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Impact of a Telephone-Based Care Management Program on Health Outcomes for Patients with Type 2 Diabetes and Hypertension

Abbegail Miller
abbey.miller10@aol.com

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Scholarly Project Advisor: Dr. Kathryn Dambrino, DNP

Faculty Reader/Advisor: Dr. Ashley Scism, DNP and Dr. David Phillippi, PhD

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Abstract

Background: Type 2 diabetes mellitus (T2DM) and hypertension (HTN) were the 7th leading cause of death in the United States, accounting for over 160,000 deaths annually. Complications related to T2DM and HTN are preventable with lifestyle modifications and medications. However, research has shown that lack of patient self-management, poor medication adherence, and physician time restraints limit disease improvement. A telephone-based care management program (CMP) provides a solution to meeting patient needs. **Purpose:** The purpose of this scholarly project was to evaluate individual biomarkers for glycemic and HTN control, as well as self-monitoring of blood glucose (SMBG) over one year of patients with T2DM and HTN who were enrolled in a middle TN primary care clinic's CMP. **Methods:** The scholarly project utilized an observational, retrospective chart review of secondary lab data and CMP interviews collected between April 2019 through August 2020. A convenience sampling technique identified eligible patients through the clinic's EMR system (n = 51). **Results:** All individual biomarkers improved, whether significant or not, by 12 months. Significant changes were found with systolic blood pressure ($p < .001$), diastolic blood pressure ($p < .001$), and body mass index ($p = .041$). Hemoglobin A1c improved from 8.1% to 7.88% ($p = .159$). However, SMBG adherence only slightly improved with CMP participation ($p = .381$). **Conclusions:** Enrollment in a telephone-based CMP is associated with improved patient care, potentially leading to improved health outcomes and reduced complications.

Keywords: Care Management Program, Chronic Disease Management, Health Outcomes, Hypertension, Type 2 Diabetes Mellitus

Introduction

Type 2 Diabetes Mellitus (T2DM) rates are increasing at extraordinary rates in the United States. According to the Centers for Disease Control and Prevention's (CDC, 2020a) National Diabetes Statistics Report 2020, median county level T2DM prevalence rates increased from 7.8% in 2004 to 13.1% in 2016. Not only are patients living with T2DM, but they are also battling the effects of hypertension (HTN). Studies found that 68.4% of people living with all forms of diabetes mellitus (DM) reported a diagnosis of HTN (CDC, 2020a). Specifically, the state of Tennessee (TN) ranked 6th in the nation for the highest prevalence of people living with T2DM (13.8%) and 7th in the nation for the highest prevalence of people living with HTN (38.7%) (United Health Foundation, 2020a, 2020b). Major risk factors for developing T2DM- and HTN-related complications include increased hemoglobin A1c (HbA1c), smoking, obesity, physical inactivity, and hyperlipidemia (CDC, 2020a). T2DM and HTN was the 7th leading cause of mortality in both the United States and TN (United Health Foundation, 2020a, 2020b).

T2DM- and HTN- related complications are preventable with lifestyle modifications and medications. However, lack of patient self-management, poor medication adherence, and provider time constraints during clinic visits limit disease improvement (Fairchild et al., 2017; Shaw et al., 2014). Time restrictions during clinic visits, combined with increasing patient complexities, reduce available educational opportunities for providers to address lifestyle modification strategies and pharmacological treatment management plans. Furthermore, T2DM and HTN disease management depends largely on self-care activities outside the clinic visit. Thus, patients must possess adequate knowledge and self-motivation to perform essential self-care activities leading to improved health outcomes (Powers et al., 2016). To address the

complex nature of chronic diseases like T2DM and HTN, care management programs (CMPs) provide a structured and supportive approach to meeting patient needs.

One such program involving telephone communications provides a plausible solution to supporting these patient needs. In 2015, the Centers for Medicare and Medicaid Services (CMS) developed a monthly, telephone-based CMP in response to the growing concerns surrounding chronic disease morbidity and mortality (CMS, 2019). The CMP proposes to improve health outcomes, reduce hospitalizations, and increase patient adherence (CMS, 2019).

Problem Statement

Reduced physician educational opportunities combined with increased reliance on patient self-care activities create difficulties implementing effective disease management plans suitable for those living with T2DM and HTN (Powers et al., 2016). Evidence suggests that current clinic practices do not meet the necessary requirements for producing positive health outcome changes (Rushforth et al., 2016). To effectively address the complex nature of chronic diseases, care management plans are known to improve efficiency, remain cost-effective, promote patient adherence, and encourage correct self-care techniques. The CMS CMP bridges the gap between physician time constraints and missed educational opportunities, allowing for frequent patient contact without the burden of a rushed clinic visit. Although this comprehensive, structured program has been implemented in a variety of clinical settings, limited research has been conducted to examine the CMS CMPs' impact on patient health outcomes (CMS, 2019).

Purpose

The purpose of the Doctor of Nursing (DNP) scholarly project was to evaluate the impact of a monthly, telephone-based CMP on individual glycemic and hypertensive biomarkers, and adherence of self-monitoring of blood glucose (SMBG) over one year for patients with T2DM

and HTN. The primary investigator's (PI) primary aim was to compare individual glycemic and hypertensive biomarkers at pre-enrollment, 6-months, and 12-months post-enrollment in the CMP. The PI's secondary aim was to determine a correlation between increased CMP participation with improved biomarkers and adherence to self-monitoring of blood glucose (SMBG) adherence. Given the increasing prevalence of T2DM and HTN in TN, evaluation of a CMP would enhance quality improvement of services at the clinical site and influence the future use of CMPs in other healthcare facilities.

Hypothesis

The PI hypothesized that enrollment in the CMP would decrease HbA1c, systolic BP (SBP), diastolic BP (DBP), body mass index (BMI), total cholesterol (TC), low-density lipoprotein (LDL), and cholesterol/HDL ratio (CHR), and increase high-density lipoprotein (HDL). Additionally, the PI hypothesized a correlation between increased participation in the CMP with improved glycemic and hypertensive biomarkers and SMBG adherence.

