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EXAMINING BIOBEHAVIORAL VARIABLES AND PREDICTORS ASSOCIATED WITH TYPE 2 DIABETES SELF- MANAGEMENT

Karin A. Emery
Virginia Commonwealth University

Examining Biobehavioral Variables and Predictors Associated with Type 2 Diabetes Self-Management

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

by

Karin Anne Emery
Bachelor of Science, Medical University of South Carolina, Charleston, SC 1997
Master of Science, Virginia Commonwealth University, Richmond, Virginia 2011
Doctor of Philosophy, Virginia Commonwealth University, Richmond, Virginia 2019

Director: Dr. Jo Robins
Associate Professor
Department of Adult Health and Nursing Systems

Virginia Commonwealth University
Richmond, Virginia
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Abstract

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By Karin A. Emery, MS

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Type 2 diabetes mellitus self-management is a challenging process that brings forward a variety of emotional responses. The purpose of this work was to explore relationships between diabetes distress, self-efficacy and resilience and outcomes of glycosylated hemoglobin, quality of life and health status. A cross sectional descriptive design was used for this pilot study of 78 individuals enrolled from an Endocrine clinic in the Midwest United States and a Primary Care clinic in the southeast United States.

Data were analyzed using descriptive statistics to characterize the sample and model variables. Spearman's correlation was completed to identify relationships among variables. A stepwise building approach was used to identify significant interactions and determine predictors of the study outcomes. The results of this study confirm the presence of facilitators and barriers in type 2 diabetes mellitus self-management and their relationships with distal outcomes. The

findings demonstrate that diabetes distress is a predictor of health status and quality of life. The findings of this study provide a link to other facilitator and barrier variables such as provider collaboration, diabetes self-management education, treatment regimen, ethnicity and years since diagnosis which can be incorporated into the comprehensive theoretical model. This study contributes to the understanding of the emotional aspect of diabetes as it relates to self-management of T2DM. Continuing this work will allow researchers to examine and better understand important factors of self-management. This ongoing work will hopefully lead to improved support in self-management efforts and better outcomes.

Chapter 1

Introduction

Statement of Problem

Diabetes mellitus represents a growing health problem with serious health complications. Over 30 million individuals in the United States have diabetes mellitus, or 9.4% of the population. The prevalence in individuals >65 remains high at 25.2%, or 12 million. There are 1.5 million new cases each year and in 2015, 84 million individuals had prediabetes. Additionally, diabetes mellitus is the 7th leading cause of death. Diabetes mellitus is also an important problem to address from a cost perspective as it creates a financial burden. The 2017 total estimated cost for care was $327 billion , an increase from $245 billion in 2012. This included $237 billion in direct medical costs and $90 billion in reduced productivity, representing a 26% increase over a five-year period (ADA, 2019).

A cornerstone of self- management is to support individuals in performing self-management activities using effective strategies that improve outcomes. For instance, the prevention of micro and macrovascular complications is essential to prevent or reduce morbidity and mortality (CDC, 2019). Quality of life is also an outcome associated with the burden of living with diabetes (ADA, 2017). Theory- driven self-management research is emerging, demonstrating the complexity of the psychosocial aspects of daily management. There is a need to determine what critical factors contribute to impactful self-management and lead to improved outcomes for those living with Type 2 diabetes mellitus (T2DM).

Background and Significance

Diabetes distress

Evidence increasingly suggests there is a psychological burden associated with T2DM (ADA, 2017; Bagnasco et al., 2014; Chew, et al., 2017; Chew et al., 2014; Gucciardi et al., 2013; Sherifali et al., 2015; Wang, 2017). T2DM distress is characterized by feelings of concern, fears and worries related to living with the chronic illness. Ultimately, these stressors and emotions have the potential to negatively impact self-management outcomes. Several studies have been conducted that showed a significant positive relationship between T2DM distress and glycosylated hemoglobin A1c (HbA1c) levels (Fisher et al., 2008; Fisher, Glasgow, & Strycker, 2010a; Fisher et al., 2012; Fisher et al., 2010b; Fisher et al., 2007; Graue et al., 2012). Also, significant relationships between lower T2DM distress and higher quality of life have been found (Graue et al., 2012; Ting et al., 2011; Wang, Wu, Hsu, 2011). More research is needed to evaluate relationships between diabetes distress and protective factors and to examine if T2DM distress is a predictor of other outcomes such as health status.

Self-efficacy

In T2DM, self-efficacy it is the perceived confidence in the ability to carry out required self- management activities of daily living, readiness to change and adherence to the regimen (Liu, 2012). Self- efficacy has been identified as a strong indicator of future behavior since the 1970's (Bandura, 1977). Additionally, self-efficacy influences the efforts and determines the persistence of those efforts in the face of failures and obstacles. People tend to avoid tasks that exceed their coping skills and undertake tasks they are capable of handling (Bandura, 1982, 1986). Self- efficacy has received increased recognition as a potential predictor of DM health behavior change (Al-Khawaldeh, Al-Hassan, & Froelicher, 2012; Bagnasco et al., 2014; Liu,

2012). As a result of these studies, findings suggest that self-efficacy may account for a variance in self-management behaviors. What is not known is how self-efficacy specifically influences outcomes such as HbA1c, quality of life and health status.

Resilience

Resilience is defined as the ability to bounce back. It is considered a positive adaptation to life and has the following attributes: (1) ability to rebound, (2) social support, and (3) self-efficacy (Garcia-Dia, DiNapoli, Garcia-Ona, Jakubowski, & O'Flaherty, 2013). A review of the literature showed seven studies examining the concept of resilience in DM. The majority of the studies only examined psychological aspects of resilience (Bahremand et al., 2015; Mertens, Bosma, Groffen, & van Eijk, 2012; Stuckey et al., 2014). It was suggested that resilience may have a positive influence on T2DM outcomes, however it has yet to be proven as further research is needed (Bradshaw, Richardson, & Kulkarni, 2007a). First, one study's results showed a negative correlation between hemoglobin A1C results and resilience (DeNisco, 2011). Second, other studies showed mixed results on impact to hemoglobin A1C (Bradshaw et al., 2007b; Steinhardt, Mamerow, Brown, & Jolly, 2009). Further research is needed to investigate if resilience influences other T2DM outcomes including quality of life and health status. Additionally, resilience has not been tested with other psychosocial factors such as distress and self-efficacy. Understanding the nature of these factors is necessary as they are pertinent to daily self-management and ultimately outcomes of that self-management, such as quality of life and health status.

Quality of Life

Quality of life is the impact of perceived health status on the ability to live a fulfilled life and there is a growing body of evidence showing self-perceptions of health are linked with

mortality (Tsai-Chung et al., 2011). Individuals with T2DM have decreased quality of life compared with individuals without chronic illness and T2DM related complications are the most important disease-specific determinant of QOL. Studies suggest that improved health status and perceived control of disease results in improved QOL (Rubin & Peyrot, 1999). Continued focus on improving health and disease trajectory are necessary to improve quality of life. The presence and utilization of internal psychosocial resources are needed to support self-management behaviors to improved disease control and quality of life (Chew et al., 2014). Utilization of resources such as self-efficacy and resilience may further support self-management and can be a future focus of intervention.

Purpose

Theory-driven self-management research is emerging to include psychosocial aspects of daily management. Guided by the Self and Family- Management Theory (Gray, Shulman-Green, Knafly, & Reynolds., 2015), we undertook the present study to explore a comprehensive model that includes facilitators and barriers and outcomes of self-management. The purpose of the study was to explore the relationships between diabetes distress, self-efficacy and resilience and outcomes of HbA1c, quality of life and health status in persons with T2DM. This is the first study examining these specific variables and outcomes within a self-management framework in the T2DM population. Information obtained from this study may be used to move the self-management science forward in this challenging population and may eventually lead to the identification and testing of novel interventions to enhance self-management and ultimately outcomes for individuals with T2DM

Summary

This chapter provided background information on the problem and significance of T2DM. The purpose of this study was to explore variables and predictors that are associated with

T2DM. The information provided justifies efforts to further examine facilitators and barriers to self- management and outcomes of the self-management. In the following chapters, a review of the literature and conceptual framework are discussed, the plan for data collection and analysis are described and the findings and discussion are presented.

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Chapter 2

Self and Family Management in Type 2 Diabetes: Influencing Factors and Outcomes

Type 2 diabetes mellitus (T2DM) impacts more than 30 million individuals in the United States. The incidence and prevalence of T2DM is increasing, resulting in significant morbidity and mortality (CDC, 2019). It is well established that glycemic control reduces risk of T2DM-related complications and remains a major focus of therapy (ADA, 2017; Inzucci et al., 2012); and there are decisions and behaviors of the individual that impact glycemic control. Self-management is a cornerstone of T2DM management and successful self-management behaviors have been shown to improve glycemic control and delay or prevent T2DM related complications (CDC, 2019). Self-management is comprised of the ability of the individual, in conjunction with family, community, and healthcare professionals to engage and manage the decisions and behaviors to engage and manage a chronic health condition (Grey, et al., 2015). According to the evidence-based Self- and family Management Theory, self-management is a dynamic phenomenon consisting four domains: (a) self and family management processes; (b) facilitators and barriers; (c) proximal outcomes; and (d) distal outcomes. Self and family management processes are influenced by facilitator & barrier factors and processes which contribute to outcomes. Proximal outcomes are a result of individual and family engagement in symptom management or treatment regimens including pharmacological therapies, diet, activity, and sleep; the importance of which is associated with their impact on health outcomes" (Grey et al., 2015). Proximal outcomes lead to the attainment of distal outcomes and include health status indicators, quality of live, and costs (Grey et al., 2015).

There is a need to determine critical factors within the domains that contribute to impactful self-management and lead to improved proximal and distal outcomes in individuals

living with T2DM. To date, this framework has not been used to assess which factors in the domains are most salient. The Self- and Family Management theory fosters an examination of relationships, assumptions and propositions to describe, implementing guiding elements of nursing and interdisciplinary practice. In the current health-care environment interdisciplinary practice is a common standard of care with each discipline brings their own lens to the patient care situation (Smith & Parker, 2015). A strong relationship between theory, research, and practice is essential to provide the foundation for nursing practice as well as direction for the nursing profession caring for this population. This paper discusses the state of the science related to T2DM self-management outcomes and presents the utility of the Self- and Family Management framework for examining factors that influence T2DM self-management. Consistent use of theory will facilitate development of new nursing knowledge and inform nursing practice to improve T2DM self-management and outcomes.

Self-Management

There is growing interest and burgeoning evidence base in chronic disease self-management program improves outcomes (Sherifali, Bai, Kenny, Warren, & Ali, 2015). A cornerstone of T2DM management is to support individuals in performing self-management activities using effective strategies that improve outcomes. The Diabetes Self-Management Education Program (DSME), is an evidence based comprehensive health intervention guided by the American Diabetes Association (ADA) national standards of care (ADA, 2017; Chrvala, Sherr, & Lipman, 2016; Gucciardi et al., 2013). DSME facilitates development of the knowledge, skills and abilities necessary for self-management and integrates needs, goals, and life experience of the individual with T2DM. DSME is designed to empower by providing individuals with tools to make informed self-management decisions (ADA, 2017).

Self-Management Outcomes

A number of systematic reviews have evaluated the effectiveness of DSME and provides an evidence-based foundation on which to further develop effective self-management interventions (Chrvala et al., 2016; Gucciardi e al., 2013). Chrvala and colleagues (2016) assessed the impact of DSME interventions on glycosylated hemoglobin (HbA1c). Specifically, the authors evaluated education mode of delivery (individual, group, combination, or remote methods), DSME provider type (delivered by solo or team), DSME delivery duration (months) and DSME contact time (hours) on changes in HbA1c. Studies eligible for inclusion in the review: (a) met definition of DSME as defined by the national standards; (b) included interventions designed to increase knowledge, skill, and ability to perform self-management; (c) comprised interventions adhering to a decision-making process that included tailored and collaboratively established self-management goals; and (d) reported HbA1c as an outcome (Chrvala et al., 2016). Team interventions administered by a diverse group of two or more healthcare professionals were associated with significant changes in HbA1c. Outcomes revealed that 69.6% of the team interventions (n=46) were associated with significant changes in glycemic control over 56.3% with individual provider interventions (n=71). This review also revealed that a combination of individual and group interventions achieved the most significant improvements in HbA1c (86%, n=18) and, in 70% of the studies (n=86), an intervention contact time of greater than 10 hours was associated with the greatest improvements in HbA1c (Chrvala, et al., 2016). Only 32.5% (n=39) of the 120 studies were theory informed. In those studies that included a theoretical framework, no consistent theory was utilized as a guiding framework (Figure 1).

