Abstract

Beliefs about Diabetes Medicine: Relationships with Patient-Related Factors, Illness-Related Factors and Medication Adherence Among Adults with Type 2 Diabetes

Background: Treatment nonadherence is a significant issue contributing to poor treatment outcomes and increased costs among individuals with diabetes. Patient perceptions about the necessity of taking prescribed medications and their concerns about these medicines predict their medication adherence. However, knowledge of the patient- and illness-related factors that affect these beliefs about diabetes medication is limited. Moreover, although the Necessity-Concerns Framework has been widely used to evaluate the relationship between beliefs about medicine and medication adherence, recent research has criticized the common analytic approach of using a simple difference score model to examine the effects of medication-related necessity beliefs and concerns and promoted the use of alternative multidimensional analyses. This study examined the relationships between patient-related factors, illness-related factors, and beliefs about medications, and used multidimensional analyses to examine the relationships between beliefs about medications and medication adherence among diverse adults with type 2 diabetes (T2D).

Methods: The present study conducted secondary analyses of data from the baseline assessment of a randomized controlled trial evaluating the effects of telephonic diabetes self-management support among 812 predominantly socioeconomically disadvantaged and ethnic minority adults with suboptimally controlled T2D. Medication beliefs were assessed using the Beliefs about Medicines Questionnaire (BMQ). Medication adherence was assessed using the

Adherence to Refills and Medications Scale-Diabetes (ARMS-D). Relationships between patient-related and illness-related factors with medication beliefs were examined using linear regressions. Polynomial regression was used to examine the relationship between medication beliefs and medication adherence.

Results: Hispanic ethnicity ($\beta=.15$ $p<.01$), insulin use ($\beta=.11$ $p<.05$), and higher number of medications ($\beta=.12$ $p<.05$) were significantly associated with stronger beliefs about the necessity in taking medications, while higher level of education ($\beta=-.09$ $p<.05$) was associated with weaker necessity beliefs. Lower income ($\beta= -.09$ $p<.05$) and Hispanic ethnicity ($\beta=.13$ $p<.01$) were significantly associated with greater concerns about medications. None of the illness-related variables were significantly associated with medication concerns. Confirmatory polynomial regression rejected the use of the difference score model. Exploratory polynomial regression determined the quadratic model to be the best fit to test the relationship between medication-related necessity and concern beliefs and adherence.

Discussion:

Individuals with indicators higher socioeconomic status (higher level of education and income) reported less perceived need and less concerns about their medications. Participants with indicators of worse disease severity (insulin use and higher number of prescribed medicines) as well as those identifying as Hispanic both reported greater perceived need for their medications; however, Hispanic participants also reported greater concerns about their diabetes medications. Confirmatory polynomial regression showed the difference score model to be an inappropriate fit in examining the relationship between medication beliefs and type 2 diabetes medication adherence. Exploratory analyses demonstrated higher-order polynomial models to be a superior fit over the linear terms and concluded that low concerns

are necessary but not sufficient for adherence and having both low concerns and high necessity beliefs is optimal for good adherence. The current study's use of improved methodological analyses to examine the relationship between medication beliefs and adherence significantly adds to the body of literature and also demonstrates the complex nature of the relationship between beliefs about medication and adherence in adults with type 2 diabetes.

Beliefs about Diabetes Medicine: Relationships with Patient-Related Factors, Illness-Related Factors and Medication Adherence Among Adults with Type 2 Diabetes

by

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Submitted in partial fulfillment of the requirements

for the degree of

Doctor of Philosophy

in the Ferkauf Graduate School of Psychology

Yeshiva University

June 2021

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Acknowledgments

I am extremely thankful to all of my committee members, classmates, family, and friends for their tremendous support throughout the process of completing my dissertation. I would like to extend my sincere gratitude to Dr. Jeffrey Gonzalez for providing me with invaluable guidance and mentorship throughout my doctoral training. You have taught me to think critically and thoughtfully, encouraging me to be the best possible researcher. I would also like to thank my other committee members, Dr. Alison Phillips and Dr. Elizabeth Walker, for your instrumental feedback, helpful advice, and expertise throughout this project. Thank you to Dr. Jonathan Feldman and Dr. Charles Swencionis for your time and investment in reading this document and kindly agreeing to contribute to my dissertation. I am incredibly grateful for the support and friendship from my Ferkauf classmates and labmates. Finally, I would like to extend my deepest appreciation for my family who have all been instrumental to my success. To my parents, Reva and Paul, thank you for guiding me, always believing in me, and supporting me down any path I choose to take. To my husband, Gabe, thank you for your incredible patience, encouragement, and unwavering love and support throughout this journey.

Table of Contents

List of Tables

List of Figures

List of Appendices

Chapter I: Background and Significance

Diabetes Overview

Diabetes Mellitus is one of the most common and costly chronic diseases in the United States (U.S.). According to the National Diabetes Statistics Report, about 34.2 million individuals in the United States are diagnosed with diabetes and 7.3 million people are estimated to have undiagnosed diabetes, representing a significant public health issue (Centers for Disease and Prevention, 2020). As of 2017, Diabetes is the 7th leading cause of death in the U.S. and accounts for about $327 billion dollars in health care costs. The highest prevalence of diabetes is found among older adults and minority populations. American Indians/Alaska Natives (14.7%), individuals of Hispanic ethnicity (12.5%), non-Hispanic Blacks (11.7%), and non-Hispanic Asians (9.2%) have a higher prevalence of diagnosed diabetes compared to non-Hispanic Whites (7.5%) (Centers for Disease and Prevention, 2020). Ethnic minority groups are also more likely to have suboptimal control of their diabetes and face increased risk of diabetes complications, as compared to Whites (Egede et al., 2011; Kirk et al., 2005; Weinstock et al., 2011).

Diabetes is a chronic disease that occurs from the insufficient production of insulin by the pancreas or the body's ineffective use of the insulin it does produces (American Diabetes Association, 2015; World Health Organization, 2018). Type 1 diabetes (T1D) is characterized by poor or nonexistent insulin production. Insulin is the hormone that regulates blood glucose levels and individuals with T1D require daily administration of insulin. Symptoms of T1D include polyuria (frequent urination), polydipsia (excess thirst), frequent hunger, weight loss, blurry vision, and fatigue (World Health Organization, 2018). Type 2 diabetes (T2D) is characterized by the body's ineffective use of insulin, also known as insulin resistance. In an individual with T2D, their pancreas makes extra insulin to compensate for insulin resistance. However, over time the pancreas may not able to keep up with the amount of insulin needed to maintain blood glucose levels and exogenous insulin, administered by injection, is needed (American Diabetes Association, 2019a; World Health Organization, 2018). Symptoms of T2D are similar to T1D; however, symptoms are often less noticeable, and the disease may not be diagnosed until several years after onset and after complications begin to arise. While T1D and T2D have different causes, interplay between genetics and environmental factors influences predisposition to both diseases. Environmental factors that may lead to T1D among those at risk include, cold weather climates and certain strains of viruses. Genetics have shown to play an even more complex role in development of T2D compared to T1D. Yet, environmental and lifestyle factors such as, obesity, also contribute to the development of T2D. T2D accounts for 90-95% of all diagnosed diabetes cases. Approximately 21.4% of US adults with T2D are undiagnosed and unaware of their hyperglycemia (Centers for Disease and Prevention, 2020).

In both types of diabetes, uncontrolled blood glucose leads to complications and poor health outcomes. Glucose accumulation in the blood may lead the cells to be starved for energy. Hyperglycemia, or high level of blood sugar, can lead to serious damage of body's systems over time, particularly in the nerves and blood vessels. Over time, elevated glucose levels may lead to damage of the kidneys, eyes, nerves or heart (American Diabetes Association, 2019a). T2D is the leading cause of new cases of blindness and end stage renal failure and adults with T2D are at greater risk for coronary heart disease, stroke, hypertension, depression, pain, polypharmacy and functional disability, compared to those without T2D (American Diabetes Association, 2018b). For both T1D and T2D monitoring of blood glucose levels over time is an important standard of care. The main ways for individuals to monitor their blood glucose levels are to use a blood glucose meter to measure levels in the moment via finger-stick, and to receive a blood test of glycated hemoglobin (HbA1c). HbA1c is a percentage value approximating an average of one's blood sugar levels over the previous three months. The recommendation for most adults, who are otherwise healthy, is to maintain a HbA1c value of less than 7%. However, recommended target values may vary based on other factors including, individuals' age and comorbid medical conditions. (American Diabetes Association, 2019b).

Due to the varying pathology and impacts of T1D and T2D, each requires unique self-management activities and treatment recommendations. T1D is treated primarily through insulin therapy, delivered via multiple daily injections or insulin pump. T2D treatment regimens are quite diverse by comparison, primarily involving oral medications but sometimes including insulin injections, either as the sole anti-hyperglycemic agent or in combination with oral medications. Furthermore, T2D disproportionally affects socioeconomically disadvantaged adults, representing a large portion of the target population for this study (Agardh et al., 2011; Gray et al., 2017). Consequently, this study focused on adults with T2D in order to provide insight to the unique relationships and challenges faced among individuals in this population.

Medication Adherence

Due to serious complications associated with uncontrolled diabetes, adherence to treatment regimens for individuals with diabetes is crucial for positive health outcomes

(Brown et al., 2016). The treatment of diabetes mellitus is complex and often involves a range of self-care behaviors such as, self-monitoring, changes in diet and exercise, as well as pharmacological therapy (American Diabetes Association, 2021a, 2021b). Pharmacological therapy can lead to improved glycemic control, with a typical reduction in HbA1c of 0.5% to 2% for oral antihyperglycemic medications (Odegard & Capoccia, 2007). Proper use of pharmacologic therapy for diabetes may also improve micro and macrovascular health outcomes of diabetes, which are often costly and avoidable (Saenz et al., 2005; Turner et al., 1999). Despite the availability of effective drug therapies for diabetes, both medication adherence and control of diabetes are generally suboptimal.

Adherence to prescribed diabetes medications in adults with T2D ranges widely from 38% to 93% (Cramer, 2004; Krass et al., 2015). This wide range in adherence rates is largely due to heterogeneity in methods of measuring adherence. When examining studies using the same adherence measure, the range of prevalence estimates of adherence is narrower as compared to studies using varying tools to assess adherence (Krass et al., 2015). In a recent systematic review, only 6 out of the 27 studies reported a high prevalence of adherence (i.e., at least 80% adherence) in their study population (Krass et al., 2015). Research has shown that adherence to diabetes treatment regimens is one of the lowest among chronic illness (DiMatteo, 2004). Sub-optimal adherence represents an important area of study and intervention, as adherence to treatment regimens, including medication, has been shown to be among the strongest predictors of positive health outcomes for diabetes such as, lower HbA1c and fasting blood glucose levels (Asche et al., 2011; Osterberg & Blaschke, 2005). However, over half of adults with type-2 diabetes have not achieved optimal glycemic control (HbA1c <7.0%), according to the National Health and Nutritional Examination

Survey (NHANES) (Casagrande et al., 2013; Polonsky & Henry, 2016). Suboptimal medication adherence is not only a major factor in poor glycemic control, it also predicts hospitalization and early mortality (Ho et al., 2006) as well as increased health care costs (Kennedy-Martin et al., 2017). One study demonstrated that in patients whose adherence level increased, risk of hospitalization declined by 13% which equated to a national annual cost savings of $4.68 billion annually (Jha et al., 2012). This research further demonstrated that patients from poorer neighborhoods with a high percentage of minority populations had even greater benefits of improved adherence as compared to patients from wealthier neighborhoods. Patients from zip codes with high minority populations and poorer areas had 23% and 19% relative reduction, respectively, in odds of hospitalization or ER visits as compared to 12% reductions for other wealthier ZIP codes with less minorities (Jha et al., 2012). Hispanics have been found to have the poorest medication adherence among racial/ethnic groups (Colby et al., 2012; Lopez et al., 2014; Piette et al., 2010). A majority of individuals in this study identify as Hispanic. Thus, understanding the barriers to medication adherence among this population represents an important area for further exploration.

Barriers to Medication Adherence

Medication nonadherence among individuals with type-2 diabetes may be related to several factors at the patient, regimen, or provider/system level (Ary et al., 1986; Capoccia et al., 2016; Wheeler et al., 2014). Common barriers to adherence include regimen complexity, medication costs, providers' lack of time or resources to train patients and monitor therapy as well as patients' health beliefs and fear of adverse effects (Baghikar et al., 2019; Iuga & McGuire, 2014; Rubin, 2005). A review of the literature examining risk factors associated with non-adherence to anti-hyperglycemic agents concluded that economic costs of prescriptions, type of diabetes medication, complexity of treatment regimen, influence of race and ethnicity, depression, and skeptical beliefs about treatment efficacy represent noteworthy factors impacting adherence (Capoccia et al., 2016). Medication costs, insurance coverage, and influence of race and ethnicity represent factors that are particularly important to consider among the population of the current study. Studies have found that adherence to diabetes medication improves with increasing Medicare Part D coverage (Gu et al., 2010; Y. Zhang et al., 2010). Similarly, adherence rates have been found to be affected by differing co-payment amounts and out-of-pocket costs such that, increases in co-payments decreased the percentage of adherent patients (Gibson et al., 2010; Ong et al., 2018). While insurance coverage has been found to attenuate the burden of costs on medication adherence, low-income racial and ethnic minorities continue to experience financial pressures that negatively impact their adherence to medications (Ngo-Metzger et al., 2012). Additional key factors for consideration include disease and treatment related factors. A number of disease-related issues have been shown to significantly impact adherence including, symptoms of illness, treatment burden, and side-effects of treatment. Individuals with chronic illness tend to neglect self-management behaviors or reduce medication adherence with varying severity or presence of symptoms (Halm et al., 2006; Mann et al., 2009a). Complexity of medication regimen and polypharmacy pose as additional barriers to medication adherence (Bailey & Kodack, 2011; Emslie-Smith et al., 2003). Side effects from anti-hyperglycemic medications are common and range in severity and frequency. Mild side effects may include gastrointestinal intolerance due to bloating, abdominal discomfort, diarrhea, and nausea. More significant side effects may include hypoglycemia and weight gain. Research demonstrates that perceptions of side effects of medications negatively impacts patients' treatment adherence (Chao et al., 2007; Wheeler et al., 2014). A study among individuals with diabetes found that perceptions of medication-related side effects significantly predicted non-adherence to anti-hyperglycemic medications, despite a large portion of study participants who communicated their concerns to treatment providers (Chao et al., 2007). Moreover, ethnic minorities report greater concerns about the harmfulness of medications as compared to non-Hispanic whites, which in turn leads to poor medication adherence and reluctance to add medicines to their treatment regimens. (Gerber, 2010; Huang et al., 2009).

A variety of factors have been shown to significantly impact medication adherence; yet, socio-demographic medical, and system level factors characterize aspects that are largely non-modifiable or inconsistent predictors medication adherence (Osterberg & Blaschke, 2005). Understanding and targeting patients' preexisting health beliefs, fears, and knowledge of treatment represent significant avenues for improvement of medication adherence (Cerkoney & Hart, 1980; Mann et al., 2009a; Shahin et al., 2019). These cognitive and psychological factors, including perceived benefit and barriers, have been shown to be associated with better adherence to diabetes medications (Nagasawa et al., 1990). Beliefs about medication, specifically, have been shown to be associated with medication adherence across several different studies (Barnes et al., 2004; Foot et al., 2016; Horne et al., 2013; Horne & Weinman, 1999; Mann et al., 2009a). Horne and Weinmann (1999) found medication beliefs to be more powerful predictors of reported adherence than clinical and sociodemographic factors. Patients not only have fears of side effects of medications, but also hold general beliefs about possible negative consequences, including long-term impacts, cost, and reliance on medications long term. Patients also report general beliefs about pharmaceuticals as a form of treatment that is overprescribed and intrinsically harmful (Horne et al., 2008, 2013).

Illness Representations and Medication Beliefs

Early research into patients' beliefs about their illnesses and medications largely used interview-based qualitative methods to explore lay beliefs without the guidance of any particular psychological theory. Studies have shown that individuals often hold prototypic beliefs or schema about certain illnesses which largely influence their representation of that disease (Bishop, 1991; Croyle & Williams, 1991). It is likely that people may also have specific preconceived notions about medicines in general or about the specific medication prescribed for their treatment (Horne, 1997). Some studies highlighted beliefs about the dual nature of medicines, in that patients believed medicines are usually both helpful and harmful at the same time. Individuals with this representation believe that medications can be efficacious and also toxic with various side effects (Lorish et al., 1990). Other studies focused on themes of the negative views about medicine including, the addictive or dependent nature of medication (Conrad, 1985), effects of long-term use (Morgan & Watkins, 1988), and general beliefs that medicines are unnatural or chemical (Conrad, 1985) or poisonous (Fallsberg & Linköping, 1991).

More recent research has examined patients' beliefs about medication in the context of various social cognition models. These models have been used to explain the role of patient beliefs and appraisals in medication adherence (Conrad, 1985). Leventhal's common-sense model of self-regulation (SRM) describes a dynamic process explaining how health-related behaviors and coping procedures (e.g. to take medication or not) are influenced by one's appraisal of health threats (Leventhal et al., 1980; Leventhal & Cameron, 1987; Petrie

& Weinman, 1997). In this model (Figure 1), the process is influenced by stimuli which include somatic symptoms and observations of one's own experiences, as well as the experiences of others (Leventhal et al., 2016). These stimuli trigger representations of illness threats, also known as illness beliefs. The SRM organizes illness beliefs into five components: identity (disease label and symptom indicator), timeline (acute or chronic nature of threat), cause (antecedent), consequences (various impacts of threat), and cure/control (ways to control or treat the health threat) (Leventhal et al., 2003). Illness beliefs consequently impact an individual's development of coping procedures and action plans to manage health threats. The SRM also accounts for the idea that one's representations of treatment, in addition to illness, may play a role in self-regulation. The model explains that adherence tends to be a 'common sense' response to implicit or explicit appraisals of treatment, in addition to illness generally, based on personal experiences or health threats (Horne et al., 2013).

Patient perceptions of the curability or controllability of their illness play a significant role in their beliefs about their treatment and consequently how it impacts actions in following treatment recommendations (Friedman, 2011). For example, when individuals believe in their own personal control and control of the treatment over their illness, they are more likely to take their medications (Ross et al., 2004). The explanatory power of this model in relation to medication adherence may be improved by assessing patients' beliefs about medication specifically (Byrne et al., 2005; Horne & Weinman, 1999; M. da G. Pereira et al., 2019). Research has demonstrated how illness perceptions can impact adherence indirectly through beliefs about treatment, such that beliefs about medicine have been found to mediate the relationship between illness representations of diabetes consequences and treatment control, and medication adherence (M. da G. Pereira et al., 2019).

Studies among asthma and hypertension patients, respectively, similarly found that greater perceived consequences and views about a more acute illness timeline were associated with doubts about treatment necessity, which predicted lower adherence to medication (Horne & Weinman, 2002; Ross et al., 2004). A more recent study found that beliefs about the need to take medicines mediated the relationship between illness representations of diabetes and medication adherence (M. da G. Pereira et al., 2019). Consequently, beliefs about medication represent an important area of research and focus to improve adherence to treatment and patient outcomes.

