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Women with Type 2 Diabetes Mellitus: Diabetes Self-Care, Diabetes Time Management, and Diabetes Distress

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WOMEN WITH TYPE 2 DIABETES MELLITUS: DIABETES SELF-CARE, DIABETES TIME MANAGEMENT, AND DIABETES DISTRESS

BY

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DEDICATION

To my husband Jeff who believed in me throughout this long journey and gave unwavering love and support. To my two sons, Connor and Kyle, for graciously sharing our precious time to allow me to write. I love you to the moon and back times infinity.

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ABSTRACT

This descriptive correlational study examined the relationships between and among diabetes self-care, diabetes time management, and diabetes distress in women with type 2 (T2DM). A gap of knowledge exists between these variables and this study, guided by Orem's self-care theory, aimed to identify these relationships and predictors of diabetes self-care. The sample (N = 188) was comprised of predominately White (81.4%) women recruited from multiple office locations, community hospitals, and diabetes support groups predominately from the Mid-Atlantic Region (64.04%). Participants voluntarily participated by responding to flyers posted in data collection locations or by electronic survey disseminated by diabetes support group newsletters. Participants completed three established survey instruments to measure the main study variables: the Diabetes Self-Management Questionnaire (DSMQ), the Diabetes Time Management Questionnaire (DTMQ), and the Diabetes Distress Scale (DSS). Survey responses were analyzed using several descriptive, bivariate, and multivariate analyses.

Study results showed a strong inverse bivariate relationship between diabetes self-care and diabetes time management and a medium inverse relationship between diabetes self-care and diabetes distress. Additionally, diabetes time management and diabetes distress showed a moderate positive relationship. A multivariate model demonstrated that time management and diabetes distress explained 37.7% of the variance in diabetes self-care, $F(2, 185) = 55.86$, $p < 0.001$. Diabetes time management was the strongest, statistically significant, unique contributor to explaining self-care ($\beta = -0.56$, $p < 0.001$). The ANCOVA

procedure showed that time management demonstrated a large effect size (0.300) and diabetes distress demonstrated a small effect size (0.016).

Chapter I

INTRODUCTION

The Problem

The Centers for Disease Control and Prevention (CDC) reports that 29.1 million or 9.3% of the United States (U.S.) population have diabetes, 21 million are diagnosed and an estimated 8.1 million remain undiagnosed. Ninety to 95 percent of the diabetes populations are diagnosed with Type 2 Diabetes Mellitus (T2DM). Diabetes Mellitus is a complex, progressive disease process and is the seventh leading cause of death (CDC, 2014). The economic impact of this disease process is extensive, with estimated costs reaching $245 billion dollars, $176 billion in direct medical expenditures and $69 billion incurred indirectly (CDC, 2014).

The complications related to T2DM are devastating to both the macrovascular and microvascular systems and, consequently, remain the major cause of heart disease and stroke (CDC, 2011). Glycosylated hemoglobin (HbA1c) is often used to determine glycemic control and severity of condition, maintaining levels within the recommended reference ranges helps minimize short-term and long-term risk factors related to T2DM. To reduce or delay potential diabetes-related complications, self-care becomes a vital mechanism for maintaining health. Diabetes self-care is the ability of an individual to understand and manage treatment guidelines to sustain glycemic control and, ultimately, maintain the goal

of minimizing complications (Carthron, Johnson, Hubbart, Strickland, & Nance, 2010; Evans, 2010; Grubbs & Frank, 2004; Kumar, 2007; Lundberg & Thrakul, 2011; Mullen & Kelley, 2006; Navuluri, 2000; Rosmawati, Rohana, & Manan, 2013; Sürücü & Kizilci, 2012).

There are approximately 12.6 million women and 13 million men diagnosed with T2DM (CDC, 2014). While men and women both experience some similar physiological complications and psychological effects of living with diabetes, there are some distinct differences in women. Women with diabetes are especially at risk for macrovascular damage related to diabetes complications; many studies have reported that women have a greater risk for stroke and cardiovascular incidents compared to men (Dantas, Fortes, & Catelli de Carvalho, 2012; Ferrara, Mangione, Kim, Marrero, & Selby, 2008; Huxley, Barzi, & Woodward, 2006; Munoz-Rivas et al., 2015; Peters, Huxley, & Woodward, 2014; Preis et al., 2009; Tenzer-Iglesias, 2014; Yusuf et al., 2004; Zandbergen, Sijbrands, Bootsma, & Lamberts, 2006).

Research studies have found that many individuals are not performing diabetes self-care at an optimal level (Bean, Cundy, & Petrie, 2007; Hernandez et al., 2014; Holt, Nicolucci et al., 2013; Peyrot et al., 2005). A lack of performing diabetes self-care warrants concern because the consequences of diabetes complications may be devastating, debilitating, and life-threatening to individuals.

Time demands for woman with diabetes. Diabetes self-care is extraordinarily time intensive. Certified diabetes educators estimate that performing routine diabetes self-care can take approximately 2 hours a day with additional time required for those newly

diagnosed or with additional needs (Russell, Suh, & Safford, 2005). Time management skills are particularly important for women dealing with the demands of multiple roles and responsibilities of a dynamic lifestyle, with little if any respite for administering self-care. More than half of U.S. women will assume caregiver responsibilities for an ill or disabled family member during their adulthood (Feinberg, Reinhard, Houser, & Choula, 2011; Lee, Colditz, Berkman, & Kawachi, 2003). Research has shown that barriers to good health and well-being for women were a lack of time and family responsibilities (McGuire, Anderson, & Fulbrook, 2014). The ability to manage time effectively may impact the success of self-care implementation.

To support the rationale and value of time management skills, the evidence has indicated that women with caregiver responsibilities and/or employment responsibilities report less self-care (Bernado, Paleti, Hoklas & Bhat, 2015; McEwen et al., 2011) as well as having an elevated HbA1c. Elevated HbA1c may be influenced by inadequate diabetes self-care. The relationship between time management and self-care should be further explored for the magnitude of its effect on women with T2DM.

Time Management. Claessens, Van Eerde, Rutte and Roe (2007) synthesized the definition of time management as "behaviors that aim at achieving an effective use of time while performing certain goal-directed activities" (p. 262). Three principal elements of time management behaviors from the literature include: goal setting and prioritization, organizational methods of time management, and organizational preferences (Adams & Jex, 1999). While there is little empirical evidence directly linking time management skills to

self-care administration, it is logical to promote time management elements of organization, planning, and prioritization.

Diabetes distress in women. The life-changing, complex, and chronic nature of diabetes self-care can lead women to feel frustrated, angry, and overwhelmed. Diabetes distress is an emotional phenomenon induced by an individual's level of concern related to self-care, perception of support, emotional burden, and accessibility to quality healthcare (Wardian & Sun, 2014). While both sexes experience diabetes distress, evidence has shown that women experience more diabetes distress compared to men (Anderson, Freeland, Clouse, & Lustman, 2001; Delahanty et al., 2007; Fisher et al., 2009; Fisher et al., 2008; Peyrot & Rubin, 1997). In study samples with both men and women, the evidence indicated that diabetes distress has an inverse relationship with diabetes self-care (Delahanty et al., 2007; Gonzalez, Shreck, Psaros, & Safren, 2015; Walker, Gebregziabher, Martin-Harris, & Egede, 2015), thus suggesting that elevated diabetes distress has a connection with decreased levels of self-care. Additionally, research found positive relationships between diabetes distress and glycemic levels (Delahanty et al., 2007; Fisher et al., 2010; Gonzalez, et al., 2015; Polonsky et al., 1995; Schmitt et al., 2015), thus suggesting that elevated diabetes distress has a connection with poor glycemic control. Diabetes distress is associated with both self-care and glycemic control, both essential elements in reducing the multiple complication of diabetes.

Social support received from friends and families are components of interpersonal distress, a subset of diabetes distress. Women often identify with the role of caregiver and provide social support to others around them; meanwhile support may not equally be

reciprocated for women. Social support is a noteworthy concept to examine because the evidence has shown that women with T2DM receive less social support compared to men (Song et al., 2012; Tang, Brown, Funnell, & Anderson, 2008). The manifestation of less social support may consequently be contributory to decreased levels of self-care.

The Problem Statement

The presence of diabetes distress has been associated with less self-care. As women have been reported to have a greater prevalence of distress, it is important to explore the phenomenon further. Studies exclusively dedicated to the examination of the influence of distress on women with diabetes are non-existent. There is also little understanding of the relationships between diabetes time management and self-care. An extensive review of the literature has found no studies examining time management with diabetes self-care or the self-care of other chronic conditions. A gap of knowledge exists between diabetes self-care, diabetes time management skills, and diabetes distress in women with T2DM.

Research Questions

The overarching research question of this study is:

1. What are the relationships between and among diabetes self-care, diabetes time management, and diabetes distress in women with T2DM?

Research sub-questions of the study are:

2. What is the relationship between diabetes time management and diabetes self-care?
3. What is the relationship between diabetes distress and diabetes self-care?

4. What is the relationship between diabetes time management and diabetes distress?

Hypothesis

The literature supports one hypothesis:

1. There is an inverse relationship between diabetes distress and diabetes self-care in women with T2DM.

Definitions of Variables

Type 2 Diabetes Mellitus (T2DM). T2DM is a complex, progressive chronic condition involving multifactorial systems where the body accumulates high levels of blood glucose. T2DM involves "at least seven organs and tissues, including the pancreas, liver, skeletal muscle, adipose tissue, brain, gastrointestinal tract, and kidney" (Cornell, 2015, p. 621). The combination of insulin resistance and the destruction of the pancreatic β-cell function leads to impaired insulin secretion (Campbell, 2009; Cornell, 2015). In this study, T2DM will be measured by the participants' self-report regarding their diagnosis of T2DM from a medical professional and prescribed medication (either oral medication or injections) to treat the condition.

Diabetes self-care. Diabetes self-care is conceptually defined as actions taken by an individual to facilitate the regulation and promotion of good health. For individuals with diabetes this specifically includes monitoring blood glucose, implementing diet regimens, incorporating exercise routines, administrating medications, monitoring foot care, symptom management and keeping healthcare appointments (Beverly et al., 2012; Feil, Zhu, & Sultzer, 2012; Munshi et al., 2013; Shreck, Gonzalez, Cohen, & Walker, 2014; Wu, Tung,

Liang, Lee, & Yu, 2014). Ultimately, the specific diabetes self-care tasks are encapsulated in an individualized treatment plan collaborated between the person with diabetes and their healthcare professional. Diabetes self-care will be operationally defined with the Diabetes Self-Management Questionnaire (DSMQ) by Schmitt, Reimer, Hermanns, Huber, and Haak (2013), which includes the assessment of diet, medication administration, blood glucose monitoring, exercise, and contact with health-care professionals (Schmitt et al., 2013).

Diabetes time management. Diabetes time management is delineated through the process of organizing, prioritizing, and implementing diabetes self-care actions on the continuum of time (Claessens, Van Eerde, Rutte, &, Roe, 2007). Each diabetes self-care action has specific time-bound elements, such as taking medication at the correct time of the day, which must be performed daily to maintain glycemic control. Operationally, diabetes time management includes multiple elements of behavioral tasks and skill sets to facilitate the completion of daily time-bound, diabetes specific self-care actions. Diabetes time management will be operationally defined by the Diabetes Time Management Questionnaire (Gafarian, Heiby, Blair, & Singer, 1999) which assesses the following elements: (a) completing tasks, (b) formulating a schedule and following it, (c) using a planning method daily, (d) feeling in control of time, (e) prioritizing and reprioritizing tasks, (f) problem solving, (g) making lists of items to do, (h) delegating, (i) deconstructing larger tasks into smaller attainable tasks, (j) assertiveness, (k) maintaining organization, (l) self-monitor the use of time, and (m) strategizing reinforcement of task completion (Gafarian, Heiby, Blair, & Singer, 1999).

Diabetes distress. Diabetes distress is the emotional impact that living with diabetes can have on an individual (Polonsky et al., 2005). Individuals managing their diabetes daily can feel overwhelmed and burdened with the perpetually daunting tasks of self-care, which is further exacerbated by concerns and worries associated with the progressive nature of the disease, general lack of support and treatment confusion. Diabetes distress will be operationally defined by the Diabetes Distress Scale (Polonsky et al., 2005), which measures the emotional burden, regimen-related distress, physician-related distress, and interpersonal-related distress.

Inclusion/Exclusion Criteria

This study is limited to English literate women, ages 18 years or older. Eligible participants must self-report a current diagnosis of T2DM by a healthcare provider for one year or longer. Participants must be currently prescribed a pharmaceutical intervention to treat their diabetes, such as oral or insulin medications. Therefore, this excludes participants who are prescribed a diet and exercise program without diabetes specific medication to manage their diagnosis. Exclusions include participants receiving dialysis therapy and those who received a kidney transplant related to diabetes, lower extremity amputation due to diabetes complications, pregnancy, and individuals who have received chemotherapy infusion or radiation for cancer in the last 12 months.

Purpose of the Study

The purpose of this study is to explore the relationships between and among diabetes self-care, diabetes time management, and diabetes distress in women diagnosed with T2DM.

Theoretical Framework

Guiding this study was Dorothea Orem's theory of self-care. Orem describes the concept of self-care as:

> The self-initiated and self-directed actions of persons to know their current and future requirements for regulating their own functioning and development and to select and use means to meet these requirements to sustain life and to promote health and well-being. (Orem, 2003, p. 217)

Using the framework of Orem's self-care theory, Richard and Shea (2011) developed a conceptual model that illustrates five associated concepts of self-care (See Figure 1). Complementing the theory of self-care, this model defines the concepts often used interchangeably in diabetes related literature (Hinder & Greenhalgh, 2012; Rahim-Williams, 2011; Richard & Shea, 2011; Riegel & Dickson, 2008; Song & Lipman, 2008; Wilkinson & Whitehead, 2009). While self-care and self-management are often used synonymously, the terms have different meanings. According to Richard and Shea (2011), self-care is simply the ability of an individual to implement behaviors and tasks to maintain and promote health. S*elf-management*, on the other hand, delineates specific elements that are embedded within the definition; "the ability of an individual, in conjunctions with family, community, and healthcare professionals, to manage symptoms, treatments, lifestyle changes, and psychosocial, cultural and spiritual consequences of health conditions" (Richard & Shea, 2011, p. 261). The conceptual model serves to provide an additional visual clarification to maximize understanding of these two terminologies. The model illustrates that self-care is the overarching phenomenon and within this concept, self-

management, and self-monitoring exist. Symptom management overlaps all three concepts (self-care, self-management and self-monitoring) and the three concepts are necessary to operationalize symptom management.

Figure 1. Self-Care conceptual Model

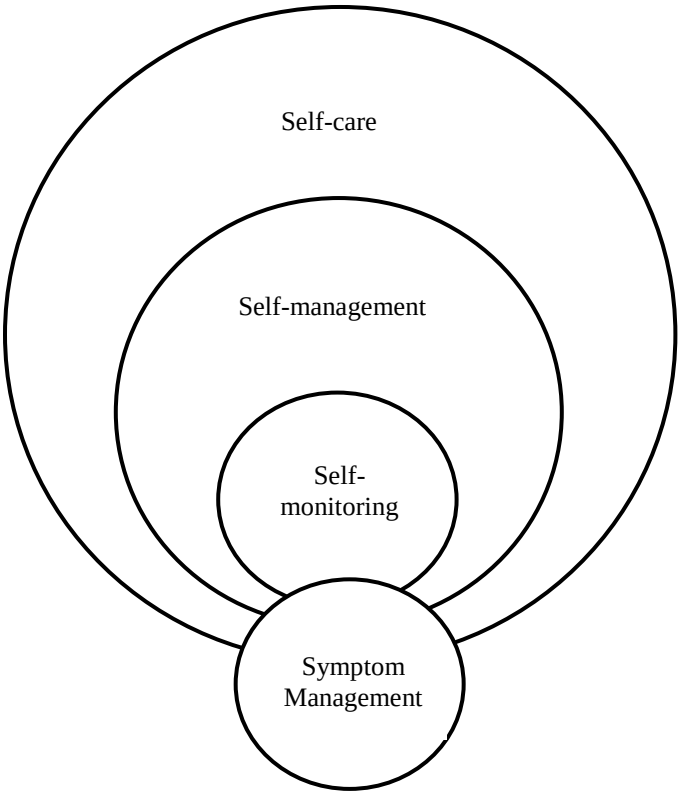


Figure 1. A conceptual model identifies self-care as a broad concept with the subsuming domains of self-management, self-monitoring, and symptom management (Richard & Shea, 2011). Permission to reproduce was obtained from Dr. Angela Richard from Division of Health Care Policy and Research, University of Colorado, Denver (Appendix A).

Orem created parameters of self-care to include three defined elements of self-care requisite: (a) actions conducted to maintain human function, known as *universal* self-care requisites, (b) actions conducted to contribute in human development, known as *developmental* self-care requisites, and (c) actions conducted with purposeful interactions for desired results, known as *health-deviation* self-care requisites (Dennis, 1997; Orem, 1995; Orem, 2003). Universal self-care is exemplified by the daily self-care actions individuals perform to maintain life, such as sleeping, eating, and hydration. Developmental self-care addresses actions required through the lifespan developmental cycles such as pregnancy or menopause. Self-care actions which originate with the presence of illness or chronic conditions (health-deviation) are identified by the necessity for actions such as the administration of medication or glucose monitoring.

Orem's theory uses specific terminology such as self-care agency and therapeutic self-care demand. "*Self-care agency* is the complex acquired capability to meet one's continuing requirements for care of self that regulates life processes, maintains or promotes integrity of human structure and functioning and human development, and promotes well-being" (Orem, 1995, p. 212). *Therapeutic self-care demand* is "self-care actions to be performed for some duration in order to meet known self-care requisites by using valid methods and related sets of [actions]" (Orem, 1995, p. 111). While the purpose of self-care behaviors is to maintain human regulatory function, limitations such as the lack of knowledge, skills or other limitations may threaten this goal (Orem, 1995). Orem does not specifically identify time management or diabetes distress in her theory of self-care;

however, there are clues and indications that these concepts align into the broad spectrum of the theory.

The element of time is encompassed in Orem's theory when she describes that self-care "must be deliberately performed continuously in time and in conformity with the regulatory requirement of individuals" (Orem, 1995, p. 172). The idea of "continuously in time" and "in conformity" as it relates to self-care indicates that some aspects of organization and time management are required. Additionally, Orem (1995) stated that self-care "requires time, expenditure of energy, financial resources, and continued willingness of persons to engage in the operations of self-care" (p. 173). The time and attention that is demanded to implement diabetes self-care does require an expenditure of energy, thus time management is indirectly inclusive in self-care. The concepts of both diabetes distress and time management can be equally portrayed within a time and space context, continuous but ever-changing and occurring in a pattern or sequence (Dennis, 1997; Orem, 1995).

The progressive nature of both diabetes treatment and self-care regimen can spike feelings of frustration or worry, which are components of distress. Daily time management, developing organizational skills and setting self-care priorities align with 'patterning' and 'sequencing' mandates (Orem, 1995). Orem (1995) often refers to the regulation of an individual's functioning and development as encompassing a range of concepts, which may include dealing with the emotional responses of living with diabetes. It is recognized that individuals diagnosed with T2DM later in life often experience a need to change self-care actions to meet the new therapeutic demands of the disease process, which when coupled with major changes and/or significant life events, can elicit emotional responses such as

diabetes distress. The feelings of distress threaten an individual's ability to perform and maintain daily diabetes self-care practices.

Significance of the Study

Screening for the presence of diabetes distress and diabetes time management skills are not routinely undertaken by health care professionals. In the certified educator's education curriculum from The Diabetes Core Curriculum Workshop (2016), diabetes distress was briefly mentioned but details of the screening instrument and the prevalence of distress were not discussed. Similarly, only brief references related to diabetes distress are presented in the American Diabetes Associate textbook, *Therapy for Diabetes Mellitus and Related Disorders (2014)*. Evidence presented in this study might, therefore, strengthen both efforts and resolve to promote routine distress screening. In addition, since time management evaluation skills are currently non-existent within the curriculum specific to diabetes educators and, moreover, not flagged for screening by healthcare professionals, the potential value of this study is to maximize the effectiveness of current and future treatment protocols for women with T2DM.

Diabetes research that may contribute to an initiative to improve the overall wellbeing of society and reduce the burdens of the complex disease process aligns with Healthy People 2020 diabetes objectives (Office of Disease Prevention and Health Promotion, 2010). The health and wellbeing of individuals with T2DM remains a momentous agenda for society. A study exclusively examining women is significant because there are substantial physiological and emotional differences between men and women who are living with diabetes.

Chapter II

REVIEW OF THE LITERATURE

The purpose of this chapter is to provide further details of the theoretical framework that guides this study and to discuss the empirical evidence regarding the relationships between and among diabetes self-care, diabetes time management, and diabetes distress. An introduction to the conceptual complexities and the foundational components of the self-care theory will be discussed and theoretical linkages with the variables will be identified. A synthesis of the empirical research will facilitate understanding of what is known and unknown, identify the knowledge gaps, and justify that there is a basis for the research questions.

Self-Care Theory

Dorothea Orem began working on the concept of self-care in the late 1950s (Denyes, Orem, & SozWiss, 2001; Orem, Taylor, & Renpenning, 1995). This led to the development of Orem's self-care theory. The self-care theory is based on the premise that self-care is a human regulatory function, defined by Orem as the elements intentionally performed by the individual to regulate his or her own functioning. Primarily, the human regulatory function includes elements that are required for continued life, growth, and development such as air, water, and food. Furthermore, human regulatory function incorporates purposeful actions

toward stimulating or maintaining internal and external conditions required to sustain as well as the executive decision making needed to initiate the actions and to promote health.

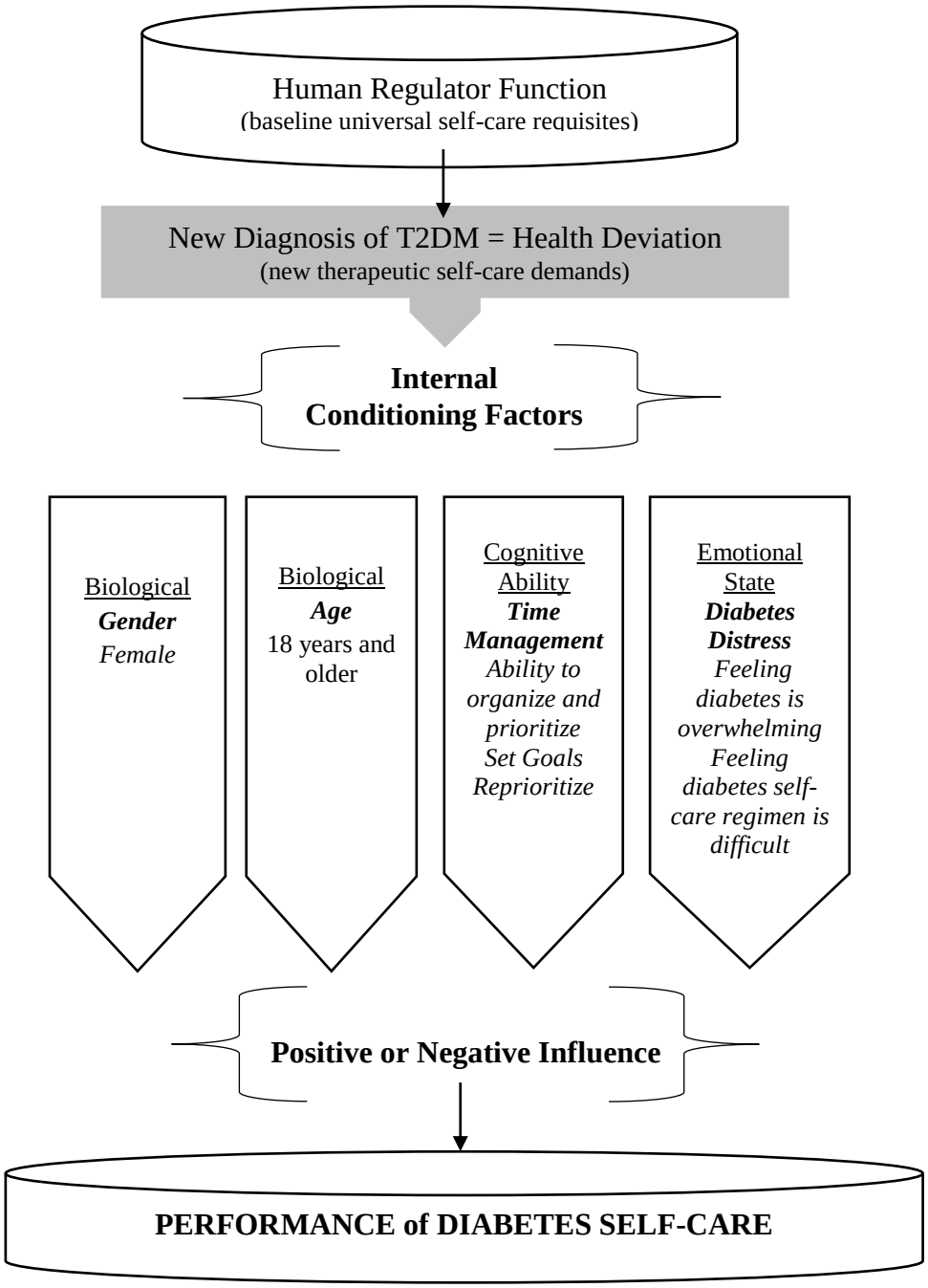
Self-care. Orem describes self-care as the engaged action of an individual to operate within the context of their respective time-place localization. In the phrase time-place localization, *time* refers to a person's level of maturity at the current moment, alluding to a specific snapshot into a person's level of maturity along his or her timeline. During the process of maturation and personal development, individuals may experience fluctuations and competing demands for self-care. As time passes, acute and/or chronic illness or health events may occur, thus changing or reprioritizing self-care actions. *Place* refers to the environment where engagement of self-care is put into action.

Conditioning factors. Conditioning factors influence an individual's ability to perform self-care. There are two types of conditioning factors, internal and external. Internal conditions include factors such as age, gender, cognitive abilities, emotional state, and health status. External conditions include the influences of social support, culture, family system, environmental factors, health-care system factors, resources, and life responsibilities. Over time, the capabilities of an individual to perform self-care can be altered by life experiences and new information which affects the conditioning factors (Orem, 1995). For the purposes of this study, only internal factors (age, gender, time management skills, and distress) are examined.

Therapeutic self-care demands. *Therapeutic self-care demands* present when a health deviation such as an acute or chronic illness occur and a new need of action to care for oneself is defined. Therapeutic self-care demands are time-specific self-care actions that

are required to maintain an individual's human regulatory function and development (Orem, 1995). Each person assumes her or his own variation of therapeutic self-care demands based on her or his unique needs and health condition. Therapeutic self-care demands are anticipated to fluctuate through the continuum of life, influenced by various conditioning factors. An emotional state like distress is a form of prolonged negative stress when a person experiences unfavorable emotion such as frustration as well as negative psychosocial distress by the perception of being unsupported. This study will examine the influence of the conditioning factors on diabetes self-care in adult women. The connections between Orem's theory and the study variables are illustrated in Figure 2. The model illustrates a flowchart beginning with the baseline self-care requisites that every individual possesses then moves to health deviation to represent when an individual is diagnosed with T2DM, and thus acquires new self-care demands. The internal condition factors (gender, age, cognitive ability, and emotional state) are illustrated as the main factors examining the influence of diabetes self-care. In this study, elements of cognitive ability are represented by diabetes time management and emotional state was represented by diabetes distress.