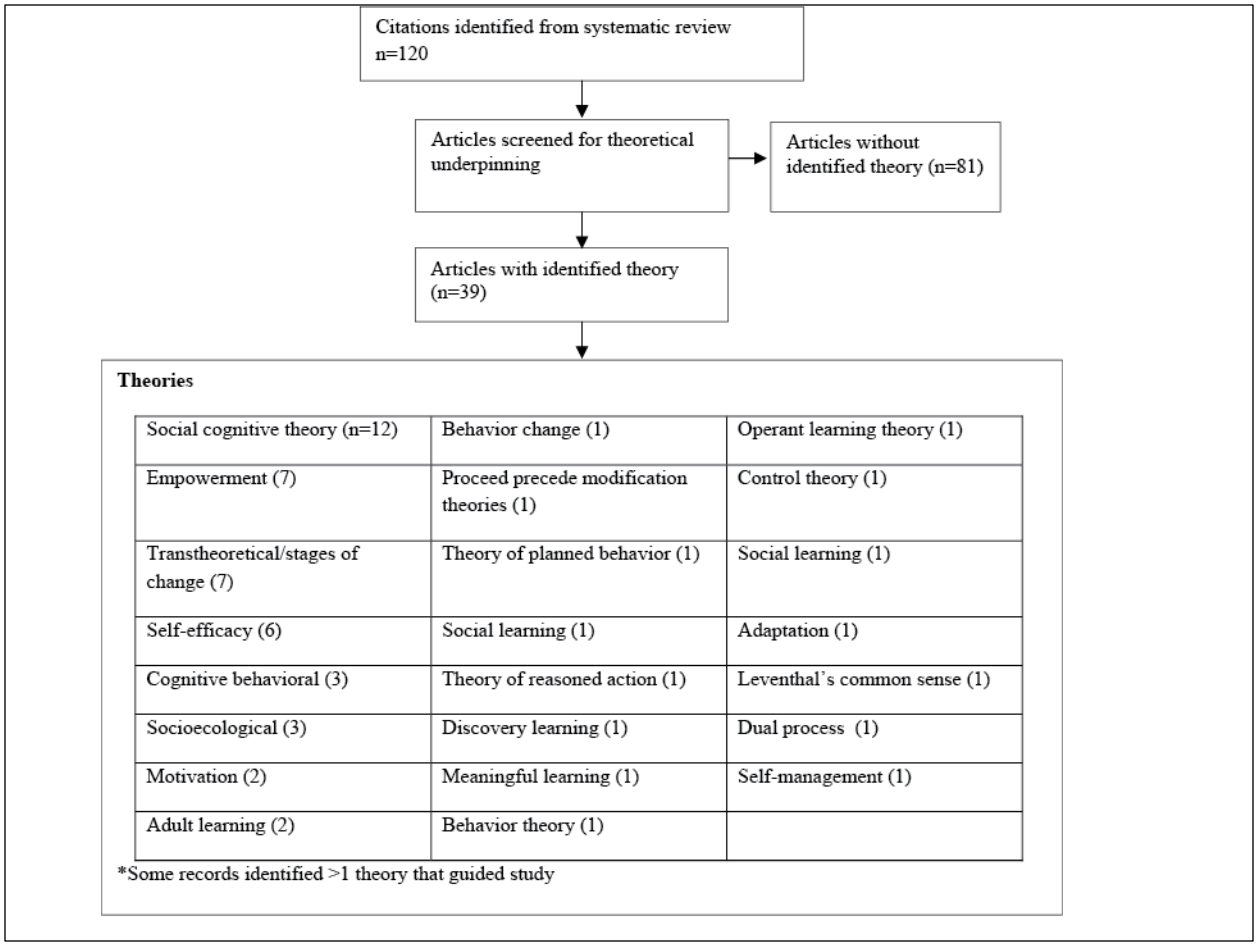


Figure 1. Search Strategy to Identify Theoretical Underpinnings.
Note: A search strategy was used to identify theory-driven research in DSME intervention studies. Citations were identified from a systematic review by Chrvala et al. (2016). Articles were then reviewed for theoretical underpinning. Data were applied in this manuscript for documentation of a gap in theory-driven T2DM research.

In another systematic review, Gucciardi and colleagues (2013) identified specific DSME intervention characteristics that improved T2DM outcomes of women of diverse ethnic backgrounds. Authors sought to identify studies that compared outcomes across racial and ethnic groups due to the disparity and lack of prevalence of T2DM in non-white populations. Studies eligible for inclusion in the review were randomized controlled trials and comparative studies that had DSME outcomes as described for minority ethnic groups. Intervention characteristics were evaluated with regard to effects on HbA1c, anthropometric measurements, physical activity and diet outcomes and included: (a) intervention setting; (b) intervention format (1 to 1 versus

group); (c) mode of delivery (face to face, written, telephone and audiovisual); (d) education strategies (didactic, goal setting, situational problem-solving, peer led, discussion groups, feedback and diaries); (e) duration (months); (f) intensity (low vs high); (g) interventionist (nurse, dietitian, community peer, or multidisciplinary team); (h) content specific components (e.g., exercise, recognition of complications); and (i) intervention design (e.g., used subject's primary language, included cultural values and assessment of individual needs). Statistical analysis determined whether the intervention characteristics had a positive or negative association with the outcomes of interest. Five intervention delivery characteristics had positive associations with 3 or more outcomes in the studies: (a) hospital-based clinic intervention setting; (b) intervention delivered to a group; (c) education strategy involved situational problem solving; (d) high intensity contact, 10 or more sessions; and (e) incorporation of dietitian (Gucciardi et al., 2013). This systematic review provides continued support for tailored interventions, specifically including a multidisciplinary approach, consideration for language and culture with a group of individuals with greater than 10 sessions.

A limited number of studies in this review included behavioral outcomes such as diabetes knowledge (n=3), quality of life (n=2) and distress (symptom or emotional) (n=2). Further, the limited number of studies containing psychosocial outcomes provides a limited view of T2DM self-management as psychosocial factors are known to impact self-management and uncover lifestyle management which is a fundamental aspect of T2DM care. Associations between these psychosocial outcomes and the intervention characteristics were not determined as they were not considered outcomes for DSME as defined by this systematic review. Only 53.8% (n=7) reported theoretical underpinnings (Figure 2). Given the small number of studies in the review,

future research is required to further explore self-management interventions in diverse ethnic groups.

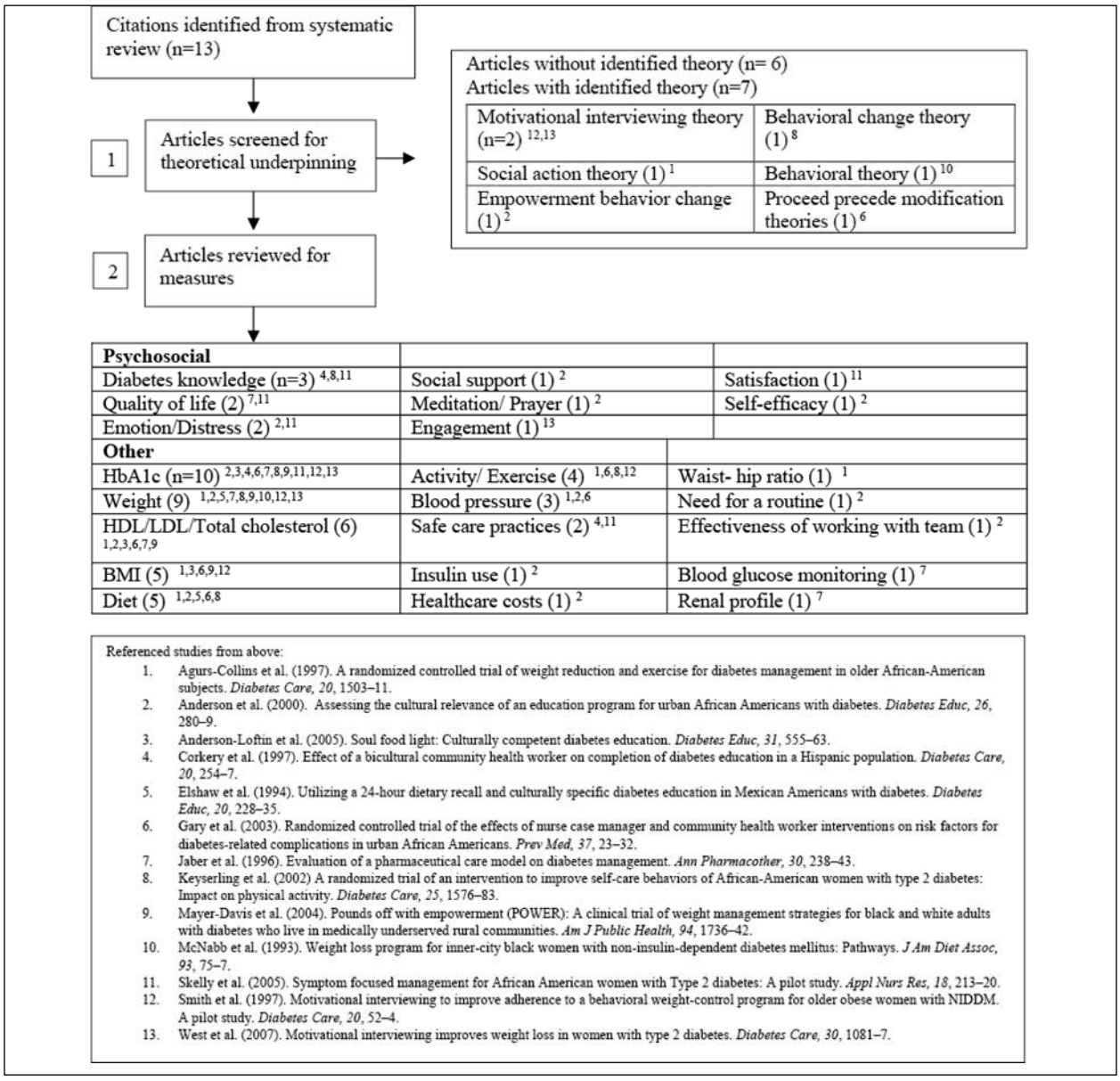


Figure 2. Search Strategy to Identify Theoretical Underpinnings and Measures of Interest
Note: A search strategy was used to identify theory-driven research and measures of interest in DSME intervention studies. Citations were identified from a systematic review by Gucciardi et al. (2013). Articles were then reviewed for theoretical underpinning and measures of interest. Data were applied for documentation of DSME measures of interest and gaps in theory-driven research.

A systematic review and meta-analysis aimed to determine the most effective DSME in older adults, aged >65. Sherifali and colleagues (2015) evaluated the effect of DSME intervention programs reported in 13 studies with any of the following five characteristics: (a) tailored interventions (n=5); (b) interventions delivered in a group setting (n=1); (c) interventions that included feedback following administration (n=2); (d) programs with a psychosocial emphasis (n=5); and (e) interventions that were administered directly by providers (n=0). Outcomes included HbA1c, lipids and blood pressure. Findings demonstrated that programs with tailored interventions (customized to situation, needs, and goals) and strategies with a psychological emphasis (coping, depression, and distress) resulted in a significant reduction in HbA1c (-0.2%). Variables most frequently reported in the studies included depression/distress (n=4), diabetes knowledge (n=3), quality of life (n=2) and social support (n=2). Consistent with other reviews, a theoretical framework was not consistently utilized. Only 15.4% (n=2) reported utilizing of theory as a guiding framework, which further contributes to the need to identify a consistent theoretical framework for future self-management research (Figure 3).

These reviews provide critical information regarding which DSME interventional characteristics report the most impactful outcomes for T2DM. Systematic reviews of DSME interventions suggest that interventions which were: (a) delivered by a diverse group of knowledgeable expert professionals; (b) delivered to a group of patients; (c) provided for a longer contact time; (d) located within a hospital-based clinic setting; and (d) provided tailored interventions and psychosocial support were all demonstrated to be the most effective strategies for impacting HbA1c outcomes. These intervention characteristics provide evidence to design these as a future focus with intervention development as well as in clinical care. An observation

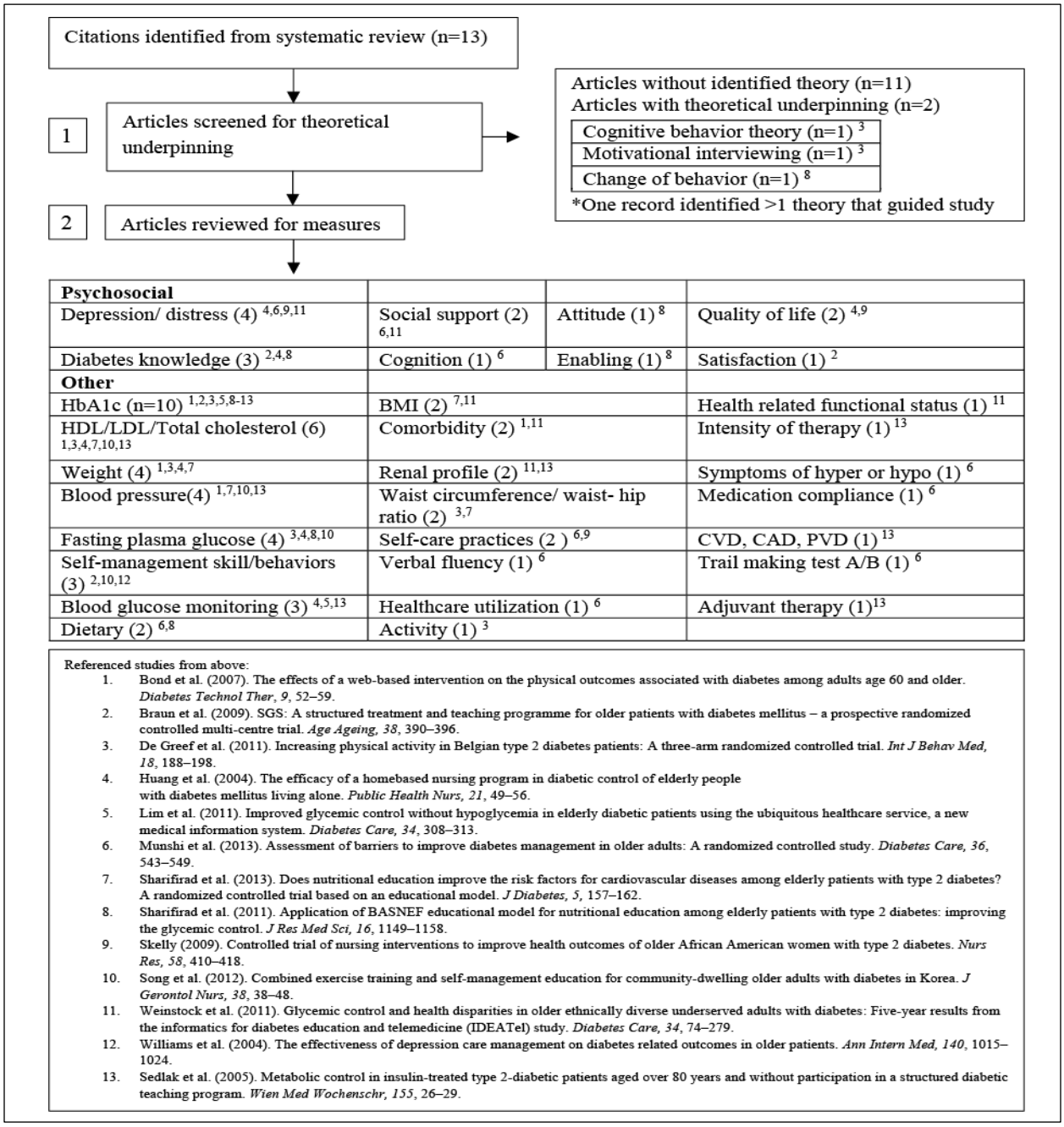
with this review points to a limited number of studies focusing on psychosocial outcomes despite the integration of life experiences in diabetes management. The perceptions of the ability to engage in self-management is an important psychosocial factor correlated with an improved self-management and treatment outcomes (ADA, 2017). Additionally, psychosocial issues are known to be barriers to SM and impact proximal and distal outcomes. The ADA developed a position statement on psychosocial care for people with T2DM (2017); providing evidence and support to examine psychosocial factors within the self and family management processes and incorporating facilitator and barrier domains into clinical care. A burgeoning evidence base provides critical information about the design and delivery of DSME interventions. However, additional research is needed to further assess the qualitative and quantitative impact of outcomes. Also lacking is use of theory based self-management research. Theory based research will provide a bridge from what is currently known and the conduct of future research as well as translation into practice to improve T2DM self-management and outcomes.

