon T-test statistic to determine if a personalized nutrition and exercise action plan in addition to bi-monthly telephone calls to the participants contributed to a decrease in the HbA1c. Level of significance was set at an alpha value of less 0.05. The observed value of the test statistics $t = 2.2714$, with $df = 62$, $p\text{-value} = 0.01292$ rejects the null hypothesis. The $p\text{-value} (0.012)$ demonstrated a significant improvement. **Conclusion:** Individualized attention and frequent reinforcement facilitated patients' need to develop and integrate self-management behaviors, thereby, reducing the HbA1c level and helping them to reach the desired goal.

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Glycosylated Hemoglobin, Personalized Exercise and Nutrition Action Plan, Behavior Change, Bi-Monthly Telephone Calls

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1. Introduction

The ADA guidelines recommend that the HbA1c goal for patients with Diabetes Mellitus (DM) should be less than 7% [1]. For every 1% reduction in the results of the HbA1c blood test, the risk of developing eye, kidney, and nerve disease is reduced by 40 percent while the risk of heart attack is reduced by 14 % [2]. Maintaining HbA1c levels less than 7% validate diabetes disease control. A strategy of improved communication and support, as well as continual evaluation will help patients begin self-management and learn how to change their lifestyles. Given the multiple challenges associated with managing diabetes, a patient's perception and motivation of their innate ability to achieve success is critical [3].

2. Statement of the Problem

A major problem recognized by the patient and the healthcare team is that generic education tools and exercise information often do not consider the patient limitations, day to day challenges, or available financial resources [4]. An individualized plan with provider support may assist the patient to be successful. Healthcare providers and patient partnerships facilitate the planning of goals and accomplishment of desired outcomes. In the past it was customary to educate patients about what to do and eat but it has proven to be a limited intervention and did not produce consistent behavioral changes. In addition, long delays between scheduled appointments caused by noncompliance and missed appointments hinder the partnership and the patient's ability to stay on target.

Significance of the Study for Nursing

The study's significance for nursing practice is based on the provision of a needed strategy to help patients achieve a goal of decreasing and maintaining HbA1c levels 7% or less. The strategy to be examined is the development of a partnership between the interdisciplinary team and patient who developed and implemented a patient centered action plan. Decreasing glycosylated hemoglobin (HbA1c) utilizing an interdisciplinary collaborative approach has shown to be a successful strategy in the fight against DM [1]. An interdisciplinary delivery care model was used to provide healthcare to patients with type 2 DM that had an HbA1c 7% and greater. The study was approved by the Internal Review Board (IRB) at Murray State University (MSU) prior to the initiation of the study and took place at a local community clinic over a 3-month period that started in August 2013 and concluded in December 2013. The interdisciplinary team consisted of a nurse practitioner (NP), a certified diabetic educator (CDE) and an exercise physiologist. The NP led the team and provided primary care, developed action plans and made bi-monthly telephone calls. The CDE and the exercise physiologist developed and educated patients on a personalized nutrition and exercise plan in accordance with the ADA guidelines. The interdisciplinary team members documented and provided evidence-based, disease-specific standard interventions, and the results of the patient outcomes were documented by the NP in the electronic health record (EHR). The outcome of the interventions from the interdisciplinary team was evaluated based on a comparison of the pre HbA1c and post HbA1c results over a three month period. The interdisciplinary delivery care model and interventions challenge health care providers to improve clinical outcomes for patients with DM.

3. Theoretical Framework

The premise of this study was based on the foundation of Bandura's health self-efficacy theory. Health self-efficacy is defined as the belief in one's capabilities to organize and execute the courses of action required to produce attainments [3]. Improvement of health self-efficacy was essential for participants to reach their individual goals due to its influence on their perception and belief in their abilities to change. In this study, health self-ef-

ficacy was to be improved through the development of an action plan that included a personalized nutrition and exercise training. Bi-monthly telephone calls were implemented to enhance the cognitive abilities of the participants to execute their action plan and adapt to behavior changes to meet desired study outcomes.

Cultural and socio-economic limitations were central to the design of the interventions implemented with the study participants. Considering that the study population was comprised predominantly of minorities, uninsured and underinsured participants, providing culturally competent care was fundamental for improved outcomes. The interdisciplinary team formulated the participant's action plans according to the culture and socio-economic status of the participants. Expectations of health self-efficacy determine what behaviors will be initiated and maintained when faced with cultural barriers [5]. The premise of health care self-management depends on patients acquiring improved health self-efficacy. This would allow patients to remain resilient with the disease management to ensure that they master the needed lifestyle changes to have a successful outcome.