Review of Evidence

T2DM and HTN

Relationship between T2DM and HTN

T2DM and HTN share similar pathophysiological processes, resulting in their close connectedness. Both conditions activate the renin-angiotensin-aldosterone system, increase oxidative stress, and release inflammatory mediators, which ultimately leads to endothelial dysfunction, insulin resistance, and HTN (Lastra et al., 2014; Pouvreau et al., 2018). Microvascular or macrovascular complications may result due to the repeated pathophysiological changes. Microvascular complications include retinopathy, nephropathy, and neuropathy. Macrovascular complications include coronary artery disease, myocardial infarction, and

cerebrovascular accidents (Fowler, 2008). One study with 318,000 participants found a direct causal relationship between worsening T2DM and its adverse effect on HTN (Sun et al., 2019). However, the study proved inconclusive on the causal relationship between worsening HTN and the associated effects on T2DM.

Several risk factors contribute to worsening T2DM and HTN, including smoking, obesity, physical inactivity, and race (Lastra et al., 2014). Those who smoke are at a 40% greater risk of developing T2DM and HTN, and experience greater difficulties adjusting insulin dosages and controlling their disease processes (CDC, 2020b). A person with a BMI greater than 30 increases their chance of developing T2DM by 28 times; furthermore, a person with a BMI exceeding 35 increases their chances of developing T2DM by 93 times (Barnes, 2011). In addition to elevated BMI, physical inactivity also contributes to insulin resistance and the development of T2DM (Venkatasamy et al., 2013). One study found that moderate exercise increased glucose uptake by 40% (Venkatasamy et al., 2013). Black, non-Hispanic individuals comprised the largest racial group of people living with T2DM (13.3%) and HTN (40.4%), while Caucasian individuals comprised the lowest percentage of individuals living with T2DM (9.4%) and HTN (27.4%)(CDC, 2020a; Valderrama et al., 2013).

Complications Related to Uncontrolled T2DM and HTN

Studies recognized specific biomarker measurements to track disease progression and its relation on developing complications related to HTN and T2DM (Adler et al., 2000; Cushman et al., 2010; Hansson et al., 1998; Kim et al., 2015; Sun et al., 2019; Turner et al., 1998; Wright et al., 2015). Specifically, an SBP greater than 130 mmHg correlated with worsening T2DM, while an SBP above 160 mmHg contributed to life-threatening complications such as cerebrovascular accidents and myocardial infarction (Adler et al., 2000; Kim et al., 2015; Sun et al., 2019).

Additional studies established that a reduced BP of less than 120/80 mmHg proved even more beneficial by decreasing cerebrovascular accidents by 41%, cardiovascular events by 51%, and death by 27% (Cushman et al., 2010; Hansson et al., 1998; Wright et al., 2015).

Researchers identified HbA1c thresholds related to microvascular and macrovascular complications (Tsugawa et al., 2012; Zoungas et al., 2012). The Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation (ADVANCE) study evaluated 11,140 patients to investigate the relationship between HbA1c and the risk of vascular complications (Zoungas et al., 2012). The researchers identified an HbA1c threshold of 6.5% for microvascular complications and 7.0% for macrovascular complications (Zoungas et al., 2012). Each one point increase in either HbA1c threshold resulted in a 38% higher risk of a macrovascular event, a 40% higher risk of a microvascular event, and a 38% higher risk of death (Zoungas et al., 2012). Even though complications arising from T2DM and HTN are well known, barriers exist that limit implementation of effective care management plans.

Barriers to Effective Care Management

Medication Adherence

Several factors correlated with decreased medication adherence, most notably patient perceptions. Normal blood glucoses (BG), non-readily observable medication impacts, previous hypoglycemic events, and inaccurate beliefs regarding T2DM and HTN curability contributed to patient adherence issues (Fairchild et al., 2017; Hajós et al., 2014; Polonsky & Henry, 2016). Two studies discovered that one hypoglycemic event contributed to medication discontinuation (Hajós et al., 2014; Polonsky & Henry, 2016). Additionally, a third study discovered 65% of people with T2DM, and 58% of people with HTN believed their diseases were curable, while historically, only 1% of patients with T2DM or HTN obtained remission (Fairchild et al., 2017).

Furthermore, research findings suggested lower income, younger age, lower education, and longer length of disease diagnoses increased skepticism toward medication treatment (Fairchild et al., 2017; Kirkman et al., 2015; Mann et al., 2009; Polonsky & Henry, 2016). Individuals who reported a household income greater than $60,000 adhered to medication treatment significantly more than those with household incomes less than $30,000 (Kirkman et al., 2015). Additionally, individuals who held graduate degrees were more likely to adhere to medication treatment than those with high school diplomas (Kirkman et al., 2015).

Provider Constraints

Healthcare providers identified time restrictions and limited knowledge as barriers to treating patients with T2DM and HTN (Shaw et al., 2014). Providers estimated that clinical visitations were limited to 20 minutes per patient (Abdulhadi et al., 2013; Rushforth et al., 2016; Shaw et al., 2014). During the short timeframe, providers must discuss proactive treatment options, provide individualized education, and address patient concerns (Abdulhadi et al., 2013; Rushforth et al., 2016; Shaw et al., 2014). Providers expressed frustration due to limited resources in conjunction with increased patient loads put forth by their facility expectations (Rushforth et al., 2016). Further restricting opportunities for improved health outcomes, providers described being uncomfortable with learning new medication recommendations, providing appropriate nutritional guidelines, encouraging effective communication strategies, and initiating injectable insulin therapy (Corriere et al., 2014; Elliot et al., 2011; Polinski et al., 2012; Rushforth et al., 2016). To counteract these physician constraints, researchers recommended quality improvement strategies targeting chronic disease management as essential components for improving patient health outcomes (Tricco et al., 2012). For example, case management initiatives promoted patient-mediated self-care activities (Tricco et al., 2012).