Self- and Family Management Framework

The National Institute of Nursing Research (NINR) supports research that engages individuals and families as active participants in self-management programs that maintain and enhance quality of life while living with a chronic disease (NINR, 2016). Additionally, self-management research encompasses strategies that account for social, cultural, economic and emotional factors that influence health and quality of life (NINR, 2016). The Self- and Family Management framework (Grey, Shulman-Green, Knafl, & Reynolds, 2015; Grey, Knafl, & McCorkle, 2006) is well established with a burgeoning evidence base across multiple chronic conditions in a variety of populations and encompasses factors that influence T2DM self-

management making it an appropriate, evidence based framework to guide the development of tailored interventions. However, the framework has not been applied in T2DM.

The Self- and Family Management Framework (Figure 4) depicts interrelated concepts and integrates them into a configuration that illustrates the complexity of Self-Management Framework (Grey et al., 2015; Grey, Knafl, & McCorkle, 2006). The framework is comprised of four major factors: (a) facilitators and barriers; (b) self-management processes; (c) proximal outcomes; and (d) distal outcomes. Self- and family management of chronic disease is considered an interactive process that influences outcomes (Grey et al., 2006). To date, research on self and family management in the T2DM population is limited; however, application of this framework in future research may elucidate the complexities of self-management in T2DM, inform interventions, and improve health outcomes.



Psychosocial			
Depression/ distress (4) [4,6,9,11]	Social support (2) [6,11]	Attitude (1) [8]	Quality of life (2) [4,9]
Diabetes knowledge (3) [2,4,8]	Cognition (1) [6]	Enabling (1) [8]	Satisfaction (1) [2]
Other			
HbA1c (n=10) [1,2,3,5,8-13]	BMI (2) [7,11]		Health related functional status (1) [11]
HDL/LDL/Total cholesterol (6) [1,3,4,7,10,13]	Comorbidity (2) [1,11]		Intensity of therapy (1) [13]
Weight (4) [1,3,4,7]	Renal profile (2) [11,13]		Symptoms of hyper or hypo (1) [6]
Blood pressure(4) [1,7,10,13]	Waist circumference/ waist- hip ratio (2) [3,7]		Medication compliance (1) [6]
Fasting plasma glucose (4) [3,4,8,10]	Self-care practices (2) [6,9]		CVD, CAD, PVD (1) [13]
Self-management skill/behaviors (3) [2,10,12]	Verbal fluency (1) [6]		Trail making test A/B (1) [6]
Blood glucose monitoring (3) [4,5,13]	Healthcare utilization (1) [6]		Adjuvant therapy (1)[13]
Dietary (2) [6,8]	Activity (1) [3]		

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Figure 3. Search Strategy to Identify Theoretical Underpinnings and Measures of Interest
Note: A search strategy was used to identify theory-driven research and measures of interest in DSME intervention studies. Citations were identified from a systematic review by Sherifali et al. (2015). Articles were then reviewed for theoretical underpinning and measures of interest. Data were applied for documentation of DSME measures of interest and gaps in theory-driven research.

Facilitators and Barriers

Facilitator and barrier factors are shown in Figure 4. These factors are known in chronic conditions to influence responses to self-management interventions and health outcomes and may be targeted for intervention (Grey et al., 2015). For example, personal characteristics, health status, availability of resources, the environment and health care system are known to influence self-management in chronic conditions (Grey et al., 2015).

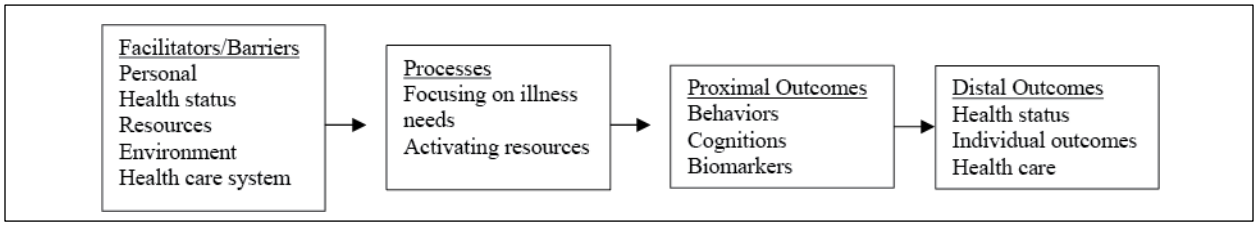

Figure 4. Manuscript 1Theoretical Framework
Note: This figure is a self and family management framework in T2 DM research, adapted with permission from Grey et al. (2015, p. 165).

Personal characteristics. Personal characteristics include knowledge, beliefs, emotions, motivations and life patterns. Knowledge and emotions have been studied in the T2DM individuals. Knowledge is required for successful self-management of T2DM (Chrvala et al., 2016). DSME interventions aimed at developing knowledge, skills and abilities improve outcomes with persons who live with the diagnosis of DM (ADA, 2017; Chrvala et al., 2016). Five studies of DSME interventions that were associated with favorable change in knowledge resulted in a reduction HbA1c (Chrvala et al., 2016). In addition, one systematic review by Bagnasco and colleagues (2104) identified four studies identifying knowledge as a personal factor influencing self-management. Thus, burgeoning evidence supports knowledge as an important aspect in DSME as education facilitates the acquisition of the requisite knowledge,

skill and ability for ongoing self-management, therefore having the potential to improve outcomes (ADA, 2017).

Research suggests that emotional well-being is an essential factor in self-management (ADA, 2017; Figure 2; Figure 3; Bagnasco et al., 2014). Emotional issues can disrupt daily management and metabolic control and affect outcomes (ADA, 2017; Lipscombe, Burns, & Schmitz, 2015; Rubin & Peyrot, 2001). Diabetes distress, one specific type of distress that can affect proximal and distal outcomes, is characterized by feelings of concern, fears and worries related to living with T2DM and diabetes self-management. Sources of distress include: (a) feelings of being overwhelmed by life with T2DM; (b) perceived lack of social support; (c) ability to realistically adhere to a treatment regimen; and (d) quality of care (Lipscombe et al., 2015). Therefore, the ADA (2017) provides guidance on screening, monitoring and management of emotional issues in individuals with T2DM and should continue to be a focus in future examination.

Health status. One objective of DSME is to improve health status, which is both a facilitator/ barrier and an end outcome of T2DM SM. Although the model incorporates concepts of co-morbidity, condition severity, symptoms and cognitive function, research suggests that health status can be conceptualized in T2DM in several ways. One systematic review identified individual factors that influenced self-management. Health status (n=2), duration of disease (n=1), presence of co-morbidity (n=1), and complexity of treatment and medications (n=2) were identified as factors that influenced self-management and identified these factors as elements for future research (Bagnasco et al., 2014). With regard to complexity of treatment regimen, one study of 223 subjects determined that if insulin was used, it independently contributed to worse glycemic control (Al-Khawaldeh, Al-Hassan, & Froelicher, 2012). Additionally, systematic

reviews of the T2DM self-management intervention studies revealed that assessments of comorbidity and medication related issues were less commonly found in studies, supporting the need for future examination of the measures within the framework (See Figure 2 & Figure 3).

Resources and environment. The model incorporates concepts of financial, equipment and community. The inclusion of resources in T2DM research is supported by ADA standards citing that disparities in T2DM outcomes are attributed to lack of resources (ADA, 2017). Research on the impact of economic resources on self-management is limited; however, concepts of financial and social resources show utility for use in self and family management in the diabetes population (Weaver et al., 2014). One qualitative study examined the impact of financial resources and social resources on self-management (Weaver et al., 2014). The study employed in-depth, semi-structured interviews of 47 randomly- selected individuals to investigate the experience and self-management of T2DM. Interviews explored the management of T2DM such as medications, dietary and activity practices as well as the role of resources, including economic, social and cultural (Weaver et al., 2014). Open-ended questions allowed subjects to elaborate on how the resources shaped the process of self-management. Researchers identified a scheme for scoring and ranged from 1 (low) to 5 (high). Each researcher independently scored each, resolved any discrepancies and averaged the scores. An intra-class correlation measure assessed inter-rater reliability. Subject groups were created based on z-scores. Subjects that scored in the "low resource" group scored low on economic resources and had the highest economic challenges. In this group, the expense of food was directly related to the consumption of a diabetes-healthy diet. Results showed that the social environment also partially compensated for the economic hardships in this group, however social engagement beyond the household was limited (Weaver et al., 2014). In contrast, the "medium resource" group had economic resources

that appeared sufficient to meet dietary and other self-management needs. However, this group had mixed results regarding social resources such that the household appeared to be supportive yet social engagement beyond the household yielded mixed results. The "high resource" group had little concern for cost for food, had a supportive social environment and participated in meaningful activities outside the home (Weaver et al., 2014).

Health Care System. The model incorporates concepts such as access, navigation, continuity of care and provider relationships. Research suggests that quality of diabetes care is an essential component in T2DM self-management (ADA, 2017; Harris, Kirsh, & Higgins, 2016). The ADA (2017) stated that there is persistent variability in the quality of diabetes care across providers and settings. One retrospective review of 988 cases investigated differences in clinical and quality measures between individuals with shared medical visits (group visits) versus usual care (1:1 with provider) in a Midwest Veterans Administration hospital (Harris et al., 2016). Results showed there were no significant differences in HbA1c, lipids, blood pressure or emergency department visits between groups. The providers of traditional care model with one provider had a significantly higher number of HbA1c and lipid panels drawn but the shared medical visit providers were more adherent to the quality metrics of prescribing angiotensin-converting enzyme inhibitors and aspirin, retinal screening and podiatry care. The authors stated that these results were consistent with three other studies that showed improved practice guideline utilization by providers with use of shared medical visits (Harris et al., 2016). There are many diabetes quality metrics to consider when evaluating diabetes management. The standards provide the healthcare team, patients, researchers, payers and other interested individuals with the components of T2DM care, treatment goals and the tools to evaluate the quality of care (ADA, 2017).

Self-management Processes

Self-management processes focus on illness needs, activating resources and living with the chronic illness. The Self- and Family Management Framework captures many concepts of interest in the T2DM population and includes the tasks and skills necessary for the physical management of the chronic illness, social support, identification of psychological resources, and the processing of emotions.

Focus on illness needs. The model includes concepts such as learning, taking ownership, and health promotion. self-management research also supports the utility of self-efficacy for the study of self and family management (Al-Khawaldeh et al., 2012; Bagnasco et al., 2014; Liu, 2012). A concept analysis defined self-efficacy as the perceived confidence in the ability to carry out a required self-management activity of daily living, readiness to change and adherence to the regimen (Liu, 2012). Self-efficacy has received increased recognition as a potential predictor of T2DM health behavior change, such as weight loss, dietary changes and exercise (Liu, 2012). One review found a positive relationship between self-efficacy and T2DM self-management behaviors in 16 studies (Bagnasco et al., 2014). In another study, individuals with higher self-efficacy reported better self-management behaviors in taking medications, glucose monitoring, diet and exercise (Al-Khawaldeh et al., 2012). Taken together, findings from these studies suggest that self-efficacy can account for variance in self-management behaviors.