4. Clinical Question

What changes occur to the HbA1c in patients with type 2 DM with the implementation of a personalized nutrition and exercise action plan reinforced with bi-monthly telephone follow up calls?

5. Review of Literature

The literature review for this study was composed of non-randomized control trials of diabetes interventions. This type of study design generally enables the researcher to pursue similarities and differences between a trial population and a typical target population [6]. The literature review focuses on recommended guidelines, self-management, nutritional and exercise interventions, as well as the impact of telephone follow up calls to improve outcomes for patients with diabetes.

5.1. Recommended Guidelines

The American Diabetes Association (ADA) [1] established recommendations that diabetic health care should be delivered with a multidisciplinary approach. The multidisciplinary team may include physicians, nurse practitioners, physician's assistants, nurses, dietitians, pharmacists, and mental health professionals. The professionals in the team should have expertise and a special interest in diabetes as well as being effective in diabetes self-management support (DSMS). Patients with diabetes need to have a team approach to care at the onset of diagnosis and throughout the course of the individual's lifetime. The ADA also recommended that patients with diabetes receive individualized *Medical Nutritional Therapy* (MNT) as needed to achieve treatment goals. The best professional to provide MNT is a registered dietitian familiar with the components of diabetes MNT. In addition, adult diabetic patients should be advised to perform at least 150 min/week of moderate-intensity aerobic physical activity (50% - 70% of maximum heart rate), spread over at least 3 days/week with no more than two consecutive days without exercise.

5.2. Self-Management

The American Association of Diabetes Educator (AADE) guidelines promote the need for self-management. Diabetes is a chronic disease that requires patient participation in managing the disease. According to the AADE (2009) [7] guidelines, self-management is the cornerstone of disease control. Diabetic patients improved HbA1c levels immediately following diabetic education and increased quality contact time with an educator; however, the benefit of self-management education has been noted to decline 1 - 3 months after the intervention. The decline in control suggests that learned behaviors change over time and should be reinforced with continual support until the behaviors are innately engrained.

Funnell and Anderson (2004) [8] recommend utilizing empowerment philosophy to improve diabetes self-management. The empowerment philosophy fosters an established partnership between patients and the health care professionals, creating a patient-centered relationship. Patients benefit from improved communication, declare greater satisfaction with healthcare, along with improved metabolic and psychosocial outcomes, and emotional well-being. Health care providers achieve recommended standards of care, improved outcomes, and greater professional satisfaction.

Whitlock, Orleans, Pender, and Allan (2002) [9] completed a study focused on using an evidence based ap-

proach to behavioral counseling interventions. Clinical settings used behavioral counseling interventions as a means of addressing relevant health care behaviors. Examples of health care behaviors that needed to be addressed for patients included lack of physical activity, poor diet, substance (tobacco, alcohol, and illicit drug) use and dependence, and risky sexual behavior. These behaviors underlie a substantial proportion of preventable morbidity and mortality in the United States. The study demonstrated that brief interventions designed to fit into routine practice and everyday lifestyles have been found to produce clinically meaningful changes in the population for a growing number of behavioral risk factors.

5.3. Nutrition

The study conducted by Muchiri, Gericke, and Rheeder (2009) [10] focused on the need for planning effective nutrition education programs for adults with type 2 diabetes in resource poor practice settings. Patients in lower socio-economic settings cite dietary adherence as the most difficult self-care area. Nutrition education should be tailored to the population instead of providing generic resources. In addition, diabetic educators should consider literacy levels by using visual materials, experiential teaching methods, repetitions of key concepts, giving a few dietary concepts at a time and tailoring the education to the socio-cultural context.

Mann (2006) [11] evaluated the nutritional recommendations for the prevention and management of diabetics to generate evidence-based recommendations. Multiple randomized controlled trials suggest it is important for health care professionals to consider personal and cultural preferences. Personal and cultural preferences play an important role in the enhancement of compliance with nutritional recommendations. The ADA guidelines recommended that dietary advice must be personalized with healthy foods that are consistent with the prevailing population-wide dietary recommendations and with an individual's preference and culture.

5.4. Exercise

The Gulve (2008) [12] study focused on the benefits of exercise in patients with diabetes. Aerobic exercises and resistance training are recommended for the beneficial effects on glucose control. In addition, aerobic exercise retards the progression of other comorbidities common in patients with diabetes and cardiovascular diseases. The Sweet *et al.* (2009) [13] study focused on autonomous motivation influences by improving self-efficacy in adults with type 2 DM who led sedentary lifestyles. The study participants were involved in a 12 month physical activity exercise training program. Patients exposed to this intervention had improved confidence to overcome barriers in the earlier stages of physical activity behavior. The Waryasz and McDermott (2010) [14] study focused on patients with type 2 diabetes in which physical activity has been documented to improve patient outcomes. Findings suggest that the healthcare provider should discuss a patient-centered exercise regimen, and refer the patient for specialized care that ensures safe and effective self-management and promotes the most current ADA exercise guidelines.