Figure 2. Diabetes Time Management and Diabetes Distress within Orem's Framework. Adapted from Orem's Self-Care Theory (Orem, 1995).



Diabetes Time Management within Self-Care Theory

Time management is not identified in the self-care theory; however, the essence of time management is within Orem's theoretical statements on self-care. For example, Orem describes self-care "as voluntary behavior guided by principles that give direction to action" (Orem, 2001, p. 45). The principles that 'give direction to action' are guided by components of time management, such as organizing and prioritizing tasks, so that individuals can perform self-care. Additionally, Orem discussed that motivation is needed to maintain the daily self-care practical skills and self-management (Orem, 2001). An individual's drive and motivation to perform a skill daily is supported through time management skills, such as strategizing, planning and goal setting. Moreover, Orem describes that the engagement of self-care actions "over time are performed by persons in stable or changing environment settings and within the context of their patterns of daily living" (Orem, 1995, p. 213). Daily living patterns refers to an individual's daily routine; the daily routine encompasses key elements of time management such as organizational methods to manage living life daily with T2DM. While living life with a chronic condition such as diabetes, the environmental setting can be stable (very little change) or changing (a deviation from routine). Individuals who experience environmental changes can use elements of time management skills, such as problem solving and reprioritization skills, to adjust to the change to maintain self-care.

Diabetes Distress within Self-Care Theory

While the term "diabetes distress" is not described in the self-care theory, a connection between the two can be identified. According to Orem, emotional state is one of

the internal conditioning factors that influence an individual's ability to perform self-care; diabetes distress is aligned into this category of emotional state. Diabetes distress occurs when various negative feelings related to living with diabetes develop and elicit emotions ranging from frustration to discouragement (Polonsky et al., 2005); these negative feelings contribute to an emotional state of distress and the distress influences the performance of self-care actions (Aikens, 2012; Fisher et al., 2010; Fisher et al., 2009; Fisher et al., 2007; Pandit et al., 2014; Wardian & Sun, 2014). Furthermore, Orem defines state of health as "characterized by soundness and wholeness of developed human structures and of bodily and mental functioning" (Orem, 2001, p. 186). Moreover, Orem states that "the physical, psychological, interpersonal, and social aspects of health are inseparable" from the health state (Orem, 1995, p. 97). Individuals experiencing diabetes distress are at risk for a reduction in their capability to perform diabetes self-care.

Diabetes Self-Care

Diabetes self-care is an integral component of the overall diabetes management process. Consistent with Orem's theory, diabetes self-care is individualized and complex. Individuals with T2DM experience a new onset of a disease state, thereby imposing new therapeutic self-care demands to maintain good health. Persons with T2DM will experience physical, emotional, and interpersonal challenges that accompany a chronic, progressive condition. To achieve and maintain good health, on-going modification of diabetes self-care evolves and changes over time as the disease state fluctuates. The figure below illustrates the proposed influences that diabetes distress and diabetes time management have on self-care on the continuum of time (See Figure 3).

Figure 3. Diabetes Self-care on a Continuum of Time

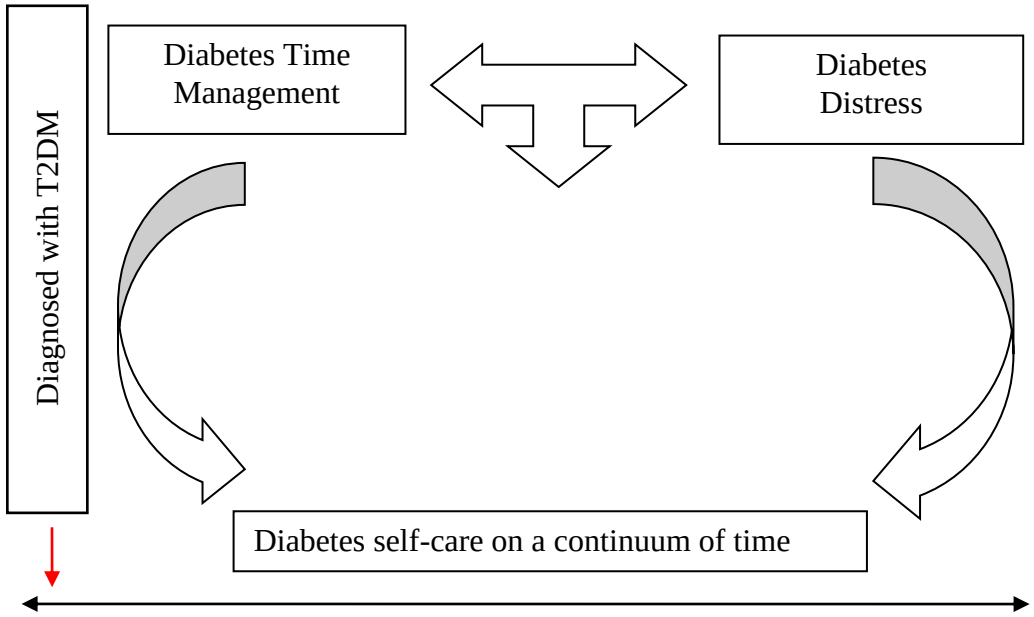


Figure 3. Individuals newly diagnosed with T2DM experience a deviation in their endocrine system posing a therapeutic self-care demand, thus requiring acquisition of new self-care skills. On the continuum of time, diabetes time management and diabetes distress may influence an individual's self-regulation.

Diabetes Self-Care Empirical Review

A plethora of studies examining diabetes self-care exist in the literature. A literature search was performed in multiple databases (CINAHL, Social Science, PsycINFO, PsycARTICLES). The search terms, diabetes self-care and diabetes self-management, were used and articles were limited to those published between 2006 to 2017, in the United States (U.S.), in English, with subjects limited to the adult range. A U.S. geographical limitation was set because self-care practices and resources may differ from other countries. All 186 articles were reviewed and articles were eliminated that pertained only to type 1 diabetes

mellitus (T1DM) or gestational diabetes. Duplicates were removed and interventional research was omitted because the focus was on new technology and educational training and thus did not address the three study variables. Five articles (two qualitative and three quantitative) were determined to be relevant and then reviewed. The empirical literature is presented methodologically, the qualitative research discusses barriers to self-care and the quantitative research discusses trends and influences on self-care behaviors.

Nagelkerk, Reick, and Meengs (2006) explored perceived barriers of diabetes self-care in Caucasian adults living in a rural setting using an exploratory, descriptive qualitative design. Purposeful sampling using a stratified method was conducted to recruit participants from a rural clinic list (Nagelkerk et al., 2006). The participants (n = 24) were divided into three focus groups with equal number of gender representation. According to Nagelkert et al. (2006), there was a significant age difference between group one (mean age = 70.3, *SD* = 5.6), and groups two and three (mean age = 57.83, *SD* = 6.7; 59.25, *SD* = 14.4, respectively). The themes that emerged on barriers to self-care were: (a) gaps in knowledge in dietary planning, (b) medical care not individualized, (c) frustration because of self-care adherence with inadequate glycemic control, (d) lack of resources, (e) group education too detailed and costly, and (f) challenges with medication adherence due to forgetfulness, lack of understanding medication purpose, and complexity of regimen (2006). Self-care barriers described by individuals were *frustration*, *lack of individualization*, *too detailed*, and *complexity of regimen*. Considering these barriers, it is understandable that individuals with T2DM experience difficulties with the self-care regimen.

Stiffler, Cullen, and Luna (2014) conducted a meta-synthesis of studies of individuals' experience with diabetes self-care. A total of 21 qualitative studies were included in the meta-synthesis. The research articles were subjected to a critical review using the Qualitative Assessment and Review Instrument (QARI) developed by the Joanna Briggs Institute (Stiffler et al., 2014). Two appraisers independently reviewed the articles to determine which met the inclusion criteria. The meta-synthesis inclusion criteria included qualitative research publications relevant to diabetes self-care or self-management, adults with either T1DM or T2DM, and empirical studies that met the standards for quality (2014). Researchers identified 95 findings, thematically categorized them into six categories, and then tested them for representativeness. Consensus among the researchers was achieved, and two meta-synthesized findings were developed. The two meta-themes were *avoidance and hindering of self-management* and *desire self-care and living life* (2014).

The one meta-theme, avoidance and hindering of self-management, was synthesized from four categories and 39 findings. The four categories included receiving the diagnosis of diabetes, helpfulness of medical professionals, fearing diabetes, and having difficulty dealing with diabetes (Stiffler et al., 2014). The research participants described experiences that may interfere with comprehending diabetes information shared by their health care professional; this can lead to further confusion and decreased adherence to self-care regimens. Furthermore, participants described elevated levels of stress triggered by the profuse amount of responsibility and time required for self-care activities. The participants reported that adhering to the prescribed treatment plan was difficult because of its complexity and challenge to modify schedules to incorporate the treatment plans. The

second meta-theme, desire for self-care and living life, was synthesized from three categories and 56 findings from the analysis. The three categories included accepting diabetes diagnosis, helpfulness of medical professionals, and finding understanding (Stiffler, et al., 2014), all of which are vitally important to the implementation of diabetes self-care regimens.

The findings exemplify the day-to-day challenges of living with diabetes ranging from unsatisfactory relationships with health care providers, inadequate social support from friends and family, a complex self-care treatment plan, and incorporating self-care into a daily schedule. While this research focused on the experience of diabetes self-care, important variables emerged that are consistent with the research proposal. The subscales of diabetes distress (provider relationship and interpersonal relationship) and diabetes time management skills are logically connected to the study participants' perceived barriers in self-care.

Song et al. (2012) examined diabetes self-care and unmet needs in adult Korean Americans (KA). The operational definition of unmet needs was the gap between what the individual identified as the amount of social support wanted and the perception of social support received. Song et al. (2012) used a secondary analysis, descriptive design from a previous study by Kim et al., (2009). Recruitment took place in the Baltimore-Washington area from multiple culturally specific sources, such as Korean churches and grocery stores. The inclusion criteria consisted of participants 30 years or older with uncontrolled diabetes defined as HbA1c greater than or equal to 7.5% (Song et al. 2012). The participants (n = 83) had a mean age of 56.5 (*SD* = 7.9), 57.8% were men, 50.6% had insurance, 49.4% had

college education, 50% had other comorbidities, and 87.9% were married (Song et al., 2012). The mean years of U.S. residency was 20.7 (*SD* = 10.4) and the mean duration of diabetes was 8.0 years (*SD* = 6.7; Song et al., 2012). Diabetes self-care was measured with the Summary of Diabetes Self-care Activities (SDSCA; Toobert, Hampson, & Glasgow, 2000). The SDSCA uses an 11-item, 7-point Likert scale to indicate the frequency of performing self-care within the last 7 days. The SDSCA Cronbach's α for the study of 0.68 (Song et al.) indicating borderline reliability (Grove, Burns & Gray, 2013). The participants' mean total score on the SDSCA was 16.8, possible range 0 – 35 (*SD* = 5.9), with higher scores representing better levels of self-care (2012). The correlated findings indicate that diabetes self-care was negatively linked with unmet needs for social support, $r = -0.282$, $p < 0.001$ and positively linked with age, $r = 0.295$, $p < 0.001$ (2012).

A regression model was used to evaluate the effect of independent variables (age, sex, education level, duration of diabetes, number of family members, comorbidity, self-efficacy, and unmet needs for social support) against the dependent variable, diabetes self-care. A regression including all 8 variables explained 29.6% of the variance in diabetes self-care, $p < 0.001$ (Song et al., 2012). Participants who received less social support ($\beta = -0.401$, $p < 0.001$) had significantly lower self-care (Song et al., 2012). A lack of social support was higher in women than men, *M* = 8.2 (*SD* = 6.3); *M* = 4.7 (*SD*= 6.4), respectively, $p = .014$ (Song et al., 2012). These findings indicated that KA women may have more unmet needs then men and that unmet needs negatively influence diabetes self-care.

In a cross-section design, Watkins, Quinn, Ruggiero, Quinn, and Choi (2013) explored the relationships among spiritual, religious beliefs, social support, and diabetes self-care in an African American (AA) population with T2DM using baseline data from a large unidentified randomized control trial. Participants (n = 132) were recruited from two federally qualified health centers (FQHC) in a Midwestern city (Watkins et al., 2013). The participants' overall mean age was 52.2 (*SD* = 12.8), with 67% women, 91% with less than $25,000 annual income, 61% high school graduates, and 81% either retired or not employed (Watkins et al., 2013). SDSCA measured diabetes self-care (no Cronbach α provided for this study). Data from Watkins et al., (2013) showed that in the last 7 days participants engaged in foot care, *M* = 4.52 days (*SD* = 2.46) and glucose monitoring, *M* = 4.14 days (*SD* = 2.47) more frequently than they exercised, *M* = 2.67 days (*SD* = 1.93). Positive relationships were found between social support and general diet (overall food consumption), $r = 0.354$, $p < 0.001$, specific diet (consumption of fruits, vegetables, and reduction of high-fat foods), $r = 0.242$, $p = 0.006$, and foot care, $r = 0.235$, $p = 0.008$ (Watkins et al., 2013).

Multiple linear regressions were performed to predict the influence of the independent variables (spiritual beliefs, social support, age, sex, and income) on the dependent variables (general diet, specific diet, physical activity, blood glucose testing, and foot care). In separate regressions, the five independent variables explained 15% of the variance in general diet ($R^2 = 0.15$), 12% of the variance in specific diet ($R^2 = 0.12$), 5% of the variance in exercise ($R^2 = 0.05$), 10% of the variance in blood sugar testing ($R^2 = 0.10$), and 9% of the variance in foot care ($R^2 = 0.09$) (Watkins et al., 2013). The low R^2

demonstrates that there are other variables not included in the regressions that influence self-care activities. In regard to individual predictors of social support, general diet, specific diet, and foot care (β = 0.29, p = 0.02; β = 0.30, p = 0.02; β = 0.30, p = 0.02, respectively) were significant (2013). Additionally, correlations suggest that certain self-care behaviors, such as foot care and general diet, are performed more frequently when social support was received. The results indicate that self-care is multifactorial.

Hernandez et al. (2014) examined patterns of diabetes self-care in two low-income ethnic groups (African American and Hispanic/Latino) using a cross-sectional, secondary analysis design. The researchers used baseline data from another research study without citation of the original study; however, the original study recruited minority participants with T2DM from a federally qualified health center (FQHC) in Chicago, Illinois. Twelve independent predictor variables including participant-related variables, biomedical/disease-related factors and psychosocial factors were evaluated for correlations to the multiple self-care dependent variables (total self-care, general diet, specific diet, exercise, blood glucose testing, foot care, and smoking) within the two minority cohorts (Hernandez et al., 2014). The participants (n= 250) had a mean age of 53.1 (*SD* =12.4), with the majority women (68.8%) with less than high school education (60.4%), incomes below $20,000 (73.6%), and with health insurance (61.6%). The study participants were African American (n = 133) and Hispanic/Latino (n =117) and their mean HbA1c value was 8.60% (*SD* = 2.37); the sample population had elevated glucose levels above the recommended target range of less than 7% (ADA, 2016).

The Summary of Diabetes Self-Care Activities (SDSCA) measured healthy eating, exercise, blood sugar testing, food care, and smoking (Hernandez et al., 2014). The psychometric results of SDSCA's reliability from the study were as follows: general diet ($\alpha = 0.85$), specific diet ($\alpha = 0.27$), exercise ($\alpha = 0.71$), blood sugar testing ($\alpha = 0.88$), and foot care ($\alpha = 0.66$), and total self-care score, $\alpha = 0.58$ (2014).

Significant findings of the predictor variables and patterns of diabetes self-care were analyzed by ethnic groups, African American (AA) and Hispanic/Latino (HL), using a series of multiple regressions. A regression, in the AA cohort, using12 independent variables explained nearly 33% of the variance in general diet ($R^2 = 0.33$) and the model was significant, F (24.67, 2), $p < 0.001$ (Hernandez et al., 2014). In a regression, in the HL cohort, 12 independent variables explained 20% of the variance in general diet ($R^2 = 0.20$) and the model was significant, F (10.39, 2), $p = 0.005$ (2014). In the AA cohort only, the individual predictors of increased age ($\beta = 0.011$, $p = 0.009$) and lower levels of education ($\beta = -0.206$, $p = 0.02$) significantly predicted general diet (2014).

A regression including all 12 independent variables explained 24% to 26% of the variance in exercise in both the AA and HL cohort ($R^2 = 0.24$; $R^2 = 0.26$), respectively. Both models were significant, F (22.99, 2), $p < 0.001$; F (7.71, 2), $p < 0.02$, respectively (Hernandez et al., 2014). In the models, the only significant predictors of less exercise, in both the AA and HL cohorts, were body mass index (BMI), $\beta = -0.021$, $p = 0.01$; $\beta = -0.025$, $p = 0.04$, and diabetes distress, $\beta = -0.187$, $p < 0.001$; $\beta = -0.131$, $p < 0.05$ (2014). The influence of diabetes distress will be discussed later in this chapter.

A regression including 12 independent variables explained 23% to 24% of the variance in foot care in the AA and HL cohort ($R^2 = 0.24$, $R^2 = 0.23$, respectively) and both models were significant, F (18.62, 2, $p < 0.001$; F (10.69, 2), $p = 0.005$, respectively. In the AA cohort, the model found that insulin-use negatively predicted less foot care, $\beta = -0.323$, $p = 0.006$ (Hernandez et al., 2014). Moreover, a regression including all 12 independent variables explained 22% of the variance of blood sugar testing in the AA cohort ($R^2 = 0.22$) and the regression was significant F(18.62, 2),
$p < 0.001$ (2014). The independent variable of gender found that the female gender significantly positively predicted blood sugar testing only in the AA cohort, $\beta = 0.225$, $p < 0.05$ (2014).

In the study by Hernandez et al. (2014), both cohorts found exercise to be the least frequent self-care activity performed, $M = 2.48$, ($SD = 2.11$) while foot care was the most frequent self-care activity performed, $M = 4.53$, ($SD = 2.47$). The findings indicated that elevated BMI is associated with lack of exercise in both cohorts while other independent variables influenced self-care differently in the two ethnic cohorts. The relatively low R^2, ranging from 0.20 - 0.33, demonstrates that there are other variables not included in the regression that influence self-care. Additionally, the significant findings in the models identified that there are some differences among cultural groups in what is most predictive of some self-care elements; however, with the low psychometric properties in the SDSCA instrument the findings cannot be generalized.

The qualitative studies (Nagelkert et al., 2006; Stiffler et al., 2014) revealed that performing the daily tasks of diabetes self-care is challenging from the participants'

perspective. The qualitative narrative shared by the study participants went beyond the linear tasks of self-care, such as medication management and monitoring glycemic control, and included the important influence of complex psychosocial components and interpersonal relationships on diabetes self-care.

The quantitative studies (Hernandez et al., 2014, Song et al., 2012, & Watkins et al., 2013) revealed trends in the performance of diabetes self-care. Diabetes foot care, which consists of examining feet and shoes daily, was the most frequently performed diabetes self-care activity (Hernandez et al., 2014; Watkins et al, 2013). The examination for skin breakdown in the feet and the examination of footwear is an activity that requires less effort and time compared to daily exercise. The least frequently performed self-care activity was exercise (Hernandez et al.; 2014; Watkins et al., 2013). Exercise includes 30 minutes of a continuous activity (Toobert, Hampton, & Glasgow, 2000) and requires an individual to exert effort and time toward this diabetes self-care recommendation. Increased age was found to be predictive of better dietary self-care (Hernandez et al., 2014; Song et al., 2012), a finding supported by others (Bean et al., 2007; Lippa & Klein, 2008; McCleary-Jones, 2011; Mier et al., 2012).

As previously mentioned, diabetes self-care includes psychosocial elements and the research findings from Watkins et al. (2013) and Song et al. (2012) found that social support was a predictive factor affecting diabetes self-care. Several other studies support these findings (Bai, Chiou, & Chang, 2009; Cosansu & Erdogan, 2013; Egede & Osborn, 2010; Holt et al., 2013; Shigaki et al., 2010). Additionally, these researchers found that specific diabetes self-care activities were predicted by social support and included the following: (a)

dietary self-care (Egede & Osborn, 2010; King et al., 2010; Rees, Karter, & Young, 2010; Tang et al., 2008; Wardian & Sun, 2014; Watkins et al., 2013); (b) weight management (Rees et al., 2010), (c) exercise (King et al., 2010; Rees et al., 2010; Wardian & Sun, 2014), (d) monitoring blood glucose (Tang et al., 2008), and (e) foot care (Watkins et al., 2013). While social support is not being directly measured in this study, social support includes the perception of emotional support from friends and family, and thus shares an element of commonality with interpersonal-related distress, a subscale of diabetes distress. Psychosocial elements, such as diabetes distress, are important to the behaviors of self-care as the evidence suggests a strong association, a finding that further supports this proposal.

Measures of Diabetes Self-Care

Lu, Xu, Zhao, and Hann (2016) reported that there are 30 developed instruments to measure diabetes self-care behaviors for individuals with T2DM. This is a large number of instruments and to narrow the search the following inclusion criteria were applied: (a) the length of the instrument is amendable for research, (b) the instrument achieved statistical reliability and validity, and (c) permission to use instrument is obtainable. Three instruments met the respective inclusion criteria, the Summary of Diabetes Self-Care Activities (SDSCA; Toobert & Glasgow, 1994), Self-Care Inventory (SCI; Le Greca, 1992), and Diabetes Self-Management Questionnaire (DSMQ; Schmitt et al., 2013). Each will be briefly discussed below.

Summary of Diabetes Self-Care Activities. The Summary of Diabetes Self-Care Activities (SDSCA) is the most commonly used self-reporting instrument for diabetes self-care (Lu et al., 2016; Schmitt et al., 2016). According to Toobert and Glasgow (1994),

Schafer first used the SDSCA in 1983 on individuals with T1DM. However, Toobert and Glasgow refined and expanded the instrument's use to include individuals with T2DM. The SDSCA measures the frequency of an individual's performance of multiple diabetes self-care activities within the last seven days. The original 12-item instrument contained five self-care subscales: (a) general diet, (b) specific diet, (c) exercise, (d) glucose testing, and (e) medication self-administration (Toobert & Glasgow, 1994). The SDSCA is a continuous, multi-dimensional instrument and it is recommended to score the self-care subscales independently and not use a composite score (Toobert & Glasgow, 1994). The rationale for the scoring method is that each subscale is relatively independent from each another and a composite score could potentially lead to the omission of valuable information and analysis (Deborah Toobert, personal communication, July 20, 2016).

Toobert, Hampson and Glasgow (2000) further analyzed the instrument using the results from seven empirical research studies and their findings suggested additions as well as removal and revisions of certain self-care subscales. Two subscales were added: 2 items on foot self-care and 1 item dichotomous question on smoking. Additional questions were added to reflect current self-care guidelines and risk reduction behaviors. One subscale, medication self-administration, was removed due to low test-retest reliability, r =0.08; p > 0.05 (Toobert, Hampson, & Glasgow, 2000). The general diet and specific diet subscales were revised and combined into one subscale called diet because the specific diet items consistently demonstrated a lack of internal consistency with Cronbach's α less than 0.70 and inter-item correlation below acceptable range, r = 0.07 - 0.23 (Toobert et al., 2000). The revised instrument's self-care subscales are the following: (a) diet (4 items), (b) exercise

(2 items), (c) blood glucose testing (2 items), (d) foot care (2 items), and (e) smoking, 1 item (Deborah Toobert, personal communication, July 18, 2016).

The SDSCA is used frequently in diabetes research and the several studies continue to demonstrate varied ranges in the instrument's reliability, subscales demonstrated Cronbach's α ranging from 0.60 to 0.93 (Nouwen et al., 2011; Perira et al., 2014; Sacco et al., 2007; Song et al., 2012) and item test-retest correlation ranging from 0.49 to 0.73 (Nouwen et al., 2011; Sacco et al., 2007). The SDSCA subscale items are relatively short, ranging from 2 to 4 items, thus the authors posit that since the subscales are clinically significant, the lower alpha scores may be considered acceptable (Perira, Pedras, & Machado, 2014). Both the original and revised SDSCA has been cross-culturally translated into nine different languages (Arabic, Chinese, Greek, Korean, Portuguese, Maltese, Spanish, Tai, & Turkish; Caro-Bautista et al., 2013; Lu, Xu, Zhao, & Han, 2016) demonstrating that this is a broadly used instrument. While the SDSCA is frequently used in diabetes research it may be best fitted for clinical use.

Self-Care Inventory. The original Self-Care Inventory (SCI) was a 13-item self-reporting instrument developed in 1988 by La Greca and colleagues and later revised (La Greca, 1992). The multidimensional Self-Care Inventory- Revised (SCI-R) is 15-items and measures the perceptions of self-care behaviors of individuals with either T1DM or T2DM over the past one to two months using a 5-point Likert scale (1 = Never to 5 = Always). The self-care items are diet (4 items), blood glucose monitoring (2 items), diabetes medication administration (3 items), safety issues on low blood glucose treatment (2 items), exercise (1 item), and preventative and routine components of diabetes self-care are 3 items (Weinger et

al., 2005). Three questions related to T1DM are omitted and not scored when individuals with T2DM complete the instrument (Weinger et al.). Scores are converted to a 0 to 100 scale and the higher the score indicates a greater level of self-care. The Cronbach's alpha was 0.87 and item-to-total correlation ranged from 0.34 - 0.67 (Weigner et al.). Polonsky et al. (1995) used the original SCI in a study and revealed the following Cronbach's alpha results for the four subscales were as follows: (a) blood glucose testing, $\alpha = 0.81$, (b) use of insulin, $\alpha = 0.53$, and (c) food, $\alpha = 0.71$, and (d) exercise, $\alpha = 0.65$. Khagram, Martin, Davies, and Speight (2013) used the SCI-R 13-item instrument in a T2DM study population (n=353). The Cronbach's alpha for the study was 0.77 and item-total correlations ranged from $r = 0.31$ to 0.53 thus meeting acceptability (Khagram et al., 2013). Furthermore, Khagram et al. (2013) recommended that the instrument's scoring method include individual items (subscales) as well as a total score due to the lack of convergent validity between the items. The SCI-R has been translated into Spanish and Catalan (Jansa et al., 2013).

Diabetes Self-Management Questionnaire. In 2009, the Diabetes Self-Management Questionnaire (DSMQ) instrument was designed and tested in Germany to measure diabetes self-care behaviors that influence glycemic control in individuals with both T1DM and T2DM (Schmitt et al., 2013). The instrument development included empirical review on behaviors that predicted glycemic control and a 37-items, 4-point Likert scale (3 = Applies to me very much to 0 = Does not apply to me) was composed for initial testing. Participants completing the questionnaire are asked to reflect on the last 8 weeks and determine the extent of diabetes self-care activities that applied to themselves during that time. The preliminary instrument was tested with hospital participants (n = 110) with a

mean age of 51 (*SD* = 16); 44% were women; 54% were diagnosed with T2DM and had a mean HbA1c of 8.5, (*SD* = 1.8; Schmitt, et al., 2013). The final analysis reduced the instrument to 16-items, 5 subscales and included glucose management (5 items), dietary control (4 items), physical activity (3 items), health-care use (3 items), and total self-care score (Schmitt et al., 2013). According to Schmitt et al. (2016), glucose management includes both monitoring of blood glucose levels and medication adherence; therefore, the two domains can be further subdivided into two additional scales, blood glucose monitoring (3 items) and medication adherence (2 items). Two independent translators who had expert knowledge on diabetes translated the measure to an English version by the forward and backward translation method (Schmitt et al., 2013); however, no current U.S. research publications or native English-speaking countries have used this instrument.

