SHARED DECISION-MAKING INTERVENTION TO IMPROVE DIABETES MEDICATION ADHERENCE

By

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DISSERTATION

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Dedication

I dedicate my Ph. D dissertation to my wife, Bernice, and our sons Christopher, Solomon, and Raphael Baba.

Abstract

A quasi-experimental study was conducted to investigate the effectiveness of a shared-decision-making (SDM) intervention using a decision aid (DA) with medication adherence and social support of African American/Black adults with type 2 diabetes. Orem's self-care theory and self-care deficit theory were the guiding frameworks to conceptually define and explain medication adherence as a self-care demand and shared decision making and social support as conditioning factors for promoting medication adherence. The medication adherence and social support levels of 31 men and women with diabetes were measured before and three months after implementing the SDM intervention. Participants' hemoglobin A1c (Hg A1C) test results were documented, and mixed-linear model analysis was conducted to determine the effectiveness of the SDM intervention. The results indicated that the diabetes medication adherence after the SDM was effective with a significant increase in the subjects' medication adherence from pretest (6.55) to posttest (7.14) (p=.001). The subjects' level of social support reduced from 42.47 before the SDM intervention to 42.42 after the SDM intervention, and social support was not significantly related to medication adherence (p=.307). Given that the increase in the subjects' medication adherence was less than the predicted level (2) in the hypothesis, further research is recommended to determine what the SDM might include for an intervention that will have a greater impact on medication adherence.

Table of Content

List of Tables

Chapter I

Introduction

Shared Decision-Making Intervention to Improve Diabetes Medication Adherence a

Diabetes mellitus (D.M.) is a metabolic disorder characterized by high blood glucose levels due to insulin resistance and insulin deficiency (World Health Organization [WHO], 2017). In 2018, the prevalence of D.M. for African American adults was 13.3%, compared to 9.4% for non-Hispanic White adults (American Diabetes Association [ADA], 2020). African American adults were thus 1.6 times more likely to be diagnosed with D.M. than non-Hispanic Whites. African American adults are two to three times more likely than non-Hispanic Whites to suffer diabetes-associated kidney failure, blindness, lower limb amputation, and mortality (U.S. Department of Health and Human Services, 2015). Shared Decision Making (SDM) is a collaborative bi-directional mutual exchange of information discussion, including collaboration leading to a routine care goal/choice (Truglio-Londrigan & Slyer, 2018). This chapter included the study's background and significance, a statement of the study's hypotheses, and a description of the theoretical framework to guide the study.

Background and Significance

D.M. is a chronic multisystem disease related to abnormal insulin production, impaired insulin utilization, or both. It results in low glucose metabolism (Lazear, 2014). The beta cells in the pancreas produce insulin, which is continuously released into the bloodstream in small pulsatile increments that maintains a normal blood glucose range of approximately 70 to 120 mg/dL in an adult (Lazear, 2014). The main types of D.M. are type 1 (T1D), type 2 diabetes (T2D), and gestational (pregnancy-associated) D.M. In T2D, the most common type of D.M., the pancreas continues to produce insulin, but the insulin produced is insufficient for the body's needs or is not effectively used by the tissues or both (ADA, 2016). Management of T2D includes eating healthy meals, performing regular physical activity, maintaining healthy body weight, and adhering to medication therapy (CDC, 2015; WHO, 2016).

The prevalence of D.M. in the United States in 2018 was 34.2 million, comprised of 26.9 million diagnosed and 7.3 million undiagnosed individuals (Centers for Disease Control and Prevention [CDC], 2020). About 1.5 million new cases of D.M. (10.5%) are diagnosed among U.S adults aged 18 years and older every year (ADA, 2020). Among African American adults aged 20 years and older, 2.3 million have diabetes, comprising 10.8% of that age group (CDC, 2015). In 2014, the age-adjusted prevalence of D.M. in African American women was 9.9 per 100 compared with the rate of 9.2 per 100 in African American men (CDC, 2015). The rate of D.M. for non-Hispanic White males is relatively low at 6.5 per 100, and the rate for non-Hispanic White females is 5.3 per 100 (CDC, 2015). The rates illustrate the disproportionate magnitude of the problem of D.M. in African American adults. D.M. is the 7th leading cause of death in the U.S. and the most common causes of kidney disease, non-traumatic lower-limb amputations, and new cases of blindness among adults (CDC, 2020). African American adults are two to three times more likely than non-Hispanic Whites to suffer diabetes-associated kidney failure, blindness, lower limb amputation, and mortality (U.S. Department of Health and Human Services [DHHS], 2015).

Despite the benefits of medication in disease management, 50% of patients with chronic diseases do not take their medication as prescribed (Lawrence et al., 2017). The rate of poor medication adherence in patients with D.M. is even higher, at 65% to 85% (Curkendall et al., 2013). Half of the 3.2 billion medication prescriptions dispensed in the U.S. yearly were not taken as prescribed (Brown & Bussell, 2011). About 12,500 deaths per year in the United States are associated with medication nonadherence. Between 33% and 69% of medication-related hospital admissions are related to medication nonadherence (Lawrence et al., 2017). Apart from poor health outcomes, medication nonadherence increases the cost of health care. Nonadherence costs range from $100 billion to $300 billion each year (Lawrence et al., 2017). African Americans with D.M. are less adherent to prescribed D.M. medication than Non-Hispanic Whites, even with the same level of access to medications (Shiyanbola et al., 2018). Much of patients' D.M. management occurs within their family and social environment. Involving family members in self-management interventions may positively influence D.M. outcomes such as medication adherence (Baig et al., 2015).

Shared Decision Making (SDM) between health professionals and patients and families is receiving national and international interest from providers, educators, and researchers and has been shown to improve medication adherence (Allen et al., 2018; Den Ouden et al., 2018; Moin et al., 2019). SDM interventions have been associated with patients' improved adherence to their medications and recommended lifestyle changes. Few intervention studies target SDM between clinicians and patients. Additionally, no studies were found to include patient family members in the SDM process. Further, no recent studies were found in which researchers investigated the effectiveness of a SDM intervention on diabetes medication adherence and family social support in African American adults. This literature gap supports a study to examine the efficacy of an SDM Decision Aid (DA) intervention on medication adherence in African American adult T2D patients.

Conceptual Framework

Dorothea E. Orem developed three major interrelated nursing theories, the theory of self-care, the theory of nursing systems, and the theory of self-care deficit. The self-care theory describes the performance or practice of activities initiated by individuals to maintain life, health, and wellbeing (Marriner-Tomey, & Alligood, 2010). Self-care promotes structural integrity, human functioning and contributes to social growth and development. People learn self-care through interpersonal relations and communication (Marriner-Tomey, & Alligood, 2010).

The nursing systems theory describes how self-care needs are met by the nurse, the patient, or both patient and nurse. Nurses exercise their nursing agency using deliberate actions, including intentionality and operations of diagnosis and regulation.

The self-care deficit theory delineates that nursing is required for individuals who are not capable of or are limited in providing continuous, effective self-care. The theory of self-care deficit was the primary guiding framework for this study. Self-care deficit is the central construct of the self-care theory. Therefore, concepts of self-care theory and self-care deficit theory were used to operationalize the study's variables (Marriner-Tomey, & Alligood, 2010). According to Orem's self-care theory, self-care is a human function performed by an individual to maintain life (Marriner-Tomey & Alligood, 2010). Self-care is influenced by a person's culture, environment, and other people (Simons, 2009). People have a natural ability to perform self-care, and individuals whose needs for self-care outweigh their ability to engage in self-care are said to have a self-care deficit (Simmons, 2009). According to Orem's theory of self-care, all patients wish to care for themselves. They can recover quickly and holistically if they are allowed to perform their self-care to the best of their ability (Marriner-Tomey, & Alligood, 2010).

Major Concepts of Orem's Theory of Self-Care Deficit

Nursing

Dorothea Orem defined nursing as the act of assisting others in the provision and management of self-care to maintain or improve human functioning at home level effectiveness (Orem, 1991). Nursing is an art through which the nursing practitioner gives specialized assistance to patients to meet self-care needs and encompasses the patient's perspective of health, the physician's perspective, and the nursing perspective. Nursing goals enable the patient or family members to meet the patient's self-care needs and maintain a state of health (Orem, 1991).

Human Beings

Human beings are conceptualized as total beings with universal and developmental needs, capable of continuous self-care (Orem, 1991). Humans are men, women, and children cared for, either singly or as social units, and are the material objects of nurses and others who provide direct care. Human beings can reflect, symbolize, use symbols, and function biologically and symbolically (Orem, 1991). Orem viewed the individual as both the agent of action (the one performing activities) and the object of the action (the one on which others act) (Kumar, 2007).

Health

Orem's self-care deficit theory describes health as structural and functional wholeness that encompasses individuals and groups (Orem, 1991). Healthy humans can reflect on themselves, symbolize experiences, and communicate with others.

Environment

The environment is comprised of physical, chemical, and biological components and includes families, culture, and community (Orem, 1991).

Self-Care

Self-care is the practice of activities that the individual initiates and performs on their behalf to maintain life, health, and wellbeing (Orem, 1991). Self-care is distinct from nursing care and dependent care (Denyes et al., 2001; Simmons, 2009).

Relationships between Relevant Concepts

The self-care deficit theory's four significant concepts relevant to this study are self-care deficit, self-care agency, conditioning factors, and nursing agency (Orem, 1991). The power and ability of individuals to engage in self-care are termed self-care agency. Shared decision making (SDM) is a self-care agency and is influenced by conditioning factors, including family members, the environment, friends, culture, and the individual's developmental stage, also stated as social support and shared decision making (SDM) (Denyes et al., 2001). The activities necessary to maintain, restore, or improve self-care are termed self-care demands, which would include medication adherence (Denyes et al., 2001). Structural and physiological changes that affect the individual's self-care performance are termed self-care deficits (Marriner-Tomey, & Alligood, 2010). Orem also described nursing agency as a complex property or attribute of people educated and trained as nurses that enables them to act, know, and help others meet their therapeutic self-care demands by exercising or developing their self-care agency (Denyes et al., 2001).

Significant Assumptions of Orem's Self-Care Deficit Theory

The significant assumptions of Orem's self-care deficit theory are:

1. Human beings are self-reliant and responsible for their care and others' care in their family who need care.
2. Each person is distinct
3. Nursing is a form of action, an interaction between two or more people
4. Successfully meeting universal and development self-care requisites is an essential component of primary care prevention and ill health
5. Knowledge of potential health problems is needed for promoting self-care behaviors
6. Self-care and dependent care are behaviors learned within a socio-cultural context

Theoretical Concepts and Links to Study Variables

Orem's self-care deficit theory was an appropriate guiding framework for the study to evaluate the effectiveness of an SDM DA intervention on diabetes medication adherence and family social support in African American/Black adults with T2D. Patients with diabetes have self-care deficits (difficulty controlling blood sugar level). Diabetic patients may require a self-care agency (ability and willpower), conceptualized as an SDM decision aid intervention. Nurses facilitate the shared decision-making process by describing diabetes medication adherence options; however, the patients decide which options from the decision aid to promote medication adherence. Therefore, an SDM DA is a self-care agency that gives patients the ability and willpower to adhere to diabetes medication therapy.

Additionally, conditioning factors (social support, family) and nursing agencies (clinicians) can promote medication adherence by reminding patients to take their medication and providing medication adherence teaching to meet their self-care demands (medication adherence). Hyperglycemia, an above-normal elevated blood sugar level, causes T2D patients to develop symptoms and not maintain self-care. Diabetic patients, therefore, lack the self-care agency needed to maintain self-care and therefore, need nursing care. Conditioning factors such as family social support is necessary to meet the self-care demands, such as medication adherence and maintenance of personal hygiene. Hyperglycemia was conceptualized as a self-care deficit and measured as hemoglobin A1C level. Medication adherence was conceptualized as self-care demand measured by the MMAS-8, while social support was conceptualized as a conditioning factor and measured by the BSSS. SDM was conceptualized as a self-care agency and measured by the use of the SDM DA intervention. The relationship between Orem's self-care deficit theory and the proposed study variables is presented in the construct, concepts, and variables table below.

Table 1

Theoretical Construct, Concepts, and Operationalization of Study Variables

Construct	Concept	Variable	Measurement
Self-care	Self-care deficit	Hyperglycemia	Blood sugar level
	Self-care demands	Medication adherence	MMAS
	Self-care agency	Ability to adhere to medication	SDM DA Choices (Patient teaching, improved dosing, enhanced communication, provider availability, Welth App)
	Conditioning factors	Social support (family)	BSSS

Purpose of the Study

The purpose of this study was to determine the effectiveness of a shared decision-making (SDM) intervention using a decision aid (DA) and family social support to improve medication adherence in African American adults with T2D. Orem's self-care deficit theory was the guiding framework to conceptually define and explain medication adherence as a self-care demand and shared decision making and social support as conditioning factors for promoting medication adherence with the use of a shared decision-making decision aid.

Hypotheses

There were two hypotheses for this study:

1. Implementing a shared decision-making intervention using a diabetes medication adherence decision aid will increase medication adherence with an average change in pretest scores on the MMAS by 2.
2. There will be a positive relationship between social support and medication adherence in patients and family members after a diabetes medication adherence shared decision aid intervention.