5.5. Telephone Follow-Up Calls

Orr, *et al.* (2006) [15] conducted a study focused on decreasing HbA1c over a 6 month period using telephone reinforcement calls as an intervention. The addition of one, two, three or four phone calls during the focused intervention led to corresponding increases in HbA1c testing adherence compared to no telephone calls. Nesari, *et al.* (2010) [16] focused on the impact of telephone follow-up interventions on the HbA1c in patients with type 2 diabetes. The nurse-led telephone follow up intervention was effective in enhancing the level of adherence to diabetes therapeutic regimen, evidenced by decreased HbA1c level. Patients were more compliant in getting the diagnostic lab completed as recommended.

Forbes, Griffiths, Milligan, and While (2010) [17] study focused on telephone follow-up to improve glycemic control in patients with type 2 diabetes. The analysis of the study suggested that telephone follow-up interventions following a more intensive targeted approach could have a positive impact on the glycemic control for type 2 diabetes. Piette, Weinberger, Kraemer, and McPhee (2001) [18] conducted a study to evaluate automated telephone management (ATDM) for patients with diabetes. This study evaluated the effects of telephone nurse follow-up as a strategy for improving diabetes treatment processes and outcomes in Department of Veterans Affairs (VA) clinics. The study concluded that the ATDM with nurse follow-up improved the process and outcomes of VA diabetes care.

6. Methods

The study design was a quantitative pre and post interventional study, analyzing aggregate data from 40 participants from a local southeastern U.S. clinic. The Wilcoxon T-test statistic, as well as a formative and summative anecdotal report, was used to evaluate the effectiveness of the interventions. In addition the participant's perception of individual improvement in health self-efficacy to maintain their current health status was elicited by the nurse practitioner at the final study session.

6.1. Design

The study was conducted with a quasi-experimental pre and post interventional design. A quasi-experimental intervention study is a nonrandomized experiment frequently used when it is not logistically feasible or ethical to conduct a randomized controlled trial. This type of design often is used to evaluate the benefits of specific interventions.

6.2. Participant Sampling

Study participants were recruited from a clinic serving predominately the working poor and uninsured population in the southeastern U.S. Patients were informed about the purpose of the project, requirements of participation, as well as the procedure for providing and withdrawing the informed consent by the primary investigator. Participants were aware that the data compiled would be in an aggregate form and all participant information would be de-identified and stored in a secure location at the clinic. Recruited participants were assured that being in the study was voluntary and would have no impact on their care provided at the clinic. The principal investigator obtained approval from the Murray State University (MSU) Institutional Review Board (IRB) and permission was obtained from the medical director of the clinic where the study was conducted.

The convenience sample consisted of 40 patients from diverse backgrounds and ethnicities who sought healthcare at the clinic. Eligibility criteria included patients diagnosed with type 2 diabetes that were 18 years old and greater. In addition, participants had to have a working telephone, baseline HbA1c greater than 7%, and willing to complete 3 scheduled appointments.

6.3. Setting

The study took place at a local clinic in the southeastern U.S. The clinic is a federally qualified health center that provides comprehensive primary care and dental services predominately to the uninsured and underinsured. The medical staff consists of 2 full time nurse practitioners (NP), 2 internal medicine physicians (MD) and 10 ancillary staff. On a typical day the clinic is staffed with 2 NPs and 1 MD who provide care to approximately 18 - 20 patients per provider. The study was subsidized with a grant from Clarksville Montgomery County Health Foundation (CMCHF) and Astra-Zeneca.

6.4. Intervention

Each of the 40 study participants had an HbA1c value collected and documented in the electronic medical record that was less than 6 months old prior to the first appointment. Participants had 3 scheduled appointments at the clinic, followed by a repeat HbA1c on the 3rd appointment. The first appointment included a clinical counseling session lasting for approximately 1.5 hours with the principal investigator scheduled in August 2013. A certified diabetic educator and exercise physiologist conducted individualized education sessions lasting approximately 2 hours during the second appointment scheduled in September 2013. After the completion of the 2nd appointments, participants received a telephone call from the principal investigator (PI) twice monthly lasting approximately ½ hour-1 hour each month using a telephonic script.

