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Philadelphia College of Osteopathic Medicine

Department of Psychology

# An Evaluation of Integrated Primary Care (IPC), IPC Plus Shared Medical Appointments, and IPC Plus Individual Behavioral Health Care on Diabetes Management

Eric Franco, M.S., M.S.

Submitted in Partial Fulfillment of the Requirements for the Degree of

June 2018

**PHILADELPHIA COLLEGE OF OSTEOPATHIC MEDICINE**
**DEPARTMENT OF PSYCHOLOGY**

**Dissertation Approval**

This is to certify that the thesis presented to us by Sarah Hittinger on the 17 day of May, 2018, in partial fulfillment of the requirements for the degree of Doctor of Psychology, has been examined and is acceptable in both scholarship and literary quality.

**Committee Members' Signatures:**

**Chairperson**

**Chair, Department of Psychology**

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## Abstract

As the health care system continues to evolve, the challenges related to successfully treating chronic conditions persist. To address these challenges, supplemental treatments, such as the shared medical appointment (SMA) and behavioral health care (BHC), have been implemented to provide patients with additional levels of psychoeducation and support in addition to treatment by their physician. The total sample used in this study was 118. The purpose of this study was to evaluate the effectiveness of integrated primary care (IPC), IPC plus SMA, and IPC plus BHC to determine if supplemental treatment combined with IPC produced greater improvement in patients with diabetes. The measures in this study were body mass index (BMI), systolic blood pressure, diastolic blood pressure, hemoglobin A1C (HbA1c), high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, and total cholesterol. To test this hypothesis, a 3 x 2 analysis of variance with repeated measures on one factor was conducted. The independent variable had three levels describing the treatment type (integrated primary care (IPC), IPC plus SMA, and IPC plus behavioral health). Outcome measures were examined at pre and posttest to determine if the conditions considered to be more integrated showed stronger treatment effects as measured by the outcome variables. Results indicated that none of the seven outcome variables showed significant improvement as a result of receiving a supplemental level of care in addition to IPC. However, four of the seven variables improved over time regardless of treatment condition. This finding suggests that perhaps the addition of SMA and BHC did not add anything over and above IPC only. Careful consideration should be applied to these results, because these particular patients were treated according to the IPC model. Therefore, physicians may have actually been providing

patients with similar interventions across conditions, such as psychoeducation and motivational interviewing, during their routine doctor visits. Thus, patients who received IPC may have actually received components included in the other two groups.

**Table of Contents**

Acknowledgements ..... iii

Abstract ..... v

Table of Contents ..... vii

List of Tables ..... ix

Chapter 1

Statement of the Problem ..... 1

Purpose of the Study ..... 9

Review of the Literature ..... 9

Chapter 2

Research Question ..... 38

Hypothesis 1 ..... 38

Hypothesis 2 ..... 38

Hypothesis 3 ..... 38

Hypothesis 4 ..... 39

Hypothesis 5 ..... 39

Hypothesis 6 ..... 39

Hypothesis 7 ..... 39

Chapter 3

Methodology ..... 41

Design ..... 41

Participants ..... 41

Measures ..... 42

Procedures ..... 45

Chapter 4

Results ..... 47

Descriptive Statistics ..... 47

Hypothesis 1 ..... 51

Hypothesis 2 ..... 52

Hypothesis 3 ..... 53

Hypothesis 4 ..... 54

Hypothesis 5 ..... 54

Hypothesis 6 ..... 54

Hypothesis 7 ..... 54
Chapter 5
Discussion ..... 56
Findings and Clinical Implications ..... 56
General Conclusions ..... 62
Limitations of the Current Study ..... 68
Future Directions ..... 72
References ..... 74

## List of Tables and Figures

Table 1. Patient Demographic Information ..... 48

Table 2. Treatment Conditions ..... 49

Table 3. Ranges, Means and Standard Deviations for Pretest Variables ..... 50

Table 4. Ranges, Means and Standard Deviations for Posttest Variables ..... 51

An Evaluation of Integrated Primary Care (IPC), IPC Plus Shared Medical Appointments, and IPC Plus Individual Behavioral Health Care on Diabetes Management

# Chapter 1: Introduction

## Statement of the Problem

In 1994, approximately 2.5% of the population had been diagnosed with diabetes (Sidney et al., 2016). By 2015, this total increased to 9.4% of the population, meaning that 30.3 million Americans had a diagnosis of diabetes, and another 84.1 million manifested prediabetes, a condition which, left untreated, often leads to *Type 2* diabetes (CDC, 2017). A major factor in the unexpected increase was the estimated number of individuals currently living with undiagnosed diabetes. The Center for Disease Control (2012) estimated that 8.1 million Americans live with undiagnosed diabetes. An estimated 1.5 million new cases of diabetes were diagnosed in Americans over the age of 18 in 2015 (CDC, 2017). Moreover, nearly one in four adults were aware they had diabetes. Rates of diabetes in the United States vary significantly by ethnicity, with American Indians/Alaska Natives (15.1%), non-Hispanic blacks (12.7%), and Hispanics (12.1%) having the three highest rates (CDC, 2017). As the number of individuals diagnosed rises each year, so does the risk of developing serious co-occurring health conditions.

In 2015, diabetes was the seventh-leading cause of death in the United States (CDC, 2017). This statistic indicates the complexity of managing a chronic illness like diabetes. One major contributing factor is improper blood glucose monitoring, which may result in *hypoglycemia*. When hypoglycemia develops, it contributes to serious

health consequences, including unconsciousness, seizures, or death (CDC, 2012). Additional complications resulting from poorly managed diabetes include high blood pressure, high LDL cholesterol, heart disease and stroke, blindness and eye problems, kidney disease, and amputations. The more complications that arise, the more money is spent attempting to treat them.

The estimated medical cost of treating diabetes in the year 2007 was $116 billion (Narayan et al., 2006). Since 2007, the total direct and indirect estimated cost of treating diabetes was $245 billion (CDC, 2012). By the year 2050, that cost is expected to double (Egede et al., 2012). The already expensive course of treatment for diabetes is further complicated by rates of *adherence* and *nonadherence*. As used in this study, adherence to medical advice is defined as follows:

> [Adherence refers to] whether a patient follows the directions offered by his/her physician in regard to performing some behaviors, or sequence of behavioral tasks, designed to ultimately improve or maintain the health or mental health of the patient, or prevent the development of illness and disease (DiTomasso, Chiumento, Singer, & Bullock, 2009, p. 291.)

The most common forms of treatment in the United States are oral medications and insulin injections (Egede et al., 2012). However, more than one-third of patients with diabetes fail to achieve the full benefit of medication as a result of nonadherence (Egede et al., 2012). Although prescribed treatment regimens by physicians are empirically based, patients are responsible for performing the necessary self-care behaviors to successfully manage their diabetes.

Once diagnosed with diabetes, an individual must perform a multitude of self-care behaviors to prevent serious health consequences or even mortality. As a self-care disease, patients are expected to become active participants in their diabetes management. These self-care behaviors encompass multiple domains and include physical activity, medication adherence, glucose monitoring, symptom management, and proper dietary choices (Weinberger, Butler, Welch, & Greca, 2005). However, patients may become overwhelmed by the treatment regimen, and their ability to adhere to their self-care plan may be compromised. As individuals with diabetes fail to keep up with their self-care, the disease progresses and additional complications arise. For some individuals, the task of simply injecting oneself is daunting. Thus, providing patients with self-management education and the assistance of a behavioral support team can increase the likelihood of adherence to a prescribed treatment regimen (Funnell et al., 2009). The involvement of a multidisciplinary approach allows health care professionals to provide necessary education specifically tailored to the needs of each patient. This is important, because patients' involvement in their own treatment plan has been shown to improve patient self-efficacy in carrying out the plan (Funnell et al., 2009). Furthermore, continuity of care, meaning that the patient sees the same physician on each visit, has been demonstrated to enhance adherence (Kripalani et al., 2007). Although variables associated with improved treatment adherence have been identified, rates of adherence remain below the preferred level.

For treatment regimens involving lifestyle changes, the nonadherence rate stands at 50% (Delamater, 2006). The reported rate of adherence to oral diabetes medication ranges between 36% and 87% (Osborn & Egede, 2012). Furthermore, although a 65%

adherence rate was reported for diet change, a 19% adherence rate to an exercise regimen was found in patients with diabetes (Delamater, 2006). Several contributing factors to nonadherence have been identified.

In their now-classic work, Meichenbaum and Turk (1987) identified multiple domains affecting adherence, including patient variables, physician variables, and treatment variables. The construct of patient beliefs lies in the domain of patient variables. Patient beliefs about the efficacy of a specific treatment can impact the potential success of an intervention. Patient beliefs may be erroneous or contain distortions, but as the physician does not typically address these misconceptions, nonadherence is more likely to occur (Meichenbaum & Turk, 1987). Erroneous patient beliefs, including little-perceived control of the body, negative self-perception, and external locus of control, have been reported to increase the risk of nonadherence (Farrell, Hains, Davies, Smith, & Parton, 2004.) Moreover, higher levels of general stress are also believed to negatively affect adherence behaviors, such as adequately monitoring blood glucose (Farrell et al., 2004). The professional relationship further impacts a patient's belief in his/her ability to carry out a physician's recommendations.

The next treatment variable contributing to nonadherence results from a a rupture in the patient-physician relationship. An underdeveloped relationship between patient and physician may result in the implementation of an intervention that the patient perceives as too complex to carry out successfully. When physicians prescribe a complex course of treatment, rates of adherence worsen (Meichenbaum & Turk, 1987). *Treatment complexity* is defined as how medications are administered, the number of medications, the frequency of administration, and the directions for taking medication (deVries, et al.,

2014). Thus, treatment complexity diminishes a patients' ability to recall the information given to them by their physician. In addition to understanding a patient's capacity to carry out a treatment regimen, physicians must also monitor a patient's response to that regimen.

A treatment plan's duration also affects adherence. When a particular treatment has continued for an extended period of time and did not result in the desired treatment effect, nonadherence was more likely to occur (Meichenbaum & Turk, 1987). Both patient and provider variables contribute to nonadherence; however, a patient's nonadherence is not necessarily intentional.

Unintentional nonadherence occurs when individuals ability to adhere is deficient because of a fundamental misunderstanding of the regimen (deVries et al., 2014). Therefore, the complexity of a particular regimen should be considered before prescribing it to a patient. Patients who intentionally deviated from their treatment regimen reported a higher degree of concern about possible negative effects of treatment that were unaddressed (deVries et al., 2014). To address the aforementioned obstacles and increase successful management of chronic illnesses, the *integrated primary care* (IPC) model was developed.

In contrast with traditional formats of health care, which blame the patient for nonadherence, the IPC model delivers behavioral health care in a primary care facility with the goal of improving patient health outcomes. In the IPC model, behavioral health consultants offer support to other medical providers, with the goal of addressing the needs of the patient completely. As a result of using a collaborative approach, IPC enables earlier detection of and intervention in behavioral health complications (Bridges

et al., 2015). Patient follow-up visits are often shorter and less frequent, another significant improvement in an integrated-care setting.

According to the IPC model, the physician first introduces the concept of integrated care. The process of a *warm handoff* follows. A warm handoff entails a face-to-face transfer of a patient from one behavioral health team member to another. Furthermore, the warm handoff introduces the behavioral health consultant to the patient and permits the description of the patient's presenting concerns (Bridges et al., 2015). The warm handoff has improved communication and coordination of care between providers in the same setting (Bryan, Corso, & Macalanda, 2014). Physicians also indicated a preference for using the warm handoff to introduce behavioral health consultants at times when they had a high volume of patients (Gouge, Polaha, & Powers, 2014).

Another pillar of an integrated health care system is the *shared medical appointment* (SMA). SMAs last between 60 and 120 minutes, and typically bring together the patient and his or her health care team, which may include the primary care physician and a behavioral health professional psychologist, social worker, or nurse practitioner (Kirsch et al., 2007). SMAs allow for improved patient access, increased satisfaction, reduced costs, improved clinical outcomes for medical procedures, and a reduced number of hospitalizations (Bronson & Maxwell, 2004). Areas of overall improvement may include body weight, blood pressure, cholesterol, blood sugar monitoring, adherence to medical recommendations, and appointment keeping.

Increased access to behavioral health care is an important factor addressed by the IPC model, due to the fact that an estimated 50 to 70% of individuals receive treatment

for co-occurring health issues by their primary care physician (Curtis & Christian, 2012). The integrated care model addresses this situation through colocation of health care providers. Colocation means that behavioral health consultants are available to meet with referred patients on the same day that they visit their primary care physician. Most times, the patients are able to remain in the same exam room throughout their visit (Bridges et al., 2015). Another benefit of colocation is that treatment plans can be specifically tailored to the patient, because a multitude of variables can now be addressed. Tailoring the treatment plan to specifically meet individual patient needs is critical, because patients have more control over possible interventions and play an important role in determining the likelihood of follow-through. Evidence indicates that patients who are involved in creating their treatment plans are more likely to adhere to them. Additional studies have indicated that active patient participation in treatment planning shown to improved adherence.