Summary

Diabetes mellitus (D.M.) affects about 34.2 million people in the U.S., making it one of the country's most critical chronic conditions (ADA, 2020). D.M.'s prevalence continues to rise, with about 1.5 million new cases of D.M. diagnosed every year (ADA, 2018). About 13% of adults in the U.S. have D.M., representing a significant economic and public health burden (ADA, 2018). Despite the benefits of medication in disease management, 50% of patients with chronic diseases do not take their medication as prescribed (Lawrence et al., 2017). The rate of poor medication adherence in patients with D.M. is even higher, at 65% to 85% (Curkendall et al., 2013). African Americans with D.M. are less adherent to prescribed D.M. medication than Non-Hispanic Whites, even with the same level of access to medications (Shiyanbola et al., 2018).

Shared decision-making has been advocated to improve the quality of patient outcomes (National Institute of Diabetes and Digestive and Kidney Diseases, 2019). In the context of diabetes management, a sound shared decision-making approach first requires that health care professionals understand current treatment recommendations and that patients receive guidance when choosing treatment options (National Institute of Diabetes and Digestive and Kidney Diseases, 2019). Shared decisions to promote diabetes management can be facilitated by using decision aids (e.g., local resources, brochures, booklets, videos) to provide evidence-based information about various therapy options and offer an opportunity to explain expected outcomes, risks, and benefits to patients for improved results (National Institute of Diabetes and Digestive and Kidney Diseases, 2019).

Chapter II

Critical Review of Relevant Literature

This chapter included support for the significance of diabetes in African Americans/Blacks. The population of African Americans with diabetes was described, and a critical review of the literature was presented, supporting the identification of a research problem. Research evidence supported a positive correlation between social support, diabetes self-management, and medication adherence. However, few studies investigated whether using shared decision-making (SDM) with a decisional aid (DA) improved medication adherence and improved family social support in patients with T2D (DiMatteo et al., 2012).

Search Strategy

A thorough search of relevant, published literature was completed by reviewing multi-disciplinary journal articles on diabetes mellitus type 2, diabetes medication adherence, and social support for African American adults with T2D. Published literature between 1991 and 2021 was obtained from PubMed, Science Direct, EBSCO, CINHAL, and Psych Articles. Relevant information was also obtained from government websites, including the Centers for Disease Control and Prevention (CDC), the American Diabetes Association, and the Department of Health & Human Services. Search terms used for article inclusion were shared decision making, diabetes medication adherence, diabetes self-management in African Americans/Blacks, interventions to improve diabetes medication adherence, and diabetes management. Search terms such as research in the United States, African American Adults, English language, and human studies were used to exclude other studies not relevant to the literature review. Thirty-two relevant articles from nursing, medicine, public health, and the social sciences were reviewed.

Significance of Diabetes

Diabetes mellitus (D.M.) is a metabolic disorder characterized by high blood glucose levels due to insulin resistance and insulin deficiency (WHO, 2017). The prevalence of D.M. in the United States in 2018 was 34.2 million, comprised of 26.8 million diagnosed and 7.3 million undiagnosed people (Centers for Disease Control and Prevention [CDC], 2020). About 1.5 million new cases of D.M. (6.7 per 1,000 persons) are diagnosed among U.S adults aged 18 years and older every year (American Diabetes Association [ADA], 2020). In 2015, the prevalence of D.M. for African American adults was 13.2%, compared to 7.6% prevalence for non-Hispanic White adults (ADA, 2016). African American adults were thus 1.7 times more likely to be diagnosed with D.M. than non-Hispanic Whites. According to the CDC (2015), among African American adults aged 20 years and older, 2.3 million had D.M. in 2014, comprising 10.8% of that age group, and the age-adjusted prevalence of D.M. in African American women was 9.9 per 100 compared with the rate of 9.2 per 100 in African American men. In contrast, the rate of D.M. for non-Hispanic White males was relatively low that year, at 6.5 per 100, and the rate for non-Hispanic White females was 5.3 per 100. The rates illustrated the disproportionate magnitude of the problem of D.M. in African American adults.

D.M. is the 7th leading cause of death in the U.S. and the most common cause of kidney disease and non-traumatic lower-limb amputations. D.M. is the leading cause of new cases of blindness among adults (CDC, 2020). About 73,000 adults ages 20 years or older suffered DM-associated non-traumatic lower-limb amputations, and 4.5 million adults developed DM-related vision problems and blindness between 2005 and 2008 (ADA, 2015). African American adults were two to three times more likely than non-Hispanic Whites to suffer diabetes-associated kidney failure, blindness, lower limb amputation, and mortality (U.S. DHHS, 2015). The annual healthcare cost for D.M. in 2014 was 245 billion, which included the cost of treatment for DM-related blindness, non-traumatic amputations, renal and heart diseases, low productivity, and absenteeism from work (CDC, 2017). The average medical expenditure incurred by people with D.M. per annum in 2016 was about $9,060 (ADA, 2018). The total per capita cost of diabetes care for African Americans was higher ($10,470) than the total per capita cost for non-Hispanic Whites at $9,800 in 2016 (ADA, 2018).

Types of Diabetes Mellitus

According to Lazear (2014), D.M. is a chronic multisystem disease related to abnormal insulin production, impaired insulin utilization, or both, which results in poor glucose metabolism. Lazear explained that the beta cells in the pancreas produce insulin, which is continuously released into the bloodstream in small pulsatile increments to maintain a normal blood glucose range of approximately 70 to 120 mg/dL in an adult. The amount of insulin released gradually increases to prevent hyperglycemia when a person eats. Insulin regulates blood sugar levels by facilitating glucose transportation from the bloodstream to the cells, stimulating glucose storage as glycogen in the liver and skeletal muscle, and inhibiting excess production of glucose (Lazear, 2014).

The main types of D.M. are type 1 (T1D), type 2 (T2D), and gestational (pregnancy-associated) D.M. T1D affects 5% of all people with D.M. The risks for T1D include genetic predisposition and viral infections, which cause the body's immune system to destroy the cells in the pancreas that produce insulin (WHO, 2016). The destruction of pancreatic cells occurs for months to years before symptoms of T1D are manifested and when the pancreas can no longer produce insulin (Lazear, 2014). T1D commonly develops in people younger than 40 years, but younger children (5-8 years) have the highest prevalence of T1D (ADA, 2016). Gestational diabetes mellitus (GDM) occurs in 2-10% of pregnancies because of the hormonal and weight changes experienced during pregnancy. GDM is typically a temporary condition, but women who experience it have an increased long-term risk of T2D (WHO, 2016).

In T2D, the pancreas continues to produce insulin, but the insulin produced is insufficient for the body's needs or is not effectively used by the tissues or both (ADA, 2016). The risks for developing T2D include older age, obesity, family history of diabetes, history of pregnancy-related D.M., impaired glucose metabolism, physical inactivity, and race/ethnicity (WHO, 2016). Common symptoms of diabetes are increased frequency of urination, thirst, hunger, blurred vision, and delayed wound healing (WHO, 2016).

The primary goal of the treatment of diabetes is to control blood sugar levels to prevent complications of the disease (CDC, 2017). People with T1D do not produce insulin and require insulin therapy to manage their symptoms (CDC, 2015). In addition to insulin, T1D is managed with dietary changes and exercise (ADA, 2016). Management of T2D includes eating healthy meals, performing regular physical activity, maintaining healthy body weight, and adhering to medication therapy (CDC, 2015; WHO, 2016). The medications used to manage T2D include both non-insulin drugs and insulin. Medications for T2D work by increasing insulin sensitivity and glucose excretion or decreasing the absorption of carbohydrates from the digestive tract (ADA, 2016). Drugs for T2D can be used in combination and administered to patients using syringes, pre-filled pens, insulin pumps, and ingestion. The choice of medication for T2D can vary depending on the individual's medical and social history, medication adherence, medication effectiveness, and cost (ADA, 2016).

People with D.M. can control the disease's symptoms with appropriate medical care and regular self-management of blood sugar (CDC, 2017). Diabetes self-management strategies include consistent blood glucose monitoring and management and adopting healthy behaviors (WHO, 2016). Seeking medical help and adhering to a medical management plan can help patients control their blood sugar levels. Recommended self-management behaviors include healthy eating and moderation, regular physical activity, and avoiding tobacco products (CDC, 2015).

T2D Medication Adherence

Management of chronic diseases such as D.M. commonly involves long-term medication use (Lazear, 2014). Medication adherence is the extent to which patients follow the provider-recommended daily medication treatment concerning timing, dosage, and frequency (Lawrence et al., 2017). Patients are non-adherent if they take less than 80% of the prescribed medication doses or take more doses than recommended (Lawrence et al., 2017).

Lawrence et al. (2017) conducted a systematic literature review of randomized clinical trials to determine the predictors for, measure, and interventions to improve adherence in selected United States extensive clinical facilities. Lawrence et al. (2017) also conducted a literature search to identify published reports in which self-report and non-self-report measures of adherence were used in the same study. Eighty-six comparisons of self-reports to non-self-reports were identified (Lawrence et al., 2017). They found that despite the benefits of medication in disease management, 50% of patients with chronic diseases did not take their medication as prescribed (Lawrence et al., 2017).

Unni et al. (2021) conducted a cross-sectional study to investigate the trends of self-reported medication non-adherence among United States adult type 2 diabetes patients using the Self-reported Medication Adherence Reason Scale (MAR-Scale). The MAR-Scale measured non-adherence "in the past seven days" on an 8-point scale ranging from 0 to 7 days. Data for the study were collected from the 2017 to 2019 National Health and Wellness Survey. Data were collected on 2,983 respondents in 2017, 5,416 in 2018, and 5,268 in 2019 (Unni et al., (2021). The researchers used frequencies to identify the reasons for non-adherence to insulin and non-insulin therapies for T2D. Based on the MAR-Scale, the self-reported medication non-adherence rate was 25% in 2017, 21% in 2018, and 27% in 2019 (Unni et al., 2021). The most common reason for non-adherence across the three years was simply forgetfulness. The following two most common reasons for T2D medication non-adherence were the long-term effects of medicines and missing doses due to a busy schedule or change in schedule (Unni et al., 2021). Respondents indicated that non-adherence to T2D lasted longer when they did not know how to take medicines or had concerns about the long-term effects of the medication, and they said cost was a problem in obtaining medications (Bingham et al., 2021).

The rate of poor medication adherence in patients with D.M. was found to be even higher, at 65% to 85% (Curkendall et al., 2013). Patients from different backgrounds, including Whites, non-Hispanic Whites, and African Americans, were selected for the study to determine the impact of a broad range of factors on medication adherence and persistence among adult patients with type 2 diabetes mellitus (Curkendall et al., 2013). The patients were recruited using

Truven Health MarketScan Research Databases of healthcare administrative claims (2009 through 2012). Curkendall et al. (2013) measured adherence and endurance using the proportion of days covered and time to discontinuation, respectively. Multivariate models were used to examine the impact of study drugs and demographic and clinical factors. The study results indicated that half of the 3.2 billion medication prescriptions dispensed in the U.S. yearly were not taken as prescribed (Brown & Bussell, 2011).

Brown and Bussel (2011) reviewed Medline-based literature on factors contributing to poor medication adherence in the United States. They found about 12,500 deaths per year in the United States were associated with medication nonadherence. Apart from poor health outcomes, medication nonadherence increased the cost of health care. Nonadherence costs ranged from $100 billion to $300 billion each year (Lawrence et al., 2017). African Americans with D.M. were less adherent to prescribed D.M. medication than Non-Hispanic Whites, even with the same level of access to drugs (Brown & Bussel, 2011; Shiyanbola et al., 2018).

Measurement of Medication Adherence

Health care professionals have a limited ability to measure medication adherence objectively. Lawrence et al. (2017) also systematically reviewed publications on medication adherence. They found that standard methods of measuring medication adherence were performing therapeutic drug concentration monitoring, disease activity measures, pillbox counts, tracking pharmacy refill records, and self-report by patients. Performing a direct, objective measurement such as monitoring drug concentration (therapeutic drug monitoring [TDM]) is only available for a small number of drugs. The test results usually reflect medication-taking behaviors for a preceding short-term (Lawrence et al., 2017). Medication adherence can also be assessed indirectly through objective disease activity measures such as blood pressure, hemoglobin A1C, or HIV plasma viral load.

Although these disease activity measures are sensitive, they do not explicitly indicate adherence because they can be affected by other factors such as stress or illness. Counting pills in a pill container can be a feasible and valuable adjunct to self-reporting. Still, patients may perceive this method as obtrusive, and it may be logistically challenging and costly for the researcher or health worker to conduct unannounced pill counts (Lawrence et al., 2017). Tracking pharmacy refill records can be an alternative, effective, and non-obtrusive method because of the ability to verify counts of medications from the dispensing facility, the prescriber, and the patient. Lam et al. (2015) conducted a comprehensive review (2005-2014) of subjective and objective measures of medication adherence, including direct measures, measures involving secondary database analyses, electronic medication packaging (EMP), pill count, and clinician assessments. According to Lam et al. (2015), refill adherence assumed that the patient's prescription-refilling patterns corresponded to the patient's medication-taking behavior and that the medication was taken as prescribed. A disadvantage of refill tracking is that partial adherence, where patients only take some of the medicines in that interval, cannot be evaluated using this method (Lam & Fresco, 2015; Lawrence et al., 2017).

