Abstract

Diabetes Self-Efficacy: Longitudinal Relationships with Diabetes Overall Self-Management, Medication Non-Adherence, Diabetes Distress, and Glycemic Control in Adults with Type 2 Diabetes

Purpose: To evaluate the longitudinal associations of diabetes self-efficacy with overall diabetes self-management, medication non-adherence, diabetes distress, and glycemic control.

Methods: This study performed secondary analyses among 812 predominantly socioeconomically disadvantaged ethnic minority adults with uncontrolled type 2 diabetes mellitus (T2DM). Repeated study measures, including diabetes self-efficacy, overall self-management activities, medication non-adherence, diabetes distress, and hemoglobin A1c (HbA1c), were collected every six months for three assessments over 12 months. Multilevel regression investigated the difference in diabetes self-efficacy between the two study groups. Multivariate and multiple linear regressions examined bidirectional relationships of diabetes self-efficacy with overall diabetes self-management activities, medication non-adherence, and HbA1c. A pathway analysis examined hypothesized constructs mediating the relationship between diabetes self-efficacy at baseline and HbA1c at 12-month follow-up.

Results: An increase of 4.19 points in the intervention group was significant (95% *CI* = -6.08, -2.30; $p < .001$) over the study time for self-efficacy. The difference in the estimated mean regression slopes was 1.87 (95% *CI* = 0.52, 3.21; $p = .006$). Diabetes self-efficacy at baseline was a significant predictor of overall self-management ($b = 0.27$, 95% *CI* = 0.23, 0.32; $p < .001$) and medication non-adherence scores at 12 months ($b = -0.03$, 95% *CI* = -

0.04, -0.02; $p < .001$). Overall diabetes self-management at baseline was a significant predictor of diabetes self-efficacy ($b = 0.35$, 95% $CI = 0.28, 0.42$; $p < .001$) and diabetes self-efficacy at 12 months ($b = -1.00$, 95% $CI = -1.33, -0.67$; $p < .001$). There was a significant indirect effect of self-efficacy at baseline on HbA1c at 12-month follow-up through medication non-adherence at 6-month follow-up ($ab = -0.005$, 95% $CI = -0.007, -0.003$; $p < .001$).

Discussion: Findings support bidirectional longitudinal associations between diabetes self-efficacy and diabetes overall self-management and medication non-adherence. Medication non-adherence mediated the association of diabetes self-efficacy with HbA1c. If these associations are causal, results suggest that interventions successfully targeting diabetes self-efficacy can benefit type 2 diabetes self-management, medication non-adherence, and HbA1c over time.

Diabetes Self-Efficacy: Longitudinal Relationships with Diabetes Overall Self-Management, Medication Non-adherence, Diabetes Distress, and Glycemic Control in Adults with Type 2 Diabetes

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Chapter I: Background

Overview

Management of hyperglycemia is a critical treatment goal in diabetes care that has been found to predict the development and progression of complications in individuals with diabetes, which in turn contribute to reduced quality of life and early mortality among individuals living with diabetes (American Diabetes Association, 2021). Individuals from ethnic/racial minority populations experience a higher prevalence of diabetes and diabetes complications than non-Hispanic White individuals (Centers for Disease Control and Prevention, 2020; Haw et al., 2021; Walker et al., 2016). Therefore, it is vital to identify factors that influence glycemic control directly and indirectly, particularly in disadvantaged groups. A distinct characteristic of diabetes management is the demanding nature of completing a diverse set of self-management activities daily, including medication taking, increasing physical activity, following a healthy diet, and monitoring blood glucose levels (American Diabetes Association, 2022; Davies et al., 2018; Nikoviotis & Ringas, 2021; Tomky, et al., 2008). Research has consistently shown that diabetes self-management activities are closely associated with glycemic control (American Diabetes Association, 2009; Beck et al., 2017; Boulé et al., 2001; Deakin et al., 2005; Odegard & Capoccia, 2007; Povey & Clark-Carter, 2007; Shrivastava et al., 2013) and risk for poor health outcomes such as hospitalization and mortality (Ho et al., 2006; Mayberry & Osborn, 2012; Sokol et al.,

2005). Thus, improving diabetes self-management is a major target of behavioral interventions to improve care outcomes among individuals with diabetes.

Among diabetes self-management activities, medication taking is a relatively independent behavior from other self-management activities (e.g., increasing exercise, eating a healthy diet, and monitoring blood glucose levels) (Delamater, 2006) and is essential to diabetes self-management and health outcomes (Khayyat et al., 2018; Lin et al., 2017; Williams et al., 2014). However, adherence to glucose-lowering medications is alarmingly low, resulting in suboptimal glycemic control and risk for poor health outcomes (Azharuddin et al., 2021; Lee & Lee, 2022). Understanding modifiable factors related to medication adherence and overall self-management can inform the development of effective interventions that can contribute to better treatment outcomes among those living with T2DM. Previous studies have reported that psychological factors have been consistently associated with medication adherence, self-management, and glycemic control among adults with T2DM (Gonzalez et al., 2008, 2015, 2016). Self-efficacy, or confidence in one's ability to execute a behavior, has long been recognized as a fundamental psychological construct underlying behavior change (Bandura, 1977, 1986). Self-efficacy correlates with diabetes self-management and glycemic control across various studies (Hurst et al., 2020; Robertson et al., 2013; Tharek et al., 2018; Vahidi et al.,2015; Walker et al., 2014). However, these relationships have been investigated cross-sectionally. Moreover, there is a paucity of literature exploring the possible bi-directional relationships between self-efficacy, diabetes overall self-management, medication adherence, and glycemic control, particularly in a socioeconomically disadvantaged population affected by diabetes health disparities.

The current study aims to conduct a secondary analysis of data from an NIH-funded trial of telephonic diabetes self-management support to examine the longitudinal relationships between diabetes self-efficacy, self-management, medication non-adherence, diabetes-related emotional distress, and glycemic control in a diverse sample of 812 adults with suboptimally controlled T2DM. The findings of this study can expand our knowledge about the impact of psychological factors on diabetes self-management activities and health outcomes and add to the growing evidence supporting behavioral and psychological interventions in improving glycemic control in patients with T2DM.

Diabetes

Diabetes is a group of metabolic diseases resulting from defects in insulin secretion or effect, the main finding being hyperglycemia (American Diabetes Association, 2014). Diabetes has become a global healthcare concern. In 2021, about 537 million people were living with the disease, corresponding to a prevalence of 10.5% worldwide in adults aged 20-79 years, and the number is estimated to reach 643 million, with the prevalence increasing to 11.3% by 2030 (International Diabetes Federation, 2021). Among the U.S. population, 38.4 million people had diabetes in 2021, 95% of which were cases of type 2 diabetes mellitus (T2DM), and the prevalence increased with age, reaching 29.2% among adults 65 years or older (American Diabetes Association, 2021). Moreover, ethnic minority groups are disproportionately affected by diabetes, with prevalence among American Indians/Alaska Native adults (13.6%) and adults of Hispanic origin (11.7%) much higher than that of non-Hispanic white adults (6.9%) (American Diabetes Association, 2021). Diabetes takes its toll on society as it has become the 8th leading cause of death and cost $413 billion in 2022 in the United States alone, including direct medical costs and reduced productivity (American

Diabetes Association, 2023; Centers for Disease Control and Prevention, 2023). People with diabetes are at higher risk of developing severe health complications such as heart disease, kidney failure, blindness, stroke, and loss of toes, feet, or legs (Centers for Disease Control and Prevention, 2020). Individuals from ethnic minorities are at increased risk of poor diabetes outcomes (Walker et al., 2016).

There are two broad categories of diabetes: type 1 diabetes mellitus (T1DM) and T2DM. T1DM is characterized by β-cell destruction in the pancreas, leading to an absolute insulin deficiency, whereas T2DM features a predominant insulin resistance with a relative insulin deficiency or a largely secretory defect with insulin resistance (Petersmann et al., 2018). Due to genetic and environmental factors, progressive loss of β-cells in T1DM or impaired function in T2DM results in hyperglycemia, putting patients at risk for developing chronic complications. T1DM and T2DM are heterogeneous, as their clinical presentation and illness progression may vary considerably (American Diabetes Association, 2022). Sometimes, diabetes ketoacidosis (DKA), a life-threatening medical condition that causes the blood to become acidic, becomes the first sign of T1DM. In contrast, DKA is less common and severe in people with T2DM (National Institute of Diabetes and Digestive and Kidney Diseases, 2022). Symptoms of T2DM, such as increased urination and thirst, fatigue, increased hunger, and unexplained weight loss, overlapping with those of T1DM, often develop slowly and go unnoticed for a long time before the diagnosis. Of note, the idea that T1DM occurs only in children and adolescents, whereas T2DM occurs only among older adults, is inaccurate, as both diseases can be diagnosed in both age groups. The prevalence of T2DM among children and adolescents has increased dramatically in the United States (American Diabetes Association, 2021).

T2DM, the most common type of diabetes, accounts for around 90% of all cases worldwide (International Diabetes Federation, 2021). Treatment regimens vary between T1DM and T2DM due to their different etiologies and pathophysiologies, and thus, they should not typically be grouped together. This study investigated the relationships between psychological constructs, managing diabetes behaviors, and blood glucose outcomes in adults with T2DM.