A second study of the instrument was conducted to further test the psychometric properties of the DSMQ. The study participants were recruited from a German hospital (n = 261). The demographic variables of the participants with T2DM (n = 111) included 37.8% women, mean age =60.4 (*SD* = 10.2); BMI = 34.4 (*SD* = 6.6); and HbA1c = 8.8 (SD =1.7; Schmitt et al., 2013). The reliability and validity of the four subscales were tested in the total study population with the following findings: (a) dietary control, $\alpha = 0.77$; (b) glucose management = 0.77; (c) physical activity, $\alpha = 0.76$; and (d) healthcare-use, $\alpha = 0.60$ (Schmitt et al., 2013). Schmitt et al. (2013) separated the participant sample by diabetes type, and psychometric testing was performed. In the T2DM group, the DSMQ's total score Cronbach α was 0.80 and the mean inter-item correlation was 0.20 (*SD* =0.17). Furthermore, the mean item-subscale correlation was 0.50 (*SD* =0.12) and the mean item-

total correlation was 0.40 (SD = 0.16). The total DSMQ score is aimed to measure diabetes self-care with the higher score indicating more desirable self-care behaviors (Schmitt et al., 2016).

A correlation between a diabetes self-care instrument and HbA1c is important because the purpose of self-care is to reduce short-term and long-term complications, and an HbA1c reduction can be achieved by glycemic control. Schmitt et al. (2013) conducted an ANOVA to correlate DSMQ with HbA1c levels. Participants with HbA1c ≥ 9.0% (n = 88, poor control) were compared to participants with HbA1c ≤ 7.5% (n = 67, good control), the ANOVA revealed that the total self-care score was significantly higher in participants with good HbA1c control, $M = 7.7$ ($SD = 1.2$), versus poor control, $M = 5.9$ ($SD = 1.8$), $p < 0.001$ (Schmitt et al., 2013). Participants with HbA1c between 7.6 – 8.9% (n = 106, moderate control) were compared to participants with good and poor control; the ANOVA revealed that the total self-care score was higher in the good control group, $M = 6.9$ ($SD = 1.4$), compared to the poor control group $M = 5.9$ ($SD = 1.8$), $p < 0.001$ (2013). These correlations demonstrated that the instrument's measurement of total self-care activities is associated with HbA1c levels.

Schmitt, Reimer, and Hermanns et al. (2016) conducted a study to analyze predictive power of the DSMQ and the SDSCA instruments explained by HbA1c levels; the study sample consisted of individuals with T1DM (n = 248) and T2DM (n = 182). A fitted model equation was used to explain the variance of the instrument's correlation with HbA1c and the differences were tested using Steiger's z-tests. According to Schmitt et al. (2016) the DSMQ explained 21% of the variation in glycemic control ($R^2 = 0.213$); significant

contributors were dietary control ($B = 0.66$, $p < 0.001$), medication adherence ($B = 0.65$, $p < 0.001$), blood glucose monitoring ($B = 0.76$, $p < 0.001$), exercise ($B = 0.38$, $p < 0.001$), health-care use ($B = 0.57$, $p < 0.001$), and sum score ($B = -0.46$, $p < 0.001$). According to Schmitt et al. (2016) the SDSCA explained 10% of the variation in glycemic control ($R^2 = 0.099$) albeit with a low R^2; significant contributors were general diet ($B = 0.75$, $p < 0.001$), specific diet ($B = 0.66$, $p < 0.001$), exercise ($B = 0.25$, $p < 0.01$), blood glucose testing ($B = 0.49$, $p < 0.001$), foot care ($B = 0.49$, $p < 0.001$), and the total score ($B = -0.31$, $p < 0.001$). A Steiger's z-test was performed to compare the results of the equations (DSMQ and HbA1c versus SDSCA and HbA1c) and the z-scores revealed that in the T2DM population, the DSMQ was statistically more significant to HbA1c then the SDSCA, $z = 3.379$, $p < 0.01$ (Schmitt et al., 2016).

The Summary of Diabetes Self-Care Activities (SDSCA), Self-Care Inventory (SCI), and Diabetes Self-Management Questionnaire (DSMQ) are valid and reliable instruments to measure diabetes self-care. SDSCA and SCI have been used in diabetes research literature for several decades with the last updated revisions of the instruments made over 15 years ago whereas the DSMQ is a newly developed instrument and has statistical reporting to validate its use. All three instruments above are acceptable for research; however, the DSMQ correlates better to HbA1c levels, -0.40 and -0.43, compared to the SDSCA, -0.10 and -0.26, and the SCI, -0.16 and -0.37 (Schmitt et al., 2016) and thus is appropriate for this study.

Diabetes Time Management

The complexity of a diabetes self-care regimen challenges individuals to organize, prioritize, reprioritize, and implement daily self-care actions that are often time relevant. Diabetes time management includes skill sets that require cognitive and behavioral elements. Individuals manage daily tasks and behaviors by using some element of time management to achieve self-care in a set time-frame.

Time Management Empirical Review

A search of the empirical literature on diabetes time management or time management of individuals with a chronic condition yielded limited results. A search was performed in multiple databases (CINAHL, Social Science, PsycINFO, PsycARTICLES). The search terms used were: (a) diabetes and time management, (b) diabetes and time use, (c) chronic disease or condition and time management, (d) self-care and time management, (e) self-management and time management between 2000-2017. Only one research article by Weigner (2015), who examined the relationship between diabetes time management and glucose control, was found to be relevant and is reviewed here. However, due to the limited empirical findings on this topic, empirical articles on time management and college academic performance were also reviewed. There are two common categories in the time management literature, time management in the workplace and time management in the academic environment. The literature on academic time management measured objective data points, such as grades, whereas work environment used data points, such as performance evaluations which may be more subjective, and thus the academic literature was selected. While the two variables, academic performance and diabetes self-care, are

uniquely different, both variables are noted to be positively influenced by time management (Macan et al., 1990; Weinger, 2015). Evidence of convergent validity can be examined by successful time management skills in academic performance measured by GPA or test scores, whereas successful time management skills in individuals with T2DM are measured by the level of self-care or glycemic control. With limited empirical data on diabetes time management, the findings from academic performance and time management are included in support of the research being proposed.

Search terms included time management and grade point average (GPA) and time management and academic performance were used in multiple databases (CINAHL, Social Science, PsycINFO, PsycARTICLES, and ERIC). The search date range was broadened from 1990 through 2017 in the U.S. to increase article numbers, and 35 articles were found. Many of the articles were eliminated because they were not relevant to time management and academic performance.

The overarching concept of time management does not have a specific theory (Claessen, Van Eerde, Rutte, & Roe, 2007); however, Macan (1994) developed a process model for time management. The time management model outlined three behavioral factors for student's time management skills as setting goals and priorities, mechanics of time management, and organizational preferences (Macan, 1994). The operational definition of diabetes time management was derived from the theoretical framework of the health compliance (HC) model which includes behavioral and situational factors that relate to diabetes compliance (Gafarian, Heiby, Blair, & Singer, 1999; Heiby, Gafarian, & McCann, 1989). The HC model (Heiby et al., 1989) posits that behavioral skills as well as personality

elements determine individual compliance regarding the diabetes regimen. Emotional-motivational factors such as attitude toward provider, self-control, and social support are important for diabetes compliance (Heiby et al., 1989).

Weinger (2015) reviewed the responses from participants with both T1DM and T2DM (n = 397) by asking them one question, "Do you mange time well?", and compared it to their level of self-care, measured by the Self-Care Inventory (SCI-R), and their HbA1c levels. Weinger (2015) analyzed the data using a simple comparison method of the SCI-R scores. The SCI-R total score range is 0 to 100. The participants with T2DM (n = 64) who reported that they managed time well were compared to a group of participants who reported that they did not manage time well (n = 55). Weigner (2015) reported that the difference between the two groups were significant, $p < 0.001$, suggesting that those who report appropriate time management also report higher levels of self-care. Additionally, when comparing the time management question to glycemic control, those who said that they managed time better had lower HbA1c values compared to those who did not manage time well (HbA1c 8.2, HbA1c 8.9) respectively, $p < 0.001$ (Weinger, 2015). The target range for HbA1c is less than 7%, thus both groups had elevated glucose levels. Converting the HbA1c to the glucose average aids in understanding the significant differences between these two groups; 8.2% HbA1c equates to a blood sugar average of 189 mg/dL and 8.9% equates to 209 mg/dL thus demonstrating a 20-point difference in glucose value. These promising results suggest a relationship between people's perception that they manage time well and perform appropriate self-care and, therefore, support this proposal.

Two studies that are relevant to time management and college academic performance were empirically reviewed. The limited and dated articles (1990-1996) found on the topic may suggest that researchers accept the relationships between the two variables and do not see a need to investigate further. Macan, Shahani, Dipboye, and Phillips (1990) conducted a correlational study on college students' time management, academic performance, and GPA. The participants (n = 165) had a mean age of 24.77 (range 16 to 44 years). Most of the participants were female, Caucasian, and single. Time management was measured using the Time Management Behavior scale (TMB), a 46-item, 4-factor, 5-point Likert scale (0 = Seldom true to 4 = Very often true). The composite TMB Cronbach's alpha was 0.68 and demonstrated borderline reliability. The dimensions of the TMB are setting goals and priorities, mechanics of planning and scheduling, perceived control of time, and preference for organization (Macan et al., 1990). The inter-item reliability between the four factors and the TMB composite score was 0.83 and achieved moderate internal consistency (Macan et al., 1990).

Academic performance was measured by self-reporting GPA and a 2-item, 7-point Likert scale (1 = very poor to 7 = very good) rating perceived academic performance. The mean GPA was 3.23 (*SD* = .055, range = 1.5 - 4.0) and the 2-item performance rating composite mean was 10.15 (*SD* = 2.25, possible range = 2 - 14). The inter-item reliability of the 2 item performance rating questions was 0.89 (Macan et al., 1990). A multiple regression was performed on five independent variables (total time management, setting goals and priorities, planning and scheduling, perceived control of time, and preference for disorganization) against GPA. The five independent variables explained 8% of the variance

in GPA ($R^2 = 0.08$). While the model demonstrated a very low R^2 it met significance, F (4, 131) = 2.89, $p < 0.05$ (Macan et al., 1990). The results indicated that there is a relationship between time management skill and GPA but that there are other variables not included in the model that influence GPA.

In a second quantitative study, Trueman and Hartley (1996) examined time management skills and academic performance in colleges students (n = 293). The sample consisted of 216 women and 77 men categorized by age into three groups: young adults less than 21 year (n= 172, mean age 19, *SD* = .07), borderline mature adults 21 to 25 years (n = 50, mean age 22.4, *SD* = 1.4), and older mature adults greater than 25 years (n = 71, mean age 34, *SD* = 6) (Trueman & Hartley, 1996). Time management was measured with the Time-Management Scale (TMS) (Britton & Tesser, 1991), a 14-item, 5-point Likert (1 = Always to 5 = Never) scale (Trueman & Hartley, 1996). The scale demonstrated a Cronbach's α of 0.79 and achieved acceptable reliability (Polit & Beck, 2017). The time management score ranged from 14 to 70, with a mean of 40.7 (Trueman & Hartley, 1996). An academic performance composite score was a sum of the work completed over the academic year using the mean score of completed course work, the mean score of taken examinations, and the mean score of course work and examinations. A correlational analysis between time management and academic performance revealed a small but significant positive relationship, $r = 0.16$, $p < 0.01$ (Trueman & Hartley, 1996).

Weinger (2015) revealed important preliminary data in the field of diabetes time management and diabetes self-care by comparing HbA1c and self-care levels in individuals who perceive to manage time well, suggesting a potential relationship between the variables.

Individuals with T2DM experience time demands to implement daily and routine diabetes self-care actions and time management is a relevant variable. Moreover, the findings from the empirical studies indicate a positive relationship between time management skills and academic performance (Trueman & Hartley, 1996; Macan et al., 1990). A gap in literature exists between time management and diabetes self-care, this proposal aims to contribute to the understanding of this relationship.

Measures of Diabetes Time Management

The Diabetes Time Management Questionnaire (DTMQ) is the first and only instrument to measure general and specific time management skills related to diabetes self-care regimen. The 49-item, 5-point Likert scale (1 = Always to 5 = Never) was developed and evaluated by Gafarian, Heiby, Blair, and Singer (1999). Gafarian and colleagues (1999) studied the instrument using a small sample (n = 60) of individuals with T1DM and T2DM. The sample was composed of 85% T2DM, 71.7% women, and a demographic mix of 32% Japanese, 30% Caucasian, 15% Hawaiian, and 23% who self-identified as other (Gafarian et al., 1999). The mean age of participants was 56.3, *SD* =16.8 (Gafarian et al.).

Data collection occurred at the offices of a diabetes center clinic where participants were screened for eligibility and consented. Participants received three questionnaires, the DTMQ, the Habits, Attitudes, and Knowledge Questionnaire of Diabetic Compliance (HAK), and the Diabetes Knowledge Schedule (DKS), and were asked to complete and return them in one week using a pre-stamped return envelope. The DTMQ, HAK and DKS were all developed by Gafarian and colleagues (1999). HAK is a 37-item scale measuring diabetes compliance (Gafarian et al., 1999; Heiby, Gafarian, & McCann, 1989) and DKS is

a 24-item scale to measure knowledge and schedules based on diabetes education literature (Gafarian et al., 1999).

Two weeks after the initial questionnaires were completed, the same questionnaires were mailed to the participant with instructions to complete and return it within 2 weeks. The test-retest average time interval was 27 days (Gafarian et al., 1999). The analysis revealed that the Diabetes Time Management Questionnaire (DTMQ) is a reliable instrument demonstrating a strong internal consistency, $\alpha = 0.82$ (Gafarian et al.). The test-retest reliability (n = 52) for the composite score (DTMQ) was significant ($r = 0.81$, $p < 0.001$) in the full scale and as were inter-item correlations ($r = 0.28$-84, $p < 0.05$), demonstrating good reliability (Gafarian et al.).

Content validity was determined by the research team who reviewed the DTMQ items for accuracy and representation in measuring diabetes time management (Gafarian et al., 1999). Criterion-related validity was tested by correlating DTMQ and the Habits, Attitudes, and Knowledge Questionnaire of Time Management (HAK-TM); the analysis revealed a significant positive association between the two instruments ($r = 0.71$, n = 60, $p < 0.001$), thus supporting the criterion validity of time management (Gafarian et al., 1999).

The intent of the construct validity is to measure how well diabetes time management is represented in the instrument (Gafarian et al., 1999). The total score of HAK did not correlate significantly with the DTMQ; however, 2 items, diet ($r = -0.31$, $p < 0.02$) and exercise ($r = -0.39$, $p < 0.01$), showed a significant negative relationship, indicating that the habits of diet and exercise had a relationship with time management (Gafarian et al., 1999). Additionally, the DKS was positively correlated with

DTMQ ($r = 0.29$, $p < 0.04$), indicating that with increased diabetes knowledge better diabetes time management skills were present (Gafarian et al.).

The Diabetes Time Management Questionnaire (DTMQ) has been used once in a study to validate the instrument. Based on the psychometric properties, the DTMQ satisfies validity and reliability requirements. Due to the limited number of participants in the study (Gafarian et al., 1999), subscales and a factor analysis were not calculated, therefore additional testing is warranted. It is likely that the data obtained from this proposed study will add to the psychometric knowledge about the DTMQ.

Diabetes Distress

Diabetes distress is defined as an individual's level of concern regarding diabetes management, supportive measures received, the emotional burden of daily living, and access to health care (Polonsky et al., 2005). The psychological phenomenon of diabetes distress is precipitated by an individual's negative reaction to living with diabetes (Aikens, 2012). Adults who have lived their lives without diabetes who later receive a new diagnosis respond with a range of emotions, evoked by the new health threat, which may lead to diabetes distress. The emotional responses that encompass diabetes distress include feeling frustration, anger, overwhelmed, or discouragement (Polonsky et al., 2005). Resources, such as family support and the relationships with health care providers, are important to help reduce the effects of negative stressors that an individual may experience.

Diabetes Distress Empirical Review

A literature search was performed in multiple databases (CINALH, Social Science, PsycINFO, PsycARTICLES). The search terms diabetes distress, diabetes distress and self-care, diabetes distress and T2DM, and diabetes distress and time management were used and articles were limited to those published between 2009 to 2017, in the U.S. and in English. All 119 articles were reviewed and articles were eliminated that pertained to T1DM, pediatrics, gestational diabetes or interventional studies, and model testing designs. The study variable, diabetes distress, has been used in the literature as both an independent and a dependent variable; this is important as researchers attempt to determine the directional relationship of distress as an influencer and/or an outcome variable. The seven retained quantitative research studies are presented in the following order: first, studies using diabetes distress as dependent variable (Aiken, 2012; Fisher et al., 2009; Wardian & Sun, 2014), then studies with diabetes distress as independent variable (Fisher et al., 2010; Pandit et al., 2014; Walker, Gebregziabher, Martin-Harris, & Edege, 2014). There were no articles found that explored the relationships between distress and time management.

Diabetes Distress as a Dependent Variable. In a secondary analysis of an earlier longitudinal study by Fisher et al. (2007), Fisher et al. (2009) conducted logistic regression analyses on eight general participant characteristics and demographic variables, seven biological variables including HbA1c and body mass index (BMI), and two measures of self-care behaviors, diet and exercise, to evaluate the prediction of diabetes distress over time in participants with low baseline distress. The study participants with T2DM (n = 332) had a mean age of 58.1 years (*SD* = 9.87) and were 53.6% women (Fisher et al., 2009). The

Diabetes Distress Scale (DDS; Polonsky et al., 2005) measured distress and the two subscales from the SDSCA measured diet and exercise. Measurements of the other general characters included major depressive disorder (MDD) measured with the Composite International Diagnosis Interview by the World Health Organization (Wittchen & Nelson, 1996), and life stressors and chronic stress measured with the Negative Life Events Scale and Chronic Stressors Scale (Turner, Wheaton, & Llody, 1995). Three participant surveys were completed over 18-months with 9.1 months between the second and third data collection.

A regression was performed to predict the influence of eight independent variables (age, education, gender, ethnicity, years since diagnosis, major depressive disorder in past year, life stresses, and chronic stress) on the dependent variable (diabetes distress). Of those, three variables positively predicted the likelihood of distress: age, OR = 0.96, $p < 0.05$, 95% CI = [0.93-0.99], gender, OR = 3.74, $p < 0.01$, 95% CI = [1.77-7.90], and chronic stress, OR = 1.12, $p < 0.05$, 95% CI = [1.02-1.22] (Fisher et al., 2009). Another regression was performed and two self-care variables (diet and exercise) were added, and the results showed five variables positively predicted the likelihood of distress: exercise, OR = 0.83, $p < 0.01$, 95% CI = [0.71-0.97]; diet, OR = 0.82, $p < 0.05$, 95% CI = [0.65-0.99]; MDD in past year, OR = 2.52, $p < 0.05$, 95% CI = [0.99-6.42]; life stressors, OR = 1.15, $p < 0.05$, 95% CI = [1.02-1.30]; and chronic stress, OR = 1.11, $p < 0.05$, 95% CI = [1.01-1.22] (Fisher et al., 2009). No R^2 was reported. The findings suggest that participants who were less physically active, ate unhealthy foods, experienced life stresses, had chronic stress, and had an episode of depression in the past year were more likely to have high diabetes distress

over time (Fisher et al., 2009). No statistically meaningful relationship was found between HbA1c and diabetes distress over time. However, of the participants who had low distress at baseline and completed all three surveys (n = 332), 17.2% of the participants (n =57) developed higher levels of diabetes distress over 18-months (Fisher et al., 2009). Univariate statistics were performed to identify the characteristics of those who developed distress over time. The results found that more women ($p < 0.001$, $M = 14$, $SD = 24.6$), younger age ($p < 0.001$, $M = 53.4$, $SD = 10.88$), less education ($p < 0.05$, $M = 13.7$, $SD = 3.43$), more frequent negative life events and chronic stresses ($p < 0.001$, $M = 4.6$, $SD = 3.36$; $p < 0.001$, $M = 6.8$, $SD = 3.70$, respectively), and previous MDD ($p < 0.001$, $M = 0.22$, $SD = 24.6$) were associated with elevated distress (Fisher et al., 2009).

In another longitudinal study Aikens (2012) conducted multiple regressions examining the relationships among five independent variables (glycemic control, medication adherence, diet, exercise, and blood glucose testing) against the dependent variables (depressive symptoms and diabetes distress) separately and over time. The study participants with T2DM (n= 253) had a mean age = 57.3 ($SD = \pm 8.3$) and 50 % were women. The participants' HbA1c value was used to measure glycemic control, Morisky Medication Adherence Scale (Morisky, Ang, Krousel-Wood, & Ward, 2008) measured medication adherence, SDSCA measured self-care (diet, exercise, and glucose monitoring), Patient Health Questionnaire-9 (Kroenke, Spitzer, & Williams, 2001) measured depressive symptoms, and the Problem Areas in Diabetes scale (PAID; Polonsky et al., 1995) measured diabetes distress. The data collection occurred at baseline and six months.

A regression including all five independent variables after adjusting for confounders and depressive symptoms found that two variables predicted diabetes distress in the model: medication adherence, $\beta = 0.20$, $p < 0.011$, and HbA1c, $\beta = 0.30$, $p < 0.001$ (Aikens, 2012). No R^2 was reported. These findings demonstrate that poor medication adherence and poor glycemic control most strongly influence diabetes distress over time.

In a secondary analysis of data from the Behavior, Emotions, and Attitudes in Diabetes (BEAD) Project, Wardian and Sun (2014) examined the relationships between self-efficacy, social support, self-care, and diabetes distress. Participants with T2DM (n = 267) had a mean age of 57.97, *SD* = 13.64 and were 56% women (Wardian & Sun, 2014). Self-efficacy was measure with a 1-item, 5-point Likert scale, social support was measured with a 2-item, 5-point Likert scale, DDS measured diabetes distress, and two subscales of the SDSCA measured diet and exercise. The alpha for the DDS in the sample was 0.92 (Wardian & Sun, 2014). Participants with T2DM (n = 267) had a mean age of 57.97 (*SD* = 13.64) and were 56% women (2014). A regression was performed including 10 independent variables (gender, age, time since diagnosis, BMI, locus of control, self-efficacy, healthcare provider support, interpersonal support, healthful eating, and exercise) against the dependent variable, diabetes distress. The results showed that the independent variables explained 46% ($R^2 = 0.458$) of the variance in diabetes distress and the overall model was significant, $F(12, 197) = 15.04$, $p < 0.001$ (2014). The model revealed that the younger participants had higher diabetes distress, $B = -0.01$, $SE = 0.004$, $p < 0.05$, and participants who ate a healthy diet had lower diabetes distress, $B = -0.08$, SE = 0.04,

$p < 0.05$ (2014). Moreover, the model showed that BMI, provider support, and self-efficacy showed a contribution to diabetes distress ($B = 0.03$, SE = 0.01, $p < 0.01$; $B = -0.11$, SE = 0.02, $p < 0.01$; $B = -0.37$, SE =0.06, $p < 0.01$), respectively (Wardian & Sun, 2014). All the significant finding had low betas. The research findings indicated that age, BMI, self-efficacy, provider support and healthy eating habits influenced diabetes distress.

Diabetes Distress as an Independent Variable. Fisher et al. (2010) performed another secondary analysis utilizing data from their original work (Fisher et al., 2007). The focus of this study was to evaluate the relationships over time between major depressive disorder (MDD), depressive symptoms, and diabetes distress to glycemic control in participants with T2DM. The study participants (n= 506) had a mean age of 57.8 (*SD*= 9.8); 57% were women, with 81% of the participants completing all three data collections over 18-months (Fisher et al., 2010). HbA1c measured glycemic control, the Composite International Diagnosis Interview measured MDD, Centers for Epidemiological Studies-Depression Scale by Locke and Putnam (Radloff, 1977) measured depressive symptoms, DDS measured diabetes distress, two SDSCA subscales were used to measured diet and exercise.

A simple correlational analysis between diabetes distress and HbA1c showed a small but significant positive relationship, $r = 0.17$, $p < 0.001$ (Fisher et al., 2010). The researcher's regression models included the unstandardized Beta (*b*), which not only provides the directionality of the study variable relationship but indicates the degree of change in the predicting variable in context to the dependent variable (Bannon, 2013). A cross-sectional regression was performed to evaluate the effect of independent variables

(sex, race, age, education, duration of condition, insulin use, BMI, complications, comorbidities, stressful events, self-care diet and exercise, major depressive disorder, depressive symptoms, diabetes distress) against the dependent variable, HbA1c. Of the independent variables in the model, excluding the demographic variables, only diabetes distress contributed a positive relationship with HbA1c, $b = 0.026$, $p = 0.006$ (Fisher et al., 2010). A time-covarying regression model was used to evaluate the three data collection covariates to predict change in the HbA1c over time; this regression included all independent variables against HbA1c. Of the variables in the model, again, only diabetes distress demonstrated a significant positive relationship to HbA1c levels over time ($b = 0.023$, $p = 0.001$), albeit with a very low beta (2010). The findings suggest that diabetes distress may influence glycemic control over time.

In another secondary analysis study, Pandit et al. (2014) examined the correlations between diabetes distress, self-care behaviors, and clinical outcomes among low-income participants. The researcher analyzed secondary data from a large clinical trial (n = 666) on diabetes self-care (original study not cited). The recruitment was conducted in 10 safety net clinics which provided care for the uninsured and underinsured. The participants' mean age was 54.8 ($SD = 11.1$) and 62.7% were women. The demographic profile indicated that 39.2% of the participants diagnosed with diabetes 10 or more years. It is unclear if the participants had T1DM, or T2DM.

In this study, the DDS measured distress, the Behavioral Risk Factor Surveillance System measured diet and exercise (CDC, 2006), clinical outcome data from participant health records included HbA1c, blood pressure, and cholesterol, and the Morisky scale

measured medication adherence. Prior to conducting their correlations and regressions, the researchers categorized the participants into three levels of distress (high, moderate, or none) as determined by the Fisher and colleagues (2012) analysis.

In the study sample, 14.1% of the participants were categorized as high diabetes distress and 27.3% categorized as moderate diabetes distress (Pandit et al., 2014). Participants with high diabetes distress were predominately younger (55.3% less than 50 years) and 73.1% were women (2014). A bivariate analysis showed a positive relationship between elevated levels of HbA1c and diabetes distress ($p < 0.001$). According to Pandit et al. (2014), participants with high distress had a mean HbA1c of 9.3% ($SD = 2.0$), moderate distress had a mean HbA1c = 8.2% ($SD = 1.8$), and no distress had a mean HbA1c = 7.8% ($SD = 1.7$). Three separate logistic regressions were performed and included five independent variables (categorized diabetes distress, age, income, gender, comorbidities) against each dependent variable (medication adherence, HbA1c, and blood pressure). Pandit et al.'s findings revealed that participants with both moderate and high levels of diabetes distress are less likely to adhere to medication regimen (OR = 0.58, $p < 0.001$, 95% CI [0.42 to 0.79]; (OR = 0.44, $p < 0.001$, 95% CI [0.27 to 0.73]; and participants with high levels of distress are more likely to have elevated HbA1c ($\beta = 1.33$, $p < 0.001$, 95% CI [0.81 to1.85]. No R^2 was provided in the research report. The results suggest that individuals with moderate and high levels of distress influence some aspects of diabetes self-care.