Factors Associated with Medication Adherence

There are several reasons why patients do not take their medications as prescribed, including provider-related causes, health system-related factors, and patient-related factors (Brown & Bussell, 2011; Shinyanbola et al., 2018; Uni et al., 2021). Brown and Bussel (2011) performed a MEDLINE-based literature review of 405 published studies between 1990 and 2010 to identify factors contributing to poor medication adherence in patients with cardiovascular diseases. They found that ineffective communication between the patient and the provider, possibly related to a patient misunderstanding a complex medication regimen or health literacy, could be associated with nonadherence (Brown & Bussell, 2011). Poor medication adherence was related to limited time spent with patients, limited access to care, and lack of health information technology (Lawrence et al., 2017).

Uni et al. (2021) analyzed self-reported medication adherence using the medication adherence reason scale (MAR-Scale). They found that the most common reasons for T2D medication non-adherence were forgetfulness, having a busy schedule, or a schedule change. Additionally, reasons for low medication adherence in African American diabetes patients included medication side effects (weakness, metallic taste, and abdominal upset), disbelief in diabetes diagnosis, and poor access to medication (high cost) and information about diabetes medication (poor literacy).

African Americans and Medication Adherence

Shiyanbola et al. (2018) researched African American adults' perception of label/identity, timeline, cause, treatment, and consequences of type 2 diabetes using a qualitative explorative, descriptive approach. A purposive sample of English-speaking African American men (n=35) and women (n=36) ages 45-60 years participated in the study. Demographic data (age, gender, marital status, and family income) and clinical characteristics (number of chronic illnesses and years with diabetes) were collected using self-reported questionnaires (Shiyanbola et al., 2018). Focus group discussions and interviews were done using interview guides and open-ended questions. The conversations and interviews were audio tape-recorded, transcribed verbatim, and analyzed using qualitative content analysis (Shiyanbola et al., 2018). The themes identified were perception of the timeline of diabetes, perception of treatment and personal control of diabetes, emotional representation of diabetes, fear and doubt of the future, anger and frustration with diabetes, and concerns about diabetes. Reasons for low medication adherence in African Americans with D.M. included concerns about medication side effects (metallic taste, weakness, and stomach upset), fear of complications (weakness and perceived sexual weakness), frustration associated with taking medicines such as remembering to take medication, the perception of illness as a curse and reaction to diabetes (anger, denial, and disbelief of D.M. diagnosis), and poor access to medicines and information about the medication (Shiyanbola et al., 2018).

Mayberry and Osborn (2012) used a mixed-method design to explore the relationships between participants' perception of family members' diabetes-specific supportive and non-supportive behaviors and participants' medication adherence and glycemic control (hemoglobin A1C). The qualitative data were collected using focus group discussions about the barriers and facilitators to diabetes management (n=45) and online surveys about barriers and facilitators of diabetes management (n=61). Eleven focus groups (six per group) were conducted with qualitative content analysis using Nvivo 9. The results showed that African Americans who reported having a high level of social support also adhered to their medications better than those who reported lower social support. The hemoglobin A1C test results of participants were extracted from their medical records. Participants' perception of family members' supportive and non-supportive behaviors was assessed with an adapted subscale from the Diabetes Family Behavior Checklist (DFBC). The quantitative data analysis revealed that about 24% of the participants had less than necessary health literacy skills and could not understand, engage, and actively apply health information to improve their health and medication adherence (Mayberry & Osborn, 2012).

Social Support

In healthcare, social support refers to emotional and practical help from others to promote health and wellbeing (Seeman, 2008). Social support can be a resource for coping and helps to adjust to living with DM (Heo et al., 2014). Reblin et a., (2008) summarized research findings in a literature review from selected publications focusing on links between social support and physical health. Health professionals commonly identify four social support forms: emotional support, instrumental support, structural support, and informational support (Reblin et al., 2008). Seeman (2008) defined emotional support as assistance provided by family and friends for patients to make them feel loved and cared for and increase their sense of self-worth. She explained that examples of emotional support include talking over a problem and providing encouragement/positive feedback. Emotional support often takes the form of nontangible types of assistance.

In contrast, she explained that instrumental/practical support is tangible assistance others may provide for patients. Forms of instrumental support include help with childcare, housekeeping, and transportation or money (Seeman, 2008). Instrumental support may involve paying for a patient's medication, picking up prescriptions, reading labels, and filling pillboxes (Scheurer et al., 2012). Informational support refers to help that others offer to patients by providing information such as sharing information about healthcare resources (Reblin et al., 2008). Structural support is available to people through family relationships, friends, and membership in clubs and organizations or social networks (Scheurer et al., 2012).

Heo et al. (2014) examined the associations between social support and various health outcomes in heart failure patients. Heo et al. (2014) collected social support data (marital status, family relationships, relationships with health care providers, social networks, emotional support, and instrumental support), symptoms, and HRQOL from 71 patients. Heart failure patients were recruited from a mid-Atlantic hospital. A cross-sectional study design was used to examine the relation of social support with physical symptoms, depressive symptoms, and HRQOL in a convenience sample of patients with HF who received care at a city hospital in the United States. Hierarchical regression was used to analyze the data (Heo et al., 2014). People with high levels of structural support from family, friends, or the community experienced less stress and coped more effectively than people without robust structural support systems (R^2=.540 and .568 respectively; p=.009 and p=.003). They reported that social support had been found to positively impact recovery in various medical illnesses ($R^2 = .062$, $p = .036$).

Relationship between Medication Adherence and Social Support in T2D

Evidence from a systematic review suggested that varying relationships between social support and medication adherence among different ages and ethnic groups exist (Miller & DiMatteo, 2013). Miller and DiMatteo reviewed 92 published articles to determine the impact of social and family support on treatment adherence in patients with diabetes. It is thought that when family members and friends provide practical and emotional support to patients with diabetes, it promotes self-esteem and reduces stress, anxiety, and depression (Bouldin et al., 2017; DiMatteo et al., 2013).

Bouldin et al. (2017) conducted a cross-sectional study using baseline data from 253 patients aged 30-70 years with poorly controlled D.M in the United States. Participants reported receiving assistance from a friend or family member in the past month. The family and friends were classified as caregivers. Multivariable linear and logistic regression models were used to evaluate the associations between having a caregiver and level of social support with five self-reported diabetes self-care behaviors: diet, foot checks, blood glucose monitoring, medications, and physical activity. African Americans with T2D who had a high level of informational and structural social support had almost twice the odds of moderate or higher medication adherence than patients with no social support (Bouldin et al., 2017).

Following the analyses of 60 published studies in a systematic review, Castello et al. (2016) found that social support was relevant for older adults because they had fewer social networks due to having comorbidities, loss, and reduced mobility. However, younger patients preferred using technological means for reminders, such as using apps and setting alarms (Castello et al., 2016)**.** The relationship between social support and medication adherence in African American diabetes patients has been inconclusive, with positive or negative associations reported in the literature.

Positive Relationships

Scheurer et al. (2012) analyzed 50 studies using the concepts social support and medication adherence in a systematic review. They concluded that positive relationships exist between social support and medication adherence among different age and ethnic groups. Further, they suggest social support promotes self-esteem and reduces stress, anxiety, and depression.

In a meta-analysis of 122 studies, Miller and DiMatteo (2013) found that medication adherence improved by 15%- 27% in patients who had practical support available to them.

Social support was also beneficial to patients with D.M. It improved their health outcomes and medication adherence by buffering stress, improving affective states, promoting self-efficacy, and influencing changes in negative health behaviors (Miller & DiMatteo, 2013). Family structural support, such as being married and living with family members, was weakly positively associated with treatment adherence ($r = 0.08$, $p < 0.05$), and the odds of medication adherence for married people were 1.27 times higher than for unmarried patients (DiMatteo et al., 2013).

Pereira et al. (2008) found a significant correlation between family cohesion and family guidance and better control of hyperglycemia in diabetes patients ($r = 0.08$, $p < 0.05$). Positive relationships were found between social support and frequent testing for blood sugar levels, blood sugar control, adherence to a diabetes meal plan, and medication adherence among African American adults with T2D ($U = 263.5$, $p = 0.05$).

According to Mayberry and Osborn (2012) African American adults with T2D, who were regularly reminded by their family and friends to take their medications and test their blood sugar levels, reported higher levels of medication adherence than those who did not have adequate social support. This positively supports the concept of social support for diabetics.

Negative Relationships

Negative social support has also been associated with adverse health outcomes (Carter-Edwards et al., 2004). They conducted a qualitative survey to evaluate the relationship between perceived social support and diabetes self-management in African American women with type 2 diabetes (Carter-Edwards et al., 2004). A convenience sample of 12 African American women with T2D who attended a Southeastern United States clinic participated in focus group discussions and responded to interview questions about social support and its impact on diabetes self-management. The focus groups and interviews lasted 1.5 to 2 hours and were audio-recorded. The qualitative data were transcribed verbatim, coded, and content analyzed to identify emerging themes. The predominant themes were perceived misunderstanding of the influence of diabetes on their lives by members of their social networks, perceived loss of independence, power, and control, help and support, and communication provided by the family members. Respondents verbalized that family members did not know how severe and uncomfortable their diabetes symptoms were; therefore, they felt criticized sometimes for not doing much to self-manage their symptoms. Perceived loss of independence was related to feeling powerless when they sometimes relied on family members to remind them to follow health-providers recommended practices such as medication adherence and diet modification. However, they also perceived reminders to take their medication, and having candid communications with family members about diabetes self-management as helpful (Carter-Edwards et al. 2004). Last, they reported that some African American women with D.M. felt criticized or nagged and sometimes guilty when receiving informational support from family members.

Gallant et al. (2007) recruited 84 participants in Upstate New York into 13 focus groups in a qualitative explorative design. The participants were 65 years and older patients with arthritis, diabetes, and heart disease. The focus groups comprised 28 White women, 32 African American women, 19 White men, and 5 African American men—the participants were living in nursing homes and assisted living facilities. The purpose of the study was to explore how family and friends influence chronic illness and self-management among older adults (Gallant et al., 2007). Each focus group session was facilitated by experienced focus group moderators and lasted one and a half to 2 hours (Gallant et al., 2007). During the focus group sessions, guided discussion questions were used to collect data about positive and negative ways family and friends contributed to managing participants' illnesses. The participants also completed a short-self-administered questionnaire that assessed their demographic and health information (type and number of chronic diseases, duration of conditions). Common themes from the surveys were direct help from family members, accommodating dietary needs, providing transportation assistance, and acting as advocates. Direct support included preparing and administering medications, offering medication reminders, and cooking healthy meals. Family supportive behaviors also included accommodating dietary needs, exercising with, and playing an active role during doctor's visits, providing transportation to doctor's visits, and sharing illness-related information. On the other hand, it was reported that some family members and friends hindered participants' attempts at self-management by not cooking meals that followed dietary guidelines, following a diet with no restrictions, not accommodating nutritional needs, tempting them with forbidden foods, discouraging physical activity, giving unwanted advice, engaging in depressing talk, and not understanding the reality of living with a chronic illness (Gallant et al., 2007).

Shared Decision-Making Interventions to Promote Diabetes Self-Management and Medication Adherence

Shared Decision Making (SDM) is a collaborative bi-directional mutual exchange of information, and includes discussion and collaboration that becomes a routine plan of care goal (Truglio-Londrigan & Slyer, 2018). SDM occurs in a participatory, collaborative, open, and respectful relationship between at least two participants, the nurse as the healthcare provider and the patient receiving the care (Truglio-Londrigan & Slyer, 2018). Further, SDM between healthcare providers, patients, and now other family members is currently receiving national and international interest from providers, educators, and researchers (Oliver et al., 2018). SDM includes a patient-centered approach and supports patients in achieving informed decisions that align with their preferences (Moin et al., 2019). SDM often incorporates decision aids (DA) to reduce decisional conflict and improve patient knowledge, perceptions, and satisfaction with care (Allen et al., 2019).

Decision Aids

Shared Decision Making (SDM) often incorporates decision aids (DA) to help reduce decisional conflict and improve patient knowledge, risk perceptions, and satisfaction with care (Allen et al., 2019). Additionally, decision aids have been developed that address many different treatment decisions, including screening decisions for prostate cancer, breast cancer, and prenatal screening, surgical choices that are available for mastectomy, hysterectomy, and prostatectomy; and choices about medicines such as the use of statins, anticoagulants, and hormone replacement therapy (Allen et al., 2019; Moin et al., 2019; Truglio-Londrigan & Slyer, 2018). However, no decisions aids were found to be developed for diabetic patients.

There has been literature written on designing an SDM program and includes the steps for SDM (Moin et al., 2019; Oliver et al., 2018; Truglio-Londrigan & Slyer, 2018). Shared decision-making helps patients to better understand what they need to do, and it has been reported that patients are more likely to follow through with the plan that they and their healthcare provider designed together (Moin et al., 2019). Health professionals may use decision aids as well as patient health records to communicate information regarding shared decision making (Oliver et al., 2018). For example, patients can access decision aids as well as relevant patient education materials through a patient portal online. The patient portal that is shared with the healthcare provider has secure messaging as well, which allows the patient to communicate regarding the healthcare plan.