Factors Influencing Medication Beliefs

As illustrated in the SRM (See Figure 1), the process by which individuals develop illness beliefs, or medication beliefs specifically, is influenced by various internal and external stimuli (Leventhal et al., 2016). Despite the wide-spread adoption and literature on this model, our knowledge of the specific factors that influence medication beliefs is limited, with most studies focusing on the determinants of illness perceptions more generally (Aalto at al., 2005). Studies have highlighted associations of various demographic and illness-related variables with illness perceptions. However, results of the specific relationships are variable, particularly across illness populations.

Patient-Related Factors. Research on individuals with cancer and hypertension demonstrates associations between older age and decreases in patients' beliefs about associated consequences and personal control of their illness (Ross et al., 2004; N. Zhang et al., 2016). Another study found that individuals with cancer over 65 years of age believed their illness was associated with more consequences, yet also reported higher beliefs of treatment control compared to individuals under 65 years (Husson et al., 2013). Studies conducted among individuals with diabetes determined that older age was significantly associated with increases in beliefs about the seriousness of their illness and treatment effectiveness (Glasgow et al., 1997; Lange & Piette, 2006). These studies also highlighted variable associations between older age and specific medication beliefs. A study among patients with hypertension found a significant relationship between older age and increases in both their concerns about taking medication as well as their beliefs about the necessity of medication for their illness (Ross et al., 2004). In contrast, a study sample of patients with T2D found associations between older age and decreases in beliefs about the necessity of taking antihyperglycemic mediation as well as decreased concerns about taking medication (Aikens & Piette, 2009).

Research has also highlighted relationship between illness beliefs and indicators of socioeconomic status such as education and income. Studies among cardiovascular and cancer patients, respectively, found that stronger beliefs about treatment and personal control (Aalto et al., 2005) and illness coherence (N. Zhang et al., 2016) are associated with higher levels of education. Another study among general pharmacy client found that higher level of education was associated with more beneficial and less harmful beliefs about medicines (Mardby et al., 2007). While research among individuals with diabetes is limited, findings have indicated relationships between level of education and increased beliefs about treatment effectiveness (Lange & Piette, 2006) and personal control as well as decreased concerns about medications (Aflakseir, 2012). One study found that patients with higher income levels endorsed lower perceived need for anti-hyperglycemic medications (Aikens & Piette, 2009) and another study demonstrated the relationship between neighborhood deprivation and diabetes medication nonadherence related to negative beliefs about the medication regimen (Billimek & August, 2013).

Various studies have also examined fatalism, or the belief that events are predetermined and thus little can be done to change the course in one’s life Fatalistic thinking is significant in the context of chronic illness, particularly diabetes, for it can serve as a barrier to self-management and medication adherence (Merriam-Webster, n.d.). The concept of fatalism is often examined in research on perceived control among ethnic minority groups, in particular Latinos. A systematic review of studies examining culturally relevant issues for Hispanics with diabetes (Caban & Walker, 2006) found several studies that highlighted fatalistic beliefs among Hispanic groups including a Puerto Rican population in Boston (Quatromoni et al., 1994), Non-Mexican American Hispanics in NYC (Zaldívar & Smolowitz, 1994), and Mexican-American individuals in Michigan and Texas (R. M. Anderson et al., 1998; Schwab et al., 1994). A study conducting focus groups with Black individuals with T2D found that participants endorsed perceptions of hopelessness, meaningless, and powerlessness related to their illness (Egede & Bonadonna, 2003). Researchers also found a significant relationship between fatalistic beliefs and poor diabetes self-management among this patient population (Egede & Bonadonna, 2003). A more recent study found similar relationships between fatalistic beliefs and poor medication adherence and self-care activities among adults with T2D (R. J. Walker et al., 2012). While these studies highlight the fatalistic beliefs among Latino/Hispanic groups, research on differences between ethnic and racial groups’ fatalism is limited. One study found that Hispanic/Latino patients endorsed higher levels of fatalistic beliefs than Black, White, and Asian patients

(Lange & Piette, 2006). Moreover, research on health beliefs other than fatalism including medication beliefs, among ethnic minority populations is limited as well. Ethnic minorities have been shown to endorse more concerns about taking diabetes medication (Huang et al., 2009; Lange & Piette, 2006). Black and Hispanic patients report more concerns about medication taking than White patients (Gerber, 2010; Huang et al., 2009; Piette et al., 2010).

As indicated from the research reviewed, individuals often develop various beliefs about health and illness across ethnic groups. Additional research is needed to further understand health and medication beliefs differences among populations, particularly ethnic minorities, often underrepresented in research. This research expands upon and enhance the current body of literature, as the majority of individuals in our patient population identify as having Hispanic/Latino and Black race or ethnicity.

Illness Related Factors. Illness-related variables have been shown to be significantly related to illness perceptions as well (Aikens & Piette, 2009; Clyne et al., 2017; Lange & Piette, 2006; Mann, Ponieman, Leventhal, & Halm, 2009). Overall, patients' with worse disease severity and greater use of medications tend to hold stronger beliefs about their need for their prescribed treatment regimens, yet also hold greater concerns about the side effects and long terms consequences of their medications (Aikens & Piette, 2009; Clyne et al., 2017). One study among individuals with T2D found that higher HbA1c levels were associated with increased beliefs about the seriousness of the illness (Lange & Piette, 2006), another study found that higher HbA1c values were associated with medication beliefs including, feeling little control over diabetes, believing it is not important to take medication when blood sugar levels are normal, and feeling that diabetes medications are difficult to take (Mann et al., 2009b).

While insulin use is often understood as indicator of disease severity among individuals with T2D, it represents a construct with unique relationships to illness beliefs and adherence. Disease severity and associated symptom experiences play an important role in shaping patients' illness representations (Petrie & Weinman, 1997). However, research has also demonstrated the significance of other contextual factors in predicting beliefs despite symptoms. Hampson and colleagues (1991) found that T2D patients using insulin reported fewer symptoms, yet still rated their diabetes more serious than patients not taking insulin. This is likely influenced by specific beliefs many individuals develop about taking insulin. While more recent research demonstrated that individuals taking insulin reported more diabetes symptoms (Asman et al., 2019), numerous studies continue to highlight patients' perceptions about the seriousness of taking insulin (Ellis et al., 2018; Noakes, 2010; Polonsky & Jackson, 2004).

A great deal of literature examines the role of psychological insulin resistance (PIR) on adherence to prescribed treatment. PIR is understood as the psychological opposition towards taking insulin (Brod, Kongso, Lessard, & Christensen, 2008). PIR not only impacts one's willingness and concerns about using insulin, it also influences the way in which someone views their illness. Consequently, this may impact a patient's adherence to self-management activities more generally. Research has shown that PIR increases an individual's view of the severity of their illness as well as their perceptions about failing to care for their health when initiation of insulin therapy is needed (Brod, Kongso, Lessard, & Christensen, 2008; Polonsky, Fisher, Guzman, Villa-Caballero, & Edelman, 2005). Individuals who take insulin, particularly those with PIR, will likely view their illness as more serious and may increase their beliefs about the necessity of taking prescribed medication pills. Studies examining insulin use have found significant associations with increased beliefs about the seriousness of one's illness and the necessity to take medications as well decreased beliefs about their doctor's ability to cure their diabetes among individuals who take insulin (Aikens & Piette, 2009; Lange & Piette, 2006; Mann et al., 2009b). Further examination into the relationship between insulin use and specific medication beliefs will help to elucidate the impact that insulin therapy may have on patients' adoption and adherence to treatment recommendations.

The number of medications an individual is prescribed represents another variable that is significantly associated with illness beliefs. Patients' beliefs about their illness and treatment influence the way health care providers prescribe their medication (Clyne et al., 2017), and are often reported as barriers to de-prescribing potentially inappropriate medication (K. Anderson et al., 2014; Cullinan et al., 2014). Conversely, individuals who take several medications may develop specific beliefs impacted by their treatment regimen. Patients prescribed multiple medications seem to hold strong beliefs about the benefits and need for their prescribed treatment regimens, particularly as it relates to symptoms relief. However, the long term use and experience of side effects often leads to an increase in concerns (Aikens & Piette, 2009; Clyne et al., 2017). In a study examining medication beliefs among older adults in primary care with polypharmacy (>5 medications), patients reported stronger beliefs about the necessity of taking medication as well as greater concerns about medications (Clyne et al., 2017). Similar findings were observed in a study among individuals with T2D (Aikens & Piette, 2009). Despite initial findings, limited research has been conducted. It is crucial to further understand the significance of these relationships in order to appreciate the role of prescribing medication and polypharmacy on illness perceptions and openness to treatment.

A recent systematic review of modifiable correlates of illness perceptions among adults with chronic illness found illness-related and psychosocial factors to have the strongest correlations with illness perceptions compared to other modifiable factors (Borge et al., 2014; Ireland & Wilsher, 2010; Karademas et al., 2016; Richards et al., 2003). This study demonstrated that physical symptoms and illness severity were related to perceptions of severe consequences and less personal control. Psychosocial factors of depression and maladaptive health beliefs were associated with less perceived control (Arat et al., 2018). More empirical research is needed to examine the patient-related and illness-related factors that predict beliefs about medication when studying an ethnic minority population with chronic disease (Aalto et al., 2005; Lange & Piette, 2006; Martin et al., 2004)

Necessity and Concerns Framework

Based on Leventhal's SRM model and previous studies demonstrating the impact of medication beliefs on medication adherence, Horne and colleagues (1999) developed the Necessary-Concerns Framework (NCF) to account for key beliefs influencing patients' common-sense evaluations of prescribed medications. They identified that previous studies provided information on the content of individuals' beliefs about medicines and suggested their association with adherence to treatment (Bishop, 1991; Conrad, 1985; Wöller et al., 1993). However, they highlighted gaps in the existing literature of primarily qualitative studies. Horne and colleagues aimed to examine how medication beliefs are cognitively organized, i.e., to determine the extent to which patients' general beliefs about medicines differed from their beliefs about specific prescribed medicines. They also aimed to further explore the relationship between medication beliefs and adherence to treatment and sought to develop a measure that systemically captured beliefs based on the principle that individuals form structured coherent beliefs about illness, which in turn influences their adherence behaviors (Horne, 1997). The principle is guided from Leventhal's SRM which explains how one's decision to take their medicine is one of many possible choices an individual may make to cope with an illness threat and adherence is more likely if the individual perceived the decisions to take medication makes 'common sense' with their knowledge, experiences, and beliefs about their illness (Horne et al., 1999).

The approach to systematically investigate the structure and prevalence of medication beliefs led to an initial method of eliciting and scoring individuals' beliefs about medicine. Key themes were derived from statements from both existing research and additional interviews conducted with patients receiving regular medication from chronic illnesses (hemodialysis and myocardial infarction). Common lay beliefs were separated into two groups: beliefs about specific medicines prescribed for particular illness and beliefs about medicines in general. A principal component analysis (PCA) was conducted to evaluate if items could be assigned a simple, coherent structure stable across different illness groups. The PCA determined that certain beliefs were organized into four factors used to develop subscales for the Beliefs about Medicines Questionnaire (BMQ). The four core themes are captured within the two sections of the BMQ: specific (specific-necessity and specific-concern) and general (general-overuse and general-harm). (Horne, 1997; Horne et al., 1999). The BMQ-specific consists of statements about perceptions about personal need for treatment (necessity beliefs) and concerns about potential adverse consequences from medicine (concern beliefs). The BMQ-General consists of statements about the overuse of medicines by doctors and the general harmful addictive nature of medicines. The Necessity-Concerns framework proposes that adherence is impacted by beliefs about the need for treatment or medicine as well as one's concerns about taking their medicine (Horne et al., 2013). Previous studies have demonstrated that the extended model of the SRM, which includes the NCF, more strongly predicts medication adherence compared to original SRM (See Figure 1 for the extended model) (Byrne et al., 2005; Horne & Weinman, 2002).

Beliefs about Medicines and Adherence

A great deal of research has demonstrated the relationship between negative medication beliefs and poorer treatment adherence (Foot et al., 2016; Horne et al., 2013). As highlighted above, patients have fears about the side effects and concerns about negative consequences of medication use including, long-term impacts, dependence on medications, and poisonous nature of medication . Since a large majority of early research on medication beliefs used qualitative methods, few studies initially investigated the relationship between beliefs about medicines and treatment adherence or other variables (Horne, 1997). One early study found that patients with Asthma who emphasized the threatening aspects of their medication were less adherent to treatment (Wöller et al., 1993). A meta-analysis of studies using the BMQ to predict adherence, found a significant positive relationship across studies between necessity beliefs and adherence and a significant negative relationship between concerns and adherence (Horne et al., 2013). However, only eight out of the 94 studies reviewed were conducted with samples including individuals with diabetes, with only six focusing solely on individuals with diabetes. While the overall meta-analysis found significant relationships between beliefs and adherence, the diabetes studies did not demonstrate significant relationships between necessity and concern beliefs and adherence when analyses were stratified by illness (Horne et al., 2013). A more recent meta-analysis was conducted to focus on stratification across different conditions and with the inclusion of newer studies (Foot et al., 2016). This study found similar results to Horne and colleagues' (2013) initial meta-analysis. Several of the diabetes studies reviewed did not find significant relationships between patients' beliefs about the need for prescribed medications or concerns about the effects of their medicines after adjusted analyses (Batchelder et al., 2014; de Vries et al., 2014; French et al., 2013; Shiyanbola & Nelson, 2011). While a handful of the studies did report significant relationships between either increased concerns about medications and worse adherence (Aflakseir, 2012) or increased beliefs about the need for medications and better adherence (Barnes et al., 2004; Schoenthaler et al., 2012), only one studied reviewed demonstrated significant relationships between both concerns and necessity beliefs with adherence (Sweileh et al., 2014). This study found that patients with greater beliefs about their need for prescribed medication and less concerns about their medication reported that they were adherent to their medications as compared to the reported beliefs of those who were non-adherent to treatment regimens. (Sweileh et al., 2014). Significant heterogeneity of measures and study design existed across studies and the number of studies focusing on diabetes populations remains limited.

The mixed findings across studies and disease types highlight the importance of conducting additional research focused on specific conditions to investigate the unique role that individual illnesses have on beliefs and adherence. Furthermore, a majority of the studies, particularly the diabetes population studies, used the Morisky Medication Adherence Scales (MMAS-4 or MMAS-8) (Sweileh et al., 2014) or the Medication Adherence Rating Scale (MARS) (Aflakseir, 2012; Barnes et al., 2004; de Vries et al., 2014; French et al., 2013). One of the reviewed studies used a medication possession ratio (MPR) based on prescription refill data. While reliability for these measures is adequate, validity has been shown to be moderate to weak for the MMAS and MARS (Culig & Leppée, 2014). This is likely influenced by their limited response choices with a binary response format as well as limited variability in the total score. Other self-report measures of adherence such as, the Adherence to Refills and Medication Scale (ARMS) demonstrate superior internal consistency and a wider range of response choices (Culig & Leppée, 2014). This measure also captures barriers to adherence of taking medications and refilling prescriptions, which is better suited to a population who may have issues with obtaining their prescriptions due to the cost, low literacy, or other barriers. The ARMS has been associated with objective measures of adherence to medication refills among a Black, inner-city study sample (Kripalani et al., 2009; Mayberry et al., 2013). With the inclusion of the two subscales, refills and medication taking, the ARMS-D also allows for providers to identify the type of nonadherence and help patient overcome specific barriers. Moreover, the ARMS-D refill subscale was found to be most predictive of HbA1c, as compared to the total ARMS-D scale and the ARMS-D medication taking subscale (Mayberry et al., 2013). This demonstrates that relationships among clinical factors may have different relationships with the different components of adherence. The majority of the previous studies conducted among patients with T2D did not assess adherence to medication refills, thus representing a significant limitation of prior research. One study examined medication refills through the use of the MPR calculated from prescription data. Participants with increased beliefs about the need for their medications demonstrated better adherence (Schoenthaler et al., 2012). However, the population studied included primarily white patients with health insurance and generally well-controlled diabetes (A1c<7). The individuals in our study population are primarily socioeconomically disadvantaged, ethnic minority patients with poorly controlled diabetes. Therefore, it is likely that unique relationships between adherence, particularly barriers to refills, and beliefs about medications will be highlighted among our study population.

Necessity-Concerns Framework: methodological limitations

Several studies have demonstrated the significance of the NCF model in predicting medication adherence; however, most researchers have either examined concerns and necessity beliefs separately or collapsed the two factors into a single dimension for their analyses (Phillips et al., 2014). Horne and colleagues developed the necessity-concerns differential (NCD) to evaluate the predictive value of the two factors, concerns and necessity, in determining adherence (Horne et al., 1999). The NCF assesses patients' positive and negative attitudes towards medication. Therefore, by calculating the difference between these two factors, researchers can evaluate the relative importance of each of these attitudes in shaping adherence. The NCD represents a cost-benefit analysis for each individual. Concerns scores are subtracted from necessity scores and thus is the difference is positive, a patient's perceived benefits of medications outweighs the costs and if the difference is negative, they perceive costs to taking their medication than benefits (Horne et al., 1999). Many researchers have used the NCD within their studies (Clifford et al., 2008; Emilsson et al., 2011; Horne et al., 2004; Horne & Weinman, 1999; Sirey et al., 2013). Research by Horne and Weinman (1999) demonstrated that the difference score was significantly associated with medication adherence and patients' whose necessity scores surpassed concerns scores reported lower adherence than patients with higher concerns scores than necessity scores. Horne and colleagues (2004) also found a higher NCD value in a high adherence group, where their necessity beliefs outweighed concerns, compared to a low adherence group. However, by constructing a difference score researchers are implying that every one-point increase in necessity beliefs has an equivalent effect on adherence as every one-point decrease in concern beliefs. This assumption is not necessarily correct and requires further investigation to determine the weighted effects of each factor (Dillon et al., 2018).

Research has also shown that necessity and concern beliefs were independently related to adherence (Aikens et al., 2005). It can be argued that the NCF more appropriately fits a bivariate evaluation plane, which indicates that individuals' behavior is determined by both reciprocal (one is high, the other is low) and non-reciprocal (both high or both low) evaluations (Cacioppo et al., 1997; Cacioppo & Berntson, 1994). Necessity and concern beliefs exist as two factors or dimensions. Thus, their relationship to adherence creates a three-dimensional model, where adherence is predicted by different combinations of patients' necessity and concern beliefs (Phillips et al., 2014). There have been some studies that have taken the different combinations of beliefs into account by creating attitude groups such as, ambivalent (high concern, low necessity), indifferent (low concern, low necessity), skeptical (high concern, low necessity), and accepting (low concern, high necessity) (Aikens et al., 2005). A study investigating predictors of adherence to diabetes medications reported that patients with skeptical beliefs about their medications were significantly more likely to be poorly adherent (i.e., Morisky measure > 1) compared to those with ambivalent or indifferent beliefs. A study examining individuals taking antidepressant medication found similar results (Aikens et al., 2005). Nonetheless, these studies continued to analyze beliefs in a single dimension. Phillips and colleagues (2014) argue for the use polynomial regression to test the NCF as a multidimensional theory. The use of polynomial linear regression proved to be robust in supporting both the reciprocal and non-reciprocal effects of the NCF in predicting medication adherence among stroke survivors (Phillips et al., 2014). Replication of these results is needed not only in other chronic illness, but also to address various limitations in the original study including, the adherence measure used and heterogeneity of drug regimens (Margolis & Gonzalez, 2014).