Telephone-Based Care Management to Improve T2DM and HTN Outcomes

Studies identified telephone-based CMPs as a strategy to enhance patient adherence, increase self-care activities, and improve health outcomes for patients with T2DM and HTN (McGloin et al., 2015; Nesari et al., 2010; Sakane et al., 2015). Nesari et al. (2010) utilized a three-day in-person educational program in addition to a telephone CMP for patients with T2DM. The telephone intervention progressed over three months and incorporated telephone interviews twice per week for one month and weekly for the remaining two months, averaging 20 minutes per session. The CMP reinforced education and addressed health behaviors, including medication adherence, diet, exercise, foot exams, and SMBG (Nesari et al., 2010). The researchers found significant improvements noted by reduced HbA1c and increased foot exams, diet, exercise, and medication adherence levels compared to baseline in the experimental group (Nesari et al., 2010). A second study incorporated three interventional levels (3, 6, or 10 telephone interviews) throughout one year to assess the intervention's impact on changes in HbA1c, BMI, diet, exercise, and alcohol intake in patients with T2DM (Sakane et al., 2015). Participants enrolled within the ten-day telephone intervention group experienced significant improvements in weight reduction, diet adherence, and fasting BG reduction, while those enlisted in the three-day telephone intervention group experienced no significant changes (Sakane et al., 2015). Similarly, multiple research studies noted clinical improvement in HbA1c and lipid levels for patients enrolled in a telephone-based CMP (Graziano & Gross., 2009; Sacco et al., 2009; Varney et al., 2014; Walker et al., 2011; Willard-Grace et al., 2015; Wolever et al., 2010).

Furthermore, limited studies exist evaluating the impact of a telephone-based CMP on patients with HTN. McGloin et al. (2015) developed a 12-week telephone intervention with

interviews conducted weekly for four weeks and biweekly for an additional eight weeks. SBP, HbA1c, DBP, and waist circumference decreased 3-months post-enrollment in the CMP (McGloin et al., 2015).

CMS CMP to Improve Health Outcomes

Heterogeneity within research elements related to the length of CMP enrollment, duration of telephone encounters, and various additional components provided an inconclusive determination of the ideal CMP design. CMS (2019) developed a comprehensive, structured CMP not previously seen within research designs, and limited research has been done to test its impact on patient health outcomes. Schurrer et al. (2017) conducted a preliminary study related to expenditure, service utilization, and quality outcomes during the 18-months following the CMS CMP's national initiation.

The preliminary study's qualitative components found that patients enrolled in the CMS CMP were overall pleased with their experience (Schurrer et al., 2017). Specifically, patients stated the monthly telephone interviews provided reassurance of care plans, reinforced education provided during clinic visits, and influenced medication adherence (Schurrer et al., 2017). Additionally, providers remarked that the CMP allowed for continuity of care, increased patient satisfaction, improved clinician efficiency, and reduced hospitalizations (Schurrer et al., 2017). Quantitative data revealed significantly increased primary care visits, reduced emergency department visits, reduced hospitalizations, and increased hospice utilization, especially for those with T2DM (Schurrer et al., 2017). A second study echoed similar findings by stating patients enrolled in the CMS CMP expressed improved satisfaction with the practice and increased communication with providers (O'Malley et al., 2017). Additionally, physicians commented on improved time management skills, which allowed for focused patient-centered interactions

during clinic visits (O'Malley et al., 2017). Presently, additional evidence is needed to support the impact of the CMS CMP on individual glycemic and hypertensive biomarkers, such as HbA1c, BP, and lipid panels.

Project Design

The DNP scholarly project utilized an observational, retrospective chart review of secondary laboratory data and CMP interviews collected between April 2019 and August 2020 through the primary care clinic's electronic health record (EHR) to evaluate the impact of a CMS CMP on individual glycemic and hypertensive biomarkers. CMP managers enrolled patients into the program before the study's initiation, and laboratory data collection followed standard care guidelines set forth by the primary care clinic. Belmont University's Institutional Review Board approved the DNP Scholarly Project as exempt in May 2020.

Clinical Setting

The primary care clinic, located in Pleasant View, TN, housed six primary healthcare providers and served over 20,000 patients of all ages. Operational hours were Monday through Saturday with a provider on-call during afterhours. The clinic offered various services, including chronic disease management, preventative visits, take-home sleep studies, in-house imaging, and monthly specialty visits by cardiology and gastroenterology. The CMP was established in April 2019 following CMS guidelines (CMS, 2019).

Pleasant View, TN, is a small, rural town located 25 miles outside of Nashville, TN, in Cheatham County (Data USA, 2020). As of 2017, 4,280 people resided within the town and 95% of the population identified as Caucasian (Data USA, 2020). The average median household income listed at $80,838, and 9% of the population lived below the poverty line (Data USA, 2020). Additionally, 12.8% of Cheatham County residents reported a T2DM diagnosis (Data

USA, 2020). TN county-level HTN prevalence rates are not available at this time. However, the TN Middle Grand Division, which includes Cheatham County, reported a HTN prevalence rate of 40.2% in 2016 (Tennessee Department of Health, 2016).

The Primary Care Clinic's CMP

From April 2019 through August 2020, the clinic enrolled 375 patients into the CMP. According to CMS (2019) guidelines, the CMP enrolled patients who experienced at least two chronic conditions expecting to last 12 months or until death, and who were at significant risk of exacerbation, death, decompensation, or functional decline (CMS, 2019). Once these conditions were verified, the clinic staff informed qualifying patients of the CMP service and obtained consent for enrollment (CMS, 2019). Under qualified physician services, clinic staff may bill Medicare or traditional and commercial insurance companies for 20, 30, or 60 minutes of clinic staff time per calendar month (CMS, 2019). Qualified health care professionals able to conduct interviews included registered nurses, licensed practical nurses, chronic care managers, and medical assistants (Balasa, 2018).

CMS (2019) outlined specific components necessary for the implementation of a CMP: structured recording of patient health information, maintenance of a comprehensive electronic care plan, manager-referred services outside the CMP, and coordinated shared patient health information. The primary care clinic's CMP managers fulfilled the outlined CMS guideline components by the structured recording of patient health information into an electronic document after each monthly interview, including narrative and yes/no answers to questions. CMP managers maintained a comprehensive electronic care plan by reconciling medications, reviewing recommended preventative services, and overseeing self-managed care adherence. Additionally, CMP managers referred patients to care management services if they deemed it

appropriate, including physical and occupational therapy, specialty referrals, community wellness programs, and counseling services. Lastly, CMP managers coordinated shared patient health information by providing and requesting patient health records for the referred service. The CMP was of no cost to patients, and patients were permitted to decline enrollment at any time.