Activating resources. The model incorporates resources that individuals and families need to activate to assist with self-management. These can include communication with the health care team, the identification of psychological and spiritual resources and managing support. The concepts of social support and resilience show promise for the study of self and family management in the T2DM population (Bradshaw, 2007; Chew et al., 2015; Grey et al.,

2015; Lipscomb, 2015; van Dam et al., 2005). Social support refers to perceived support and resultant satisfaction; and the literature demonstrates a correlation of social support to well-being and emotional health (van Dam et al., 2005). There is some evidence that social support influences self-management. One systematic review identified six studies that tested a social support interventions on T2DM outcomes (van dam et al., 2005). Authors reported that social support influenced outcomes of behavior, quality of life, knowledge and biologic measures (van dam et al., 2005). A longitudinal study of 1135 individuals found a negative correlation with diabetes distress levels and perceived social support (Lipscomb et al., 2015). Another study by Chew and colleagues (2015) found that despite 76% of subjects reporting positive social support, no significant associations were found between social support and HbA1c results. Thus, while social support is a factor influencing T2DM self-management, results are mixed indicating a need for further research.

The second activating resource is resilience. Resilience is defined as the ability to bounce back, adapt and cope with a stressful event, adversity or change (Bradshaw et al., 2007). One intervention study by Bradshaw et al. (2007) tested the efficacy of a resiliency training approach for individuals who had received prior standard diabetes education. Researchers suggest that significant improvements in psychosocial outcomes, such as resilience, can be very influential in improving overall health (Bradshaw et al., 2007).

Proximal Outcomes

Proximal outcomes can be seen as mediators of the outcomes of Self- and Family Management. These include changes in behavior, cognitions and biomarkers and lead to distal outcomes. Proximal outcomes frequently examined in self-management intervention studies are ones specifically targeted at behavior or lifestyle changes as these changes can lead to improved

T2DM distal outcomes. The concepts seen most frequently in research and demonstrate the most utility for self and family management are: diet, exercise, self-management behaviors, glucose monitoring, self-care and HbA1c (Gucciardi, 2013; Sherifali, 2015). One review of 13 studies showed diet (n=5) and exercise (n=4) were concepts of most interest (Gucciardi, 2013). Similarly, another review of 13 studies found self-management behaviors (n=3), glucose monitoring (n=3), self-care practices (n=2), diet (n=2) and activity (n=1) as concepts of most interest (Sherifali, 2015). In addition to self-management behaviors and lifestyle changes, the most frequently examined outcome in self-management intervention studies is the biomarker HbA1c. HbA1c was measured in 77% of the studies in both systematic reviews (Figure 2; Figure 3). HbA1c reflects glycemic control, averaging glucose levels over the prior three months and is a strong predictor for diabetes complications (ADA, 2017).

Distal Outcomes

Distal outcomes include health status, quality of life, and health care, such as access and utilization. Research on T2DM self-management suggests health related quality of life is essential to consider as it is a long-term outcome found in multiple reviews of the literature (Figure 2; Figure 3; Bagnasco et al., 2014). Individuals with T2DM report decreased quality of life as compared with individuals without chronic illness and complications; it is the chronicity and it was identified that complications of T2DM as the consistently disease-specific determinant of quality of life. Studies suggest that improved health status and perceived control of disease results in improved quality of life (Rubin & Peyrot, 2001). Continued focus on improving health and disease trajectory are necessary to improve quality of life individuals with T2DM.

Conclusion

self-management is the cornerstone of T2DM management. Effective self-management has been shown to improve glycemic control, which is critical for improving T2DM outcomes. Prior research has provided evidence for the development of self-management interventions. The Self and Family Management framework has demonstrated utility in a number of chronic diseases but has not been used in T2DM. The use of the Self- and Family Management framework provides a new approach for understanding self-management in the T2DM individual as well as developing and testing of self-management interventions. This will support the further integration of theory, research and practice, and strengthen the nursing profession. In conclusion, the Self- and Family Management framework is presented for use in DM self-management research in hopes to further knowledge, advance the field and transform health.

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Chapter 3

Methods

This chapter describes the design, sample and setting, data collection procedures, variables and measures and analysis.

Design, Sample and Setting

A cross sectional descriptive design was used to examine relationships among facilitators and barriers to self-management and outcomes that are the consequences of the management. Dependent variables were HbA1c, quality of life and health status. Independent variables were diabetes distress, self-efficacy and resilience. The theoretical framework is illustrated in Figure 5. Sample size was determined using an a priori sample size calculator. For a significance level of α=0.05, three predictor variables, 80% power and an effect size of 0.15, a sample of 76 subjects was needed. Inclusion criteria were: 18 years or older, diagnosed with T2DM, and able to speak and read English. Recruitment sites for the study included (a) an Endocrine clinic in the Midwest United States (US) that follows approximately 2500 individuals with T2DM, and (b) a Primary Care clinic in the southeast US that follows approximately 1972 individuals with T2DM.

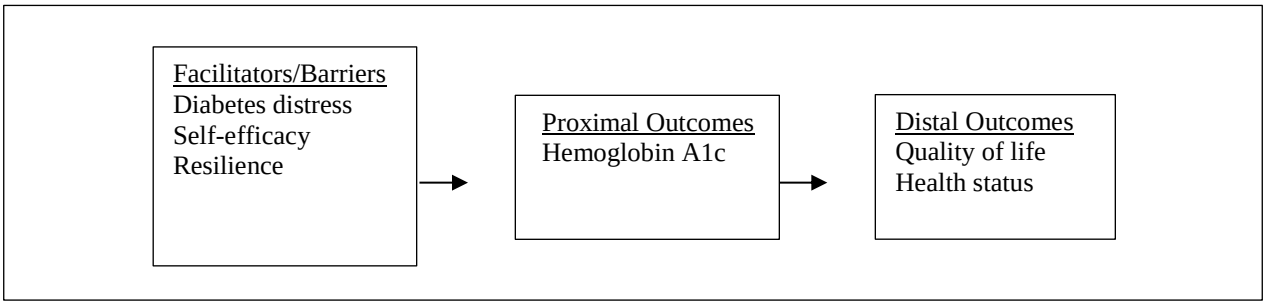

Figure 5. Self and Family Management Framework in T2DM research.
Adapted and reprinted from Nursing Outlook, 63, M. Grey, D. Shulman- Green, K. Knafl, & N. R. Reynolds, A Revised Self and Family Management Framework, p. 165, 2015, with permission from Elsevier and primary author.

Prior to initiation, the study was approved by the institutional review boards at the researchers' university and each of the clinic institutions. Potential subjects, scheduled for follow up clinic visits, were identified by clinic staff and evaluated for eligibility. Eligible patients met with study staff after the scheduled clinic visit. Study staff explained the study and obtained informed consent. Following informed consent, a blood sample via finger stick for HbA1c was collected and six questionnaires were administered. Data collection took approximately 20 minutes.

Variables and Measures

The demographic variables (gender, age, ethnicity, education, employment and household income) and clinical characteristics (length of T2DM diagnosis, treatment regimen, prior participation in T2DM self-management education [DSME], and collaboration with health care provider) were self-reported on a demographic questionnaire.

T2DM distress was measured using the Problem Areas in Diabetes scale (PAID) scale (Polonsky et al., 1995). The PAID scale is a self-administered, valid and reliable instrument that captures the breadth and severity of emotional distress from living with T2DM and its treatment, including guilt, anger, frustration, depressed mood, worry and fear. It consists of 20 items that employ a 5-point Likert scale format response of 0 (not a problem) to 4 (serious problem). Scores are added and multiplied by 1.25, generating a total score between 0-100, with higher scores indicating greater T2DM distress. It has demonstrated strong reliability, Cronbach's alpha =0.95 (Polonsky et al., 1995). Cronbach's alpha =0.96 in this study.

Diabetes self-efficacy was measured using the Diabetes Self-Efficacy Scale (DSES) (Self-management Resource Center, 2018). The instrument was developed for DSME by the Sanford Patient Education Research Center and was based on a prior instrument, the Chronic

Disease Self-Efficacy Scale. The research center determined the need for a diabetes specific self-efficacy scale which lead to the creation of the DSES. The number of items were reduced from the original scale and the 8-item DSES measure was first developed and tested in Spanish. It includes the management domains of diet, exercise, management of hyper- and hypoglycemia. Each item ranges from 1 (not at all confident) to 10 (totally confident). The score of the scale is the mean of the eight items. Higher scores indicate greater self-efficacy related to self-management. The English version of the DSES has demonstrated strong reliability and validity, Cronbach's alpha= 0.85 and test-retest validity= 0.80 (Ritter, Lorig, & Laurent, 2016). Cronbach's alpha =0.84 in this study.

Resilience was assessed with the Resilience Scale (RS-14) and measures five resilience characteristics including self-reliance, purpose, equanimity, perseverance and authenticity (The Resilience Center, 2019). It was developed from the original 25-item Resilience Scale (RS) to reduce completion time. It consists of 14 items on a 7-point Likert scale 1 (strongly disagree) to 7 (strongly agree). Resilience scores are obtained by summing each item for a total score. Scores range from 14 to 98; very low resilience= 14- 56, low resilience= 57-64, on the low end= 65- 73, moderate= 74- 81, moderately high= 82- 90, and high= 91- 98 (Aiena et al., 2015). Internal consistency alpha coefficient for the RS and the RS-14= 0.97 and Cronbach's alpha= 0.89 to 0.96 (The Resilience Center, 2016). Cronbach's alpha= 0.95 in this study.

Glycemic control was measured by HbA1c, an indirect measure of average glycemia. Based on current guidelines, a reasonable HbA1c result is <7%. (ADA, 2017). HbA1c was performed via fingerstick and analyzed with the A1c Now+ point-of care assay device. *A1c Now+* was certified by National Glycohemoglobin Standardization Program (NGSP) and thus Clinical Laboratory Improvement Amendments (CLIA) waived. The A1c Now+ automatically

runs internal controls and quality checks. Initial accuracy testing was completed in multiple studies. Using a NGSP method, fingerstick comparative testing with 189 subjects resulted on average at 99% and venous sampling of 110 subjects resulted on average at 99.7%. Initial precision testing was conducted with a specialized protocol. Two whole blood samples, one of approximately 6% HbA1c (low) and one of approximately 9% HbA1c (high) were tested 4 times a day over 20 days, for a total of 80 assays per low/high level. Overall coefficient of variation (CV%) precision testing included within day and between day and resulted in 3.00% CV for the low HbA1c value and 4.02% CV for the high HbA1c value. The performance meets requirements for NGSP certification (PTS Diagnostics, 2018).

The Audit of Diabetes Dependent Quality of Life (ADDQOL-19) measure was selected to evaluate quality of life (Bradley et al., 1999). The ADDQOL-19 measures the perceived impact of T2DM on quality of life, specifically addressing emotional, physical and social functioning. The instrument was developed from a review of existing instruments and input from health professionals and persons with T2DM. It consists of 19 items. First, quality of life is rated on a 7-point Likert scale from "excellent" to "extremely bad." Second, the subject rates the impact of quality of life by T2DM on a 5-point Likert scale by rating how quality of life would be without T2DM from "very much better" to "worse." Remaining items on the instrument sections rate how T2DM affects a specific aspect of life (impact rating) and how important the specific aspect is to quality of life (importance rating). Scales range from -3 to +1 (impact rating) and 0 to +3 (importance rating). A weighted score is calculated for each of the 19 items. Lower scores indicate lower quality of life. A mean weighted impact ADDQOL-19 score is calculated for the entire scale across all 19 items. Cronbach's alpha= 0.84, 0.89- 0.90 (El Achhab et al., 2008). Cronbach's alpha =0.88 in this study.

Health status was assessed with the 12- item short form (SF-12v2). It was developed from the original 36-item short form (SF-36) instrument to reduce completion time. It consists of 12 items from each of the 8 domains of the SF-36 and measures physical or mental health status. Therefore, two composites scores are derived, the physical health composite score (PCS) and a mental health composite score (MCS). Norm based scores are used, with a mean of 50 and standard deviation of 10. Higher scores indicate better health. Cronbach's alpha = 0.90 (PCS) and 0.85 (MCS) (Christensen, 2013). Cronbach's alpha =0.88 (PCS) and 0.84 (MCS) in this study.

Analysis

The study sample was characterized using demographic and clinical variables. Means and standard deviation are reported for continuous variables and frequencies and percentages are reported for categorical variables. Spearman's rank correlation coefficient was used to test for associates between independent and dependent variables. Additional testing was completed to evaluate for multicollinearity and the variance inflation factor showed none was present.

A stepwise model building approach was used to identify the main effects and interactions between specific categorical demographic variables and outcomes. A main effect is the action that a single variable has on a dependent variable. In step 1 of the model building, main effects (ethnicity, treatment regimen, DSME status, provider collaboration and years since diagnosis) were added into the model. Next, potential two way interactions (interactions of order 2) were added into the model. This process would test if two variables simultaneously interact with each other on the dependent variable, leading to potential significant differences, greater than what each would affect the dependent variable on their own. Step 2 of the model building included significant interactions in a refined model. In step 3, interactions with a $p>0.1$ were excluded from the model. Table 3 depicts the final model, that includes dependent variables and the statistically significant interactions.

A regression using a stepwise model-building approach examined factors predicting HbA1c, health status and quality of life. Step 1 of the model building included all three potential independent variable predictors. Level of significance was assessed. Step 2 included the significant variable and then other variables added into the model one by one to assess for the R-square change and F change p-value. Data were analyzed with SPSS 25 statistical software and Optum PRO CoRE version 1.4 software. The level of significance was set at $\alpha = 0.05$. Prior to data analysis, reliability of instruments was performed.

Summary

In summary, the present study was a correlational descriptive design. The relationships among variables and predictors of self-management were explored in individuals with T2DM from clinics in the Midwest and Southeastern United States. Instruments diabetes questionnaire, PAID, DSES, RS-14, ADDQOL-19, SF-12v2 and A1cNow+ were used to gather the data. The collected data were analyzed using SPSS 25 and Optum Pro Core software. The findings of this study are presented in Chapter 4, Examining Biobehavioral Variables and Predictors Associated with Type 2 Diabetes Self-Management manuscript.