The most frequently used treatments associated with improving adherence in an integrated behavioral health center are action-oriented, evidence-based interventions consistent with a cognitive behavioral orientation (Bridges et al., 2015). Furthermore, these interventions ensure that patients are more than passive observers of their treatment. An increased number of treatment options are positively associated with an enhanced initial *buy-in* to treatment, increased likelihood of following through with treatment, and better adherence to medication regimens (Davidson, Tondora, Miller, & O'Connell, 2015). The enhanced treatment provided by the IBHC model not only results in stronger adherence rates, but it also reduces the cost of managing diabetes.

The integrated care approach focuses on preventing illness rather than managing it. The goal is a preventative approach aimed at treating symptoms early, as opposed to treating subsequent complications. The Affordable Care Act (ACA), enacted in 2010, provides incentives to hospitals that greatly reduce their number of readmissions, but hospitals that rank in the top 25% will face sanctions (Orszag & Emanuel, 2010). In a similar fashion, physicians and hospitals that coordinate patient care with other professionals and prevent hospitalizations will be rewarded. The goal is to reduce the use of ineffective treatment approaches while increasing the use of cost-effective treatments.

Several studies have demonstrated the utility of the integrated behavioral health care model. The Johns Hopkins School of Medicine conducted a study over the course of eight months, using an integrated-care team consisting of registered nurses and primary care physicians to implement an integrated-care model. Patients were taught self-management skills, which included skills for early detection of symptom exacerbation (Grumbach & Grundy, 2010). Results of the study included a 24% reduction in total days hospitalized, 15% fewer visits to the emergency room, a 37% decrease in days in a skilled nursing facility, and an annual savings of $75,000 per nurse deployed by the practice (Leff et al., 2009). Another study, conducted by BlueCross BlueShield, implemented the use of the *patient-centered medical home* (PCMH), a visit to a patient's home by a collaborative behavioral health care team targeting diabetes. Patients participating in the PCMH showed a 36.3% decrease in inpatient hospitalizations after one year compared to the control group (Grumbach & Grundy, 2010). The PCMH patients also significantly improved on measures of LDL cholesterol levels, eye exams, reduced BMI, consistent HbA1c testing, and a HbA1c level of less than 8 (Grumbach &

Grundy, 2010). These studies indicate that collaboration between physicians and behavioral-health consultants produces desirable results, including diminished exacerbation of symptoms, reduced financial burden, fewer inpatient hospitalizations, and enhanced treatment progress.

## Purpose of the Study

The traditional primary care visit consists of a one-on-one meeting between a patient and clinician. However, this format may be inappropriate for addressing such chronic disease as diabetes, which requires complex ongoing treatment (Egger et al., 2014). An integrated primary care model combats this inadequacy by allowing health care professionals to collaborate and address fully the multitude of presenting problems related to diabetes (Blount, 2003). The purpose of the present study was to evaluate the treatment effects of integrated primary care plus shared medical appointment, integrated primary care plus behavioral health care, and integrated primary care alone, as measured by a number of health outcomes.

## Review of the Literature

### Diabetes Mellitus

*Diabetes mellitus* is a chronic illness characterized by the body's inability to produce or properly use insulin. The four clinical classes of diabetes mellitus are *Type 1, Type 2, gestational*, and other types of diabetes caused by genetic factors, such as pancreatic disease or genetic deficits in insulin (ADA, 2010).

### Type 1

Type 1 diabetes commonly manifests in the early stages of life and is considered a chronic condition. It is characterized by destruction of *beta cells* in the pancreas that

naturally produce insulin and commonly results in an absolute deficiency of insulin (Wolsdorf et al., 2007) Type 1 diabetes accounts for approximately 5% of diabetes diagnoses (Wolsdorf et al., 2007). Symptoms of Type 1 diabetes include increases in appetite, weight loss, and urination, decreased energy, irritability, muscle cramps, changes in vision, anxiety, altered ability to perform at school or work, headaches, chest pain, breathing difficulty, stomach pain, nausea and diarrhea or constipation.

**Type 2**

Type 2 diabetes is the most common type, affecting 90-95% of individuals with a diabetes diagnosis (Quinn, 2004). Type 2 differs from Type 1 in that the pancreas still produces insulin, but the insulin is misused. As a result, Type 2 diabetes may also be referred to as insulin resistance. Over time, the pancreas becomes unable to produce the necessary amounts of insulin needed to properly regulate blood glucose levels. Symptoms of Type 2 diabetes include frequent urination, increased appetite, fatigue, weight loss, weakness, and frequent infections (ADA, 2012).

**Prevalence rates**

As of 2002, approximately 6% of the population of the United States had diabetes, and it ranked as the nation's seventh-leading cause of death (American Journal of Preventative Medicine, 2002). Approximately 41 million Americans are at risk of becoming diabetic. Age has been shown to be a contributing factor to diabetes diagnoses, as evidenced by the approximately 20% of Americans over 65 years of age who are affected (Quinn, 2004). Approximately 151,000 people younger than age 20 years are diagnosed with diabetes each year, and one of every 400 children is diagnosed with Type 1 or juvenile diabetes (Quinn, 2004). The Centers for Disease Control and Prevention

(2003) has estimated that as the population ages, the number of diabetes diagnoses will increase by 165% between 2000 and 2050. The large number of individuals diagnosed with diabetes, combined with the estimated increase in diagnoses, highlights the importance of utilizing variables proven to facilitate adherence.

**Adherence in Patients with Diabetes**

In order to successfully implement a treatment regimen, adherence on the part of the patient is a critical treatment variable. Identifying potential obstacles aids the creation of a strategy to overcome these barriers, thus increasing adherence.

Medical adherence is defined as follows:

> Whether a patient follows the directions offered by his/her physician in regard to performing some behaviors, or sequence of behavioral tasks, designed to ultimately improve or maintain the health or mental health of the patient, or prevent the development of illness and disease (DiTomasso, Chiumento et al., 2009, p. 291.)

Several factors, including the patient, physician-patient relationship, treatment regimen, and characteristics of the treatment setting, influence adherence (DiTomasso, Chiumento et al., 2009). Therefore, the use of formal assessment on an individualized basis is a critical means of determining potential obstacles to adherence. Clinicians trained in CBT may perform the assessment, because that training has specifically prepared them to identify these factors (DiTomasso, Chiumento et al., 2009). Physicians, on the other hand, are likely to be more astute at determining whether or not patients are adhering to their prescribed regimens. Together, the CBT clinician and physician would be wise to review medical records and charts to determine causal factors. Special

attention should be paid to the patient's attitudes, beliefs, behaviors, feelings, situational factors, and any other potential obstacles (DiTomasso, Chiumento et al., 2009).

**Economic Costs Associated with Diabetes**

According to the ADA (2012), three categories of indirect costs are attributed to diabetes: *absenteeism, presenteeism*, and inability to work. Absenteeism is defined as the number of days an individual does not attend work due to poor health. Individuals with diabetes have been found to miss more days of work than the general population (CDC, 2013). Presenteeism means that although individuals are present at work, their health prevents them from performing to their full potential. Lost productivity at work or absenteeism was estimated to produce a loss in earning potential of approximately $5 billion. Among the population of individuals with diabetes, medical expenditures were approximately 2.3 times higher than if they did not suffer from the disease (ADA, 2007). As the number of diabetes diagnoses increase, the productivity of the workforce decreases.

The ADA (2012) estimated that the total number of individuals diagnosed with diabetes approached 17.5 million, and the number of individuals diagnosed with diabetes in the year 2050 is expected to increase significantly (Narayan, Boyle, Geiss, Saaddine, & Thompson, 2006). In 2012, the estimated total cost of diabetes treatment was $245 billion. This total had risen sharply since 2007, when the estimated cost was $174 billion (ADA, 2007). The $245 billion included $176 billion in excess medical expenditures and $69 billion associated with loss of productivity (ADA, 2007). For every $5 spent on providing health care, $1 was spent on individuals with diabetes (ADA, 2007).

Results of the 2012 study by the ADA estimated that individuals with diabetes are 2.4 times more likely to be forced out of the workforce and collect disability. Reduced productivity occurs in individuals with diabetes not only in the workforce but also outside the workforce. Examples of reduced productivity outside the workplace include for family members providing care for individuals with diabetes, inability to perform household chores, and lost activity in the community._A final consideration is that premature mortality is more likely to occur in individuals with diabetes, eliminating future economic contributions by them (ADA, 2012).

## Medical Consequences Associated with Diabetes

### Foot problems

Diabetes is responsible for more than 50% of lower extremity amputations (Reiber, Lipsky, & Gibbons, 1998). In a population of Medicare patients with diabetes, the risk of having a lower limb amputated was approximately 10% (Wrobel, Mayfield, & Reiber, 2001). Contrary to the popular belief that amputations of the foot are caused by vascular-related complications, the initial indicator of an infection begins with a foot ulcer (Ulbrecht, Cavanagh, & Caputo, 2004). The development of foot ulcers is caused by *loss of protective sensations* (LOPS). LOPS involves a sensory loss in the foot, which permits skin injury or irritation without the accompanying pain that would typically be caused by these conditions (Ulbrecht et al., 2004). The problem is further complicated because patients often believe their ability to sense pain has not changed, making them less likely to take action to prevent injury from escalating to a higher level of severity, or more likely to continue behavior that exacerbates their foot's condition.

In order for a diabetes-related foot problem to devolve into an amputation, three conditions contribute to the loss of protective sensations that eventually leads to skin breakdown: dorsal deformity, high plantar pressure, and dry skin. The dorsal region is the area of the foot most susceptible to LOPS (Ubrecht et al., 2004). A shoe that no longer fits properly because of swelling in the foot is a major culprit in skin breakdown in the dorsal region. Another trigger is dry skin on the heel of the foot that may crack easily, creating a locus of infection. Once infection and/or ischemia occurs as a result of the breakdown of skin, amputation may be the only solution (Ubrecht et al., 2004).

**Eye complications**

*Diabetic retinopathy* is characterized by the growth of new blood vessels on the retina and posterior surface of the vitreous, and it is more likely to occur in individuals with Type 1 diabetes (Fong et al., 2004). Diabetic retinopathy is defined by the ADA (2011) as "damage to the small blood vessels in the eye that can lead to vision problems." M*acular edema* is another complication, which is characterized by thickening of the retina resulting from leaky blood vessels (Fong et al., 2004). Diabetic retinopathy is the leading cause of legal blindness in individuals aged 20 to 74 years in the United States (ADA, 2011; Zhang et al., 2010). Risk factors increasing the likelihood of developing retinopathy include high blood glucose, high blood pressure, and smoking (ADA, 2011).

Individuals diagnosed with Type 2 diabetes show a rate of retinopathy of over 60% (Fong et al., 2004). The Type 1 diabetes population infrequently develops retinopathy in the first three to five years after diagnosis. However, over the course of the next two decades of their lives, nearly all of the Type 1 population will develop retinopathy (Fong et al., 2004). Diabetic retinopathy is linked to several conditions that

cause loss of vision: d*etachment of the retina*, *parietal or vitreous hemorrhage*, *glaucoma*, and macular edema (Fong et al., 2004). Diabetic retinopathy is complicated by the fact that symptoms do not often emerge until the condition is well advanced.

The two main forms of retinopathy caused by diabetes are *nonproliferative* and *proliferative*. Nonproliferative retinopathy is also known as background retinopathy. More common than proliferative retinopathy, it is considered as the less serious of the two types (ADA, 2011). It results in the closing off or weakening of blood vessels in the eye, causing blood vessels to leak blood, fat, and fluid into the eye (ADA, 2011). Nonproliferative retinopathy typically presents as blurred vision, but blindness is uncommon (ADA, 2011). The second type, proliferative retinopathy, causes the formation of new and unnecessary blood vessels that do not grow in the same way as normal blood vessels (ADA, 2011). The newly formed blood vessels are fragile and easily ruptured during such activities as sleeping or exercising (ADA, 2011; Butler et al., 2005). Once the blood vessels are ruptured, the eye fills with blood, blocking light from entering the retina; eventually scar tissue forms that shrinks, tearing the retina to and potentially causing blindness (ADA, 2011).

**Neuropathy**

High levels of blood glucose can cause *neuropathy* either directly or by dramatically slowing or stopping blood flow (ADA, 2011). The three types of neuropathy present in individuals with diabetes are *peripheral*, *autonomic*, and *focal*. Diabetic peripheral neuropathy is defined as peripheral, somatic, or autonomic nerve damage attributable solely to diabetes mellitus (Pinzur, 2011). It alters an individual's ability to experience sensations in their extremities, most commonly in the feet, but also

occurring in the fingers (ADA, 2011). In some individuals, the sensation is decreased to such an extent that they are unable to feel painful stimuli, but in others pain intensifies to the degree that anything covering their feet becomes painful (ADA, 2011). Neuropathy often takes many years to develop among individuals with diabetes who have had consistently high glucose levels (ADA, 2011).