Four CMP managers conducted monthly telephone interviews to their assigned patients. The managers asked general questions regarding medication adherence, medication side effects, new medications or diagnoses, and future follow-up appointments. If no follow-up appointment existed, or the patient requested an appointment, the manager scheduled one at that time. After questioning the patient on general concerns, the manager progressed into specific questions associated with T2DM and HTN. T2DM-related questions concerned regular SMBG, BG readings above 200 or below 70, symptoms experienced with low BG, times of BG readings, proper insulin usage, and weight changes. Pertinent HTN-related questions focused on at-home BP readings and symptoms, such as dizziness upon standing, lower extremity swelling, and headaches. The manager notified the provider of any abnormal readings or measurements, and the provider made medication changes or scheduled emergent appointments. Following the interview, patients asked questions, expressed concerns, or provided any additional information. Once the interview concluded, the manager submitted the documentation to the patient's EHR and billed the insurance company for the appropriate amount of time.

Project Population

The PI utilized a purposive sampling technique based on available patient information. The DNP scholarly project participants included clinic patients enrolled in the CMP for one year as of August 2020. Inclusion criteria required participants to be at least 18 years of age, enrolled

in Medicaid or Medicare services, have an International Classification of Diseases-10 diagnosis (ICD-10) of T2DM and HTN, have a baseline HbA1c greater than 7.0%, and a baseline BP greater than 120/80 mmHg. The study excluded participants if they did not meet the inclusion criteria mentioned above.

The American Diabetes Association (2020) recommends patients with T2DM achieve an HbA1c of less than 7.0%, and the American College of Cardiology (Carey & Whelton, 2018) designates HTN as a BP greater than 120/80 mmHg. Thus, the PI only included participants not reaching optimal glycemic and BP management levels.

Sources of Data

The EHR system included all available participant information. The PI obtained permission to access the EHR from the clinics' owner and chief medical officer. Demographic information obtained included age, race, gender, type of insurance, alcohol status, and smoking status. Laboratory data collected included HbA1c, SBP, DBP, BMI, TC, HDL, LDL, and cholesterol/HDL ratio. Information retrieved from the documented interviews included yes/no answers to SMBG, billing codes, and the total number of documented interviews over 12 months. All information, excluding demographic information, was obtained at pre-enrollment, 6-months, and 12- months post-CMP enrollment. The PI did not use any additional data collection instruments.

Data Collection Process

Data collection began on September 1, 2020 and concluded on October 10, 2020. An encrypted Excel spreadsheet stored the de-identified participant health information and demographics within a password-protected computer. A second password-protected electronic tablet held a separate encrypted document that contained an identification key with the

participants' names and birthdays, which prevented duplicate recording of health information. Once data collection was completed, the PI destroyed the identification key document to protect participants' confidentiality and privacy. Additionally, triple screening of managers' patient profiles supported quality assurance measures.

The PI screened participants for inclusion by searching each manager's assigned participants' profiles—the profiles listed each participant and their ICD-10 diagnosis in alphabetical order. After confirmation of a T2DM and HTN diagnosis, the PI confirmed participants consented and were enrolled into the CMP program as of one year in August 2020. Thirdly, the PI verified baseline HbA1c, and BP measurements met the inclusion criteria. Lastly, the PI recorded the number of documented interviews, demographics, and health information obtained from laboratory documents and CMP interviews onto the Excel spreadsheet.

Statistical Analysis

IBM SPSS Statistics, Version 27.0 was used for the statistical analysis. Descriptive statistics were performed on sample demographics, including age, gender, race, alcohol and smoking status, the total number of telephone interventions over one year, and baseline adherence to SMBG. The percentage of missing data was calculated for each biomarker data set. If the data set had less than 5% missing data, the sample's mean was used in place of the missing information. If the data set had greater than 5% missing data, an independent samples *t*-test comparing means of missing information with all scale variables was used to determine missing at random information. If data were determined to be missing at random, a linear regression imputation tool was used to calculate missing data points. Due to data not being missing at random, all LDL measurements, 6-month HDL, 6-month TC, and 6-month CHR were taken out of the data set completely.

The repeated-measures ANOVA statistical test was performed to compare the means of individual biomarkers at baseline, 6-months, and 12-months post-enrollment in the CMS CMP. The paired *t*-test was used to compare the means of biomarkers collected at baseline and 12-months post-enrollment in the CMS CMP. Lastly, multiple independent-samples *t*-tests evaluated the statistical significance of associations between the sample's mean individual biomarkers and the number of telephone interviews, grouped as either participating in all telephone interviews or less than 12 telephone interviews**.**

Theoretical Framework

The Information-Motivation-Behavioral Skills (IMB) model provided the theoretical framework for the DNP scholarly project. Fisher and Fisher (1992) developed the IMB model to explain AIDS-preventative behavioral change. Since its development, the IMB model has been used to predict positive health behavior changes in many different patient populations including patients living with chronic conditions, such as T2DM and HTN (Gao et al., 2013; Mayberry & Osborn, 2014; Osborn & Egede, 2010; Osborn et al., 2010). The IMB model utilizes three constructs of information, motivation, behavioral skills, and the relationships between them to explain health behavior changes (Fisher & Fisher, 1992).

The IMB Model posits that individuals will perform positive health behaviors if they are well-informed about the behavior, personally and socially motivated to perform the behavior, and skilled enough to enact and sustain the behavior through all circumstances (Osborn & Egede, 2010). First, health care providers present patients with accurate information regarding the health behavior and the necessary steps to achieve health behavior changes. According to Fisher and Fisher (1992), information should be behavior-specific, relevant, and targeted based on knowledge deficits. Second, a patient requires personal and social motivation to apply the

information, cultivating health behavior changes. Personal motivation relates to individual attitudes regarding the health behavior, and social motivation includes perceptions of social norms and the availability of social support for changing health behaviors (Osborn & Egede, 2010). An individual may be highly informed and skilled; however, without motivation to enact change, the individual will not pursue healthy behaviors (Fisher & Fisher, 1992). Lastly, behavioral skills include objective and perceived skills necessary to correctly perform the health behavior and a sense of self-efficacy for doing so with confidence (Fisher & Fisher, 1992). The three combined constructs ultimately lead to improved health behaviors and outcomes, which reinforces continued information gathering and maintenance of motivation levels (Fisher & Fisher, 1992).