The SDM process involves gathering information from scientific evidence along with available community resources for discussion of benefits and risks related to their healthcare decisions (Moin et al., 2019). After providing the information to the patient, the healthcare provider checks back with the patient to ensure they understand the choices related to their diagnosis. The provider then assists patients in evaluating the available options based on their goals and concerns. To understand patients' preferences, they are asked what is important to them and what their concerns are. During the evaluation of options, the provider facilitates discussion of choices as well as allowing patients time to think things over and ask further questions before making a final decision. The next step is to assist the patient to follow through with their plan of care. Once final discussion of any possible challenges with the healthcare provider has taken place the final plan is implemented and the measures of improved health are evaluated as appropriate (Moin et al., 2019).

There is no single "right" health care decision in many situations because all choices about treatment, medical tests, and health issues come with pros and cons (Moin et al., 2019). SDM is vital in these types of cases. For example, when no one option has a clear advantage and when benefits and harms of each option affect patients differently the decision of pros and cons need to be discussed (Truglio-Londrigan & Slyer, 2018).

According to Allen et al. (2019) decision aids (DA) are used to help patients make informed choices about their healthcare that take into account the patient values and preferences. DAs are a part of a shared decision-making process, which encourages active participation of patients in their own healthcare decisions. Patient decision aids may have many options for resources that can be accessed and allows the patient to choose what will work best for their own personal healthcare needs. The DA not only provides information on options, but also creates the opportunity for communication with the healthcare provider regarding clarifications on disease process as well as helping the healthcare provider to better understand personal values of the patient and how they may associate with different features of the offered resources.

Moint et al. (2019) states that decision aids (DA) are intended to supplement and support patient decisions regarding their improved adherence to medications and consequently their health status. Patient decision aids also aim to improve the quality of decisions. Decision quality is the extent to which patients choose and receive healthcare interventions that are consistent with their informed and considered values (Allen et al., 2019). Further, patient decision aids are used for complex decisions requiring more detailed information and more careful consideration regarding improved health status. Complicated decisions need to have multiple options that include features that people value differently. Therefore, the best choice depends on the personal value that a person places on the benefits, harms, and scientific uncertainties presented in the DA (Ottawa Hospital Research Institute, 2020).

Researchers who investigated the effectiveness of SDM on health outcomes have found positive and significant relationships between shared decisions and health outcomes (Allen et al., 2018; Den Ouden et al., 2017; Moin et al., 2019; Oliver et al., 2018). In a qualitative case study, Oliver et al. (2018) evaluated the use of SDM between hospice nurses, patients, and family members. The study's purpose was to assess using 8 SDM elements when in hospice care home visits. The SDM elements were based on Makoul's Model of identifying Options. The options were:

1. Define the problem.
2. Identify options.
3. Discuss risks and benefits.
4. Patient family preferences.
5. Patient/family self-efficacy.
6. Nursing recommendation.
7. Assess patient family recommendations.
8. Decide a treatment option

Oliver et al. (2018) used secondary data analyses of a subsample of audio recordings from a nationwide national hospice study. The national survey recruited 65 nurses from hospice agencies in four U.S. regions. The hospice nurses volunteered to be audio recorded while in their nursing home visits with cancer patients. Sixty-five nurse visits were selected as a stratified subsample for maximum variance based on years of nursing experience, nurse race, and nurse gender. The recordings' revealed that hospice nurses used SDM to promote patients' care decisions, which also corroborated other researchers' findings (Allen et a., 2018; Den Ouden et al., 2017). Hospice nurses were found to use all the recommended elements of SDM during home visits. However, not all features were used at each visit. The most frequently used SDM element was defining a problem, while the least used element was assessing patient and family understanding (Oliver et al., 2018). Two (3%) of the nurse visits contained all nine elements, and

5 (8%) demonstrated all but one of the elements. Nearly one-quarter (22%) used 6–7 elements, and 28% used 4–5 elements (Oliver et al., 2018).

Allen et al. (2018) investigated provider and patient shared decision intervention's effectiveness with a Left Ventricular Assist Device in a randomized clinical trial. They found modestly improved patient decision quality (Allen et al., 2018). The clinical trial had a sample of n=248 comprising 135 patients in the intervention group and 113 in the control group and spanned from 2015 to 2017 (Allen et al., 2018). The authors found that patient knowledge (mean test performance) during the decision-making improved from 59.5% to 64.9% in the control group versus 59.1% to 70% in the intervention group (adjusted difference of 5.5%; p =0.03) (Allen et al., 2018). There was a stronger correlation between stated values and patient-reported treatment choices in the intervention group (difference in Kendell's tau 0.28; 95% CI, 0.05-0.45). Two (3%) nurse visits contained all nine elements, 5 (8%) demonstrated all but one of the elements. Nearly one-quarter (22%) used 6–7 elements, and 28% used 4–5 elements. However, it is essential to note that there was no correlation between stated values and actual treatment received within six months for the intervention group compared with the control group (difference in Kendell's tau 0.01; 95% CI, .24- 0.25) (Allen et al., 2018). There also were no differences in decision conflict or decision regret (Allen et al., 2018).

In a related study, Den Ouden et al. (2017) investigated the effectiveness of shared goal setting and decision making to achieve treatment targets in patients with T2D aged 60-80 years in a cluster-randomized trial in a comprehensive primary care Dutch facility. Seventy-four patients were randomly assigned to the treatment group who received an SDM support aid. In contrast, 79 patients were randomly assigned to the control group that received regular treatment or treatment as usual (Ouden et al., 2017). The intervention included SDM with personalized goal setting and a DA. During the 24 months of the trial, hemoglobin A1C and cholesterol levels were analyzed for the two groups at baseline and after 12 and 24 months (Ouden et al., 2017). The results of the study revealed that at baseline, 26.4% of the SDM group had already achieved all three treatment goals; this improved to 31.8% at 24 months (C.G.; 25.3%) RR 1.26 (95% CI 0.89-1.95) (Den Ouden et al., 2017). Mean systolic B.P. decreased in the SDM group (-5.4 mmHg $p<0.01$); however, mean hemoglobin A1C and total cholesterol levels did not change (Den Ouden et al., 2017). Making a shared decision resulted in a 20% higher proportion of people who achieved all their treatment goals from baseline to follow-up at 24 months, but there was no improvement in the control group (Den Ouden et al., 2017). It is important to note that this was one Dutch facility where this study was done. No research has been found that has used SDM in African American subjects. Further, there has been no SDM used in diabetic African American subjects.

Improvement of patient health outcomes using an SDM intervention corroborated other researchers' findings (Allen et al., 2018; Oliver et al., 2018). Other studies have shown that taking the patient's treatment preferences into account and making shared decisions resulted in a higher proportion of people who achieved all their treatment goals (Den Ouden et al., 2017; Allen et al., 2018). Though the difference between groups did not reach significance, the researchers attributed the higher 24% instead of the presumed 10% proportion of participants as those that had already achieved all three treatment goals at baseline (Den Ouden et al., 2017).

Similarly, Moin et al. (2019) conducted a study on the effectiveness of a prediabetes SDM intervention using a cluster randomized control trial. The study participants were overweight/obese adults with prediabetes (BM1 $\geq$ 24 kg/m^2 and Hb A1C 5.7-6.4%) n=351(Moin et al., 2019). The participants were recruited from 10 SDM intervention clinics in a sizeable United States regional health system. The intervention group participated in face-to-face SDM visits with a pharmacist who used a DA to describe prediabetes and three possible options for diabetes prevention. The options were 1) diabetes prevention program (DPP) with or without metformin; 2) metformin only; 3); and usual care (Moin et al., 2019). The study's finding indicated that DPP and metformin uptakes were higher among SDM participants (n=351) than among the group receiving usual care without SDM. SDM patients were also more likely to use metformin than the control group (19% v 1.6%, p=.001) (Moin et al., 2019). Weight documentations at 12 months showed that adjusted mean weight loss for participants was higher in the SDM group than it was in the care as usual group (-5.2Ibs [SD 11.2] vs. -.0.2 Ibs [SD 10.9] P=.001) (Moin et al., 2019). The authors concluded that a pharmacist led SDM prediabetes intervention significantly increased patients' uptake of DPP and or metformin at four months and weight loss at 12 months (Moin et al., 2019).

Since SDM was included in the 2001 Institute of Medicine report and section 3506 of the Affordable Care Act (ACA), the effectiveness of SDM has been evaluated in a few studies, including cardiovascular patients, hospice patients, and prediabetes patients (Allen et al., 2018; Oliver et al., 2018; Moin et al., 2019). No studies were found that investigated the effectiveness of an SDM intervention to diabetes medication adherence in African American adults. Also, SDM researchers often focused on the shared decision choices of patients without involving family members. Additionally, they have not done any research on an underserved population, such as African Americans and Blacks. Therefore, the purpose of this study was to determine the effectiveness of a SDM DA intervention with T2D medication adherence and family social support among African American and Black adults.

Summary

Diabetes affected about 34.2 million people in the U.S. in 2018, making it one of the most prevalent chronic conditions (ADA, 2020). D.M.'s incidence continues to rise, with about 1.5 million new cases of D.M. diagnosed every year (ADA, 202o). About 13% of adults in the U.S. have D.M., representing a significant economic and public health burden (ADA, 2018). According to the ADA (2018), T2D is about twice as prevalent in African Americans and Blacks as in Non-Hispanic Whites. People with D.M. have an increased risk for numerous complications, including diabetic retinopathy, neuropathy, nephropathy, cardiovascular disease, amputations, and premature death. Diabetes can be complicated for patients because it requires several physician visits, monitoring, medications, and recommended self-management behaviors.

Self-management of D.M. is a critical component of managing the disease. Family members can be essential in promoting patients' adherence to recommended medication therapy, regular exercises, and dietary restrictions. Patients' efforts to manage their D.M. principally occur in social settings and alter family and social dynamics (Baig et al., 2015). SDM interventions have been associated with patients' improved adherence to their medications and recommended lifestyle changes. Few D.M. intervention studies target SDM between clinicians, patients, and family members. No study was found that evaluated the effectiveness of an SDM between clinicians, patients, and family members on diabetes mediation adherence. Therefore, the purpose of this study was to determine the efficacy of an SDM DA intervention on medication adherence and family social support in African American/Black adult T2D patients.

Chapter III

Methods and Measurements

Chapter III described the research design, sample, sampling methods, research setting, and measurement methods for the study. Procedures proposed for selecting research subjects, data collection, human subjects' protections, and the proposed data analysis plan were also presented. The study's design was quasi-experiment with two hypotheses: 1) Implementing a shared decision-making intervention using a diabetes medication adherence decision aid will increase medication adherence with an average change in pretest scores on the MMAS by 2; and 2) There will be a positive relationship between social support and medication adherence in patients and family members after a diabetes medication adherence shared decision aid intervention. A convenience sampling method was used to recruit eligible African American/Black adults with type 2 diabetes receiving care in a Southern U.S. facility.

Research Design

This study used a quasi-experimental one-group pretest-posttest design to determine the effectiveness of a shared decision-making (SDM) intervention using a decision aid (DA) and family social support to improve medication adherence in African American/Black adults with T2D. Researchers use the one-group pretest-posttest design to measure research variable scores before and after an intervention, then compare the difference between pre and post-scores (Knapp, 2016). In nursing research, the one-group pretest-posttest design is used when the random assignment to treatment and control groups is not practical and if there are ethical concerns in randomizing subjects to specific interventions (Knapp, 2016). In this study, the researcher could not randomly assign subjects to treatment and control groups because nurses in the clinic were administering the DA for all subjects. There was an intervention/manipulation for this study, a convenience sample was used, and there was one group; thus, random assignment was not made

Sample

Sample Selection

The study population consisted of African American or Black adult males and females with T2D ages 18 and older who spoke English and could verbalize how they self-managed their care and were receiving medical care at a southern U. S. wellness center. Participants were included in the study sample if they took prescribed oral anti-glycemic medications with or without insulin therapy for at least three months prior to the study. Previous studies recruited T2D patients with three months or more extended history of the condition to hopefully ensure that the patients understood the recommended management of the disease by their caregivers (Allen et al., 2018; Den Ouden et al., 2018; Moin et al., 2019). Pregnancy, mental impairment (diagnosed mental health condition), and illicit drug use were exclusion criteria for participation in the study. Patients with chronic co-morbid conditions such as T1D and stroke were excluded from the study. Comorbidities and polypharmacy can contribute to a patient's medication adherence (Allen et al., 2018). Therefore, to control for these confounding variables, they were excluded.

Sampling strategy

The sampling method of the study was convenience sampling. In convenience sampling, subjects will be eligible for participation in the study if they meet the inclusion criteria (Grove et al., 2013). This sampling method will include all potentially eligible patients18 or older receiving care at the clinic; thus, it is a convenience sample.

Sample Size

The sample size needed for the study was determined using a power analysis (Grove et al., 2013). The G* power analysis results for the paired t-test using an effect size of .4 and power of 0.80 resulted in 41 participants required to test the study hypotheses. The medium effect size was used because the larger the effect size, the stronger the relationship between the two variables. If the difference between two groups' means is greater than .2 standard deviation, the difference is substantial if it is statistically significant (Sullivan & Feinn, 2012). The researcher set out to recruit four additional subjects during pre-testing to compensate for possible attrition.