In a correlational study, Walker, Gebregziabher, Martin-Harris, and Edege (2014) examined the relationships between socioeconomic and psychological factors including fatalism, self-efficacy, depression, diabetes distress, psychological distress, social support,

and perceived stress, diabetes knowledge, self-care, health outcome measures, and quality of life. The participants (n = 615) had a mean age of 61 years (*SD* = 10.9), were 38.4% women, were diagnosed with T2DM with a mean HbA1c of 7.9%, *SD* = 1.8 (Walker et al., 2014). The instruments presented below are limited to the variables that met significance. The Diabetes Fatalism Scale (Egede & Ellis, 2009) measured fatalism, Perceived Diabetes Self-Management Scale (Wallston, Rothman, & Cherrington, 2007) measured self-efficacy, and DDS measured diabetes distress. The SDSCA measured diabetes self-care and the Morisky Medication Adherence Scale measured medication adherence. Glycemic control levels extracted from medical records over the last six months provided the HbA1c data.

Separate multiple linear regressions were performed with 17 independent variables, which included diabetes distress, against the dependent variables of diabetes self-care and glycemic control. The results showed that together, the 17 independent variables explained 24% of the variance ($R^2 = 0.238$) in medication adherence. In the model, four independent variables made a statistically significant contribution to the model: fatalism and self-efficacy were positive with low betas ($B = 0.03$, $p < 0.05$, 95% CI [0.01 to 0.05]; $B = 0.05$, $p < 0.05$, 95% CI [0.01 to 0.09], respectively); and diabetes distress and perceived stress were negative with stronger betas ($B = -0.58$, $p < 0.001$, 95% CI [-0.91 to -0.25]; $B = -0.12$, $p < 0.001$, 95% CI [-0.18 to -0.05], respectively (Walker et al., 2014). Another regression showed that together, the 17 independent variables explained 23% of the variance ($R^2 = 0.23$) in general diet. The following variables showed a significant contribution to the model: fatalism and self-efficacy were positive with low betas ($B = 0.03$, $p < 0.05$, 95% CI [0.01 to 0.05]; $B = 0.12$, $p < 0.001$, 95% CI [0.08 to 0.15], respectively), and diabetes

distress was negative with a stronger beta, $B = -0.46$, $p < 0.05$, 95% CI [-0.79 to -0.13] (2014). Moreover, a regression showed that together, the 17 independent variables explained 23% of the variance ($R^2 = 0.23$) in HbA1c. The following variables made a significant contribution to the model: self-efficacy was negative, $B = -0.12$, $p < 0.001$, 95% CI [-.15 to -0.08], and distress was positive with a stronger beta, $B = 0.43$, $p < 0.05$, 95% CI [0.14 to 0.72] (2014). In the study, diabetes distress significantly influenced medication adherence, general diet, and glycemic control.

Hernandez et al. (2014), previously discussed in the self-care empirical review, separately performed a series of regressions using numerous independent variables including diabetes distress for two minority cohorts, African American (AA) and Hispanic/Latino (HL). DDS measured diabetes distress and SDSCA measured diabetes self-care.

A linear regression was performed using 12 independent variables against the dependent variable, total diabetes self-care. The results showed that together, the 12 independent variables explained 16% of the variance in total self-care ($R^2 = 0.16$), with diabetes distress making a significant negative contribution ($\beta = -0.158$, $p = 0.007$) to the model (Hernandez et al., 2014). Two regressions including all independent variables against general diet were performed separately on data from the African American (AA) and Hispanic/Latino (HL) cohort. The model for the AA cohort explained 33% of the variance in general diet ($R^2 = 0.33$) with a significant negative contribution to the model by diabetes distress ($\beta = -0.202$, $p < .0001$). The model for the HL cohort explained 20% of the variance in general diet ($R^2 = 0.20$) with a significant negative contribution to the model

diabetes distress, β = -0.116, p = 0.005 (Hernandez et al., 2014). The findings demonstrated that diabetes distress influences unhealthy diet behaviors. Again, linear regressions were performed for each cohort, including all the independent variables against the dependent variable, exercise. The AA cohort results demonstrated that the model explained 26% of the variance in exercise (R^2 = 0.26) with a significant negative contribution by diabetes distress, β = -0.187, p = 0.0005 (Hernandez et al., 2014). No significant contribution by diabetes distress to exercise was found in the HL cohort.

In the seven reviewed studies, diabetes distress was used as both an independent and dependent variable in correlations, and, theoretically, functioned as an influencer and an outcome variable. The findings from the empirical studies consistently demonstrated that diabetes distress correlated with elements of self-care and glycemic control. Several researchers found that diet adherence (Fisher et al., 2009; Fisher et al., 2012; Polonsky et al., 1995; Polonsky et al., 2005; Walker et al., 2014) and medication adherence (Aikens, 2012; Gonzalez et al., 2015; Pandit et al., 2014; Walker et al., 2014) were negatively influenced with the presence of diabetes distress. While not all researchers examined exercise with the same instrument, of the articles reviewed, Polonsky, Fisher, Earles et al. (2005) and Fisher, Mullen, Staff et al. (2009) found that exercise was negatively influenced by diabetes distress. The research consistently found that individuals with diabetes distress had elevated HbA1c compared to individuals with no distress (Gonzalez et al., 2015; Pandit et al., 2014; Aikens, 2012; Fisher et al., 2010). The presence of moderate to high levels of diabetes distress occurred in 41.4% to 60% of the study participants (Fisher, Hessler, Polonsky, & Mullan, 2012; Pandit et al., 2014), and high levels of distress were found in approximately

18% to 35% of study participants (Aikens, 2012; Fisher et al., 2009; Fisher et al., 2008). Diabetes distress has been identified to be more prevalent in women than men (Fisher et al., 2009; Fisher et al., 2008; Delahanty et al., 2007; Anderson et al., 2001; Peyrot & Rubin, 1997).

Measures of Diabetes Distress

Psychological and behavioral responses in diabetes have been studied for years (Bradley, 2006) with the first print of "Handbook of Psychology and Diabetes" published in 1994. The first instrument to measure diabetes distress was developed in the 1990's as the concept was newly emerging. Two instruments, both by Polonsky and colleagues, have been developed to measure diabetes distress and will be presented in chronological order.

Problem Areas in Diabetes Scale. Problem Areas in Diabetes Scale (PAID) was developed by Polonsky and colleagues (1995) to measure psychological adjustment and emotional functioning in individuals with diabetes. The instrument assesses an individual's response to living with diabetes by measuring feelings of anger, frustration, and interpersonal distress, with the higher score representing greater emotional distress experienced by the individual (Polonsky et al., 1995). The total score of the instrument identifies the emotional distress related to living with diabetes (Polonsky et al., 1995).

The original PAID consisted of 20-items using a 6-point Likert scale, ranging from 1 (No problem) to 6 (A serious problem), and the item total ranges from 24 to 144. However, later the instrument was modified to a 5-point Likert scale ranging from 0 (Not a problem) to 4 (Serious problem), with an item total range from 0 to 100 (Welch, Weinger, Anderson, & Polonsky, 2003). The instrument was initially tested in an all-female

population (n = 451), predominately diagnosed with T1DM (82.4 %) with an age range between 13 and 60 years, mean = 36.3 years (*SD* = 1.4). Polonsky (1995) reported internal reliability with a coefficient alpha of 0.95 and a strong item correlation with a general psychological distress measurement ($r = 0.63$). A negative correlation ($r = -0.25$ to -0.28, $p < 0.0005$) was shown between PAID and specific self-care behaviors such as, blood glucose testing, use of insulin, and diet (Polonsky et al., 1995). PAID has been studied in individuals with both T1DM and T2DM and has an overall Cronbach alpha coefficient greater than $\alpha = 0.90$ (Karlsen, Oftedal, & Bru, 2012; Sigurdardottir & Benediktsson, 2008; Welch et al., 2003; Snoek, Pouwer, Welch, & Polonsky, 2000; Welch et al., 1997).

Diabetes Distress Scale. Polonsky and colleagues (2005) developed a new instrument, Diabetes Distress Scale (DDS), based on what they learned from of the PAID instrument. Similar to PAID, the DDS measures the emotional burdens and worries some individual's experience when living with diabetes (Polonsky et al., 2005). The pilot DDS was a 28-item, 6-point Likert scale, ranging from 1 (No problem) to 6 (A serious problem), and after the exploratory factor analyses, the instrument was reduced to 17-items (2005). A study was conducted to evaluate the DDS and participants were recruited at three separate locations (San Diego, Honolulu, and Boston) and from different settings including a primary care clinic waiting room, a diabetes clinic, a study diabetes management program, and a non-study diabetes management program. The majority (83.3%) of the total participants (n = 504) were diagnosed with T2DM, the mean age was 56.3, and 52.3% were men (Polonsky et al., 2005).

A factor analysis (Polonsky et al., 2005) found four subscales: (a) Emotional burden (5 items), α= 0.88, (b) Regimen-related distress (5 items), α= 0.90, (c) Physician-related distress (4 items), α= 0.88, and (d) Interpersonal-related distress (3 items), α = 0.88 (Polonsky et al., 2005). The Cronbach alpha for the total scale was 0.93. The three distinct ranges developed to categorize the levels of diabetes distress using mean item scores are as follows: (a) Score less than 2 = little to no distress, (b) Score 2 - 2.9 = moderate distress, and (c) Score 3 or more = high distress (Fisher et al., 2012). Since DDS was developed in 2005, it is the predominate measure researchers use to examine diabetes distress (Fisher et al., 2013; Fisher et al., 2007; Schmitt et al., 2015; Shreck et al., 2014; Pandit et al., 2014; Walker et al., 2014; Wardian & Sun, 2014).

The instruments developed by Polonsky and colleagues (1995; 2005) measure diabetes distress. PAID measures psychological adjustment and emotional functioning of individuals with diabetes whereas DDS includes measurement of the interpersonal and regimen-related distresses. Both instruments, PAID and DDS, demonstrate consistent validity and reliability and to measure the phenomena of diabetes distress in individuals with T2DM. DDS is the most current and updated instrument to measure distress (Polonsky et. al, 2005) and, therefore, is the instrument of choice to use in research.

Summary

The overall theoretical framework that underpins this study is Orem's self-care theory. A logical connection between the self-care theory's internal conditioning factors (age, gender, time management, and distress) and the performance of diabetes self-care is established through the empirical literature findings.

The empirical review focused on the adult population and did not include female specific studies; however, there were a few articles that examined age and used gender comparisons when analyzing relationships with self-care and distress (Fisher et al., 2009; Fisher et al., 2008; Delahanty et al., 2007; Anderson et al., 2001; Peyrot & Rubin, 1997). Study findings demonstrated that age influences diabetes self-care in both a positive and negative direction; increased age showed better dietary behaviors (Hernandez et al., 2014; Song et al., 2012) whereas exercise was the least performed self-care behavior in the adult population (Hernandez et al., 2014; Watkins et al., 2013). The female gender was associated with better blood sugar testing and insulin-use (Hernandez et al., 2014). Furthermore, age and gender played a significant role in distress where younger adults and being female were influencers (Fisher, et al., 2009; Pandit et al., 2014; Wardian & Sun, 2014). There is a gap in literature in understanding how age and gender may influence diabetes time management.

The current literature on diabetes self-care and time management supports a relationship between these two variables. Weinger (2015) broke ground with evidence that time management has a relationship with both self-care and glycemic control. An instrument specific to diabetes time management has been developed (Gafarian et al., 1999), although it remains underutilized in the literature. Diabetes distress demonstrated bidirectional relationships with self-care and glycemic control, not by model testing, but rather by examining distress as a dependent or independent variable (Akins, 2012; Fisher, et al., 2010; Fisher, et al., 2009; Pandit et al., 2014; Walker et al., 2014). Several aspects of self-care have been shown to be negatively influenced by distress; similarly, the presence of

diabetes distress has been shown to influence aspects of self-care. Whether cause or effect, researchers have established that diabetes distress is a pertinent, relevant issue affecting many individuals with diabetes (Aikens, 2012; Fisher et al., 2012; Pandit et al, 2014). The evidence suggests that the female diabetes population suffers from diabetes distress more often than men; therefore, researching diabetes distress and self-care in women is supported (Fisher et al., 2009; Fisher et al., 2008; Delahanty et al., 2007; Anderson et al., 2001; Peyrot & Rubin, 1997).

While diabetes distress and diabetes time management have not been studied together, there are some commonalties shared between distress and time management. Ye, Shim, and Rust (2012) found that the presence of psychological distress influenced the avoidance of health care. Avoidance is a time management strategy deficit. Avoidance can be precipitated for many reasons; however, this study posits that being overwhelmed and frustrated are potential factors that may impact time management thus linking the two variables. In a student population, Oksanen, Laimi, Björklund, Löyttyniemi, and Kunttu (2017) found that psychological distress was associated with concentration problems. Executing self-care tasks requires focus and attention, and are elements of time management skills; consequently, distress may serve to distract an individual from applying these needed skills. The two instruments, DDS and DTMQ, have several questions that ask participants to rate their feelings and the topics share common themes. For example, the DDS asks, "feeling *overwhelmed* by the demands of living with diabetes", and the DTMQ asks "I feel *overwhelmed* by what I need to do in a day". The DDS asks, "feeling that diabetes is *taking up too much of my mental and physical energy* every day", and the DTMQ asks, "I feel like

there is *not enough time* in a day" (Gafarian et al., 1999; Polonsky et. al 2005). While the instruments are measuring different concepts, the emotions of feeling overwhelmed and the concern for time overlap between the two scales.

Diabetes is a chronic progressive condition and the goal of diabetes self-care is to maintain glycemic control to prevent systemic complications. Effective self-care has been demonstrated to be a predictor of better glycemic control (Sousa & Zauszniewski, 2005; Song, Ratcliffe, Tkacs, & Riegel, 2011). Understanding the attributes that influence women's ability to provide self-care needs further exploration. The findings from this study will lend better understanding and may have the potential to be translated into practice through the development of patient-centered interventions for women.

Chapter III

METHODOLOGY

Study Design

A descriptive correlational design, as defined by Polit and Beck (2017), describes the relationships between and among the study variables without implication of causality. This study examined the relationships between and among diabetes self-care, diabetes time management, and diabetes distress using a convenience sample. This design was selected because relationships between all three study variables have not been established in the literature and future hypothesis development may transpire from the study's results. The purpose of this chapter is to describe the study's sample population, sample size, data collection instruments, and methods of data collection and analyses.

Description of the Population and Sample

The population of this study was women 18 years and older who were diagnosed with T2DM and for greater than one year. The sample included women from Bucks County and Montgomery County in Pennsylvania as well as a sample of women across the United States. To ensure study participants met the eligibly criterion, seven screening questions (Appendix B), as defined by this study, were asked.

Sample size and statistical power. The sample size and statistical power were calculated to determine the number of participants required to strengthen the study. To calculate a baseline study sample size, a power analysis was conducted using the *F* test, linear multiple regression fixed mode, R^2 deviation from zero, medium effect size, and a priori power of 0.80 with an alpha of 0.05 (Bannon, 2013). According to Bannon (2013), a stronger power will facilitate the detection of an effect and an effect size identifies the impact of the effect between variables. Using the G*Power sample size formula, the three predictor variables (diabetes self-care, diabetes time management, and diabetes distress) yielded a total sample size of 99. Additionally, there were 13 covariate variables; therefore, the G*Power analysis was recalculated using 16 predictor variables and yielded a total sample size of 143.

Setting

The setting varied as the surveys were completed on either paper in a physician practice or diabetes center or an uncontrolled, natural setting for the electronic survey (smart phone, tablet, or home commuter). The environment potentially ranged from an interruptive setting to a quiet setting.

Recruitment. Two different recruitment processes were developed for the study. Recruitment for the paper survey occurred in the three physician offices and two diabetes centers where flyers were placed in the office waiting rooms (Appendix C). Recruitment using the electronic survey was disseminated and networked by a leader of diabetes support group through newsletter email communications and by hospital nursing leaders by email communication in two hospitals located in Bucks County and Montgomery County,

Pennsylvania. The electronic survey had an invitation letter to participants (Appendix D). All study participants were provided a letter of solicitation (Appendix E) about the study and included an explanation of the purpose, estimated time for completion, briefly described instruments, anonymity and voluntary nature of the study, storage of data, investigators' contact information, and potential risks. Participants voluntarily completed the paper survey or accessed the survey link and therefore, consent was implied (Grove, Burns, & Gray, 2013). The researcher was blinded to the names and email addresses of the study participants. The paper survey participants received $10.00 cash for the reimbursement of the time as the estimated completion time was 25 minutes. Due to the anonymity of the electronic survey, it was not feasible for the researcher to disseminate $10.00 cash to electronic survey participants.

Data Collection Procedures

According to Dillman, Smyth, and Christian (2014), mixed-mode survey designs are used when a researcher wants to lower costs, reduce measurement error, and improve timeliness in survey response. Ward, Clark, and Zabriski (2014) examined differences between paper and electronic survey responses and the overall findings indicated there were minimal differences between the two data collection methods. This study used both paper and electronic data collection methods.

Participants recruited in the physician office and diabetes center completed paper surveys and were returned to the receptionist who then secured the forms in a lock box that was only accessed by the researcher. Participants were given $10.00 cash for reimbursement of time by the office employees when surveys were returned.

Participants recruited electronically received an invitation to access an anonymous link through Qualtrics® survey software. Participants were warned that by clicking on the survey link they will be redirected to a Qualtrics® browser to complete the survey. Response to surveys usually occurs immediately and within three weeks (Silva & Duarte, 2014). Partially completed surveys remained open for three weeks, at which time the survey was saved and closed.

The paper and electronic survey began with an eligibility screening. The eligibility criterion consists of seven questions; participants who completed the electronic survey were permitted to advance to the study questions if the entire eligibility questions were true. The additional questions included the Diabetes Self-Management Questionnaire (DSMQ; Appendix F), Diabetes Time Management Questionnaire (DTMQ; Appendix G), Diabetes Distress Scale (DDS; Appendix H), and demographic profile (Appendix I). According to Dillman's guidelines (2014), sensitive questions were placed at the end of the survey and therefore, the demographic profile questions were the last section of the survey. Each questionnaire included instructions on how to complete the survey.

Data collection period was from September 2018 through January 2019. The paper surveys were entered into Excel and double checked to validate data was entered correctly. The electronic surveys from Qualtrics were exported into Excel. All the data is stored on a USB memory key and kept in a locked, secured desk for three years.

Instrument and Measurement Methods

Diabetes self-care was measured by the Diabetes Self-Management Questionnaire (Schmitt et al., 2013), time management was measured by the Diabetes Time Management

Questionnaire (Gafarian et al., 1999), and diabetes distress was measured by the Diabetes Distress Scale (Polonsky et al., 2005).

The three selected instruments were reviewed below for reliability and degree of validity. This section outlines the instruments scoring methods and rational for use. Permission to use the above-mentioned instruments was obtained from the instrument developers (Appendix J, K & L). Three volunteers completed all 97 questions on paper in approximately 25 minutes.

Diabetes Self-Management Questionnaire (DSMQ). The DSMQ was developed by Schmitt et al. (2013) to measure diabetes self-care behaviors that influence glycemic control in individuals with both T1DM and T2DM. The DSMQ is a 16-item instrument with 4 dimensions and one item rating overall self-care; the dimensions include glucose management (5 items), dietary control (4 items), physical activity (3 items), and healthcare-use (3 items). The subscale term, healthcare-use, is used interchangeably with physician contact; to be consistent, only one term (physician contact) will be used throughout this paper. Glycemic management includes two subscales, medication adherence (2 items) and blood glucose management (3 items). The items use a 4-point Likert scale: *Applies to me very much* = 3 points, *applies to me to a considerable degree* = 2 points, *applies to me to some degree* = 1 point, and *does not apply to me* = 0 points. A few questions related to blood sugar testing have an option to select "treatment is not a part of my self-care" and these items are not scored (items 1, 6 and 10). For individuals who are not instructed by their provider to check their blood sugars, none of the three respective items will apply to them. The instrument has nine negative items that are reversed-scored; a higher score

represents more effective self-care. To lower the scale's reading level, permission was obtained from the instrument developer to replace "hypoglycemia" with "low blood sugar" on question 13. Additionally, the medical terminology "diabetes" was removed from the reading level calculation because it is assumed that an individual diagnosed with diabetes will be familiar with this word. The readability statistics was calculated using Flesch-Kincaid and the DSMQ is at 8th grade reading level.

Details of DSMQ development, including reliability, are provided in chapter 2. Overall, internal reliability for all subscales was acceptable but for physician contact which had a Cronbach's alpha of .60 (Schmitt et al., 2013). The recent Schmitt et al. (2017) published study found the following Cronbach's alphas in dietary control ($\alpha = 0.79$), medication adherence ($\alpha = 0.75$), blood glucose management ($\alpha = 0.83$), physical activity ($\alpha = 0.74$), and physician contact ($\alpha = 0.72$). This demonstrates an acceptable alpha for the healthcare-use subscale. Additional research (Bukhsh et al., 2017; Mehravar, 2015; Yadav, 2016) conducted in Asia, studied T2DM populations using the DSMQ. Bukhsh et al. (2017) and Mehravar (2015) reported Cronbach's alphas in dietary control ($\alpha = 0.88$; $\alpha = 0.72$), glycemic management ($\alpha = 0.91$; $\alpha = 0.80$), physical activity ($\alpha = 0.89$; $\alpha = 0.80$), physician contact ($\alpha = 0.73$; $\alpha = 0.81$), respectively. The Cronbach's alpha from other studies were acceptable, $\alpha = 0.96$ (Bukhsh, 2017), $\alpha = 0.72$ (Mehravar, 2015), and $\alpha = 0.84$ (Yadav, 2016).

The structure of the DSMQ was determined using factor analysis. The initial exploratory factor analysis (EFA) suggested a four-factor structure. The minimum loading was set at ≥ 30 (Schmitt et al., 2013). The instrument structure was validated by the

confirmatory factory analysis (CFA) and goodness of fit was tested in both the four-factor structure and the one-facture structure. Both structures demonstrated nonsignificant x^2, the comparative fit indexes (CFI) were ≥ 0.95, the root mean square errors of approximation (RMSEA) were ≤ 0.053, and the PCLOSE was 0.50 (Schmitt et al., 2013). The PCLOSE is a conversion of the RMSEA to show statistical significance (Reinard, 2015). A CFA by Bukhsh (2017) showed the CFI was

≥ 0.95, Tucker Lewis Index (TLI) ≥ 0.95, RMSEA ≤ 0.06. According to Weston and Gore (2006), guidelines for good acceptable fit include nonsignificant x^2, CFI > 0.90, and RMSEA < 0.01. Thus, these findings suggest a good fit, but for the higher RMSEA. The self-care total score was used for correlations in this study. Each subscale and total score were calculated using a formula (actual sum of items divided by possible maximum sum of items x 10); thus, transforming scores are between 0 to 10 (Schmitt et al., 2013).

Diabetes Time Management Questionnaire (DTMQ). The DTMQ was developed by Gafarian et al. (1999) to measure diabetes time management skills. The 49-item, 5-point Likert scale (1 = *Always* to 5 = *Never*) and the original scoring range is from 49 to 245. Higher DTMQ scores indicate less effective time management skills. The psychometric properties of the instrument were only tested once; the mean instrument score from this sample (n = 60) was 120.56 (*SD* = 21.15) (Gafarian et al., 1999). The readability statistics were calculated using Flesch-Kincaid and the DTMQ is at 6th grade reading level.

The reliability of the instrument demonstrated a Cronbach's alpha total score of α = 0.82 (Gafarian et al., 1999). Content validity was determined by the research team who reviewed the DTMQ items for accuracy and representation in measuring diabetes time

management (Gafarian et al.). Criterion-related validity was tested by correlating DTMQ and the Habits, Attitudes, and Knowledge Questionnaire of Time Management. The analysis (n = 60) revealed a significant positive association between the two instruments (r = 0.71, $p < 0.001$), thus supporting the criterion validity of time management (Gafarian et al.). Additionally, the DTMQ was positively correlated with Diabetes Knowledge Schedule (r = 0.29, $p < 0.04$), indicating that with increased diabetes knowledge better diabetes time management skills were present (Gafarian et al.).

Since the DTMQ was developed in 1999, a few questions required updating by the researcher of this proposal study to reflect appropriate diabetes regimen changes. Permission for updating the questions was granted by the instrument developer who deemed the changes appropriate (Appendix K). For this study, there were three questions (14, 29, and 31) that had question stem revisions and two questions (10 and 21) with answer stem revisions.

Question 14 originally stated, "When I take my diabetes medication (insulin or pills) before a meal, I take it 30-35 minutes prior to eating". This question required updating due to a newer type of insulin that works rapidly after administration and requires food consumption within 15 minutes after medication. Thus, question 14 was modified by the researcher to reflect this change and now reads, "When I take my diabetes medication (insulin or pills) before a meal, I take it at the appropriate time prior to eating depending on my medication type *(example, rapid acting insulin peaks in 15 minutes, regular insulin peaks in 30 minutes, some oral medications must be taken with meals)*".

Questions 29 and 31 both refer to goal setting. Both original question stems will remain the same; however, the examples, written in parenthesis after the question were both revised. Both question stem examples used the term "jog" to give examples of an exercise plan. To make the examples more inclusive to the general population, walk/jog replaced the term jog so those who are unable to jog but do walk for exercise can identify with the example. Questions 10 and 21 refer to blood sugar testing. For individuals who have not been instructed by their provider to check blood sugars, an option to select "blood sugar measurement is not required as a part of my self-care" was added to the answer stem.

A total time management score was used for correlations in this study. The revision of questions 10 and 21 creates a disparity in total scores between participants who are instructed to check blood sugar levels (49 total questions) and those who are not instructed to (47 total questions). In order to analyze participants as a cohort, a score conversion method has been established. The sum score is divided by the total possible score (either 235 or 245), then multiplied by 10 to convert the score to a 1 to 10 scale for equity. For example, participants who complete 47 questions, due to the two not applicable questions, will use 235 as the total possible score (215 sum score divided by 235 total possible score = 0.9 x 10 = 9.1). The instrument has fourteen negative items that were reversed-scored.

Diabetes Distress Scale (DDS). The DDS was developed by Polonsky et al. (2005) to measure diabetes distress within the last month. The DDS is a 17-item scale with 4 dimensions and includes emotional burden (5 items), physician-related distress (4 items), regimen-related distress (5 items), and diabetes-related interpersonal distress (3 items) and a total diabetes distress score (Polonsky et al., 2005). The instrument uses a 6-point Likert

scale (1 = *no problem* to 6 = *series problem*). The total score possible range is 17 to 102. To lower the scale's reading level, the medical terminology "diabetes" was removed from the calculation because it is assumed that an individual diagnosed with diabetes will be familiar with this word. Using the Flesch-Kincaid formula, the DDS is at an 8th grade reading level.

The reliability of DDS was fully described in chapter 2 and Polonsky and colleagues (2005) initially established Cronbach alphas for emotional burden ($\alpha = 0.88$), regimen-related distress ($\alpha = 0.90$), physician-related distress ($\alpha = 0.88$), interpersonal-related distress ($\alpha = 0.88$), and total distress ($\alpha = 0.93$). Four more recent studies by Chew et al. (2015), Gonzalez et al. (2014), Schmitt et al. (2015), and Wardian and Sun (2014) only used the DDS total score and found similar Cronbach alpha's to Polonsky's ($\alpha = 0.94$, $\alpha = 0.95$, $\alpha = 0.89$, $\alpha = 0.92$, respectively). An exploratory factor analysis (EFA) was performed and suggested a four-factor structure and a total score.