The number of individuals with diabetes who experience peripheral neuropathy is estimated as between 60 to 70% (ADA, 2011). It is the most common type of neuropathy among individuals with diabetes and the leading cause of amputation (Davies et al., 2006). Two major predictors have been identified as direct contributors to peripheral neuropathy: diabetes and metabolic control. The development of peripheral neuropathy is likely also facilitated by *nephropathy*, proliferative retinopathy, cardiovascular disease, and genetic predisposition (Pinzur, 2011). Peripheral neuropathy may present as asymptomatic and comprises both positive and negative symptoms. Negative symptoms include a loss of sensation and/or strength; positive symptoms include pain or the feeling of something pricking the skin (Davies et al., 2006).

The second type of neuropathy is autonomic neuropathy. Autonomic neuropathy damages autonomic nerves in the body, which are responsible for an individual's heart beating or digestion (ADA, 2011). Damage to these autonomic nerves presents in numerous ways, including bladder problems, erectile dysfunction, vaginal dryness and decreased sexual desire in women, as well as blood pressure, skin, and heart problems (ADA, 2011).

The third type of neuropathy is focal neuropathy, which is characterized by damage to a single nerve or group of nerves (ADA, 2011). It develops similarly to the

other types in that blockage of blood to a nerve is often responsible. Focal neuropathy is not a chronic condition, typically lasting anywhere between two and 18 weeks. The best known type of focal neuropathy is *carpal tunnel syndrome*, which occurs more often in individuals with diabetes. Carpal tunnel syndrome results in a tingling or burning sensation or numbness (ADA, 2011).

**Diabetic ketoacidosis (DKA)**

*Diabetic ketoacidosis* is a condition that causes individuals with diabetes to enter a diabetic coma, which involves passing out for an extended period of time (ADA, 2015). Diabetic ketoacidosis occurs when cells in the body do not receive the amount of glucose needed for energy. The necessary amount of glucose is not delivered, because the body is not producing enough insulin to use the glucose. The body then begins to burn fat to produce energy (ADA, 2015). The process of burning fat to provide energy results in the production of *ketones*. As ketones build up, blood becomes more acidic, poisoning the body from the inside. DKA, the development of high levels of ketones (ADA, 2015), is a slowly developing disease, and early symptoms include severe thirst or dry mouth, frequent urination, high blood glucose levels, and high levels of ketones in the blood (ADA, 2015). As the ketoacidosis progresses, additional symptoms, such as constant fatigue, dry skin, nausea and vomiting, difficulty breathing, and confusion or difficulty paying attention, may develop (ADA, 2015). In severe circumstances, DKA can lead to death.

**Nephropathy**

Nephropathy, also known as kidney disease, is exacerbated by high blood glucose and hypertension (ADA, 2011). Nephropathy results in toxins/waste remaining in the body, which disrupts proteins and nutrients that should remain in the bloodstream (ADA, 2011). The kidneys, which are responsible for filtering waste for excretion in urine, are no longer capable of performing this task, resulting in chronic renal failure.

Diabetes mellitus is the leading cause of chronic renal failure worldwide (Duran-Salgado & Rubio-Guerra, 2014). Diabetic nephropathy occurs in approximately 30% of cases of Type 1 and Type 2 diabetes and is the leading cause (43%) of *end-stage renal disease* (ESRD), the complete failure of the kidneys (ADA, 2011; Choudhury, Tuncel, & Levi, 2010). In 2008, 48,374 individuals with diabetes started treatment for ESRD, and 202,290 people with ESRD caused by diabetes survived through chronic dialysis or a kidney transplant (CDC, 2011). The major reason that nephropathy often results in ESRD is that patients do not notice it until 80% of their kidney function has been compromised (CDC, 2011).

Research has shown that individuals with Type 1 diabetes who developed diabetic nephropathy have a significantly higher likelihood of developing coronary heart disease. If an individual was born with Type 1 diabetes, the risk of developing coronary heart disease after suffering from nephropathy for 20 years increased by 29% (Ryden et al., 2007). Nephropathy has also been shown to increase the risk of stroke by a factor of 10 (Ryden et al., 2007). High blood pressure is a major complicating factor in both nephropathy and hypertension. Therefore, lowering blood pressure is a major goal in reducing the risk of developing nephropathy.

**Stroke**

The risk of ischemic stroke increases drastically for individuals with diabetes. The risk of stroke for individuals with diabetes is more than double that of nondiadetic individuals (Luitse, Biessels, Rutten, & Kappelle, 2012). Ischemic strokes result from an immediate reduction in cerebral blood flow (Brott & Bogousslavsky, 2000). In countries considered as high income, stroke is the second leading cause of long-term disability (Luitse, et al., 2012). The mortality rate of individuals with diabetes following a stroke increases regardless of the person's age, the type of stroke suffered, or the stroke's severity (Bellolio, Gilmore, & Stead, 2011).

Ongoing research is underway to determine the proper way to immediately manage blood sugar following a stroke. A trial was conducted, during which intensive insulin treatment was compared to usual care following a stroke (Bellolio et al., 2011). The results indicated that intense attempts to restrict blood sugar to a tight range immediately after a stroke did not improve any deficits resulting from the stroke. However, the study found that immediately after a stroke, patients are susceptible to hypoglycemia, which has been shown to cause brain damage and death (Bellolio et al., 2011). The costs associated with diabetes are not limited to the physical arena.

## Levels of Care

### Traditional Diabetes Management

Once a diagnosis of Type 1, Type 2, or gestational diabetes is established, dietary change becomes an intense focus of treatment. Identifying a daily diet with the appropriate caloric intake based on the patient's body weight is an important step in dietary change. The diet entails closely monitoring sugar and carbohydrate intake. The goal of the diet is to assist the patient in maintaining blood glucose levels within the normal range of 60 to 120 mg/dl. The patient is responsible for consistently managing their blood glucose levels throughout the day.

In order to maintain appropriate levels, the patient must check his or her blood glucose levels on a regular basis, usually before and after meals or snacks. Blood glucose control is an important predictor of many chronic complications. Each 1% reduction in hemoglobin A1c over 10 years is associated with a 21% reduction in diabetes-related deaths, a 14% reduction of heart attacks, and a 37% reduction in microvascular complications (Norris, Lau, Smith, Schmid, & Engelgau, 2002). The hemoglobin A1c test is used to check patients' control of their blood glucose levels over a three-month period. The recommended hemoglobin A1c level is 6.5 or below. A hemoglobin A1c level in the recommended range means that the patient's blood glucose levels are managed properly on a daily basis. The usual treatment regimen involves the use of insulin, as well as lifestyle changes to regulate blood glucose levels.

Patients diagnosed with Type 1 diabetes are treated with insulin injections, diet, and exercise. Different types of insulin used to treat Type 1 diabetes are *rapid-acting (Humalog*), *short-acting* (*Regular*), *intermediate-acting* (*NPH*), long-acting (*Ultralente*),

and *premixed* (Humalog 75/25 and Humalog 50/50; Inzucchi, 2001). A patient with diabetes may require rapid-acting insulin in situations in which they need to quickly reduce a high blood glucose level. Insulin should be taken 5 to 15 minutes prior to or immediately before a meal. When this is not possible, a patient may inject insulin immediately after a meal to reduce blood glucose levels (Hess-Fischl, 2004). Short- and intermediate-acting insulin should be taken 30 minutes prior to meals or snacks, and long-acting insulin can be used once a day to help regulate blood glucose levels. Premixed insulin contains either regular or rapid-acting insulin. An insulin consisting of a 75/25 mix of rapid-acting and regular insulin should be taken 5 to 15 minutes prior to or immediately following a meal. A 50/50 insulin mix should be taken 30 minutes prior to a meal, because 50% is rapid-acting insulin (Hess-Fischl, 2004). Despite the effectiveness of the traditional management of diabetes using medication, supplemental treatment alternatives are available to increase adherence to specific medication regimens.

Three potential factors of physician-only treatment that impact successful diabetes treatment are beliefs, attitudes, and knowledge, patient-provider communication, and the health-care system (Nam, Chesla, Stotts, Kroon, Janson, 2011). Deficits in each of these components underscore the need for an integrated approach to reduce potential deficits in individual team members.

A physician's attitudes and beliefs about diabetes management can be more significant than his or her knowledge about treating diabetes. A physicians' beliefs can influence the course of treatment, depending on whether or not the physician views diabetes as a serious illness. One study indicated that many of the physicians polled considered Type 2 diabetes a nonserious disease (Puder & Keller, 2003). The impact of a

perception of the illness can significantly impact the recommended course of treatment and treatment outcome. The addition of behavioral health team members may offer additional insight and understanding to ameliorate the impact that living with diabetes has on an individual.

In the health care system, upwards of 75% of individuals with diabetes receive treatment from only their primary care physician (Shumaker, Schron, Ockene, & McBee, 2004). Primary care physicians typically see a patient for 10-15 minutes, due to limitations imposed on them by their schedules. At each appointment, an individual with diabetes has a limited amount of time to comprehend and learn to implement their treatment regimen. The restrictions that physicians face have adverse effects on adherence rates in diabetic patients.

Research indicates that approximately 33% of diabetic patients treated in primary care correctly follow their physician's plan (Shumake, Schron, Ockene, & McBee, 2004). A potential explanation for this lies in the confluence of behavioral, psychological, and emotional variables that accompany living with diabetes. Self- management is a critical component of controlling diabetes. If patients are unable to communicate difficulties interfering with proper diabetes care, the physician may believe the patient is deliberately nonadherent (Nam, Chesla, Stotts, Kroon, & Janson, 2011). Due to the psychological and emotional components of diabetes management, the implementation of CBT can facilitate a patient's willingness to persist with their glycemic control.

**Cognitive Behavioral Therapy for Diabetes**

Research indicates that less than 50% of patients achieved the recommended target of an A1c level less than 7 (Hoerger, Segel, Gregg, & Saaddine, 2008), notwithstanding the fact that studies have shown that poor glycemic control heightens risk of complications. This information implies that strict glucose control can be difficult for the majority of diabetes patients (Snoek et al., 2001). An estimated 10-25% of adults who present with persistent glycemic control also struggle to adhere to medical recommendations (Snoek et al., 2001). A potential explanation for this positive correlation lies in the patient's beliefs and attitudes regarding health and behavior change. For instance, it is common for patients with past difficulty sustaining a consistent glycemic index to develop negative attitudes or attributions about their own abilities. The reason for implementing a cognitive behavior therapy (CBT) regimen is to modify negative beliefs and attitudes about managing diabetes and related complications (Snoek et al., 2001). Ultimately, the goal of introducing CBT techniques is to increase adherence through modifying negative attitudes and beliefs. The use of a comprehensive approach addressing self-care, education, and cognitive restructuring of underlying negative attitudes has demonstrated positive effects on adherence (Rubin, Peyrot, & Saudek, 1989).

Although research using CBT to directly target diabetes is scarce, a study using a Cognitive Behavioral Groups Training (CBGT) was implemented in a Type 1 diabetes population. The sample consisted of individuals who were identified as having significant difficulty managing their HbA1c. The focus of the group was on cognitive restructuring, in which patients were encouraged to identify and challenge inaccurate

beliefs. In this study, four topics were addressed in the groups: the cognitive-behavioral model of diabetes; stress and diabetes; worry about diabetes complications; social relationships (Snoek et al., 2001). Consistent with CBT, weekly homework was assigned at the end of each session. Results of the study showed a 0.8% decrease in HbA1c and were considered important because of the challenging patients used in the study. The use of CBT allowed for additional behavioral support while also modifying or restructuring any existing negative beliefs or attitudes associated with diabetes management.

**CBT for Diabetes-Related Depression and Adherence**

Individuals with diabetes are twice as likely to suffer from depression compared to the general population (ADA, 2011). Depressive episodes are also more likely to recur and be more severe in diabetic patients. Depression is a major factor affecting a patient's ability to adhere to their physician's recommendations (ADA, 2011). In consequence, depression in diabetes patients has been linked to poorer glycemic control, nonadherence, and mortality (Gonzalez et al., 2008). In order for effective diabetes treatment to take place, the identification and treatment of possible depressive symptoms are vital. Compared to nondepressed diabetes patients, depressed patients are at an increased risk of experiencing functional impairments in their ability to manage their illness (Katon & Sullivan, 1990; Lustman, Clause, & Carney, 1989).

An additional study was designed to measure the treatment effect of *Cognitive Behavioral Therapy for Adherence and Depression* (CBT-AD) on adherence, depression, and HbA1c. CBT-AD consisted of an introduction to CBT, increasing pleasurable activities and monitoring mood, monitoring thoughts and cognitive restructuring, problem-solving skills particularly related to diabetes, and relaxation training (Safren et

al., 2013). Following completion of four months of CBT-AD, diabetes patients with comorbid depression improved their adherence to medication by 21%, and were 30% more likely to adhere to a medication regimen than patients who received a normal course of treatment. The goal of the Shared Medical Appointment (SMA) is achieving a higher level of integrated care used to promote positive self-care and improve adherence by diabetic patients.