Research Setting

A wellness center in the southern U.S. was the setting of the study. It is a Federally Qualified Health Center serving the community. Federally qualified health centers are community-based organizations that receive Medicare benefits to provide comprehensive primary care and preventive care such as health, oral, and mental health care/substance abuse services. Regardless of their ability to pay insurance status, people of all ages can access the services (U.S. DHHS, 2015). It is a nurse-led center that provides primary care and management of chronic diseases such as D.M., asthma, hypertension, and obesity for all ages. The clinic can receive and attend to about 800 patients. The center's mission is to provide access to care for people in need to reduce or eliminate health disparities among high-risk populations. The clinic offers services to over 800 patients, out of which about 100 have D.M. (Texas Tech University Health Sciences Center, 2019).

Measurement Methods

Key Study Variable Measurement Instruments

The Morisky Medication Adherence Scale-8 (MMAS-8) was used to measure self-reported medication-taking behaviors of African American/Black adults with T2D (Morisky et al., 2008; Appendix B). The MMAS-8 is an eight-item scale with yes = 0 or no = 1 scores for items 1, 2, 3, 4, 6, and 7. For item 5, yes is scored 1, and no is 0. Participants' responses are worth 8 points. The score reflects the adherence to the medication regime for the subject. The 8th item is a 5-point Likert item scored from zero to four. The Likert item's response is scored 1 for option a, and each of b-e is worth 0 (Morisky et al., 2008).

The items are summated to yield total scores that can be categorized to reflect high to low medication adherence where high adherence = 8, moderate adherence = 6-7, and low adherence = 0-5 (Mosiky et al., 2008). The MMAS-8 is a practical instrument for the measurement of self-reported medication adherence. It is a paper and pencil scale, simple and easy to score (Morisky et al., 2008). The MMAS-8 has been found to have strong internal consistency, and test-retest reliability of 0.928 (Spearman's $r = 0.928$; $p < 0.001$). The psychometric properties of the MMAS-8 were evaluated in a study of 1,367 patients with hypertension. The instrument thus has strong reliability. The researcher did not find studies in which the MMAS-8 was used to evaluate diabetes medication adherence. Before its use in the study, permission to use the MMAS-8 was requested from the instrument's copyright holder, D. E. Morisky. The copyright holder did not require a permit to use the paper and pencil version of the instrument, which, according to the tool's author, is not as accurate as the online version. The tool's online version was not available for this study; therefore, the paper-pencil version was used.

The Berlin Social Support Scale (BSSS) was used to measure social support in study participants. The BSSS was developed to measure social support's cognitive and behavioral aspects with adult cancer patients and their partners (Schulz & Schwarzer, 2004). Additionally, it has been used to measure social support among patients with different health conditions such as diabetes, hypertension, and heart disease (Schulz & Schwarzer, 2004). No studies have been found in which the BSSS was used to evaluate patients with diabetes.

There are six subscales (perceived support, provided support, received support, need for social support, support seeking, and protective buffering) in the BSSS. The received support subscale, which consists of 13 items, will be used to measure both the cognitive and behavioral aspects of social support (Schulz & Schwarzer, 2004). Participants will rate their agreement with statements on a 4-point scale ranging from 1-4, where 1 = strongly disagree, 2 = somewhat disagree, 3 = somewhat agree, and 4 = strongly agree. The scale scores are obtained by summing and then averaging the responses across the 13 items. Negative items are reversed (numerical scoring run opposite). Scores on the received support subscale of the BSSS will be interpreted as follows: High social support (50-52), moderate social support (40-49), and low social support (13-39) (Schulz & Schwarzer, 2004). The BSSS (received support subscale) is practical to use, requiring only paper and pencil participant responses. It is straightforward to score (Schulz & Schwarzer, 2004). The BSSS (received social support) was reliable in a validation sample of N = 457 cancer patients, with a Cronbach's alpha = 0.83 Schulz & Schwarzer, 2004). Permission to use the BSSS was obtained from the copyright holder of the instrument.

Demographic Variable Measurement

Demographic variables were measured using a researcher-developed questionnaire to describe the study participants. (Appendix D). Age, education level, income level, and duration of diagnosis were measured at the ratio level of measurement. Gender and marital status were measured at the nominal level of measurement. Subjects were asked to self-identify as African Americans/Black and indicate if they received social support from their family members to promote diabetes medication adherence. Age was measured because previous researchers have found that older individuals were more likely to adhere to medication therapy than younger individuals (Sousa et al., 2006). Educational level was measured because previous studies showed differences between education and medication adherence among African American/Black adults with T2D (Clark & Utz, 2014). Duration of diagnosis was measured because a short illness span was related to higher social support and better diabetes self-care in African American adults than a more extended illness period (Sousa et al., 2006). Gender at birth is an essential attribute of the study participants, which will be measured to describe the study sample (Grove et al., 2013). Marital status was measured because differences in medication adherence were found among African American and Black adults with different matrimonial statuses (Clark & Utz, 2014). Income level was measured because it was associated with medication adherence among African American Adults with T2D (Sousa et al., 2006).

Table 2

Descriptive Data Analysis Plan

Variables	Level of Measurement	Descriptive Statistical Procedures
Age Education level Level of income Duration of diagnosis	Interval/ratio	Range, Mode, Median (*M.D.*), Mean *(x)*, Standard Deviation (*S.D.*)
Gender Marital status	Nominal	*f*, *%*, Mode
DA choices	Nominal	*f*, *%*, Mode
Social support Medication adherence	Ordinal	*f*, *%*, Range, MD, Mode

Procedures

The researcher visited the clinic 2-5 times a week to meet prospective subjects attended by nurse practitioners at the wellness center. The researcher obtained permission and support from the wellness center management to conduct these visits. A nurse consulting room was available for participants to sit down and complete their responses while at the clinic. During each visit, the researcher observed COVID-19 prevention protocols according to the clinic and IRB guidelines, such as washing hands/using hand sanitizers before and after interacting with patients, wearing a face mask, and maintaining six feet distancing. The researcher followed the IRB direction regarding subject protection during COVID 19, and provision was made in the consent for contact via zoom/email as needed for IRB COVID 19 phases.

Shared Decision-Making Intervention

Shared Decision Making (SDM) encourages health care professionals and patients to make health care decisions together, using scientific evidence and including patients' needs and preferences. Additionally, SDM has been advocated to improve communication quality with the patient (National Institute of Diabetes and Digestive and Kidney Diseases, 2019). The SDM approach requires that health care professionals understand current treatment recommendations and that patients receive treatment options instead of just being told what they must do (National Institute of Diabetes and Digestive and Kidney Diseases, 2019). The researcher developed a SDM DA for this study by identifying and documenting available community resources in two different health facilities that offer vulnerable patients services to promote medication adherence. The SDM DA also provided ways patients could improve medication adherence (see appendix D). The DA included an application that primarily supplied medication reminders and recorded medication adherence history. The community resource facilities provided free prescription medication, diabetes medication adherence education, and transportation services for eligible patients. Patients with insurance coverage but who had difficulty making copays could also receive help from community resource centers. Transportation services offered by the community included transporting patients to pharmacies for prescription refills and healthcare provider appointments. All DA possibilities were discussed with healthcare providers at the clinic in regard to referring patients to access the free services and using the online mobile application to promote diabetes medication adherence as part of the SDM process. The online application "Wellth Mobile APP" helped remind patients to take their medication and record their medication adherence daily. It is important to note that no type of decision aide was being used, nor shared decision making before this study was initiated. Therefore, all data would be a zero for data collection purposes as there was no data to collect as a pre survey of the SDM DA because it was the intervention introduced for the study. Using Makoul's Model for the intervention process was as follows:

1. Define the problem; the researcher identified the gap in knowledge regarding the use of an SDM DA; described the decision aid and the options available to each subject.
2. Identify options using the DA of community resources; the patients indicated which SDM DA options helped promote their medication adherence and chose at least three options. The researcher then recommended those choices to the nurse practitioner in charge of the patient care for referral and implementation. The researcher provided a subject-coded copy of the SDM DA to the implementing healthcare provider and the patient to check-mark the chosen options and then implement them. The check-marked copy was then returned to the researcher for data input.
3. Discussion of the risks and benefits of medication adherence; before and during the SDM DA implementation, the researcher encouraged patients to ask questions.
4. Patient family preferences and self-efficacy were completed; patients were encouraged to involve family members during the SDM DA implementation to assist in making the best decisions.
5. The researcher discussed the SDM DA options with each subject and a family member to help them make informed decisions.
6. During the decision-making process, the researcher ensured the services would be available to the patients after discussing options and preferences with them.
7. Decisions were made final after being informed of all options and asking about needs regarding subjects' medications. (Oliver et al., 2018).

Data Collection Process

The researcher visited the clinic 2-5 times a week to meet prospective subjects seen by nurse practitioners at the wellness center. The researcher obtained permission and support from the wellness center management to conduct these visits. A nursing consulting room was available for subjects to sit down and complete their responses while at the clinic. During each visit, the researcher observed COVID-19 prevention protocols set forth by the clinic and the IRB, such as washing hands/using hand sanitizers before and after interacting with patients, wearing a face mask, and maintaining six feet distancing. The following steps were taken to recruit subjects for the study during the visits.

Pre-Intervention Session

1. The regular visits were in consulting rooms where nurse practitioners provided diabetes care services to patients. The attending nurse practitioner first told the patient and a family member about the study verbally using the information on the study brochure (Appendix I) and asked the patient for permission for the researcher to speak to them. The nurse practitioner introduced the researcher and the patient if the patient verbalized interest. The researcher then provided information about the study using the brochure, answered questions, and left the room to allow the subject to consider joining the research study. The researcher then knocked on the door and asked to enter, and then asked if there were any further questions regarding the study and if they would like to join the study. If yes, and they met eligibility criteria, the researcher continued; if no, the researcher thanked them for their time, directed them back to the nurses' station, and left

the room. The subject was asked to provide their cell phone numbers for a follow-up call within 2 and 4 weeks after the initial visit as part of the consent (Appendix J).

2. The researcher left the brochure and copy of the consent form with the subject and the family member.
3. The researcher informed the subjects that the brochure had the researcher's name, phone number, and email and explained the study. The researcher asked the subjects to read and refer to it as needed.
4. The researcher administered three surveys: 1) Patient Profile to know about the subject; 2) Morisky Medication Adherence Scale (MMAS-8) to identify how the subject was taking their diabetes medication as prescribed by the doctor; 3) The Berlin Social Support Scale (BSSS) to determine if the subject was getting help from their family regarding diabetes management.
5. The researcher discussed several options that might help them take their medications regularly and asked them to choose three or more options. The researcher told them that if they needed more time, they could take about five minutes to think about them and discuss with their family the best choices, and then let the researchers know which options they wished to choose.
6. The researcher also obtained the hemoglobin A1C test result from the nurse practitioner who reviewed the chart and provided the lab result for research purposes.

Intervention Session

1. The researcher called subjects on their cell phones twice within one to four weeks to determine if they benefited from their chosen options and took their medications.

2. The researcher asked subjects if they had any problems or could not get the support they needed during the calls.

Post-Treatment Session

1. Subjects were asked to visit the clinic approximately after four weeks. The researcher administered the same surveys (MMAS-8 and BSSS) again during that visit
2. Posttest hemoglobin A1C test results were documented a second time within 3 to 4 months after the pre-intervention data collection.
3. Pretest and post-test data were analyzed using the proposed descriptive data analysis plan. Hemoglobin A1C test results were one of the predictors for the multiple linear regression analysis.

Ethical Considerations

Potential risks for violation of ethical research principles in the study included disclosing participants' personal information. All precautions were taken, and the data was locked in a cabinet behind a locked door in the researcher’s office at the University Health Sciences Center. The research data was also shared with the researcher’s dissertation committee on a OneDrive in a shared folder. Additionally, subjects were at risk for feeling uncomfortable answering any health questions or discussing personal needs to make the best possible SDM DA selections. The only other noted risk was that the subject could become fatigued as they completed the questionnaires. The study's actual procedures had no risks beyond what usually happens on a typical day, making it a minimal risk study. The resources provided during the study could benefit subjects according to their specific needs, such as learning about available transportation, medications, and other available community resources.

Before data collection, the researcher obtained permission to conduct the study from the Institutional Review Board (IRB # 21-057) associated with the clinic, and a reciprocity agreement was obtained with the University of Texas at Arlington IRB. Each participant received a written and verbal explanation of the study's purpose and process, including the risks and benefits (Grove et al., 2013). Subjects were volunteers and had the right to decline to sign the informed consent or refuse to participate in the study without any retribution. Subjects' data were stored behind a locked door (Office #HSC 2C141) in a locked cabinet where only the researcher had the key and access. The electronic data from the surveys were saved on an encrypted computer with a secure password. The data will be kept for three years after data analysis and then destroyed. A shared OneDrive folder was created by faculty and shared with the researcher and the statistician who was also on the dissertation committee. The folder was secured with a password for access.

Last, a subject identification number was created to protect the identity of the subjects. This identification number consisted of first and last name initials, month and day of the pretest, and subject number. For example, A=10, B=11, C=12, and so forth; if Abe Lincoln was the subject, the code AL,10-21-09-20-001, was assigned for the subject. This identification number is essential to link pre and post-test scores and hemoglobin A1C numbers to the same subject to compute differences between pretest and posttest scores.