Polynomial Regression

Polynomial regression represents a novel and valuable analysis for examining the combined effects of necessity and concerns beliefs on medication adherence. Polynomial regression is based on the concept of analyzing two predictor variables that are commensurate or of the same conceptual domain. Thus, any difference in standing of the two predictors is interpretable in a meaningful way (Edwards, 2002). This type of analysis is particularly useful for measuring the NCF. The NCF represents a model with two factors or dimensions of beliefs that are two ends of the same construct. Their relationship to adherence creates a three-dimensional (3-D) model and polynomial regression allows for the examination of these relationships on a 3-D plane as a continuous model, rather than analyzing the factors separately or by dichotomizing the variables into groups (Phillips et al., 2014). By dichotomizing the variables, the interpretability of the results is reduced, with the findings not as robust as continuous models (Altman & Royston, 2006). Furthermore, polynomial regression tests higher order terms to determine if there is an interaction between the effects of the predictors, necessity and concerns (i.e., curvilinear effects show higher at extremes). Representations of the different approaches used to examine the relationships between the NCF and adherence can be seen in Figure 2.

Polynomial regression has traditionally been incorporated in social psychology research with regard to various commensurate predictors affecting outcomes in the work environment, such as perceived organizational and supervisory support predicting levels of affective commitment to the company (Shanock et al., 2010). It has also been used to evaluate behavioral intentions versus formed behavioral habits in predicting future behavior (Danner et al., 2008). Phillips and colleagues (2014) adopted the use of polynomial regression to study the NCF and patient adherence on a stroke-survivor population. Their results supported past findings that adherence is lower when concerns outweigh necessity beliefs and vice versa. However, this study also demonstrated that the strict difference score model that is implied in previous analyses of the NCF is not the best-fitting model to examine these relationships. Patients with stronger concerns and stronger necessity beliefs ("ambivalent") about medication had lower reported adherence than patients with weaker concerns and weaker necessity beliefs ("indifferent"). These findings highlight both reciprocal and non-reciprocal effects on adherence. More recent studies using polynomial regression to evaluate the NCF found similar results examining patients with different medical conditions (Dillon et al., 2018; West et al., 2018). While Phillips and colleagues study found the linear model to be the best fit, these additional studies found either the linear or quadratic model to be the best-fitting model depending on the medical condition. This seems to reflect differences between populations studied and highlights the importance of replication of results across different study or illness populations.

Study Rational/Innovation

The aim of the current study is to comprehensively assess the relationships between contextual factors, medication beliefs, and adherence among a diverse group of individuals with T2D, as hypothesized through the extended SRM. These relationships represent important areas for both research as well as clinical work. By evaluating the role of various patient-related and illness-related factors within the SRM, using improved methodological analyses, we can better understand the nature of these relationships and which ones are particularly significant or important to address in real-world practice. Limited studies have examined the relationship between contextual factors and medication beliefs within an ethnically diverse diabetes population. Therefore, the current study is innovative and notably contributes to the current body of literature. Having a greater understanding of the specific factors that shape medication beliefs, researchers and clinicians can develop tailored interventions and treatments sensitive to the beliefs held by specific populations. By understanding that adherence may be influenced by complex attitudes towards beliefs (i.e., ambivalence or indifference), clinicians may be better equipped to discuss specific barriers to adherence with their patients.

This study is crucial for addressing key methodological limitations in past research and replicating recently proposed innovative methods for assessing these relationships. Replication of findings is particularly important to examine how these findings may be different in various study populations. T2D represents a unique chronic condition that can present with a heterogenous set of symptoms and self-management routine for each patient (Karalliedde & Gnudi, 2014). Moreover, this illness disproportionately effects socioeconomically disadvantaged and ethnic minority groups, which represents a large portion of our patient population (Gray et al., 2017). It is important to understand the nature of these relationships within this population that may present differently than previously studied groups. By conducting these analyses within our population, it provides researchers and clinicians with specific and novel information with the hope to guide clinical care for patients in the future. Finally, past research has largely used adherence measures with moderate to weak validity. Our study uses statistically sound adherence measures with strong internal consistency to improve overall methods for examining the proposed relationships.

Specific Aims

Aim 1: Evaluate the contributions of patient-related variables in predicting medication beliefs

- H1: Higher level of education and higher household income will be significantly associated with increased beliefs about the necessity of taking medication
- H2: Older age and Hispanic ethnicity will be significantly associated with decreased beliefs about the necessity of taking medication
- H3: Older age, higher level of education, and higher household income will be significantly associated with decreased concerns about taking medication
- H4: Hispanic ethnicity will be significantly associated with increased concerns about taking medication

Aim 2: Evaluate the contributions of illness-related variables in predicting medication beliefs

- H1: Insulin use, higher number of medications, and higher HbA1c will be significantly associated with increased necessity beliefs about taking medication

- H2: Insulin use, higher number of medications, and higher HbA1c will be significantly associated with increased concerns about taking medication

Aim 3: Evaluate the extent to which patients' medication beliefs are associated with medication adherence by using polynomial regression

- H1: Polynomial regression analyses will reject the use of the constrained difference score model to examine the relationship between necessity and concern beliefs and adherence
- H2: Polynomial regression will test polynomial models of increasing term order to determine the best fitting model for evaluating the relationship between necessity and concern medication beliefs and adherence

Chapter II: Design and Methods

Description of the Study

This project conducted a secondary analysis of data from the baseline visit of a longitudinal, randomized effectiveness trial, entitled “Translating telephonic diabetes self-management support to primary care providers” (IRB 2012-422, PIs: Gonzalez and Wu). The NYC Care Calls or “Tele-SMS” program has completed data collection and is currently in the process of analyzing the data for the larger study. The RCT focuses on the effectiveness of a diabetes self-management and distress-management support program delivered via phone in improving individuals’ self-management, glycemic control, and emotional well-being. This telephonic support program is compared to a lower intensity enhancement of standard of care, which involves provision of print materials for participants on related topics of diabetes management, emotional distress, depression and stress management. The aims of the current study examine the specific relationships with individuals’ medication beliefs and adherence as well as introduce novel methods for analyzing these relationships. This study builds upon the foundation of the parent study to evaluate these relationships in more detail as they relate to the study population.

Study Design of the Parent Study

The NYC Care Calls program is a 12-month prospective randomized trial comparing the effectiveness of Tele-SMS to enhanced usual care (J. S. Gonzalez et al., 2020). This program expanded upon previously evaluated Tele-SMS studies by including new content for emotional distress management. The enhanced usual care condition (EUC), or control condition, provided participants with print materials in the mail on topics related to diabetes self-management and stress management. The experimental Tele-SMS condition consisted of stepped tiers of increasing intensity level based on the participant's baseline HbA1c and distress. Participants in this treatment arm received 6-12 calls over 1-year focusing on psychoeducation about diabetes self-management and strategies for stress management. Levels of treatment were intensified by increasing the frequency of calls the participant received. Individuals in the experimental condition also received the same print materials as participants in the EUC. The materials and the phone calls were offered in both English and Spanish to each treatment condition. All data for the study were derived from the baseline assessment, prior to any intervention. Complete details of the rationale and methods of the parent study can be reviewed in the study design paper (J. S. Gonzalez et al., 2020).

Participants and Recruitment

Screening, Recruitment, and Attrition. Participants were recruited through primary care practices (PCP) affiliated with the New York City (NYC) Department of Mental Health and Hygiene's (DOHMH) Primary Care Information Project (PCIP). The PCIP supports the adoption of electronic medical records (EMR) and quality improvement projects among small PCPs to facilitate the use of population health tools through shared patient panel management. The PCIP network includes PCPs throughout the five boroughs of NYC. The aim of parent study was to target a study population that reflects the racial, ethnic, and gender profile of individuals with T2D in NYC. Diabetes is highly prevalent among minorities, particularly Blacks and Hispanic/Latinos (Centers for Disease Control and Prevention, 2017), who make of a significant portion of the population in NYC, 22.8% and 29.2%, respectively

(Health, 2016). Furthermore, minority populations frequently experience a high prevalence of diabetes complications, poor access to high-quality care, and reduced health literacy (Control & Prevention, 2017; Gray, Barton, Azam, & Bonnett, 2017). Therefore, the targeted study sample represents an ideal population to examine my aims.

For this study, potentially eligible participants were identified through the query functionality in the EMR systems at affiliated PCPs and were sent letters on the clinic stationary by PCIP on behalf of the primary care providers After one week, prevention outreach specialists made telephone calls to the individuals who received letters and did not opt-out of the study. On each call, the outreach specialists explained the purpose and nature of the call and proceeded with describing the study and initiating the eligibility screening procedures if the individual expressed interest in the study.

Power analysis for the parent study determined that a sample size of 700 participants were needed for a complete analysis. It was estimated that 875 participants needed to be enrolled to anticipate 20% attrition rate in order to yield a final sample size of 700. The NYC Care Calls study completed data collection with 812 participants (J. S. Gonzalez et al., 2020). Thus, the power analysis conducted for the larger parent study suggests that sufficient enrollment numbers have been reached to complete our proposed secondary analyses.

Eligibility Criteria. Inclusion criteria included: 1) Adults 21 years of age or older; 2) diagnosed with T2D for at least one year; 3) receiving diabetes treatment from participating PCIP practices; 4) recent HbA1c ≥ 7.5% from EMR; 5) ability to speak English or Spanish with access to a telephone; 6) willingness to give informed consent to participant and accept random assignment.

Exclusion criteria included: 1) stated intention to move out of NYC area or change PCP during the next year; 2) cognitive impairment (i.e., confusion) as determined by DOHMH staff.

Measures

After informed consent, outreach specialists collected baseline data prior to randomization. EMR-based outcome data (6-month and 12-month) and self-reported follow up data were also collected by outreach specialists. Only the following baseline assessment data were used for these secondary analyses. The outreach specialists were assigned a list of participants to contact for self-reported data while remaining blind to group assignment. Assurances were also made that no intervention participant is contacted by his/her own Tele-SMS interventionist. All self-report study measures have been translated into Spanish as well.

Demographic information. A basic demographic questionnaire was used to gather information regarding a variety of background characteristics including age, race, ethnicity, marital status, education, household income, occupation, birthplace, years living in the U.S., family structure, health insurance coverage, employment status, and duration of diagnosed diabetes. Questions regarding medical treatment including list of diabetes medications and insulin use, were also integrated into the background questionnaire.

Glycosylated hemoglobin. HbA1c levels recorded in PCIP practice EMR systems were collected for analysis at assessment time points, at baseline (no more than 3 months prior to enrollment), at 6-months post randomization (+/- 1.5 months), and at 12 months post randomization (+/- 1.5 to 3 months post). If HbA1c levels were not recorded in the practice EMR system, study staff attempted to extract information from the HbA1c registry with consent of the participant.

Beliefs About Medicines Questionnaire (BMQ*).* The BMQ is a validated 18-item, self-report measure assessing individual's specific and general beliefs about medications, including whether they are harmful or beneficial. The measure is divided into two sections, BMQ-Specific, which includes 10 items assessing individuals' beliefs about specific diabetes medications prescribed for personal use, and BMQ-General, which includes 8 items assessing individuals' beliefs about medication use and medicines in general. Only the BMQ-Specific was used for this study. The BMQ-Specific is comprised of two 5-item subscales, assessing beliefs about the necessity of prescribed medication for managing one's illness and concerns about the potential side effects or adverse consequences of taking the medication (Horne & Weinman, 1999). Responses are scored on a 5-point Likert scale ranging from 1 (strongly agree) to 5 (strongly disagree). Higher scores on the scales indicate more disagreement with the statements and thus weaker necessity and concern beliefs. The BMQ has been widely used and validated among a variety of patient populations, including diabetes (Jimenez et al., 2017). It has shown to have good validity and reliability across studies, ranging from .55 to .86 for the Necessity Scale, and .65 to .80 for the concerns scale (Aikens & Piette, 2009; Horne et al., 1999; Jimenez et al., 2017). The BMQ-Specific scale for this sample proved to have adequate internal consistency with Cronbach's alphas of .74 and .71 for the Necessity and Concerns scales, respectively.

Adherence to Refills and Medications Scale-For Diabetes (ARMS-D). The ARMS-D is a validated 11-item, self-report measure assessing medication adherence with questions related to one's ability to take and refill medications across different situations that may create barriers to medication taking. The ARMS-D was modified from the original ARMS to specifically capture medication adherence among individuals taking diabetes medication, rather than across all predicted medications and therefore is a more appropriate measure for this study population. Responses are scored on a 4-point Likert scale ranging from 1 (none of the time) to 4 (all of the time). Questions assess occurrences of forgetting or missing medication and thus higher scores on the measure indicate worse adherence. The ARMS-D has two subscales as well: Medication Taking and Refills. The medication taking subscales is comprised of questions related to forgetting or intentionally missing medications. The refills subscale is comprised of questions related to running out of medications due to intentionally or unintentionally not having the prescription refilled. This measure has shown good validity and reliability ($\alpha = 0.86$) as well as independently predicting glycemic control (Mayberry et al., 2013). The medication taking and refills subscales have shown to have good ($\alpha = 0.84$) and acceptable ($\alpha = 0.71$) reliability, respectively. The ARMS-D total score for this sample proved to have high internal consistency with Cronbach's alpha of 0.78. Internal reliability for the medication taking subscales was also high ($\alpha = 0.82$), while the reliability for the refills subscale in our sample was poor ($\alpha = 0.5$). Items within the refills subscale were further examined and it was determined that reliability would not be significantly improved by eliminating any items. Therefore, the full refills subscale was retained for analysis.

Data Analysis

Overview of approach

Statistical analyses were conducted using SPSS software version 25.0. Visual inspection of the data and descriptive statistics were conducted to assess for normality and multicollinearity between study variables. Data cleaning and screening procedures inspected for outliers and missing values. Descriptive statistics were also used to inform sample characteristics and Pearson correlations were conducted to examine correlations between study variables.

Aim 1: Multiple linear regression was conducted to test the independent contributions of patient-related (e.g., age, education, household income, and Hispanic ethnicity) variables on necessity and concerns medication beliefs. Only the BMQ-Specific scale was used for this analysis. Two sets of analyses were performed with each subscale of the BMQ-Specific to examine the independent contributions of predictor variables on an individuals' beliefs about the necessity of their diabetes medications and their concerns about their diabetes medications.

Aim 2: Hierarchical linear regression models were conducted to test the independent contributions of illness related (e.g., insulin use, number of medications, HbA1c) variables on necessity and concern beliefs, after controlling for patient-related variables. Similar to Aim 1, only the BMQ-Specific scale was used for this analysis and two sets of analyses were performed with each subscale. In each model, patient-related variables (e.g., age, education, household income, and Hispanic ethnicity), were entered into step 1 and illness related variables were entered into step 2.

Aim 3: Polynomial regression analyses were conducted to evaluate the multidimensional effect of necessity and concern medication beliefs on self-reported adherence. The first step assessed the accuracy of the strict algebraic difference score and evaluated the appropriateness for use of the difference scores in this sample. Relative fit of the difference score model was determined by reviewing four criteria: 1) the unconstrained regression model ($Z=b_0+b_1X+b_2Y$) must explain a significant amount of variance in predicting adherence; 2) the regression coefficients for the necessity and concerns scales must be significant and in the expected direction (reciprocal effects i.e. necessity beliefs positively predict adherence and concerns negatively predict adherence); 3) the magnitude of the necessity and concerns coefficients must be equal, according to the constraints of the two-dimensional difference score model; 4) higher order models do not explain significant variance beyond the linear terms.

If the difference score is rejected, the second step of the analysis conducts polynomial regression models of increasing order to determine which model (linear, quadratic, cubic) is the best fit for this sample. Hierarchical linear regression evaluated the models of increasing order by entering the terms of each order model together as a step into the regression. The highest order model that explains significant incremental variance in medication adherence was determined the best fitting model. The concerns and necessity beliefs subscales were scale-centered to reduce multicollinearity. Response-surface analysis was conducted as well to aid with interpretation of the three-dimensional effects of necessity and concern beliefs on medication adherence.

Power Analysis

Power analyses were conducted to determine the likelihood of yielding statistically significant results (Cohen, 1988). G*Power 3.1 was used for a priori power analysis (Faul et al., 2007).

Aim 1: Power analysis indicated the necessary sample size for conducting regression models with a medium effect size (f^2=.15), six predictors, and 80% power, is at least 61 participants for these analyses.

Aim 2: Power analyses indicated that for regression models with medium effect size (f^2=.15), nine predictors, and 80% power, a sample size of at least 72 is required to complete these analyses.

Aim 3: In order to conduct a polynomial regression testing the incremental variance of higher order interaction terms, power analyses indicated that the sample size required with a small effect size (f^2=.02) and 80% power, is at least 485 participants. This likely represents a conservative minimum but this study has ample sample size to conduct this aim.

Ethics

The current study is included under the larger parent study, which has been approved by the Institutional Review Board at the Albert Einstein College of Medicine of Yeshiva University (IRB 2012-422).

Risks and Benefits

The study procedures were minimal risk to participants. Measures are noninvasive, and most assessments have been used in past research without adverse incidents. Potential risks include disclosure of confidential information and discomfort in discussing the assessment material. All study participants are given informed consent through a process which informs participants of the use of PHI and selected elements of patients' medical records from EMR systems. All study data (EMR based data and self-report measures) are recorded under study ID number and kept under password protected computer systems. Only study investigators have access to this information. This study cannot guarantee direct benefits; however, the findings of this study may add to our body of knowledge and inform future interventions for individuals with diabetes.

Chapter III: Results

The following chapter will present the main findings of the study hypotheses outlined above. I will first describe how the study data was cleaned and reviewed in preparation for data analysis. I will then present the descriptive statistics for all main study variables and the findings for each statistical test performed for the study hypotheses.

Recoding procedures:

The income variable was recoded from the original five groups (20-29K, 30-39K, 40-49K, 50K or more) into two groups (Income over 20K, Income under 20k) to aid in interpretation of the results, as 65% of participants with income data had a reported income less than $20,000/year and the remaining 34% of participants with income data were distributed across the four income groups. The education variable was also recoded from the original six groups (8th grade or less, 9th-11th grade, Grade 12 or GED, some college or technical school completed trade or technical school, college 4 years or more) into three groups (Less than High School, High School, Beyond High School). The original distributions of the scales can be been in Appendix A, supplemental table 1 and supplemental figures 1 and 2.

The race variable was collected as a separate variable from the ethnicity variable to include six categories (Black, White, Asian, Native American/Pacific Islander, American Indian/Alaska Native, and Other). Preliminary analyses were conducted to determine the utility of combining the ethnicity and race variables for the analyses. Three groups were created: Hispanic (N=697, 86%), Non-Hispanic Black (N=89, 11%), Non-Hispanic Other (N=21, 2.6%). There were not enough cases of Non-Hispanic Other to be included into the analyses due to the limited number of participants identifying with that category (N=21). Further analyses were conducted to examine differences between the Non-Hispanic Black and Non-Hispanic Other groups. These two groups exhibited a sample-level difference among education level (X^2 (2, 110)= 13.15, p<.001) (See appendix A, supplemental table 2). Partial correlations were conducted to examine the impact of controlling for education on the outcome variables (See appendix A, supplemental table 3). Education level did not alter any of the outcome results and therefore it was determined that the Non-Hispanic Black and Non-Hispanic Other variables could be combined to create one binary category for the ethnicity variable: Hispanic ethnicity.