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Chapter 4

Examining Biobehavioral Variables and Predictors Associated with Type 2 Diabetes Self-Management

Type 2 diabetes mellitus (T2DM) affects over 30 million individuals in the United States and represents a growing health problem with serious health complications (CDC, 2019). Self-management is fundamental to glycemic control and the prevention or reduction of T2DM-related complications (CDC, 2019; ADA, 2017). Effective self-management is essential to prevent or reduce morbidity and mortality (CDC, 2019).

Evidence increasingly suggests there is a psychological burden associated with T2DM (ADA, 2017; Bagnasco et al., 2014; Chew, et al., 2017; Chew et al., 2014; Gucciardi et al., 2013; Sherifali et al., 2015; Wang, 2017). To achieve management goals, challenging and demanding activities must take place, possibly resulting in chronic stressors and negative emotions. Many of these activities include choosing and preparing healthy foods, integrating regular physical activity into activities of daily living, monitoring for impact of choices on blood glucose control and recognizing when health care providers are needed to resolve issues. Ultimately, these stressors and emotions have the potential to negatively impact self-management outcomes. The presence and utilization of internal psychosocial resources are needed to support self-management behaviors to improved disease control and quality of life (Chew et al., 2014).

Theory-driven self-management research is emerging to include psychosocial aspects of daily management. Guided by the Self and Family- Management Theory (Gray et al., 2015), we undertook the present study to explore a comprehensive model that includes facilitators and barriers and outcomes of self-management. The purpose of the study was to explore the

relationships between T2DM distress, self-efficacy and resilience and outcomes of glycosylated hemoglobin (HbA1c), quality of life and health status in persons with T2DM.

Conceptual Framework

The use of theoretical models in research is critical to understanding behavior change and guiding the development of interventions to support those living with T2DM. The mechanisms underlying self-management are not fully understood. Based on previous work by Gray and colleagues, a Self and Family-Management Framework (2015) was developed to provide direction on future research and guide the testing of theory- based research in chronic illness. The authors' focus on self and family- management theory unraveled the many influencing factors across chronic conditions and identified the potential outcomes from enhanced management. While evidence of use of the Gray and colleague framework is not seen in the T2DM self- management literature, application of the framework to conceptualize self and family management in the T2DM population was recently outlined by Emery and colleagues (2019) to advance the field of T2DM self-management research.

Figure 6 represents the dynamic interplay of important psychosocial factors that have previously been examined in T2DM studies. Facilitators and barriers to T2DM self- management include T2DM distress, self- efficacy and resilience and are described as interactive and influence daily management of T2DM. Consequences of management may lead to better outcomes such as glucose control, health status and quality of life.

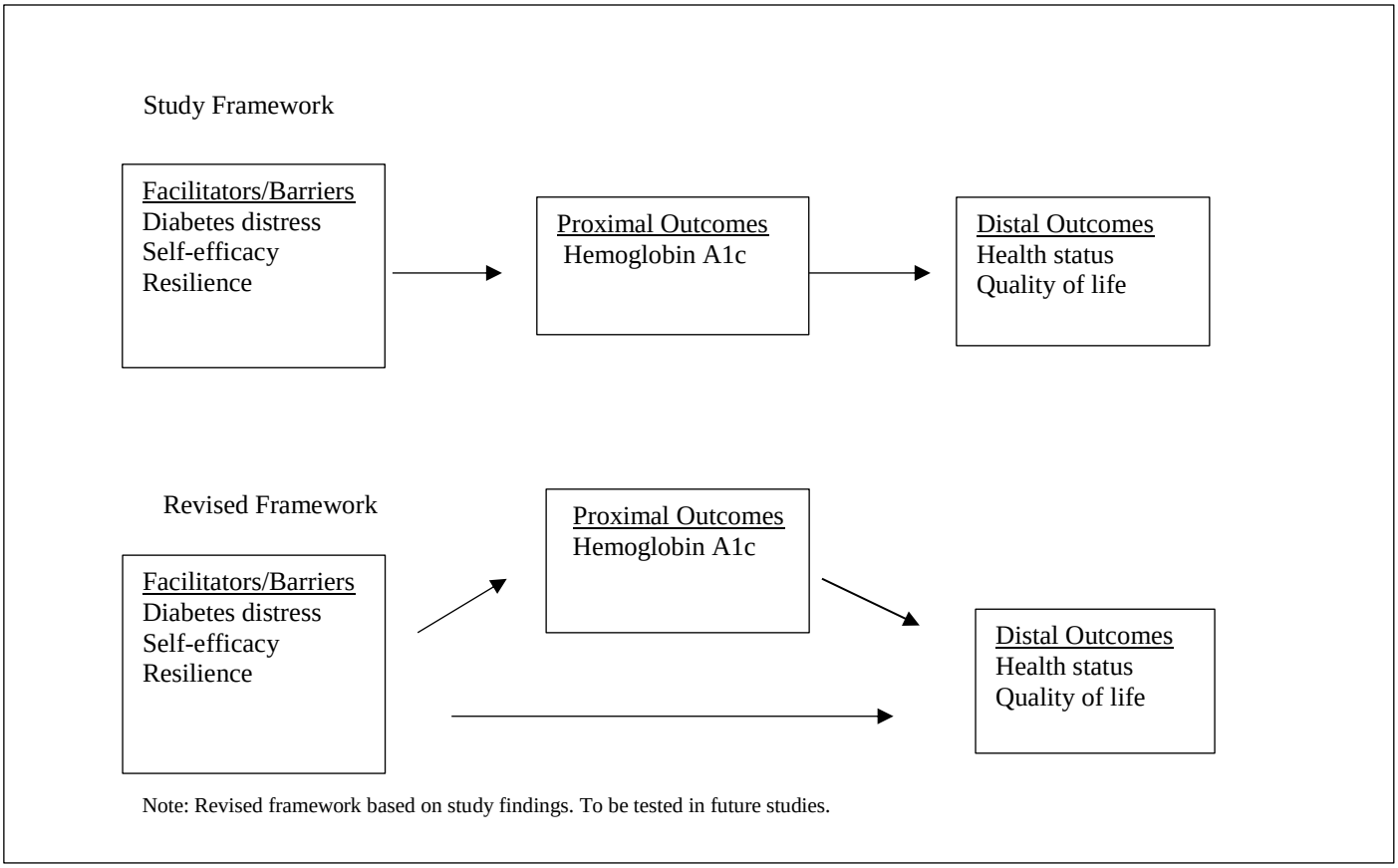

Figure 6. Self and Family Management Framework in T2DM research study.
Depicts framework that guided study and a revised framework based on study findings. Adapted and reprinted from Nursing Outlook, 63, M. Grey, D. Shulman- Green, K. Knafl, & N. R. Reynolds, A Revised Self and Family Management Framework, p. 165, 2015, with permission from Elsevier and primary author.

The model depicts T2DM distress, which refers to the unique burdens and worries associated with the experience while managing with T2DM (Fisher et al., 2014; Fisher et al., 2012). T2DM distress influences self- management and is associated with poor glucose control, elevated HbA1c levels (Fisher et al., 2007; Fisher et al., 2008; Fisher et al. 2010a; Fisher et al., 2010b; Fisher et al., 2012; Graue et al, 2012). As a consequence, when a person with T2DM draws on internal resources, distress can be reduced and quality of life can be improved (Graue et al., 2012; Ting et al., 2011; Wang et al., 2011).

The model also depicts the use of self-efficacy, an internal resource defined as the perceived confidence in the ability to self- manage (Liu, 2012). It is considered a protective

factor in the reduction of T2DM distress (Wardian et al., 2014; Kim et al., 2015; Wang, 2017). Resilience, another protective factor that promotes well-being, is defined as the ability to bounce back, face adversity or hardship and successfully adapt (Aiena et al., 2015; Bradshaw et al., 2007b). Previous studies have shown that higher resilience influences glycemic control (Yi et al., 2008; De Nisco, 2011), buffers worsening HbA1c and self-management in the face of rising distress levels (Yi et al., 2008), and is associated with decreased distress levels (Wang et al., 2017). Understanding the nature of these factors is necessary as they are pertinent to daily self-management and ultimately outcomes of that self-management, such as quality of life and health status.

Lastly, due to the self-management demands that living with T2DM places on the individual, it is no surprise that health status and quality of life are widely recognized as important health outcomes in multiple systematic reviews (Bagnasco et al., 2014; Gucciardi et al., 2013; Sherifali et al., 2015; Speight, 2009). The general consensus is that quality of life is (a) multidimensional, involving psychological, physical and social aspects; (b)subjective, how management and treatment impact life in ways important to the individual, and (c) dynamic, changing over time due to influences (Speight, 2009). Health status may be important for quality of life and measuring health status may provide important insights into challenges faced by those living with T2DM (Speight, 2009).

In summary, psychosocial factors play a central role in behavior change and T2DM self-management. Without effective self-management, there is suboptimal glucose control, which increase T2DM -related complications and deterioration in quality of life. Understanding the associations between distress, self-efficacy and resilience with the outcomes of glucose control, quality of life and health status may provide insight into the complexities of self-management.

Subjects, Materials, Methods

Design, Sample, and Setting

The sample size for this cross-sectional study was determined using an a priori sample size calculator. For a significance level of $\alpha=0.05$, three predictor variables, 80% power and an effect size of 0.15, a sample of 76 subjects was needed. Inclusion criteria were: 18 years or older, diagnosed with T2DM, and able to speak and read English. Recruitment sites for the study included (a) an Endocrine clinic in the Midwest United States (US) that follows approximately 2500 individuals with T2DM, and (b) a Primary Care clinic in the southeast US that follows approximately 1972 individuals with T2DM.

Data Collection Procedures

Prior to study initiation, the study was approved by the institutional review boards at the researchers' university and each of the clinic institutions. Potential subjects, scheduled for follow up clinic visits, were identified by clinic staff and evaluated for eligibility. Study staff explained the study to eligible individuals and obtained informed consent. Following informed consent, a blood sample via finger stick for HbA1c was collected and six questionnaires were administered. Data collection took approximately 20 minutes.

Variables and Measures

The demographic variables (gender, age, ethnicity, education, employment and household income) and clinical characteristics (length of T2DM diagnosis, treatment regimen, prior participation in T2DM self-management education [DSME], and collaboration with health care provider) were self-reported on a demographic questionnaire.

T2DM distress was measured using the Problem Areas in Diabetes scale (PAID) scale (Polonsky et al., 1995). The PAID scale is a self-administered, well validated and reliable

instrument that captures the breadth and severity of emotional distress from living with T2DM and its treatment, including guilt, anger, frustration, depressed mood, worry and fear. It consists of 20 items that employ a 5-point Likert scale format response of 0 (not a problem) to 4 (serious problem). Scores are added and multiplied by 1.25, generating a total score between 0- 100, with higher scores indicating greater T2DM distress. It has demonstrated reliability, Cronbach's alpha =0.95 (Polonsky et al., 1995). Cronbach's alpha =0.96 in this study.

Self-efficacy was measured using the Diabetes Self-Efficacy Scale (DSES) (Self-management Resource Center, 2018). The instrument was developed for DSME by the Sanford Patient Education Research Center and was based on a prior instrument, the Chronic Disease Self-Efficacy Scale. The research center determined the need for a T2DM s specific self-efficacy scale which lead to the creation of the DSES. The number of items were reduced from the original scale and the 8-item DSES measure was first developed and tested in Spanish. It includes the management domains of diet, exercise, management of hyper- and hypoglycemia. Each item ranges from 1 (not at all confident) to 10 (totally confident). The score of the scale is the mean of the eight items. Higher scores indicate greater self-efficacy related to self-management. The English version of the DSES has demonstrated strong reliability and validity, Cronbach's alpha= 0.85 and test-retest validity= 0.80 (Ritter, Lorig, & Laurent, 2016). Cronbach's alpha =0.84 in this study.

Resilience was assessed with the Resilience Scale (RS-14) and measures five resilience characteristics including self-reliance, purpose, equanimity, perseverance and authenticity (The Resilience Center, 2019). It was developed from the original 25-item Resilience Scale (RS) to reduce completion time. It consists of 14 items on a 7-point Likert scale 1 (strongly disagree) to 7 (strongly agree). Resilience scores are obtained by summing each item for a total score. Scores

range from 14 to 98; very low resilience= 14- 56, low resilience= 57-64, on the low end= 65- 73, moderate= 74- 81, moderately high= 82- 90, and high= 91- 98 (Aiena et al., 2015). Internal consistency alpha coefficient for the RS and the RS-14= 0.97 and Cronbach's alpha= 0.89 to 0.96 (The Resilience Center, 2016). Cronbach's alpha =0.95 in this study.

Glycemic control was measured by HbA1c, an indirect measure of average glycemia. Based on current guidelines, a reasonable HbA1c result is <7% (53 mmol/mol) (ADA, 2017). HbA1c was performed via fingerstick and analyzed with the A1c Now+ point-of care assay device. *A1c Now+* was certified by National Glycohemoglobin Standardization Program (NGSP) and thus Clinical Laboratory Improvement Amendments (CLIA) waived. The A1c Now+ automatically runs internal controls and quality checks. Initial accuracy testing was completed in multiple studies. Using a NGSP method, fingerstick comparative testing with 189 subjects resulted on average at 99% and venous sampling of 110 subjects resulted on average at 99.7%. Initial precision testing was conducted with a specialized protocol. Two whole blood samples, one of approximately 6% HbA1c (42 mmol/mol) (low) and one of approximately 9% HbA1c (75 mmol/mol) (high) were tested 4 times a day over 20 days, for a total of 80 assays per low/high level. Overall coefficient of variation (CV%) precision testing included within day and between day and resulted in 3.00% CV for the low HbA1c value and 4.02% CV for the high HbA1c value. The performance meets requirements for NGSP certification (PTS Diagnostics, 2018).