Data Analysis Plan

SPSS was used for statistical analysis. First, data was checked for any errors or missing elements. Descriptive statistics were calculated to describe the characteristics of the sample. Descriptive statistics such as frequencies and percentages were calculated for nominal variables such as gender and marital status. Frequency, percent, mode, and median were calculated for ordinal variables measured, such as social support and medication adherence. Frequency, percent, mode, median, range, mean, and standard deviation were calculated for continuous variables, namely age, education level, income level, and diagnosis duration. Additionally, SDM DA choices were also analyzed using descriptive statistics to indicate preferences that subjects chose. The SDM DA intervention included several choices available to the subjects, which were 1) patient teaching for better understanding of the disease process; 2) education regarding better understanding of dosing of medication (once daily, 90-day medication supply); 3) enhanced communication between patients and the clinician for a more open conversation so that the needs of the patient can be better understood; 4) increased provider availability to answer any questions the patient may have about their medication; and 5) the use of an online medication adherence application (Wellp APP) that reminds patients to take their medication and gives them monitory rewards for taking their medications as prescribed. A linear-mixed effects model test was conducted to evaluate the subjects' medication adherence before and after the SDM intervention and determine the relationship between medication adherence and social support, hemoglobin A1C, duration with T2D, age, gender, and the choices in the decision aid.

Hypotheses

The hypotheses of the study were:

1. Implementing a shared decision-making intervention using a diabetes medication adherence decision aid will increase medication adherence with an average change in pretest scores on the MMAS by 2.

2. There will be a positive relationship between social support and medication adherence in patients and family members after a diabetes medication adherence shared decision aid intervention.

Social support and medication adherence were measured using the Berlin social support received subscale and the Morisky medication adherence scale (MMAS-8), respectively, before and after participants' intervention.

Table 3

Hypotheses, Operational Measurements, and Statistical Tests

Hypotheses	Operational Measurements	Statistical Test
1. Implementing a shared decision-making intervention using a diabetes medication adherence decision aid will increase medication adherence with an average increase in pretest scores on the MMAS by 2.	SDM DA Morisky Medication Adherence Scale (MMAS-8)	Descriptive statistics Linear-Mixed Effects Model
2. There will be a positive relationship between social support and medication adherence in patients and family members after a diabetes medication adherence shared decision aid intervention.	Berlin Social Support Scale (BSSS)	Linear-Mixed Effects Model

To evaluate the effectiveness of the SDM DA intervention to promote medication adherence, a linear-mixed effects model analysis was performed. Researchers use linear-mixed effects modeling to examine the dependent variable while simultaneously taking into account variability within and across subjects as well as other variables (Brown, 2021). Medication adherence was the dependent variable in this study, and the SDM DA, social support and hemoglobin A1C were the independent variables. The model also adjusted for the subjects' age, gender, duration of T2D, and level of education.

Delimitations

Delimitations are boundaries or limitations the researcher sets to ensure that the study's aims and objectives are not impossible to achieve. Delimitations describe the reasons for rejecting a particular course of action during the research process and the options available (Theofanidis & Fountouki, 2018). The purpose of this study was to determine the effectiveness of a shared decision-making (SDM) intervention using a decision aid (DA) with family social support to improve medication adherence in African American/Black adults with T2D. Therefore, the sample was restricted to adult African American/Black T2D patients who had difficulties adhering to the medication plan. Family social support included participants' family members and their perspectives to promote diabetes medication adherence.

Summary

A pretest-posttest quasi-experimental study was conducted to determine the effectiveness of an SDM DA intervention for type 2 diabetes medication adherence with family social support in African American/Black adults. Forty-one subjects were sampled from a West Texas clinic. Descriptive statistics were used to describe the characteristics of the sample, and a linear mixed-effects model test was conducted to determine the effectiveness of the SDM DA intervention with family social support and hemoglobin A1C on medication adherence before and after an SDM DA intervention. SDM DA choices were analyzed using descriptive statistics. SPSS version 28 was used for all analyses.

Chapter IV

Findings

This chapter contained the results of data analyses of the quasi-experimental study to determine the effectiveness of a shared decision-making (SDM) intervention using a decision aid (DA) and family social support to improve medication adherence in African American/Black adults with T2D. The hypotheses of the study were:

1. Implementing a shared decision-making intervention using a diabetes medication adherence decision aid will increase medication adherence with an average increase in pretest scores on the MMAS by 2.
2. There will be a positive relationship between social support and medication adherence in patients and family members after a diabetes medication adherence shared decision aid intervention.

The convenience sampling method was used to recruit eligible African American/Black adults with type 2 diabetes receiving care in a southern U.S. facility. Descriptive statistics were completed for subject characteristics and results of the SDM DA choices. Once the analysis of the intervention was completed further data analysis using linear-mixed effect modeling was done to determine the mean differences between pretest and posttest data. Linear mixed model analysis was done to determine if family social support and hemoglobin A1C on medication adherence was impacted after the SDM DA intervention.

Results

Descriptive Statistics

Descriptive statistics were used to describe the characteristics of the subjects, which is found in Table 4 below.

Table 4
Descriptive Statistics

Variables	Frequency	Preintervention (%)	Postintervention (%)
Demographics			
Age[a]		51.6	51.6
Gender			
Male	6	14.4	14.6
Female	35	85.4	85.4
Level of Education			
Elementary School	5	15.5	15.5
Middle School	3	7.3	7.3
High School	24	58.5	58.5
College	5	12.2	12.2
Graduate School	1	2.5	2.5
Medication			
Oral	1	78	78
Insulin	32	2.4	2.4
Oral & Insulin	8	19.5	19.5
SDM-DA Choices[a]			
Enhance	28	--	90
Communication	21	--	29
Improved Dosing	8	--	67
Provider Availability	5	--	16
Online App			
Outcomes			
Medication Adherence		6.55	7.14
Social Support		42.47	42.42
Hemoglobin A1C		8.16	8.02
Duration (years)		8	8

Descriptive statistics are mean (STD) for continuous variables

Demographics

Ages, Gender, Duration with Diabetes, and Level of Education of the Subjects

The data from table 4 indicates that the participants' average (mean) age was 51.63 years. Thirty-five participants (85.4%) were females, and 6 (14.6%) participants were males. The average time participants lived with T2D was eight years. The time participants lived with T2D ranged from 1 to 39 years. The majority of the participants' highest level of education was high school, representing 58.5 %. Eight participants completed elementary school representing 19.5%, while 5 (12.2%) had a college degree. Three participants (7.3%) completed middle school, and 1 (2.4%) had a postgraduate degree.

Type 2 Diabetes Medication

The majority of the participants, (32) 78.0%, took oral medications. Nine participants (19.5%) took both insulin and oral diabetes medication.

Pre-Intervention and Post-Intervention Medication Adherence, Social Support and Hemoglobin A1C of the Subjects

The descriptive statistics from table 4 above indicate that the average level of medication adherence before the SDM DA intervention was (6.55); however, after the SDM DA intervention, participants' medication adherence increased by 0.59 to 7.14 on the MMAS-8 scale. In contrast, the average social support the subjects received during pretesting was higher (42.47) than posttest social support (42.42) on the Berlin Social Support Scale (BSSS). The average Hemoglobin A1C level of the participants before the SDM intervention was higher (8.16%) than after the SDM DA intervention (8.02%).

Linear-Mixed Effects Model Analysis

Linear-mixed effect modeling was performed using SPSS to determine the effectiveness of the SDM-DA intervention on diabetes medication adherence in African American/Black subjects. Medication adherence was the dependent variable, and social support and hemoglobin A1C were the independent variables. The model also adjusted for the subjects' age, gender, duration of T2D, and level of education.

Table 5.

Effects of Time, Age, Duration, Hemoglobin A1C, Social Support, Gender, and Education on Medication Adherence after the SDM-DA Intervention

Variable	Estimate	95% Confidence Lower Bound	Interval Upper Bound	T Statistic	P. Values
Time	0.57	0.24	0.90	3.19	0.001
Age	0.02	-0.02	0.05	3.60	0.271
Duration	0.01	-0.02	0.04	0.85	0.403
A1C	-0.00	-0.10	0.09	-0.10	0.917
Social Support	-0.03	-0.10	0.03	-1.04	0.307
Gender	-0.33	-1.17	.51	-0.80	0.429
Education	0.19	-0.13	.51	1.23	0.232

Dependent Variable: Medication Adherence

The results of the fixed effects estimate in table 5 indicate that there was a significant increase in medication adherence from pretest to post-test (P =.001). The increase in the subjects' medication increased from 6.55 at the pretest to 7.14 after the SDM-DA intervention. Therefore, the three-month SDM-DA intervention to improve the medication adherence of African American/Black T2D patients was effective. However, the increase in medication adherence by 0.59 is less than the predicted increase of 2 in the hypothesis. Therefore, further research on the SDM DA might include further options that have a greater impact on medication adherence.

The estimates of fixed effects table (5) revealed that individually, social support, hemoglobin A1C, age, gender, duration with T2D, and level of education did not significantly predict the medication adherence of the subjects.

Summary

The purpose of the study was to investigate the effectiveness of a shared-decision-making (SDM) DA intervention on medication adherence and social support of African American adults with type 2 diabetes. The medication adherence and social support of male and female adult patients (N=31) were measured before and three months after the SDM DA intervention implementation. The subjects' hemoglobin A1C test results were documented. A mixed-linear effect model test was performed with medication adherence as the dependent variable and social support, hemoglobin A1C, and SDM DA choices as the predictors. The model also adjusted for the subjects’ age, gender, duration with type 2 diabetes, and level of education. The data analysis indicated that the SDM DA intervention was effective as there was a significant change in the subjects’ medication adherence from Pretest to post-test over the three months (p=.001). However, individually, none of the other independent variables significantly predicted the subjects’ medication adherence.

Chapter V
Discussion

This study aimed to determine the effectiveness of a shared decision-making (SDM) intervention using a decision aid (DA) and family social support to improve medication adherence in African American/Black adults with T2D. Orem's self-care theory and self-care deficit theory were the guiding frameworks to conceptually define and explain medication adherence as a self-care demand and shared decision making and social support as conditioning factors for promoting medication adherence. This chapter discussed the study's results regarding the participants' level of medication adherence and the relationship between medication adherence, social support, and hemoglobin A1C levels using an SDM DA. Also, the researcher evaluated the study findings and described the significance and implications of the results concerning the findings of previous researchers.

Shared Decision-Making Interventions to Promote T2D Medication Adherence

A linear mixed effect model computed on medication adherence revealed a significant increase in the subjects' medication adherence from pretest (6.54) to posttest (7.14). Therefore, the SDM DA intervention was effective. Further, individually, there was no significant relationship between the subjects' medication adherence and social support, hemoglobin A1C, age, duration with T2D, gender, and level of education.

Hypothesis One

The first hypothesis was implementing a shared decision-making intervention using a diabetes medication adherence decision aid will increase medication adherence with an average increase in pretest scores on the MMAS by 2. Ninety percent (28) of the participants requested enhanced communication with the healthcare team. The second choice 67% (21) was improved provider availability, which included participants spending 10-30 minutes interacting with the provider about their medication adherence options during their appointments. The least chosen option 16.13% (5) was the online medication adherence assistance application that could be used on a smartphone or computer. There was an increase in medication adherence by .59 on the MMAS-8; however, the increase was lower than the researcher anticipated. The mean increase (.59) in the medication adherence of the subjects after implementing the SDM decision aid was less than the predicted 2 in the first hypothesis. Since the SDM intervention was relatively short (three months) it would be prudent to conduct another study using a more extended SDM intervention that might lead to a higher increase in the subjects' medication adherence, as predicted in hypothesis 1. The result of this study yields positive results for the SDM DA, but not with the same positive results as the findings of Den Ouden, Vos, and Rutten (2017) that after an SDM intervention with personalized goal setting, hemoglobin A1C and cholesterol levels for two groups of heart disease patients improved by 31.8% at 24 months (C.G.; 25.3%) RR 1.26 (95% CI 0.89-1.95). Also, mean systolic blood pressure decreased in the SDM group (-5.4 mmHg p<.01) (Den Ouden et al., 2017).

Hypothesis 2

The results of this study did not support the second hypothesis, which was there will be a positive relationship between social support and medication adherence in patients and family members after a diabetes medication adherence shared decision aid intervention. The estimates of fixed effects table (5) revealed that individually, social support, hemoglobin A1C, age, gender, duration with T2D, and level of education did not significantly predict the medication adherence of the subjects. There was an insignificant relationship between social support and medication adherence in patients and family members after a diabetes medication adherence shared decision aid intervention (p=.307). Previous researchers have illustrated positive health outcomes after shared decision-making. Moin et al. (2019) enrolled participants from 10 SDM intervention clinics in a sizeable United States regional health system. The intervention group participated in face-to-face SDM visits with a pharmacist who used a DA to describe prediabetes and four possible options for diabetes prevention; diabetes prevention program (DPP) with or without metformin, metformin only, or usual care (Moin et al., 2019). The study's findings indicated that DPP and metformin uptakes were higher among SDM participants (n=351) than those receiving usual care without SDM.

Implications for Nursing

This study suggested that during patient care of African American/Black adults with diabetes, nurses should endeavor to communicate closely with patients and provide detailed information about patients' prescribed medications, including other medication options, the side effects, and strategies to remember to take medication. Additionally, the use of a decision aide along with involving family members in patient care by sitting in, listening, and actively participating in patient teaching can promote positive family social support. However, patients should be allowed to decide if they would like to have a family member participate in their care and which family members to include. Future nursing research should explore a longer duration (more than three months) of an SDM DA intervention to improve medication adherence and family social support in African American adults with type 2 diabetes. Additionally, further research could include exploration of other possible options for the DA that patients might prefer instead of those offered for this study.