The BMQ-specific subscales, Necessity and Concerns, were reverse scored so that higher scores on each subscale indicated stronger beliefs to aid in interpretation of the results. These predictor variables for the polynomial regression were then scale-centered to further aid in interpretation. Polynomial terms were created using the centered predictor variables including, quadratic terms, cubic terms, and quartic terms.

Subscales for the ARMS-D measure were created for supplementary analyses. Subscales include the Medication Taking Subscale and Refills Subscale. Supplemental analyses were conducted with ARMS-D subscales (See appendix D).

Missing Data

In the total sample (N=812), 36% of participants were missing values for income level (missing cases n=292). Supplemental analyses were conducted to evaluate the impact of the missing data on the main analyses. Descriptive statistics were examined for the sample of individuals who were missing values for reported income (See appendix A, supplemental table 4). Crosstabs and t-tests compared participants with and without income data. Participants who indicated their income level were significantly different from those who did not indicate income level in education level and Hispanic ethnicity (See appendix A, supplemental table 5). There were no other significant differences between income responders and non-responders.

A robustness analyses was conducted to determine the impact of the income variable on the relationship of other variables with the medication belief outcome variables. High (Income over 20K) and Low (Income under 20K) income values were each imputed for participants with missing income data (See appendix A, supplemental table 6). Regression analyses were conducted for each imputation and compared to the base analyses that excluded cases with missing income data. Results of the robustness analyses indicated that missingness of the income variable does not seem to significantly impact the outcome variables, as the coefficients of the variables for each high- and low-income imputation fell within the confidence limits of the base analysis. Additional analyses were conducted to further assess the potential impact of the missing income data and reduced sample size on relationships in the models (See appendix A, supplemental table 7). Regression models with and without the income variable were tested and compared to the base analyses: 1) model excluding the income variable all together, 2) model with the income variable after participants with missing income data were excluded, 3) model without the income variable after participants with missing income data were excluded. Results demonstrate no significant changes in the relationships between study variables across all four regression models. Consequently, the income data were deemed appropriate to utilize in the analyses. Pairwise deletion was used for all analyses.

In the total sample, 8% of participants (N=63) were missing at least one value for diabetes medications due to unrecognizable or unidentifiable medication names recorded. Missing data is attributed to examiner error in recording information and thus assumed to be missing at random. Individuals with missing medications data were excluded from analyses.

Participants

812 participants completed the baseline assessments of the study. Table 1 displays the average age of the participants was 59.2, with slightly more females than males, 56% to 43%, respectively. The majority of participants were Spanish speaking (78%) and identified as having Hispanic ethnicity (85%). The highest level of education completed was high school for most of the sample (74%) and over half of those who reported their income indicated earning less than 20k per year. Participants had an average of 12.4 years since diagnosis of Diabetes and over a third were prescribed insulin. On average, participants reported higher level of beliefs about the necessity of taking diabetes medication than their level of concerns about taking diabetes medication. This finding is consistent with previous studies, whose participant samples also had a higher average levels of necessity beliefs on average than concerns about medications (Dillion 2018, Phillips 2014, Aikens and Piette 2009). Furthermore, the majority of participants (94%) endorsed high levels of necessity beliefs (i.e., scores greater than scale midpoint), yet 71% of the participants endorsed strong concerns about medications as well (i.e., scores greater than scale midpoint). These figures are somewhat higher than previous studies; thus, representing a higher average level of reported concerns and necessity beliefs among our study population overall (Horne et al.,

2004; Neame & Hammond, 2005). The majority of participants reported a high level of adherence (i.e., scores lower than scale midpoint), with 36% of study participants reporting perfect adherence.

Descriptive Statistics

Descriptive statistics including, mean, median, range, frequencies, skewness and kurtosis, were examined for each variable in the analyses (Table 2). Scatter plots and histograms were generated for each primary outcome variables to evaluate whether variables were normally distributed. Variables were examined for multicollinearity and homoscadacity as well. Mahalanobis distance was calculated to examine outliers; extreme outliers ($p<.01$) were removed from the analyses. After removal of extreme outliers, the ARMS-D medication adherence variable was found to be positively skewed. A log transformation was conducted to improve normality for the variable (Table 3). Transformation improved skewness of the ARMS-D variable. Analyses were conducted with both the original and transformed ARMS-D variable to determine the extent to which the skewed variable affected the results. The original ARMS-D variable was presented in the main analyses for ease of interpretation and purposes of cross-validation with future studies. Results from analyses with the transformed variable are presented in supplemental tables (Appendix C).

Main Analyses

Bivariate relationships between study variables

The relationships among continuous patient-related factors, illness related factors, medication beliefs, and medication adherence were examined using Pearson product-moment correlations (Table 4). Age was positively associated with necessity beliefs ($r= .10$, $p<.001$); however, it was not found to be significantly associated with concerns. Number of diabetes medications was positively associated with necessity beliefs (r=.12, p<.001) and was not significantly associated with concerns. A1c was not found to be significantly associated with either necessity or concerns beliefs. Age (r= -.19, p<.001) and necessity beliefs (r= -.13, p<.001) were both significantly associated with better medication adherence as measured by the ARMS-D, while A1c (r= .10, p<.001) and Concerns (r=.18, p<.001) were significantly associated with worse adherence. Most study variables that were significantly associated with the full scale ARMS-D adherence measure were also associated with the refills and medication taking subscales. Of note, A1c was significantly associated with the medication taking subscale, yet was not found to be significantly associated with the refills subscale.

Table 5 displays descriptive statistics for categorical patient-related and illness-related factors by each medication belief. Hispanic participants reported greater concerns (M=3.12 SD=.73, p<.001) and greater necessity beliefs (M=3.585 SD=.59, p<.001) compared to non-Hispanic participants. Participants with an income under $20,000/year reported higher concerns (M=3.08 SD=.72, p<.05) and higher necessity (M=3.86 SD=.59. p<.05) than participants with an income over $20,000/year. Those who reported their highest level of education as less than high school reported higher necessity beliefs (M=3.95 SD=.53, p<.001) and higher concerns (M=3.17 SD=.73, p<.05) than both individuals with a high school education and those with education beyond high school. Finally, participants who are prescribed insulin reported higher necessity beliefs (M=3.91 SD=.56, p<.001) than those who are not prescribed insulin. Insulin users did not report significantly different concerns than participants not using insulin.

Descriptive statistics for categorical patient-related and illness-related factors by reported adherence are displayed in Table 6. Hispanic participants reported better adherence

(M=13.60 SD=3.3) compared to non-Hispanic participants (M=14.68 SD=4.5, $p<.05$). Adherence was not significantly different between education, income, or insulin user groups.

Aim 1

Multiple linear regressions were conducted to test the independent contributions of age, education, household income, and Hispanic ethnicity variables on necessity and concerns medication beliefs, as can be seen in Table 7. Models for each beliefs scale, necessity and concerns, were generated. Assumptions were met (See appendix B, supplemental figure 3&4) and 509 cases were included in the models after removal of outliers and pairwise deletion due to missing income data. All patient-related variables were entered together in the first step. Income was negatively associated ($\beta= -.09$, $p<.05$) and Hispanic ethnicity was positively associated with concern beliefs ($\beta= .13$, $p<.01$). The concerns model overall was significant ($F(4,509)=4.77, p<.001$) and patient-related variables explained 3.6% of the variance in concern beliefs. Within the necessity model, higher level of education ($\beta= -.09$ $p<.05$) was negatively associated with necessity beliefs and Hispanic ethnicity was positively associated with necessity beliefs ($\beta= .15$, $p<.01$). The overall model was significant ($F(4,508)=6.80, p<.001$) and patient-related variables explained 5.1% of the variance in necessity beliefs. Based on these findings, this hypothesis was partially supported, as the relationship between concerns and Hispanic ethnicity and income supported the proposed hypotheses, however, the relationship between necessity beliefs and education and Hispanic ethnicity proved to be opposite the proposed hypotheses.

Aim 2

Hierarchical linear regression was conducted to test the independent contributions of insulin use, number of medications and HbA1c on necessity and concern beliefs, after controlling for patient-related variables (Table 8). Models for each beliefs scale, necessity and concerns, were generated. Assumptions were met (See appendix B, supplemental figure 5&6) and 465 cases were included in the models after removal of outliers and pairwise deletion due to missing income data. Patient-related variables were entered into step 1 as covariates, and illness-related variables were entered into step 2.

None of the illness-related variables were significantly associated with concern beliefs; however, insulin use (β=.11, $p<.05$) and number of diabetes medications (β=.12, $p<.05$) were both positively associated with necessity beliefs. The overall concerns model was significant ($F(7,465)=2.59$, $p<.05$). Covariates (step 1) explained 3.5% of the variance in concerns and illness related variables (step 2) explained .3% additional variance in concerns beliefs. Hispanic ethnicity proved to be only variable significantly associated with concern beliefs in this model. The overall necessity beliefs model was significant ($F(7,465)=7.55$, $p<.001$). Covariates explained 6.3% of the variance in necessity beliefs and illness related variables explained an additional 4% variance in beliefs about necessity. Based on these findings, this hypothesis was partially supported, as the relationship between necessity and insulin use and number of diabetes medications was consistent with our hypotheses; however, no significant relationships were found between illness-related variables and concerns.

Aim 3

Confirmatory Polynomial

Four criteria were evaluated to assess the accuracy of the strict algebraic difference score and evaluate the appropriateness for use of the difference scores in this sample. The algebraic difference score model was rejected, as higher order terms predicted significant incremental variance to the unconstrained model as compared to linear terms (Table 9).

Assumptions were met (See appendix B, supplemental figure 7) and 788 cases were included in the models after removal of outliers. Testing the first criterion demonstrated that the unconstrained polynomial model explained significant variance in the outcome [$F(2,787)=22.55$, $p<.001$]. Criterion two showed that the coefficients for necessity ($B= -.850$, $p<.001$) and concerns ($B= 1.040$, $p<.001$) were significant and in the expected direction. However, for the third criterion, the unconstrained model did not explain significant incremental variance over the constrained model [$F(1,785)=.595$, $p=.441$]. Therefore, the coefficients did not prove to be of significantly differing magnitude and the fourth criterion was tested to evaluate whether higher order models explain significant variance beyond the linear terms. Higher order terms were found to predict significant incremental variance to the unconstrained model [Increase in $R^2=.018$, $F(2,782)=4.98$, $p<.01$)]. Thus, the relationship between X and Y is best explained by higher order models in this sample.

Exploratory Polynomial

The difference score model was rejected, and thus exploratory polynomial regression analyses were conducted to test higher order polynomial terms for concerns and necessity beliefs to establish model fit (Table 10). The highest order model that explained significant incremental variance in medication adherence determined the best fitting model. The linear (R^2 change=.054, $p<.001$), quadratic (R^2 change=.018, $p=.002$), cubic (R^2 change=.020, $p=.020$), and quartic (R^2 change=.023, $p<.001$) models all predicted the outcome. While the cubic and quartic model demonstrated significant incremental variance in this sample, these findings appear to be influenced by a handful of discrepant cases and the additional higher order terms added only minor curvatures with no significant alteration to the overall shape of the surface. It is also unlikely for the cubic and quartic models to uphold with cross-validation in other samples (Edwards, 1994, 2002). Moreover, the outcome variable was found to be positively skewed and sensitivity analyses were conducted with a log transformed adherence variable (See appendix C, supplemental table 8&9). Results from these analyses demonstrated that the quadratic model was the highest order model to explain significant variance in the outcome. Nevertheless, the non-transformed data is presented for ease of interpretation. Based on the findings from the sensitivity analyses and support for cross-validation, the quadratic model was interpreted and graphed as the best fitting model. Response surface analysis was conducted to aid in interpretation of the three-dimensional effects of beliefs on adherence (Figure 3).

As illustrated in figure 3, adherence was highest when necessity beliefs were high and concerns were low, and adherence was lowest when necessity beliefs were low, and concerns were high. This demonstrates intuitive and reciprocal effects as supported by the NCF. Non-reciprocal effects were also evident: adherence was slightly higher when concerns and necessity beliefs were both low, than when concerns were high and necessity beliefs were high. These effects would not have been identified without the use of the three-dimensional analysis of these relationships. Furthermore, adherence decreased more sharply at the extreme low values of necessity and high values of concerns, as can be seen in the figure.

Chapter IV: Discussion

The purpose of this study was to examine the associations among patient-related and illness-related factors with T2D medication beliefs as well as the associations among medication beliefs and medication adherence through an exploratory multidimensional modeling approach. Several significant relationships were found among patient-related and illness-related factors with medication beliefs. Polynomial regression rejected the use of the difference score model for testing the relationships between medication beliefs and adherence this sample. Exploratory analyses demonstrated that higher order polynomial models explained significant incremental variance in predicting medication adherence and thus are a superior fit over the linear terms.

The first aim of the study was to evaluate the contributions of patient related variables in predicting beliefs about the necessity of taking medication as well as concerns about taking medications. It was hypothesized that a higher level of education and higher household income would be significantly associated with increased necessity beliefs, while older age and Hispanic ethnicity would be significantly associated with decreased necessity beliefs. Results showed that Hispanic ethnicity and education level were significantly associated with necessity beliefs; however, the direction of these relationships ran counter to our expectations. Those with more than a high school level of education perceived their diabetes medication regimen as less necessary for maintaining their health than those with lower education levels and Hispanics perceived a greater necessity of taking their diabetes medications than non-Hispanics, which in this sample were primarily comprised of those who self-identified as Non-Hispanic Black/African American (11%) or Non-Hispanic White (2.6%). Age and income were not independently associated with necessity beliefs within multivariate analyses.

In terms of concerns beliefs, it was hypothesized that older age, higher level of education, and higher household income would be negatively associated with concerns about taking diabetes medications, while Hispanic ethnicity would be positively associated with greater concerns. Findings revealed significant relationships between income and Hispanic ethnicity with concerns beliefs. Income was negatively correlated with concerns and Hispanic ethnicity was positively correlated with concerns, both supporting the proposed hypotheses of the relationships. Education not independently associated with concerns within the multivariate model.

Numerous studies have highlighted increased concerns related to taking prescribed medications among ethnic minorities, and particularly among Hispanic individuals (Aikens & Piette, 2009; Huang et al., 2009; Lange & Piette, 2006). This study supports this finding; however, more limited research has been conducted examining the relationship between ethnicity and beliefs about the necessity of taking diabetes medication. Research by Aikens and Piette (2009) studied this relationship and while they found the relationship to be negatively correlated, it was not found to be statistically significant in their analyses. Studies have indicated that due to the increased concern about medications among ethnic minorities, these individuals are likely have weaker views about the necessity of taking mediation (Piette et al., 2010). However, as can be seen in this study, individuals identifying as Hispanic reported higher concerns and higher beliefs about the necessity of taking their diabetes medications. One qualitative study demonstrated that African American and Mexican Americans mentioned more doubts about whether prescribed medications were necessary as compared with white participants (Lynch et al., 2012). Research has also demonstrated that Latinos have been more likely to report greater concerns about side effects, development of dependency, and associated costs of medications as compared to African Americans (Huang et al., 2009). Latino/Hispanic patients have also reported higher levels of fatalism as compared to White, Black, and Asian patients (Lange & Piette, 2006). Previous literature has provided various explanations for why minorities tend to report higher concerns about taking medications including, cultural beliefs and perceived discrimination (Hill-Briggs et al., 2005; Piette et al., 2006). It is possible that while they have higher concerns, factors such as medication related information may lead to increased beliefs about necessity.

The current study used the variables of level of education and yearly household income as markers of socioeconomic status. Few studies have examined the independent relationships of these factors with beliefs, and consequently previous findings have been somewhat variable. While our results demonstrated a significant association between education level and necessity beliefs, it was not in the expected direction. This may be related to the limited research examining these relationships specifically among individuals with T2D. Previous studies have primarily focused on other conditions, which are likely viewed very differently by patients. Moreover, in the context of the literature examining the Beliefs about Medicine Questionnaire, few studies have focused on participant samples of primarily Hispanic ethnicity and low socioeconomic status. (Mann et al., 2009a). The majority of participants in this study identified as Hispanic (85%) was Spanish-speaking (78%), with a household income of less than $20,000 per year, and a high school education or less. Among those who identified as non-Hispanic, 81% identified as Black/African American. Thus, our study was limited in its examination of ethnic/racial differences relative to non-Hispanic Whites. Moreover, 66% of the participants reporting income indicated earning less than $20,000/year. This further limits comparisons between lower income individuals to those earning higher levels income and null findings or those opposite our expectation may be influenced a floor effect of the distribution of income and education. Nonetheless, these findings provide valuable information into the complex nature of individuals' beliefs about their medicines due to the limited availability of research in this area overall.

The second aim of the study was to evaluate contributions of illness-related variables in predicting necessity beliefs and concerns about taking diabetes medications. It was hypothesized that insulin use, higher number of medications, and higher HbA1c would be significantly associated with increased necessity beliefs and increased concerns. Findings revealed that both insulin use, and number of prescribed diabetes medications were positively correlated with beliefs about the necessity of taking one's diabetes medication, supporting the proposed hypothesis. HbA1c was not found to be significantly associated with necessity beliefs in both bivariate and multivariate models. None of the illness-related variables were significantly associated with concerns in bivariate or multivariate models.

These findings are consistent with previous literature indicating that individuals who use insulin often rate their diabetes as more serious and severe thus rate their beliefs about the necessity of taking their diabetes medications higher (Aikens & Piette, 2009; Brod et al., 2008; Hampson et al., 1991; Polonsky et al., 2005). Research has also shown that the more medications patients take, the stronger views they have about the necessity of taking their prescribed treatment (Aikens & Piette, 2009; Clyne et al., 2017). The lack of significant findings related to illness-related variables and concerns highlights the multitude of factors that may impact individuals' beliefs about medicine. While some studies have demonstrated the relationship between certain illness-related factors, limited research exists and largely suggests variability in findings. Of note, it has been supported that necessity and concern beliefs are associated with different determinants, such that necessity beliefs were associated with more clinical variables, and concerns or perceived harmfulness of medications were associated with more psychosocial or demographic variables (Aikens et al., 2008; Aikens & Piette, 2009). Participants in this study on average were diagnosed with diabetes for over 12 years. It is possible that patients who are newly diagnosed with diabetes or newly prescribed medicines hold stronger concerns about the harmful effects of the medication. Overall, this sample reported higher beliefs about the need to take medications than their concerns about diabetes medications. This is supported by a recent study which found that the general beliefs about the harmful or addictive effects of medication among newly diagnosed T2D patients decreased from the initiation in the study (less than a year after receiving diabetes diagnosis) to follow up four months later following their routine education consultations (M. G. Pereira et al., 2020). The lack of significant findings among illness-related factors with concerns may be influenced by the longer duration of diagnosed diabetes among study participants. Differences in severity or presence of side-effects of medications among our study population compared to other illness populations may have influenced our findings as well. It is possible that the participants in our study perceived a lower level illness symptoms or side-effects from their medications overall, thus contributing to the null findings of the relationship between illness-related factors and concerns. Research has shown that patients with diabetes report less concerns than patients with other illnesses including, asthma, renal failure, cardiac disease, and psychiatric disorders (Horne et al., 1999). Endorsement of higher levels of concerns in other study populations may be a result of higher levels of perceived side-effects of medications and therefore, these results may vary among different illness populations.