**Shared Medical Appointment**

The Shared Medical Appointment is an increasingly important practice in the field of behavioral health. The Shared Medical Appointment (SMA) was developed to provide patients with a more expansive and flexible model to assist with managing the complexity of diabetes (Kirsch et al., 2007). Its development stemmed from Wagner's *Chronic Care Model* (1998), which placed emphasis on identifying patients at the highest risk for complications. The development of the SMA was also facilitated by a lack of access on the part of the patient to integrated behavioral health care. A shared medical appointment addressed multiple needs of the patient and also enhanced physicians' productivity (Bronson & Maxwell, 2004). The goal of the SMA is to provide necessary support and patient education that may be lacking in a traditional visit to the doctor. Shared medical appointments are also designed to facilitate necessary follow-up visits.

The structure of the SMA includes a series of one-on-one encounters with a physician and behavioral health specialist (Bronson & Maxwell, 2004). The SMA typically takes between 60 and 120 minutes and includes eight to 20 patients (Kirsch et al., 2007). The first phase is a group visit with the physician and the behavioral health specialist; the second phase involves bringing participants into a group, which shares

psychoeducation information (Bronson & Maxwell, 2004; Kirsch et al., 2007). During the SMA, the physician and behavioral health care specialist play distinct roles. The physician's role is to evaluate, examine and treat patients in a fashion similar to a typical doctor visit; he or she also assumes responsibility for documenting the patient's medical history (Bronson & Maxwell, 2004). Behavioral specialists provide informed consent and maintain the confidentiality of patient information, and engage in discussion with the patient while the physician performs other roles, providing appropriate referrals if necessary, and ensuring that the patient receives adequate time to address their questions and concerns (Bronson & Maxwell, 2004). A SMA entails a higher level of integration among health care professionals, meaning that information is routinely exchanged between them. The SMA provides patients with the highest level of integrated care, because they receive treatment from multiple providers who address different treatment issues. The necessary interventions are separate yet connected, in that they address different obstacles faced by the patient. Patient satisfaction, as well as the effectiveness of treatment, has improved in patients who have participated in an SMA (Wagner et al., 2001).

A study by Wagner et al. (2001) was conducted with a population of Type 2 diabetes patients who were randomly assigned to physician-only treatment or a shared visit. Results indicated that diabetic patients who received group treatment over a two-year period had fewer visits to the emergency room, fewer disability days, and more improvement in their health status (Wagner et al., 2001). Another randomized study involving individuals with Type 2 diabetes patients took place over a four-year period to determine the utility of an SMA as measured by HbA1c and weight loss (Trento et al.,

2002). Prior to treatment, individuals in the study had a mean HbA1c of 7.4 at baseline. Participants in the shared medical appointment had an average decrease to 7.0, but individuals receiving standard treatment experienced a rise in average HbA1c level to 8.6 (Trento et al., 2002). Diabetic patients in the shared visit group lost an average of 2.6 k.g., compared to an average loss of 0.9 k.g. in the control group (Trento et al., 2002).

Patients participating in an SMA are more likely to experience a higher level of patient satisfaction. Following the SMA, 85% of patients requested another shared group visit for their next appointment (Bronson & Maxwell, 2004). In the same group, 79% of the patients rated their experience of participating in an SMA as excellent (Bronson & Maxwell, 2004). This result indicates that although individuals spent less time with a physician during an SMA, patients were able to obtain knowledge and skills through interacting with other individuals experiencing a similar health problem. A developing camaraderie potentially enabled patients to create a network of social support outside of their physician's office. Individuals also reported a sense of accountability to follow up with recommended treatment due to the group dynamic.

A potential pitfall of an SMA is a low turnout. A low turnout may make the SMA costlier and less efficient than a standard physician-only appointment (Bronson & Maxwell, 2004). Patients may be unfamiliar with this format and consequently opt not to participate (Bartley, & Haney, 2010). Another potential difficulty that accompanies orchestrating a successful SMA lies in creating a comfortable learning atmosphere for the patients. One factor that limited the effectiveness of the SMA was physicians or behavioral specialists who treated it like a class. The group sessions are more effective when they are executed similarly to a medical encounter rather than lecturing patients on

proper care (Bronson & Maxwell, 2004). It is also important to consider that not all patients are appropriate SMA participants. Examples include individuals who will not maintain confidentiality, who are hearing or cognitively impaired, or who require an interpreter (Bronson & Maxwell, 2004).

**Motivation to Change**

*Motivational interviewing (*MI) is a core component of the SMA. MI has been defined as "a collaborative conversation style for strengthening a person's own motivation and commitment to change" (Miller & Rollnick, 2013, p. 12). It is a client-centered intervention that aims to change behavior through an exploration of the patient's motivation to change (Miller & Rollnick, 2013). The use of motivational interviewing in an integrated care setting can be an integral part of treatment, because it challenges health-care professionals to resist what Miller & Rollnick have termed the "righting reflex" (2013, p. 9). The righting reflex is the "belief that you must convince or persuade the person to do the right thing" (Miller & Rollnick, 2013, p. 11). In order to resist this urge, physicians are encouraged to step aside from the role of the fixer, instead focusing on how to create the best course of action for a particular patient (Miller & Rollnick, 2013).

The use of MI to enhance behavioral change in patients with a chronic medical condition, such as diabetes, is often counteracted by a certain degree of ambivalence. Ambivalence arises when individuals are aware of a necessary behavioral change but are unsure about their need to implement it (Miller & Rollnick, 2013). In order to work through ambivalence, Miller and Rollick (2013, pg. 10) assert the need to evoke "change talk" from the patient. Change talk describes a patient's ability to use their own

motivational statements about why change is important to enable a necessary behavioral change (Miller & Rollnick, 2013). The premise of change talk is important, because hearing oneself present reasons for change increases the likelihood of performing the associated behaviors (Miller & Rollnick, 2013).

Miller and Rollnick (2013) posited partnership, acceptance, compassion, and evocation as four vital components of MI. The first component, partnership, emphasizes the fact that the patient and physician are both considered as experts in treating the chronic condition (Miller & Rollnick, 2013). The physician has expertise in medical knowledge and practice, but the patient is the expert on their own body. It requires forming an active collaboration, with the goal of avoiding coercion and creating an environment conducive to change (Miller & Rollnick, 2013). Acceptance of what the client brings is the second vital component of MI (Miller & Rollnick, 2013, p. 15). In the MI framework, acceptance has four principles: *absolute worth*, *accurate empathy*, *autonomy support*, and *affirmation* (Miller & Rollnick, 2013). Compassion is the third component. In MI, compassion differs from its typical definition; it does not focus on feelings or emotions and should not be confused with sympathy. Instead, it describes the prioritization of the patient's needs and overall welfare (Miller & Rollnick, 2013). Evocation is the final component of MI. According to Miller and Rollnick (2013, p. 17), the message of evocation to the patient is "You have what you need, and together we will find it". This sends the message to patients that each possesses personal strengths and skills that will be utilized effectively in making a positive behavioral change (Miller & Rollnick, 2013).

Due to the complexity of managing diabetes, MI has been applied as a supplemental treatment to enhance adherence in patients. The literature indicates that MI should be utilized in combination with other front-line treatments to manage chronic illness, because it emphasizes patient-centered care and positive affects on the patient-physician relationship (Anstiss, 2009). When MI was implemented with individuals with diabetes, evidence indicated that patients obtained greater knowledge and understanding of diabetes, a more accurate perception of diabetes and one's ability to manage it, as well as increased motivation to make behavioral changes (Rubak, Sandbaek, Lauritzen, Borsch-Johnson, & Christensen, 2009). MI has also been linked to improvements in weight loss, BMI, and HbA1c in a population of participants with diabetes (West, DiLullo, Bursac, Gore, & Greene, 2007). Further research indicated the efficacy of MI in targeted glycemic control. In a population of individuals with Type 1 diabetes, MI contributed to long-term improvement in glycemic control, quality of life, and self-reported overall psychological wellbeing (Channon et al., 2007). Improvements in glycemic control significantly reduce the likelihood of developing or exacerbating the severe co-occurring conditions associated with poorly managed diabetes.

## Behavioral Health Target Variables

### Body- Mass Index (BMI)

During the 1970s, *Body Mass Index* (BMI) emerged through the application of a mathematical construct in which weight is a quadratic function of height (Muller, 2016). BMI soon gained favor as a measure preferable to relative weight. Three main points in the current literature support the utility of BMI: Weight is not a linear function of an individual's height, therefore BMI uses a formula consistent with research indicating that

increases in weight are proportionate to height squared; BMI does not depend on one's stature; research on BMI has demonstrated its correlation with fat mass (Muller, 2016).

As the number of individuals in the population diagnosed with diabetes increased, it coincided with an increase in specific risk factors. Obesity and being overweight are two of the most significant but modifiable risk factors associated with diabetes. Research over the past 30 years has demonstrated that adult obesity has risen, which coincided with a 33% increase in diabetes diagnoses from 1988 to 1994 and 2005 to 2010 (Menke, Rust, Fradkin, Cheng, & Cowie, 2014).

In terms of BMI, adult obesity is defined as being equal to or greater than 30 $kg/m^2$. National surveys were conducted from 1988 to 2010 using BMI to measure classification of adults' weight. From 1988 to 1994, 22.3% of the population surveyed was classified as obese. This percentage rose to 30.5% from 2000 to 2002, and to 35.9% from 2009 to 2010 (Menke, Rust, Fradkin, Cheng, & Cowie, 2014). These results were the basis of a study that examined the connection between the rising diabetes rate and the increase in obesity as measured by BMI. The study's results indicated that diabetes risk increased concurrently with obesity in the United States, and that BMI was the most prominent risk factor in the onset of Type 2 diabetes (Menke, Rust, Fradkin, Cheng, & Cowie, 2014). In contrast, successful weight management through lifestyle change significantly improved outcomes in diabetes patients.

Throughout the literature, evidence associated increased physical activity for approximately 30 minutes per day with a decreased risk of developing Type 2 diabetes (Hu et al., 2004). Further research has examined the relationship between the amount of physical activity, BMI, and an individual's ability to successfully manage their blood

glucose (Hu et al., 2004). Individuals who participated in the study met the BMI criteria for obesity (BMI > 30). The participants then self-reported their level of physical activity (light, moderate, or active) and recorded the amount of time one spent partaking in the activity (low, moderate, or high). The outcome measure for these individuals was blood glucose. The results of the study indicated that individuals who had more impairment in their ability to regulate glucose were more likely to be from lower educational backgrounds, have higher mean values of BMI and high blood pressure, and to be obese (Hu et al., 2004). In addition, reduction in BMI and a moderate level of physical activity proved to be protective factors against the development of Type 2 diabetes (Hu et al., 2004).

**Blood Pressure/ Hypertension**

Diabetes is a significant independent factor contributing to the development of cardiovascular disease (ADA, 2011). High blood pressure also negatively impacts various parts of the body and increases an individual's risk of developing additional complications (ADA, 2011). Research indicates that up to 70% of deaths in diabetes patients are attributable to cardiovascular ailments (Choma, Griffin, Kaltenbach, Greevy, & Roumie, 2011). Another 70% of individuals with diabetes also have hypertension or are actively managing high blood pressure with medication (ADA, 2011). Moreover, hypertension in a diabetic patient is especially threatening due to its connection with diabetic neuropathy, which is developed by approximately 20-30% of diabetic patients (Banach, Aronow, Serban, Rysz, Voroneanu, & Covic, 2015).

When hypertension develops, blood in the body flows at an increased rate, forcing the heart to work harder (ADA, 2011). More stress is placed on the heart, resulting in

arterial damage and the production of a fatty tissue known as *atheroma* (ADA,2011). The formation of atheroma results from the arteries becoming narrow or blocked completely, resulting in a reduction of blood flow (ADA, 2011). When this occurs, an individual becomes more susceptible to heart attack, stroke, and other complications.

When an individual is diagnosed with diabetes, they face new challenges, including strict blood pressure management. Individuals with high blood pressure and diabetes are 4 times more likely to die compared to individuals who have neither of these conditions (ADA, 2011). Previous research has identified risk factors, such as baseline uncontrolled blood pressure, required use of oral medication, as opposed to insulin or diet and exercise, and prescription of three or more medications to control blood pressure.

A study was conducted in a population of veterans to examine blood pressure control in individuals newly diagnosed with diabetes (Choma, Griffin, Kaltenbach, Greevy, & Roumie, 2011). The aim of the study was to determine one's ability to successfully control blood pressure in the first two years after diagnosis. Participant's blood pressure was measured at baseline and in 6-month increments, until the 2-year threshold had been reached. In accordance with the American Diabetes Association recommendation for blood pressure, the target goal was <130/80 mmHg (ADA, 2010). Results indicated that approximately 65% of the participants met the ADA standard for blood pressure control after 6 months and at the 2-year follow-up (Choma, Griffin, Kaltenbach, Greevy, & Roumie, 2011). After the 6-month measurement, however, no further improvements were observed. Several explanations were proposed, including medication adherence, the effort of the patient or their physician, and a sedentary lifestyle (Choma, Griffin, Kaltenbach, Greevy, & Roumie, 2011).