The total diabetes distress score was used for correlations in this study. To calculate the total distress score, the items from the instrument are summed, and then divided by the total item numerator (17) to produce a mean item value. Fisher et al., (2012) conducted a correlational study to determine clinically meaningful scoring cut off points to define categories of diabetes distress. As a result, a score of less than 2 indicates little to no distress, a score range of 2.0 to 2.9 indicates moderate level of distress, and 3 or more indicates high level of distress (Fisher, 2012). These categories help define the characteristics of the participants.

The respective instruments were chosen because they have demonstrated reliability and some degree of validity in a T2DM population. The instruments adequately measure the variables of interest to the study. The DTMQ is the only known instrument to measure diabetes time management and this study will aid in further psychometric analysis of that instrument.

Covariate data. The 13 covariate variables included: age, employment, work environment, caregiver roles, neglect self-care, years with diabetes, other health conditions, last HbA1c, medication regimen, diabetes status, income, education, and race/ethnicity. The electronic survey collected participant residency location. The covariate variable questions were developed with consideration of a low reading level. The readability statistics were calculated using Flesch-Kincaid and were at 7th grade reading level.

Data Collection Method. There were two different survey methods, paper and electronic. The paper survey was available to suburban Philadelphia (Bucks and Montgomery County) in Pennsylvania whereas the electronic survey reached participants in several regions in the United States.

Analysis of Data

The paper and electronic surveys were combined into one compatibility format to import and analyze using IBM Statistical Package for the Social Sciences® (IBM SPSS® version 25). Multiple procedures were deployed to answer the research questions and explore potential relationships between the dependent variable (diabetes self-care), independent variables (diabetes time management and diabetes distress), and covariate variables. Prior to conducting any statistical analysis, the imported data was reviewed for

data integrity. Data cleaning using frequency procedures were performed to identify missing responses, to calculate the proportion of missing data, and to evaluate patterns of missing data (Bannon, 2013). Reverse scores were transformed. Internal consistency reliability procedures were performed on all three instruments. Tests of assumptions were performed to determine normal distribution, multicollinearity, homoscedasticity, and linearity necessary for performing regressions (2013).

Univariate analysis. The purpose of univariate analysis is to describe the characteristics of each variable (Bannon, 2013). The DSMQ, DTMQ, and DDS are continuous variables and the total score produces an interval data point where univariate tests measures central tendency and dispersion (mean, median, standard deviation, and range) (Bannon, 2013). The covariate variables contained both continuous and categorical data where univariate analyses were applied to generate frequencies and percentages.

Bivariate analysis. To address the research questions, bivariate and multivariate analyses were conducted to examine how the independent variables (diabetes time management and diabetes distress) were related to the dependent variable (diabetes self-care), as well as, the relationship between time management and diabetes distress. The purpose for these analyses were to identify which independent variables were statistically significantly correlated ($p < 0.05$) with diabetes self-care and then include them in the final multiple regression (Bannon, 2013). To analyze the relationships between time management and self-care and diabetes distress and self-care (all continuous variables), Pearson's *r* correlations were performed to determine statistical significance, directionality (positive or negative), and effect size (-1 to +1) (Bannon, 2013). To analyze the

relationships between diabetes self-care and the covariate variables, One-Way ANOVA, chi-square, and t-test were performed.

Multivariate analysis. The purpose of a multivariate analysis was to identify the strongest predictor of the dependent variable (DV) and to measure the combined impact of a set of variables on the DV. The aim of the multivariate analysis was to predict the value of diabetes self-care based on the other independent variable, to explain the variance of the regression model, and explain the contributions from each predictor toward the variance explained in diabetes self-care (Bannon, 2013). Diabetes self-care is a continuous variable and therefore, a linear regression was the appropriate test to perform. In a multiple regression, statistical significance ($p < 0.05$) for the overall model was noted in the ANOVA model. Directionality between the predictor variables and diabetes self-care were measured by Unstandardized Beta (*B*) and a statistically significant value indicates positive relationships (2013). Effect size is more complex in regressions. In a regression, the standardized beta identifies which predictor is strongest in the model. Moreover, the R effect size (small = 0.01, medium = 0.06, large = 0.14) in the regression indicates the amount of variance in self-care explained by the set of predictors (2013). Furthermore, evaluating the proximity of the R^2 and adjusted R^2 values indicates generalizability in the findings (2013).

Ethical Considerations

The Institutional Review Board (IRB) at Seton Hall University approved the study prior to recruitment and data collection (Appendix M). Additionally, IRB approval was received to data collect at the healthcare organization (Appendix N). A Qualtrics® account

was established through Seton Hall University using authentication access rules to secure participant information and storage of data for the electronic surveys. All completed surveys did not include participant identifying information and the researcher did not have access to any names or email addresses. Email recipient received blinded communication which protected the identity of potential participants. The email invitation and letter of solicitation explained to the recipients that participation in the study is voluntary. Participation in the study poses minimal risk of harm and therefore, a written consent was waived as the completion of the questionnaire indicated consent (Grove, Burns, & Gray, 2013).

Chapter IV

FINDINGS

Introduction

The purpose of this chapter is to report the study's findings and address the research questions and one hypothesis. The chapter outlines the data collection process and describes the demographic and descriptive variables of the participants. The three instruments deployed in the study [Diabetes Self-Management Questionnaire (DSMQ); Diabetes Time Management Questionnaire (DTMQ); and Diabetes Distress Scale (DDS)] were analyzed for reliability. The survey completion methods (paper and electronic) were examined using t-tests and chi-square tests. The covariate variables were analyzed using multiple bivariate analyzes (Pearson's correlation, One-way ANOVA, and t-tests). Additionally, the main study variables (diabetes self-care, diabetes time management, and diabetes distress) were examined using both bivariate analysis and multivariate regression.

Description of Sample

The total sample used in the study was 188. The paper survey (n = 83) was collected at multiple sites located in Bucks and Montgomery County, Pennsylvania (PA) and the electronic survey (n = 105) collected by means of diabetes support networks and employees in Bucks and Montgomery County, PA community hospitals. The paper survey had an

ineligibility rate of 8.7% (n = 8). The electronic survey had an abandonment rate of 20.9% (n =43) and an ineligibility rate of 34.2% (n = 56). The majority (64.04%) of the total representation was from the Mid-Atlantic Region (n =114), (Table 1 and Table 2).

Table 1

Participation Location of Paper Survey (n=83)

Location by Office Setting	N	Percent
Diabetes Center	18	21.7%
Physician Office	65	77.6%
Total	83	100.0%

Table 2

Participation of Electronic Survey by US Census Regions (n = 95) *

Location by United States Census Regions	N	Percent
New England	4	2.1%
Mid-Atlantic	31	16.5%
East North Central	9	4.8%
West North Central	4	2.1%
South Atlantic	13	6.9%
East South Central	5	2.7%
West South Central	7	3.7%
Mountain	8	4.3%
Pacific	14	7.4%
Total	95	100%

*Total number of respondents was 105, 10 who preferred not to answer were excluded.

Demographic and descriptive characteristics. The women in the study had a mean age of 60.66 (*SD* = 12.35) and had a duration of living with diabetes for 13 years (*M* =13.08, *SD* = 10.40), (Table 3). The women were predominately white (81.4%) of mixed income and education levels. Less than a quarter of the women (22.3%) preferred not to identify income level, however, the remaining participants were nearly equally distributed among the income brackets.

Approximately 50% of the women had some level of college education, with the largest group (24.5%) having some college education with no degree. Nearly thirty percent (29.9%) of the women reported employment status as full-time or part-time, 19.1% reported unemployment, and 35.6% as retired (Table 4). Of the participants who worked (n= 114), 54.4% reported a favorable work environment to perform diabetes self-care, leaving approximately 31.6% reporting somewhat and not at all favorable (Table 5).

Table 3

Range, Mean and Standard Deviation of Age & Duration of Diabetes (N = 188)

Self-Reported Characteristics	Range	*M (SD)*
Age	20-88	60.66 (12.35)
Diabetes duration in years	1-56	13.08 (10.40)

Table 4

Frequency Table on Participant's Characteristics (N = 188)

Characteristics	N	Percent
Race/Ethnicity		
African	16	8.5%
Asian	10	5.3%
Latino	1	0.5%
Mixed	2	1.1%
Other	6	3.2%
White	153	81.4%
Total	188	100%
Income		
< $30,000	35	18.6%
[$30,001, $50,000]	32	17.0%
[$50,001, $70,000]	19	10.1%
[$70,001, $100,000]	28	14.9%
> $100,001	32	17.0%
Prefer not to answer	42	22.3%
Total	188	100%
Education		
Below high school	14	7.4%
High school	34	18.1%
Some college (no degree)	46	24.5%
Associate's degree	21	11.2%
Bachelor's degree	37	19.7%
Graduate degree	29	15.4%
Doctorate	7	3.7%
Total	188	100%
Employment		
Full time	56	29.9%
Part time	21	11.2%
Retired	67	35.6%
Unemployed	36	19.1%
Prefer not to answer	8	4.3%
Total	188	100%

Table 5

Frequency Table on Work Environment (n = 114)

Favorable Work Environment	N	Percent
Always favorable	62	54.4%
Often favorable	16	14.0%
Somewhat favorable	23	20.2%
Not at all favorable	13	11.4%
Total	114	100%

The health characteristics of the self-reported HbA1c levels were somewhat evenly distributed among the all the categories (Table 6). Thirty-four percent of the women reported the ADA recommended target range of a HbA1c 6.5 or less and 28.7% viewed their diabetes as getting better, whereas 19.1% had HbA1c levels 8 or greater and 21.8% viewed their diabetes as getting worse. The largest percentage of women (42%) had three or more health conditions other than diabetes. Oral medication was the most frequent diabetes treatment regimen (52.1%). The majority of the women (67.6%) reported rarely neglecting self-care. The largest percentage of women (67.6%) identified as having one additional caregiver role compared to thirty-two percent (32.4%) of the women that reported no additional caregiver roles (Table 7).

Table 6

Frequency Table on Participant's Health Characteristics (N = 188)

Self-Reported Characteristics	N	Percent
Recent HbA1c		
< 6	20	10.6%
6.1 – 6.5	44	23.4%
6.6 – 7.0	22	11.7%
7.1 – 7.5	45	23.9%
7.6 – 8.0	11	5.9%
> 8	36	19.1%
I don't know HbA1c	10	5.3%
Total	188	100%
Other health conditions		
1	33	17.6%
2	56	29.8%
3 or more	79	42.0%
None	15	8.0%
Not sure	5	2.7%
Total	188	100%
Diabetes Status		
Diabetes is getting better	54	28.7%
Diabetes is staying the same	93	49.5%
Diabetes is getting worse	41	21.8%
Total	188	100%
Medication regimen		
Oral medication only	98	52.1%
Combination oral medication and insulin	57	30.3%
Insulin pen or syringe injection only	27	14.4%
Insulin pump only	6	3.2%
Total	100	100%
Neglect self-care		
Rarely	127	67.6%
Half the time	54	28.7%
Most of the time	7	3.7%
Total	188	100%

Table 7

Characteristics of Caregiver Roles (N = 188) *and the Number of Roles Identified* (n = 127)

Self-Reported Characteristics	N	Percentage
Caregiver Roles		
No additional caregiver roles	61	32.4%
Additional caregiver roles	127	67.6%
Total	188	100%
Characteristics of Caregiver Roles		
1 caregiver role	79	62.2%
2 caregiver roles	37	29.1%
3 caregiver roles	11	8.7%
Subtotal caregiver roles	127	100%

Study Variables

The independent and dependent variables were measured using three instruments and all three instruments' scores were transformed to a 0 to 10 scale as outlined in each instrument's instructions. Diabetes self-care was measured using the DSMQ with the higher score indicating better self-care skills. The sample (N =188) self-reported effective self-care (*M* = 7.29, *SD* 1.40). Diabetes time management was measured using the DTMQ with the higher score indicating less effective time management skills. The overall sample reported a total score (*M* = 4.98, *SD* = 0.83) which showed approximately an average level of time management skills. Diabetes distress was measured using DDS with cut off points to identify distress levels (score 2 < = little to no distress: score 2.0 to 2.9 = moderate levels of distress; ≥ 3 = high levels of distress). The sample self-reported a moderate level of distress (*M* = 2.24; *SD* = 1.05), (Table 8).

Table 8

Range, Median, Mean, and Standard Deviation of the Diabetes Self-Care Questionnaire, Diabetes Time Management Questionnaire, and Diabetes Distress Scale (N = 188)

Instrument	Range	Median	Mean	*SD*
Diabetes Self-Care	3.75-9.58	7.29	7.11	(1.40)
Subscale dietary control	0-10	5.83	5.55	(1.98)
Subscale glucose management	0-10	8.0	7.83	(1.85)
Subscale physical activity	0-10	6.66	6.01	(2.74)
Subscale physician contact	2.22-10	10	8.97	(1.76)
Diabetes Time Management	2.97-7.18	5.02	4.98	(0.83)
Diabetes Distress Scale	1-6	1.94	2.24	(1.05)
Subscale emotional burden	1-6	2.2	2.45	(1.28)
Subscale physician distress	1-6	1	1.57	(1.15)
Subscale regimen distress	1-6	2.2	2.61	(1.35)
Subscale interpersonal distress	1-6	1.66	2.18	(1.37)

Instrument Reliability

The study's instruments and subscales were tested for reliability using IBM SPSS® Statistics (Version 25), (Table 9). The Diabetes Self-Management Questionnaire (DSMQ) employed to measure diabetes self-care consisted of 16 items and four subscales. The total DSMQ score had a high level of internal consistency, as determined by Cronbach's alpha of 0.83 according to Bannon (2013). The subscales glucose management ($\alpha = 0.73$) and physical activity ($\alpha = 0.74$) met the recommend Cronbach's alpha whereas dietary control ($\alpha = 0.68$) and physician contact ($\alpha = 0.64$) did not meet the recommended Cronbach's alpha of 0.7 or higher (Bannon, 2013). The DSMQ subscales for this study showed lower Cronbach's alpha compared to other publications (Bukhsh et al., 2017; Mehravar, 2015; Schmitt et al., 2013)

Table 9

Test of Reliability for Main Study Instruments and Subscales from Study Participants (N = 188)

Instrument	Cronbach's Alpha	N of Items
Diabetes Self-Care (DSMQ)	0.83	16
Subscale dietary control	0.68	4
Subscale glucose management	0.73	5
Subscale physical activity	0.74	3
Subscale physician contact	0.64	3
Diabetes Time Management (DTMQ)	0.89	49
Diabetes Distress (DDS)	0.93	17
Emotional burden	0.90	5
Physician distress	0.92	4
Regimen distress	0.90	5
Interpersonal distress	0.76	3

The Diabetes Time Management Questionnaire (DTMQ) employed to measure diabetes time management skills consisted of 49 items and no subscales. The total DSMQ has a high level of internal consistency, as determined by Cronbach's alpha of 0.89. The DSMQ for this study showed a higher Cronbach's alpha compared to Gafarian et al.'s (1999) study.

The Diabetes Distress Scale (DDS) employed to measure diabetes distress consisted of 17 items and four subscales. The total DDS score had a high level of internal consistency, as determined by a Cronbach's alpha of 0.93. The subscales met the recommended Cronbach's alpha, emotional burden ($\alpha = 0.90$), physician distress ($\alpha = 0.92$), regimen distress ($\alpha = 0.90$), and interpersonal distress ($\alpha = 0.76$). The total DDS and

subscales for this study showed a similar Cronbach's alpha compared to other publications (Chew et al., 2015; Gonzalez et al., 2014, Schmitt et al., 2015; Polonsky et al., 2005; Wardian et al., 2014).

Missing Data. The completed electronic surveys had no missing data. The paper survey contained 13 missing data points out of 8,245 data points in the file (0.16%). Of the 13 missing data points, two were on age and three were on race/ethnicity. The race/ethnicity question was the last question on the back of the paper and the location contributed to the inadvertently missed questions. The remaining eight missed questions were random among the Likert-scales, possibly due to the paper format. The missing data was replaced using K-nearest neighbors (KNN) imputation (James, Witten, Hastie, & Tibshirani, 2013). There was no pattern or common theme related to the limited missing data from the main study variables.

Paper versus Electronic Surveys

To understand the paper and electronic participant groups, several statistical procedures were conducted. Table 10 presents independent t-tests applied to determine if there were differences in diabetes self-care, diabetes time management, diabetes distress, age, and years living with diabetes between the two groups. Levene's test of assumption resulted in no violation. There was no statistically significant difference in diabetes self-care between paper (M = 7.16, SD = 1.43) and electronic survey (M = 7.06, SD = 1.37), M_D = -0.10, 95% CI [-0.50 to 0.30], t (186) = -0.490, p = 0.625. There was no statistically significant difference in diabetes time management between paper (M = 4.98, SD = 0.86) and electronic (M = 4.99, SD = 0.80), M_D = 0.00, 95% CI [-0.236 – 0.245], t (186) = 0.03, p

= 0.97. There was a statistically significant difference in diabetes distress between paper (*M* = 2.02, *SD* = 0.95) and electronic (*M* = 2.42, *SD* = 1.09), M_D = 0.406, 95% *CI [*0.105 to 0.707],

t (186) = 2.66, *p* < 0.01. There was a statistically significant difference in age between paper (*M* = 63.54, *SD* = 12.79) and electronic (M = 58.39, *SD* = 11.55), M_D = -5.152, 95% *CI [*-8.66 to -1.64], *t* (186) = -2.89, *p* =0.00. There was a statistically significant difference in years of living with diabetes between paper (*M* = 15.24, *SD* = 10.18) and electronic (*M* =11.31, *SD* = 10.30), M_D = -3.875, 95% *CI [*-6.84 to -0.90], *t* (186) = -2.573, *p* = 0.011.

Table 10

Independent T-test Comparison Between Survey Method and Continuous Variables.

	Paper		Electronic		
Variable	*M*	*SD*	*M*	*SD*	*t (df)*
Diabetes self-care	7.16	(1.43)	7.06	(1.37)	0.49 (186)
Diabetes time management	4.98	(0.86)	4.99	(0.8)	0.03 (186)
Diabetes distress	2.02	(0.95)	2.42	(1.09)	2.66** (186)
Age	63.54	(12.79)	58.39	(11.6)	-2.89** (186)
Years living with diabetes	15.24	(10.18)	11.37	(10.3)	-2.57** (186)

** *p* < 0.01

Table 11 presents a chi-square test for association conducted between survey methods (paper and electronic) with the covariate variables that met the test of assumption. Test of assumption were performed on all the covariate variables; all but two covariates violated the assumptions in that the expected cell frequencies were less than five.

Therefore, a chi-square test was performed on income and employment as the expected cell frequencies were greater than five.

Table 11

Cross Tabulation of Survey Method with Income and Employment

	Survey Method				
	Paper	Electronic			
	n (%)	n (%)	$X^2(df)$	φ	Sig.
Income			14.05 (5)	0.27	0.015*
< $30,000	18 (51.4%)	17 (48.6%)			
$30,001 - $50,000	20 (63.5%)	12 (37.5%)			
$50,001 - $70,000	7 (36.8%)	12 (63.2%)			
$70,001 - $100,000	5 (17.9%)	23 (82.1%)			
> $100,000	16 (50.0%)	16 (50.0%)			
Prefer not to answer	17 (40.5%)	25 (59.5%)			
Total	83 (100%)	105 (100%)			
Employment			15.31 (3)	0.28	0.002*
Full time	13 (22.8%)	44 (77.2%)			
Part time	11 (52.4%)	10 (47.6%)			
Retired	40 (54.1%)	34 (45.9%)			
Unemployed	19 (52.8%)	17 47.2%)			
Total	83 (100%)	105 (100%)			

*$p < 0.05$

The results showed there was a small (φ = 0.27) statistically significant association between survey method and income, $X^2(5, N = 188) = 14.05$, $p = 0.015$. There was a small

($\varphi = 0.28$) statistically significant association between survey method and employment, $X^2(3, N = 188) = 15.13$, $p = 0.002$.

The paper survey group had older participants with more years of living with diabetes. The electronic survey group had a higher level of diabetes distress, earned a higher income and had more full-time employment. There was no difference in the diabetes self-care score and diabetes time management score between the groups. The associations of additional covariate variables were unable to be determined due to the violation of assumptions.

Statistical Analyses

The assumptions for the analyses were checked prior to implementing statistical procedures. According to Field (2009), when testing normality in large samples, it is better to analyze the distribution in graphs and the values of skewness and kurtosis over the calculated level of significance. The ratios of kurtosis and skewness were evaluated. Kurtosis (0.473) was less than twice the standard error of kurtosis (0.348); however, the distribution was slightly skewed with the ratio of skewness (-0.72) greater than twice the standard error of skewness (0.175). The number of outliers were less than 1% (n = 5) and were the lowest scores, however, the 5% trimmed mean (7.07) was higher than the mean 6.99, *SD* = .113. This indicates that the higher scores were extreme values and influenced the mean. Test of normality was analyzed again with the outliers removed (N=188). Based on the ratio method, skew (-0.354) was not greater than twice the standard error (0.177 x 2 = .354). Kurtosis (-0.534) was less than twice the standard error (0.353 x 2 = .706) (Bannon, 2013). The calculations indicate the sample was approximately normally distributed.

Additional support for normally distributed sample was demonstrated by the graphic representation of a Normal Q-Q Plot where according to Pallant (2010) a reasonably straight line suggests normal distribution. A paired t-test was conducted to compare the difference between two sample groups (N = 193 representing the original sample collected and N = 188 representing the sample with 5 outliers removed) among the main study variable (Table 12). No statistically significant difference was found, $r > 0.05$. To meet the assumptions of no undue influence the 5 outliers were removed from the sample and the total study size used for this study was N= 188, 83 paper (44.1%) and 105 electronic (55.9%).

Table 12

Paired T-test Comparison Between of N =193 and N=188 Participants for Main Study Variables.

Variable	N = 193 *M (SD)*	N =188 *M (SD)*	t(*df*)
Diabetes self-care	*M*= 6.99 *(SD*= 1.57)	*M*= 7.11 (*SD* = 1.40)	0.739 (187)
Diabetes time management	*M*= 5.30 *(SD*= 0.86)	*M*= 4.98 *(SD* = 0.83)	-0.549 (187)
Diabetes distress	*M*= 2.27 *(SD*= 1.06)	*M*= 2.24 *(SD* = 1.06)	-0.256 (187)

Bivariate Analyses

Bivariate analyses were conducted to explore the relationships between the dependent variable, the independent variables (diabetes time management, diabetes distress) as well as the covariate variables (age, years living with diabetes, income, education, employment, favorable work environment, neglect self-care, health conditions, diabetes status, caregiver roles, and HbA1c).

Table 13 presents the results of Pearson's correlation analysis between diabetes self-care and all the other continuous variables (diabetes time management, diabetes stress, age and years living with diabetes). In accordance with Bannon (2013), the interpretation of Pearson's correlation effect size was small ($r = 0.10$), medium ($r = 0.30$), and large ($r = 0.50$). Preliminary analysis was tested and there were no violations of normality, linearity, and homoscedastic. There was a statistically significant, strong inverse relationship self-care and time management,

r (n = 186) = -0.605, $p < 0.001$; that is, low diabetes self-care indicates poor self-care and a higher diabetes time management score indicates less effective time management skill. There was a statistically significant, medium inverse correlation between self-care and distress, r (n = 186) = -0.331, $p < 0.00$; as self-care decreases, distress levels increase. There was a statistically significant, medium positive correlation between time management and distress, r (n = 186) = 0.394, $p < 0.001$, indicating that inefficient time management skills were related to higher levels of distress. There were no statistically significant relationships between age and self-care, r (n = 186) = 0.05, $p = 0.445$, and years of living with diabetes, r (n = 186) = -0.030, $p = 0.678$.

Table 13

Bivariate Correlations (Pearson's) for Continuous Variables (N=188)

Variable	1	2	3	4	5
1. Diabetes self-care	_	-0.605**	-0.331**	0.056	-0.030
2. Diabetes time management		_	0.394**	-0.183*	0.007
3. Diabetes distress			_	-0.288**	-0.144
4. Age				_	0.459**
5. Years living with diabetes					_

** $p < 0.01$ level, * $p < 0.05$ level (2-tailed).

One-way ANOVA analyses conducted to explore if a mean difference in diabetes self-care differs by the covariate variables (income, education, employment status, work environment, self-care neglect, other health conditions, diabetes status, and caregiver roles). Test of assumptions were performed and Levene's test for homogeneity of variance was not violated, $p > 0.05$. In accordance with Bannon (2013), the interpretation of ANOVA's η2 effect size was small ($n^2 = 0.01$), medium ($n^2 = 0.06$), and large ($n^2 = 0.14$). The analyses indicated there were no statistically significant differences in the following variables: income, F (5,182) = 0.153, p = 0.200; education, F (6, 181) = 1.263, p = 0.274, other health conditions, F (4, 183) = 1.15, p = 0.334; and caregiver roles F (3, 184) = 2.49, p = 0.061. Additionally, the HbA1c variable was re-categorized into a dichotomous variable. Using the ADA recommended HbA1c target range, group 1 was categorized into HbA1c within target range (6.5 or lower) and group 2 was categorized into HbA1c above target range (6.6 or higher). An independent t-test was conducted to compare the diabetes self-care scores for

HbA1c in target range and above target range. There was no statistically significant difference between self-care based on HbA1c in target range (M = 7.39, SD = 1.38) and HbA1c above target range (M = 6.98, SD = 1.41; t (176) = 1.87, p = 0.06, two-tailed). However, the one-way ANOVA analyses did find statistically significant differences in diabetes self-care based on employment, work environment, neglect self-care, and perception of diabetes (Table 14).

Diabetes self-care showed a statistically significant difference between groups based on the levels of employment, F (4, 183) = 4.47, p = 0.002. The difference in mean score between the work status groups had a small effect size, measured by η2 (0.02). Post-hoc comparisons using Tukey HSD test indicated that the mean group score for those *working full time* (M = 6.51, SD = 1.37) was significantly lower from *part time* (M = 7.60, SD = 1.35), *retired* (M = 7.60, SD = 1.35), and *unemployed* (M = 7.55, SD = 1.48). No other mean scores for employment groups were significantly different from each other.

Table 14

One-way ANOVA Tests for Mean Difference in Diabetes Self-Care Between Categorical Levels of Employment, Work Environment, Self-Care Neglect, and Diabetes Status

Variable	N	*M*	*SD*	*F (df)*	*p*
Employment[1]				4.47 (4, 183)	0.002
Full time*	56	6.51	(1.37)		
Part time*	21	7.6	(1.35)		
Retired*	67	7.21	(1.28)		
Unemployed*	36	7.55	(1.48)		
Prefer not to answer	8	7.08	(1.06)		
Total	188	7.11	(1.4)		
Work Environment[2]				3.77 (3, 110)	0 .013
Always favorable*	62	7.4	(1.39)		
Often favorable	16	6.72	(0.84)		
Somewhat favorable*	23	6.49	(1.48)		
Not at all favorable	13	6.46	(1.5)		
Total (unemployed excluded)	114	7.01	(1.41)		
Neglect Self-Care[3]				7.9 (2, 185)	0.00
Rarely*	127	7.37	(1.32)		
Half the time*	54	6.66	(1.4)		
Most of the time*	7	5.95	(1.5)		
Total	188	7.11	(1.4)		
Diabetes Status[4]				14.20 (2, 185)	0.00
Getting better*	54	7.84	(1.08)		
Staying the same*	93	7	(1.45)		
Getting worse*	41	6.42	(1.27)		
Total	188	7.11	(1.4)		

Note: *Asterisk indicates post-hoc test significant differences.