Aim three of this study sought to evaluate the extent to which patients' medication beliefs are associated with medication adherence through the implementation of polynomial regression, a novel methodological approach. This approach was used to test the Necessity-Concerns Difference Score (NCD) typically used in previous research to analyze the predictive value of the score in determining adherence. As described earlier, several limitations exist with the use of this methodology. A confirmatory approach was conducted to test whether the NCD or the constrained model was the best fitting model to examine the relationship between medication beliefs and adherence. It is referred to as the constrained model due to the limitations of the constraints it imposes, i.e., the implication that every one-point increase in necessity beliefs has an equivalent effect on adherence as every one-point decrease in concerns. It was hypothesized that the constrained model would be rejected as the best fitting model through the examination of four specific criteria described in the description of the analyses section. Results from the study supported our hypotheses and the constraints implied by the NCD were found to be inaccurate. Higher order terms in the regression predicted significant incremental variance to the unconstrained model as compared to linear terms. Our findings support previous research that demonstrated the NCD is not the best fitting model through the implementation of polynomial regression (Dillon et al., 2018; Phillips et al., 2014; West et al., 2018).

Following the confirmatory analyses, an exploratory approach was conducted to test polynomial models of increasing term order to determine the best fitting model for examining the relationship between medication beliefs and adherence. Due to this novel approach, limited research has been conducted using this methodology to examine the NCF. It has been supported by a handful of studies that the NCD is not the best fitting model, yet research thus far has produced variable findings as to which polynomial model is the best fit to examine these multidimensional relationships. These studies were conducted across different illness populations and only one other known study to date has implemented this approach among a diabetes population. Consequently, our findings represent an important contribution to the replication of prior results and have implications for future studies.

The quadratic model was found to be the best-fitting model in our study to assess the multidimensional relationships. Reciprocal and non-reciprocal effects were evident in the findings. Reciprocal effects demonstrated that adherence was highest when necessity beliefs were high and concerns were low, and adherence was lowest when necessity beliefs were low and concerns were high. Non- reciprocal effects showed that adherence was slightly higher when concerns and necessity beliefs were both low, than when concerns was high and necessity beliefs were high. Upon inspection of the graph and results from the regression, a curvilinear effect of concerns can be seen. Results show significant interaction between necessity beliefs and concerns, such that the effect on adherence is exponentially worse as concerns increase and necessity beliefs decrease. When concerns are elevated, adherence improves as necessity beliefs increase. However, adherence is poorest when both necessity and concerns are high as compared to when both are low. Thus, is can be concluded that low concerns are necessary but not sufficient for adherence and having both low concerns and high necessity beliefs is optimal for good adherence.

These results are noteworthy in extending the current body of research assessing the multidimensional relationships between medication beliefs and adherence among individuals with T2D. Similar to a large body of literature assessing the relationship between beliefs and adherence, we confirmed the reciprocal, intuitive relationship between higher concerns and lower necessity beliefs to be associated with poorer adherence. However, most of these studies looked at these constructs separately (Horne et al., 2004; O'Carroll et al., 2010), used the difference score model (Clifford et al., 2008; Horne & Weinman, 1999, 2002) or created categories with cut off scores for the medication beliefs (Clatworthy et al., 2009; Mann et al., 2009a). However, as noted throughout our paper, these methodologies hold several limitations that may increase type 1 and type 2 errors (Dillon et al., 2018). Our study not only demonstrated that the use of the NCD is inaccurate, but also highlighted non-reciprocal relationships between the constructs that would not have otherwise been seen without the use of these analyses.

Only a few previous studies are known to have utilized polynomial regression to examine the relationships between medications beliefs as assessed by the BMQ and medication adherence. Our results support both the reciprocal and non-reciprocal effects found in these previous studies demonstrating that individuals with indifferent attitudes (low concerns and low necessity) have higher reported adherence than individuals with ambivalent attitudes (high concerns and high necessity) (Dillon et al., 2018; Phillips et al., 2014; West et al., 2018). Research conducted within a stroke survivor population and a study examining three different chronic conditions (diabetes, asthma, cardiovascular conditions) both concluded the linear model was the best fitting model for their samples (Phillips et al., 2014; West et al., 2018). The current study was consistent with research among patients with hypertension who also found the quadratic model to be the best fit (Dillon et al., 2018). Variations in findings likely reflect differences both in the illness population studied as well as the adherence measure that was used. The quadratic model demonstrates additional curvature effects with sharper increases or decreases at extreme values of necessity and concern beliefs. The type of adherence measured is important to consider as respondents may not infer the same meaning between distances on each step on the Likert response scale (Dillon 2018). Therefore, non-linear relationships as well as more extreme values may arise due to wider range of response choices. The ARMS-D adherence measure used in our study demonstrates superior internal consistency and a wider range of response choices as compared to the measures used in previous studies (Culig & Leppée, 2014; Mayberry et al., 2013).

The ARMS-D also includes questions related to barriers to both taking and refilling medications. The inclusion of these subscales in this measure allowed for additional analyses to be conducted in addition to the total adherence scale. It is important to note that the poor internal reliability of the refills subscale in our sample represents a limitation affecting interpretation of these results. Supplemental analyses of ARMS-D subscales revealed that the quadratic model was also best suited for assessing the relationship between medications beliefs and the refills adherence subscale. Contrastingly, the difference score model was proven to be accurate in capturing the relationship between medication beliefs and barriers to medication taking specifically, as the unconstrained models did not explain any additional variance in the outcome. It is possible that when it comes to barriers to refilling medications individuals may be more influenced by the complex, non-linear relationships between their beliefs about the need for medication and their concerns; while when it comes to barriers to medication taking alone, it is most fitting to examine the extent to which necessity beliefs outweigh concerns. Most of the previous research, including those using polynomial regression, that examine the relationship with BMQ constructs and adherence use self-report measures that do not capture barriers to refilling of medications (Dillon et al., 2018; Foot et al., 2016; Horne et al., 2013; Phillips et al., 2014; West et al., 2018). Our study provides a unique contribution to the literature and highlights the distinctive relationship between medications beliefs and different components of medication non-adherence.

Limitations:

There are several limitations to consider within the current study. The larger RCT parent study used a longitudinal study design. However, we conducted an observational, cross-sectional analyses of the baseline data from the study and thus we cannot make any conclusions about the causality of observations. It is notable to consider that the variables examined in this study may be influencing each other bidirectionally and it is possible that participants' behavior (i.e., adherence) influenced the development of their beliefs. While it is a limitation, the cross-sectional nature of this study allowed for further examination of the relationship between a range of factors and medication beliefs as well as replication of novel analyses investigating the multidimensional relationships between beliefs and adherence.

Some of methods for data collection and the participant sample used for this study can be considered additional limitations. The parent study was a self-management intervention delivered via telephone. All study measures and data were also collected over the phone. While several advantages are associated with the use of telephonic approaches in research studies (Chamany et al., 2015; E. A. Walker et al., 2011) there are some limitations to consider including, a need for shorter interview duration, absence of visual or non-verbal cues that may provide additional information, and the need for participants to have consistent access and coverage to telephone plans (Novick, 2008). Furthermore, medication adherence was measured using self-report rather than objective measures such as, electronically monitored adherence. While the self-report measure used in this study is deemed reliable and valid and often shows relationships with outcomes of equal magnitude to objective measures, self-reported information may be susceptible to bias (Mayberry et al., 2013). Furthermore, our ability to examine the subscales of the adherence measure was limited by the low reliability of the refills subscale.

Generalizability of the study sample is another potential limitation. The population of our study consisted primarily of ethnically diverse and socioeconomically disadvantaged patients. While this population represents one with limited prior research and thus important in adding to the current body of literature, our findings cannot not be easily generalized to the larger population. The majority of the participants in this study were Hispanic and Spanish-speaking; other ethnic/racial groups were not highly represented. The demographic make-up of the sample also impacts variability in responses to the main study variables, in particular reported income. While five ranges of response choices were provided for income, the majority of study participants reported an income of less than $20,000 per year. This population of this sample was also limited to individuals with T2D. It is possible that the relationships between study variables may differ for individuals with other medical conditions or chronic illnesses.

Additional limitations of this study relate to the completeness of data and distribution of responses. A significant number of participants chose not to respond to the question about yearly household income. About 36% of participants were missing values for income level. Considerable supplementary analyses were conducted to evaluate the extent to which this missing data and reduced sample size impacted the results. It was deemed that this missing data did not appear to meaningful impact findings. Nonetheless, we cannot determine whether or not this information is missing at random i.e., if specific factors led certain participants to leave out information about their income. It is important to carefully consider the potential role of missing income data in the context of our findings. Finally, the finding that the medication adherence data from our sample was significantly positively skewed represents a limitation of our study. Results from both the original data and log transformed data were presented to aid in interpretation and promote transparency. Yet, the skewness of the outcome variable poses as a limitation to the fit with the statistical approach, which assumes normality of distribution.

Implications for Research:

The findings of our study notably contribute to the current body of literature in several areas. Limited prior research exists on the specific contextual factors associated with medication beliefs. Medication beliefs play a crucial role in patients' adherence to their prescribed treatment regimens as understood through the extended Common-Sense Self-Regulatory Model (SRM) (Horne et al., 1999). In fact, studies have shown that the extended SRM more strongly predicts medication adherence compared to the original SRM, which does not include medication beliefs specifically in the model (Byrne et al., 2005; Horne & Weinman, 2002). Having an increased understanding of the stimuli that influence medication beliefs significantly contributes to our theoretical understanding of this model. The focus of our study among ethnically diverse and socioeconomically disadvantaged patients represents another noteworthy contribution to the limited existing research among this population in this area of study. Minority populations have the highest prevalence of diabetes as compared to non-Hispanic Whites (Centers for Disease Control and Prevention, 2017). Our study specifically examines the relationships between key demographic factors and medication beliefs, as this represents an area with a paucity of research among this patient population. These contributions allow for improved development of appropriate interventions. Interventions informed by theoretical frameworks, specifically those targeting beliefs about medication, have proven to be most successful (Holmes et al., 2014). By understanding that factors, such as Hispanic ethnicity and lower income are associated with increased concerns, and insulin use and increased number of medications are associated with increase necessity beliefs, researchers can tailor interventions accordingly to target those beliefs associated with poor adherence and illness outcomes.

The current study is crucial for addressing key methodological limitations in the study of the Beliefs about Medicine (BMQ) questionnaire and replicating proposed innovative methods for assessing the relationships between medication beliefs and adherence. Only a few previous studies have implemented the use of polynomial regression to evaluate the multidimensional effects these relationships. Consequently, analyses thus far have been exploratory until sufficient replication of findings is produced. Our research is crucial in replication and cross-validation of results to add to the new body of literature. Implementation of this methodology across study and illness populations is crucial. As described above, T2D represents a unique chronic condition that disproportionally effects socioeconomically disadvantaged and ethnic minority groups. Our findings established both reciprocal and non-reciprocal relationships between medication beliefs and adherence. By using this enhanced methodological approach, we demonstrated a curvilinear relationship, such that adherence is exponentially worse as concerns increase. It shows that necessity and concerns do not have a linear, one-to-one relationship on their effect on adherence overall. Of note, the difference score model proved to be the appropriate fit in examining the relationship between medication beliefs and the medication taking adherence subscale, suggesting that the NCD likely has some continued utility when evaluating different components of adherence. These relationships would not have been seen with the use of more standard or widely used statistical analyses alone and it provides important information about our study population based on which more targeted interventions can be developed.

Clinical Implications:

The current study also contributes significantly to considerations for the clinical application of these findings. Our research highlights the importance of both patient-related and illness-related factors in their association with beliefs about medication. Notably, Hispanics were more concerned and held stronger beliefs about their need for diabetes medication as compared to non-Hispanics in our study. This pattern exists independent of income and education level, consistent with other research (Aikens & Piette, 2009). It was been widely recognized that minorities, particularly Hispanics, perceive more discrimination and distrust in health care systems (Lillie-Blanton et al., 2000; Piette et al., 2006, 2010). Consequently, providers should be mindful to provide culturally sensitive care and interventions while addressing patients' viewpoints and concerns about their treatment regimens. The relationship between illness-related factors and beliefs about the need for taking diabetes medication represents another significant area for consideration in clinical practice. It was clear in our findings that individuals with indicators of more serious or advanced illness status (insulin use, increased number of diabetes medications) reported higher perceived need for taking prescribed medications. This demonstrates an important area for health care providers to intervene with patients who have less advanced or serious illness and who may hold weaker beliefs about the need for adhering to prescribed treatment regimens. T2D is a chronic illness which, if left untreated, can lead to serious complications (American Diabetes Association, 2018a). Proper use of pharmacologic therapy can not only prevent complications but can also improve micro and macrovascular health outcomes of diabetes (Turner et al., 1999). By addressing individuals' beliefs about the necessity of their medication, particularly those with less advanced diabetes, providers may help their patients to develop improved self-management and prevent serious complications.

Our findings regarding the inaccurate application of the BMQ difference score model as well as the novel non-linear relationships established between medication beliefs and adherence prove to be important information for clinical interventions as well. It is important for providers to be mindful of the complex relationship between patients' concerns related to the harmful effects of medication as well as their beliefs about the need for taking prescribed medication. A unique contribution of our study was the finding that adherence is exponentially worse as concerns increase and necessity beliefs decrease Thus, low concerns are necessary but not sufficient for adherence and having both low concerns and high necessity beliefs is optimal for good adherence. While it is still important for patients to hold stronger necessity beliefs as compared to concerns, it is also important to address patients who have high concerns and high necessity beliefs (ambivalent). The finding that individuals with ambivalent beliefs have somewhat worse adherence than those with indifferent beliefs (low concerns, low necessity) is consistent with prior research (Dillon et al., 2018; Phillips et al., 2014; West et al., 2018) and represents a potential area for intervention. Our research supports the notion that clinicians should not only inquire about the relative difference between patients' concerns and necessity beliefs but also consider the absolute levels (Phillips et al., 2014).

Future Directions:

Future research is critical to strengthen our understanding of the relationship between contextual factors, beliefs about medicine, and medication adherence. While the current study notably contributed to the current body of literature, it will be important to both replicate findings and address key limitations from our study in future work. Future studies would benefit from examining these relationships within a longitudinal study design. This would allow for researchers to draw conclusions about causality and temporal relationship between medication beliefs and adherence. The present study analyzed these relationships within the baseline session of a larger, longitudinal RCT. It would be prudent to replicate findings with the complete data across time points of the study. While the study did not specifically aim to modify medication beliefs, it would be beneficial to examine how both beliefs and medication adherence may have changed following the intervention or across time for those in the control group. It would allow us to examine how complex medication beliefs may influence participants' medication taking behaviors in the future.

Another avenue for future research is the incorporation of affective states or psychological conditions. A key component of the Common Sense Model is the representation of emotions that runs parallels to illness representations in their influence on coping procedures and consequently appraisal of treatment or illness conditions (Figure 1). Numerous studies have demonstrated that mental health conditions, such as depression and anxiety, as well as emotional reactions to illness or treatment such as, diabetes distress, can significantly impact treatment adherence (J. Gonzalez et al., 2017; J. S. Gonzalez et al., 2008, 2016). These concepts were not specifically assessed in the current study. Future studies would benefit from examining the role of emotions within the relationships between patient-related factors, illness-related factors, medication beliefs and treatment adherence. It would add to our understanding of the theoretical underpinnings of these relationships and provide more context for how these relationships impact patients with complex issues and needs in real world situations.

Finally, it is imperative for future studies to continue to replicate findings using polynomial regression to analyze the multidimensional effects of concerns and necessity beliefs on medication adherence. The present study demonstrated how the commonly used BMQ difference score model proved to be inaccurate and thus we have provided further support to the use of polynomial regression to evaluate these relationships. Indeed, this methodology remains novel with only a handful of studies demonstrating its application. For this reason, cross-validation of findings is critical, particularly across different illness populations as well among patient populations similar to our study participants. It will allow future researchers to highlight patterns, test solid hypotheses, and draw conclusions for the development of improved, targeted care.