Application

The IMB model served as a theoretical framework for understanding how the CMS CMP improves patient health outcomes. The CMS CMP addresses each component of the IMB Model during the monthly interviews. The CMP provides opportunities to reiterate information given to patients during clinical visits, such as proper medication administration, the importance of medication adherence, and correct BG and BP monitoring. Furthermore, the CMP provides motivation through positive reinforcement techniques such as praise when the patient improves upon previously difficult tasks. Additionally, the program promotes social support through frequent person-person connections by telephone, information sharing of healthy meal alternatives, and connecting patients to sponsored community wellness programs. The CMS CMP assesses behavioral skills by asking questions related to self-monitoring of BG and BP, administering diabetic medications based on mealtimes, educating on hypo/hyperglycemia correction strategies, and providing a time for patients to raise questions regarding care

management. In summary, the CMS CMP reinforces vital disease-management information, provides personal and social motivational support, and evaluates behavioral skills to encourage positive health behavioral change, ultimately leading to improved health outcomes and reduced mortality and morbidity rates (Gao et al., 2013; Mayberry & Osborn, 2014; Osborn et al., 2010; Osborn & Egede, 2010). See Figure 1 for the IMB Model diagram.

Results

Demographics

A total of 51 participants met the inclusion criteria (N = 51). Table 1 presents the sample's demographic characteristics. Two-thirds of the participants were female (66.7%, n = 34). In terms of race, 80.4% (n = 41) of the participants identified as white, 9.8% (n = 5) identified as non-white, and 9.8% (n = 5) of the participants did not include their race. The mean age of the participants was 67.78 (SD = 8.29) years. The majority of participants declined both smoking and alcohol intake (72.5%, n = 37; 84.3%, n = 43). Additionally, over half of the participants partook in all 12 CMS CMP telephone interviews (58.8%, n = 30).

Individual Biomarkers for Glycemic and HTN Control

Table 2 displays participants' mean glycemic and hypertensive biomarkers at baseline and 12-months post-enrollment in the CMS CMP. The last column depicts the overall change in biomarker means, represented as either an overall decrease (-) or increase (+) in mean changes.

Repeated-Measures ANOVA

Table 3 depicts the repeated-measures ANOVA results for changes in glycemic and hypertensive biomarkers collected at baseline, 6-months, and 12-months post-enrollment in the CMS CMP. The Mauchly's Test of Sphericity was non-significant and assumed normal for HbA1c (p = .159), SBP (p = .679), and DBP (p = .430). However, the Mauchly's Test of

Sphericity was significant for BMI ($p < .001$). The Greenhouse-Geisser correction was used for BMI. Table 5 displays the Bonferroni post-hoc analysis for statistically significant results using the repeated-measures ANOVA.

HbA1c. The repeated-measures ANOVA was non-significant for HbA1c, $F(2,100) = 1.87$, $p = .159$, $\eta^2 = 0.04$, indicating no statistically significant differences between baseline, 6-months, and 12-months post-enrollment HbA1c.

SBP. Statistically significant differences were revealed between participants' mean SBP at baseline, 6-months, and 12-months post-enrollment, $F(2,100) = 34.23$, $p < .001$, $\eta^2 = 0.41$. The Bonferroni post-hoc analysis indicated significant changes between baseline SBP ($M = 140.75$, $SD = 14.28$) and 6-months post-enrollment SBP ($M = 128.20$, $SD = 11.01$); $p < .001$. Additionally, significant differences were detected between baseline SBP ($M = 140.75$, $SD = 14.28$) and 12-months post-enrollment SBP ($M = 128.92$, $SD = 8.820$); $p < .001$. SBP did not significantly change between 6-months and 12-months post-enrollment in the CMS CMP.

DBP. Statistically significant differences existed between participants' mean DBP at baseline, 6-months, and 12-months post-enrollment, $F(2, 100) = 20.54$, $p < .001$, $\eta^2 = 0.29$. The Bonferroni post-hoc analysis indicated significant changes between baseline DBP ($M = 83.08$, $SD = 6.88$) and 6-months post-enrollment DBP ($M = 75.80$, $SD = 7.25$); $p < .001$. Statistically significant changes also existed between baseline DBP ($M = 83.08$, $SD = 6.88$) and 12-months post-enrollment DBP ($M = 75.27$, $SD = 7.73$); $p < .001$. Mean DBP did not significantly change between 6-months and 12-months post-enrollment.

BMI. Using the Greenhouse-Geisser test, statistically significant differences existed between participants' mean BMI at baseline, 6-months, and 12-months post-enrollment, $F(1.52, 75.52) = 3.70$, $p = .041$, $\eta^2 = 0.07$. The Bonferroni post-hoc analysis revealed a near-marginal

significance between baseline BMI (*M* = 36.10, *SD* = 7.88) and 12-months post-enrollment BMI (*M* = 35.21, *SD* = 7.89); *p* = .056. Mean BMI did not significantly change between baseline and 6-months post-enrollment, and 6-months post-enrollment to 12-months post-enrollment.

Paired t-Test

Table 4 depicts the paired *t*-test results. The paired *t*-test indicated no statistically significant differences between baseline TC (*M* = 192.64, *SD* = 59.26) and 12-months post-enrollment TC (*M* = 187.40, *SD* = 49.06); *t*(50) = 0.89, *p* = .379, Cohen's *d* = 0.124; between baseline HDL (*M* = 45.62, *SD* = 13.56) and 12-months post-enrollment HDL (*M* = 47.16, *SD* = 15.91); *t*(50) = -1.38, *p* = .175, Cohen's *d* = -0.193; and between baseline CHR (*M* = 4.53, *SD* = 1.78) and 12-months post-enrollment CHR (*M* = 4.29, *SD* = 1.65); *t*(50) = 1.51, *p* = .137, Cohen's *d* = 0.212.

The paired *t*-test revealed a near-marginal statistically significant change in baseline SMBG (*M* = 1.68, *SD* = 0.48) and 12-months post-enrollment SMBG (*M* = 1.82, *SD* = 0.39); *t*(33) = -1.97, *p* = .058, Cohen's *d* = -0.33.

Comparing Number of Telephone Interviews with Biomarkers and SMBG Adherence

Independent Samples *t*-Test. Table 6 illustrates the results of the independent *t*-tests. Statistically significant differences were found in the independent *t*-test indicating patients with higher baseline DBPs (*M* = 85.86, SD = 4.51) took part in fewer telephone interventions than those with lower baseline DBPs (*M* = 81.83, *SD* = 7.62); t(47.92) = 2.77, *p* = .008, Cohen's *d* = 0.72. No other statistically significant differences were found between the association of telephone interviews with changes in biomarkers.