The phone calls were also used to assess patient's health self-efficacy behaviors and provide additional instructions and education. The health self-efficacy assessment included a discussion about the patient's perception of how they are meeting the action plans objective and to provide guidance and encouragement and motivation for adherence to the interventions. The principal investigator also assessed whether additional appointments were necessary to meet the study's outcome but none were necessary. The third appointment scheduled in December lasted for approximately 1 hour, and repeat HbA1c was done as well as a general discussion about the

participant's knowledge and perception of the effectiveness of the interventions and individual health self-efficacy.

7. Results

The initial aggregate data of participants in the study demonstrated an overall decrease in HbgA1c. During the 3-month study, participants' aggregate mean postHbgA1c decreased from 9.4% to 7.9%. The most significant changes occurred with three participants' who had a decrease in HbgA1c of 11.8% to 7.3%, 11% to 6.8%, and 13.1% to 10%. Twenty-two participants had a combined 22.1 point HbgA1c decrease. The following figures (Figure 1 and Figure 2) and calculation analysis table (Table 1) demonstrates the aggregate trend of the HbgA1c data pre and post intervention.

The Wilcoxon T-test statistic used to analyze the data, indicated a value of the T-test statistics was (2.2714), with a p-value of (0.01292) indicating that the interventions improved the post HbgA1c. The p-value measures consistency between the results actually obtained in the study rather than by chance. A p-value less than 0.05 indicated that the interventions are statistically significant [19]. The bi-monthly telephone calls were an excellent motivational and encouragement tool that affected the patient's health self-efficacy and behavior that resulted in an improved outcome. The trend in the post-HbgA1c supports the findings of the literature reviews and the teaching/learning care delivery model delivered by the NP and the multidisciplinary team. The study also provides a suggested treatment guideline for patients with type 2 DM with an HbgA1c > 7%. The personalized exercise and nutrition action plans that was developed and implemented by the certified diabetic educator (CDE) and exercise physiologist also impacted the postHbgA1c. The bi-monthly telephone calls were an excellent motivational and encouragement tool that affected the patient's health self-efficacy and behaviors that resulted in an improved outcome. Participant's perceptions based on Bandura's self-efficacy were also evaluated. The health self-efficacy evaluation included an assessment of the participant's innate belief to execute the action plan and remain committed to develop changed behavior modifications and remain resilient.

Table 1. Statistically significant improvement with the pre-HbgA1c and post-HbgA1c.

	MEAN	SD	IQR	0%	25%	50%	75%	100%	N
AGE	49.9	9.96	13.5	26	43.5	52.0	57.0	74.0	36
PRE-HBGA1C	9.4	1.50	1.93	7	8.4	9.2	10.3	13.1	36
POST-HBGA1C	7.4	3.34	2.40	0	6.8	8.2	9.2	12.8	36

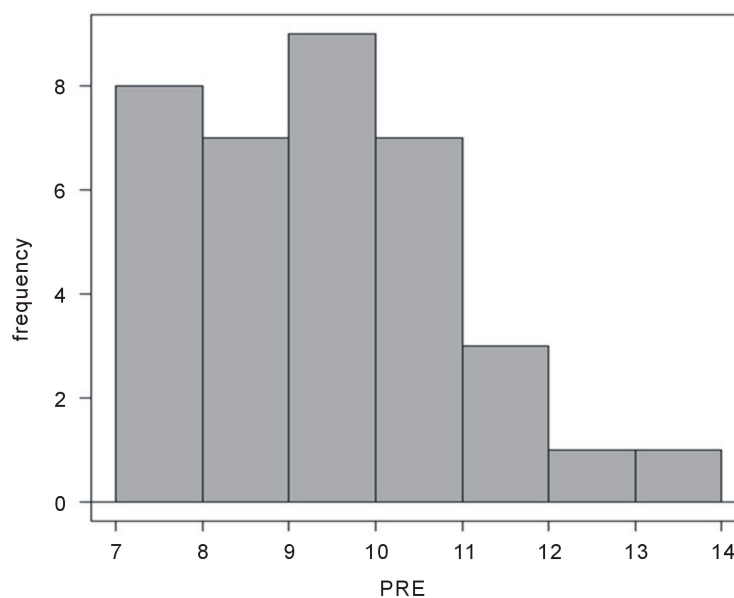


Figure 1. The preHbgA1c histogram aggregate data demonstrating multiple intervals with increase HbgA1c compared to the post HbgA1c.