Tables

Table 1
Participant Baseline Descriptive Statistics (N=812)

Variable	M(SD) or N(%)
Age	59.2 (10.8)
Sex	
Female	462 (56.9%)
Male	350 (43.1%)
Hispanic Ethnicity (n=808)	697 (85.8%)
Race (n=646)	
Black	150 (23.2%)
White	123 (19%)
Asian	6 (.9%)
Native Hawaiian/Pacific Islander	1 (.2%)
American Indian/Alaska Native	23 (3.6%)
Other	343 (53.1%)
Preferred Language for study	
English	179 (22%)
Spanish	633 (78%)
Education Level (n=806)	
Less than high school	278 (34.5%)
High school	329 (40.8%)
Beyond high school	199 (24.7%)
Income (n=520)	
Less than 20K	343 (66%)
Greater than 20K	177 (34%)
Duration of Diabetes (n=801)	12.4 (9.2)
BMI (kg/m2) (n=779)	33.6 (7.23)
Insulin use	292 (36%)

Table 2
Main Continuous Study Variables

Variable (n)	M(SD)	Min	Max	Skewness		Kurtosis	
				Statistic	Standard Error	Statistic	Standard Error
Age (812)	59.2 (10.8)	25	92	-.203	.086	.149	.171
HbA1c (812)	9.4 (1.8)	8	18	1.319	.086	1.477	.171
# Diabetes Meds (812)	1.84 (.95)	0	6	.485	.086	.706	.171
Necessity (804)	3.80 (.61)	1	5	-.691	.086	1.007	.172
Concerns (806)	3.07 (.73)	1	5	-.058	.086	-.853	.172
Adherence (811)	13.75(3.5)	11	41	2.188	.086	8.425	.171
Adherence: Med Taking (803)	8.73(2.49)	7	25	2.038	.086	5.931	.172
Adherence: Refills (810)	5.0 (1.61)	4	16	1.967	.086	5.06	.172

Table 3
Log Transformed Adherence Variable

Variable (n)	Skewness		Kurtosis	
	Statistic	Standard Error	Statistic	Standard Error
Log Adherence	1.212	.086	1.464	.171

Table 4
Pearson Correlation Coefficients Between Continuous Predictor Variables and Study Outcomes

	Age	A1c	Number Diabetes Medications
BMQ Specific Concerns	-.01	-.00	-.01
BMQ Specific Necessity	.10**	-.01	.12**
ARMS-D: Total Adherence	-.19**	.10**	-.05
ARMS-D: Refills	-.12**	.05	.00
ARMS-D: Med Taking	-.17**	.11**	-.07*

*p<.05 **p<.01; Higher scores on ARMS-D=worse adherence

Table 5
Descriptive Statistics for Categorical Patient-Related and Illness-Related Factors by Medication Belief

Variable	Necessity			Concerns		
	N	M (SD)		N	M (SD)	
Hispanic Ethnicity			p<.001			p<.001
Yes	690	3.85 (.59)		691	3.12 (.73)	
No	110	3.53 (.66)		111	2.79 (.67)	
Income			p<.05			p<.05
Less than 20K	340	3.86 (.59)		342	3.08 (.72)	
Over 20K	177	3.71 (.61)		176	2.91 (.72)	
Education			p<.001			p<.05
Less than HS	277	3.95 (.53)		275	3.17 (.73)	
HS	325	3.77 (.60)		328	3.05 (.73)	
Beyond HS	196	3.68 (.69)		197	2.96 (.72)	
Insulin			p<.001			p=.349
No	514	3.75 (.62)		516	3.05 (.73)	
Yes	290	3.91 (.56)		290	3.10 (.73)	

Table 6

Descriptive Statistics for Categorical Patient-Related and Illness-Related Factors by Adherence

Variable	Adherence (ARMS-D)		
	N	M (SD)	
Hispanic Ethnicity			p<.05
Yes	696	13.60 (3.3)	
No	111	14.68 (4.5)	
Income			p=.490
Less than 20K	342	13.83 (3.6)	
Over 20K	177	13.60 (3.6)	
Education			p=.074
Less than HS	278	13.47 (2.9)	
HS	328	13.72 (3.3)	
Beyond HS	199	14.20 (4.4)	
Insulin			p=.836
No	519	13.73 (3.6)	
Yes	292	13.78 (3.2)	

Note. Higher scores on ARMS-D=worse adherence

Table 7

Multiple Linear Regression Analysis for Patient-Related Variables Predicting Medication Beliefs (n=509)

	Necessity Beliefs			Concerns Beliefs		
	β	p	R^2	β	p	R^2
			.05			**.04**
Education	**- .09**	**.045**		-.05	.290	
Age	.05	.240		-.06	.228	
Income	-.07	.124		**-.09**	**.047**	
Hispanic Ethnicity	**.15**	**<.001**		**.13**	**.003**	

Bolded items have $p<.05$

Table 8
Hierarchical Linear Regression Analyses for Illness-Related Variables Predicting Medication Beliefs (n=466)

	Necessity Beliefs				Concerns Beliefs			
	Model 1		Model 2		Model 1		Model 2	
Variable	β	p	β	p	β	p	β	p
Education	-.07	.151	-.07	.133	-.05	.346	-.04	.369
Age	**.10**	**.030**	**.10**	**.032**	-.06	.196	-.06	.241
Income	-.10	**.046**	**-.09**	**.049**	-.08	.086	-.09	.066
Hispanic	**.14**	**.002**	**.14**	**.002**	**.13**	**.005**	**.13**	**.006**
Insulin			**.11**	**.031**			.04	.403
A1c			.05	.312			.02	.713
# Diabetes Meds			**.12**	**.017**			-.05	.295
R^2	.063		.103		.035		.038	
F for change in R^2	7.73**		7.55**		4.19*		2.59*	

Bolded items have p<.05; **p<.001 *p<.05

Table 9
Confirmatory Polynomial Regression (n=788)

	B	95% CI	p-value	R^2
Model 1				.054
Difference score (necessity-concerns)	.194	.137 to .251	<.001	
Model 2				.054
Necessity	-.850	-1.267 to -.432	<.001	
Concerns	1.040	.703 to 1.377	<.001	
Model 3				
Step 1				.054
Necessity	-.850	-1.267 to -.432	<.001	
Concerns	1.040	.703 to 1.377	<.001	
Step 2				.072
Necessity squared	.741	.250 to 1.232	.003	
Interaction term (XY)	-.914	-1.533 to -.296	.004	
Concerns squared	-.155	-.634 to .324	.526	

To support the difference score (Model 1), we find that the polynomial model (Model 2) is significant (R2 = 0.054, p<.001); the coefficients for Necessity and Concerns beliefs are significant and in the expected direction. However, the coefficients did not prove to be of significantly differing magnitude (i.e., the unconstrained Model 2 did not predict significant incremental variance to the constrained Model 1) [F(1,785)=.595 p=.441]. Therefore, criteria 4 was tested (Model 3), demonstrating that higher order terms predict significant incremental variance to the unconstrained model [Increase in R^2=.018, F(3,782)=4.98, p<.01). Thus, the difference score model proved to be inaccurate.

Table 10
Exploratory Polynomial Regression (n=787)

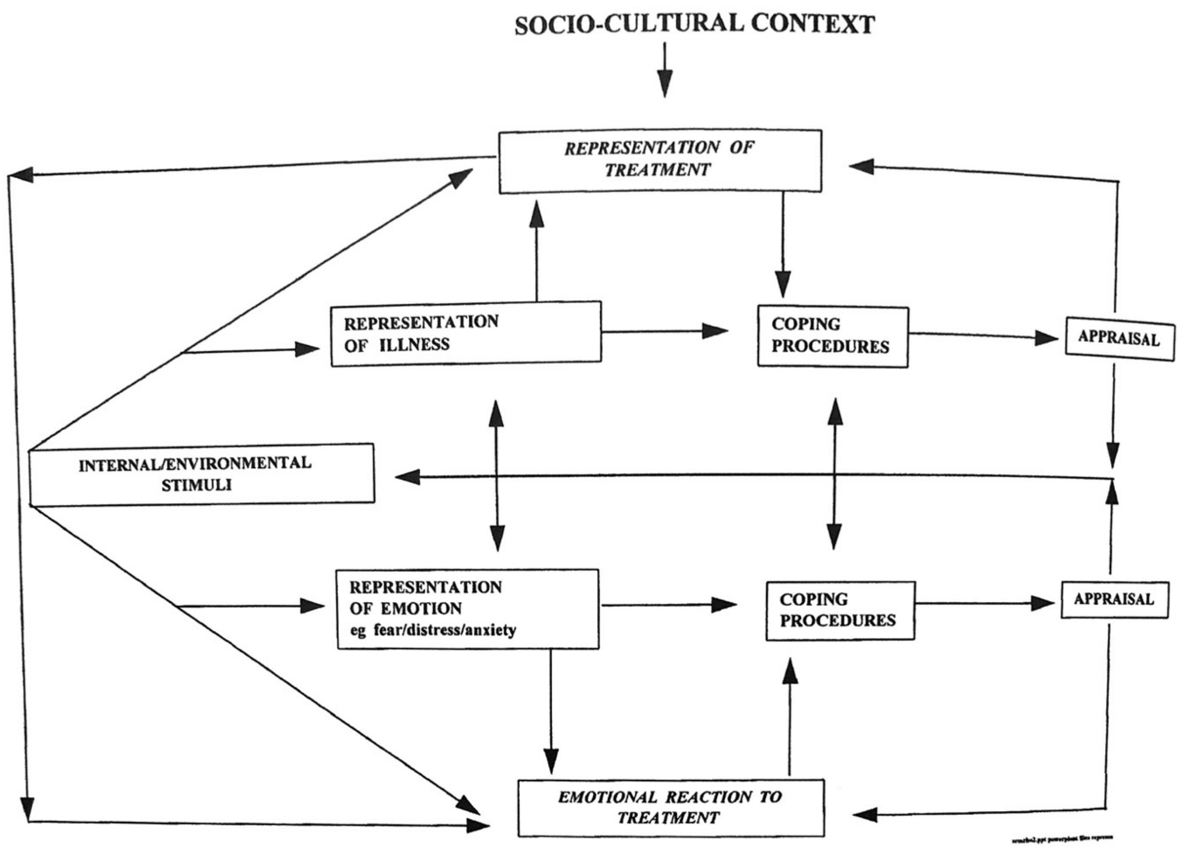
	B	95% CI	p-value	R^2
Model 1: Linear				.054**
Necessity	-.850	-1.267 to -.432	**<.001**	
Concerns	1.040	.703 to 1.377	**<.001**	
Model 2: Quartic				.072*
Necessity	-1.883	-2.664 to -1.103	**<.001**	
Concerns	1.884	1.256 to 2.511	**<.001**	
Necessity squared	.741	.250 to 1.232	**.003**	
Interaction Term (XY)	-.914	-1.533 to -.296	**.004**	
Concerns squared	-.155	-.634 to .324	.526	
Model 3: Cubic				.092*
Necessity	-2.177	-3.043 to -1.310	**<.001**	
Concerns	2.589	1.770 to 3.408	**<.001**	
Necessity Squared	1.248	-.211 to 2.707	.094	
Interaction Term	-3.256	-4.599 to -1.913	**<.001**	
Concerns squared	.391	-.530 to 1.312	.405	
Necessity Cubed	-.191	-.844 to .461	.565	
2Necessity X Concerns	1.574	.787 to 2.362	**<.001**	
2Concerns X necessity	-.396	-1.290 to .498	.385	
Concerns Cubed	-.331	-.885 to .223	.241	
Model 4: Quartic				.116*
Necessity	-.913	-2.412 to .586	.232	
Concerns	1.545	.280 to 2.810	**.017**	
Necessity Squared	2.293	.617 to 3.968	**.007**	
Interaction term	-4.916	-6.595 to -3.237	**<.001**	
Concerns Squared	1.598	.209 to 2.987	**.024**	
Necessity Cubed	-2.582	-4.934 to -.231	**.031**	
2Necessity X Concerns	6.600	3.990 to 9.211	**<.001**	
2Concerns X necessity	-3.326	-5.566 to -1.086	**.004**	
Concerns cubed	.256	-.846 to 1.358	.648	
Necessity quartered	.792	-.074 to 1.657	.073	
3Necessity X Concerns	-2.221	-3.308 to -1.134	**<.001**	
2NecessityX 2Concerns	1.713	.456 to 2.969	**.008**	
Necessity X 3Concerns	-.301	-1.526 to .924	.630	
Concerns quartered	-.288	-.862 to .286	.326	

All four models significantly predicted adherence [Increase in R^2=.023, $F(5,773)=4.04$, $p<.01$).
Bolded items have $p<.05$.

Figures

Figure 1

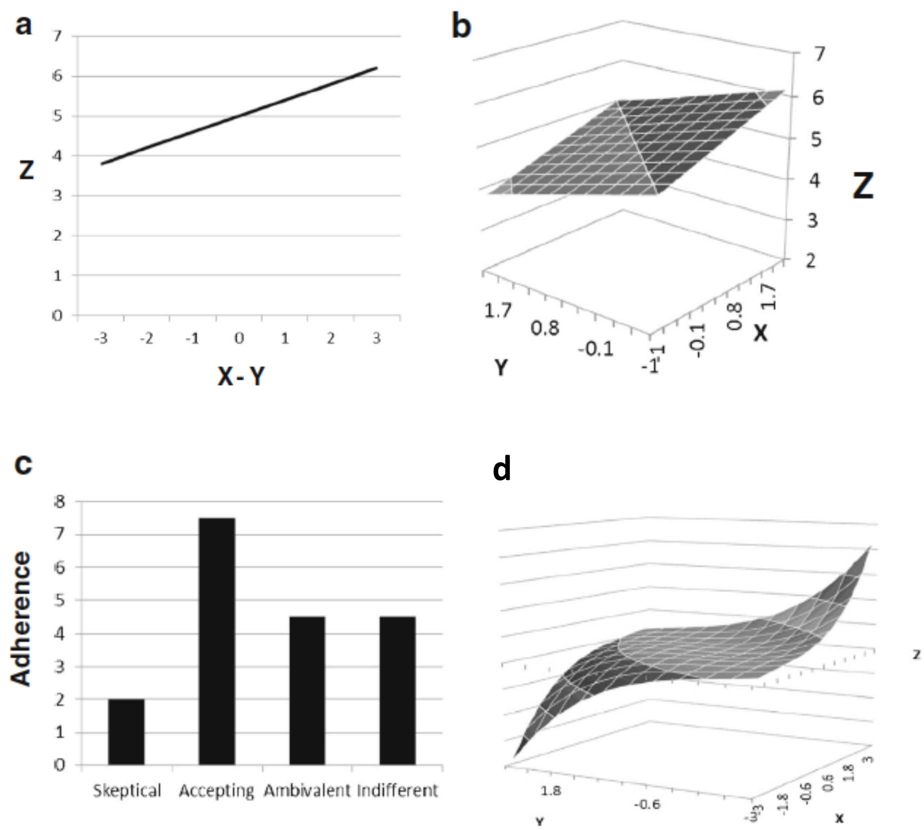
Illustrative model of how treatment beliefs are incorporated into Leventhal's SRM.



Note. Taken from Horne, R. (1997). Representations of Medication and Treatment: Advances in Theory and Measurement. In Petrie, K.J & Weinman J.A. (Eds.) *Perceptions of Health & Illness* (p.176). Harwood Academic Publishers.

Figure 2

Approaches to plot NCF relationship with adherence

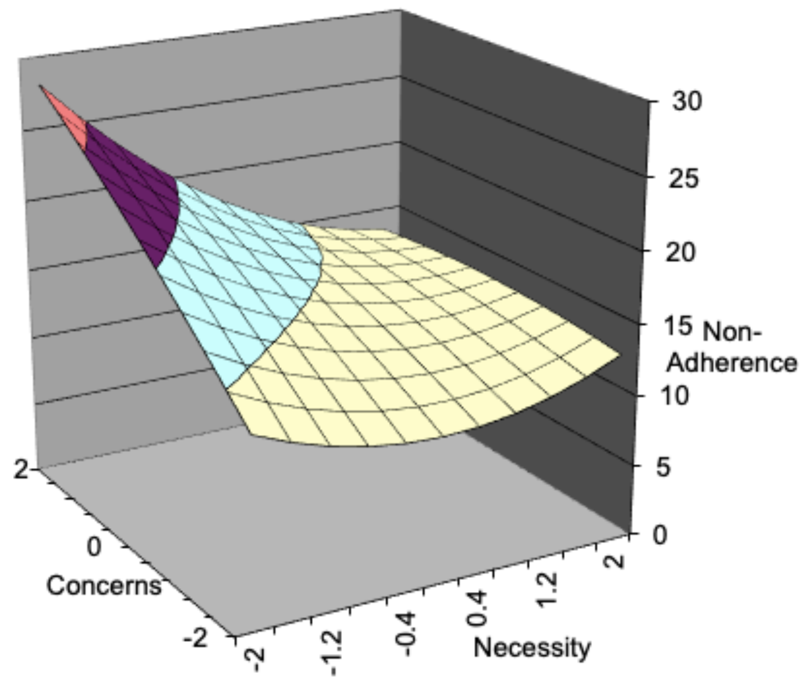


Note. **Figure a** represents a hypothetical, two-dimensional graph of the algebraic difference score model and the regression equation $Z=b_0+b_1(X-Y)$. **Figure b** represents a hypothetical three-dimensional graph of the model as figure **a** and a graph of the equation $Z=b_0+b_1X+b_2Y$, where the outcome is the same for all values of X and Y when X=Y. **Figure c** represents the hypothetical four attitude groups created by splitting the necessity and concerns scales at their median value. **Figure d** represents a hypothetical three-dimensional graph of the cubic model depicting the coupled effects of necessity (X) and concern (Y) beliefs on adherence (Z), where adherence increases exponentially as necessity beliefs exceed concerns decreases exponentially as concerns exceed necessity beliefs.

Images taken from Phillips, L. A., Diefenbach, M. A., Kronish, I. M., Negron, R. M., & Horowitz, C. R. (2014). The necessity-concerns framework: A multidimensional theory benefits from multidimensional analysis. *Annals of Behavioral Medicine*, *48*(1), 7–16.

Figure 3

Observed Three-Dimensional Relationship between Concerns, Necessity, and Adherence.



Note. Higher scores on ARMS-D=worse adherence

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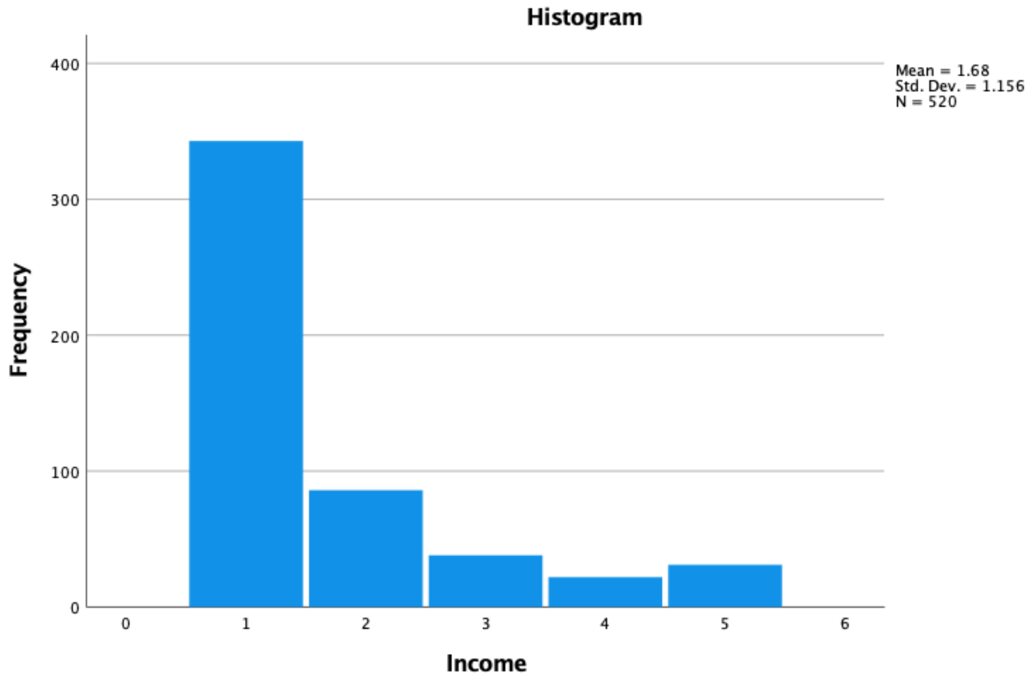
Appendix A
Preliminary Analyses

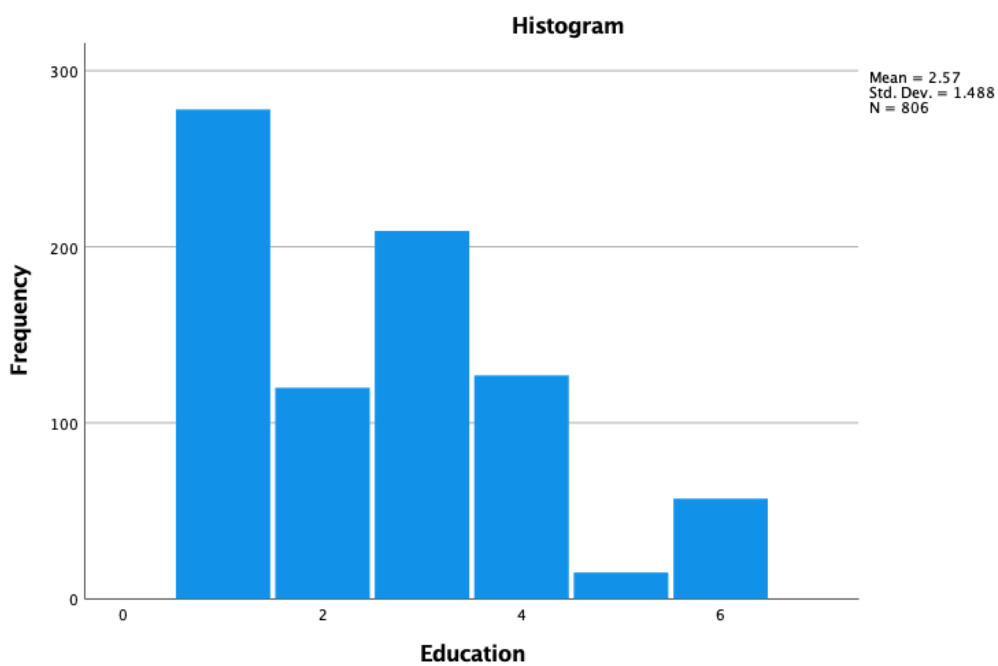
Supplemental Table 1:
Participant Baseline Descriptive Statistics for Original Income and Education Scales