Theoretical Concepts and Links to Study Variables

Orem's self-care deficit theory was the guiding framework for the study to evaluate the effectiveness of an SDM DA intervention on diabetes medication adherence and family social support in African American adults with T2D. The subjects of the study did not have adequate information regarding strategies to promote T2D medication adherence and control their blood sugar levels. Hyperglycemia was their self-care deficit, and the SDM DA intervention was the self-care agency to promote medication adherence. Social support was conceptualized as a conditioning factor for promoting T2D medication adherence. The nurse practitioners (nursing agency) used the SDM DA intervention (self-care agency) to facilitate medication adherence by providing information about patients' prescribed medications, the side effects, and strategies to remember to take medication. The SDM DA intervention (Self-care agency) was found to significantly promote the subjects' medication adherence. The subjects' self-care demand, conceptualized as medication adherence, significantly increased after the SDM DA intervention ($p=.001$).

Limitations of the Study

This study was a quasi-experimental one-group pretest-posttest design to determine the effectiveness of a shared decision-making (SDM) intervention using a decision aid (DA) and family social support to improve medication adherence in African American/Black adults with T2D. There was an SDM intervention to promote medication adherence. A convenience sample was used, and all potentially eligible patients18 or older receiving care at the clinic were included in the study. There was one group; thus, no random assignment was made. The researcher could not randomly assign subjects to treatment and control groups because nurses in the clinic were administering the DA to all subjects. The lack of randomization limited the study's ability to conclude a causal association between the SDM DA intervention and the participants' medication adherence after the intervention. A G* power analysis determined that a sample of 41 subjects was needed to investigate the effectiveness of the SDM DA intervention.

Approval was given to recruiting 46 participants in anticipation of attrition. Forty-one participants initially consented to be part of the study, but ten withdrew because of COVID-19 related reasons. Also, the health facility later closed because of the pandemic. Therefore, the final sample size was 31. The subjects of this study represent a population of low-income African/Black adults in a rural Southern American community; thus, results cannot be generalized to other African Americans.

Conclusion

A quasi-experimental one-group pretest-posttest design was used to determine the effectiveness of a shared decision-making (SDM) intervention using a decision aid (DA) and family social support to improve medication adherence in African American/Black adults with T2D. A final convenience sample (N=31) of African American male/Black and female adult type 2 diabetes patients received a shared decision-making intervention to improve the medication adherence and family social support. The subjects' levels of medication adherence, social support, and hemoglobin A1C were measured before and after the intervention. A linear mixed-effects model was conducted to evaluate the effectiveness of the SDM DA intervention and the relationship between medication adherence and social support, and hemoglobin A1C. The results indicated that the SDM DA intervention promoting T2D medication adherence was effective. There was a significant change in medication adherence from pretest (6.55) to posttest (7.14) within the three months of intervention. There was an insignificant positive relationship between social support and medication adherence. The study findings imply that implementing a medication adherence shared decision intervention using a decision aid is associated with improved medication adherence and hemoglobin A1C levels. Recommended T2D medication adherence strategies include greater communications that involve patients in discussions about medication types, dosing, extended contact time between patients and their healthcare providers, and providing information and resources to promote medication adherence. Given that the increase in medication adherence (by 0.59) was less than the predicted 2 on the MMAS-8, further research is recommended to determine if an extended duration of an SDM intervention will lead to higher medication adherence.

Summary

The purpose of the study was to investigate the effectiveness of a shared-decision-making (SDM) intervention using a decision aid (DA) on medication adherence and social support of African American/Black adults with type 2 diabetes. The medication adherence and social support levels of male and female adult patients were measured before and three months after implementing the SDM DA intervention. The subjects' hemoglobin A1C test results were also documented to conduct a linear-mixed model test to determine the effectiveness of the SDM DA intervention to promote medication adherence. After the SDM intervention, there was a statistically significant increase in the subjects' medication adherence. However, the margin of increase in medication adherence was less than the researcher predicted in the study's hypothesis. Further research should include a longer duration of the SDM DA intervention. Additionally, future research could include exploration of possible options other than what was provided in the DA for this study.

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Appendix A
Morisky Medication Adherence Scale (MMAS-8)

1. Do you sometimes forget to take your pills? Yes No
2. People sometimes miss their medications for reasons other than forgetting. Thinking over the past 2 weeks, were there any days when you did not take your medicine? Yes No
3. Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it? Yes No
4. When you travel or leave home, do you sometimes forget to bring along your medicine? Yes No
5. Did you take all your medicine yesterday? Yes No
6. When you feel like your symptoms are under control, do you sometimes stop taking your medicine? Yes No
7. Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan? Yes No
8. Do you often have difficulty remembering to take all your medicine?
   a. Never/rarely
   b. Once in a while
   c. sometimes
   d. Usually
   e. All the time

Appendix B

The Berlin Social Support, Received Support Subscale

Think about the person (s) who is close to you, such as your spouse, partners, child, or friend. How did they react to you during the past one month?

Respond to the statements in the table by encircling 1, 2, 3, or 4 after each corresponding statement where 1 strongly disagrees, 2 somewhat disagrees, 3 is somewhat agreed, and 4 is strongly agree

1. They showed me that they love and accept me	1 strongly disagree	2 somewhat disagree	3 somewhat agree	4 strongly agree
2. They comforted me when I was feeling bad	1 strongly disagree	2 somewhat disagree	3 somewhat agree	4 strongly agree
3. They left me alone (-)	4 strongly disagree	3 somewhat disagree	2 somewhat agree	1 strongly agree
4. They did not show much empathy for my situation (-)	4 strongly disagree	3 somewhat disagree	2 somewhat agree	1 strongly agree
5. They criticize me (-)	4 strongly disagree	3 somewhat disagree	2 somewhat agree	1 strongly agree
6. They made me feel valued and important	1 strongly disagree	2 somewhat disagree	3 somewhat agree	4 strongly agree
7. They expressed concern about my condition	1 strongly disagree	2 somewhat disagree	3 somewhat agree	4 strongly agree
8. They encouraged me not to give up	1 strongly disagree	2 somewhat disagree	3 somewhat agree	4 strongly agree
9. They were there when I needed them	1 strongly disagree	2 somewhat disagree	3 somewhat agree	4 strongly agree
10. They took care of many things for me	1 strongly disagree	2 somewhat disagree	3 somewhat agree	4 strongly agree
11. They took care of things I could not manage on my own	1 strongly disagree	2 somewhat disagree	3 somewhat agree	4 strongly agree
12. They helped me find something positive in my situation	1 strongly disagree	2 somewhat disagree	3 somewhat agree	4 strongly agree
13. They suggested things that might distract me from worrying about my situation	1 strongly disagree	2 somewhat disagree	3 somewhat agree	4 strongly agree

Appendix C

Demographic Variable Measurement

1. What is your gender at birth (sex)? ○ male ○ female
2. What is your age? ________ years old
3. What is your current marital status?
   ○ Single ○ Married ○ Divorced
   ○ Widowed ○ Separated

4. How many years/months has it been since you were diagnosed with type 2 diabetes months/years (circle appropriately)

5. What medications are you taking to manage your diabetes?
   - o Oral medicine (pills)
   - o Insulin
   - o Oral medicine (pills) and insulin

6. What is your level of education?
   - o Elementary school o Middle School o High school o College degree o Postgraduate degree
7. What is your gross yearly household income? _______________dollars per year?
   - o How many dependents do you have? ________________

Appendix D

Decision Aid for Diabetes Medication Adherence

Types of Strategies	Resources	Specific Strategies	Healthcare provider's implementation	Patient confirmation of implementation
Patient Teaching, Diabetes Medication Adherence, and Prescription Support	-Assess and set patient-specific medication adherence goals by asking each patient to identify 2 medication adherence goals after describing available options with them. Prescription medication and transportation assistance	Larry Combest Community Health & Wellness Center Prescription Assistance Program University Medical Center		
Improved Dosing Regimens	Simplification of the treatment regimen -Once-daily dosing -Use 90-day supplies of medicine	Larry Combest Community Health & Wellness Center		
Enhanced communication between patient and clinicians	Cultivate an open, friendly environment. -Take a patient-centered approach using open-ended questions to identify medication adherence goals. -Involve patients in the decision-making process -Discuss the risks, benefits, and potential side effects of each medication	Larry Combest Community Health & Wellness Center		
Increased provide availability	-Convenient appointment scheduling -Expanded clinic hours (e.g., early/late hours, evenings, weekends) -Telehealth encounters	University Medical Center Larry Combest Community Health & Wellness Center		
Online resource	Support reminder app: Wellth Mobile APP	Free Onlne APP		

Appendix E
Letter of Support/Permission to Collect Data

LARRY COMBEST
COMMUNITY HEALTH &
WELLNESS CENTER
TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENtER

Re: Permission to Conduct Research Study

June 4, 2020

Dear David,

I have reviewed your proposed research titled Shared Decision-Making Intervention to Improve Diabetes Medication Adherence and Family Social Support and permit you to conduct the following activities at the Larry Combest Community and Wellness Center (LCCHWC) and the Combest Central Community Health Center locations.

1. Visit the Wellness center 2-5 times a week to display or distribute brochures with your contact information (name, phone number, and email) within the premises of the center.
2. Visit the Wellness center 2-5 times a week to recruit participants until the required sample size of up to 46 is obtained.
3. Enroll eligible patients who meet the sample criteria and agree to participate in the Study by requesting them to provide informed consent to participate in the Study.
4. Administer demographic questionnaire, the Morisky medication adherence scale (MMAS-8), and the Berlin Social Support (BSSS [received support]) to enrolled subjects in-person at the center or via virtual means including emails and zoom meeting. A nursing consulting room will be available for participants to sit down and complete their responses while at the clinic.
5. Perform follow-up with patients via phone calls and emails.
6. Obtain patients' consent and permission to collect hemoglobin AIC data at enrollment of subjects and 3-4 months after pretest data collection.

During the conduct of the activities above, you are required to follow the Wellness center's policy regarding privacy and confidentiality to the letter. The nursing team will be available to assist you when necessary and I encourage you to provide your maximum cooperation. You can commence your Study at the center anytime from June 20, 2020, and continue up to April 30, 2021. If you have questions or would like to reach me, please do so by phone or email.

Thank you for your time,

Linda McMurry, DNP, R.N., NEA-BC
Executive Director, LCCHWC
Professor, TTUHSC School of Nursing

Appendix F

Permission to Use the Morisky Medication Adherence Scale

From: trubow1@gmail.com <trubow1@gmail.com>
Sent: Friday, December 27, 2019 6:27 PM
To: Baba, David <david.baba@mavs.uta.edu>
Cc: Behan, Deborah Fern <dgreen@uta.edu>
Subject: RE: Morisky Research Contact Form

Hi David,

We only license the Morisky Widget MMAS-8 software because it has much higher sensitivity and predictive validity than the MMAS-8 paper questionnaire. We do not require a license for the MMAS-8 paper questionnaire.

Condition and medication specific Morisky Widget MMAS-8 tests offer true positive sensitivity of 93% as compared to the generic MMAS-8 paper questionnaire at 73% sensitivity, which means that 27 out of 100 patients answering the paper MMAS-8 are misdiagnosed for their level of medication adherence.

In addition we only license organizations, never individuals. The University of Texas already has a perpetual Morisky Widget MMAS license.

All licensees must participate in training and certification on the correct use of the Morisky Widget.

Best
Steve
Steven Trubow
MMAS Research LLC USA
Coronado California
MMAS Research France SAS
Paris France
MMAS Research Italy SRL
Vicenza Italy
(+1)360-824-0701
www.morisky.org
SEE the new I-Phone Morisky Kiosk in the APP Store
SEE our partners Emocha's Video Direct Observation Therapy

- NIH-funded Hopkins study: emocha secured 94% average adherence and saved ~$1400/patient.
- CDC report: In the aftermath of Hurricane Harvey, patients using emocha achieved 97% medication adherence whereas those without had to pause treatment.

Appendix G

Permission to Use the Berlin Social Support Scales

Schwarzer, Ralf <ralf.schwarzer@fu-berlin.de>
Thu 12/26/2019 2:47 PM

To:

- Baba, David;
- health@zedat.fu-berlin.de

Cc: Behan, Deborah Fern

http://www.psyc.de/WORDPRESS/wordpress/requests/

Prof. Dr. Ralf Schwarzer
Freie Universität Berlin, Psychology
Habelschwerdter Allee 45
14195 Berlin, Germany
Email | ralf.schwarzer@fu-berlin.de
WEB | http://my.psyc.de
ORCID | http://orcid.org/0000-0002-0069-3826
Twitter | https://twitter.com/schwarzer1
BLOG | https://theemeritus.wordpress.com/
Research in Wroclaw, Poland | http://www.care-beh.eu/

- Reply

Reply all
Forward

Baba, David
Thu 12/26/2019 1:07 PM

To: health@zedat.fu-berlin.de
Cc: Behan, Deborah Fern

Dear Dr. Schwarzer,
I am David Baba, a Ph.D. nursing candidate at the University of Texas at Arlington. I am proposing to conduct my doctoral dissertation on shared decision making to improve diabetes medication adherence and family social support. My dissertation Chairperson is Dr. Deborah Behan, copied in this email. I wish to seek your permission and approval to use the Berlin Social Support Scales to measure social support.