Chi-Square Analysis. Table 7 depicts the results of the chi-square analysis for comparing the number of telephone interviews, as greater than or equal to 12 versus less than 12

interviews, with SMBG adherence. SMBG adherence did not statistically change from baseline (p = .744, Cramer's V = .742) to 12-months post-enrollment in the CMP (p = .381, Cramer's V = .350).

Discussion

Key Findings

The PI's primary aim for the DNP scholarly project was to analyze the primary care clinic's CMP impact on individual glycemic and hypertensive biomarkers compared at pre-enrollment to 6-months and 12-months post-enrollment. The PI's secondary aim for the DNP scholarly project was to determine a correlation between increased CMP participation with improved biomarkers and SMBG adherence.

Glycemic and Hypertensive Biomarkers

Overall, glycemic and hypertensive biomarkers improved whether or not the results were statistically significant, implying a clinical significance for better health outcomes for those with T2DM and HTN. Most notably, SBP (p < .001, η^2 = 0.41), DBP (p < .001, η^2 = 0.29), and BMI (p = .041, η^2 = 0.07) significantly improved from baseline to 6-months and 12-months post-enrollment in the CMP. Participants' mean SBP reduced to less than 130 mmHg, suggesting curtailment of T2DM and its associated complications (Adler et al., 2000; Kim et al., 2015; Sun et al., 2019). Additionally, the project's findings reflected previous study findings, which indicate CMP enrollment significantly reduces BP and BMI decreasing the risk of macrovascular and microvascular complications associated with T2DM and HTN (Eakin et al., 2013; McGloin et al., 2015; Sakane et al., 2015; Varney et al., 2014).

HbA1c and lipid measurements were not statistically significant. However, positive changes within the measurements suggest clinical significance for possible improvements in

health outcomes. Furthermore, the American Diabetes Association (2021) recommends reducing HbA1c to below 8.0, which this cohort achieved at 12-months post-enrollment in the CMP (M = 7.88). Participants' mean HbA1c reduced by 2.4%, mean TC reduced by 2.7%, mean HDL increased by 3.4%, and mean CHR reduced by 5.3%. The findings mirror several research studies in which HbA1c and lipid levels improved (Graziano & Gross., 2009; Sacco et al., 2009; Varney et al., 2014; Walker et al., 2011; Willard-Grace et al., 2015; Wolever et al., 2010).

CMP Participation

Over half of the patients partook in all CMP telephone interviews over one year, with a mean of 10 interviews (N = 30, M = 10.2), indicating high retention rates and patient participation. When comparing CMP participation with changes in biomarkers, those who partook in less than 12 interviews had higher baseline DBPs (M = 85.86) than those who partook in all 12 interviews (M = 81.17, p = .008, Cohen's d = 0.72). While not statistically significant, HbA1c and BMI lowered in those who participated in all interviews (M = 7.69; M = 33.75) compared to patients who missed interviews (M = 8.14, Cohen's d = 0.36; M = 37.30, Cohen's d = 0.46). The Sakane et al. (2015) study found similar positive results when evaluating increased CMP participation with changes in BMI and fasting BG. However, the DNP scholarly project did not find a correlation between SMBG adherence and CMP participation. The PI suspects inconsistent documentation of SMBG adherence as a contributor to the insignificant findings, as evident by only 22 responses for the 12-month collection period.

Practice Implications

The DNP scholarly project results add to the existing body of literature regarding CMPs' impact on patient outcomes and emphasizing the need to connect with patients outside the clinical visit. Not only does a telephone-based intervention provide an accessible form of

communication, but it also reflects the vital components outlined by the IMB model for behavioral change. The IMB model illustrates how CMP managers can impact patient care through supportive interactions, motivational communication, and behavioral change education facilitating adherence with self-care activities. When patients feel supported, it enhances their motivation to make essential lifestyle medication choices.

Practice implications for the clinic include standardized educational protocols for CMP managers regarding disease management and documentation, conducting studies that evaluate health outcomes for other chronic diseases, and collecting subjective information detailing patients' experiences with the CMP and how it has affected their disease process. Care managers should focus specifically on medication adherence and SMBG adherence documentation. A more detailed analysis of medication adherence and SMBG adherence could lead to a better understanding of barriers to effective HTN and T2DM self-management at this clinic (Powers et al., 2016). Additionally, CMS (2019) proposes that a structured CMP will reduce hospital readmissions, morbidity, and mortality rates in those with chronic conditions. While biomarker data suggested improvement, evaluation of hospital readmission, morbidity, and mortality data for patients at this primary care clinic would provide a stronger evidence of CMP impact on patient outcomes.

Strengths and Limitations

A strength of the DNP scholarly project included being the first evaluation of this particular primary care clinic’s CMP. The project provides a baseline patient data assessment for those with T2DM and HTN, which may be helpful for future comparative evaluations of patient outcomes in this clinic. Furthermore, the clinic staff can replicate the project’s design process to continue quality improvement evaluations of their CMP, and to assess the CMP's impact on other

chronic conditions or patient populations. The care managers enrolled a high volume of patients within the first year, providing opportunities for a variety of quality research and practice improvements. To the PI's knowledge, this project was one of the first to openly evaluate a CMS CMP on individual glycemic and hypertensive biomarkers for patients living with T2DM and HTN.

Several limitations were identified throughout the DNP scholarly project. Limitations within the CMP's design, CMP's implementation process, and homogeneity of subjects provided inconclusive support for the CMP's generalizability. The project's participants were primarily white and female with a mean age of 67, limiting the findings' generalizability within the United States. The majority of those diagnosed with T2DM in the United States are male and Hispanic, with a mean age of 40-64 years (CDC, 2020a). The implementation process was highly dependent on consistent managerial training and the managers' knowledge regarding T2DM and HTN. Additionally, patient-manager relationships may have impacted patients' willingness to confide troublesome information in fear of repercussions. The PI could not collect or analyze subjective patient opinions regarding experiences with the CMP and how it affected their disease processes. Evaluation of the CMP was dependent on information provided by patients and correct recording of the information by managers, notably subjective recordings of SMBG. Missing data from the managers' documentation may have contributed to nonsignificant research findings. Additionally, a relatively small sample size may have influenced significance.