Variable	N(%)
Income (n=520)	
Less than 20,000	343 (66%)
20,000-29,0000	86 (16.5%)
30,000-39,000	38 (7.3%)
40,000-49,000	22 (4.2%)
50,000 or more	31 (6%)
Education (n=806)	
8th Grade or Less	278 (34.5%)
9th to 11th Grade	120 (14.9%)
Grade 12 or GED	209 (25.9%)
Some college or technical school	127 (15.8%)
Completed Trade or Technical School	15 (1.9%)
College 4 Years or More	57 (7.1%)

Supplemental Figure 1:
Histogram of Original Income Variable Distribution



Supplemental Figure 2:
Histogram of Original Education Variable Distribution



Supplemental Table 2:
Analyses Examining Sample Level Differences Between Race/Ethnicity Groups

	Education				
	Less than HS	HS	Beyond HS	Total	Chi Square
Race/Ethnicity					$X^2 = 13.15$*
Non Hispanic Black	10	56	23	89	
Non Hispanic Other	2	5	14	21	

*p<.01

Supplemental Table 3:
Comparison of Relationships Between Race/Ethnicity and Medications Beliefs with and Without Controlling for Education

	Original Correlations		Partial correlations controlling for education	
	Necessity	Concerns	Necessity	Concerns
Hispanic	-.18**	-.16**	-.16**	-.14**
Non Hispanic Other	.13*	.05	.11*	.03
Non Hispanic Black	.12**	.14**	.11*	.12*

*p<.05 **p<.001

Supplemental Table 4:
Participant Baseline Descriptive Statistics of Full sample Vs. Subsample of Participants with Missing Income Data

	Full sample (N=812)	Subsample (n=292)
Variable	M(SD) or N(%)	M(SD) or N(%)
Age	59.2 (10.8)	59.5 (10.9)
Sex		
Female	462 (56.9%)	175 (59.9%)
Male	350 (43.1%)	117 (40.1%)
Hispanic Ethnicity	697 (85.8%)	262 (89.7%)
Race		
Black	150 (23.2%)	39 (19.7%)
White	123 (19%)	41 (18.8%)
Asian	6 (.9%)	2 (1%)
Native Hawaiian/Pacific Islander	1 (.2%)	0
American Indian/Alaska Native	23 (3.6%)	5 (2.4%)
Other	343 (42.2%)	121 (58.2%)
Preferred Language for study		
English	179 (22%)	37 (12.7%)
Spanish	633 (78%)	255 (87.3%)
Education Level		
Less than high school	278 (34.5)	127 (44.3%)
High school	329 (40.5%)	104 (36.2%)
Beyond high school	199 (24.5%)	56 (19.5%)
Income		
Less than 20K	343 (42.2%)	N/A
Greater than 20K	177 (21.8%)	
Duration of Diabetes	12.4 (9.2)	12.4 (9.3)
BMI (kg/m2)	33.6 (7.2)	33 (7.4)
Insulin use	292 (36%)	95 (32.5%)
HbA1c	9.4 (1.8)	9.5 (1.8)
# of Meds	1.8 (.95)	1.8 (.9)
BMQ Necessity	3.8 (.61)	3.8 (.61)
BMQ Concerns	3.1 (.73)	3.2 (.73)
ARMS-D Adherence	13.8 (3.5)	13.7 (3.3)

Supplemental Table 5:
Analyses Examining Sample Level Differences Between Income

	Education				
	Less than HS	HS	Beyond HS	Total	Chi Square
Income					$X^2 = 19.44$**
No Missing data	151	225	143	519	
Missing Data	127	104	56	287	

**p<.001

	Hispanic ethnicity			
	Not Hispanic	Hispanic	Total	Chi Square
Income				$X^2 = 5.67$*
No Missing data	85	435	520	
Missing Data	30	262	292	

*p<.05

Supplemental Table 6: Robustness Analyses of Missing Income Data Across All Four Models

Aim 1: Necessity Beliefs Outcome

	Base Analysis (N=509)		High income Imputation (N=789)	Low Income Imputation (N=788)
	B	95% CI	B	B
Education	-.07*	-.146 to -.002	-.10*	-.09*
Age	.00	-.002 to .008	.00	.00
Income	-.09	-.202 to .025	-.08	-.05
Hispanic Ethnicity	.24*	.099 to .388	.26**	.26**

**p<.001 *p<.05

Aim 1: Concerns Beliefs Outcome

	Base Analysis (N=509)		High income Imputation (N=791)	Low Income Imputation (N=790)
	B	95% CI	B	B
Education	- .05	-.135 to .041	-.09*	-.07*
Age	.00	-.010 to .002	-.00	-.00
Income	-.14*	-.278 to -.002	-.00	-.14*
Hispanic Ethnicity	.26*	.088 to .441	.33**	.31**

**p<.001 *p<.05

Aim 2: Necessity Beliefs Outcome

	Base Analysis (N=466)		High income Imputation (N=721)	Low Income Imputation (N=715)
	B	95% CI	B	B
Education	-.06	-.133 to .018	-.10*	-.09*
Age	.01*	.001 to .011	.00	.00
Income	-.12*	-.238 to -.001	-.08	-.07
Hispanic Ethnicity	.24*	.088 to .391	.25**	.21*
Insulin	.13*	.012 to .253	.12*	.12*
A1C	.02	-.016 to .050	-.00	.00
# of Diabetes Meds	.08*	.014 to .140	.08*	.08*

**p<.001 *p<.05

Aim 2: Concerns Beliefs Outcome

	Base Analysis (N=466)		High income Imputation (N=721)	Low Income Imputation (N=716)
	B	95% CI	B	B
Education	-.04	-.136 to .051	-.09*	-.07
Age	-.00	-.010 to .003	-.00	-.00
Income	-.14	-.285 to .009	.01	-.13
Hispanic Ethnicity	.26*	.077 to .452	.34**	.30**
Insulin	.06	-.086 to .213	.09	.09
A1C	.01	-.033 to .049	-.01	-.01
# of Diabetes Meds	-.04	-.120 to .037	-.02	-.03

**p<.001 *p<.05

Supplemental Table 7: Additional Analyses of Missing Income Data Across All Four Models

Aim 1: Necessity Beliefs Outcome

	Full sample analyses			Participants with missing income data filtered out	
	Base analyses (N=509, pairwise deletion of missing income cases)		Income variable not included (N=786)	Income variable included (N=508)	Income variable not included (N=507)
	B	95% CI	B	B	B
Education	-.07*	-.146 to -.002	-.10**	-.07*	-.09*
Age	.00	-.002 to .008	.00*	.00	.00
Income	-.09	-.202 to .025	N/A	-.09	N/A
Hispanic Ethnicity	.24*	.099 to .388	.26**	.24*	.26*

**p<.001 *p<.05

Aim 1: Concerns Beliefs Outcome

	Full sample analyses			Participants with missing income data filtered out	
	Base analyses (N=509, pairwise deletion of missing income cases)		Income variable not included (N=788)	Income variable included (N=509)	Income variable not included (N=508)
	B	95% CI	B	B	B
Education	- .05	-.135 to .041	-.09*	-.05	-.07
Age	.00	-.010 to .002	-.00	-.00	-.00
Income	-.14*	-.278 to -.002	N/A	-.14*	N/A
Hispanic Ethnicity	.26*	.088 to .441	.34**	.26*	.28*

**p<.001 *p<.05

Aim 2: Necessity Beliefs Outcome

	Full sample analyses			Participants with missing income data filtered out	
	Base analyses (N=466, pairwise deletion of missing income cases)		Income variable not included (N=719)	Income variable included (N=465)	Income variable not included (N=463)
	B	95% CI	B	B	B
Education	-.06	-.133 to .018	-.10*	-.06	-.07*
Age	.01*	.001 to .011	.01*	.01*	.01*
Income	-.12*	-.238 to -.001	N/A	-.12*	N/A
Hispanic Ethnicity	.24*	.088 to .391	.25**	.24*	.26*
Insulin	.13*	.012 to .253	.12*	.13*	.13*
A1c	.02	-.016 to .050	-.00	.02	.01
# Diabetes Meds	.08*	.014 to .140	.08*	.08*	.08*

**p<.001 *p<.05

Aim 2: Concerns Beliefs Outcome

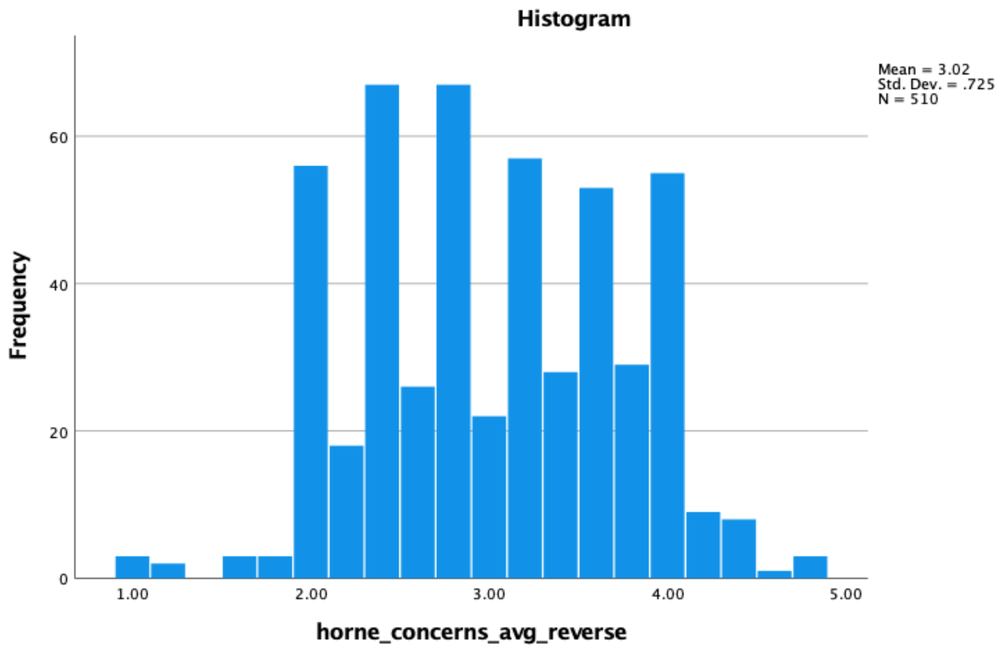
	Full sample analyses			Participants with missing income data filtered out	
	Base analyses (N=466, pairwise deletion of missing income cases)		Income variable not included (N=720)	Income variable included (N=465)	Income variable not included (N=463)
	B	95% CI	B	B	B
Education	-.04	-.136 to .051	-.09*	-.04	-.06
Age	-.00	-.010 to .003	-.00	-.00	-.00
Income	-.14	-.285 to .009	N/A	-.14	N/A
Hispanic Ethnicity	.26*	.077 to .452	.32**	.26*	.28*
Insulin	.06	-.086 to .213	.09	.06	.06
A1c	.01	-.033 to .049	-.01	.01	.01
# Diabetes Meds	-.04	-.120 to .037	-.02	-.04	-.03

**p<.001 *p<.05

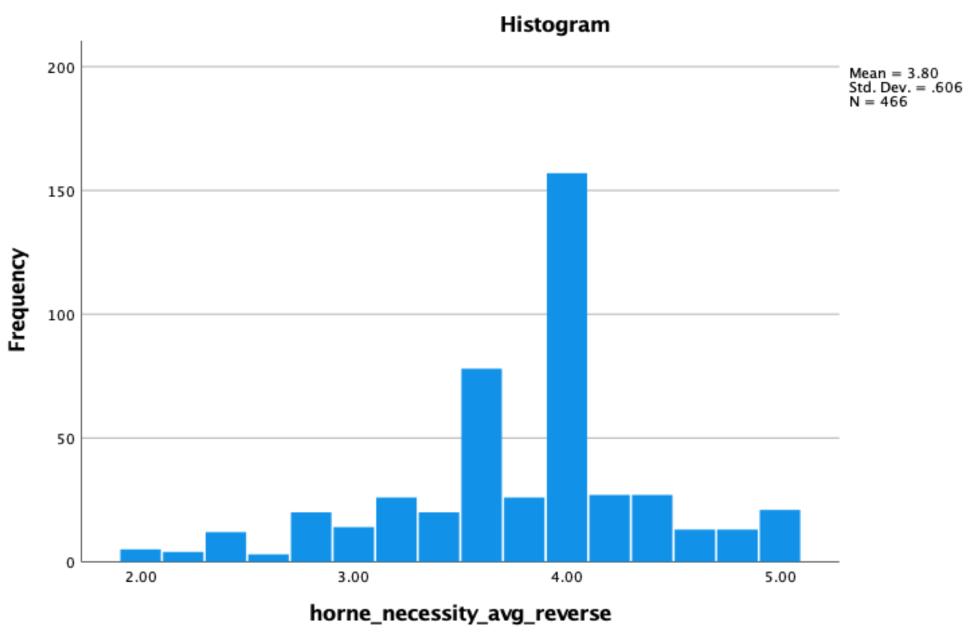
Appendix B

Histograms of Main Outcome Study Variables

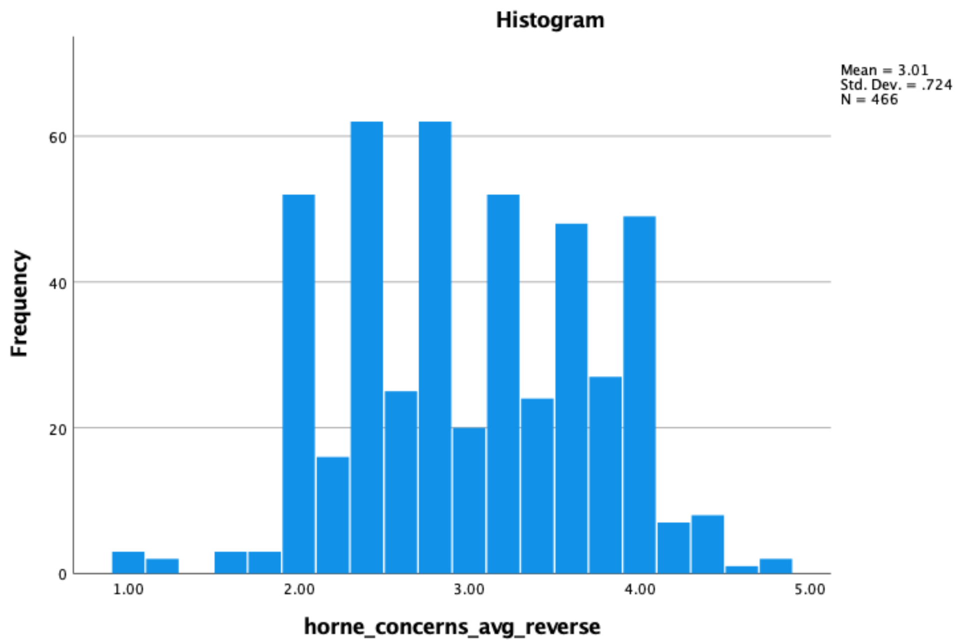
Supplemental Figure 3: Histogram of BMQ Concerns Scores for Aim 1 (n=510)



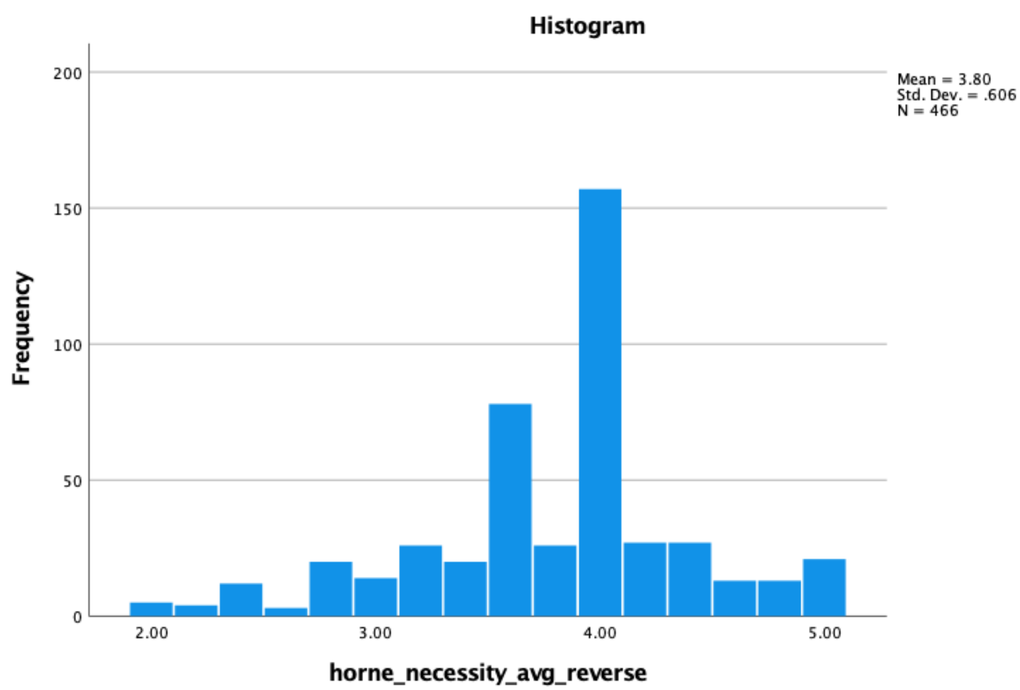
Supplemental Figure 4: Histogram of BMQ Necessity scores for Aim 1 (n=510)