Glycemic Control. To delay the progression of diabetes and prevent the severe consequences of its complications, clinical management of diabetes focuses on the maintenance of well-regulated glycemia. Glycated hemoglobin A1c (HbA1c) levels have been the gold standard for assessing glycemic control and treatment efficacy in patients with T2DM (Umpierrez & P. Kovatchev, 2018). HbA1c approximates the patient's average blood sugar level over the previous three months. As the largest and longest intervention study ever undertaken in diabetes, the UK Prospective Diabetes Study (UKPDS) sought to answer one primary question for managing T2DM: Does improved glycemic control reduce the incidence of complications (King et al., 1999)? The UKPDS, which recruited over five thousand participants with a median follow-up time of 10 years, demonstrated that the incidence of clinical complications was significantly associated with glycemia, with a 1% reduction in mean HbA1c correlated with reductions in risk of 21% for diabetes-related deaths (Stratton et al., 2000). This landmark study exerted an enormous impact on worldwide guidelines on T2DM management, including the International Diabetes Federation (IDF) guidelines, Canadian Diabetes Guidelines, and the National Institute for Clinical Excellence (NICE) UK guidelines for the management of T2DM (Home, 2008). A recent clinical trial has established HbA1c as a significant predictor of future diabetes complications

(Laiteerapong et al., 2019). American Diabetes Association recommends an HbA1c value of less than 7% without significant hypoglycemia as appropriate for adults (American Diabetes Association, 2022). Early cross-sectional research in T2DM patients indicated that Hispanic participants had poorer glycemic control than non-Hispanic White individuals, African American individuals, and Asian-Indian individuals (Misra & Lager, 2009), and non-white race independently predicted higher HbA1c levels (Rothman et al., 2008). Additionally, individuals with higher socioeconomic statuses were associated with improved glycemic control than those with lower socioeconomic statuses (Bi et al., 2010; Houle et al., 2015).

Inadequate glycemic control among patients with T2DM is a significant risk factor for developing diabetes complications, including macrovascular (e.g., cardiovascular disease) and microvascular diseases (e.g., retinopathy, nephropathy, and neuropathy) (Haghighatpanah et al., 2018). Improved glycemic control has long been linked to lessening the risks of microvascular complications such as retinopathy, neuropathy, and nephropathy in T2DM (Vijan, 1997; Gaster & Hirsch, 1998). In a multicenter trial with over 10,000 participants with T2DM (Ismail-Beigi et al., 2010), the Action to Control Cardiovascular Risk in Diabetes (ACCORD) study found that intensive glycemic control in HbA1c was associated with reductions in albuminuria, an established risk factor for impaired renal functioning (Meguro et al., 2009) and cardiovascular disease (Savage et al., 1996). A similar result was reported in the Veterans Affairs Diabetes Trial (VADT), which recruited 1,791 military veterans with a mean age of 60.4 years (Duckworth et al., 2009). The Action in Diabetes and Vascular Disease (ADVANCE) trial, conducted at 215 collaborating centers in Asia, Australasia, Europe, and North America, highlighted the crucial role of glycemic control in reducing nephropathy in older adults with T2DM (ADVANCE Collaborative

Group, 2008). These studies have revealed that glycemic control is beneficial to reducing albuminuria in elderly patients with T2DM. However, research findings regarding improved glycemic control's role in macrovascular complications are inconsistent. For example, Demirtunc and colleagues (2009) revealed that poor glycemic control might affect macrovascular complications such as cardiovascular events. However, Duckworth and colleagues (2009) indicated that intensive glycemic control was not associated with a difference in the time from randomization to the first occurrence of a major cardiovascular event, as compared to patients randomized to standard glucose control.

Despite the importance of glycemic control in relation to avoiding complications of diabetes, many individuals with T2DM do not reach the recommended targets for glycemic control. For example, the National Health and Nutrition Examination Surveys (NHANES) data suggests that 52.5% of adults with T2DM had an HbA1c less than 7% and Hispanic patients were less likely to achieve HbA1c less than 8% than non-Hispanic whites (Stark Casagrande et al., 2013). A recent retrospective cohort study in a national cohort of 1,140,634 veterans with diabetes corroborated racial/ethnic differences in diabetes control: Compared with non-Hispanic whites, non-Hispanic Blacks (OR 1.11, 95% CI 1.09–1.14) and Hispanics (OR 1.36, 95% CI 1.09–1.14) had a higher odds of uncontrolled HbA1c level (Hunt et al., 2020).

Research demonstrates that suboptimal adherence to glucose-lowering medications may be a major factor in explaining the gap between the effects of HbA1c observed in clinical trials of glucose-lowering medications and reductions observed in community samples (Carls et al., 2017). Carls and colleagues (2017) concluded that poor medication

adherence was the most crucial factor underlying the gap between clinical efficacy and real-world effectiveness of T2DM medications. Diabetes is managed mainly by individuals, and medication adherence is one aspect of the overall diabetes self-management regimen that patients must largely self-manage.

Consequently, the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) pointed out that both daily self-management and medical therapy are fundamental to helping patients navigate their self-management with confidence and achieving treatment goals (Davies et al., 2018). Moreover, a position statement of the American Diabetes Association emphasizes psychosocial factors impacting diabetes self-management, including emotional well-being and socioeconomic factors (e.g., poverty, access to care, and health insurance coverage) (Young-Hyman et al., 2016). Research has mainly focused on psychosocial factors associated with self-management in patients with T2DM.

T2DM self-management and medication adherence. Self-management activities, also called self-care activities, refer to behaviors undertaken by individuals to manage their disease (Glasgow & Strycker, 2000). Patients with T2DM must deal with a complex set of behaviors daily to manage diabetes. For individuals with type 2 diabetes, patient engagement in self-management activities is critical in achieving treatment goals: preventing or delaying complications and maintaining the quality of life (American Diabetes Association, 2022; Davies et al., 2018). According to the American Association of Diabetes Educators, self-management behaviors to promote healthy outcomes consist of healthy eating, physical activity, monitoring indicators of diabetes control (including blood glucose and HbA1c),

taking medications, problem-solving, and healthy coping (Nikoviotis & Ringas, 2021). All these behaviors have been found to be associated with better glycemic control, reduction of complications, and improvement in quality of life (Alma'aitah et al., 2022; American Diabetes Association, 2009; Beck et al., 2017; Boulé et al., 2001; Deakin et al., 2005; Odegard & Capoccia, 2007; Povey & Clark-Carter, 2007; Shrivastava et al., 2013; Wang et al., 1998). Poor self-management is common in patients with T2DM and is related to an increased risk of suboptimal glycemic control, complications, and mortality (Asche et al., 2011; Currie et al., 2012). Thus, behavioral interventions are designed to target diabetes self-management and emotional well-being outcomes. However, studies are lacking on the role of behavioral interventions in improving an individual's confidence in implementing self-management activities in the context of emotional distress related to managing diabetes. This study attempted to fill in some information missing in the literature by investigating the relationships in predominantly low socioeconomic adults with suboptimally controlled T2DM.

Medication taking is an integral part of diabetes self-management, which consists of different behaviors, including filling a prescription, taking the correct number of medications daily on time, and continuing treatment for the prescribed time. The American Diabetes Association suggested that patients with T2DM start pharmacotherapy at diagnosis, with metformin monotherapy as the first-line choice, followed by combination therapy a few years later to maintain HbA1c values at target (American Diabetes Association, 2022). Many individuals with T2DM eventually require insulin injection as the disease progresses. Behaviorally, medication adherence determines the effectiveness of pharmacologic approaches to glycemic treatment. A body of research shows the crucial role of adherence to

glucose-lowering drugs in achieving glycemic control (Asche et al., 2011; Capoccia et al., 2016; Krapek et al., 2004). Poor medication adherence was the driver behind the elusive attainment of glycemic control (Edelman & Polonsky, 2017). In contrast, improved medication adherence was associated with reduced risk for cardiovascular disease and long-term all-cause mortality (Kim et al., 2018). Although adherence was associated with improved glycemic control and other health outcomes, medication adherence remains a significant challenge for people with diabetes.

Suboptimal medication adherence is common in T2DM (Carls et al., 2017; Edelman & Polonsky, 2017; Polonsky & Henry, 2016). A recent systematic literature review describes a median medication adherence rate of 51.2% (range 9.4% - 84.3%) in patients with T2DM (Evans et al., 2021). Another systematic review of medication adherence with diabetes medication has revealed that adherence rates in some cases were reported to be as low as 33% among patients having a medication possession ratio (MPR) of 80% or more (Capoccia et al., 2016). An adherence measure, MPR, refers to the proportion of a period where a medication supply is available (Andrade et al., 2006). In an earlier systematic review, Krass and colleagues (2015) reported that adherence to T2DM medication ranged from 38.5 to 93.1%. The authors found that just slightly higher than 20% of 27 studies in the literature review reported an optimal adherence rate of ≥ 80% and concluded that varying tools measuring adherence contributed to a wide range of results. The problematically low adherence rates hinder good glycemic control and lead to adverse outcomes. Among patients with medication non-adherence, defined as taking less than 80% of prescribed medications, all-cause hospitalization and mortality increased significantly (Ho et al., 2006). Moreover, medication nonadherence predicts poor glycemic control over time in patients with T2DM

(Egede et al., 2014). In a systematic literature review, Evans and colleagues (2021) pointed out that better medication adherence in individuals living with T2DM predicts reduced rates of complications, less inpatient hospitalization, and lower overall healthcare expenditure. As medication adherence is independent of other aspects of managing diabetes (Delamater, 2006), there is a growing interest in identifying factors that specifically contribute to poor adherence to antidiabetic medications.