**Cholesterol**

*Cholesterol* is "a fatty substance that is an essential component of cell membranes and is used by the body for insulating nerve fibers" (Metzenger & AMA, 2006, p. 94). There are two main types of cholesterol, *high-density lipoprotein* (HDL) cholesterol and *low-density lipoprotein* (LDL). HDL cholesterol is often referred to as good cholesterol, while LDL is dubbed bad cholesterol. High levels of LDL cholesterol result in fatty build-ups in the arteries (Metzenger & AMA, 2006). HDL cholesterol is responsible for helping to clear these fatty deposits, which is why having a good ratio between HDL and LDL is beneficial (Metzenger, & AMA 2006). The measurement of fat that stores energy released between meals to fuel the body is termed *triglycerides* (Metzenger & AMA, 2006). The recommended target levels for each type of cholesterol are as follows: LDL cholesterol below 100 mg/dl, HDL cholesterol above 40 mg/dl for men and above 50 mg/dl for women, and triglyceride level below 150 mg/dl (ADA, 2011). When cholesterol levels do not meet the recommended standards, significant complications arise.

The vast majority of cardiac complications in diabetic patients are caused by a reduction of blood flow in the arteries caused by a blockage. Individuals with diabetes are already considered to be at higher risk of developing narrow blood vessels. High cholesterol is another factor that greatly increases a diabetic patient's likelihood of experiencing cardiovascular problems (ADA, 2011). High cholesterol and triglycerides contribute significantly to the hardening of the arteries. As the arteries harden and function less efficiently, blood builds up along the walls of the blood vessels (ADA, 2011).

**Hemoglobin A1c (HbA1c)**

The initial onset of diabetes occurs when either the body is unable to make enough insulin or it misuses insulin that is produced. In either instance, glucose in the body is unable to make its way into various cells in the body. Instead, blood glucose levels become too high, because glucose remains in the blood (Reddy, 2009). It is also common for the excess glucose remaining in the body to cause weight gain as well as damage blood vessels and nerves (ADA, 2009). Glucose is perhaps the most important term to understand in diabetes management. It is also commonly referred to as blood sugar and mainly enters the body in the form of carbohydrates (ADA, 2009).

Hemoglobin A1c is a test used to measure blood glucose levels over a 3-month period in an individual with diabetes (Reddy, 2009). More specifically, the concentrations of hemoglobin molecules that have glucose attached to them are measured as a percentage (ADA, 2011). An individual without diabetes typically has hemoglobin A1c levels within the range of 4% to 6% (Reddy, 2009). In the diabetes population, the goal for hemoglobin A1c is < 6.5% (Reddy, 2009). In order to reduce or change blood glucose levels, the ADA (2011) recommends reducing food consumption, altering the types of food consumed, increasing physical activity, and the alteration of insulin levels by a medical professional. Years of accumulated research has indicated the importance of successfully regulating blood glucose levels.

Two landmark studies showed the importance of glucose control and its relationship with the prevention of diabetes or reduction in the risks associated with diabetes: *The Diabetes Control and Complications Trial* (DCCT) and the *United Kingdom Prospective Diabetes Study* (UKPDS). The DCCT was conducted over a ten-

year span from 1983-1993 in the United States and Canada. The inclusion criteria required having Type 1 diabetes for at least 1 year but less than 15 years. A group of 1,441 individuals who met the criteria participated in the study. The aim of the DCCT was to determine whether standard blood glucose management was sufficient to reduce diabetes-related complications or if treatment required a more intensive approach (Lasker, 1993). For the purpose of the study, individuals in the intensive glucose control group were given the goal of maintaining A1c levels at < 6%, as opposed to < 6.5%. and were given either an insulin pump or multiple injections daily, as compared to individuals who received only 1-2 insulin injections (NIH, 2008; ADA, 2011). The study examined three major complications: eye disease, kidney disease, and cardiovascular disease (NIH, 2008). The results on the DCCT revealed that individuals receiving the more intensive treatment regimen had a 76% reduction in the risk of developing diabetic retinopathy, a 54% reduction in the progression of diabetic retinopathy in individuals with early signs of the disease, a 50% risk reduction for kidney disease, a 60% reduction in the development of nerve damage, and a 35% reduction in cholesterol levels (ADA, 2001; Lasker, 1993; NIH, 2008).

The UKPDS had a sample of 5,102 individuals who were recently diagnosed with Type 2 diabetes (ADA, 2011; King, Peacock, & Donnelly, 1999). The study aimed to build on the results of the DCCT study, which examined only Type 1 diabetes. The study's goal was to answer several questions and concerns related to diabetes management, including whether intensive blood pressure control affected complications, whether an individual's quality of life was affected by intensive blood glucose control, and cost-effectiveness of intensive blood glucose control (King, Peacock, & Donnelly,

1999). Results of the UKPDS indicated that individuals who received intensive intervention targeting blood glucose levels experienced a 25% reduction of risk of microvascular complications (eyes and nerve disease), a 44% reduction of risk of stroke, a 56% reduction of risk of heart failure, and reduction of risk for heart attack and mortality from a diabetes-related complication (ADA, 2011; King, Peacock, & Donnelly, 1999).

## Chapter 2: Research Question

Does a higher level of integrated care (SMA) produce better diabetes treatment outcome than lower levels of integrated care, such as BHC plus IPC and IPC as measured by A1c change, blood pressure change, BMI change, and LDL change?

**Hypothesis 1**

Individuals with diabetes who received the highest level of integrated care in the form of IPC plus shared medical appointment will show significantly more improvement in measures of BMI, as compared to IPC plus cognitive behavioral therapy. Each combined treatment regimen will show more significant improvement than IPC alone.

**Hypothesis 2**

Individuals with diabetes who received the highest level of integrated care in the form of IPC plus shared medical appointment will show significantly more improvement in measures of systolic blood pressure, as compared to IPC plus cognitive behavioral therapy. Each combined treatment regimen will show more significant improvement than IPC alone.

**Hypothesis 3**

Individuals with diabetes who received the highest level of integrated care in the form of IPC plus shared medical appointment will show significantly more improvement in measures of diastolic blood pressure, as compared to IPC plus cognitive behavioral therapy. Each combined treatment regimen will show more significant improvement than IPC alone.

**Hypothesis 4**

Individuals with diabetes who received the highest level of integrated care in the form of IPC plus shared medical appointment will show significantly more improvement in measures of hemoglobin A1c, as compared to IPC plus cognitive behavioral therapy. Each combined treatment regimen will each show more significant improvement than IPC alone.

**Hypothesis 5**

Individuals with diabetes who received the highest level of integrated care in the form of IPC plus shared medical appointment will show significantly more improvement in measures of HDL, as compared to IPC plus cognitive behavioral therapy. The two combined conditions will each show more significant improvement than IPC alone.

**Hypothesis 6**

Individuals with diabetes who received the highest level of integrated care in the form of IPC plus shared medical appointment will show significantly more improvement in LDL compared to IPC plus cognitive behavioral therapy. Each combined treatment regimen will show more significant improvement than IPC alone.

**Hypothesis 7**

Individuals with diabetes who received the highest level of integrated care in the form of IPC plus shared medical appointment will show significantly more improvement in a measure of total cholesterol, as compared to IPC plus cognitive behavioral therapy. Each combined treatment regimen will show more significant improvement than IPC alone.

**Overall Rationale.** An integrated care approach is consistent with the theory that providing individuals with an additional support system will increase their likelihood of adhering to medical recommendations. Improvements in diabetes management have been linked to the use of a behavioral health support team, because the psychosocial needs of the patient are also met. Therefore, individuals receiving an additional form of treatment combined with IPC are expected to show significant improvement in the outcome measures.

# Chapter 3: Methodology

## Design

This study is a nonrandomized, uncontrolled, naturalistic, cross-sectional quantitative evaluation of integrated medical services using archival data from four urban health care centers (Roxborough, Lancaster, Cambria & Family Medicine) associated with the Philadelphia College of Osteopathic Medicine. The study examined the differences in hemoglobin A1c, blood pressure, body mass index (BMI), and low-density lipoprotein (LDL) across treatment conditions. Comparisons of the outcome measures were based on whether individuals participated in a shared medical appointment (SMA), behavioral health care (BHC) services (6-8 sessions of cognitive behavioral therapy), or integrated primary medical care. The study pitted integrated medical care and behavioral health care conditions against a more fully integrated level of care (including SMA) and examined each of these modalities relative to treatment as usual. Integrated primary care was considered treatment as usual.

### Participants

The participants were selected from Philadelphia College of Osteopathic Medicine's health care facilities. The health care centers are located throughout various underserved locations of Philadelphia; in general, participants' socioeconomic status was low. Participants were previously recommended for a higher level of care due to an inability to manage their diabetes or received medical care as usual from their physician. Individuals recommended to a higher level of care participated in one of two conditions: 1) Shared Medical Appointment (SMA) or 2) behavioral health care (BHC) services. The minimum age for participants was 18.

**Inclusion criteria**

The subjects participated in one of the treatment intervention conditions and must have been diagnosed with Type 1 or Type 2 diabetes that was considered by their medical care provider to be poorly managed (i. e., HbA1c > 8). Participants were age 18 or older, and were patients at one of PCOM's health care centers. They must have received only one of three types of care.

**Exclusion criteria**

The exclusion criteria were as follows: under the age of 18; lacking a documented diagnosis of diabetes; not a patient sat one of PCOM's four health care centers; not participated in one of the three treatment conditions.

**Measures**

All deidentified data were extracted from the patient's charts on the NextGen electronic medical record by a consultant with the Department of Family Medicine.

**Demographic information Sheet.** Measures included the participant's age, gender, race, and ethnicity.

**Glycated Hemoglobin (HbA1c)**

*Glycated hemoglobin* develops when hemoglobin, a protein in red blood cells that carry oxygen throughout the body, combines with glucose in an individual's blood. HbA1c is often used as a diagnostic test for diabetes. HbA1c testing provides an overall picture of an individual's average blood sugar levels over a period of weeks or months. The sample is measured by a fasting plasma glucose test. The current recommended diagnostic cutoff by the American Diabetes Association (ADA) is an HbA1c < 6.5. To test HbA1c, a medical professional takes a blood sample from the patient's finger or arm,

which is then laboratory-tested. For the purpose of the study, the most recent HbA1c tests will be extracted from the patient's electronic health record by the investigator.

**Body Mass Index (BMI)**

Individuals who are considered overweight or obese are more likely to develop Type 2 diabetes and other medical problems. Upwards of 75% of individuals living with Type 2 diabetes are currently obese or were at one point in time (ADA, 2011). BMI is calculated by dividing weight in pounds by height in inches squared and multiplying by a conversion factor of 703 (weight [lb]/height [in]$^2$ x 703). The physician should calculate a patient's BMI at each visit, and the American Diabetes Association (2011) recommends immediate calculation and documentation in the patient's medical record. The patient's BMI will be extracted from their chart by the principal investigator. The patient's BMI following the completion of their level of care will be compared to their BMI prior to treatment to determine the effectiveness of the intervention. BMI classifies an individual's weight into the categories of underweight (below 18.5), normal weight (18.5-24.9), overweight (25.0-29.9), and obese (30.0 and above). The development of diabetes complicates one's ability to successfully manage weight. Individuals who are overweight are already more likely to put more pressure on their bodies to function properly (ADA, 2011).

Research has indicated that if the weight inside the abdomen is higher than on the hips and thighs, cells within the body are likely less sensitive to insulin (Metzenger & AMA, 2006). Insulin production in an overweight individual is more difficult to regulate and therefore complicates diabetes management. The body then becomes resistant to insulin, and many overweight individuals require higher doses. The ADA recommends

that individuals with a BMI over 25 $kg/m^2$ or greater should be considered at risk for developing diabetes. Approaches to improve BMI typically require significant lifestyle change, including exercise and reducing daily caloric intake.

**Cholesterol**

**C**holesterol is measured by means of a fasting blood sample, most commonly taken from the patient's arm. The blood sample is then analyzed in a laboratory. Once the results are received, the data are entered into the patient's electronic health record. The investigator of this study extracted these deidentified data to compare the effect of several interventions on a patient's cholesterol levels. High LDL cholesterol has been linked to an increased risk of coronary heart disease (CHD), to which individuals with diabetes are already more susceptible. Lowering an individual's LDL cholesterol has been shown to reduce the risk of developing CHD. The ADA recommendation for LDL cholesterol is < 100 mg/dl, although a lower guideline of LDL < 70 mg/dl has been proposed. The calculated LDL is a formulation using measurements of total cholesterol, HDL cholesterol, and triglycerides. In contrast, high HDL cholesterol is associated with lower risk of CHD. In males, an HDL cholesterol < 40 is considered a risk for CHD and in females < 50. The most common type of fat in the human body are triglycerides. A high triglyceride level of 150 or more is correlated with increased risk of developing heart disease or stroke.