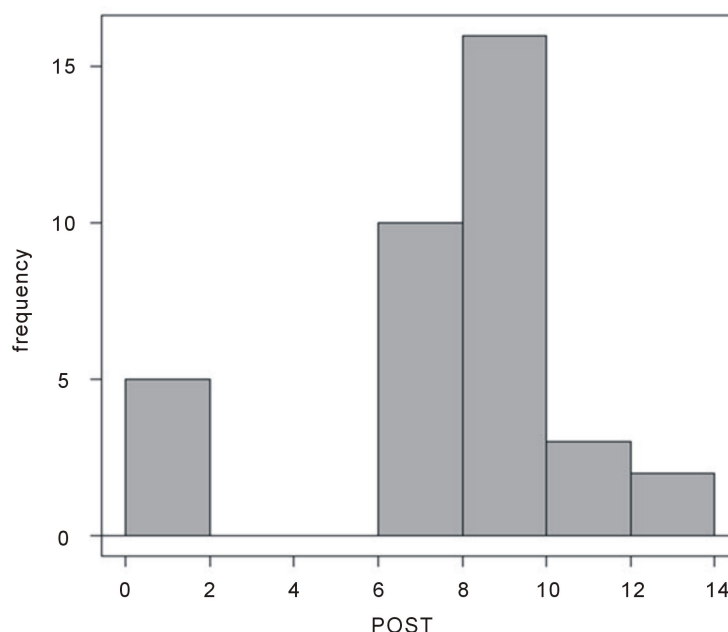


Figure 2. Histogram with the aggregate data demonstrating lower bars at various intervals compared to the pre-HbgA1c implying that the interventions contributed to an improved HbgA1c.

8. Limitations of the Study

Limitations of the study included a small convenience sample size and location of the clinic in the southeastern U.S serving predominately underinsured and the uninsured. The study started with 40 participants and concluded with 35 participants. Five participants withdrew from the study for individual reasons. In regards to the bi-monthly telephone calls, consistency was an issue. Thirty participants received bi-monthly telephone calls and 5 participants received a monthly call due to various reasons such as work schedules and other obligations. Other extraneous factors that contributed to the limitations of the study were whether the participant's had family support that embraced the changes in the nutrition plans or whether the participants were capable of shopping for groceries or preparing the meals according to the CDE recommendations. Participant's ability to arrange transportation to the clinic for their scheduled appointments and avoid delays with the implementing the study's interventions also contributed to the study's limitation. In addition the study participants' biometric changes such as weight loss, increased activity and medication compliance could have impacted the postHbgA1c.

The design of the study was a quasi-experimental pretest and posttest design which lacks randomization, and often demonstrates causality between an intervention and an outcome. This design also has a potential for regression to the mean as well as the potential to introduce bias. The results of the interventions would be more precise if the study utilized a control group in which one group would have received the personalized nutrition and exercise action without the bimonthly telephone calls while the second group would have received the personalized nutrition and exercise plans as well as the bi-monthly telephone calls. The benefit of using a control group compared to a quasi-experimental pretest and posttest design is that it this design would have been have clearly demonstrated which variable influenced the HbgA1c.

9. Conclusion

The management of DM requires a multidisciplinary approach that includes physicians, nurses, dietitians, and other selected specialists. Individualizing an exercise and nutrition plan based on a patient's social, cultural and physical limitation helps to ensure compliance with the treatment plan. The study's participants had a combined 22.1 point decrease as well as a decrease in the post HbgA1c mean of 8.4% compared to the pre HbgA1c of 9.4%. The Wilcoxon T-test statistic used to analyze the data indicated that the interventions are statistically significant

with a p-value < 0.05. The findings from this quality improvement study have led to treatment recommendations for type 2 diabetic patients with an HbA1c >7 at the clinic. Health care providers should utilize an interdisciplinary team composed of providers who are knowledgeable with the ADA treatment guidelines. Nutrition and exercise action plans should be personalized according to the patients' culture, finances, physical limitations and community resources. Participants that are uninsured and underinsured would benefit from community resources such as information of local food banks or local markets where they can purchase or receive fresh fruits and vegetables at little or no cost as well as the location of walking trails and availability of free exercise classes at a local community centers or churches. Healthcare providers should also assess whether patients have transportation to their appointments to avoid delays in treatment the plan and to ensure medications prescribed are affordable. In addition, to ensure that patient maintain their success with the treatment plan it is recommended to utilize Bandura's health self-efficacy theory and principles to influence the patient's perception in health self-efficacy to complete the treatment plan and change behaviors to meet desired goal and maintain long term success.

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Shondell V. Hickson is the principle investigator and guarantor of this work (this quality improvement project was done in partial fulfillment of Murray State University DNP program capstone requirement) and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Timothy Leszsack served as an exercise physiologist during the study by developing individualized action plans and educating patients on exercise interventions.

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