Barriers to Diabetes Self-Management and Medication Adherence

Common obstacles to medication adherence in patients with T2DM can be classified into three categories: patient factors, provider factors, and healthcare system factors (Osterberg & Blaschke, 2005). At the patient level, reasons for not taking their medications included forgetfulness, conflicting priorities, the decision to omit doses, lack of information, and emotional factors (Cramer & Spilker, 1991). Complex regimens, lack of explanation about medication, not considering a patient's affordability and lifestyle, and therapeutic relationships with patients are contributors on the part of providers (Osterberg & Blaschke, 2005). Several studies have confirmed that the complexity of the T2DM medication regimen was significantly associated with poorer adherence (Coleman et al., 2012; de Vries et al., 2014; Saini et al., 2009). Higher out-of-pocket costs for antidiabetic medications predicted poorer adherence (Kirkman et al., 2015; Piette et al., 2004). Polonsky and colleagues (2014) found that higher ratings of patients with T2DM on the overall quality of communication with their physicians at the time of diagnosis were linked to better adherence to hypoglycemic medications. At the system level, limited access to healthcare and high drug costs have been identified as barriers to adherence (Osterberg & Blaschke, 2005), suggesting

that individuals with low socioeconomic status are disproportionately affected as a result. It is worth noting that 45% of patients with T2DM fail to achieve an adequate A1c level (< 7%) due to suboptimal medication adherence (Polonsky & Henry, 2016). Thus, identifying modifiable factors becomes crucial to addressing the nonadherence issue.

Diabetes-related Distress. Emotional distress has also been linked to problems with medication adherence and overall self-management in diabetes (Polonsky et al., 1995; Rubin, 2005). A growing body of literature has highlighted the consistent relationships between depressive symptoms, diabetes-related distress, and poor medication adherence and self-management in patients with T2DM (Gonzalez et al., 2008, 2015, 2016; Fisher et al., 2016). Diabetes-related distress (DRD) refers specifically to emotional distress related to the burdens of living with diabetes (Skinner et al., 2019), which includes implementing self-management behaviors such as monitoring blood glucose, taking medication, eating a healthy diet, and getting sufficient physical activity. Polonsky and colleagues coined this term two decades ago that encapsulated patients' psychosocial adjustment to diabetes (Polonsky et al., 1995). Fisher and colleagues (2008) reported a prevalence of diabetes distress of around 42% among adults with T2DM in a diverse and multi-ethnic sample. A systematic review and meta-analysis indicated that diabetes distress is a prominent issue in patients with T2DM and the overall prevalence of DRD was 36% in this population (Perrin et al., 2017). Higher DRD has been found to be associated with demographic factors (e.g., younger age and ethnic minority status) and clinical characteristics (e.g., shorter diabetes duration, using insulin, a higher body mass index, and the presence of neuropathy) (Fisher et al., 2015; Joensen et al., 2013; Stoop et al., 2014), and psychosocial factors (e.g., lack of social support) (Fisher et al., 2015; Schiøtz et al., 2012). Moreover, studies have revealed racial/ ethnic disparities in the

prevalence of DRD, with Hispanic people having significantly higher levels of DRD than African American individuals, Chinese American individuals, and non-Hispanic white people (Fisher et al., 2015; Peyrot et al., 2014). Clinical settings are also related to diabetes distress. Stoop and colleagues (2014) have revealed that diabetes distress levels in patients with T2DM were considerably lower in primary care than in secondary care.

DRD is assessed using brief, self-report scales. Three of the most widely used measures are the Problem Areas in Diabetes (PAID) scale, the Diabetes Distress Scale (DDS), and the Type 1 Diabetes Distress Scale (T1-DDS) (Fisher et al., 2019). The PAID, a 20-item scale scored on a 5-point Likert scale, from 'not a problem' to 'a serious problem,' yields an overall diabetes distress score ranging from 0 to 100 (Polonsky et al., 1995). Scores ≥ 40 are considered 'significant diabetes distress' (Welch et al., 1997). The DDS contains 17 items, each rated on a 6-point Likert scale, from 'not a problem' to 'a serious problem' (Polonsky et al., 2005). The scale yields a total diabetes distress score and scores for four subscales: emotional burden, physician distress, regimen distress, and interpersonal distress. Total and subscale scores are calculated using mean item scores, which can be categorized as little or no distress (< 2.0), moderate distress (≥ 2.0 and ≤ 2.9), and high distress (≥3.0). Clinically significant diabetes distress typically includes categories of moderate and high mean scores (Fisher et al., 2012). The T1-DDS is a 28-item scale that addresses sources of diabetes distress among adults with T1DM (Fisher et al., 2015). Most scales, including the PAID, DDS, and T1-DDS, have inherent limitations. The total score captures contextual factors that might be sources of distress but do not reflect specific emotional experiences related to living with diabetes. Polonsky and colleagues (2022) highlighted that there is a "mismatch" between the definition of diabetes distress and how it is measured. To address

these limitations, the Type 2 Diabetes Distress Assessment System (T2-DDAS) was developed and validated (Fisher et al., 2022). The 29-item T2-DDAS consists of a core measure (8 items, $\alpha = .94$) assessing the intensity of the emotional diabetes distress and seven source scales ($\alpha s = .73$ to .90) (Fisher et al., 2022). The items are scored on a 5-point Likert scale, from "1 = not a problem" to "5 = a very serious problem," with a mean scale score above 2 indicating elevated diabetes distress.

DRD does not imply the presence of psychopathology (Fisher et al., 2019), although diabetes distress overlaps with depressive symptoms. However, a crucial difference between the measurement of DRD and depressive symptoms is that the assessment of depressive symptoms does not involve any inquiry about the specific context that explains those symptoms (Fisher et al., 2016). The clinical relevance of distress has received significant research attention. A wealth of literature has demonstrated that diabetes distress is consistently linked to problematic levels of self-management (Schmidt et al., 2018; Skinner et al., 2019). It would be clearly anticipated that feeling overwhelmed or fearful about managing the demands of diabetes over time could lead to reduced self-management activities. Although some studies have found that higher DRD was associated with suboptimal glycemic control (Fisher et al., 2009; Indelicate et al., 2017; Schmitt et al., 2021), the association with HbA1c was modest at best after twenty-five years of diabetes distress research (Skinner et al., 2019). Skinner and colleagues (2019) pointed out that diabetes distress is likely to indirectly affect HbA1c by mediating self-management activities affected by psychosocial constructs, including diabetes knowledge, social support, skill sets, and confidence in implementing treatment regimens.

Diabetes Self-Efficacy

Diabetes self-management requires behavior change and maintenance over time to achieve health benefits. Among the most studied psychological factors that influence behavior change and maintenance is the construct of self-efficacy. Self-efficacy refers to one's belief in the ability to perform specific tasks necessary to attain designated types of performances (Bandura, 1977). Bandura regarded self-efficacy as a critical determining factor underlying personal behavior change, from initiating health habits to succeeding and maintaining the habit changes (Bandura, 2004). Research shows that self-efficacy improves engagement in health-promoting activities and treatment adherence among patients with chronic diseases (Roncoroni et al., 2019), and self-efficacy is associated with health behaviors in patients with various chronic diseases (Arnold et al., 2005; Sarkar et al., 2007). Moreover, socioeconomic status has been found to be positively associated with an individual's general self-efficacy (Bielderman et al., 2014; Han et al., 2014). Rather than a general belief about one's confidence to perform in various behavioral domains, the definition of self-efficacy provided in Bandura's early writings and subsequent empirical research shows that self-efficacy beliefs are specific in nature.

In contrast to general self-efficacy, diabetes self-efficacy refers to an individual's belief about the ability to conduct self-management activities related to diabetes management (Trief et al., 2009). To measure self-efficacy in the context of diabetes, it is essential to select a self-efficacy scale adapted to measure an individual's confidence in implementing tasks related to overall diabetes management. For example, Sarkar and colleagues (2006) assessed self-efficacy across an ethnically diverse sample of patients with T2DM using an eight-item

diabetes self-efficacy scale that covered both diabetes-specific domains (e.g., change in diet) and general health aspects (e.g., get medical attention). This study measured diabetes self-efficacy using the same eight items (Sarkar et al., 2006), which is an important improvement over other studies that used general self-efficacy measures (Bielderman et al., 2014; Han et al., 2014; Roncoroni et al., 2019). The extant literature has supported the relationship between higher self-efficacy for better diabetes self-management and improved blood glucose control in patients with T2DM (Hurst et al., 2020; Robertson et al., 2013; Sigurðardóttir et al., 2005; Tharek et al., 2018; Vahidi et al., 2015; Walker et al., 2014). In a randomized clinical trial ($N = 1443$) aiming to study the role of diabetes self-efficacy in glycemic outcomes in older, ethnically diverse patients with T2DM, poorer baseline diabetes self-efficacy was found to be associated with higher baseline HbA1c, enhanced diabetes self-efficacy over time following intervention (Telemedicine case management) was related to improved glycemic control, and diabetes self-efficacy mediated the effect of the intervention on enhanced glycemic control (Trief et al., 2009). Additionally, Trief and colleagues (2009) reported that some clinical and demographic variables were associated with poorer glycemic control over time, including longer diabetes duration, being younger, male, and Black or Hispanic race/ethnicity.