Recognizing COVID-19

More recently, the COVID-19 pandemic substantially impacted primary health care providers and physicians' ability to treat patients with chronic diseases, such as T2DM and HTN. Social distancing restrictions, personal protestive equipment shortages, and shift toward

telemedicine visits led to limitations for in-person visits. An ongoing, weekly national survey of primary care physicians reported that 75% of patients could not utilize virtual medical care in April 2020 (Primary Care Collaborative, 2020). April 2020 marks the CMP's first anniversary and the start of the 12-month data collection period. While routine laboratory data were collected, it is unknown if patients could meet with physicians in-person or virtual to discuss necessary treatment plan changes. Furthermore, it is unclear if this project's findings would have yielded different results in a non-pandemic year. The current lack of in-person appointments further emphasizes the need for standardized, telephone-based CMPs to improve health outcomes for all patients.

Conclusion

To address the complex nature of chronic diseases like T2DM and HTN, CMPs provide a structured and supportive approach to meeting patient needs. The CMS CMP telephone-based approach bridges the gap between physician time constraints and missed educational opportunities, allowing for frequent patient contact without the burden of a rushed clinic visit. The DNP scholarly project found an overall improvement in glycemic and hypertensive biomarkers suggesting clinical significance for using a telephone-based CMP. However, future studies are indicated to examine patient populations that are generalizable to the United States.

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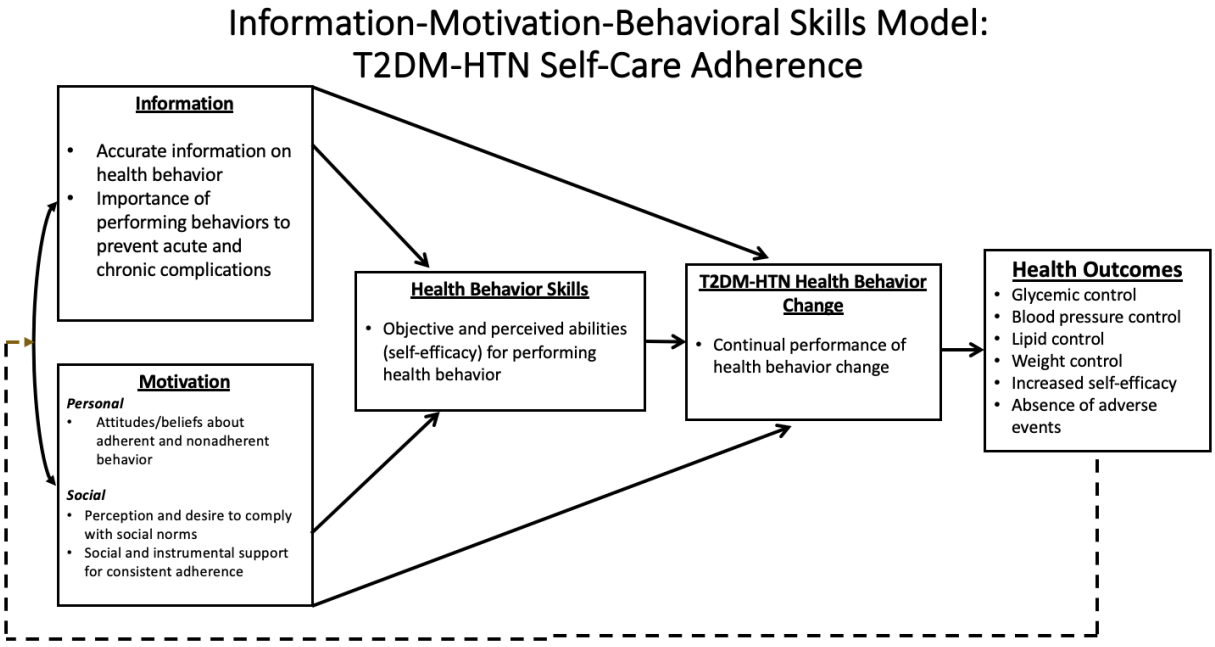
Figure 1

Information-Motivation-Behavioral Skills Model



Note. Fisher and Fisher's theoretical model conceptualizes the necessary constructs for health behavior change. Adapted from Fisher & Fisher (1992).

Table 1

Demographics

Baseline Characteristics	*n*	*%*	*M(SD)*
Age			67.78(8.29)
50-59	7	13.7%	
60-69	24	47.1%	
70-79	15	29.4%	
≥80	5	9.8%	
Gender			
Female	34	66.7%	
Male	17	33.3%	
Race			
White	41	80.4%	
Black	2	3.9%	
Hispanic	1	2.0%	
Other	2	3.9%	
NA	5	9.8%	
Smoking Status			
Yes	14	27.5%	
No	37	72.5%	
Alcohol Status			
Yes	8	15.7%	
No	43	84.3%	
# of Telephone Interviews			
<12	21	41.2%	
≥12	30	58.8%	
SMBG			
Yes	32	62.7%	
No	13	25.5%	
NA	6	11.8%	

Table 2

Baseline and 12-month Biomarkers with % Mean Change Overtime

Baseline Biomarkers	*n*	*%*	*M(SD)*	12-Month Biomarkers	*n*	*%*	*M(SD)*	*%* Change in Mean
HbA1c			8.1%(1.06)	HbA1c			7.9%(1.27)	-2.47%
<7.0%	0	0%		<7.0%	12	23.5%		
7.0-7.9%	28	54.9%		7.0-7.9%	19	37.3%		
8.0-8.9%	14	27.5%		8.0-8.9%	15	29.4%		
9.0-9.9%	6	11.8%		9.0-9.9%	2	3.9%		
≥10%	3	5.9%		≥10%	3	5.9%		
SBP			140.75(14.28)	SBP			128.92(8.82)	-8.4%
<120	0	0%		<120	6	11.8%		
120-129	10	19.6%		120-129	24	47.1%		
130-139	16	31.4%		130-139	16	32.4%		
140-149	13	25.5%		140-149	3	5.9%		
150-159	3	5.9%		150-159	2	3.9%		
≥160	9	17.6%		≥160	0	0%		
DBP			83.08(6.88)	DBP			75.27(7.73)	-9.4%
<70	1	2.0%		<70	10	19.6%		
70-79	9	17.6%		70-79	35	68.6%		
80-89	30	58.8%		80-89	5	9.8%		
≥90	11	21.6%		≥90	1	25		
BMI			36.10(7.88)	BMI			35.21(7.89)	-2.5%
18.5-24.9	3	5.9%		18.5-24.9	4	7.8%		
25-29.9	10	19.6%		25-29.9	11	21.6%		
30-34.9	14	27.5%		30-34.9	11	21.6%		
35-39.9	8	15.7%		35-39.9	10	19.6%		
≥40	16	31.4%		≥40	15	29.4%		
TC			192.64(59.26)	TC			187.40(49.06)	-2.7%
<200	29	56.9%		<200	31	60.8%		
≥200	22	43.1%		≥200	20	39.2%		
HDL			45.62(13.56)	HDL			47.16(15.91)	+3.4%
≤40	18	35.3%		≤40	19	37.3%		
41-59	27	52.9%		41-59	25	49%		
≥60	6	11.8%		≥60	7	13.7%		
CHR			4.53(1.78)	CHR			4.29(1.65)	-5.3%
≤4.44	23	45.1%		≤4.44	30	58.8%		
>4.44	28	54.9%		>4.44	21	41.2%		