**Blood Pressure**

Blood pressure is measured by a medical health professional during each routine diabetes visit. Their physician then immediately enters the patient's blood pressure into their electronic health record. For the purpose of this study, the investigator will extract

and record the blood pressure of patients who met inclusion criteria for the study According to the ADA, individuals who have hypertension, defined as blood pressure of 140/90 mm Hg or greater, are at a significantly heightened risk of developing diabetes. Blood pressure is measured using two inputs, the systolic and the diastolic. Systolic blood pressure represents the pressure in blood vessels when the heart is beating. Diastolic blood pressure represents the pressure in blood vessels between each heartbeat.

**Procedure**

The current study was conducted using archival records from the NextGen patient database of PCOM's health care centers. NextGen is an electronic medical health record used by physicians to document patient's progress on physician-measured variables, as well as laboratory tests results. The NextGen system allows seamless treatment from multiple medical and behavioral health professions. NextGen enables various health care providers to identify patients and view their complete treatment history. In consequence, NextGen promotes the use of integrated care for treatment of individuals who present with multiple medical conditions. The NextGen electronic health record improves patient engagement and health outcomes and promotes continuity of care. Data retrieval was archival; the data were originally collected by physicians and behavioral health professionals at the health care centers. From the health record, the investigator identified patients meeting inclusion criteria and recorded the level of care received by each patient (IPC, IPC + SMA, IPC + BHC) and corresponding outcome measures (i.e., HbA1c, BMI, blood pressure, cholesterol). The archival data were then deidentified by a professional staff consultant of the Department of Family Medicine, and only the aforementioned categories of information were extracted and entered into an SPSS 24

database. Deidentification entailed the removal of direct patient identifiers, including names, medical record numbers, social security numbers, the location of services received, and telephone numbers. Their patient identifiers were replaced with randomly generated but valid numbers. The data were analyzed to identify differences in outcome measures based on the level of treatment in which the patient participated. Participant data pertaining to one of three different treatment conditions (IPC, SMA, BHC) on seven measures (BMI, systolic blood pressure, diastolic blood pressure, HbA1c, LDL cholesterol, HDL cholesterol, and total cholesterol) were evaluated to determine if a higher level of care was associated with more successful diabetes management. The principal investigator, with the aid the Chairman of the Department of Family Medicine, identified patients meeting the criteria for inclusion who had received one of the three treatments, as well as any individuals who received a combination of these treatments. Too few such patients existed to warrant analysis. The data were coded into an SPSS database to include age, gender, and ethnicity.

# Chapter 4: Results

## Descriptive Statistics

To investigate the effect of integrated primary care (IPC) and IPC combined with participation in shared medical appointments and behavioral health care about diabetes management, a sample of archival patient data originally collected at the various Philadelphia College of Osteopathic Medicine health care centers was extracted from the NexGen database. A total of 474 patients' data met criteria for elevated hemoglobin A1c > 8 upon entry into the study. The total of patients receiving only IPC was highly disproportionate to the numbers in the other conditions. Rather than opting to retain an extremely disproportionate number of participants in the first treatment condition, a random sample of 40 participants was selected to represent the larger group and compared to individuals who received one of the other treatment conditions. After doing so, the study's total sample size fell to 126. Frequency distributions for age, gender, race, and ethnicity are shown in Table 1. A total of 55 were male (45.8%), and 63 were female (52.5%). Participant ages ranged from 25-85 years; the mean age was 57.25 years old, with a standard deviation of 11.2. Markedly fewer patients fell into the youngest category, and the overwhelming majority fell in the range of 41-85. In regard to race, the majority of the participants indicated that they were African American, with only 7 (5.8%) identifying as White/Caucasian. In regard to ethnicity, the majority reported that they were Non-Hispanic, with very few participants endorsing the other categories.

Table 1.

*Participant Demographic Information*

| Characteristic | **n** | **%** |
|---|---|---|
| Gender | | |
| Male | 55 | 45.8 |
| Female | 63 | 52.5 |
| Age | | |
| 18-29 | 2 | 1.6 |
| 30-40 | 6 | 4.8 |
| 40-85 | 118 | 93.7 |
| Race | | |
| African American | 110 | 91.7 |
| White/Caucasian | 7 | 5.8 |
| Unknown | 1 | .8 |
| Ethnicity | | |
| Declined to Specify | 3 | 2.5 |
| Non-Hispanic | 112 | 93.3 |
| Hispanic or Latino | 2 | 1.7 |
| Unknown | 1 | .8 |

Each patient's outcome measures were reported in accord with the treatment condition they received, as reported in Table 2. Treatment condition 1 comprised 40 patients (33%), who received integrated primary care only; treatment condition 2 comprised 36 patients (30%), who received integrated primary care and participated in at least one shared medical appointment; condition 3 comprised 42 patients (35%), who received integrated primary care and cognitive behavioral therapy with a behavioral health specialist.

Table 2.

*Treatment Conditions*

| | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|
| Condition 1 | 40 | 33.3 | 33.9 | 33.9 |
| Condition 2 | 36 | 30.0 | 30.5 | 64.4 |
| Condition 3 | 42 | 35.0 | 35.6 | 100.0 |
| Total | 118 | 100.0 | 100.0 | |

**Pretest and posttest scores on dependent variables**

As shown in Table 3, the scores of the participants on all measures at pretest are provided. BMIs ranged from18.95 to 55.61, with a mean of 34.14 and standard deviation of 7.14. Systolic blood pressure ranged from 95 to 204, with a mean of 133.45 and standard deviation of 19.52. Diastolic blood pressure ranged from 61 to 120, with a mean of 80.78 and standard deviation of 11.01. Hemoglobin A1c ranged from 6.8 to 16.4, with a mean of 10.53 and standard deviation of 2.14. Hdl cholesterol ranged from 14 to 133, with a mean of 49.00 and standard deviation of 16.36. Ldl cholesterol ranged from 53 to

206, with a mean of 110.64 and standard deviation of 37.15. Total cholesterol ranged from 108 to 376 with a mean of 192.47 and standard deviation of 50.0

Table 3.

*Ranges, Means and Standard Deviations for Pretest Variables*

| Variable | Range | Mean | Standard Deviation |
|---|---|---|---|
| BMI | 18.95-55.61 | 34.14 | 7.14 |
| Systolic Blood Pressure | 95-204 | 133.45 | 19.52 |
| Diastolic Blood Pressure | 61-120 | 80.78 | 11.01 |
| Hemoglobin A1c | 6.8-46.4 | 10.53 | 2.14 |
| HDL Cholesterol | 14-133 | 49.00 | 16.36 |
| LDL Cholesterol | 53-206 | 110.64 | 37.15 |
| Total Cholesterol | 108-376 | 192.7 | 50.02 |

In Table 4, the scores of the participants on all measures at posttest are presented. On the posttests measures**,** BMI ranged from 21 to 59, with a mean of 34.66 and standard deviation of 7.71. Systolic blood pressure ranged from 86 to 110, with a mean of 132.31 and standard deviation of 19.48. Diastolic blood pressure ranged from 54 to 110, with a mean of 78.62 and standard deviation of 10.33. Hemoglobin A1c ranged from 6 to 15, with a mean of 9.17 and standard deviation of 2.28. Hdl cholesterol ranged from 26 to 76, with a mean of 47.27 and standard deviation of 11.83. Ldl cholesterol ranged from

16 to 195, with a mean of 96.37 and standard deviation of 34.94. Total cholesterol ranged from 109 to 317, with a mean of 171.49 and standard deviation of 41.12.

Table 4

*Ranges, Means and Standard Deviations for Posttest Variables*

| Variable | Range | Mean | Standard Deviation |
|---|---|---|---|
| BMI | 21-59 | 34.66 | 7.71 |
| Systolic Blood Pressure | 86-110 | 132.31 | 19.48 |
| Diastolic Blood Pressure | 54-110 | 78.62 | 10.33 |
| Hemoglobin A1c | 6-15 | 9.17 | 2.28 |
| HDL Cholesterol | 26-76 | 47.27 | 11.83 |
| LDL Cholesterol | 16-195 | 96.37 | 34.94 |
| Total Cholesterol | 109-317 | 171.49 | 41.12 |

**Hypothesis 1: BMI**

The first hypothesis predicted that individuals with diabetes who received the highest level of integrated care in the form of integrated primary care (IPC) and a shared medical appointment will show significantly more improvement in measures of BMI compared to individuals receiving the behavioral health intervention. These two conditions were predicted to show significantly more improvement than integrated primary care. To test this hypothesis, the current study's author conducted a 3 x 2 analysis of variance with repeated measures of one factor. The independent variables were the type of treatment (IPC, IPC plus SMA, and IPC plus behavioral health) and time

(pretest to posttest). BMI was the dependent variable. The analysis revealed that *Box's test*, which tests the null hypothesis that the observed covariance matrices of the dependent variables are equal across groups, was not significant: Box's $M = 3.15$, $F(6,227501) = .510$, $p = .801$. Test of within-subjects effect demonstrated a nonsignificant change from pretest to posttest: $F(1,104) = .576$, $p = .450$; partial eta squared = .006. *Levine's test* of equality of error variance on each dependent variable was not significant. On the test of between-subjects effects, a significant effect for treatment condition emerged: $F(2,104) = 3.603$, $p = .031$, eta squared = .065. Post hoc *Tukey analysis* revealed a significant difference between treatment condition 1 (IPC) and 2 (IPC plus SMA): $p = .024$, with IPC plus SMA having a significantly higher BMI. No other comparisons were significant.

**Hypothesis 2: Systolic Blood Pressure**

For this hypothesis, a 3 x 2 ANOVA with repeated measures on one factor was conducted on the dependent variable of systolic blood pressure. The analysis revealed that *Box's test*, which tests the null hypothesis that the observed covariance matrices of the dependent variables are equal across groups, was not significant: Box's $M = 8.66$, $F(6,255619) = 1.405$, $p = .208$. Partial eta squared was equal to .018. The test of within-subjects effects demonstrated a nonsignificant change from pretest to posttest $F(1,109) = 1.96$, $p = .16$, partial eta squared = .018, a small effect. Levine's test of equality of error variances on each dependent variable was not significant for the posttest blood pressures but differed on the pretests. The test of the between-subjects effect revealed no significant effect for treatment condition: $F(2,109) = .022$, $p = .978$, eta squared = .000.

**Hypothesis 3: Diastolic Blood Pressure**

To test this hypothesis, a 3 x 2 ANOVA with repeated measures on one factor was conducted on the dependent variable of diastolic blood pressure. The analysis revealed that Box's test, which tests the null hypothesis that the observed covariance matrices of the dependent variables are equal across groups, was not significant: Box's $M$ = 3.56, F(6,255619) = .578, $p$ = .748). The test of within-subjects effects demonstrated a significant change from pretest to posttest: F(1,109) = 5.527, $p$ = .02; partial eta squared = .048, a small effect. Levine's test of equality of error variance on the pretest and posttest was not significant. The test of the between-subjects effects revealed no significant effect for treatment condition: F(2,109) = 1.11, $p$ = 332, partial eta squared = .02.

**Hypothesis 4: Hemoglobin A1c**

A 3 x 2 ANOVA was conducted to evaluate the potential impact of treatment across time for hemoglobin A1c. The analysis revealed that Box's test, which tests the null hypothesis that the observed covariance matrices of the dependent variables are equal across groups, was not significant: Box's $M$ = 6.188, F(6,207186.20) = 1.00, $p$ = .423. The test of within-subjects effect demonstrated a significant change from pretest to posttest: F(1,96) = 27.39, $p$ =.000, partial eta squared = .222. Levine's test of equality of error variance on the pretest and posttest were not significant. The test of the between-subjects effect revealed no significant effect for treatment condition: F(2,96) = .405, $p$ = 668; eta squared = .008.

**Hypothesis 5: HDL Cholesterol**

The dependent variable for this analysis was HDL cholesterol. The analysis revealed that Box's test, which tests the null hypothesis that the observed covariance matrices of the dependent variables are equal across groups, was not significant: Box's *M* = 9.608, F*(*6,78660.07) = 1.521, *p* = .167. The test of within-subjects effect demonstrated no significant change from pretest to posttest: F*(*1,58) = 1.468, *p* = .23, partial eta squared = .025. Levine's test of equality of error variance on the pretest and posttest was not significant. Test of the between-subjects effect revealed no significant effect for treatment condition: F*(*2,58) = 1.127, *p* = 331, eta squared = .037

**Hypothesis 6: LDL**

The dependent variable for this 3 x 2 ANOVA with a repeated measure on one factor was LDL cholesterol. The analysis revealed that Box's test, which tests the null hypothesis that the observed covariance matrices of the dependent variables are equal across groups, was not significant: Box's *M* = 7.284, F*(*6,76853.38) = 1.151, *p* = .329). The test of within-subjects effect demonstrates a significant change from pretest to posttest: F*(*1,56) = 5.527, *p* = .022, partial eta squared = .090. Levine's test of equality of error variance on each dependent variable was not significant. The test of the between-subjects effect revealed no significant effect for treatment condition: F*(*2,56) = .490, *p* = .615, eta squared = .017.