1. Employment indicated the mean self-care for part time and retired was significantly higher than the mean full time.

2. Work environment indicated the mean self-care for always favorable work environment was significantly higher than the mean somewhat favorable work environment.

3. Neglect self-care indicated the mean self-care for rarely neglect was significantly higher than neglect half the time and most of the time.
4. Diabetes status indicated the mean self-care for diabetes getting better was significantly higher than staying the same and getting worse.

Diabetes self-care showed a statistically significant difference between groups based on the levels of a favorable work environment, F (3, 110) = 3.77, p = 0 .013. Post-hoc comparisons using Tukey HSD and test of between-subjects effects were conducted. The self-care mean score for work environment group *always favorable* (M = 7.40, SD = 1.39) was significantly different ($p < 0.05$) from *the somewhat favorable* work environment group (M = 6.49, SD = 1.48). The η2 (0.09) indicated that the covariate variable work environment has a medium effect on diabetes self-care.

Diabetes self-care showed a statistically significant difference between groups based on the levels of self-care neglect, F (2, 185) = 7.9, $p < 0.01$. Post-hoc comparisons using Tukey HSD and test of between-subjects effects were conducted. There were statistically significant differences in mean scores for diabetes self-care between three categories of self-care neglect groups, *rarely neglect* (M = 7.37, SD = 1.32), *neglect half the time* (M = 6.66, SD = 1.40) and *neglect most of the time* (M = 5.95, SD = 1.50). The η2 (0.08) indicated that the variable self-care neglect had a medium effect on diabetes self-care.

Diabetes self-care showed a statistically significant difference between groups based on the levels of diabetes status, F (2, 185) = 14.20, $p < 0.001$. Post-hoc comparisons using Tukey HSD and test of between-subjects effects were conducted. The self-care mean comparison were statistically significant between getting better (M = 7.84, SD = 1.08), staying the same (M = 7.00, SD = 1.45) and getting worse (M = 6.42, SD = 1.27). The η2 (0.13) indicated that the variable diabetes status had a medium approaching large effect on self-care.

Multivariate Analysis

The main study variables (diabetes self-care, diabetes time management, and diabetes distress) demonstrated statistically significant relationships between each other in the bivariate analyses and therefore a simultaneous regression analysis was conducted to evaluate the independent variables impact on diabetes self-care (Table 15). Furthermore, the regression was intended to answer the overarching research question to determine the relationship between and among the main study variables. Collinearity statistics were run using the main study variables and demonstrated no evidence of multicollinearity. Test of assumptions were checked and no violation of normality, linearity, homoscedastic were violated.

The full model summary was statistically significant, $R^2 = 0.377$, adjusted $R^2 = 0.370$, F (2, 185) = 55.86, $p < 0.001$. The full model accounted for 37.7% of the variance in diabetes self-care. Diabetes time management was significantly related to diabetes self-care (B = -0.95, β = -0.56, $p < 0.001$) whereas diabetes distress was not (B = -0.15, β = -0.11, p = 0.08). The ANCOVA procedure was performed to calculate the η2 effect size on the model.

Time management demonstrated a large effect size (0.300) and diabetes distress had a small effect size (0.016).

Table 15

Simultaneous Regression Predicting Diabetes Self-Care from Diabetes Time Management and Diabetes Distress.

Variable	B	SE	β
Diabetes time management score	-0.95	0.11	-0.56**
Diabetes distress score	-0.15	0.08	-0.11
R^2	0.37		
F	55.86		
ΔR^2	0.37		
ΔF	55.56		

Note: * $p < 0.05$, ** $p < 0.001$. Full Model: R Squared = 0.377, Adjusted R Squared = 0.370, F (2, 185) = 55.86, $p < 0.001$.

Research Questions. The overarching research question of this study was to explore how the independent variables (diabetes time management and diabetes distress) influenced the dependent variable (diabetes self-care) and this question was answered in the simultaneous regression model. Diabetes time management and diabetes distress explained 37.7% of the variance in diabetes self-care, F (2, 185) = 55.86, $p < 0.001$. Diabetes time management was the strongest, statistically significant, unique contributor to explaining self-care ($\beta = -0.56$, $p < 0.001$) where diabetes distress in the model was not statistically significant ($p > 0.05$). The sub-research questions were answered from the bivariate correlational analyses: (1) the relationship between time management and diabetes self-care showed a strong, inverse statistically significant relationship, r (n =186) = -0.60, $p < 0.001$); (2) the relationship between diabetes distress and diabetes self-care showed an inverse, medium statistically significant relationship, r (n = 186) = 0.33, $p < 0.001$); and (3) the

relationship between time management and diabetes distress showed a medium, positive, statistically significant relationship, r (n =186) = 0.39, $p < 0.001$).

The study's hypothesis stated that an inverse relationship between diabetes distress and diabetes self-care exists among women with T2DM. The statistically significant findings from Pearson's correlation supports rejecting the null hypothesis, therefore, the study's hypothesis is accepted.

Summary

Bivariate relationships between the main study variables were statistically significant (diabetes self-care, diabetes time management, and diabetes distress). Multivariate relationships among the main study variables explained 37.7% of the variance in diabetes self-care. Diabetes time management evidenced a considerably large effect upon diabetes self-care and remained the only statistically significant predictor in the model.

The psychometric properties of the instruments used in the study met the acceptable levels of internal consistency with reported $\alpha > 0.80$. Slight bias was found between the two survey methods (paper vs. electronic) where the paper survey group was older and lived with diabetes longer. Whereas, the electronic survey group had slightly higher diabetes distress levels, income, and full-time employment.

Chapter V

DISCUSSION of FINDINGS

The purpose of this chapter is to discuss the statistical findings written in chapter 4 and analyze the outcomes as they relate to the existing body of knowledge and the theoretical framework. The chapter will conclude with a discussion of the study's strengths and limitations. For the purposes of clarity, "this study" and "current study" will be used throughout the discussion to reference the research conducted in this dissertation.

Introduction

The purpose of this descriptive correlational study was to explore the relationship between and among diabetes self-care, diabetes time management, and diabetes distress. Data was collected by means of both paper and electronic methods from the Mid-Atlantic U.S. Region, as well as, an electronic method across the U.S. Participants (N =188) were asked to complete a survey consisting of three validated instruments, the Diabetes Self-Management Questionnaire (DSMQ), the Diabetes Time Management Questionnaire (DTMQ), the Diabetes Distress Scale (DDS), as well as, the patient profile questions. Data was analyzed in IBM SPSS® Statistics (Version 25).

Statistical analyses included descriptive statistics, validation of the three instruments, bivariate analysis, and multivariate analysis. Bivariate relationships between the covariate variables and the dependent variable were conducted using t-test, ANOVA, and Pearson's

correlation when appropriate, as well as, to test the relationships among the main study variables using multivariate analysis (simultaneous regression).

Diabetes Self-Care

Diabetes self-care was measured by the Diabetes Self-Management Questionnaire (DSMQ, Schmitt et al., 2013). The mean score for the current study was 7.11, *SD* = 1.40, with a range of 3.75-9.58. The mean score for the initial norming study of the DSMQ was 6.6, *SD* =1.6 (2013). In this study, the DSMQ demonstrated reliability with a Cronbach's alpha of ($\alpha = 0.83$) and was slightly higher compared to the initial norming study ($\alpha = 0.80$), thus supporting its use in future studies. The difference between the self-care scores from Schmitt et al. (2013) and this current study may be attributed to the data collection sites; Schmitt et al. collected in a hospital setting from both genders and this study collected in an outpatient/support group setting. According to Schmitt et al., a cut-off score of ≥ 6 equates to optimal self-care. The overall scores from the two respective studies demonstrated participants with optimal self-care performance. The self-care range from this study was 3.75 to 9.58, and thus some participants were below the 6-point cut off which indicates the sample included participants with different self-care skills.

To date, the DSMQ has not been found in research literature of studies conducted in the U.S.; however, based on this study's findings this instrument is appropriate for use in measuring a total diabetes self-care score in the U.S. The initial norming study was conducted in Germany (Schmitt et al., 2013) and the use of the instrument appeared in nearby continents. The international articles depicting studies using DSMQ reported similar reliability, $\alpha = 0.82$ (Ghimire & Devi, 2018) and $\alpha = 0.84$ (Al-Khaledi et al., 2017;

Leelavathi et al., 2018; Nasab et al., 2017). These respective studies were conducted in Eastern and Asian countries with differing cultures and ethnicity from this current study. While this study tested the DSMQ in a predominately White population, the aforementioned studies (Al-Khaledi et al.; Ghimire & Devi; Leelavathi et al.; Nasab et al.) showed that the instrument was validated in culturally and ethnically diverse populations.

Diabetes self-care and covariates. Bivariate analyses were conducted to explore the relationship between diabetes self-care and the covariates (age, years living with diabetes, income, education, employment, favorable work environment, neglect self-care, health conditions, diabetes status, caregiver roles, and HbA1c). In this study, the participants had a mean age of 60. The CDC (2017) statistic fact sheet reported the age group with the most diabetes diagnoses was 45-65 years of age. The age of the study's sample was representative of the general diabetes population, 95% of whom have T2DM (CDC, 2017). According to the CDC Diabetes Report (2017), White women represent 6.8% of the diabetes prevalence rate and the health disparities report states that 55.3% of the U.S. diabetes population are minority groups (CDC, 2017). The study's demographic representation was predominately White (81.4%). and was not representative of the general population. The lack of diverse representativeness may be due to the convenience sampling method (Gray, Grove, & Sutherland, 2017).

In this study, the mean age was 60.66, SD = 12.3. This study had a wide range of the age 20 to 88 years of age. The current study found that diabetes self-care was not statistically significantly correlated with age, r = 0.50, p = 0.45. This finding is consistent with other international studies (Bukhsh et al., 2017; Ghimire & Davi, 2018), whose

participants were ethnically and culturally diverse, and found no correlation between diabetes self-care and age, $r = 0.02$, $p > 0.05$; $\varphi = 1.61$, $p > 0.05$, respectively. Bukhsh et al. and Ghimire et al. both used the DSMQ to measure self-care. Interestingly, Bukhsh et al. had younger aged participants ($M = 51.3$, $SD = 10.4$) with lower DSMQ score ($M = 4.8$, $SD = 2.6$), whereas Ghimire et al. had participants with both similar age ($M = 60$, $SD = 10.3$) and self-care score ($M = 7.77$, $SD = 2.2$) to this current study. This is important because it demonstrates that study participants with differing cultural backgrounds (from Pakistan and Nepal) had consistent findings with this study's non-diverse participants. Contrary to this study, Schmitt et al. (2013) and Song et al. (2012) showed moderate, statistically significant correlations between diabetes self-care and age ($r = 0.31$, $p < 0.001$; $r = 0.29$, $p < 0.001$, respectively). Schmitt et al. and this study had participants with similar age ($M = 60.4$, $SD = 10.2$; $M = 60.66$, $SD = 12.35$, respectively) and relatively similar self-care scores. However, Song et al. (2012) used the Summary of Diabetes Self-Care Activities (SDCA) instrument to measure total self-care. The instrument (SDCA) demonstrated an unacceptable Cronbach's alpha ($\alpha = 0.68$) according to Bannon (2013), and therefore the significant findings may be less reliable. The discrepancy between Schmitt et al. and this study's results on age cannot be explained. The theoretical framework states that internal conditioning factors influence an individual's ability to perform self-care with age being one of the biological factors. With one conflicting finding of the relationship between age and diabetes self-care, the support for age as an internal conditioning factor to influence diabetes self-care is inconclusive.

There was no statistically significant relationship between diabetes self-care and duration of diabetes in this study, r = - 0.30, p = 0.67. The mean duration of diabetes diagnosis for the current study is 13.08 years, SD = 12.3, with a range of 1-56. This study's finding is consistent with the other studies that also found no statistically significant correlation between diabetes self-care using DSMQ and duration of diabetes (Bukhsh et al., 2017; Schmitt et al., 2013), r = 0.11, p > 0.05; r = 0.18, p > 0.05, respectively. A small portion (6.4%, n = 12) of participants from this study reported having diabetes between 1 to 1.5 years with a mean diabetes self-care score of 7.28, SD = 1.5. Thus, this study's finding supports the premise that the mastery of diabetes self-care is not correlated by the duration of diagnosis based on the mean years.

One-way ANOVA analyses were conducted to determine if a mean difference in diabetes self-care differed by income, education, other health conditions, employment status, work environment, caregiver role, self-care neglect, and diabetes status. In this study, there were no statistically significant differences in diabetes self-care based on income levels, F (5, 182) = 0.153, p = 0.20. Several relevant studies used to examine diabetes self-care did not include income level in their analyses (Bukhsh et al., 2017; Ghimire et al., 2018; Hernandez et al., 2014; Schmitt et al., 2013; Song et al., 2012). However, similar to this study, Zhang et al. (2012), a study conducted in the U.S., found no difference (p > 0.05) in diabetes health utility score based on income levels. The diabetes health utility score includes concepts of diabetes self-care, as well as, other elements (mobility, self-care, activity, discomfort and anxiety). While the diabetes self-care

measurements for this study and Zhang et al. were different, the finding support this study's finding that income levels and diabetes self-care are not associated.

In the current study, there was no statistically significant difference in diabetes self-care based on education levels, F (6, 181) = 1.263, p = 0.274. Contrary to this study, Ghimire et al. (2018) found a statistically significant association between education (literate vs. illiterate) and diabetes self-care, $\chi = 7.82$, $p < 0.05$. The discrepancy in results may be explained by design differences: Ghimire et al. administered the DSMQ to the study participants, whereas in this study literacy was an inclusion criterion and the participants independently completed the survey. Additionally, Ghimire et al. measured education as literate and illiterate and this study measured education starting at the secondary level and above.

An overwhelming majority of the participants (89.4%) in this study had at least 1 or more health condition(s) other than diabetes. The findings showed no statistically significant difference in diabetes self-care based on the number of additional health conditions, F (4,183) = 1.15, p = 0.334). This finding may be explained as other disease related self-care activities overlap with diabetes self-care such as eating healthy foods, exercise, and medication administration.

In the current study, there was a statistically significant difference in diabetes self-care based on employment status, F (4, 183) = 4.47, p = 0.002. This finding is consistent with a study by Ghimire et al. (2018) who found a statically significant association between diabetes self-care and occupation, $\varphi = 7.98$, $p > 0.05$. The categories for occupation (service, business, unemployed, and retired) used by Ghimire et al. differed from those used

in this study but both studies included unemployed and retired. Moreover, this study found that those participants who worked showed a statistically significant difference in diabetes self-care based on favorable work environment, F (3, 110) = 3.77, p = 0 .013. A landmark study (Cleal, Willaing, Stuckey, & Peyrot, 2019) conducted a large scale (N =328) qualitative analysis with the purpose to explore diabetes-related barriers related to work outside of the home. A theme emerged from the study identifying "the demands for work conflict with the demands of diabetes self-care" as a barrier to perform diabetes self-care (Cleal, et al. 2019, p. 92). Further descriptions of barriers included the "clinical management of diabetes and the time needed to attend to this" and "the work situation is not amenable to taking time out to medicate or monitor" (Cleal et al., 2019, p. 93). While this current study did not evaluate the levels of work demand, Cleal et al. found a difference between favorability of one's work environment and diabetes self-care. Again, the concept of time emerged from the qualitative analysis signifying the value and challenge for individuals with T2DM to deploy diabetes time management. This study's findings supports the relationship that employment status influences the performance of diabetes self-care and may be explained in that competing work demand interferes with self-care (Cleal et al., 2019). Cleal et al. did not specifically address favorable work environment for diabetes self-care; however, in the current study an unfavorable working environment was associated with less self-care and thus a negative external conditioning factor related to self-care.

In the current study, there was no statistically significant difference between diabetes self-care and caregiver roles, F (3, 184) = 2.49, p = 0.061. McKwen et al., (2011) examined competing time demands as the independent variable (caregiver role, employment

responsibilities, and both caregiver role and employment responsibilities) with the outcome variables of self-care behaviors (exercise, foot self-care, and medication administration) and self-care processes (aspirin use, dilated eye exam, podiatry food exam, HbA1c tested, influenza immunization, cholesterol assessed, and proteinuria tested). Self-care was analyzed in a regression model (adjusted for age, race/ethnicity, education, income, duration of diabetes diagnosis, diabetes treatment, health status) that found that in women (N = 2,874), the role of caregiving only, employment responsibilities only, and both caregiving was not statistically significant ($p > 0.05$) to self-care behaviors (exercise, $\beta = 0.48$, $\beta = 0.44$, $\beta = 0.47$: foot self-care, $\beta = 0.63$, $\beta = 0.61$, $\beta = 0.60$; medication administration, $\beta = 0.50$, $\beta = 0.43$, $\beta = 0.46$, respectively). McEwen et al. used a dichotomized self-care measurement to examine individual diabetes self-care activities rather than a total self-care score. While McEwen et al. measured self-care differently, their study found that in women employment responsibilities, 5.24(95% CI, 5.12-5.36), $p = 0.002$ and the combination of employment responsibilities and caregiver roles, 5.10(95% CI, 4.85-5.35), $p = 0.020$ were related to lower levels of self-care processes. Caregiving roles alone were not related to self-care processes, $p > 0.05$, thus supporting this study's findings. While self-care processes are different from measuring self-care activities, it is important to note that self-care processes overlap with the overall self-care concept. The differences between the demands from either caregiver roles and employment responsibilities are unclear from this study. The findings show that the responsibilities and demands from employment are influential on performing diabetes self-care, while caregiver roles are not. Future research

studies addressing the relationship between diabetes self-care and employment requires further exploration and should include elements of time demands.

Single questions on the perception of self-care neglect and health status were incorporated in this study to explore the participant's understanding of and engagement in self-care practices. This study had participants rank their frequency of self-care neglect due to caring for someone else and their diabetes status. The majority of the participants (67.6%) reported rarely neglecting self-care. Additionally, the majority of this study's participants (78.2%) reported their diabetes status as either getting better or staying the same. Each covariate variable (levels of self-care neglect and diabetes status) demonstrated statistically significant differences between groups and diabetes self-care, F (2, 185) = 7.9, $p < 0.01$; F (2, 185) = 14.20, $p < 0.001$, respectively. There is a logical assumption that if individuals neglect self-care and perceive their diabetes status as worsening, then their diabetes self-care score will be lower. The findings from this study confirms this assumption as the diabetes self-care score was statistically significant between the self-care neglect and diabetes status categories.

The lack of a statistically significant relationship between diabetes self-care and HbA1c levels was an unexpected finding, t (176) = 1.87, $p = 0.06$. Previous studies (Bukhsh et al., 2017; Schmitt et al., 2013) found large to medium negative relationships between the two variables, $r = - 0.78$, $p < 0.001$; $r = - 0.40$, $p < 0.001$, respectively. The different findings might be explained by differing data sources: both Bukhsh et al. and Schmitt et al. collected the HbA1c values directly from the participant's medical records using raw scores and this study relied on the participant's self-report using categorical

values. Self-report laboratory values are not reliable because participants may have poor memory recall or feel the pressure to give better values (Gray et al., 2017).

Covariate summary. In the current study the following covariates were not associated with diabetes self-care: age, duration of diabetes diagnosis, income, education, number of other health conditions, or caregiver roles. Glycemic control, measured by the HbA1c levels, while not significant in this study, may not be a valid result due to participant's self-reporting, and therefore is considered an inconclusive finding. Employment, favorable work environment, self-care neglect, and diabetes status were associated with diabetes self-care and thus should be included in future research to understand the associations with diabetes self-care outcomes.

Diabetes Time Management

Diabetes time management, an understudied variable, was measured by the Diabetes Time Management Questionnaire (DTMQ, Gafarian et al., 1999). To date, the DTMQ has not been found in research literature and this is the first study examining DTMQ as an independent variable. The mean score for the current study was 4.98, $SD = 0.83$, with a range of 2.9 -7.18. The instrument demonstrated reliability as the Cronbach's alpha was higher in this study ($\alpha = 0.89$) compared to the initial study ($\alpha = 0.82$), supporting its use in future studies (Gafarian et al.). It should be noted that this study used a total score conversion formula that differed from the norming study, which took the sum score and divided by the total possible score, then multiplied by 10 to convert the score to a 1 to 10 scale for equity. In this study the total score was used, making the data interval level. In the initial 1999 DTMQ norming study of Gafarian et al. collected data from participant with

T1DM and T2DM from an outpatient setting and included both genders. The DTMQ scores was 120.56, *SD* = 21.15 and when the conversion formula used in this study was applied, it demonstrated a mean score of 4.9 (Gafarian et al.). The current study and the norming study's mean scores were similar.

Diabetes time management and covariates. Bivariate analyses were conducted to explore the relationship between diabetes time management self-care and the covariates (age and years living with diabetes). While Gafarian et al. (1999) did not analyze demographic variables in the DTMQ norming study, the information provided showed their participants were younger with a mean age of 56.3 and included more minority groups with only 30% White participants. Age and years living with diabetes diagnosis were analyzed with diabetes time management. In the current study diabetes time management had a small, statistically significant negative correlation with age; as diabetes time management improved age increased,

$r = -0.18$, $p = 0.012$. While this study does not support a relationship between age and diabetes self-care, diabetes time management and age has demonstrated a relationship. Orem's self-care theory emphasizes cognitive ability as an internal conditioning factor influencing self-care. Diabetes time management represents aspects of cognitive function because it includes both a skill set and the essential functions of memory, problem solving, decision making, and attention to current situation. The framework used in this study may support a model revision with age displayed as a biological factor influencing elements of cognitive ability (diabetes time management).

In this study, diabetes time management and years of living with diabetes diagnosis had no correlation, $r = 0.007$, $p = 0.96$. There are no additional published studies to compare covariate characteristics with diabetes time management skills. This suggests diabetes time management is a variable that is not fully understood and additional research needed.

Diabetes time management and diabetes self-care. The current study is the first to analyze the relationship between diabetes self-care and diabetes time management. A Pearson's correlation showed that a strong statistically significant inverse relationship exists between the two variables, $r = -0.60$, $p = 0.001$. The inverse relationship indicates that poor diabetes self-care was associated with less effective diabetes time management. This is the first study to demonstrate a statistically significant relationship between diabetes time management and diabetes self-care. This finding indicates that the relationship between diabetes time management and diabetes self-care is an under-explored topic. The theoretical framework of Orem's self-care theory identifies cognitive ability as an internal condition factor that influences the individual's self-care. Cognitive ability, identified as diabetes time management skills, has shown to negatively influence self-care. Thus, this finding supports Orem's theory.

Diabetes Distress

Diabetes distress was measured by the Diabetes Distress Scale (DDS, Polonsky et al., 2005). The mean score for the current study was 2.24, $SD = 1.05$, with a range of 1-6. The instrument demonstrated reliability as the Cronbach's alpha was similar in this current study ($\alpha = 0.93$) to the initial study ($\alpha = 0.93$) (Polonsky et al.). In the initial DDS norming

study, Polonsky et al. collected data from participants with T2DM in an outpatient setting. Unfortunately, the mean DDS total score was not published in the norming study. Later studies by Chew, Vox, Pouwer, and, Rutten (2018), Fisher et al. (2012) and Wardian and Sun (2014) had similar DDS mean scores compared to the current study (*M* = 2.3, *SD* = 1.4; *M* = 2.4, *SD* = 0.88; *M* = 2.4, *SD*= 0.99, respectively). While the three studies focused on T2DM population with a majority of female respondents (56-57%), the ethnic/race composition differed. Chew et al. reported participants were from Malaysia, whereas, those of Fisher et al. and Wardian and Sun were from the U.S.

Fisher et al. (2012) conducted a secondary analysis to establish the DDS cut-off points to identify individuals with T2DM whom report high levels of distress. According to Fisher et al., who used multiple regression findings and curvilinear effects to determine cut-off scores, stated a score < 2 equates to little or no distress, 2.0-2.9 equates to moderate distress, and ≥ 3 equates to high distress. The prevalence of moderate to high levels of diabetes distress in the current study was compared to others. The diabetes distress total score from this study was categorized using the cut-off points defined by Fisher et al. and it was found that this study had 25% (n = 47) participants with moderate diabetes distress and 26.6% (n=50) high diabetes distress. Fisher et al. and Pandit et al. (2014) published the prevalence of diabetes distress from their participants and showed moderate (27.4%; 27.3%, respectively) and high (18%; 14.1%, respectively) levels. The comparison indicates that this study had more participants with high diabetes distress. In this study, participants with no diabetes distress (48.4%, n = 91) had optimal diabetes self-care scores (*M* = 7.61, *SD* = 1.1), whereas, both moderate and high distressed participants had relatively the same

diabetes self-care scores (M = 6.66, SD 1.5; M = 6.61, SD = 1.3, respectively). This finding indicates that diabetes self-care is not distinguished between moderate and high levels of distress and this means the presence of either moderate or high levels of distress equally influences the performance of diabetes self-care. Pandit el al. (2014) examined the differences between none, moderate, and high levels of distress and health behaviors, Pandit showed that both moderate and high levels of distress predicated the likelihood of medication adherence, OR = 0.58, $p < 0.001$, 95% CI = [0.42 – 0.79]; OR = 0.44, $p < 0.001$, 95% CI = [0.27 – 0.73], respectively. Additional research is needed to examine the levels of diabetes distress and total diabetes self-care.

Diabetes distress and covariates. Bivariate analyses were conducted to explore the relationship between diabetes distress and the covariates (age and years living with diabetes). In this study there was a small, statistically significant negative correlation between diabetes distress and age, $r = -0.28$, $p < 0.01$. The results showed that there is less diabetes distress in women who are older. Similarly, Polonsky et al. (2005) reported nearly the exact statistical finding showing a small, significant negative correlation between diabetes distress and age, $r = -0.29$, $p < 0.001$. Other studies reported consistent finding that participants with higher levels of diabetes distress were younger (Fisher, 2009; Pandit et al., 2014; Wardian & Sun, 2014).

In the current study, there was no statistically significant correlation between diabetes distress and years of diabetes diagnosis, $r = -0.14$, $p = 0.052$. Though counter intuitive, similar findings have been reported by other studies using the DDS (Fisher, 2009; Pandit et al., 2014; Wardian & Sun, 2014). It should be noted that the current study had

participants with greater years since diabetes diagnosis (M = 13.08, SD = 10.40) compared to two studies (Fisher, 2009; Wardian & Sun, 2014), M = 7.5, SD = 6.73; M = 5.06, SD = 6.36, respectively. This study cannot explain this finding further but supports a conclusion that duration of diabetes does not influence the level of diabetes distress.

While this study does not show a statistically significant relationship between diabetes self-care and age, there is a consistent finding that diabetes distress and age are correlated in both this study and in the literature (Fisher, 2009; Pandit et al., 2014; Polonsky et al., 2005; Wardian & Sun, 2014). Orem's self-care theory emphasizes emotional state as an internal conditioning factor influencing self-care. The framework used in this study may support a model revision with age displayed as a biological factor influencing emotional state (diabetes distress).