Note. % change in mean indicates an overall change in the sample mean

Table 3

Repeated-Measures ANOVA

Variable	*M*	*SD*	*F* ratio	*df*	Partial Eta square	*p*
A1c			1.87		0.04	0.159
Baseline	8.10	1.06		2		
6-Months	8.16	1.50		2		
12-months	7.88	1.27		2		
SBP			34.23		0.41	<0.001***
Baseline	140.75	14.28		2		
6-Months	128.20	11.01		2		
12-Months	128.92	8.82		2		
DBP			20.54		0.29	<0.001***
Baseline	83.08	6.88		2		
6-months	75.80	7.25		2		
12-months	75.27	7.73		2		
BMI			3.69		0.07	0.041**
Baseline	36.10	7.88		1.51		
6-months	35.73	8.09		1.51		
12-months	35.21	7.89		1.51		

*near-marginal significance $p<0.06$
**$p<0.05$
***$p<0.001$

Table 4

Paired t-Test

Variable	*M*	*SD*	*t*	*df*	*p*	Cohen's *d*	95% Confidence Interval	
							Lower Bound	Upper Bound
TC			0.89		0.379	0.12	-6.62	17.09
Baseline	192.64	59.26		50				
12-Months	187.40	49.06		50				
HDL			-1.36		0.175	-0.19	-0.47	0.09
Baseline	45.62	13.56		50				
12-Months	47.16	15.91		50				
CHR			1.51		0.137	0.21	-0.07	0.48
Baseline	4.53	1.78		50				
12-Months	4.29	1.65		50				

*near-marginal significance $p<0.06$
**$p<0.05$
***$p<0.001$

Table 5

Bonferroni Post Hoc Analysis of Repeated-Measures ANOVA

Variable	*MD*	*SE*	*p*	95% Confidence Interval	
				Lower Bound	Upper Bound
SBP					
Baseline x 6-Months	12.55	1.79	<0.001***	8.12	16.98
Baseline x 12-months	11.82	1.71	<0.001***	7.59	16.06
6-months x 12-Months	-0.72	1.61	1.00	-4.70	3.25
DBP					
Baseline x 6-months	7.28	1.32	<0.001***	4.01	10.54
Baseline x 12-month	7.81	1.28	<0.001***	4.65	10.98
6-months x 12-months	0.54	1.48	1.00	-3.18	4.21
BMI					
Baseline x 6-months	0.36	0.22	0.29	-0.17	0.89
Baseline x 12-months	0.88	0.36	0.056*	-0.02	1.79
6-months x 12-months	0.52	0.38	0.52	-0.41	1.45

*near-marginal significance $p<0.06$
**$p<0.05$
***$p<0.001$

Table 6

Independent Samples t-Test for Comparing Number of Telephone Interviews with Biomarkers

Variable	<12 Telephone Interviews		≥12 Telephone Interviews		*df*	*t*	*p*	Cohen's *d*
	M	*SD*	*M*	*SD*				
HbA1c								
Baseline	8.24	1.14	7.99	1.01	49	0.82	0.415	0.23
6-Months	8.24	1.46	8.10	1.55	49	0.33	0.743	0.09
12-Months	8.14	1.53	7.69	1.04	49	1.26	0.212	0.36
SBP								
Baseline	140.67	13.18	140.80	15.22	49	-0.03	0.974	-0.01
6-Months	125.81	11.42	129.87	10.58	49	-1.31	0.198	-0.37
12-Months	130.61	9.69	127.73	8.12	49	1.15	0.256	0.33
DBP								
Baseline	85.86	4.51	81.13	7.62	47.92****	2.77	0.008**	0.72
6-Months	76.00	7.13	75.67	7.45	49	0.16	0.873	0.05
12-Months	74.78	6.76	75.60	8.44	49	-0.37	0.716	-0.10
BMI								
Baseline	38.23	8.30	34.60	7.33	49	1.64	0.107	0.47
6-Months	37.57	8.16	34.44	7.94	49	1.37	0.178	0.39
12-Months	37.30	7.75	33.75	7.79	49	1.61	0.114	0.46
TC								
Baseline	183.57	59.21	198.99	59.46	49	-0.91	0.366	-0.26
12-Months	175.69	46.00	195.60	50.21	49	-1.44	0.156	-0.41
HDL								
Baseline	45.81	13.76	45.49	13.65	49	0.08	0.934	0.02
12-Months	46.93	19.69	47.32	13.00	49	-0.09	0.932	-0.02
CHR								
Baseline	4.32	1.85	4.69	1.76	49	-0.73	0.469	-0.21
12-Months	4.13	1.67	4.40	1.66	49	-0.56	0.580	-0.16

*near-marginal significance $p<0.06$
**$p<0.05$
***$p<0.001$
****Equal variances not assumed

Table 7

Chi-Square Analysis to compare SMBG with Number of Telephone Interviews

SMBG	Yes		No		Fisher's Exact	Cramer's V
	n	%	*n*	%		
Baseline					0.744	0.048
≥12 Interviews	22	47.8%	8	17.4%		
<12 Interviews	11	23.9%	5	10.9%		
12-Months Post-Enrollment					0.381	0.350
≥12 Interviews						
<12 Interviews	21	60%	4	11.4%		
	7	20%	3	68.6%		