Most studies of diabetes self-efficacy have been cross-sectional (Indelicato et al., 2017; Sarkar et al., 2006; Trief et al., 2009). A growing body of research points to the evidence supporting the association of higher diabetes self-efficacy with better self-management. For example, earlier research shows that individuals with higher levels of self-efficacy were better able to manage their diabetes self-management, including exercise, self-monitoring of blood glucose, foot care, diet, and insulin use (Hurley et al., 1992; Gao et al.,

2013; Sarkar et al., 2006). Specifically, Hurley and colleagues (1992) recruited 142 inpatient adults who followed complex insulin requirements to manage their hyperglycemia and found that higher self-efficacy, assessed with the Insulin Management Diabetes Self-Efficacy Scale (IM-DSES) with an adequate internal consistency ($\alpha = .82$), was a predictor of improved self-management activities one month later.

In an ethnically diverse sample of patients with T2DM ($N = 408$), Sarkar and colleagues (2006) found that a higher diabetes self-efficacy score was associated with better diet, more exercise, increased self-monitoring of blood glucose, and better foot care. In another cross-sectional study, Gao and colleagues (2013) examined pathways through which constructs such as self-efficacy and diabetes self-management operate to improve glycemic control in patients with T2DM. Self-efficacy was assessed with the Chinese version of the Diabetes Management Self-Efficacy Scale with 20 items (C-DMSES) (Vivienne et al., 2008) and diabetes self-management behavior was evaluated with the 11-item revised Summary of Diabetes Self-management Activities (SDSCA) scale (Toobert et al., 2000). The study indicated that higher diabetes self-efficacy was associated with enhanced diabetes self-management behaviors, which, in turn, were directly linked to improved glycemic control (Gao et al., 2013). An earlier systematic review and meta-analysis of biobehavioral determinants of glycemic control in type 2 diabetes reported that diabetes self-efficacy was the most consistent predictive factor of adherence behaviors (Brown et al., 2016).

Aiming to explore what factors contribute to successful self-management among people with diabetes, Fisher and colleagues (2014) recruited 392 participants who were randomized to one of three study arms: computer-assisted self-management, computer-

assisted self-management and problem-solving, and minimal intervention in comparison with the other two interventions and reported the independent role of high self-efficacy in predicting better improvements in diet and physical activity compared to individuals with low self-efficacy among patients with T2DM (Fisher et al., 2014). The trial used a 14-item diabetes self-efficacy scale ($\alpha = 0.89$) (Lorig et al., 1996) and pointed out that higher baseline self-efficacy was associated with reduced fat intake and improved physical activity at 12-month follow-up (Fisher et al., 2014). A recent systematic literature review, a mix of cross-sectional and longitudinal studies, of factors related to glycemic control in diabetic patients concluded that higher self-efficacy predicts better self-management and enhanced HbA1c levels among adult patients with T2DM (Cheng et al., 2019). Longitudinal studies can establish the sequence of these constructs, identify their changes over time, and shed light on cause-and-effect relationships. Thus, further research is needed to explore the longitudinal associations between diabetes self-efficacy, diabetes self-management, diabetes distress, and glycemic control over time.

Prior studies also found evidence of racial and ethnic differences in diabetes self-efficacy (Kim et al., 2014; Sarkar et al., 2006). For example, Sarkar and colleagues (2006) reported that Hispanic people had lower levels of diabetes self-efficacy than non-Hispanic White individuals and African American individuals among individuals with T2DM. Kim and colleagues (2014) found that non-Hispanic White individuals had higher levels of diabetes self-efficacy than Hispanic/Latino, African American, and Asian American individuals. Considering the racial/ethnic results of diabetes self-efficacy levels, improving diabetes self-efficacy will likely benefit ethnic minority patients more for daily self-management of their diabetes regimen.

There is a potential bidirectional relationship between diabetes self-efficacy and self-management in patients living with T2DM. Bandura's social cognitive theory posits that self-efficacy is influenced by four sources of information: performance accomplishments, vicarious experience, verbal persuasion, and physiological and affective information (Bandura, 1977, 1986, 1995, 1997). It would be anticipated from the aforementioned cross-sectional studies that poor performance in self-management activities (e.g., not taking medication as prescribed) could result in low self-efficacy in diabetes self-management. Relatedly, intervention focusing on the necessity of medication, reducing diabetes distress, and improving communication through interactive education and problem-solving with an interventionist would help promote self-efficacy in self-management activities. A randomized controlled trial in African American adults with poorly controlled type 2 diabetes comparing a community-based diabetes self-management education (DSME) plus 12 weekly phone calls and 3 monthly calls from community health workers to DSME alone revealed that the increase in self-efficacy was larger in the intervention group than in the control group (Presley et al., 2020). Sadler and colleagues (2017) reported that diabetes self-management education and support (DSME/S) was associated with a significant increase in self-efficacy in following provider recommendations (e.g., taking medications for diabetes and checking blood glucose), whereas comparison participants with no intervention showed no significant change in self-efficacy.

Moreover, the research findings support the potential mediating role of self-management linking diabetes self-efficacy to glycemic control. An earlier cross-sectional study ($N = 141$) in patients with T1DM or T2DM of relationships among self-management agency, self-efficacy, self-management, and glycemic control reported that better self-

efficacy leads to better self-management management, which resulted in enhanced glycemic control (Sousa et al., 2005). A recent study supports the mediating role of self-management behaviors in depicting the influence of self-efficacy on glycemic control in patients with T2DM (Lee et al., 2016). Lee and colleagues (2016) conducted a cross-sectional study (N = 295) in patients with T2DM using a 14-item Chinese version of self-efficacy for diabetes management scale (Sharoni & Wu, 2012). The study found that significant pathways were from self-efficacy to self-management behaviors and from self-management behaviors to HbA1c levels (Lee et al., 2016). The cross-sectional design of these studies highlights the need for prospective research on pathways that can shed light on the relationships between psychological constructs, behavioral factors, and glycemic control to facilitate the creation of theory-based intervention programs for patients with T2DM.

The Current Study

In coping with diabetes, diabetes self-efficacy and DRD are inextricably linked. In a T2DM study examining the impact of baseline patient characteristics on interventions to reduce diabetes, Fisher and colleagues (2014) found that adults with T2DM who participated in a randomized controlled trial to evaluate an intervention to reduce diabetes distress and had high baseline self-efficacy experienced greater improvements in diabetes distress related specifically to the T2DM treatment and self-management regimen (regimen distress, one of four subscales of the Diabetes Distress Scale); they also experienced greater improvements in diet and exercise. Although a growing body of literature supports the conclusion that diabetes self-efficacy is negatively associated with diabetes distress (Lin et al., 2017; Wang et al., 2023; Wardian & Sun, 2014; Zheng, et al., 2018), the role of diabetes distress in the

relationship between diabetes self-efficacy and glycemic control in T2DM over time is understudied.

A longitudinal examination of diabetes self-efficacy, diabetes distress, medication non-adherence and overall self-management, and glycemic control over time would also allow for the evaluation of diabetes distress as a potential mediator of the associations between diabetes self-efficacy on the one hand and overall self-management, medication non-adherence, and glycemic control on the other. A rationale for the expectation is linked to Bandura's research on self-efficacy, which posits the associations of self-efficacy with an individual's emotional well-being (Bandura, 1977). Self-efficacy has been found to be associated with negative affect (e.g., feeling depressive) in children in the context of perceived academic inefficacy (Bandura et al., 1999). Bandura and colleagues (1982) highlighted an inverse relationship between higher self-efficacy and lower levels of emotional distress. This study explored the possible bidirectional associations between diabetes self-efficacy and diabetes-related distress. Additionally, the current study investigated the hypothesized mediational roles of diabetes-related distress, overall self-management, and medication non-adherence in the relationship between diabetes self-efficacy and glycemic control (Hypothesized Model).

Study Rationale/Innovativeness

The current study aims to comprehensively investigate the relationships between diabetes self-efficacy, diabetes-related distress, overall self-management activities and medication non-adherence, and glycemic control in a predominantly ethnic minority and socioeconomically disadvantaged sample of adult patients with suboptimally controlled T2DM who were recruited for participation in a randomized controlled trial of telephonic self-management support (Gonzalez et al., 2020). Clarifying these relationships in a longitudinal study with a large sample of underrepresented adults living with T2DM contributes to the extant literature by examining the predictive power of self-efficacy over time and elucidating diabetes distress as a potential mechanism through which diabetes self-efficacy might influence overall self-management activities and medication non-adherence, and glycemic control. More specifically, despite a body of research supporting the higher prevalence of diabetes in racial and ethnic minorities and higher rates of diabetes complications (i.e., albuminuria and retinopathy) and worse glycemic control in non-Hispanic Black and Hispanic adults than non-Hispanic whites (Canedo et al., 2018; Haw et al., 2021; Osborn et al., 2013), studies are lacking in uncovering the psychological or behavioral pathways linking diabetes self-efficacy to glycemic control, particularly in an ethnically diverse and low socioeconomic population of patients with T2DM who experience diabetes health disparities, including less access to diabetes preventive care (e.g., HbA1c testing and retinal examinations) (Haw et al., 2021). The current study can fill the gaps in the literature.

Specific Aims

Aims 1. To study the impact of telephonic self-management support on diabetes self-efficacy among predominantly disadvantaged and ethnic minority adults with suboptimally controlled type 2 diabetes.

Hypothesis: Participants randomly assigned to telephonic self-management support will experience a significant increase in diabetes self-efficacy over time, relative to those assigned to enhanced usual care.

Aim 2. To examine baseline diabetes self-efficacy as a predictor of diabetes self-management, medication non-adherence, and glycemic control after 12 months.