The purpose of my proposed Study is to evaluate the effectiveness of a Shared Decision Making (SDM) Decisional Aid (DA) intervention on T2D medication adherence and family social support in African American adult T2D patients.

Sincerely,
David

Appendix H
IRB Approval Letter

TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER

INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS FWA # 00006767 LUBBOCK/ODESSA IRB #00000096

NOTIFICATION OF INITIAL APPROVAL
January 25, 2021
PRINCIPAL INVESTIGATOR: Alyce Ashcraft, PhD
STUDY TITLE: Shared Decision-Making Intervention to Improve Type 2 Diabetes Medication Adherence and Family Social Support (Baba-SDM)
IRB #: L21-057
SUBMISSION REFERENCE #: 084810
TYPE OF REVIEW: EXPEDITED
RISK ASSIGNMENT: Expedited/Minimal
APPROVAL DATE: 01/25/2021
NUMBER OF SUBJECTS AT THIS SITE: 46

SPECIFIC INFORMATION PERTAINING TO THIS APPROVAL
Documents reviewed and approved include:
IRB Application version 1.1 Protocol version date 1/25/2021
Consent/HIPAA form version date 1/25/2021 Research Brochure
Research 2020 Letter of Support

Recommendation: This research project was reviewed by the TTUHSC Lubbock IRB using the expedited review procedure. The board determined that the research satisfies the criteria for expedited review because it presents no more than minimal risk to participants and meets expedited review criteria of category 7: research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

The research has been determined to meet criteria for approval in accordance with 45 CFR 46.111. Continuing review reporting is not required.

Approval: The TTUHSC Human Research Protection Program Manual includes a policy discontinuing the requirement for continuing review for research projects that have been designated as Expedited/Minimal Risk research. Please note that an expiration date has not been assigned for this project as it has been determined that:
the research presents no more than minimal risk to subjects, and
the research meets criteria for expedited review in accordance with 45 CFR 46.110(b)(1).

Consent form: The consent form has been stamped as approved without an expiration date. You are responsible for maintaining signed consent forms for a period of at least three years after study completion.

Study Personnel Currently Approved to Conduct the Research: David Baba
Reporting: The principal investigator must report to the IRB any serious problem, adverse effect, or outcome that occurs with frequency or degree of severity greater than that anticipated. In addition, the principal investigator must report any event or series of events that prompt the temporary or permanent suspension of a research project involving human subjects.
Modifications: Changes or modifications in a research project must have approval by the IRB prior to initiation. When modifications are deemed necessary to prevent immediate harm to a subject, changes or modifications must be reported to the IRB within 24 hours.
Study Completion: If this project is completed within the approval period, you are required to submit a Study Closure report. The study project is considered completed when:

Investigators will not contact subjects for further information related to this project,
Access to subject health care records are no longer required for information related to this project,
All IRB requests for information have been completed and no longer require an investigator response, and
A summary report has been completed. This must be attached to the Closure report.

****UNIVERSITY MEDICAL CENTER of LUBBOCK****
If this research is to be conducted at University Medical Center (Lubbock) or involves UMC services/resources and/or medical records, the PI will need to contact Ann Purdom, UMC Director of Clinical Research (ann.purdom@umchealthsystem.com) or Michael Economidis, UMC Associate General Counsel (michael.economidis@umchealthsystem.com) for review and permission prior to initiation of the research.

****CLINICAL TRIAL REGISTRATION****
ClinicalTrials.gov is a directory of federally and privately supported research trials designed to test the effect of experimental drugs, devices, and procedures for many diseases and conditions. If this project is a clinical trial as designed by the FDA, DHHS, or the NIH, the sponsor is required to register the trial at ClinicalTrials.gov prior to the enrollment of the first participant. In addition, if Medicare might be billed for any items or services utilized in this study, registration at ClinicalTrials.gov is mandatory. The 8-digit number assigned by ClinicalTrials.gov is required on Medicare claims for items or services provided in clinical trials. If the trial has not been registered by the study sponsor, it may be the Principal Investigator's responsibility to register the trial.
For more information, see the regulatory summary here. If you need a ClinicalTrials.gov account, please contact Chad Copeland (Chadley.Copeland@ttuhsc.edu).

GENERAL INFORMATION
The Texas Tech University Health Sciences Center Institutional Review Boards are duly constituted (fulfilling FDA requirements for diversity), allows only those IRB members who are

independent of the investigator and sponsor of the study to vote/provide opinion on the study, has written procedures for initial and continuing review, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements defined in 21 CFR (Code of Federal Regulations) Parts 50 and 56, and ICH (International Conference on Harmonization) guidance relating to GCP's (Good Clinical Practice).

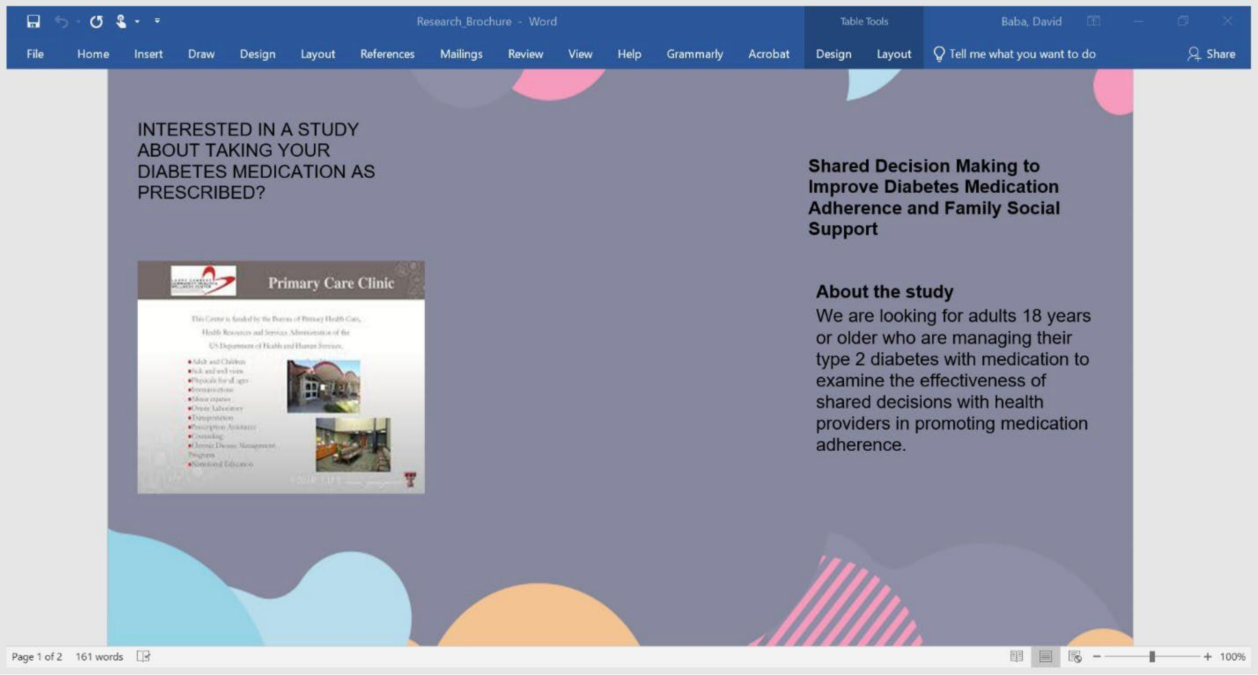
The Texas Tech University Health Sciences (TTUHSC) Center Policies and Procedures are available for reference on the TTUHSC Human Research Protection Program Website (https://ttuhsc.imedris.net/).

TTUHSC Lubbock/Odessa Institutional Review Board 3601 4th Street STOP 8146
Lubbock, TX 79430

806-743-4753

Appendix I

Research Brochure

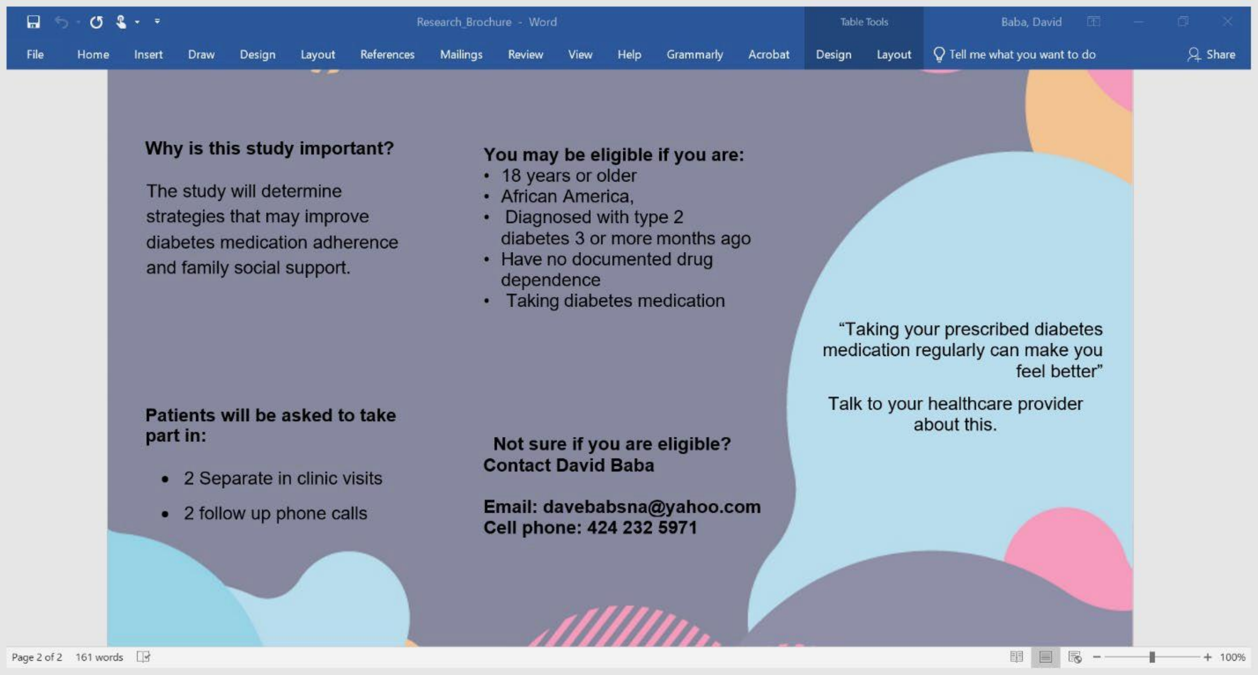


INTERESTED IN A STUDY ABOUT TAKING YOUR DIABETES MEDICATION AS PRESCRIBED?

Shared Decision Making to Improve Diabetes Medication Adherence and Family Social Support

About the study

We are looking for adults 18 years or older who are managing their type 2 diabetes with medication to examine the effectiveness of shared decisions with health providers in promoting medication adherence.



Why is this study important?

The study will determine strategies that may improve diabetes medication adherence and family social support.

Patients will be asked to take part in:

- 2 Separate in clinic visits
- 2 follow up phone calls

You may be eligible if you are:

- 18 years or older
- African America,
- Diagnosed with type 2 diabetes 3 or more months ago
- Have no documented drug dependence
- Taking diabetes medication

Not sure if you are eligible? Contact David Baba

Email: davebabsna@yahoo.com
Cell phone: 424 232 5971

"Taking your prescribed diabetes medication regularly can make you feel better"

Talk to your healthcare provider about this.

Appendix J

Informed Consent

This consent form is not valid without a TTUHSC IRB stamp in the lower left corner of each page.

CONSENT TO TAKE PART IN A SOCIO-BEHAVIORAL RESEARCH STUDY

This is a research study for people who voluntarily choose to take part. Please take your time to make a decision, and discuss the study with the study team, family, and friends if you wish.

STUDY TITLE: Shared Decision-Making Intervention to Improve Diabetes Medication Adherence and Family Social Support

INVESTIGATORS: Principal Investigators: Deborah Behan, Ph.D., RN-BC, Alyce S. Ashcraft, PhD, RN
Co-Investigator: David Baba,
CONTACT TELEPHONE NUMBERS: (424) 232-5971 David Baba

(You may contact the investigators at the numbers listed above during normal business hours if you have any unexpected complications.)

INSTITUTION: Texas Tech University Health Sciences Center, Lubbock, Texas

1. What am I being asked to do?

We are asking you to take part in a research study to find out whether having a discussion between healthcare providers and African American adult males and females ages 18-89 years with diabetes can improve regular taking of diabetes medication and family support in African American adults with diabetes. We are asking you to take part in this research study because you are African American and take diabetes medication.

2. Taking part in this study is your choice.

You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it or have someone read it to you. Talk to the study investigator, family, or friends about the risks and benefits of taking part in the study. It is important that you have as much information as you need and that all your questions are answered. See the “What if I have questions?” section for other places you can get answers if necessary.

3. Why is this study being done?

This study is being done because we are interested in knowing how involving African American adults with diabetes in deciding their diabetes management can help them to take their diabetes medications as ordered by their healthcare providers and how it can also promote support from their families to take their drugs.

We hope that the results of this study will help us to learn whether African American males and females 18-89 years who are involved in discussions about options for taking