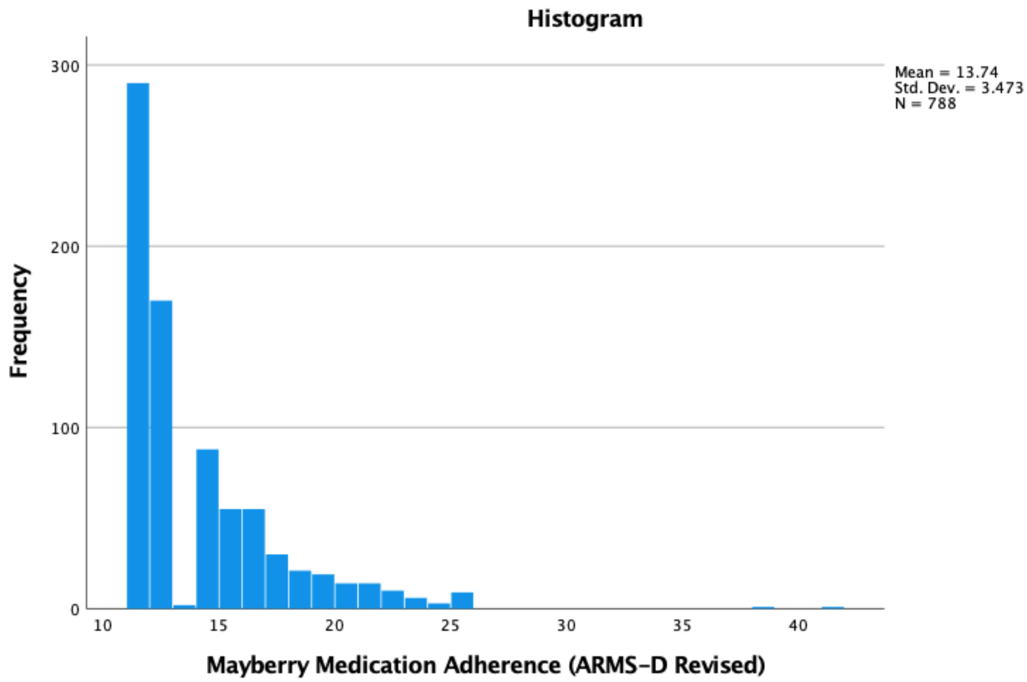
Supplemental Figure 5: Histogram of BMQ Concerns scores for Aim 2 (n=466)



Supplemental Figure 6: Histogram of BMQ Necessity scores for Aim 2 (n=466)



Supplemental Figure 7: Histogram of ARMS-D scores for Aim 3 (n=788)



Appendix C

Polynomial Regression with Log-Transformed ARMS-D

Supplemental Table 8:
Confirmatory Polynomial Regression (n=788) with Log-transformed ARMS-D measure

	B	95% CI	p-value	R^2
Model 1				.050
Difference score (necessity-concerns)	.005	.004 to .007	<.001	
Model 2				.051
Necessity	-.021	-.032 to -.009	<.001	
Concerns	.028	.019 to .037	<.001	
Model 3				
Step 1				.051
Necessity	-.021	-.032 to -.009	<.001	
Concerns	.028	.019 to .037	<.001	
Step 2				.063
Necessity squared	.016	.002 to .029	.003	
Interaction term (XY)	-.019	-.036 to -.002	.004	
Concerns squared	-.006	-.019 to .007	.526	

To support the difference score (Model 1), we find that the polynomial model (Model 2) is significant (R2 = 0.051, p<.001); the coefficients for Necessity and Concerns beliefs are significant and in the expected direction. However, the coefficients did not prove to be of significantly differing magnitude (i.e., the unconstrained Model 2 did not predict significant incremental variance to the constrained Model 1) [F(1,785)=1.181 p=.227]. Therefore, criteria 4 was tested in Model 3, demonstrating that higher order terms predict significant incremental variance to the unconstrained model [Increase in R^2=.012, F(3,782)=3.23, p<.05).

Supplemental Table 9:
Exploratory Polynomial Regression (n=787) with Log-transformed ARMS-D measure

	B	95% CI	p-value	R^2
Model 1: Linear				.051**
Necessity	-.021	-.032 to -.009	**<.001**	
Concerns	.028	.019 to .037	<**.001**	
Model 2: Quadratic				.063*
Necessity	-.043	-.064 to -.021	**<.001**	
Concerns	.046	.029 to .063	**<.001**	
Necessity squared	.016	.002 to .029	**.023**	
Interaction Term	-.019	-.036 to -.002	**.028**	
Concerns squared	-.006	-.019 to -.007	.371	
Model 3: Cubic				.074
Necessity	-.046	-.070 to -.023	**<.001**	
Concern	.061	.038 to .083	<**.001**	
Necessity Squared	.011	-.029 to .052	.578	
Interaction term	-.061	-.098 to -.029	**.001**	
Concerns Squared	.003	-.022 to .028	.818	
Necessity Cubed	.003	-.015 to .021	.745	
2Necessity X Concerns	.029	.007 to .050	**.010**	
2Concerns X necessity	-.005	-.030 to .019	.663	
Concerns cubed	-.008	-.024 to .007	.284	

*p<.05, **p<.001; Bolded items have p<.05; The linear and quadratic models significantly predicted the adherence. Thus, the quadratic model, as the highest order, is the best fitting model for predicting ARMS-D scores [Increase in R^2=.012, F(3,782)=3.23, p<.05).

Appendix D

Results of Analyses with ARMS-D Subscales

Supplemental analyses were conducted using the ARMS-D subscales: Refills and Medication Taking. Four criteria were evaluated to assess the accuracy of the strict algebraic difference score and evaluate the appropriateness for use of the difference score for each subscale.

Refills:

In the analyses for the refills subscale, the algebraic difference score model was rejected, as higher order terms predicted significant incremental variance to the unconstrained model as compared to linear terms (Supplemental table 10). Assumptions were met and 797 cases were included in the models after removal of outliers. Testing the first criteria demonstrated that the unconstrained polynomial model explained significant variance in the outcome [F(2,787)=5.196, p=.006]. Criteria two showed that the coefficients for necessity (B= -.168, p=.094) and concerns (B= .245, p=.003) in the expected direction. However, only concerns was found to be statistically significant. For the third criterion, the unconstrained model did not explain significant incremental variance over the constrained model [F(1,784)=.435, p=.510]. Therefore, the coefficients did not prove to be of significantly differing magnitude and the fourth criterion was tested to evaluate whether higher order models explain significant variance beyond the linear terms. Higher order terms were found to predict significant incremental variance to the unconstrained model [Increase in R^2=.021, F(3,781)=5.73, p<.01). Thus, relationship between X and Y is best explained by higher order models in this sample.

The difference score model was rejected, and thus exploratory polynomial regression analyses were conducted to test higher order polynomial terms for concerns and necessity beliefs to establish model fit (Supplemental table 11). The highest order model that explained significant incremental variance in medication adherence determined the best fitting model. Similar to the full adherence scale, the linear (R^2 change=.013, p=.006), quadratic (R^2 change=.021 p<.001), cubic (R^2 change=.022, p<.001), and quartic (R^2 change=.029 p<.001) models all predicted the outcome. Therefore, the quartic model is the best fitting model for predicting medication adherence in this sample. Response-surface analysis was conducted to aid with interpretation of the three-dimensional effects of necessity and concern beliefs on medication adherence. Consistent with the full adherence scale, additional higher order terms of cubic and quartic models added only minor curvatures with no significant alternation to the overall shape of the surface. Thus, response surface analysis was conducted for the quadratic model to support interpretation and cross-validation (Supplemental figure 7).

Adherence was lowest when necessity beliefs were low, and concerns were high and adherence was highest when both necessity beliefs and concerns were high. Interestingly, this contrasts with the intuitive and reciprocal effects as supported by the NCF. Additional, non-reciprocal effects were also evident though the finding that adherence was slightly higher when concerns and necessity beliefs were both low, than when concerns was low and necessity beliefs were high. These effects would not have been identified without the use of the three-dimensional analysis of these relationships. Furthermore, adherence increased more sharply at the extreme values of necessity beliefs as can be seen in the figure.

Medication Taking:

In the analyses for the medication taking subscale, the algebraic difference score model was not rejected, as higher order terms did not predict significant incremental variance to the unconstrained model as compared to linear terms (Supplemental table 12).

Assumptions were met and 780 cases were included in the models after removal of outliers. Testing the first criteria demonstrated that the unconstrained polynomial model explained significant variance in the outcome [F(2,779)=26.85, p<.001]. Criteria two showed that the coefficients for necessity (B= -.713, p<.001) and concerns (B= .791, p<.001) were significant and in the expected direction. However, for the third criterion, the unconstrained model did not explain significant incremental variance over the constrained model [F(1,777)=.194, p=.660]. Therefore, the coefficients did not prove to be of significantly differing magnitude and the fourth criterion was tested to evaluate whether higher order models explain significant variance beyond the linear terms. Higher order terms did not predict significant incremental variance to the unconstrained model [Increase in R^2=.007, F(3 ,774)=1.97, p=.117)]. Consequently, the difference score model proved to be the best fitting model for the ARMS-D medication taking subscale and exploratory analyses were not needed to examine higher order models.

Supplemental Table 10:
Confirmatory Polynomial Regression (n) with ARMS-D Refills Subscale

	B	95% CI	p-value	R^2
Model 1				.013
Difference score (necessity-concerns)	.043	.016 to .070	.003	
Model 2				.013
Necessity	-.168	-.365 to .029	.094	
Concerns	.245	.086 to .404	.003	
Model 3				
Step 1				.013
Necessity	-.168	-.365 to .029	.094	
Concerns	.245	.086 to .404	.003	
Step 2				.028
Necessity squared	.413	.181 to .645	<.001	
Interaction term (XY)	-.406	-.697 to -.114	.007	
Concerns squared	-.087	-.313 to .140	.453	

To support the difference score (Model 1), we find that the polynomial model (Model 2) is significant (R2 = 0.013, p<.05); the coefficients for Necessity and Concerns beliefs are in the expected direction. However, only Concerns was significant in Model 2. Moreover, coefficients did not prove to be of significantly differing magnitude (i.e., the unconstrained Model 2 did not predict significant incremental variance to the constrained Model 1) [F(1,784)=.435 p=.510]. Therefore, criteria 4 was tested (Model 3) demonstrating that higher order terms predict significant incremental variance to the unconstrained model [Increase in R^2=.021, F(3,781)=5.73, p<.01). Thus, the difference score model proved to be inaccurate.

Supplemental Table 11:
Exploratory Polynomial Regression (n=787) with ARMS-D Refills Subscale

	B	95% CI	p-value	R^2
Model 1: Linear				.013*
Necessity	-.168	-.365 to .029	.094	
Concerns	.245	.086 to .404	**.003**	
Model 2: Quadratic				.034*
Necessity	-.737	-1.105 to -.369	**<.001**	
Concerns	.625	.329 to .921	**<.001**	
Necessity squared	.413	.181 to .645	**<.001**	
Interaction Term	-.406	-.697 to -.114	**.007**	
Concerns squared	-.087	-.313 to .140	.453	
Model 3: Cubic				.056*
Necessity	-.803	-1.212 to -.394	**<.001**	
Concerns	.951	.565 to 1.338	<**.001**	
Necessity Squared	.281	-.407 to .970	.442	
Interaction term	-1.395	-2.028 to -.761	**<.001**	
Concerns Squared	.168	-.266 to .603	.447	
Necessity Cubed	.087	-.220 to .395	.577	
2Necessity X Concerns	.673	.301 to 1.044	**<.001**	
2Concerns X necessity	-.184	-.607 to .237	.380	
Concerns Cubed	-.174	-.435 to .088	.192	
Model 3: Quartic				.085**
Necessity	-.154	-.859 to .552	.669	
Concerns	.523	-.072 to 1.118	.085	
Necessity Squared	.731	-.057 to 1.519	.069	
Interaction term	-2.254	-3.044 to -1.464	**<.001**	
Concerns Squared	.588	-.065 to 1.242	.078	
Necessity Cubed	-.970	-2.076 to .136	.086	
2Necessity X Concerns	3.154	1.926 to 4.382	**<.001**	
2Concerns X necessity	-1.878	-2.932 to -.823	**<.001**	
Concerns cubed	.050	-.469 to .568	.851	
Necessity quartered	.334	-.074 to .741	.108	
3Necessity X Concerns	-1.104	-1.615 to -.593	<**.001**	
2Necessity X 2Concerns	1.008	.416 to 1.599	**.001**	
Necessity X 3Concerns	-.123	-.700 to .453	.675	
Concerns quartered (Y^4)	-.023	-.293 to .247	.867	

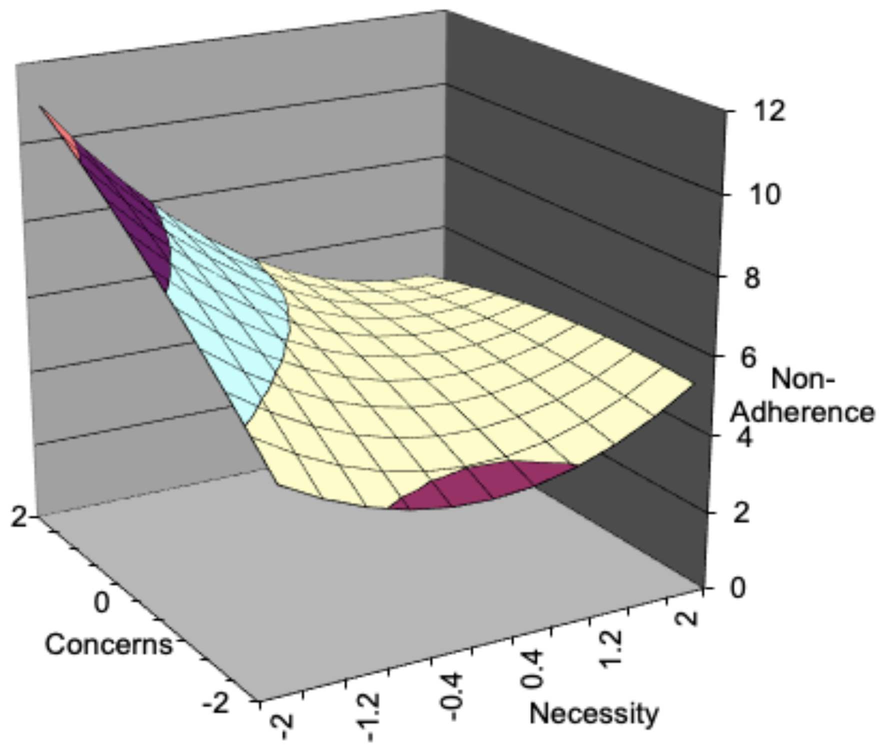
*p<.05, **p<.001, Bolded items have p<.05; All four models significantly predicted adherence [Increase in R^2=.029, $F(5,772)$=4.81, p<.001).

Supplemental Table 12:
Confirmatory Polynomial Regression (n=780) with ARMS-D Medication Taking Subscale

	B	95% CI	p-value	R^2
Model 1				.064
Difference score (necessity-concerns)	.153	.112 to .193	<.001	
Model 2				.065
Necessity	-.713	-1.014 to -.412	<.001	
Concerns	.791	.550 to 1.033	<.001	
Model 3				
Step 1				.065
Necessity	-.713	-1.014 to -.412	<.001	
Concerns	.791	.550 to 1.033	<.001	
Step 2				.072
Necessity squared	.244	-.113 to .602	.180	
Interaction term (XY)	-.499	-.948 to -.050	.029	
Concerns squared	-.049	-.394 to .295	.778	

To support the difference score (Model 1), we demonstrate that the polynomial model (Model 2) is significant (R2 = 0.065, p<.001); the coefficients for Necessity and Concerns beliefs are significant and in the expected direction. However, the coefficients did not prove to be of significantly differing magnitude (i.e., the unconstrained Model 2 did not predict significant incremental variance to the constrained Model 1) [F(1,777)=.194 p=.660]. Therefore, criteria 4 was tested (Model 3), demonstrating that higher order terms did not predict significant incremental variance to the unconstrained model [Increase in R^2=.007, p=.117, F(3,774)=1.97, p=.117). Thus, the difference score model proved to be accurate within this model using the Medication Taking subscale.

Supplemental Figure 7:
ARMS-D Refills Subscale: Observed Three-Dimensional relationship between Concerns, Necessity, and Adherence



Note. Higher scores on ARMS-D=worse adherence

Appendix E
Study Questionnaires

BELIEFS ABOUT MEDICINE- SPECIFIC (HORNE)

We would like to ask you about your personal views about medicines prescribed for you. These are statement other people have made about their diabetes medicines. Please tell me how much you agree or disagree with them. There are no right or wrong answers. We are interested in your personal views.

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
1. My health, at present, depends on my diabetes medicines	(1) ☐	(2) ☐	(3) ☐	(4) ☐	(5) ☐
2. Having to take my diabetes medicines worries me	(1) ☐	(2) ☐	(3) ☐	(4) ☐	(5) ☐
3. My life would be impossible without my diabetes medicines	(1) ☐	(2) ☐	(3) ☐	(4) ☐	(5) ☐
4. Without my diabetes medicines I would be very ill	(1) ☐	(2) ☐	(3) ☐	(4) ☐	(5) ☐
5. I sometimes worry about long-term effects of my diabetes medicines	(1) ☐	(2) ☐	(3) ☐	(4) ☐	(5) ☐
6. My diabetes medicines are a mystery to me	(1) ☐	(2) ☐	(3) ☐	(4) ☐	(5) ☐
7. My health in the future will depend on my diabetes medicines	(1) ☐	(2) ☐	(3) ☐	(4) ☐	(5) ☐
8. My diabetes medicines disrupt my life	(1) ☐	(2) ☐	(3) ☐	(4) ☐	(5) ☐
9. I sometimes worry about becoming too dependent on my diabetes medicines	(1) ☐	(2) ☐	(3) ☐	(4) ☐	(5) ☐
10. My diabetes medicines protect me from becoming worse	(1) ☐	(2) ☐	(3) ☐	(4) ☐	(5) ☐

ARMS-D (MAYBERRY)

I will now ask you how often you have missed taking your diabetes medicines over the last 30 days. If you are taking more than one diabetes medicine, please answer the questions by thinking about your daily experiences, on average, with all of the diabetes medicines you take, not just a certain medicine. We know that most patients with diabetes have trouble taking their medicines consistently. There are no right or wrong answers.

	None of the time	Some of the time	Most of the time	All of the time
1. How often do you forget to take your diabetes medicine(s)?	(1) ☐	(2) ☐	(3) ☐	(4) ☐
2. How often do you decide not to take your diabetes medicine(s)?	(1) ☐	(2) ☐	(3) ☐	(4) ☐
3. How often do you forget to get your diabetes prescription(s) filled?	(1) ☐	(2) ☐	(3) ☐	(4) ☐
4. How often do you run out of your diabetes medicine(s)?	(1) ☐	(2) ☐	(3) ☐	(4) ☐
5. Skip a dose of diabetes medicine(s) before you go to the doctor?	(1) ☐	(2) ☐	(3) ☐	(4) ☐
6. Miss taking your diabetes medicine(s) when you feel better?	(1) ☐	(2) ☐	(3) ☐	(4) ☐
7. Miss taking your diabetes medicine(s) when you feel sick?	(1) ☐	(2) ☐	(3) ☐	(4) ☐
8. Miss taking your diabetes medicine(s) when you are careless?	(1) ☐	(2) ☐	(3) ☐	(4) ☐
9. Forget to take your diabetes medicine(s) when you are supposed to take it more than once a day?	(1) ☐	(2) ☐	(3) ☐	(4) ☐
10. Put off refilling your diabetes medicine(s) because they cost too much money?	(1) ☐	(2) ☐	(3) ☐	(4) ☐
11. Plan ahead and refill your diabetes medicine(s) before they run out?	(1) ☐	(2) ☐	(3) ☐	(4) ☐