H2A: Higher baseline diabetes self-efficacy scores will predict better end-of-study overall diabetes self-management, adjusting for study arms.

H2B: Higher baseline diabetes self-efficacy scores will predict better end-of-study medication adherence, adjusting for study arms.

H2C: Higher baseline diabetes self-efficacy scores will predict improved end-of-study glycemic control, adjusting for study arms.

Aim 3. To examine baseline overall diabetes self-management, medication non-adherence, and glycemic control as predictors of self-efficacy after 12 months.

H3A: Better baseline overall self-management will predict better end-of-study diabetes self-efficacy, adjusting for study arms.

H3B: Higher baseline medication adherence scores will predict better end-of-study diabetes self-efficacy, adjusting for study arms.

H3C: Better baseline glycemic control will predict better end-of-study diabetes self-efficacy, adjusting for study arms.

Aim 4. To investigate diabetes self-management, medication non-adherence, and diabetes distress as potential mediators of the associations between baseline diabetes self-efficacy and 12-month HbA1c

Hypothesis: Diabetes self-management, medication non-adherence, and diabetes distress measured at 6 months will mediate the association between baseline diabetes self-efficacy and 12-month HbA1c.

Chapter II: Design and Methods

Description of the Study

The original data source of this project is the large randomized controlled trial (RCT): the New York City (NYC) Care Calls study, an effectiveness trial of telephone-delivered T2DM self-management support. Details of recruitment and the RCT study protocol have been published (Gonzalez et al., 2020). Briefly, the original study focuses on the effectiveness of telephone-delivered diabetes self-management and distress management support (Tele-SMS) in improving glycemic control, emotional well-being, and self-management among predominantly ethnic minority individuals with suboptimally controlled T2DM. The control group receives enhanced usual care, which includes print-based educational materials only related to diabetes treatment and self-management, diabetes distress, and depression. This study conducted a secondary analysis of data from the parent study to examine research questions regarding the study's aims.

Study Design of the Parent Study

NYC Care Calls is a 12-month randomized controlled trial examining the effectiveness of Tele-SMS compared to enhanced usual care (EUC). Eight hundred and twelve English or Spanish-speaking adults with an A1c greater than or equal to 7.5% were randomly assigned to either EUC, the control condition, or Tele-SMS, the treatment group, that consisted of both educational and behavioral skill-based sessions delivered via phone, in

addition to a participant workbook and print-based educational materials. Participants in the treatment group received 6 -12 calls over the course of 1-year. The number of calls, or stepped tiers, was decided upon the HbA1c levels, the severity of emotional distress symptoms, and diabetes distress scores at baseline. Participants in the control group received print materials only. There were three waves of data collection, including baseline data, mid-study, and end-study. This study analyzed data derived from the three time points.

Participants and Recruitment

Participants were recruited from primary care practices participating in the NYC Department of Health and Mental Hygiene (DOHMH)'s Primary Care Information Project (PCIP). The PCIP seeks to improve the uptake of EMRs among primary care practices in medically underserved communities. Among the 26 practices that met the panel size requirement of over 100 adult patients, eleven finally participated, and they were geographically spread out over four boroughs, exclusive of Staten Island.

Potential participants were identified on the EMR systems at those participating practices accessible to PCIP and sent letters. One week later, the study team placed a follow-up phone call.

The parent study aimed to detect a clinically meaningful HbA1c difference of 0.5% at an alpha level of .05. Power simulation estimated a sample size of 875 in order to arrive at a power of 83%, assuming an attrition rate of 20% that would produce a final sample of 700. The parent study enrolled 812 participants, providing a sufficient sample size for this secondary analysis.

Eligibility and Exclusion Criteria. Same as the parent study of NYC care calls, individuals were considered eligible to participate if they met the criteria: 1) adults ≥ 21

years old; 2) a diagnosis of type 2 diabetes; 3) an A1c value ≥ 7.5% within the last three months; 4) English or Spanish speaking; 5) access to a telephone; 6) willingness to give informed consent and accept random assignment.

Exclusion criteria: 1) intended to move out of NYC or change primary care providers within the next year; 2) presented cognitive impairment as determined by the study team.

Procedure

Enrollment Screen. PCIP sent letters to potential participants on behalf of their primary care providers. The letters provided an introduction to the study and opt-out instructions. A week later, the study team contacted potential participants via phone to conduct a brief screen.

Baseline Visit. Eligible participants were scheduled to complete informed consent and baseline assessment interviews via phone before being randomly assigned to Tele-Self-management Support or EUC. Baseline data collection included HbA1c within the past three months, results for the PHQ-8 depression scale and the Diabetes Distress Scale, blood pressure, BMI, and other surveys.

Follow-up Visit. Based on the assessment schedule, participants were reassessed via phone and EMR data extraction at six and twelve months post-randomization.

Participant Incentives. All participants received coupons worth $10 redeemable at NYC farmers' markets. In addition, a blood glucose log, a pillbox, a pedometer, and a magnet depicting a healthy plate were mailed to participants for retention purposes.

Measures

Measures were completed at baseline and 6- and 12 months post-randomization.

Demographic Information. Demographic information was collected using a questionnaire that included age, gender, race/ethnicity, marital status, education levels, annual household income, employment, birthplace, years living in the U.S., family structure, availability of health insurance, and duration of diabetes. Covariates consisted of participant demographic and socioeconomic characteristics, including age, gender, race/ethnicity, education levels, and household income; clinical attributes included years of diabetes and BMI.

Glycosylated Hemoglobin A1c. HbA1c levels were extracted from EMR at baseline (within three months prior to enrollment), at 6 months post-randomization (+/- 1.5 months), and at 12 months post-randomization (1.5 months prior – 4 months post).

Diabetes Self-Efficacy. Diabetes self-efficacy (DSE) was evaluated with the validated 8-item questionnaire (Skaff et al., 2003). The 8-item scale was based on a contextual model assessing control belief, behavior, and health among individuals with T2DM (Skaff et al., 2003), developed by Coyne and Smith (1991) for use in cardiac patients. A sample question includes "How confident are you in taking medicine regularly?" Four responses ranged from "1 = not sure at all" to "4 = very sure." Total scores range from 8 to 32, with a higher score indicating better confidence in conducting diabetes-related self-management activities. The scale measures self-efficacy related to self-management and domains related to general health (e.g., getting medical attention). Sarkar and colleagues (2006) reported adequate reliability ($\alpha = 0.78$) and scale validity in diverse groups of patients with T2DM.

Diabetes Self-Management. To measure overall diabetes self-management (DSM), a 5-item scale ($\alpha = 0.68$) was used (Heisler et al., 2003). The scale was designed to reflect how

well patients feel able to manage aspects of their diabetes care and has been found to be a valid reflection of self-management behaviors (Kaplan, 2000). The five items correspond to five key self-management activities: taking medication, monitoring blood glucose, eating a healthy diet, physical activities, and foot care. A sample question includes, “Over the past year, how difficult has it been for you to do each of the following exactly as the doctor who takes care of your diabetes suggested?” Five responses ranged from “1 = So difficult that I couldn’t do it at all” to “5 = Not difficult, I got it exactly right.” A response of “Not applicable” is available for each item. A total score is achieved by summing all five responses and translating them to a score ranging from 0 to 100, with higher scores representing better treatment adherence in the five domains. Internal consistency was acceptable in the current sample (α = .64).

Medication Non-Adherence. Medication non-adherence (MNA) was measured using the 11-item self-report Adherence to Refills and Medication Scale for Diabetes (ARMS-D) (Mayberry et al., 2013). This measure has independently predicted HbA1c in individuals with T2DM (Mayberry et al., 2013). Sample items include “How often do you decide not to take diabetes medicine(s)?” and “How often do you put off refilling your diabetes medicine(s) because they cost too much money.” Responses range from 1 = ‘‘none of the time’’ to 4 = ‘‘all of the time.’’ An overall adherence score was achieved by adding up all responses, with higher scores presenting more problematic medication adherence. The scale has shown good reliability (α = 0.86) and validity and is also available in Spanish (Mayberry et al., 2013). Internal consistency was acceptable in the current sample (α = .77).

Diabetes-Related Distress. The Diabetes Distress Scale (DDS) was used in the parent study to assess overall problems and "hassles" related to living with T2DM, including four subscales (i.e., emotional burden, provider-related distress, regimen-related distress, and interpersonal distress) (Polonsky et al., 2005). The DDS is a 17-item questionnaire with good reliability ($\alpha > .87$) and validity that uses a 6-point Likert-type response from "1 = not a problem" to "6 = a very serious problem" with higher scores representing higher diabetes distress (Polonsky et al., 2005). In the NYC Care Call study, the response scale was revised to a 4-point scale (i.e., "1 = not a problem" to "4 = a serious/very serious problem") to facilitate administration via phone (Gonzalez et al., 2020). A sample item related to emotional burden includes "Feeling that diabetes is taking up too much of my mental and physical energy every day." Other sample items include "Feeling that my doctor does not know enough about diabetes and diabetes care," "Feeling that I am often failing with my diabetes routine," and "Feeling that friends or family do not appreciate how difficult living with diabetes can be" that measure provider-related, regimen-related, and interpersonal distress, respectively. The overall score for the DDS is calculated as a mean of item responses. Clinically significant diabetes distress refers to a mean score of moderate distress (≥ 2.0 and ≤ 2.9) and high distress (≥ 3.0) (Fisher et al., 2012). The current study chose a mean DDS score to indicate overall distress because of living with T2DM. Internal consistency was acceptable in the current sample ($\alpha = .93$).