**Hypothesis 7: Total Cholesterol**

The dependent variable for this analysis was total cholesterol. The analysis revealed that Box's test, which tests the null hypothesis that the observed covariance matrices of the dependent variables are equal across groups, was not significant: Box's *M*

= 8.865, $F(6,78660.07) = 1.375$, $p = .220$. Test of within-subjects effect demonstrates a significant change from pretest to posttest: $F(1,58) = 11.61$, $p = .001$, partial eta squared = .167. Levine's test of equality of error variance on each dependent variable was not significant. The test of the between-subjects effect revealed no significant effect for treatment condition: $F(2,58) = .00$, $p = 1.00$; eta squared = .00.

# Chapter 5: Discussion

## Findings and Clinical Implications

A traditional primary care visit is a one-on-one meeting between a patient and clinician. However, this format may be inappropriate for addressing chronic diseases like diabetes, which require complex ongoing treatment (Egger et al., 2014). The use of an integrated primary care model counteracts this problem by allowing health care professionals to collaborate with the patient and each other, thus fully addressing the multitude of presenting problems related to diabetes (Blount, 2003). The present study was performed to determine whether additional treatment in the form of IPC plus SMA or IPC plus behavioral health care, in the form of cognitive behavioral therapy, would improve health outcomes in diabetic patients compared to diabetic patients who received IPC alone, as measured by 7 outcome variables. Generally speaking, with the exclusion of BMI, when significant changes were observed, the treatment groups did not differ significantly in outcome.

Of the 7 outcome variables, none showed improvement as a result of receiving a higher level of care in addition to IPC. However, 4 of the 7 variables improved over time, regardless of treatment condition. This is an interesting finding, suggesting that perhaps the addition of SMA and behavioral health care did nothing beyond what is accomplished by IPC alone. Given the nature of the present evaluation, especially the number of uncontrolled variables, many reasons for this finding are possible, and the results should not be taken as demonstrating that these treatments may not be effective when implemented under more controlled conditions using a standardized treatment delivery protocol. In addition, outcomes that may have been more likely to be affected

by SMA and CBT were not available for analysis in this study. The findings for each outcome are discussed below.

**BMI**

In the single instance in which BMI did not change over time, a treatment condition effect obtained; those receiving IPC only did significantly better than IPC plus SMA. Although neither of these treatments provided targeted behavioral treatment for weight control, why the IPC group fared better is perplexing.

This finding may have resulted from the fact that individuals who participate in a SMA are generally considered in worse physical condition than the average patients, and their diabetes is considered to be "out of control" (Edelman et al., 2012). At PCOM, patients receive a recommendation to participate in a SMA if their hemoglobin A1c is > 8. However, no standardized criterion is in place for referral to the additional treatments. Patients who participated in a SMA may have faced more challenges to their lifestyle habits than the patients in IPC only. In the literature, one of the dominant factors correlated with high BMI in adulthood is being overweight in adolescence (Goran, 2001). Environmental factors that contribute overweight adolescents include an environment in which healthy foods were not readily available from a young age, as well as access to foods that are inexpensive but have a high caloric content (Cugnetto et al., 2007). Considering that PCOM's health care centers are located in urban areas, and the majority of patients were underserved, access to healthier food may have been limited. In addition to diet, lack of physical activity is associated with a higher BMI (Cugnetto et al., 2007). Environmental and socioeconomic status may have played a role in the amount of physical activity in which an individual engages. Potential factors limiting physical

activity include lack of access to or unavailability of facilities or a perception that one's environment is unsafe. The race of the participants was another factor impacting the population of this study.

The majority of the participants were African American, and research indicates that during adolescence, African Americans are less likely to experience societal pressures to be thin and more likely to be influenced by members of their family (Parnell et al., 1996; Yates, Edman, & Aruguete, 2004). African American women have also been demonstrated to show less concern about being thin than Caucasian women and are more flexible in their perception of beauty (Wilfey et al., 1996; Yates, Edman, & Aruguete, 2004). Compared to females from a variety of other races, African American women had the highest BMI (Yates, Edman, & Aruguete, 2004). African American females constituted the largest single segment of this study's population.

**Systolic Blood Pressure**

In systolic blood pressure, no significant differences emerged related to condition, time, or condition x time interaction. The mean systolic blood pressure for the pre and posttest groups were both above 130, which is generally considered as stage 1 hypertension (Tello, 2017). Therefore, absence of change was not the result of individuals maintaining a healthy systolic blood pressure over time. To the contrary, the observed systolic blood pressures remained in a range that would be considered mildly problematic. A systolic blood pressure that is 20 points higher than the recommended cutoff doubles an individual's risk for heart attack, stroke, heart failure, and aortic aneurysm (Tello, 2017). Alterations in diet have proven to be the most effective front-line treatment for high systolic blood pressure, and have lowered systolic pressure by 11

points or more. Each additional healthy lifestyle change contributes a further 4- to 5-point reduction (Tello, 2017). In fact, dietary change alone is often prescribed for individuals who have hypertension, but lack any family history of cardiovascular disease (Tello, 2017).

**Diastolic Blood Pressure**

On DBP, no significant differences by treatment condition were present. However, a significant reduction appeared over time, from 80.78 to 78.62. The drop of 2.16 units on the posttest represented exit from the elevated range. The American Diabetes Association (ADA, 2017) recommendation for diastolic blood pressure is < 90, although it advised that individuals at high risk for cardiovascular disease may benefit from a target of < 80. This significant improvement placed the study's participants well within the recommended range for the general public of < 90 mmHg and also within the stricter guideline of < 80 mmHg for individuals at heightened risk for cardiovascular complications (ADA, 2017). Research on the impact of high blood pressure has observed that a diastolic blood pressure 10 points above the cutoff doubles the risk of death from heart attack, stroke, or another cardiovascular condition, such as heart failure (Tello, 2017). Macrovascular complications, such as stroke, are the leading cause of death in patients with diabetes, causing more than 60% of fatalities (Howard et al., 2000). Individuals who survive a macrovascular complication are often left permanently disabled and/or experience significant medical consequences.

**Hemoglobin A1c**

In hemoglobin A1c, the primary dependent measure in this study, no significant differences by treatment condition emerged. Nevertheless, patients improved over time,

regardless of the treatment they received. In A1c, participation in treatment was associated with a drop of 1.36% in A1c. Research indicated that decreases in hemoglobin A1c were associated with reduced mortality rates, lower risk of myocardial infarction, and reduction in microvascular complications (Karyekar, Frederich, & Ravichandran, 2013). These reductions were consistent, whether HbA1c was reduced to within the recommended range or not. Additional data from the *United Kingdom Prospective Diabetes Study* (UKPDS, 1998) indicated that each 1% decrease in HbA1c correlated with a 21% reduction in mortality risk, a 14% reduction in myocardial infarction, and 37% reduction in microvascular complications, such as retinopathy, nephropathy, and neuropathy.

**HDL Cholesterol**

Results on variable 5, HDL cholesterol, did not indicate any differences by condition, time, or interaction effect. Although no significant differences were observed, the mean HDL cholesterol was in the normal range on the pre and posttest measure. The normal range for HDL cholesterol is 40 to 59 milligrams per deciliter (mg/dl). HDL cholesterol of 60 mg/dl and above is the recommended range by physicians, and HDL cholesterol of < 40 mg/dl increases the risk of developing heart disease. Research results in the literature on the role of HDL and its connection with diabetes are mixed. When it is < 40 mg/dl, studies have identified it as among a host of other variables (i.e., parental history of diabetes, elevated blood pressure, and impaired fasting glucose level) contributing to the development of Type 2 diabetes (Schmidt et al., 2005; Wilson, Meigs, & Sullivan, 2007). Additional research indicates that HDL cholesterol combined with

high triglycerides is a marker for Type 2 diabetes, but does not directly impact its development (De Silvia et al., 2011).

**LDL Cholesterol**

Results for LDL cholesterol did not indicate differences by condition, but that participants' LDL cholesterol did improve over time. Participants' LDL cholesterol fell by 14.27 points, from 110.64 to 96.37. This reduction in LDL cholesterol signifies that the mean patient cholesterol in the posttest achieved the primary goal of LDL < 100 mg/dl for the diabetic population (ADA, 2017). Individuals who test within the recommended LDL cholesterol range have demonstrated a 9% reduction in all-cause mortality, a 21% reduction in major vascular events, and reduced risk of cardiovascular disease (Eldor & Raz, 2009). Combined with the development of diabetes, LDL cholesterol increased the chance of cardiovascular disease by 12% (Howard et al., 2000). The exacerbated risk has been observed in increases of LDL cholesterol as small as 10 mg/dl in a population of individuals between the ages of 45 and 74 (Howard et al., 2000). The study described LDL cholesterol as a "strong independent predictor of coronary heart disease in an individual with diabetes" (Howard at al., (2000) p. 830). Thus, strong emphasis is placed on aggressively controlling LDL cholesterol in patients diagnosed with diabetes to reach the target level of < 100 mg/dl.

**Total Cholesterol**

**N**o differences by condition appeared in total cholesterol, but participants' total cholesterol improved by 19.48 over time. Total cholesterol is not a variable typically associated with diabetes management. The literature indicates that improvement in LDL cholesterol level has a more direct relationship with positive health outcomes (Eldro &

Raz, 2009). However, when patients have triglyceride levels of at least 200 mg per dL, the current guidelines recommend the use of the formula total cholesterol level minus HDL cholesterol level. The target goal in the diabetic population is < 10 mg per dL (Armstrong, 2006). Triglycerides were not included as an outcome variable in this study, but mean outcome for total cholesterol minus HDL cholesterol on the posttest measure would place patients in the recommended range for total cholesterol at 124.22.

**General Conclusions**

Overall, the results of the study indicate that combining additional treatment with IPC does not produce differential treatment effects, despite the literature's advocation of the use of BHC and SMAs. The divergence may result from PCOM's establishment of an IPC model in their health care centers, which has proven to promote patient success without supplemental treatment. This IPC model employs a patient-centered and team-based approach, led by the physician, with significant collaboration between team members and the patients. The team-based approach strives to provide optimum care across several patient domains with the goal of producing behavioral changes that will improve a patient's ability to manage their diabetes effectively (ADA, 2015).

Another potential reason for the results is that common treatment elements may exist across all of the three conditions, and perhaps these elements cannot be distinguished with complete clarity. This implies that regardless of the type of treatment, parallel techniques are likely delivered across the treatment conditions. In the present context, then, as part of the IPC model, PCOM physicians may actually provide patients with similar interventions across conditions, such as psychoeducation and motivational interviewing, during their typical doctor visits. A physician employed in an IPC facility

may also be more familiar with the cognitive-behavioral model and may implement some of these techniques independently. This may have created “bleed over” effects from one condition to another in the present study.

Bleed over effects occur when treatment or program effects cross over to different treatment conditions than intended, and consequently make it difficult to determine if a treatment group member received treatment only from their assigned condition (Allen, Latessa & Smith, 2015). In this study, bleed over effects may have resulted in individuals in the IPC condition receiving treatments also associated with BHC and SMAs, such as behavioral, cognitive, and motivational interviewing interventions. Furthermore, individuals who are patients at the same health care center are likely to treated by the same physicians, who could be utilizing behavioral and cognitive techniques during a typical office visit. If this indeed occurs, patients in the IPC condition would be more likely to improve without additional treatments. Unfortunately, given the archival nature of this study, it was not possible to perform a treatment integrity analysis to ascertain precisely what treatment modalities were delivered to patients.

Furthermore, PCOM’s health care centers are a considered level 3 *patient-centered medical homes* (PCMH). There are 6 elements of the PCMH outlined by the National Committee for Quality Assurance (NCQA, 2017). The elements are: 1) patient-centered access, 2) team-based care, 3) population health management, 4) care management and support, 5) care coordination and care transitions, 6) performance measurement and quality improvement (NCQA, 2017). In order to receive accreditation as a PCMH, each of the 6 elements must be present in the practice (NCQA, 2017). In addition to incorporating each of the 6 elements, health care practices are rated on a level

from *1* to *3*, based on a points system that indicates the degree to which the practice meets the NCQA requirements. The scoring breakdown is as follows: 35-59 points (Level 1), 60-84 points (Level 2), and 85-100 points (Level 3) (NCQA, 2017).