Health status was assessed with the 12- item short form (SF-12v2), developed from the original 36-item short form (SF-36) instrument to reduce completion time. It consists of 12 items from each of the 8 domains of the SF-36 and measures physical or mental health status. Therefore, two composites scores are derived, the physical health composite score (PCS) and a mental health composite score (MCS). Norm based scores are used, with a general population

mean of 50 and standard deviation of 10. Higher scores indicate better health. Cronbach's alpha = 0.90 (PCS) and 0.85 (MCS) (Christensen, 2013). Cronbach's alpha =0.88 (PCS) and 0.84 (MCS) in this study.

The Audit of Diabetes Dependent Quality of Life (ADDQOL-19) measure was selected to evaluate quality of life (Bradley et al., 1999). The ADDQOL-19 measures the perceived impact of T2DM on quality of life, specifically addressing emotional, physical and social functioning. The instrument was developed from a review of existing instruments and input from health professionals and persons with T2DM. It consists of 19 items. First, quality of life is rated on a 7-point Likert scale from "excellent" to "extremely bad." Second, the subject rates the impact of quality of life by T2DM on a 5-point Likert scale by rating how quality of life would be without T2DM from "very much better" to "worse." Remaining items on the instrument sections rate how T2DM affects a specific aspect of life (impact rating) and how important the specific aspect is to quality of life (importance rating). Scales range from -3 to +1 (impact rating) and 0 to +3 (importance rating). A weighted score (impact * importance) is calculated for each of the 19 items. An average weighted impact (AWI) ADDQOL-19 score is calculated for the entire scale across applicable domains. Scores range from -9 (maximum negative impact of T2DM) to +3 (maximum positive impact of T2DM). Cronbach's alpha= 0.84, 0.89- 0.90 (El Achhab et al., 2008). Cronbach's alpha= 0.88 in this study.

Data Analysis

The study sample was characterized using demographic and clinical variables. Means and standard deviation are reported for continuous variables and frequencies and percentages are reported for categorical variables. Spearman's rank correlation coefficient was used to test for

associates between independent and dependent variables. Additional testing was completed to evaluate for multicollinearity and the variance inflation factor showed none was present.

A stepwise model building approach was used to identify the main effects and interactions between specific categorical demographic variables and outcomes. A main effect is the action that a single variable has on a dependent variable. In step 1 of the model building, main effects (ethnicity, treatment regimen, DSME status, provider collaboration and years since diagnosis) were added into the model. Next, potential two way interactions (interactions of order 2) were added into the model. This process would test if two variables simultaneously interact with each other on the dependent variable, leading to potential significant differences, greater than what each would affect the dependent variable on their own. Step 2 of the model building included significant interactions in a refined model. In step 3, interactions with a $p>0.1$ were excluded from the model.

A regression using a stepwise model-building approach examined factors predicting HbA1c, health status and quality of life. Step 1 of the model building included all three potential independent variable predictors. Level of significance was assessed. Step 2 included the significant variable and then other variables added into the model one by one to assess for the R-square change and F change p-value. Data were analyzed with SPSS 25 statistical software and Optum PRO CoRE version 1.4 software. The level of significance was set at $\alpha = 0.05$. Prior to data analysis, reliability of instruments was performed.

Results

Descriptive Statistics

A total of 78 subjects were enrolled in the study. The mean age was 63.10 (*SD* 9.53); 56% (n= 44) were female; 76% (n= 59) indicated they were White/Caucasian; 47% (n= 37) had

some college or received an Associate or Bachelor's degree; and 97% (n= 74) had health insurance. A total of 49% (n= 37) were not employed or retired with 34% (n= 25) reporting an annual household income between $25,000 and $49,999. Over half of the subjects (51%, n= 39) reported having a combination treatment regimen (insulin and oral medication). The majority of the subjects had received DSME (56%, n= 43) and 87% (n= 65) reported that they collaborated with their health care provider regarding their diabetes management. On average, time since diagnosis was 14.22 years (*SD*= 10.49). Demographic and clinical characteristics are presented in Table 1.

Table 1. Sample Demographics (n= 78)*

Characteristics	N (%)	Mean (*SD*)	Range
Age		63.10 (9.53)	43-91
Gender			
Female	44 (56%)		
Male	28 (36%)		
Ethnicity			
White	59 (76%)		
Black	17 (22%)		
Hispanic	1 (1%)		
Native	1 (1%)		
Highest Level of Education			
High school diploma	32 (41%)		
Some college to Bachelor's	37 (47%)		
Master's or higher	9 (12%)		
Insurance			
NO	2 (3%)		
YES	74 (97%)		
Employment			
Not employed or retired	37 (49%)		
Part-time	11 (15%)		
Full-time	27 (36%)		
Income			
<25,000	15 (21%)		
25- 49,999	25 (34%)		
50- 74,999	18 (25%)		
75- 99,999	9 (12%)		
100- 124,999	2 (3%)		
>125,000	4 (6%)		
Treatment regimen			

Lifestyle	4 (5%)		
Oral	23 (30%)		
Injectable	11 (14%)		
Combination	39 (51%)		
DSME			
NO	34 (44%)		
YES	43 (56%)		
Collaboration with provider			
NO	10 (13%)		
YES	65 (87%)		
Length of diagnosis (years)		14.22 (10.49)	0-40
Length of diagnosis (months)			
1 month	2 (3%)		
2 months	1 (1%)		
6 months	2 (3%)		

*Valid percent reported

Facilitators and barriers to self-management. Subjects indicated lower T2DM distress based on a mean score of 20.53 (*SD*=18.48; range 0-69) on the PAID questionnaire. Highest reported distress was worry about the future (*M*= 1.39, *SD*= 1.29) and guilt or anxiety when get off track (*M*= 1.32, *SD*= 1.12). Lowest reported distress was friends or family are not supportive (*M*= 0.40, *SD*= 0.83) and unsatisfied with provider (*M*= 0.45, *SD*= 0.93). Subjects had higher self-efficacy than average with a mean of 7.32 (*SD*= 1.61; range 1-10) on the DSES questionnaire. Highest self-efficacy was judgment, changes in illness and visit provider (*M*= 7.83, *SD*= 2.18) and- knowledge regarding what to do with high or low blood glucose levels (M= 7.76, SD= 2.30). The lowest self-efficacy was exercise (*M*= 6.37, *SD*= 2.68) and choosing appropriate foods (*M*= 6.96, *SD*= 2.45). Subjects also reported moderate resilience (*M*= 80.27, *SD*= 14.39; range 20-98) on the RS-14 questionnaire. Highest resilience was-others rely on me (*M*= 6.15, *SD*= 1.05) and life has meaning (*M*=6.15, *SD*= 1.12). Lowest resilience was seen with self-discipline (*M*= 5.06, *SD*= 1.54) and ability to handle many things at a time (*M*= 5.29, *SD*= 1.55).

Proximal outcome of self-management: HbA1c. The mean HbA1c was 7.35% (*SD*= 1.37, range 5.1-11.0) [M= 56.88 mmol/mol, SD=15.00, range 32-97].

Distal outcomes of self- management: Health status and quality of life. Forty-six percent (n= 36) of the subjects scored above the physical health population mean norm of 50. Seventy-six percent (n= 60) of the subjects scored above the mental health population mean norm of 50. The average weighted impact quality of life score was -1.74 (SD= 1.90, range -7.58-+0.11). General quality of life was rated between "good" and "very good" (*M*= 1.46, *SD*= 0.96, range -2 - +3), general impact of T2DM on quality of life was rated "alittle better" to "much better" (*M*= -1.32, *SD*= 1.03, range -3 - +1) and the average weighted impact of T2DM on quality of life was -1.74 (*SD*= 1.90). The highest negative impact rating was seen in freedom to eat (*M*= -1.31, *SD*= 0.77) and freedom to drink (*M*=-1.00, *SD*= 1.01). Additionally, the highest importance rating was family (M= 2.71, SD= 0.65) and close personal relationships (M=2.43, SD= 0.77).

Correlational Analysis

Spearman's correlation was used to determine associations among variables (see Table 2). There were multiple significant associations between variables in this study. In particular, there was a negative correlation between the facilitators and barriers of self-management. Similarly, there were negative associations between T2DM distress and distal outcome variables. Self-efficacy and resilience had a positive relationship with distal outcome variables. Lastly, there was a positive correlation between distal outcomes. HbA1c was not significantly associated with variables in the study.

Table 2. Spearman's Correlation of Variables: Facilitator and Barriers, Proximal and Distal Outcomes

Variable	1 DD	2 SE	3 RES	4 HbA1c	5 PCS	6 MCS	7 QOL	8 DX
1. DD	1.0							
2. SE	-0.439 0.000	1.0						
3. RES	-0.423 0.000	0.519 0.000	1.0					
4. HbA1c	0.181 NS	-0.073 NS	0.005 NS	1.0				
5. PCS	-0.367 0.001	0.332 0.003	0.406 0.000	0.021 NS	1.0			
6. MCS	-0.410 0.000	0.215 NS	0.401 0.000	-0.153 NS	0.143 NS	1.0		
7. QOL	-0.627 0.000	0.291 0.010	0.310 0.006	-0.151 NS	0.240 0.034	0.302 0.007	1.0	
8. DX	0.021 NS	0.174 NS	-0.032 NS	0.087 NS	-0.070 NS	-0.203 NS	-0.152 NS	1.0

Note. DD – diabetes distress; SE – self- efficacy; RES– resilience; HbA1c– glycosylated hemoglobin; PCS – physical health; MCS – mental health; QOL – quality of life; DX – years since diagnosis; NS – not significant

Stepwise Model Building Approach for Interaction

Table 3 depicts the final model, that includes dependent variables and the statistically significant interactions.

Table 3. Variable Interactions

Terms in the models	Dependent variable								
	HbA1c			MCS			QOL		
	Df	F	p-value	Df	F	p-value	Df	F	p-value
Ethn	2	5.577	0.022	2	0.524	0.595	2	1.695	0.198
Tx	3	5.026	0.004	3	5.746	0.002	3	0.914	0.440
DSME	1	0.922	0.341	1	4.162	0.046	1	3.900	0.053
Prov	1	3.557	0.065	1	2.437	0.124	1	4.160	0.046
DX	1	0.585	0.448	1	11.916	0.001	1	4.561	0.037
TX * DX	3	4.906	0.004	3	6.656	0.003	-	-	-
Ethn * DX	1	6.001	0.018	-	-	-	-	-	-
Provider * DX	1	3.119	0.083	-	-	-	1	4.070	0.048
DSME * Provider	-	-	-	1	2.835	0.098	1	4.506	0.038
TX * DSME	-	-	-	3	3.760	0.030	-	-	-

Note. HbA1c– glycosylated hemoglobin; MCS – mental health; QOL – quality of life; TX –treatment regimen; DX – years since diagnosis; Ethn – ethnicity; Provider – collaboration with provider; DSME– diabetes self-management education

Proximal outcome interactions: HbA1c. Higher average HbA1c was seen in the subjects who reported collaboration (NO/YES collaboration with healthcare provider) at each of the self-reported years since diagnosis within the sample. Subjects with injectable and combination treatments had higher HbA1c levels at the number of years since their diagnosis. Conversely, lifestyle and oral treatment regimens had lower HbA1c at the number of years since diagnosis. Also, subjects with white ethnicity had higher HbA1c at the number of years since diagnosis, followed by Black ethnicity.

Distal outcome interactions: Mental health and quality of life. There were no significant interactions for the physical health outcome and therefore the model selection was terminated at step 2. However, the mental health model demonstrated three significant interactions. Subjects who reported oral and injectable regimens and attended DSME had higher

mental health scores. In contrast, subjects who reported combination treatment had slightly higher mental health when DSME was not attended. Four subjects reported lifestyle treatment and mental health was higher in the subjects who did not attend DSME (n=2). Also, subjects who reported having a lifestyle treatment regimen had increased mental health over the years since diagnosis. Subjects with a combination treatment regimen at had fairly consistent mental health at the years since diagnosis. The injectable treatment regimen had a mental health downward trend at years since diagnosis. Lastly, both groups of provider collaboration had higher mental health if they also attended DSME.

There were two significant interactions for the quality of life outcome. Those who collaborated with their providers had higher quality of life over time the years of diagnosis. In contrast, those who reported no collaboration with health care provider had a downward quality of life trend. Also, subjects that attended DSME and collaborated with their provider had better quality of life.

Regression Analysis

Table 4 shows the full regression models. T2DM distress, self-efficacy and resilience were not significant predictors of HbA1c. No further steps in the HbA1c regression were completed. Using an iterative process, the final physical health model included T2DM distress as a predictor (B= -0.14, p= 0.021), F= $F_{(3,74)}$= 8.035; Adjusted R-square= 0.215, p= 0.000. The final mental health model included T2DM distress as a predictor (B= -0.15, p= 0.005), F(3,74)= 5.852; Adjusted R-square= 0.159, p= 0.001. The final quality of life model included T2DM distress as a predictor (B= -0.05, p= 0.000), F(3,74)= 11.277; Adjusted R-square= 0.286, p= 0.000.