Data Analyses

Preliminary analyses. Statistical analyses were conducted using IBM's Statistical Package for the Social Sciences (SPSS) Version 28 and Mplus Version 8.8. An intention to treat (ITT) sample ($N = 812$) was used for the analyses. Descriptive statistics (means and

standard deviations for continuous variables; frequencies and percentages for discrete variables) were calculated for the sociodemographic characteristics (i.e., age, gender, primary language spoken, race/ethnicity, education levels, household income), clinical characteristics (duration of diabetes, BMI), and all study-related variables (HbA1c, self-efficacy, diabetes-related distress, overall diabetes self-management, and medication non-adherence). To identify potential covariates, Pearson product-moment and biserial correlations were conducted as appropriate depending on the scale of the two variables to determine the direction and strength of associations between baseline study variables and sociodemographic factors or clinical characteristics to identify potential confounders and other useful covariates.

Recoding procedures

To facilitate analysis and interpretation, the household annual income variable was recoded into two groups (i.e., Income > $ 20K and Income <= $20K) from the original five groups (less than $20K, $20-29K, $30-39K, $40-49K, and $50K or above). The education variable was also recoded into two groups (i.e., High school or less and Above high school) from the original six groups (8^{th} grade or less, 9^{th} – 11^{th} grade, grade 12 or GED, some college or technical school, completed trade or technical school, college four years or more).

The race/ethnicity variable was recoded into four groups (i.e., white, Hispanic, Non-Hispanic Black, and Non-Hispanic other) from the original six categories (white, Black, Asian, Native/American/Pacific Islander, American Indian/Alaska Native, and Other).

Primary analyses

Aims 1. Multilevel regression was performed to estimate the difference in diabetes self-efficacy between the treatment group (Tele-SMS) and the control condition (EUC) using data from three time periods: baseline, mid-study, and end of the study. The formal equations for the model are as follows:

Level 1:

$$Y_{ij} = \beta_{0j} + \beta_{1j}X_{ij} + e_{ij}$$

Level 2:

$$\beta_{0j} = \gamma_{00} + \gamma_{01}W_j + \mu_{0j}$$

$$\beta_{1j} = \gamma_{10} + \gamma_{11}W_j + \mu_{1j}$$

The two-level model specified random intercepts and slopes, and level-1 and level-2 predictor variables were used. Measure times (i.e., baseline, 6 and 12 months after randomization) were nested within participants. Therefore, we used measure times as a level-1 predictor and study groups (i.e., Tele-SMS vs. EUC) as a level-2 predictor. The outcome variable was diabetes self-efficacy, and the explanatory variables were study groups, measure times, and the interaction of these two estimated at all three-time points. The intercept β_{0j} and the slope β_{1j} were allowed to vary across study groups.

At level 2, the intercept and slope coefficients from level 1 were regressed on study groups (i.e., W_j, the level-2 predictor). The parameterγ_{00} represented the expected intercept when the study group was the control group, whereas the parameterγ_{01} indicated the difference in the intercept between intervention and control groups. Similarly, the

parameterγ_{10} represented the estimated slope in the control group, whereas the parameter γ_{11} showed the difference in the slopes between intervention and control groups. Moreover, the parameterγ_{11} reflected a potential cross-level interaction between the level-1 predictor (i.e., measure times) and the level-2 predictor (i.e., study groups). The analyses for Aim 1 did not include covariates due to randomization at the level of the patient after completion of informed consent and baseline assessment (Gonzalez et al., 2020).

Aim 2. The primary explanatory variable was diabetes self-efficacy scores at baseline, whereas outcome variables were end-of-study overall self-management, medication non-adherence, and HbA1c. Multivariate regressions were conducted to investigate the relationship between diabetes self-efficacy and outcome variables of interest. The linearity of continuous variables and homogeneity of variance were reviewed by visually inspecting the scatterplot and using Levene's test. Robust standard errors was used to remedy heteroscedasticity (Mansournia et al., 2021). We adjusted the self-efficacy for the correlates identified in the preliminary analyses and study groups to address potential confounders. Results were presented as regression coefficients with 95% confidence intervals.

Aim 3. The explanatory variables were scores of diabetes overall self-management, medication non-adherence, and HbA1c collected at baseline, respectively. The outcome variable was diabetes self-efficacy at the end of the study. Similar to Aim 2, multiple linear regressions were conducted to examine the relationships of interest. For consistency, we included the same covariates similarly as in Aim 2. The linearity of continuous variables and homogeneity of variance were reviewed by visually inspecting the scatterplot and using

Levene's test. Results were presented as regression coefficients with 95% confidence intervals.

Aim 4. Mediational analyses with imputed data were conducted in Mplus Version 8.8. Mediation helps understand the mechanism that links variables of interest through empirically testing hypotheses about the pathways of influence (Hayes & Rockwood, 2017). The hypothesized model manifested the direct and indirect effects of diabetes self-efficacy, diabetes distress, overall self-management, and medication non-adherence on glycemic control. Furthermore, our study used panel data from three-wave data collection, whereas previous studies used either cross-sectional data analysis or baseline and 12-month data collection (Fayed et al., 2022; Fisher et al., 2014).

Model fit was assessed with CFI (comparative fit index), TLI (Tucker Lewis Index), and RMSEA (root mean square error of approximation). Good and excellent fit is defined by a CFI and TLI of greater than 0.90 and 0.95, respectively; and an RMSEA of < 0.05 or < 0.08 represents excellent or good model fit, respectively (Hu & Bentler, 1999). The hypothesized model was tested using maximum likelihood with robust standard errors (MLR) analyses in Mplus Version 8.8.

Missing data

The parent study is a randomized clinical trial, so participants showed similar baseline characteristics between the intervention and control groups. However, missing data might introduce seriously biased findings in the randomized clinical trial. When missing data occurs, particularly if the proportions are well above 5%, as in our study, it is important not to ignore cases with missing information (Jakobsen et al., 2017). Excluding cases with missing data leads to less power and not sticking to the intent-to-treat principle (Enders, 2017). Therefore, results may not apply to the original full sample. If the missingness mechanism is not MCAR, complete case analysis (i.e., excluding cases with missing information) may lead to biased results (Carreras et al., 2021). While single imputation is one of two primarily used methods to manage missing data, second only to complete case analysis in the primary analysis, it depends on unrealistic assumptions of the missing values (e.g., the missing values are equal to the last observed ones) (Jakobsen et al., 2017). In contrast to single imputation methods, multiple imputation performs different plausible values for each missing one, thus reducing false precision and providing accurate estimates of missing values of interest (Hayati Rezvan et al., 2015; Li et al., 2015; Schafer & Graham, 2002). If the proportions of missing data are large (above 5%), data are missing on both explanatory and outcome variables, and the MAR assumption is plausible, multiple imputation has been considered as a valid method for handling missing data in randomized clinical trials and for most types of data (Jakobsen et al., 2017). In our study, we believe the assumption of missing at random can be applied to our missing data. As such, we used multiple imputations for analyses in the current study.

In the total sample (N = 812), 47% of participants were missing demographic variables, and 84% were missing values for continuous variables over the course of the study period. Specifically, missingness for demographic variables ranged from 0% for gender and primary language to 36% for household income. Missingness for continuous variables ranged from 0% for age, DDS, and DSE at baseline to 44.2% for A1c at 6 months follow-up (Appendix A, Table A1). Missing values were imputed by multiple imputations in IBM SPSS (Version 29.0.1.0). All analyses were performed based on the pooled results of five imputations.

Power Analysis

The current study is a secondary analysis using data from the New York City (NYC) Care Calls study. Participant recruitment for the parent study had been completed at the time of this study. Therefore, we cannot conduct an a priori analysis for this study. To our knowledge, no similar studies have been published on which our power calculation can be based. Power analyses for this study were based on the aims and hypotheses. Power estimates were calculated using the statistical software G*Power 3.1 (Faul et al., 2009). An alpha level of .05 and a sample size of 812 were used for power analyses. A small effect size of 0.2 was selected for power calculation.

A post-hoc test for repeated measures with two groups (Tele-SMS vs. EUC) and three measurements (baseline, mid-study, and end-of-study) calculated a sample size of 812 with a power greater than 95% to detect a small effect size of 0.2.

Ethics

This study is a secondary analysis of a parent study with a large sample size. The parent study has been approved by the Institutional Review Board at the Albert Einstein College of Medicine of Yeshiva University (IRB 2012-422).

Risks and Benefits

There were few risks associated with participation in the current study. No invasive physical procedures were involved in this study. Participants already took noninvasive assessments measuring psychological constructs and behavioral activities. Participants may not feel comfortable answering some questions. Participants who were experiencing severe emotional distress or suspected of a diagnosis of major depressive disorder would be advised to read the educational materials provided and discuss with health providers. Participants were provided a toll-free number for mental health assessment and treatment referral. If participants presented suicidal ideation or were at risk of harming themselves or others, they would be immediately transferred to the LifeNet service.

There was a potential risk of confidential information being lost and discomfort being experienced when discussing the treatment or measures. To minimize the risks, all study participants gave informed consent, which informed them of using PHI and selected clinical information from EMR. All participants were assigned study identification codes, and study data were password-protected in a designated computer system. Data documentation was locked in cabinets. Information containing identifiers was only accessible to research members who complied with GCP requirements.