Diabetes distress and diabetes self-care. The current study found a moderate, statistically significant inverse correlation between diabetes self-care and diabetes distress, r = 0.33, $p = \leq 0.001$. The challenge of examining diabetes distress and diabetes self-care as noted in the literature (Akins, 2012; Fisher et al., 2009; Pandit et al., 2014; Walker et al., 2014; Wardian & Sun, 2014), is that the majority of the articles used SDSCA subscales for measuring diabetes self-care rather than a total self-care score. An exception is Hernandez et al. (2014) who used both the self-care subscales and self-care total score. However, Hernandez et al. (2014) reported a low Cronbach's alpha of 0.58 for SDSCA's total self-care score, which indicates poor reliability and implies poor predictive validity, according to Ratanawongsa et al. (2015). The development of the SDSCA instrument was based on the premise that diabetes self-care behaviors are relatively independent from one another and,

thus, should be measured individually (Toobert, D., personal communication, July 18, 2016). In the current study, the diabetes self-care conceptual model used the overarching phenomena that includes all the individual self-care behaviors within the broad diabetes self-care concept. Therefore, to explore the global phenomena in a measurable totality with diabetes distress the total diabetes self-care score was analyzed in this study. As noted earlier, the DSMQ total score in the current had a Cronbach's alpha of .83, demonstrating good reliability.

The literature supports a statistically significant relationships between diabetes distress with self-care subscale for dietary adherence (Fisher et al., 2009; Fisher et al., 2012; Polonsky et al., 1995; Polonsky et al., 2005; Walker et al., 2014) and medication adherence (Aikens, 2012; Gonzalez et al., 2015; Pandit et al., 2014; Walker et al., 2014). The current study measured diabetes distress and diabetes self-care by validating a correlational relationship. There is no equivalency when comparing self-care subscales and self-care total score with diabetes distress, however, the findings do support that some aspects of diabetes self-care influences diabetes distress. Diabetes distress represents as an emotional state, capturing the feelings of being overwhelmed or feeling that diabetes self-care may be challenging at times. The findings support the theoretical framework in which diabetes distress, representing the internal conditioning factor of an emotional state (Orem, 1995), influences self-care.

Diabetes distress and diabetes time management. This current research study is the first to analyze the relationship between and among diabetes distress and diabetes time management. A Pearson's correlation showed that a medium statistically significant inverse

relationship exists between the two variables, $r = 0.39$, $p = \leq 0.001$, indicating less time management skills is associated with higher levels of distress. The link between these two variables supports the theoretical framework as both elements of cognitive ability (diabetes time management) and emotional state (diabetes distress) are related and contribute to self-care performance. The relationship among diabetes time management and diabetes distress is further clarified in the simultaneous regression where the full model was statistically significant. Diabetes time management demonstrated a greater effect size ($\eta 2 = 0.300$) over diabetes distress ($\eta 2 = (0.016)$. While the full model accounted for 37% of the variance in diabetes self-care, only diabetes time management remained statistically significant ($B = -0.56$, $p < 0.001$). Diabetes time management, an under-utilized variable, has demonstrated its powerful impact on diabetes self-care. There are no additional published studies to compare diabetes time management skills and diabetes distress, making this finding important to expanding understanding of diabetes care.

Strengths

There are several strengths of this study. The data collection sources were comprised from multiple sites and reached participants from several regions across the U.S., although the majority of the respondents lived in the Mid-Atlantic region (64.04%). The participants demonstrated diverse income and education levels. The completion of the surveys was remarkable with only 0.16% missing data points. This is the first study to examine diabetes self-care, diabetes time management, and diabetes distress. The instruments used to measure the main study variables met the statically criteria for reliability according to published standards by Leard Statistics (2015). Additionally, this was the first study in the

North America to use the DSMQ instrument. The results of this study support the use of the DSMQ offering assistance to future researchers measuring and evaluating diabetes self-care. Additionally, this study aids in the understanding of the powerful impact that diabetes time management skills may have in the diabetes community for women.

Limitations

There were several limitations to this study, the first one being the data collection method, which was convenience sampling. Convenience sampling may introduce bias as those who completed surveys may be more engaged and motivated with their self-care. While the mean age of the study was representative of the general diabetes population, the predominately White sample (81.4%) grossly under-represents minority groups as 55.3% of the U.S. diabetes population are minority groups (CDC, 2017). Therefore, this lack of representation limits the generalizability of the study (Gray et al., 2017). Furthermore, the paper survey participants (44%, n = 83) completed the study in an office setting and received $10.00 for reimbursement of time, thus introducing monetary associations with survey completion, a source of uncontrolled bias (Gray et al.). Incentive pay introduces direct and indirect survey bias (Kulka, Eyerman, McNeeley, 2005). In this study, potential direct bias could include converting reluctant participants who would otherwise not complete the survey as well as introducing measurement error where the participants feel obligated to give desirable responses rather than a true response. Moreover, in this study the potential indirect bias was minimized because recruitment in the office was primarily done by flyer; however, when interested participants inquired office staff about the study they may have unconsciously behaved with confidence and optimism due to an expected

assumption that incentive pay increases participant cooperation. The electronic participants did not receive monetary incentives, thereby introducing potential motivational differences between paper and electronic participants.

The DSMQ subscale, dietary control, did not meet the Cronbach's alpha criteria ($\alpha = 0.68$), and therefore had reduced reliability. This was an unexpected outcome because the dietary control subscale was reported as reliable by other studies (Nasah et al., 2017; Schmitt et al., 2017), $\alpha = 0.76$; $\alpha = 0.79$, respectively. The lower Cronbach's alpha may have no explanation, this study's data collection methods differed from other studies using DMSQ in that the collection included a variety of venues (clinics, diabetes center, hospital employees, and support group networks). The study collected data using three validated self-reports. Self-reporting data is convenient for the researcher; however, it poses a threat to accuracy as the data points are subjective (Gray et al., 2017).

Chapter VI

SUMMARY, IMPLICATIONS, AND CONCLUSIONS

Summary

This descriptive correlational study implemented a survey method to explore the relationships between and among diabetes self-care, diabetes time management, and diabetes distress. A convenience sample of 188 women with T2DM participated in the study. The sample was predominately White and the majority of the participants were from the Mid-Atlantic Region of the United States. There was a large inverse correlation between diabetes self-care and diabetes time management, $r = -0.60$, $p < 0.001$, that is, low diabetes self-care indicates poor self-care and a higher diabetes time management score indicates less effective time management skill. There was a medium inverse relationship between diabetes self-care and diabetes distress $r = 0.33$, $p < 0.001$, as self-care decreases, distress levels increase. Next, there was a medium positive relationship between diabetes time management and diabetes distress $r = 0.39$, $p < 0.001$, indicating that inefficient time management skills were related to higher levels of distress.

Covariates were evaluated in this study for potential relationship with diabetes self-care. Diabetes self-care demonstrated statistically significant differences between the following covariate levels: employment, favorable work environment, self-care neglect, and

diabetes status. This study was not designed to explore these covariates to the fullest extent; however, based on the small to medium effect size between diabetes self-care and these covariates, it is recommended to expand research to include employment status and favorable work environment as covariates along with diabetes time management and diabetes distress.

Multiple regression analysis was employed to explore the multivariate relationship among the independent variables and the dependent variable. The simultaneous regression model was statistically significant F (2, 185) = 55.86, $p < 0.001$ and explained 37.7% of the variance in diabetes self-care. Diabetes time management was the strongest predictor of diabetes self-care while diabetes distress remained a statistically insignificant predictor despite previously demonstrating a moderate bivariate relationship. The η2 effect size for diabetes time management was large where as diabetes distress was small; this distinction identifies that the main findings from this study is the powerful relationship between and among diabetes self-care and diabetes time management.

This is the first study in the U.S. to specifically examine the impact of theory-based internal conditioning factors (diabetes time management and diabetes distress) together on diabetes self-care. The one study hypothesis regarding the inverse relationship between diabetes self-care and diabetes distress was supported. This is also the first study in the U.S. to use the DSMQ, which is a reliable instrument to measure diabetes self-care in totality and includes the overarching concepts of self-management, self-monitoring, and symptom management. The DSMQ instrument supports the self-care conceptual model further clarifying the definition of diabetes self-care by measuring the concept reliably.

Implications

This study expanded Orem's self-care theory by including disease specific variables as internal conditioning factors to show the influence on self-care. While this study's theoretical model initially proposed age as a biological factor influencing diabetes self-care, the results for this study supported age as a biological factor influencing both elements of cognitive ability (diabetes time management) and emotional state (diabetes distress). This is consistent with other researchers who identified that diabetes distress was influenced by age (Fisher, 2009; Pandit et al., 2014; Wardian & Sun, 2014). Furthermore, this study supports Orem's framework in that both diabetes time management and diabetes distress negatively influence self-care and age demonstrates an indirect link to self-care.

Improving patient outcomes. The findings from this study have implications for nurses and other health care professionals who work with patients to improve diabetes self-care practices, as well as, key stake holders invested to improve population health management and reduce costs associated with T2DM. This study shows that diabetes time management and diabetes distress negatively impact diabetes self-care, with time management as the strongest predicator. Diabetes time management, an under-studied variable in individual's with T2DM, has the potential to be a contributor to improve patient outcomes. Diabetes remains the 7th leading cause of death in the U.S., moreover, a report in 2018 indicated that the diabetes death rate increased by 2.4% (Murphy, Xu, Kochanek, & Arias, 2018). It is time to call attention to the cognitive abilities and proficiencies of diabetes time management among women with T2DM. This study showed that younger aged women reported less abilities to execute diabetes time management, thus early

screening to identify deficiencies may contribute to improved diabetes self-care. The leading national diabetes associations (American Diabetes Association and American Association of Diabetes Educators) and local diabetes support groups have a vital role to support recognition and screening of diabetes time management. Key stakeholders, such as insurance companies and technology industries that focus on population health management, can further support initiatives to improve patient outcomes by addressing diabetes time management.

Moderate to high levels of diabetes distress remain prevalent among individuals with T2DM as demonstrated in this study and others (Chew et al., 2016; Fisher et al., 2012; Pandit et al., 2014; Schmitt et al., 2017). Findings suggest that the relationship between diabetes self-care and diabetes distress needs further examination to understand what interventions may reduce the moderate to high levels of distress and improve diabetes self-care outcomes. Previous researchers found significant relationships between subscales of self-care and diabetes distress (Akins, 2012; Fisher et al, 2009; Fisher et al. 2012; Gonzalez et al., 2015; Pandit et al., 2014; Polonsky et al., 1995; Polonsky et al., 2005; Walker et al., 2014) but these findings may be strengthened by using a reliable instrument to measure the overarching concepts of self-care.

Future research. The results of this study provide a framework to explore theoretical-based internal conditioning factors that impact diabetes self-care on women in the U.S. Recommendation for future research on this topic include the following: (a) sampling techniques that include more diverse ethnic and racial participants, (b) consent to obtain HbA1c values directly from healthcare provider to improve accuracy, (c) inclusion of

participants with T1DM, and (d) inclusion of men. Replication of this study, with consideration of the aforementioned recommendations, would contribute this study's findings and contribute to an under-studied phenomenon. More immediately, future research on the psychometric knowledge of the DSMQ instrument must be conducted because the instrument reliably measures diabetes self-care. There is an opportunity to further support the self-care conceptual model, which clarifies the distinction between diabetes self-care and diabetes self-management, interchangeable terms used in the diabetes literature (Hinder & Greenhalgh, 2012; Rahim-Williams, 2011; Richard & Shea, 2011; Riegel & Dickson, 2008; Song & Lipman, 2008; Wilkinson & Whitehead, 2009), and thus urge researchers to use consistent theoretically supported definitions.

It is recommended that future research needs to build upon the result of this study and others related to diabetes self-care and employment (Cleal et al., 2019; Ghimire et al., 2018; McKwen et al., 2011) by examining the potential impact of diabetes time management and diabetes distress. In this study younger aged participants had worse diabetes time management, higher levels of distress, and are generally more likely to be employed. Ideally, the researcher should include more discrete variables defining specific work environment, actual hours worked, duration of breaks, access to food, ease to measure blood sugar and so forth.

Finally, long term future research needs focus on diabetes time management interventional studies whereby improvement in diabetes self-care and outcomes measures are evaluated. This the first study to identify that diabetes time management is a large statistically significant predictor of diabetes self-care. Now that diabetes time management

has been identified as impactful to diabetes self-care on predominately White woman, it is recommended that healthcare professionals evaluate the how these individuals are managing time and self-care.

Conclusion

The findings of this study add new body of knowledge about internal conditioning factors related to diabetes self-care. This is the first known study to measure the influence of diabetes time management on diabetes self-care and to examine the relationships between and among diabetes time management and diabetes distress. Although this study examined two predictor variables among diabetes self-care in women with T2DM, diabetes time management had a stronger effect size compared to diabetes distress. While there was no correlation between diabetes self-care and age, the younger participants had less ability to execute diabetes time management and had higher levels of distress.

New evidence identifying the strong relationship and predictiveness of diabetes time management with diabetes self-care supports the immediate need for more research. Practice changes do not occur solely from the results of one study and, therefore, replication and additional studies using diabetes time management and diabetes self-care are imperative. This study supports the finding of previous research in relation to the inverse relationship between aspects of diabetes self-care and diabetes distress (Akins, 2012; Fisher et al, 2009; Fisher et al. 2012; Gonzalez et al., 2015; Pandit et al., 2014; Polonsky et al., 1995, Polonsky et al., 2005; Walker et al., 2014).

Healthy People 2020's diabetes goal is to reduce the burden of the disease and improve the quality of life for individuals with diabetes mellitus (ODPHP, 2010). Several

strategic diabetes objectives are outlined to guide nurses and healthcare providers of which several incorporate concepts of diabetes self-care, such as increase blood glucose monitoring to a minimum of once daily, annual and biannual provider visiting including specialists, and management of HbA1c (ODPHP, 2010). Cognitive abilities and emotional state are integral components influencing diabetes self-care and requires the attention of healthcare professionals. To meet the Healthy People 2020 goal and objectives, identifying factors that hinder the ability to perform optimal diabetes self-care require further investigation, specifically diabetes time management and diabetes distress.

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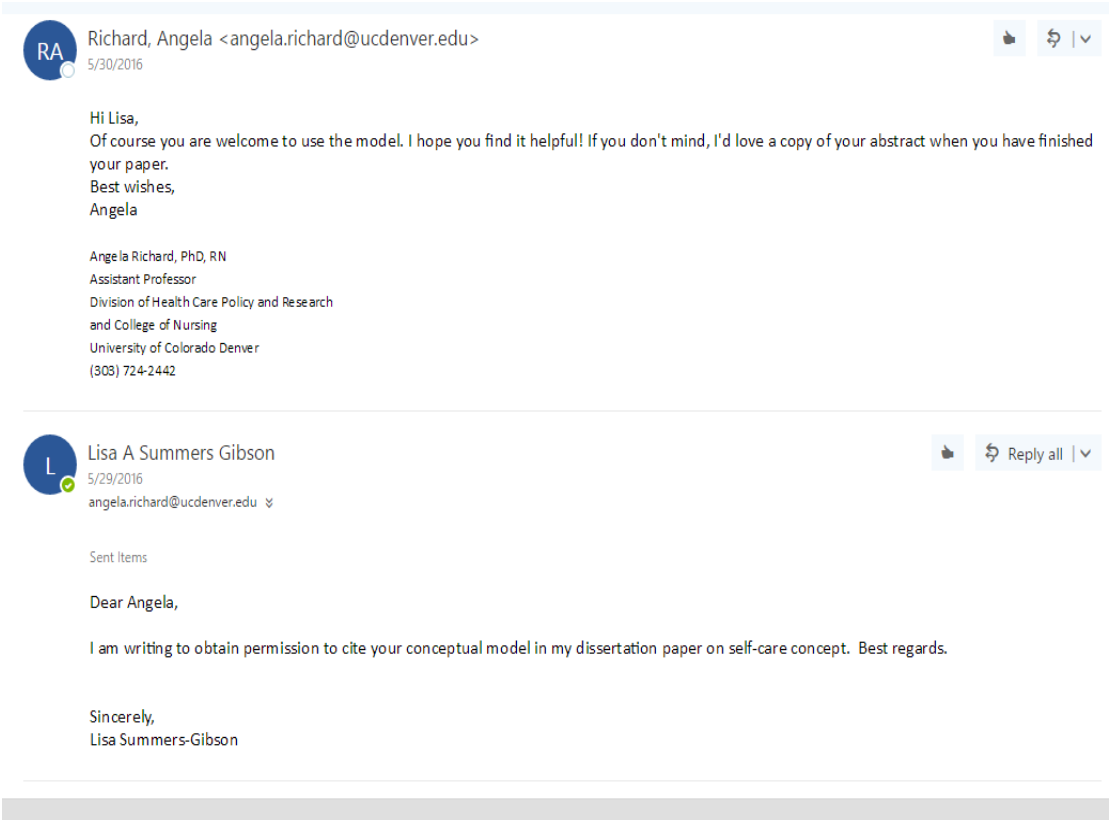
VIII. APPENDICES

APPENDIX A

Permission to use self-care conceptual model



RA

Richard, Angela <angela.richard@ucdenver.edu>
5/30/2016

Hi Lisa,
Of course you are welcome to use the model. I hope you find it helpful! If you don't mind, I'd love a copy of your abstract when you have finished your paper.
Best wishes,
Angela

Angela Richard, PhD, RN
Assistant Professor
Division of Health Care Policy and Research
and College of Nursing
University of Colorado Denver
(303) 724-2442

L

Lisa A Summers Gibson
5/29/2016
angela.richard@ucdenver.edu

Reply all

Sent Items

Dear Angela,

I am writing to obtain permission to cite your conceptual model in my dissertation paper on self-care concept. Best regards.

Sincerely,
Lisa Summers-Gibson

APPENDIX B

Eligibility Criteria

1. I am a woman diagnosed with type 2 diabetes and take medication to treat my diabetes.	True	False
2. I have been diagnosed with type 2 diabetes for one year or longer.	True	False
3. I am 18 years or older	True	False
4. I do **NOT** receive kidney dialysis and I have **NOT** had a kidney transplant related to my diabetes.	True	False
5. I do **NOT** have a lower leg amputation due to diabetes complication.	True	False
6. I am **NOT** pregnant.	True	False
7. I have **NOT** received chemotherapy infusion or radiation for cancer in the last 12 months.	True	False

APPENDIX C

Office Flyer (paper survey)

Seton Hall University

Study Title: Women with Type 2 Diabetes Mellitus: diabetes self-care, diabetes time management, and diabetes distress

- Volunteers wanted for a Research Study
- The purpose of this research is to explore the relationships of diabetes self-care, diabetes time management, and diabetes distress in women with type 2 diabetes mellitus.
- To be eligible for the study you must be a female, 18 years and older, and diagnosed with type 2 diabetes.
- There is no direct benefit to take the study; however the results of the study may benefit future programs for women.
- $10.00 cash is given to you for your time to complete the survey.

Questions about the study, please contact: Lisa Summers-Gibson (Primary Investigator) at lisa.summersgibson@student.shu.edu or call (973) 761-9306.

APPENDIX D

Invitation Letter to Participate (Electronic Survey)

Hello, my name is Lisa Summers-Gibson. I am a PhD student at Seton Hall College of Nursing. I would like to invite you to participate in a research study. The purpose of the study is to learn more about women with type 2 diabetes. The study will look at how diabetes self-care, time management skills, and diabetes distress may impact self-care.

If you are a woman 18 years or older and diagnosed with type 2 diabetes for at least one year or long you may be able eligible. To take the survey click on the anonymous link here: (insert web address). Your participation is voluntary. If you decide to opt out of the survey do so by exiting out of the website. It may take about 25 minutes to complete the survey. All of the data is strictly confidential. The responses cannot be linked back to you. There is no direct benefit to you but the results of the study may benefit future diabetes programs for women.

APPENDIX E

Letter of Solicitation (Paper Survey)

Researcher's Affiliation:

The researcher for this study is a doctoral candidate at Seton Hall University College of Nursing in New Jersey. This study is in partial fulfillment of the requirements for a PhD in Nursing.

Purpose:

The purpose of the study is to learn how time management and diabetes distress affects diabetes self-care. There are 95, brief questions. It takes about 25 minutes to complete.

Procedure:

The participant can take the survey at any time on paper. Participant can return survey to the office clerk.

Instruments:

There are three scales in the survey. The Diabetes Self-Care Questionnaire to rate self-care. The Diabetes Time Management Questionnaire to rate time management skills. The Diabetes Distress Scale to rate distress related to living with diabetes. For example, "Feeling that diabetes is taking up too much of my mental and physical energy every day". The last part of the survey has general questions about the participant such as caregiver roles, work hours, and education.

Voluntary Nature:

The study is voluntary. A participant can decline or change their mind at any time while taking the survey. A participant will not have any changes to their normal care as a result of taking or not taking he survey.

Anonymity:

The participant's name will remain unknown. The researcher is blind to the participant's name. The survey cannot link any answers back to the participant.

Confidentiality:

The data from the survey is strictly private. The surveys returned to the office clerk will be stored in a locked box. The researcher will secure the completed surveys in a locked file desk for 3 years. Only the researcher has access to the surveys. The data is limited to the researcher and faculty mentor.

Risk:

Taking the survey does not put a participant at risk. There is no direct benefit in taking the survey. In the event bad feelings occur please contact a health care provider to talk.

Benefit:

The results from this study may help future diabetes programs for women.

Contacts:

If a participant has any questions about the study, please contact either: Lisa Summers-Gibson (Primary Investigator) at lisa.summersgibson@student.shu.edu or call (973) 761-9306 or Dr. Pamela Galehouse (Dissertation Chair) at pamela.galehouse@shu.edu or call (973) 761-9294. If a participant has questions on the rights as a study participant, contact the Seton Hall University Institutional Review Board Director, Dr. Mary Ruzicka at irb@shu.edu or call (973) 313-6314.

Letter of Solicitation (Electronic Survey)

Researcher's Affiliation:

The researcher for this study is a doctoral candidate at Seton Hall University College of Nursing in New Jersey. This study is in partial fulfillment of the requirements for a PhD in Nursing.

Purpose:

The purpose of the study is to learn how time management and diabetes distress affects diabetes self-care. There are 97, brief questions. It takes about 25 minutes to complete.

Procedure:

The participant will take the survey on a website called (Qualtrics®). The survey can be taken on a smart phone, tablet, or computer. Use caution when using the internet. Close internet browser when complete. It is helpful to find a private place to answer the questions.

Instruments:

There are three scales in the survey. Diabetes Self-Care Questionnaire to rate self-care. Diabetes Time Management Questionnaire to rate time management skills, and Diabetes Distress Scale to rate distress related to living with diabetes. For example, "Feeling that diabetes is taking up too much of my mental and physical energy every day". The last part has general questions. Questions like the participant's view of diabetes, work hours, and education etc.

Voluntary Nature:

The study is voluntary. A participant can take the survey. A participant can decline or change their mind at any time. To opt out just close the web browser. No change in your normal care will result from not taking the survey.

Anonymity:

The participant's name will remain unknown. The researcher is blind to the participant's email and name. The survey cannot link any answers back to the participant.

Confidentiality:

The data from the survey is strictly private. All survey responses will be stored on a flash drive. The flash drive will be locked in a secured desk for at least 3 years. Only the researcher has access to the flash drive. The data is limited to researcher and mentor.

Risk:

Taking the survey does not put one at risk. There is no direct benefit in taking the survey. In the event bad feelings occur please contact a health care provider to talk.

Benefit:

The results may help future diabetes programs for women.

Contacts:

If a participant has any questions about the study, please contact either: Lisa Summers-Gibson (Primary Investigator) at lisa.summersgibson@student.shu.edu or call (973) 761-9306 or Dr. Pamela Galehouse (Dissertation Chair) at pamela.galehouse@shu.edu or call (973) 761-9294. If a participant has questions on the rights as a research participant, please contact the Seton Hall University Institutional Review Board Direct, Dr. Mary Ruzika at irb@shu.edu or call (973) 313-6314.

Consent:

A completed survey implies that a study participant has consented to the research study.

APPENDIX F

Diabetes Self-Management Questionnaire (DSMQ)

The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the **last 8 weeks**, please specify the extent to which each statement applies to you.	Applies to me very much	Applies to me to a consider-able degree	Applies to me to some degree	Does not apply to me
1. I check my blood sugar levels with care and attention. ☐ *Blood sugar measurement is not required as a part of my self-care.*	☐3	☐2	☐1	☐0
2. The food I choose to eat makes it easy to achieve optimal blood sugar levels.	☐3	☐2	☐1	☐0
3. I keep all doctors' appointments (appointments with health professionals) recommended for my diabetes treatment.	☐3	☐2	☐1	☐0
4. I take my diabetes medication (e. g. insulin, tablets) as prescribed (very accurately).	☐3	☐2	☐1	☐0
5. Occasionally I eat lots of sweets or other foods rich in carbohydrates (more often than would be good).	☐3	☐2	☐1	☐0
6. I record my blood sugar levels (or analyse the value chart with my blood glucose meter/computer). ☐ *Blood sugar measurement is not required as a part of my self-care.*	☐3	☐2	☐1	☐0
7. I tend to avoid diabetes-related doctors' appointments (appointments with health professionals).	☐3	☐2	☐1	☐0
8. I am regularly physically active to improve my diabetes treatment.	☐3	☐2	☐1	☐0
9. I strictly follow dietary recommendations given by my doctor or diabetes specialist.	☐3	☐2	☐1	☐0
10. I do not check my blood sugar levels frequently enough to achieve good blood glucose control. ☐ *Blood sugar measurement is not required as a part of my self-care.*	☐3	☐2	☐1	☐0

11. I avoid physical activity, although it could improve my diabetes.	☐3	☐2	☐1	☐0
12. I tend to forget or skip my diabetes medication (e.g., insulin, tablets).	☐3	☐2	☐1	☐0
13. Sometimes I have real 'food binges' (not triggered by low blood sugar).	☐3	☐2	☐1	☐0
14. Regarding my diabetes care, I should see my medical practitioner(s) more often.	☐3	☐2	☐1	☐0
15. I tend to skip planned physical activity.	☐3	☐2	☐1	☐0
16. My diabetes self-care is poor.	☐3	☐2	☐1	☐0

APPENDIX G

Diabetes Time Management Questionnaire

The following statements describe time management skills related to managing daily diabetes self-care routines. Select the appropriate response that best describes yourself using 1 (Always) to 5 (Never).