Independent variables	*B*	*SE*	*p*
Full Model: Predictors for HbA1c			
Diabetes distress	0.16	0.10	0.121
Self-efficacy	-0.33	1.24	0.794
Resilience	0.17	0.14	0.221
$F_{(3,74)}$= 1.095; *p*= 0.357; Adjusted R-square= 0.004			
Full Model: Predictors for PCS			
Diabetes distress	-0.14	0.06	0.021
Self-efficacy	1.05	0.71	0.145
Resilience	0.13	0.08	0.122
$F_{(3,74)}$= 8.035; *p*= 0.000; Adjusted R-square= 0.215			
Full Model: Predictors for MCS			
Diabetes distress	-0.15	0.05	0.005
Self-efficacy	-0.30	0.65	0.651
Resilience	0.12	0.07	0.105
$F_{(3,74)}$= 5.852; *p*= 0.001; Adjusted R-square= 0.159			
Full Model: Predictors for Quality of Life			
Diabetes distress	-0.05	0.01	0.000
Self-efficacy	0.00	0.13	0.997
Resilience	0.01	0.02	0.660
$F_{(3,74)}$= 11.277; *p*= 0.000; Adjusted R-square= 0.286			

Table 4. Regression Models

Note. Variance inflation factor (VIF) for each predictor are the same for each model above: Diabetes distress = 1.269; self-efficacy = 1.394; resilience = 1.397.

Discussion

The purpose of the study was to explore the relationships between T2DM distress, self-efficacy and resilience and outcomes of HbA1c, quality of life and health status in persons with T2DM. Demographic and clinical variables and their relationship with HbA1c, quality of life and health status were also examined.

Descriptive Statistics

The subjects in the study are similar to state and national T2DM demographic trends (United Health Foundation, 2019). The largest age group in the United States living with T2DM is 65+ (22.6%), with the highest percentage of male (11.2%) and female (10.5%). Highest education numbers were in the category of some college or less and also had lower income. Oral treatment was the most common treatment regimen in T2DM individuals (CDC, 2017). One difference in the study sample is related to ethnic composition. In the United States, T2DM disproportionately affects minority groups, yet the largest ethnic group in the study sample was White (United Health Foundation, 2019). Future studies with a more diverse sample are needed. Also, subject report of participation in DSME was 56%. Participation in DSME is highly based on population and the levels of resources available in the healthcare setting. In discussion with clinical site partners, referral to DSME largely depends on provider attitude and DSME participation rates nationally are significantly lower.

Facilitators and barriers to self- management. Subjects in this study had lower T2DM distress than was reported in previous studies (Snoek et al., 2011; Nicolucci et al., 2013; Yi et al., 2008). This finding may be attributed to higher self-efficacy and resilience in the study subjects. It also may be attributed to the amount of years since diagnosis and less complex treatment regimens. The subjects in this study were more distressed over the future and getting

off track with self-management. This finding may be due to the average age of the study sample and the fact sources of distress change over time. Support and provider satisfaction were highlighted as strengths in this study. Although the average age in the group had T2DM for over 14 years, five subjects had T2DM less than 12 months at recruitment. Subjects in this study had higher self-efficacy than was seen in another study with 186 subjects (M=6.87, *SD*=1.76) (Self-management Resource Center, 2018). The lowest confidence was rated in exercise and food choices which is a common finding in practice. Access to multiple sources of information may be related to the low confidence areas. The internet may be a source of misinformation, leading to confusion about exercise and appropriate food choices. Also, resilience was scored on the high end of moderate resilience. This finding is similar to the average resilience published by the authors of the instrument, 84.4 (SD=10.2, range 35-98) (The Resilience Center, 2019). Subjects felt that life had meaning yet continue to struggle with self-discipline and handling multiple priorities at once. This is consistent with topics rated low self-efficacy and high distress. The ADA guidelines (2017) suggested that health care providers collaborate with their patients to identify the burden of self-management, specifically identifying distress and perceived self-efficacy for self-management behaviors.

Proximal and distal outcomes of self-management: HbA1c. HbA1c results in this study were consistent with other T2DM studies (Daher et al., 2015; Fisher et al., 2009; Snoek et al., 2011; Yi et al., 2008). While the HbA1c target is 7% (53 mmol/mol), it is common for individuals with T2DM to be above the targeted range. The CDC (2017) noted that 15.6% of adults with diabetes had a HbA1c value higher than 9% (75 mmol/mol). There was one subject in this study with HbA1c result of 11% (97 mmol/mol), therefore 1.3% of the subjects were at this HbA1c value. Although this was an outlier, 53.8% of the study subjects had HbA1c results

>7% (53 mmol/mol) which demonstrates the ongoing self-management challenges for T2DM individuals. It is important to mention that current T2DM guidelines promote a partnership between the healthcare team and patients in shared decision-making to help reduce HbA1c through self-management efforts. It is known that HbA1c reduction can improve health outcomes for patients. However, striving to meet these management goals, while having a suboptimal HbA1c level, can often times be a source of T2DM distress. Healthy People 2020 has a goal to reduce the burden of T2DM and improve quality of life. The objective is to reduce the proportions of individuals with an A1c >9% (Healthy People.gov, 2019). Therefore, reduction of A1c will continue to be a focus in the future of T2DM self-management research to further elucidate contributing factors in the wide range of HbA1c values.

This sample reported lower physical health and higher mental health than the general United States population. Physical health and mental health scores tend to vary over the lifespan. Specifically, mental health increases with age and physical health decreases (Utah Department of Health, 2001). This finding was consistent with the average age and years since diagnosis in our sample. Likewise, in a retired population, there is more time for self-care and potentially better mental health. Results indicated that subjects felt that overall quality of life was good, however it was negatively impacted by T2DM. This is no surprise as T2DM is known to negatively impact quality of life (ADA, 2017; Jing et al., 2018). These quality of life results are similar to another study of 3609 subjects with T2DM (Donald et al., 2013).

The ADA guidelines (2017) stated that improved clinical outcomes, including glucose control, health status and quality of life were key goals of T2DM and should be measured and monitored as routine care. They can be a focus of DSME and support to enhance decision-

making, self-management behaviors, problem solving and collaboration with the health care team.

Correlations

Associations between facilitators and barriers. There were significant negative associations with the facilitators and barriers in the conceptual model. Specifically, T2DM distress was negatively associated with self-efficacy and resilience. This is an expected finding considering distress is a negative psychosocial factor and self-efficacy and resilience are positive psychosocial factors. Resilience was also found to be negatively associated with distress in another study (Wang et al., 2017). Self-efficacy was positively associated with resilience in this study. . Both are considered facilitators of self-management in the conceptual model and a positive association would be expected. Prior to this study, resilience had not been tested with other psychosocial factors such as distress and self-efficacy in the T2DM population. Further research is needed.

Associations between facilitators and barriers and outcomes of self-management. T2DM distress was not associated with HbA1c levels in this study, however previous studies showed an association (Fisher et al., 2008; Fisher, Glasgow, & Strycker, 2010a; Fisher et al., 2012; Fisher et al., 2010b; Fisher et al., 2007; Graue et al., 2012). This may be due to the average 7.35 HbA1c in the sample and/or there were fewer drivers of distress. Furthermore, T2DM distress was negatively associated with other outcomes in the conceptual model such as physical health, mental health and quality of life. This is consistent with other studies showing a negative association between T2DM distress and quality of life (Graue et al., 2012; Ting et al., 2011; Wang et al., 2011).

Self-efficacy was also positively associated with physical health and quality of life outcomes. Previous studies demonstrated that self-efficacy was a predictor of self-management behavior change (Al-Khawaldeh et al., 2012; Bagnasco et al., 2014; Liu, 2012). However, there was a gap regarding how self-efficacy influenced outcomes such as HbA1c, health status and quality of life. It is beneficial to examine how the confidence is achieved and through which means, such as through a facilitator or through a shared decision making approach between the patient and provider.. This study adds to the body of knowledge related to correlates of self-efficacy and outcomes and supports the need for future research using the self and family management framework.

This study did not find an association with resilience and HbA1c. Previous studies demonstrated mixed results in regard to the HbA1c outcome. One study showed a negative association between HbA1c and resilience (DeNisco, 2010) while other studies showed mixed results (Bradshaw et al., 2007b; Steinhardt et al., 2009). In this study resilience was positively associated with physical health, mental health and quality of life. Further research is needed to investigate associations between resilience and outcomes of health status and quality of life. It has been suggested that resilience may have a positive influence on T2DM outcomes, however it has yet to be proven as further research is needed (Bradshaw, Richardson, & Kulkarni, 2007a). Understanding the nature of these facilitator and barrier factors is necessary as they are pertinent to daily self-management and may ultimately impact outcomes of that self-management, such as quality of life and health status.

Associations between outcomes of self-management. HbA1c was not associated with other outcomes in this study. However, a previous study demonstrated HbA1c was associated with average weighted quality of life scores (Daher et al., 2015). It is not surprising

that physical health and mental health were positively associated with quality of life as studies suggest that improved health status and perceived control of disease results in improved quality of life (Rubin & Peyrot, 1999). The years since diagnosis was not associated with outcomes in this study, yet a review of other studies showed that the longer the duration since diagnosis, the more negative impact to quality of life and health status (Jing et al. 2018). Continued focus on improving health and disease trajectory are necessary to improve quality of life.

Interactions

Proximal outcome interactions: HbA1c. There were multiple interactions related to the HbA1c outcome. First, higher average HbA1c was seen in the subjects who reported collaboration at their years since diagnosis. It would be expected that provider collaboration would occur with patients who have elevated HbA1c results as they focus on meeting self-management goals. Furthermore, pay for performance and/or payor reimbursement may drive collaboration to meet established quality metrics. Patients may also feel that they are expected to collaborate when management goals are not met. Next, subjects with injectable and combination had higher HbA1c levels at years since diagnosis. This would be expected as higher HbA1cs would warrant more invasive interventions. Additionally, it is consistent with a study that determined that if insulin was used as a treatment regimen, it independently contributed to worse glycemic control (Al-Khawaldeh, Al-Hassan, & Froelicher, 2012). Also, it would be expected that lifestyle and oral treatment regimens would have lower HbA1c because early in the diagnosis as fewer invasive strategies are needed to control blood glucoses & prevent complications. The last interaction was between ethnicity types at levels of years since diagnosis. Subjects with white ethnicity had higher HbA1c at years since diagnosis, followed by Black ethnicity. This finding may be explained by the ethnic composition of the recruitment sites.

Distal outcome interactions: Mental health and quality of life. There were three mental health outcome interactions. First, subjects with oral and injectable treatment regimens with DSME had higher mental health. Subjects who reported combination treatment had slightly higher mental health when DSME was not attended. Fours subjects reported lifestyle treatment and mental health was higher in the subjects who did not attend DSME (n=2). One reason for this is that patients with less complex regimens may believe they are doing well with self-management on their own. Upon diagnosis, the ADA algorithm suggests initiation of DSME and metformin oral medication. Although there is evidence of improved outcomes with DSME intervention (ADA, 2017; Emery et al., 2019), patients may get advice from individuals that are not part of the healthcare team. In addition, the point at which DSME occurred for each subject was not collected during the study. A second interaction was mental health scores was between treatment regimen categories at levels of years since diagnosis. Since lifestyle regimen is the least complex, it would be expected to have an increased mental health. As treatment regimen gets more complex, mental health is reduced. When insulin is added, the patient oftentimes believes/senses their diabetes is getting worse. Lastly, subjects who collaborated with health care provider and attended DSME had higher mental health. A goal of collaboration would be enhanced outcomes. Based on T2DM standards, DSME is an effective intervention for T2DM (ADA, 2017).

There were two quality of life outcome interactions. Collaboration status was important to quality of life scores at years of diagnosis. This is no surprise as the current guidelines focus on collaboration with the health care team to improve T2DM individuals. Also, subjects that attended DSME and collaborated with their provider had higher quality of life. This finding is consistent with the mental health interaction.

Regression

T2DM distress was the only significant predictor in the physical health, mental health and quality of life models. We believe this is because we examined a relatively healthy population with regimens that were not complex. If this same study could be replicated in a clinic where the average A1c was much higher (8.5-10.5%), we believe other results would be significant. When a stepwise approach was conducted, T2DM distress accounted for 17% of the physical health variance, 25% of the mental health variance and 30% of the quality of life variance. Although some of the outcome variables were explained by T2DM distress, it is important to continue to explore other factors that may influence these outcomes. Based on the results, we propose testing of a revised model as noted in Figure 6 in future studies.

In summary, T2DM distress was a predictor of the distal outcomes in the conceptual model. The multiple interactions show that collaboration, DSME, treatment regimen, ethnicity and years since diagnosis are important factors to consider while examining self-management. The facilitators and barriers in the conceptual model were significantly associated with distal outcomes and should be further explored.

Limitations

There are several limitations to this study. First, this was a cross-sectional design. Therefore, it is not possible to infer causality or to see changes over time. Second, data was obtained from two locations in the United States with a sample size of 78. While utilizing multiple recruitment sites assists with generizability of results, a smaller sample size was a limitation. As the two recruitment sites were similar, they differ with regards to ethnic composition of the T2DM population and the on-site availability of on-site Certified Diabetes Educators. To comply with the wishes of the sites, we were unable to do comparative analyses

between participants from the two sites. Also, DSME and collaboration demographic questions were not defined for subjects during data collection, thus, they could have been interpreted differently by participants rendering measure of these characteristics less reliable and valid. Additionally, the majority of subjects had T2DM for many years with satisfactory HbA1c results. Future studies may be targeted at newly diagnosed individuals, individuals with higher HbA1c, those with challenging social determinants of health and studies with a longitudinal design.