Potential benefits included increased knowledge through participation in the intervention, although this study cannot guarantee direct benefits. The findings of this project

might expand our understanding and knowledge of study variables that could inform the development of interventions beneficial to individuals with T2DM whose profiles are similar to the study participants.

Chapter III: Results

Descriptive Statistics

There were 812 participants in the study sample. The baseline demographic and clinical characteristics after multiple imputations are displayed in **Table 1**. The mean age of the participants was 59.2 (*SD* = 10.8), with approximately 57% females. Spanish was the primary language spoken (78%). Most participants were Hispanic (62.7%), followed by non-Hispanic Black (18.5%), white (15.1%), and non-Hispanic Other (3.7%). Slightly over 75% reported high school or less education; over 71% of participants indicated a household annual income of less than $20K. The average body mass index was 31.2 (*SD* = 6.4) and they had an average of 12.4 years (*SD* = 9.1) since diagnosis of diabetes mellitus with a mean HbA1c of 9.3% (*SD* =1.8). The study sample indicated an overall mean score of 71.4 (*SD* = 20.4) for diabetes self-efficacy, self-management score of 76.7 (*SD* = 17.0), medication non-adherence score of 13.8 (*SD* = 3.5), and DDS score of 1.8 (*SD* = 0.7).

Main Analyses

Bivariate relationships between continuous and categorical variables. Table 2 shows Pearson product-moment correlations among continuous variables (i.e., age, BMI, duration of diabetes diagnosis) and primary study variables at baseline (i.e., HbA1c, diabetes self-efficacy, overall self-management, medication non-adherence, and diabetes distress).

Age was negatively associated with HbA1c (r = -.24, p < .001), medication non-adherence (r = -.19, p < .001), and diabetes distress (r = -.14, p < .001). Age was also positively associated with overall self-management (r = .21, p < .001). Body mass index was negatively associated with overall self-management (r = -.17, p < .001). Duration of diabetes diagnosis was found to be negatively associated with HbA1c (r = -.08, p < .05), in addition to a weak and significant positive relationship with diabetes distress (r = .09, p < .05). Within the main study variables, HbA1c at baseline was negatively associated with diabetes self-efficacy (r = -.07, p = .05) and overall diabetes self-management (r = -.10, p < .05). Moreover, HbA1c was found to be positively associated with medication non-adherence scores as measured by the 11-item ARMS-D questionnaire (r = .11, p < .05) and diabetes distress (r = .08, p < .05). Of note, moderate strength in correlations was found between diabetes self-efficacy and overall self-management (r = .55, p < .001) and diabetes distress (r = -.47, p < .001), whereas diabetes self-efficacy was negatively associated with medication non-adherence scores (r = -.31, p < .001). Additionally, overall diabetes self-management was negatively associated with medication non-adherence scores (r = -.33, p < .001) and diabetes distress (r = -.41, p < .001). Medication non-adherence scores were positively associated with diabetes distress (r = .33, p < .001).

Table 3 displays the mean difference in study variables for categorical variables at baseline. Female participants were significantly lower than males in HbA1c, t(810) = -1.99, p = .047; also, females were significantly lower than males in diabetes self-efficacy scores, t(810) = -3.76, p < .001. Participants whose race/ethnicity was Hispanic were significantly lower in diabetes self-efficacy than those whose race/ethnicity was non-Hispanic, t(810) = -2.70, p = .007. Participants whose primary language was Spanish were significantly lower

than English-speaking ones in diabetes self-efficacy scores, $t(810) = -3.44$, $p < .001$; Spanish-speaking participants were significantly lower than English-speaking ones in medication non-adherence scores, $t(810) = -3.23$, $p < .001$; moreover, Spanish speaking participants were significantly higher than English speaking participants in diabetes distress scores, $t(810) = 2.98$, $p = .002$. Participants whose family annual income was below $20K were significantly lower than those whose family income was $20K or above in HbA1c, $t(810) = -3.05$, $p = 0.002$; they were also significantly lower than participants with a family annual income of $20K or above in diabetes self-efficacy, $t(810) = -5.96$, $p < .001$. Additionally, they were significantly higher than participants with a family annual income of $20K or above in diabetes distress scores, $t(810) = 3.17$, $p = .002$.

Aim 1. Table 4 shows the mean DSE scores in the two groups at baseline, 6 and 12 months after randomization. The mean DSE score at baseline was 71.7 ($SD = 20.0$) in the intervention group ($N = 409$) and 71.2 ($SD = 20.8$) in the control group ($N = 403$). The mean difference of 0.5 ($SE = 1.43$, 95% $CI = -3.31, 2.31$) at baseline was not significant ($p = .73$). The intervention group scored higher on average 6 and 12 months after randomization than the control group, and the mean differences at these two time points (95% $CI = 1.2, 6.0$; 1.8, 6.6) were significant ($p = .01$) and ($p = .03$), respectively. Univariate and multilevel analyses were conducted to test the differences in diabetes self-efficacy between intervention and control groups by the end of the study. In univariate analysis, the DSE scores increased in both groups. The mean DSE scores increased by 0.46 points ($SD = 19.66$, 95% $CI = -2.39$, 1.46) between end of the study and baseline and was not significant ($p = .64$) in the control group, whereas an increase of 4.19 points ($SD = 19.43$, 95% $CI = -6.08, -2.30$) in the

intervention group was significant ($p < .001$) at the same time interval (Appendix A, Table A2).

Multilevel regressions were performed to examine the clustered data (i.e., three measurement occasions were nested within participants). **Table 5** displays the results of the two-level regression analysis (Level 1 predictor was times of repeated measure: baseline, 6 and 12 months after randomization; Level 2 predictor was study groups). The level-1 residual variance was $\sigma_{ij}^2 = 152.01$, 95% *CI* [135.68, 168.35], $p < .001$. The estimated coefficient γ_{11} was 1.87 (95% *CI* = 0.52, 3.21), indicating the difference in the estimated mean regression slopes (Intervention minus Control). The value of γ_{11} in our study was significant ($p = .01$), suggesting a significantly steeper slope in the intervention group than in the control group. The estimated regression coefficient γ_{01} for the regression of the random intercept on study groups was 2.78 (95% *CI* = 0.70, 4.85), representing an average of 2.78 points higher DSE scores in the intervention group than in the control group over the course of one-year follow-up ($p = .01$).

The estimated intercept, γ_{00}, for the regression of the random intercept on study groups was 72.04 (95% *CI* = 70.48, 73.60) in the control group ($p < .001$). Therefore, an average DSE score of 72.04 was expected over time in the control group. The expected intercept for the intervention group was 74.82 (72.04 + 2.78). As such, participants in the intervention group had an average DSE score of 74.82 over a 12-month period. Additionally, γ_{10}, the estimated intercept for the regression of the random slope on study groups was 0.23 (95% *CI* = -0.73, 1.19), which was the estimated slope of the regression line for the regression of DSE on the study groups in the control group ($p < .64$). Consequently, the expected slope in the

intervention group was equal to the sum of $\gamma_{10} + \gamma_{11} = 0.23 + 1.87 = 2.10$, demonstrating that the slope of the regression line is flatter for the control group than for the intervention group.

Aim 2. Overall self-management, medication non-adherence, and HbA1c at 12 months were regressed separately on diabetes self-efficacy at baseline after adjusting for sociodemographic variables (age, gender, language spoken, household annual income, education levels, and race/ethnicity), clinical characteristics (body mass index and duration of diabetes diagnosis), and study groups (intervention vs control) (Appendix A, Tables A4-6).

Table 6 gives information about regression coefficients for the predictors. The model explains about 21.4% of the variance in overall self-management at 12 months ($R^2 = .214$). The regression model of overall self-management at 12 months on diabetes self-efficacy at baseline was significant, $F(12,799) = 18.10$, $p < .001$. Diabetes self-efficacy at baseline predicted overall self-management at 12 months ($b = 0.27$, 95% $CI = 0.23, 0.32$). Similarly, our regression analysis revealed that a separate model accounted for about 8.9 % of the variance in medication non-adherence at 12 months ($R^2 = .089$). The regression model of medication non-adherence at 12 months on diabetes self-efficacy at baseline was significant, $F(12,799) = 6.48$, $p < .001$. Consequently, diabetes self-efficacy at baseline was a significant predictor with a negative relationship to medication non-adherence scores at 12 months ($b = -0.03$, 95% $CI = -0.04, -0.02$). Furthermore, another model explains about 7.3 % of the variance in HbA1c at 12 months ($R^2 = .073$). The overall regression model of HbA1c at 12 months on diabetes self-efficacy at baseline was significant, $F(12,799) = 5.28$, $p < .001$. However, diabetes self-efficacy at baseline fell short of a significant predictor ($b = -0.004$, 95% $CI = -0.010, 0.002$) with a negative relationship to HbA1c values at 12 months. These findings supported most of our hypotheses that higher diabetes self-efficacy at baseline would predict better overall self-

management and better medication adherence 12 months after randomization. However, diabetes self-efficacy at baseline was not a statistically significant predictor of HbA1c at the end of the study after adjusting for study group, other sociodemographic factors, and clinical characteristics.