	Always	**Often**	**Sometimes**	**Rarely**	**Never**
1. I have enough time to accomplish my daily responsibilities.	1	2	3	4	5
2. I use my time effectively and efficiently.	1	2	3	4	5
3. I am concerned about how I manage my time.	1	2	3	4	5
4. I wake up and go to sleep at approximately the same time every day and night.	1	2	3	4	5
5. I take my diabetes medication (insulin or pills) at approximately the same time each day.	1	2	3	4	5
6. I meet deadlines (pay bills on time, show up for appointments on time).	1	2	3	4	5
7. I eat my meals at approximately the same time each day.	1	2	3	4	5
8. I schedule exercise into my routine at least three or more times per week.	1	2	3	4	5
9. I put off doing things I want to get done even when I have the time to do them.	1	2	3	4	5
10. I schedule blood glucose monitoring into my daily routine at set times. □ *Blood sugar measurement is not required as a part of my self-care.*	1	2	3	4	5

11. When I have more to do than I can accomplish in a day, I prioritize things so the most important ones can be done first.	1	2	3	4	5
12. I keep my diabetes healthcare plan on a regular schedule.	1	2	3	4	5
13. I feel overwhelmed by what I need to do in a day.	1	2	3	4	5
14. When I take my diabetes medication (insulin or pills) before my meal, I take it at the appropriate time prior to eating (*example, rapid acting insulin peaks in 15 minutes, regular insulin peaks in 30 minutes, some pills are taken with food*.)	1	2	3	4	5
15. When I have more to do than I can accomplish in a day, I can't seem to figure out where to begin.	1	2	3	4	5
16. I procrastinate (put things off).	1	2	3	4	5
17. When I have a lot of things to do, I like to get the hardest tasks out of the way first.	1	2	3	4	5
18. When I exercise, it is at approximately the same time each week.	1	2	3	4	5
19. I make list of things I have to do each day.	1	2	3	4	5
20. I make list of things that I have to get done eventually.	1	2	3	4	5
21. I check my blood glucose approximately 30 to 45 minutes prior to eating. □ *Blood sugar measurement is not required as a part of my self-care.*	1	2	3	4	5
22. I get upset when I can't get the things done I had wanted to that day.	1	2	3	4	5

23. When something unexpected interrupts my plan, I reschedule, for another time, the things I had planned to do.	1	2	3	4	5
24. If things aren't done myself, they are rarely done right.	1	2	3	4	5
25. I organize my schedule with a planner or calendar.	1	2	3	4	5
26. I accomplish what I set out to do on a daily basis.	1	2	3	4	5
27. I procrastinate (put things off) on the thing I need to do for my diabetes.	1	2	3	4	5
28. When I have a lot of things to do, I like to start with the easiest things first.	1	2	3	4	5
29. I set specific goals (example, I am going to walk/jog three miles every morning at 7:00AM) rather than general goals (example, I am going to start exercising more often).	1	2	3	4	5
30. When there is someone to help me out on a task or project, I will let that person do a share of the work.	1	2	3	4	5
31. I set goals that are reasonable (example, on the first day of a new exercise plan, jogging/walking 1/2 mile instead of 3 miles).	1	2	3	4	5
32. When a task seems too large or difficult, I cut it down to size.	1	2	3	4	5
33. I feel guilty when I don't finish a task.	1	2	3	4	5
34. I reward myself with something special when I finish a task.	1	2	3	4	5
35. I feel like there is not enough time in a day.	1	2	3	4	5

36. I am able to find a balance between both work and leisure time.	1	2	3	4	5
37. I do not feel in control of my time.	1	2	3	4	5
38. I know where my time goes.	1	2	3	4	5
39. I set goals for improving my diabetes control (example, losing 10lbs in 3 months; lowering my glycosylated hemoglobin [HbA_{1c}] by 1% every three months).	1	2	3	4	5
40. I keep my diabetes supplies (blood glucose testing strips and meter, syringes, etc.) in an organized place where I can always find them.	1	2	3	4	5
41. When I don't accomplish my goal, I know the reason why.	1	2	3	4	5
42. When unexpected changes occur in my schedule which may affect my diabetes control, I am able to make quick decisions about modifying my diabetes regimen (example, *adjust the amount of medication you take or the amount food you eat*).	1	2	3	4	5
43. I feel good when I finish a task.	1	2	3	4	5
44. I often find myself doing things which interfere with my diabetes healthcare plan simply because I hate to say "no" to people.	1	2	3	4	5
45. I plan my day before I start it.	1	2	3	4	5
46. I find myself waiting a lot without anything to do.	1	2	3	4	5

47. I find myself rushing to get things done at the last minute.	1	2	3	4	5
48. I keep a record of my blood glucose values.	1	2	3	4	5
49. There is room for improvement in the way I manage my time.	1	2	3	4	5

APPENDIX H

Diabetes Distress Scale

DIRECTIONS: Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 17 items may have distressed or bothered you DURING THE PAST MONTH and select the appropriate number.

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very bothersome to you, you might circle "6".

	Not a Problem	**A Slight Problem**	**A Moderate Problem**	**Somewhat Serious Problem**	**A Serious Problem**	**A Very Serious Problem**
1. Feeling that my doctor doesn't know enough about diabetes and diabetes care.	1	2	3	4	5	6
2. Feeling that diabetes is taking up too much of my mental and physical energy every day.	1	2	3	4	5	6
3. Not feeling confident in my day-to-day ability to manage diabetes.	1	2	3	4	5	6
4. Feeling angry, scared and/or depressed when I think about living with diabetes.	1	2	3	4	5	6
5. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	1	2	3	4	5	6
6. Feeling that I am not testing my blood sugars frequently enough.	1	2	3	4	5	6
7. Feeling that I will end up with serious long-term complications, no matter what I do.	1	2	3	4	5	6

8. Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6
9. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	1	2	3	4	5	6
10. Feeling that diabetes controls my life.	1	2	3	4	5	6
11. Feeling that my doctor doesn't take my concerns seriously enough.	1	2	3	4	5	6
12. Feeling that I am not sticking closely enough to a good meal plan.	1	2	3	4	5	6
13. Feeling that friends or family don't appreciate how difficult living with diabetes can be.	1	2	3	4	5	6
14. Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	1	2	3	4	5	6
16. Not feeling motivated to keep up my diabetes self-management.	1	2	3	4	5	6
17. Feeling that friends or family don't give me the emotional support that I would like.	1	2	3	4	5	6

APPENDIX I

Participant Profile

1. What is your current age in years? _____

2. Select your employment status.
    a. I am not currently employed
    b. I am employed part time
    c. I am employed full time
    d. I am retired
    e. I prefer not to answer

3. Rate how favorable it is for you to take care of your diabetes at work *(example: take medication or check your blood sugar)*?
    a. Not at all easy
    b. Somewhat easy
    c. Often easy
    d. Always easy
    e. Does not apply to me

4. Select all the caregiver roles that you identify with. You can select more than one. Select all that apply to you.
    - ☐ Care for self only
    - ☐ Care for children or grandchildren
    - ☐ Care for spouse or partner
    - ☐ Care for parent(s) or other family members

5. How often do you not take care of your own diabetes self-care because you caring for someone else?
    a. Most of the time
    b. Half the time
    c. Rarely
    d. Does not apply to me

6. How many years have you had diabetes? _____

7. Identify the number of health conditions, <u>other than diabetes,</u> that you may have such as high blood pressure, asthma, weak bones, heart problems etc.
    a. I do not have any other health condition(s).
    b. I am not sure if I have any other health condition(s).
    c. I have 1 other health condition
    d. I have 2 other health conditions
    e. I have 3 or more other health conditions

8. What was your last glycosylated hemoglobin [HbA_{1c}] or A1C?
    a. Less than 6.0
    b. 6.1 to 6.5
    c. 6.6 to 7.0
    d. 7.1 to 7.5
    e. 7.6 to 8.0
    f. Greater than 8.0
    g. I don't know my A1C

9. How would you best describe the diabetes medications your doctor prescribed?
    a. Oral medications only *(i.e. Metformin*)
    b. Oral Medications and insulin (*includes insulin pens or pump, examples: Lantus, Novolog, Humulin)*
    c. Insulin pens/injections only
    d. Insulin pump only

10. From your point-of-view, rate the current state of your diabetes:
    a. My diabetes is getting worse
    b. My diabetes is staying the same
    c. My diabetes is getting better

11. What is your family household income?
    a. Less than $30,000
    b. $30,001 to $50,000
    c. $50,001 to $70,000
    d. $70,001 to $100,000
    e. Greater than $100,001
    f. I prefer not to answer

12. What is the highest degree or level of education that you have completed?
    a. Less than high school
    b. High school graduate (or equivalent)
    c. Some college (no degree)
    d. 2-year degree (Associate's)
    e. 4-year degree (Bachelor's)
    f. Professional degree (Master's)
    g. Doctorate

13. What is your race/ethnicity? You may select more than one if applicable.
    - ☐ American Indian or Alaska Native.
    - ☐ Asian.
    - ☐ Black or African American.

- Hispanic or Latino.
- Native Hawaiian or other Pacific Islander.
- White.

APPENDIX J

Permission to use Diabetes Self-Management Questionnaire (DSMQ)

From: Schmitt Andreas <schmitt@diabetes-zentrum.de>
Sent: Monday, December 12, 2016 7:35 AM
To: Lisa A Summers Gibson
Subject: AW: Diabetes Self-Management Questionnaire

Dear Mrs. Summers-Gibson,

Thank you for your kind request. Your interest in the DSMQ is appreciated. If you would like to use the scale for your valuable research, you are kindly invited to do so. Please find attached the original 16 item version and the revised version together with a scoring guide. Please decide yourself whether you want to use the scale or not and, if yes, which version you want to use. In case of doubt, choose the longer version - it contains most of the original items, hence estimation of a 16-item sum score comparable to the original one would be applicable.

If you have trouble to make a decision between the SDSCA and DSMQ, you might think about taking both. The SDSCA is the accepted standard although everyone knows about the limitations. With both tools you would be have more options for your data analysis.

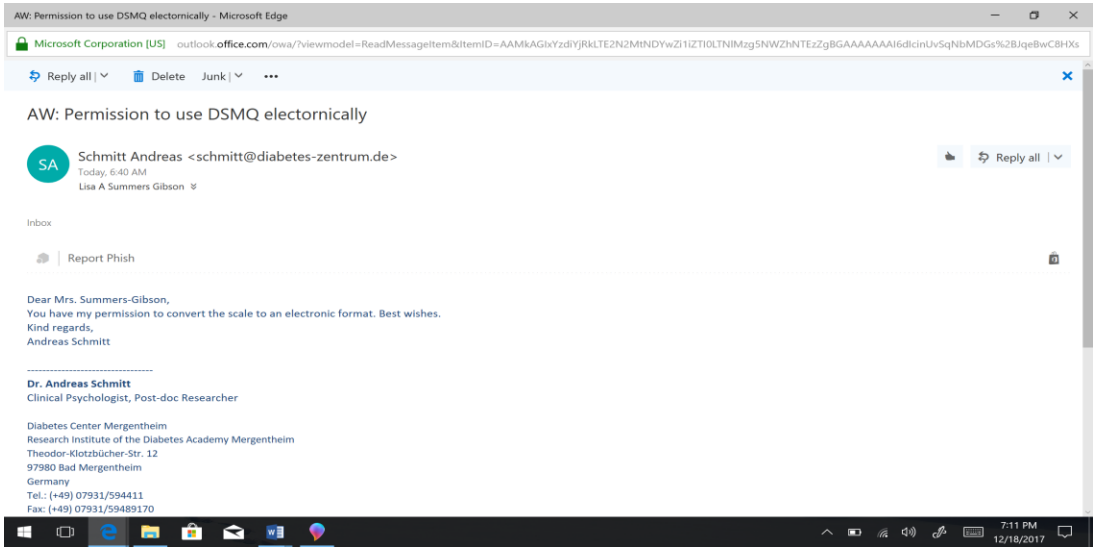
I would really like to get into your study more deeply. What's the main topic and potential expectations? Why women exclusively? 10.000 emails is a large number. How many participants do you plan to collect?

Where are you located anyways? Which university/department?

Best wishes from Germany,

Andreas Schmitt

Dr. Andreas Schmitt
Clinical Psychologist, Post-doc Researcher
Diabetes Center Mergentheim
Research Institute of the Diabetes Academy Mergentheim
Theodor-Klotzbücher-Str. 12
97980 Bad Mergentheim


AW: Permission to use DSMQ electornically - Microsoft Edge
Microsoft Corporation [US] outlook.office.com/owa/?viewmodel=ReadMessageItem&ItemID=AAMkAGIxYzdiYjRkLTE2N2MtNDYwZi1iZTI0LTNlMzg5NWZhNTEzZgBGAAAAAAAI6dIcinUvSqNbMDGs%2BJqeBwC8HXs
Reply all | Delete Junk | ...
AW: Permission to use DSMQ electornically
SA
Schmitt Andreas <schmitt@diabetes-zentrum.de>
Today, 6:40 AM
Lisa A Summers Gibson
Reply all
Inbox
Report Phish
Dear Mrs. Summers-Gibson,
You have my permission to convert the scale to an electronic format. Best wishes.
Kind regards,
Andreas Schmitt
Dr. Andreas Schmitt
Clinical Psychologist, Post-doc Researcher
Diabetes Center Mergentheim
Research Institute of the Diabetes Academy Mergentheim
Theodor-Klotzbücher-Str. 12
97980 Bad Mergentheim
Germany
Tel.: (+49) 07931/594411
Fax: (+49) 07931/59489170
7:11 PM
12/18/2017

APPENDIX K

Permission to use Diabetes Time Management Questionnaire

RE: DTMQ/HAK instrument

Celeste Gafarian

Reply

To:

'LISA' <lisaa_summers@msn.com>;

'Elaine Heiby' <heiby@hawaii.edu>;

Tue 9/15/2015 8:42 PM

Inbox

Hi Lisa,

You can use the questionnaire and you do not need our permission to use it. We had the questionnaire printed in the article so that people can freely use it. After the questionnaire was created and the article was published, I never used the questionnaire again. I see on the internet that 20 people have cited the article, but I don't know if that means they used the questionnaire in a study. If you type Diabetes Time Management Questionnaire into Google, a link will come up for www.ncbi.nlm.nih.gov. Under that link and next to my name, it says "cited by 20". You can click on that and find the list of articles that have cited the article. However, as I said, it does not mean that they used the questionnaire in a study. That is the only information I have. I think Elaine may have worked with a student who might have modified the questionnaire in some way, but I really don't know if that is correct. She would have to tell you about that.

Good luck, Celeste Gafarian

From: LISA [mailto:lisaa_summers@msn.com]
Sent: Tuesday, September 15, 2015 3:57 PM
To: Elaine Heiby <heiby@hawaii.edu>
Cc: Celeste Gafarian <gafarian@hawaii.edu>
Subject: RE: DTMQ/HAK instrument

Aloha Elaine and Celeste,
Thank you for corresponding. I am a PhD Nursing Candidate at Seton Hall

University. I came across your instrument published in 1999. I could not find this instrument used in other studies. I was wondering if you might have some references for me to review regarding using the diabetes time management questionnaire. Additionally, if I wanted to use your instrument for my study what are the terms and permission to use this questionnaire. Thank you again for your time. Sincerely, Lisa Summers-Gibson

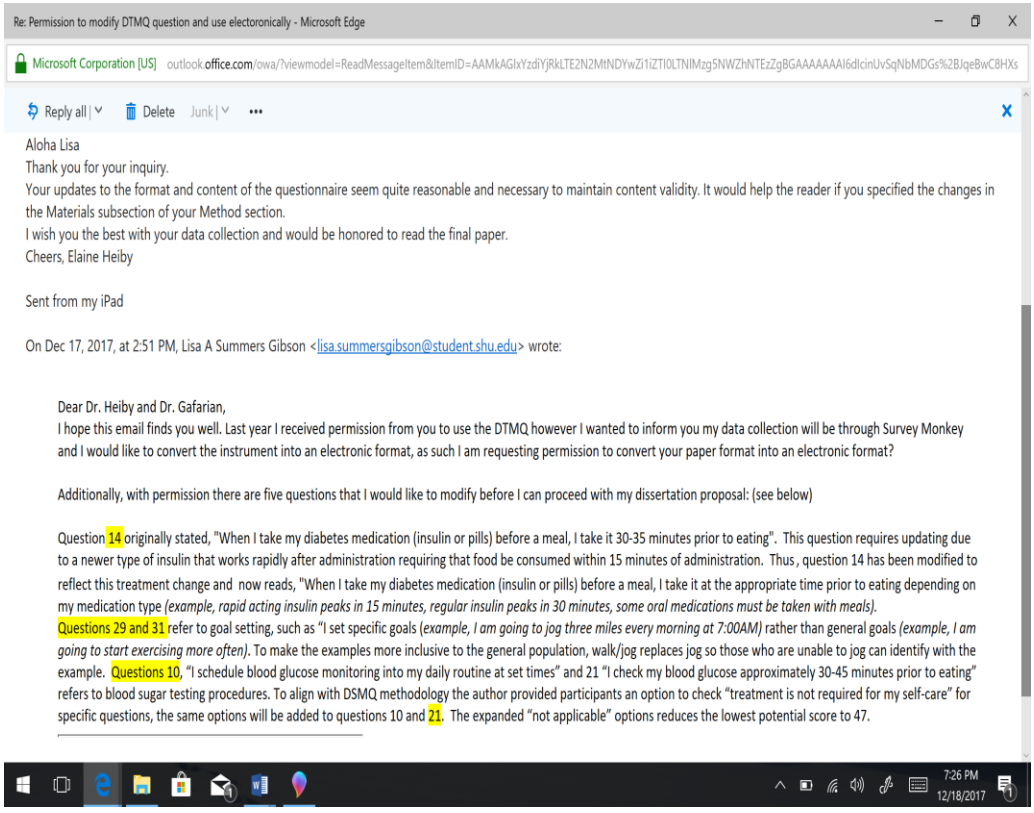
---

Subject: Re: DTMQ/HAK instrument
From: heiby@hawaii.edu
Date: Mon, 14 Sep 2015 17:44:44 -1000
CC: gafarian@hawaii.edu
To: lisaa_summers@msn.com

Aloha Lisa. Thank you for your interest in this work. I included Celeste Gafarian in this reply as she is an author of the instrument and continues to investigate adjustment to a diabetes regimen.

I have retired but have retained the same email address. Please let me know if I may be of assistance.

Cheers, Elaine



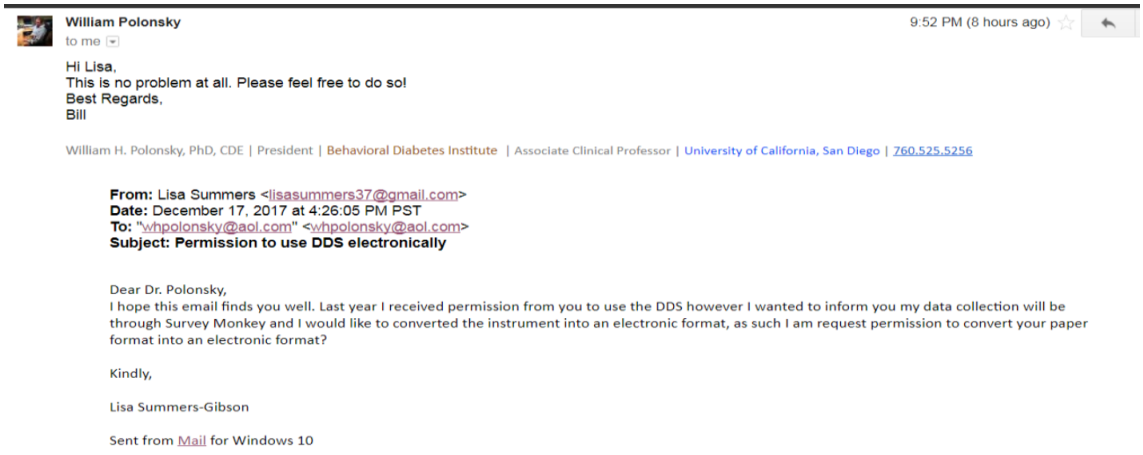
APPENDIX L

Permission to use Diabetes Distress Scale

William Polonsky <whp@behavioraldiabetes.org> 7:01 PM (1 hour ago)

to me

Hi Lisa,
You are more than welcome to use the DDS!
FYI, for DDS copies or more information, please see: http://behavioraldiabetes.org/scales-and-measures/#1448434304099-9078f27c-4106
Good luck with your study.
Best Regards,
Bill
William H. Polonsky, PhD, CDE | President | Behavioral Diabetes Institute | Associate Clinical Professor | University of California, San Diego | 760.525.5256
From: Lisa Summers <lisasummers37@gmail.com>
Date: July 24, 2016 at 9:24:45 AM PDT
To: whpolonsky@aol.com
Subject: DDS (permission to use)
Dear Dr. Polonsky,
I am a PhD Nursing student at Seton Hall University. I am writing to ask permission to use the DDS in my research study.
Very Truly Yours,
Lisa Summers-Gibson, MSN/Ed, RN, CDE



William Polonsky 9:52 PM (8 hours ago)
to me

Hi Lisa,
This is no problem at all. Please feel free to do so!
Best Regards,
Bill

William H. Polonsky, PhD, CDE | President | Behavioral Diabetes Institute | Associate Clinical Professor | University of California, San Diego | 760.525.5256

From: Lisa Summers <lisasummers37@gmail.com>
Date: December 17, 2017 at 4:26:05 PM PST
To: "whpolonsky@aol.com" <whpolonsky@aol.com>
Subject: Permission to use DDS electronically

Dear Dr. Polonsky,
I hope this email finds you well. Last year I received permission from you to use the DDS however I wanted to inform you my data collection will be through Survey Monkey and I would like to converted the instrument into an electronic format, as such I am request permission to convert your paper format into an electronic format?

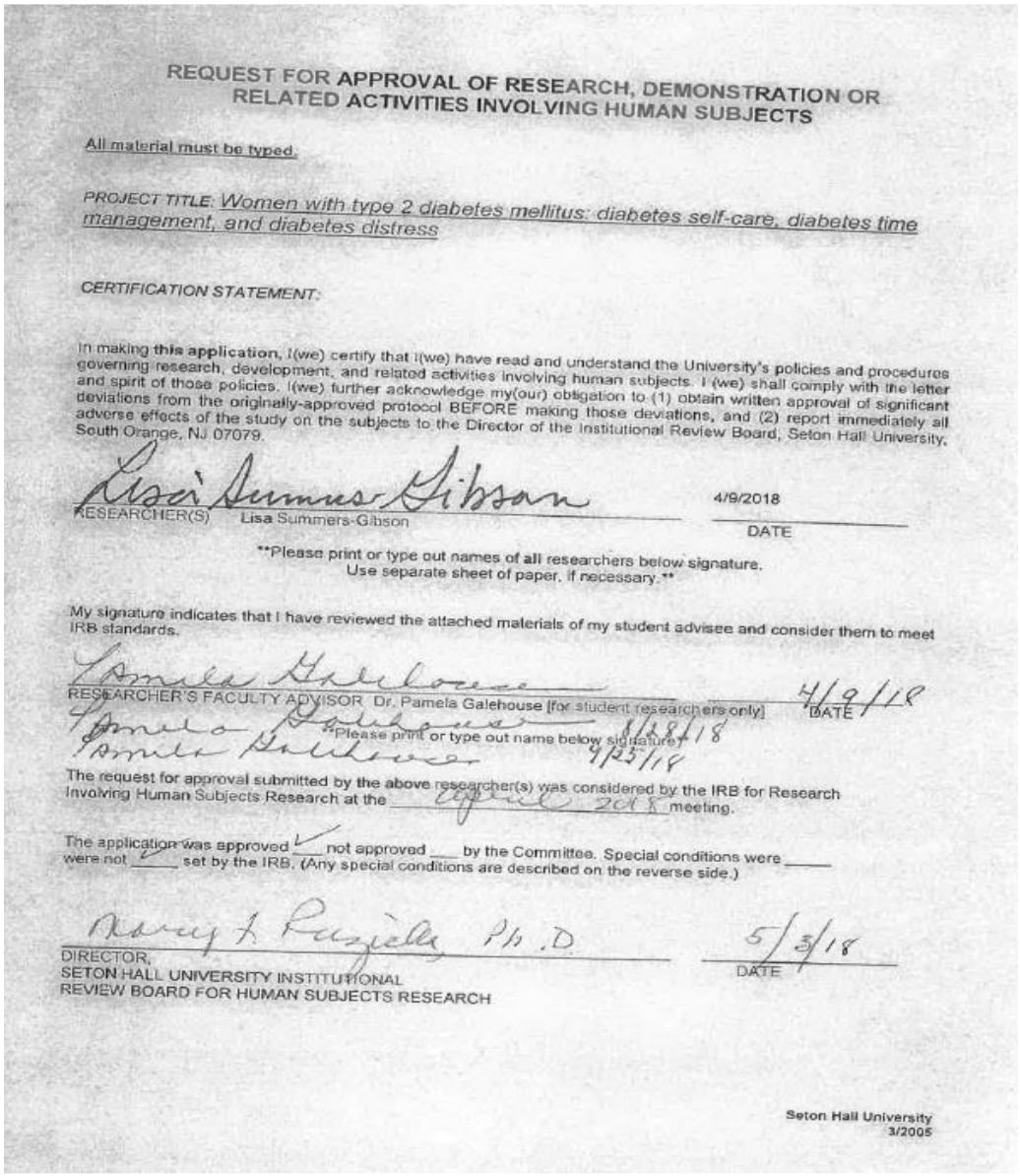
Kindly,

Lisa Summers-Gibson

Sent from Mail for Windows 10

Appendix M

Seton Hall University IRB Approval Letter



REQUEST FOR APPROVAL OF RESEARCH, DEMONSTRATION OR RELATED ACTIVITIES INVOLVING HUMAN SUBJECTS

All material must be typed.

PROJECT TITLE: *Women with type 2 diabetes mellitus: diabetes self-care, diabetes time management, and diabetes distress*

CERTIFICATION STATEMENT:

In making this application, I(we) certify that I(we) have read and understand the University's policies and procedures governing research, development, and related activities involving human subjects. I (we) shall comply with the letter and spirit of those policies. I(we) further acknowledge my(our) obligation to (1) obtain written approval of significant deviations from the originally-approved protocol BEFORE making those deviations, and (2) report immediately all adverse effects of the study on the subjects to the Director of the Institutional Review Board, Seton Hall University, South Orange, NJ 07079.

Lisa Summers-Gibson — 4/9/2018

RESEARCHER(S) Lisa Summers-Gibson — DATE

Please print or type out names of all researchers below signature. Use separate sheet of paper, if necessary.

My signature indicates that I have reviewed the attached materials of my student advisee and consider them to meet IRB standards.

Pamela Galehouse — 4/9/18

RESEARCHER'S FACULTY ADVISOR Dr. Pamela Galehouse [for student researchers only] — DATE

Pamela Galehouse 4/9/18

**Please print or type out name below signature

Pamela Galehouse 4/13/18

The request for approval submitted by the above researcher(s) was considered by the IRB for Research Involving Human Subjects Research at the April 2018 meeting.

The application was approved ✓ not approved ___ by the Committee. Special conditions were ___ were not ___ set by the IRB. (Any special conditions are described on the reverse side.)

Nancy J. Ruzicka, Ph.D. — 5/3/18

DIRECTOR, SETON HALL UNIVERSITY INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH — DATE

Seton Hall University
3/2005

Appendix N

Site Location IRB Approval Letter

Mercy Health System
Institutional Review Board

August 9, 2018

Lisa Summers-Gibson
St. Mary's Hospital

Dear Lisa:

This is written acknowledgement of the approval regarding your research protocol,

- MHS #2018-41, entitled, "Women with Type 2 Diabetes Mellitus: Diabetes Self-Care, Diabetes Time Management, and Diabetes Distress".

The protocol was reviewed and approved by Dr. Jose Missri, Chairman Mercy Health System IRB and the Board Members of the MHS IRB. You may start your research immediately.

An annual review of your study will be due on or before August 1, 2019.

Thank you for using the MCMC Institutional Review Board.

Sincerely,

Dianne Palomba
MHS Institutional Review Board Administrator

Cc: Jose Missri, MD

IRB Exemption from St. Mary Medical Center

From: "Lori A. Lupinacci" <LLupinacci@stmaryhealthcare.org>
Sent: Wednesday, August 8, 2018 5:17 PM
To: Lisa Summers-Gibson <Lisa.Summers-Gibson@stmaryhealthcare.org>
Subject: RE: research study

I hereby pronounce you EXEMPT!

Good luck with your study!

Lori Lupinacci, CIP
IRB Coordinator
St Mary Medical Center

llupinacci@stmaryhealthcare.org

W 215.710.6449

1201 Langhorne-Newtown Rd
Langhorne, PA 19047