Summary

This cross-sectional study examined the relationships between T2DM facilitators and barriers of self-management and proximal and distal outcomes of effective self-management. The results of this study confirm the presence of facilitators and barriers in T2DM self-management and their relationships with distal outcomes using the Self and Family Management conceptual model (Gray et al., 2015). Based on the results, we propose testing of a revised framework in future studies as noted in Figure 6. The findings of this study provide a link to other facilitator and barrier variables such as provider collaboration, DSME, treatment regimen, ethnicity and years since diagnosis which can be incorporated into the comprehensive T2DM Self and Family Management model by Emery and colleagues (2019). This study contributes to the understanding of the emotional aspect of diabetes as it relates to self-management of T2DM. Continuing this work will allow researchers to examine and better understand important factors of self-management. This ongoing work will hopefully lead to improved support in self-management efforts and better outcomes. This was the first T2DM study to utilize the Self and Family management framework.

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Chapter 5

Discussion

The purpose of the study was to explore the relationships between T2DM distress, self-efficacy and resilience and outcomes of HbA1c, quality of life and health status in persons with T2DM. Demographic and clinical variables and their relationship with HbA1c, quality of life and health status were also examined.

Descriptive Statistics

The subjects in the study are similar to state and national T2DM demographic trends (United Health Foundation, 2019). The largest age group in the United States living with T2DM is 65+ (22.6%), with the highest percentage of male (11.2%) and female (10.5%). Highest education numbers were in the category of some college or less and also had lower income. Oral treatment was the most common treatment regimen in T2DM individuals (CDC, 2017). One difference in the study sample is related to ethnic composition. In the United States, T2DM disproportionately affects minority groups, yet the largest ethnic group in the study sample was White (United Health Foundation, 2019). Future studies with a more diverse sample are needed.

Facilitators and Barriers to Self- Management

Subjects in this study had lower T2DM distress than was reported in previous studies (Snoek et al., 2011; Nicolucci et al., 2013; Yi et al., 2008). This finding may be attributed to higher self-efficacy and resilience in the study subjects. It also may be attributed to the amount of years since diagnosis and less complex treatment regimens. The subjects in this study were more distressed over the future and getting off track with self-management. This finding may be due to the average age of the study sample and the fact sources of distress change over time. Support and provider satisfaction were highlighted as strengths in this study. Although the

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Proximal and Distal Outcomes of Self-Management: HbA1c

HbA1c results in this study were consistent with other T2DM studies (Daher et al., 2015; Fisher et al., 2009; Snoek et al., 2011; Yi et al., 2008). While the HbA1c target is 7% (53 mmol/mol), it is common for individuals with T2DM to be above the targeted range. The CDC (2017) noted that 15.6% of adults with diabetes had a HbA1c value higher than 9% (75 mmol/mol). There was one subject in this study with HbA1c result of 11% (97 mmol/mol), therefore 1.3% of the subjects were at this HbA1c value. Although this was an outlier, 53.8% of the study subjects had HbA1c results >7% (53 mmol/mol) which demonstrates the ongoing self-management challenges for T2DM individuals. It is important to mention that current T2DM guidelines promote a partnership between the healthcare team and patients in shared decision-

making to help reduce HbA1c through self-management efforts. It is known that HbA1c reduction can improve health outcomes for patients. However, striving to meet these management goals, while having a suboptimal HbA1c level, can often times be a source of T2DM distress. Healthy People 2020 has a goal to reduce the burden of T2DM and improve quality of life. The objective is to reduce the proportions of individuals with an A1c >9% (Healthy People.gov, 2019). Therefore, reduction of A1c will continue to be a focus in the future of T2DM self-management research to further elucidate contributing factors in the wide range of HbA1c values.

This sample reported lower physical health and higher mental health than the general United States population. Physical health and mental health scores tend to vary over the lifespan. Specifically, mental health increases with age and physical health decreases (Utah Department of Health, 2001). This finding was consistent with the average age and years since diagnosis in our sample. Likewise, in a retired population, there is more time for self-care and potentially better mental health. Results indicated that subjects felt that overall quality of life was good, however it was negatively impacted by T2DM. This is no surprise as T2DM is known to negatively impact quality of life (ADA, 2017; Jing et al., 2018). These quality of life results are similar to another study of 3609 subjects with T2DM (Donald et al., 2013).

The ADA guidelines (2017) stated that improved clinical outcomes, including glucose control, health status and quality of life were key goals of T2DM and should be measured and monitored as routine care. They can be a focus of DSME and support to enhance decision-making, self-management behaviors, problem solving and collaboration with the health care team.

Correlations

Associations Between Facilitators and Barriers

There were significant negative associations with the facilitators and barriers in the conceptual model. Specifically, T2DM distress was negatively associated with self-efficacy and resilience. This is an expected finding considering distress is a negative psychosocial factor and self-efficacy and resilience are positive psychosocial factors. Resilience was also found to be negatively associated with distress in another study (Wang et al., 2017). Self-efficacy was positively associated with resilience in this study. . Both are considered facilitators of self-management in the conceptual model and a positive association would be expected. Prior to this study, resilience had not been tested with other psychosocial factors such as distress and self-efficacy in the T2DM population. Further research is needed.

Associations Between Facilitators and Barriers and Outcomes of Self-Management

T2DM distress was not associated with HbA1c levels in this study, however previous studies showed an association (Fisher et al., 2008; Fisher, Glasgow, & Strycker, 2010a; Fisher et al., 2012; Fisher et al., 2010b; Fisher et al., 2007; Graue et al., 2012). This may be due to the average 7.35 HbA1c in the sample and/or there were fewer drivers of distress. Furthermore, T2DM distress was negatively associated with other outcomes in the conceptual model such as physical health, mental health and quality of life. This is consistent with other studies showing a negative association between T2DM distress and quality of life (Graue et al., 2012; Ting et al., 2011; Wang et al., 2011).

Self-efficacy was also positively associated with physical health and quality of life outcomes. Previous studies demonstrated that self-efficacy was a predictor of self-management behavior change (Al-Khawaldeh et al., 2012; Bagnasco et al., 2014; Liu, 2012). However, there

was a gap regarding how self-efficacy influenced outcomes such as HbA1c, health status and quality of life. It is beneficial to examine how the confidence is achieved and through which means, such as through a facilitator or through a shared decision making approach between the patient and provider.. This study adds to the body of knowledge related to correlates of self-efficacy and outcomes and supports the need for future research using the self and family management framework.

This study did not find an association with resilience and HbA1c. Previous studies demonstrated mixed results in regard to the HbA1c outcome. One study showed a negative association between HbA1c and resilience (DeNisco, 2010) while other studies showed mixed results (Bradshaw et al., 2007b; Steinhardt et al., 2009). In this study resilience was positively associated with physical health, mental health and quality of life. Further research is needed to investigate associations between resilience and outcomes of health status and quality of life. It has been suggested that resilience may have a positive influence on T2DM outcomes, however it has yet to be proven as further research is needed (Bradshaw, Richardson, & Kulkarni, 2007a). Understanding the nature of these facilitator and barrier factors is necessary as they are pertinent to daily self-management and may ultimately impact outcomes of that self-management, such as quality of life and health status.

Associations Between Outcomes of Self-Management

HbA1c was not associated with other outcomes in this study. However, a previous study demonstrated HbA1c was associated with average weighted quality of life scores (Daher et al., 2015). It is not surprising that physical health and mental health were positively associated with quality of life as studies suggest that improved health status and perceived control of disease results in improved quality of life (Rubin & Peyrot, 1999). The years since diagnosis was not

associated with outcomes in this study, yet a review of other studies showed that the longer the duration since diagnosis, the more negative impact to quality of life and health status (Jing et al. 2018). Continued focus on improving health and disease trajectory are necessary to improve quality of life.

Interactions

Proximal Outcome Interactions: HbA1c

There were multiple interactions related to the HbA1c outcome. First, higher average HbA1c was seen in the subjects who reported collaboration at their years since diagnosis. It would be expected that provider collaboration would occur with patients who have elevated HbA1c results as they focus on meeting self-management goals. Furthermore, pay for performance and/or payor reimbursement may drive collaboration to meet established quality metrics. Patients may also feel that they are expected to collaborate when management goals are not met. Next, subjects with injectable and combination had higher HbA1c levels at years since diagnosis. This would be expected as higher HbA1cs would warrant more invasive interventions. Additionally, it is consistent with a study that determined that if insulin was used as a treatment regimen, it independently contributed to worse glycemic control (Al-Khawaldeh, Al-Hassan, & Froelicher, 2012). Also, it would be expected that lifestyle and oral treatment regimens would have lower HbA1c because early in the diagnosis as fewer invasive strategies are needed to control blood glucoses & prevent complications. The last interaction was between ethnicity types at levels of years since diagnosis. Subjects with white ethnicity had higher HbA1c at years since diagnosis, followed by Black ethnicity. This finding may be explained by the ethnic composition of the recruitment sites.

Distal Outcome Interactions: Mental Health and Quality of Life

There were three mental health outcome interactions. First, subjects with oral and injectable treatment regimens with DSME had higher mental health. Subjects who reported combination treatment had slightly higher mental health when DSME was not attended. Fours subjects reported lifestyle treatment and mental health was higher in the subjects who did not attend DSME (n=2). One reason for this is that patients with less complex regimens may believe they are doing well with self-management on their own. Upon diagnosis, the ADA algorithm suggests initiation of DSME and metformin oral medication. Although there is evidence of improved outcomes with DSME intervention (ADA, 2017; Emery et al., 2019), patients may get advice from individuals that are not part of the healthcare team. In addition, the point at which DSME occurred for each subject was not collected during the study. A second interaction was mental health scores was between treatment regimen categories at levels of years since diagnosis. Since lifestyle regimen is the least complex, it would be expected to have an increased mental health. As treatment regimen gets more complex, mental health is reduced. When insulin is added, the patient oftentimes believes/senses their diabetes is getting worse. Lastly, subjects who collaborated with health care provider and attended DSME had higher mental health. A goal of collaboration would be enhanced outcomes. Based on T2DM standards, DSME is an effective intervention for T2DM (ADA, 2017).

There were two quality of life outcome interactions. Collaboration status was important to quality of life scores at years of diagnosis. This is no surprise as the current guidelines focus on collaboration with the health care team to improve T2DM individuals. Also, subjects that attended DSME and collaborated with their provider had higher quality of life. This finding is consistent with the mental health interaction.

Regression

T2DM distress was the only significant predictor in the physical health, mental health and quality of life models. I believe this is because we examined a relatively healthy population with regimens that were not complex. If this same study could be replicated in a clinic where the average A1c was much higher (8.5-10.5%), we believe other results would be significant. When a stepwise approach was conducted, T2DM distress accounted for 17% of the physical health variance, 25% of the mental health variance and 30% of the quality of life variance. Although some of the outcome variables were explained by T2DM distress, it is important to continue to explore other factors that may influence these outcomes.

In summary, T2DM distress was a predictor of the distal outcomes in the conceptual model. The multiple interactions show that collaboration, DSME, treatment regimen, ethnicity and years since diagnosis are important factors to consider while examining self-management. The facilitators and barriers in the conceptual model were significantly associated with distal outcomes and should be further explored.

Limitations

There are several limitations to this study. First, this was a cross-sectional design. Therefore, it is not possible to infer causality or to see changes over time. Second, data was obtained from two locations in the United States with a sample size of 78. While utilizing multiple recruitment sites assists with generizability of results, a smaller sample size was a limitation. Additionally, the majority of subjects had T2DM for many years. Future studies may be targeted at newly diagnosed individuals, individuals with higher HbA1c, those with challenging social determinants of health and studies with a longitudinal design. HbA1c results

for the sample were satisfactory. Results in the psychosocial measures may be different in a sample with greater HbA1c.

Summary

This cross-sectional study examined the relationships between T2DM facilitators and barriers of self-management and proximal and distal outcomes of effective self-management. There are several implications for theory. This is the first study with T2DM individuals guided by the Self and Family Management conceptual model (Gray et al., 2015). The results of this study confirm the presence of facilitators and barriers in T2DM self-management and their relationships with distal outcomes using the Self and Family Management conceptual model (Gray et al., 2015). Findings also confirm that T2DM distress is a predictor of self-management outcomes. Future studies guided by the Self and Family Management conceptual model (Gray et al., 2015) are needed to examine other facilitator and barriers and outcomes.

There are several implications for practice. The findings of this study provide a link to other facilitator and barrier variables such as provider collaboration, DSME, treatment regimen, ethnicity and years since diagnosis which can be incorporated into the comprehensive T2DM Self and Family Management model by Emery and colleagues (2019). Results of this study showed the value of DSME and provider collaboration which can be implemented in the healthcare settings, to include referrals to Certified Diabetes Educators and DSME. Findings also support the need to consider the impact that treatment regimen has on mental health and HbA1c as there were mental health and HbA1c differences based on treatment regimen. This study contributes to the understanding of the emotional aspect of diabetes as it relates to self-management of T2DM. Continuing this work will allow researchers to examine and better

understand important factors of self-management. This ongoing work will hopefully lead to improved support in self-management efforts and better outcomes.

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Vita

Karin Anne Emery was born on July 9, 1974, in Rapid City, South Dakota and is an American citizen. She graduated from Wando High School, Mt. Pleasant, South Carolina in 1992. She received her Bachelor of Science in Nursing degree from the Medical University of South Carolina College of Nursing in 1997 and Master of Science in Nursing degree from Virginia Commonwealth University's School of Nursing in 2011. She worked as an RN in multiple emergency department settings. She worked at Virginia Commonwealth University Health System from 2004- 2014 where she held multiple formal leadership roles. In fall of 2014, she moved to Sioux Falls, South Dakota to work in academics. She has a focus in graduate and undergraduate nursing courses at South Dakota State University and is the coordinator of the Master's Administration Program. She received grant funding for her dissertation project.