At the time of the study, the PCOM health care centers were considered to meet the highest standard and are designated as level 3 PCMH, according to the NCQA (2014). Therefore, it is incumbent upon the IPC to provide individuals with a higher level of care than they would receive during a visit to a primary care office that either does not subscribe to an IPC model or meets the criteria of a lower level PCMH. In addition to the care provided in the office, the IPC emphasizes the use of resources in the community, such as exercise programs, senior centers, and self-help groups (Bodenheimer, Wagner, & Grumbach, 2002). Research has indicated that participation in the PCHM was associated with better performance on such measures as weight loss and diabetes management, particularly improvements in hemoglobin A1c (Shi, Lee, Chung, Liang, Lock, & Sripipatana, 2017).

Individuals with diabetes have been shown to have as much as a 160-200% higher likelihood of experiencing comorbid depression compared to the general population (Gonzalez et al., 2010). The confounding variable of depression decreases the likelihood of a patient following through with the numerous self-care practices associated with successful diabetes management. A randomized control trial was completed using patient data from Massachusetts General Hospital, Ferkauf Graduate School of Psychology, and Albert Einstein College of Medicine to examine the impact of CBT for depression and its effects on poorly controlled Type 2 diabetes (Safren et al., 2013). This study specifically targeted the outcome variable of hemoglobin A1c as a measurement of secondary

improvement associated with a reduction in depression. Participants in the study either received CBT for depression plus “treatment as usual” or only “treatment as usual” (Safren et al., 2013). Individuals receiving CBT for depression participated in an average of 9-12 sessions. The CBT group received motivational interviewing, behavioral activation and mood monitoring, cognitive restructuring, problem-solving training, and relaxation training (Safren et al., 2013). At the conclusion of the study, individuals who received a combination of CBT for depression plus treatment for diabetes as usual achieved a greater reduction on HbA1c, improved medication adherence, increased glucose monitoring, and a reduction in depression scores (Safren et al., 2013).

As the field of integrated behavioral health care continues to grow, information about the patient’s response to specific levels of integration is critical. The results of this study provide empirically supported information that could be used to improve the treatment of individuals with diabetes who have struggled to begin or maintain a successful diabetes management regimen. These results offer insights into levels of improvement associated with each of the 3 levels of care, and the impact each level has on the outcome variables of BMI, cholesterol, blood pressure, and HbA1c. The information can assist in adapting the necessary level of integrated care to the patient in order to facilitate a successful patient-tailored approach. The role of the behavioral health consultant could evolve into an advocate for the patient, while simultaneously empowering both the patient and the treatment team.

Information gleaned by this study also differs from the literature in the added role PCOM’s health care centers play as a training facilities for D.O. students. At PCOM, the SMAs are conducted with a D.O. student and a behavioral health intern, without the

presence of one of the attending physicians with whom patients may have a longstanding relationship. Therefore, this SMA visit may be the first time a particular patient has met both students. It is possible that this in itself alters the dynamic of the visit and places the patient in a situation in which health care professionals with whom they are unfamiliar are asking them questions regarding physical and psychological health. This poses the potential confounding variable of trust between the patient and their health care team members. Research has shown that patient's ratings of their physician's interpersonal skills are strongly related to trust (Coulter, 2002). The personality of the health care team members may unintentionally send a negative message to patients regarding their ability or medical knowledge. Patients also reported common themes associated with trust, such as honesty, openness, responsiveness, having their best interests in mind, and willingness to be vulnerable (Coulter, 2002). Patients may consequently be less likely to accept medical advice from health care team members with whom they have limited familiarity. Efforts to improve the relationship between the patient and physician have increased positive outcomes and levels of trust (Mainous, Baker, Love, Gray, Gill, 2001). One way of achieving such improvements would entail the attending physicians meeting with patients prior to participation in the SMA to explain procedure and answer question, potentially provide a warm handoff to the other team members.

In addition to building a relationship with the health care team from the start of the visit, research targeting weight loss has indicated that SMA effectiveness increased by extending session duration and by the SMAs meeting more frequently (Palaniappan et al., 2011). At this time, no set schedule for SMAs exists at any of the pertinent health care center; participants may possibly attend only one SMA. Although participation in

an SMA yields a higher level of patient-centered care, attending only one session may not produce a significant result. Moreover, patient follow-up with physicians after the SMA should be monitored. If possible, individuals who participated in the SMA may benefit from referral to specific diabetes support groups as a way to increase continuity within the group. Research has also demonstrated that particular patients may not be comfortable disclosing the severity of their illness in a group format or may suffer from low self-efficacy related to their ability to control their chronic illness (Due-Christensen, Zoffman, Hommel, & Lau, 2012). To address these concerns, the use of cognitive behavioral therapy may be an important precursor to addressing potential barriers prior to referral to an SMA. Other factors supporting positive SMA outcomes that should be considered include a low number of patients per group, providing information regarding the utilization of family and peer support when available, clarification of the topics covered in the group education sessions, and potentially increasing patient engagement through shared group experience (Kirsch et al., 2017).

The study may also supplement existing literature regarding the development of training programs for utilization in an integrated care setting. In addition, diabetes management can be taxing on physicians, possibly causing frustration when patients do not follow through with recommendations. The findings also imply that a stronger clinical focus on diabetes management education during medical school may be appropriate. This education could include training that addresses the multitude of variables involved in the patient's ability to follow through with a treatment regimen. In the long run, specific techniques designed to improve diabetes management may

potentially reduce the cost of health care, improve treatment time, and prevent diabetes from worsening.

**Study Limitations**

The main limitation of this study is that it is not a randomized control trial; rather it represents an evaluation of services provided by the PCOM health care centers. Evaluative research's purpose is to assess the worth or success rates of a particular technique or method (Payne & Payne, 2004). When IPC, CBT, or SMA are considered in this study, a number of variables potentially operate in each treatment condition. The treatments delivered were not based on standardized protocols per se. The nonrandomized design makes the study more susceptible to confounding variables between the groups, which may have impacted the results of the study. Therefore, this study is best viewed as presenting a broad-stroke perspective, completed as an evaluation of services offered at the PCOM health care centers. As described earlier, it is also likely that there were bleed over effects across the conditions that could minimize potential differences between them.

When considering the results of this study, it is also important to consider additional unmeasured effects of participation in cognitive behavioral therapy or a SMA. SMAs are designed to provide additional self-management education to patients, teach motivational interviewing techniques, and offer peer group support (Edelman et al., 2012). Other outcome measures of SMAs, such as patient satisfaction, improved quality of care, motivation to change, and decreases in specialty and emergency room visits, were not measured in this study (Sanchez, 2011). SMAs are not intended to directly target the parameters measured in this study, such as HbA1c. Instead, patients learn

skills regarding proper diabetes management, and they are ultimately in charge of whether or not to employ these skills in their everyday lives. In addition, studies have indicated that SMAs are associated with increased patient satisfaction, more diabetes-related knowledge, improved self-management, lifestyle and behavior change, improved depression scores, increased motivation to change, increased quality of life, and decreased stress (Culhane-Pera et al., 2005; Dickman, Pintz, Gold, & Kivlahan, 2012; Menon et al., 2017; Pieber et al., 1995; Rygg, Rise, Gronning, & Steinsbekk, 2012).

Evidence in the literature suggests that patient motivation affected performance following an SMA and may impact whether or not an individual returned for an additional SMA. Sanchez (2011) found that individuals deemed unmotivated to manage their diabetes had higher A1c levels and did not return for their follow-up SMA visit. Additional research conducted on a patient population diagnosed with Type 1 diabetes found that the benefits of a SMA were not significantly greater than a traditional visit to a physician on the outcome measure of HbA1c (Everest et al., 2016). This study proposes SMAs as a valid alternative to a traditional medical visit.

It should also be noted that the number of SMAs attended by the patient was not recorded in this study. This may be an important factor in determining whether individuals who participated in multiple SMAs had better outcome measures than individuals who participated in fewer or only one. It is possible that participation in more than one SMA may be necessary to produce a clinically significant improvement over IPC alone. This possibility is consistent with Menon et al. (2017), in which African Americans who participated in four SMAs over a period of 6 months experienced a decrease in HbA1c from 8.2, to 7.1. Moreover, research has indicated that cognitive

behavioral therapy positively impacts diabetes management by targeting secondary factors not measured in this study.

Also, data indicating the interval between SMA and outcome measures were unavailable for analysis by this study. The interval between SMA and outcome measures is an important consideration for future research, because individuals may experience stronger motivation immediately after an SMA

Another significant limitation of this study is the lack of diversity in its population. Philadelphia College of Osteopathic Medicine's four health care centers are located in urban areas. The population in this study is more likely to be affected by significant barriers that are less likely to be faced by individuals with a higher socioeconomic status. These barriers include access to care, safe housing, insurance, and transportation. These individuals may require a higher level of integrated care than the general population, which would affect the generalizability of the results to other populations. A larger scaled study would allow for more precise identification of specific individual factors occurring in the study's population and so create an opportunity to identify specific subgroups for whom SMAs are particularly effective (Kirsh, 2017).

The use of BMI as an outcome measure faces doubts about its utility due to inconsistencies in the research. BMI was chosen because it allows a larger overall picture than weight loss, which fluctuates more drastically. However, BMI has limitations of its own that require consideration in interpreting this study's results. First, growing concern is evident in the literature about the relationship between aging and BMI. Of particular concern is the accuracy of BMI in individuals who are middle-aged or older, as well as in menopausal women (Prentice & Jebb, 2001). The concern is that in

an aging population, the percentage of body fat increases; BMI may not accurately attribute increases in body fat in this group (Prentice & Jebb, 2001).

Another variable impacting the accuracy of BMI is race and ethnicity. Because BMI isa one-size-fits-all classification, differences in body type related to cultural factors are not included in measures of BMI. For example, in contrast to Caucasians, other races and ethnicities have manifested significant differences in BMI that are acknowledged by the classification system (Prentice & Jebbs, 2001). Military personnel and athletes are another subset of the population that may be represented inaccurately by BMI; these individuals have more muscle mass than the general population, which presents a greater likelihood of inaccurate classification as overweight or even obese (Prentice & Jebbs, 2001). A final potential shortcoming is that although BMI may provide a uniform classification system, it does not provide such critical information as the location of body fat. Large amounts of upper body fat have been associated with an increase in heart disease and diabetes (Nuttall, 2015). Therefore, the classification of an individual's BMI alone fails to provide or assess critical information needed to identify the complete range of risk factors.

Another limitation of this study is that it did not take into account the time elapsed since an individual was diagnosed with diabetes. This factor may be important, because newly diagnosed individuals may react to their treatment regimen differently from individuals who were diagnosed a number of years earlier. Self-efficacy is an important variable related to the interval since diagnosis. Self-efficacy has proven to decrease in newly diagnosed patients who undergo an intensive diabetes treatment regimen (Thoolen, Ridder, Bensing, Gorder, & Rutten, 2006). An increase in self-reported depressive

symptoms in newly diagnosed patients was an important confounding variable related to decreased self-efficacy (Thoolen, Ridder, Bensing, Gorder, & Rutten, 2006). However, when self-efficacy was examined in a group of individual who were diagnosed more than two years earlier, it decreased when these patients received nonintensive care (Thoolen, Ridder, Bensing, Gorder, & Rutten, 2006).

Physicians included in this study are mainly D.O. students drawn from a single osteopathic medical school. Also, the sample size was small. These factors may limit the external validity of the results. Moreover, the study does not account for the personal style of the physician or behavioral health expert throughout the conditions.

**Future Directions**

According to the ADA (2012), a significant gap exists in the literature regarding SMAs in which the same standardized curriculum was implemented in both a control and an intervention group. A standard SMA curriculum may help control for some of the confounding variables, such as the depth of the physician's knowledge about diabetes. In addition, clinical trials in which the same health care professionals provided services in the one-on-one and SMA visits are lacking. No studies exist in which SMAs and traditional individual appointments occurred on the same day (ADA, 2012). The implementation of an SMA may also be more beneficial when a professional trained specifically in diabetes management, such as a diabetic nurse, provided diabetes education (ADA, 2012). Another gap in the literature exists concerning long-term monitoring of patients subsequent to participation in an SMA. One possible explanation for the scarcity of data is that the implementation of the SMA is a relatively recent

development. However, further data could be mined regarding potential improvement in participants over longer periods of time.

The results of this study can assist in the development of a training curriculum for physicians that specifically target diabetes management. The research may also offer advocacy for patients who might otherwise be considered as difficult to work with by providers. This study also focused only on diabetes management subsequent to a diabetes diagnosis. Future research targeting prediabetes and an effective course of treatment to prevent the development of Type 2 diabetes would be invaluable.

In conclusion, this study only examined outcome variables regarded as directly linked to successful diabetes management. However, the literature lacks consistency about outcome variables that can be directly attributed to BHC or SMA (Kirch, 2017). The study also did not investigate potential individual factors in that may affect a patient's capacity to improve in those outcome variables. Therefore, research that includes psychological and biological measures would be useful in exploring the potential impact of treatments, allowing researchers to determine whether or not reductions in psychological stressors improve a patient's ability to manage diabetes successfully.

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