Aim 3. Multiple regression was performed to examine the associations of overall self-management, medication non-adherence, and HbA1c at baseline with diabetes self-efficacy at 12 months after adjusting for sociodemographic variables, clinical characteristics, and study groups (intervention vs. control). Diabetes self-efficacy at 12 months was regressed on explanatory variables, including overall self-management, medication non-adherence, and glycemic control (i.e., HbA1c) at baseline. The model explains approximately 26.5% of the variance in diabetes self-efficacy at 12 months (R^2 = .265). The overall regression model was significant, $F(14, 797) = 20.55$, $p < .001$. **Table 7** shows information about regression coefficients for the primary predictors. As measured by the 5-item scale, overall self-management was a significant predictor with a positive relationship to diabetes self-efficacy at 12 months (b = 0.35, 95% CI = 0.28, 0.42). Moreover, as measured by the ARMS-D questionnaire, medication non-adherence score was a significant predictor with a negative relationship to diabetes self-efficacy at 12 months (b = -1.00, 95% CI = -1.33, -0.67). Specifically, lower scores on the ARMS-D questionnaire, an indicator of better medication adherence, predicted higher diabetes self-efficacy 12 months after study randomization. HbA1c values at baseline, although negatively associated with diabetes self-efficacy at 12 months, were not a significant predictor (b = -0.26, 95% CI = -0.88, 0.36; p = .42). A list of adjusted variables and their corresponding regression coefficients are given (Appendix A, Table A7). These findings were consistent with most of our hypotheses: better baseline overall

self-management and medication adherence predicted higher end-of-study diabetes self-efficacy, adjusting for sociodemographic variables, clinical characteristics, and study group (intervention vs. control). However, no significant relationship was found between baseline HbA1c values with diabetes self-efficacy at 12 months.

Aim 4. Mplus Version 8.8 was used to study the hypothesized mediating roles of overall self-management, medication non-adherence, and diabetes distress at mid-study (i.e., six months after randomization) in linking diabetes self-efficacy at baseline to glycemic control as indicated by HbA1c at study end (i.e., 12 months after randomization), after adjusting for covariates (age, gender, language, education, household annual income, race/ethnicity, BMI, and duration of diabetes diagnosis), and study group (intervention vs control).

Our study first assessed three hypothesized mediators at 6-month follow-up (see Figure 1), diabetes distress, overall self-management, and medication non-adherence, mediating the relationship between diabetes self-efficacy at baseline and HbA1c at 12-month follow-up (see Table 8). As shown in Figure 2, those reporting higher self-efficacy at baseline were independently and significantly associated with lower diabetes distress at 6-month follow-up (a = -0.012, 95% CI = -0.014, -0.010). However, diabetes distress at 6-month follow-up was not significantly associated with HbA1c at 12-month follow-up. The direct effect of self-efficacy at baseline on HbA1c at 12-month follow-up fell short of significance, independent of its indirect effects (c' = -0.002, 95% CI = -0.009, 0.004). Figure 3 displays a path model predicting HbA1c at a 12-month follow-up with overall self-management as the mediator. Those reporting higher self-efficacy at baseline were significantly associated with better overall self-management at 12-month follow-up (a = 0.321, 95% CI = 0.282, 0.361). There was no significant relationship between overall self-management at 6-month follow-up and

HbA1c at 12-month follow-up. As shown in Figure 4, those reporting higher self-efficacy at baseline reported significantly better medication non-adherence at 6-month follow-up (a = -0.046, 95% CI = -0.056, -0.035). Higher medication non-adherence scores (i.e., more medication adherence-related problems) at 6-month follow-up were, in turn, significantly associated with higher HbA1c at 12-month follow-up (b = 0.110, 95% CI = 0.066, 0.153). Although the direct effect of self-efficacy at baseline on HbA1c at 12-month follow-up fell short of significance (c' = 0.001, 95% CI = -0.005, 0.007), an indirect effect of self-efficacy at baseline on HbA1c at 12-month follow-up through medication non-adherence at 6-month follow-up (ab = -0.005) was statistically significant, 95% CI [-0.007, -0.003].

In summary, our model (Figure 1) identified a significant indirect path of self-efficacy at baseline on HbA1c at 12-month follow-up through medication non-adherence at 6-month follow-up.

Complete Case Analysis

Completer analyses were performed to compare the results with those of imputed data.

Descriptive Statistics

There were 812 participants in the study sample. The baseline demographic and clinical characteristics before multiple imputations were displayed (Appendix A, Table A8). The mean age of the participants was 59.2 (SD = 10.8), with approximately 57% females. Spanish was the primary language spoken (78%). Most participants were Hispanic (62.7%), followed by non-Hispanic Black (18.5%), White (15.1%), and non-Hispanic Other (3.7%). Slightly over 75% of participants reported high school or less education, and 66% of participants indicated a household annual income of less than $20K. The average body mass

index was 31.3 (*SD* = 6.5), and they had an average of 12.4 years (*SD* = 9.2) since diagnosis of diabetes mellitus with a mean HbA1c of 9.3% (*SD* =1.8). The study sample indicated an overall mean score of 71.4 (*SD* = 20.4) for diabetes self-efficacy, self-management score of 76.8 (*SD* = 17.1), medication non-adherence score of 13.8 (*SD* = 3.5), and DD score of 1.8 (*SD* = 0.7).

Main Analyses

Aim 1. Multilevel regressions were performed to examine the clustered data (i.e., three measurement occasions were nested within participants). The results of the two-level regression analysis (Level 1 predictor was times of repeated measure: baseline, 6 and 12 months after randomization; Level 2 predictor was study groups) are displayed (Appendix A, Table A9). The level-1 residual variance was σ_{ij}^2 = 187.33, 95% *CI* [160.53, 214.12], p < .001. The estimated coefficient γ_{11} was 1.42 (95% *CI* = -0.33, 3.16), indicating the difference in the estimated mean regression slopes (Intervention minus Control). The value of γ_{11} was not significant (p = .112), suggesting a not meaningfully steeper slope in the intervention group than in the control group. The estimated regression coefficient γ_{01} for the regression of the random intercept on study groups was 2.01 (95% *CI* = -0.39, 4.41), representing an average of 2.01 points higher DSE scores in the intervention group than the control group throughout one-year follow-up, p = .100.

The estimated intercept, γ_{00}, for the regression of the random intercept on study groups was 73.25 (95% *CI* = 71.47, 75.03) in the control group (p < .001). Therefore, an average DSE score of 73.25 was expected over time in the control group. The expected intercept for the intervention group was 75.26 (73.25 + 2.01). As such, participants in the intervention

group had an average DSE score of 75.26 over a 12-month period. Additionally, γ_{10}, the estimated intercept for the regression of the random slope on study groups was 1.96 (95% *CI* = 0.69, 3.23), which was the estimated slope of the regression line for the regression of DSE on study groups in the control group ($p = .002$). Consequently, the expected slope in the intervention group was equal to the sum of $\gamma_{10} + \gamma_{11} = 1.96 + 1.42 = 3.38$, demonstrating that the slope of the regression line is flatter for the control group than for the intervention group. These findings were similar to those of analyses with multiple imputations.

Aim 2. Table A10 in Appendix A summarizes information about regression coefficients for the predictors. The model explains about 25.6% of the variance in overall self-management at 12 months ($R^2 = .256$). The regression model of overall self-management at 12 months on diabetes self-efficacy at baseline was significant, $F(12, 269) = 7.718$, $p < .001$. Diabetes self-efficacy at baseline predicted overall self-management at 12 months ($b = 0.304$, 95% *CI* = 0.214, 0.394). Similarly, our regression analysis revealed that a separate model accounted for about 13.7% of the variance in medication non-adherence at 12 months ($R^2 = .137$). The regression model of medication non-adherence at 12 months on diabetes self-efficacy at baseline was significant, $F(12, 268) = 3.544$, $p < .001$. Consequently, diabetes self-efficacy at baseline was a significant predictor with a negative relationship to medication non-adherence scores at 12 months ($b = -0.031$, 95% *CI* = -0.049, -0.013). Furthermore, another model explains about 6.8 % of the variance in HbA1c at 12 months ($R^2 = .068$). The overall regression model of HbA1c at 12 months on diabetes self-efficacy at baseline was significant, $F(12, 348) = 2.121$, $p = .015$. However, diabetes self-efficacy at baseline fell short of a significant predictor ($b = -0.008$, 95% *CI* = -0.017, 0.002) with a negative relationship to HbA1c values at 12 months. A list of adjusted variables and their corresponding regression coefficients are

given (Appendix A, Tables A11-13). These findings were consistent with those of imputed data analyses.

Aim 3. The model explains approximately 27.9% of the variance in diabetes self-efficacy at 12 months (R^2 = .279). The overall regression model was significant, $F(14, 267) = 7.385$, $p < .001$. **Table A14** in Appendix A displays information about regression coefficients for the primary predictors. As measured by the 5-item scale, overall self-management was a significant predictor with a positive relationship to diabetes self-efficacy at 12 months (b = 0.427, 95% CI = 0.293, 0.561). Moreover, as measured by the ARMS-D questionnaire, medication non-adherence scores were a significant predictor with a negative relationship to diabetes self-efficacy at 12 months (b = -1.452, 95% CI = -2.197, -0.707). Specifically, lower scores on the ARMS-D questionnaire, an indicator of better medication adherence, predicted higher diabetes self-efficacy 12 months after study randomization. HbA1c values at baseline, although negatively associated with diabetes self-efficacy at 12 months, were not a significant predictor (b = 0.230, 95% CI = -1.014, 1.474, p = .716). A list of adjusted variables and their corresponding regression coefficients are given (see Appendix A, Table A15). These findings were consistent with those of analyses with multiple imputations.

Aim 4. As shown in Figure B1 in Appendix B, participants reporting higher self-efficacy at baseline reported lower diabetes distress (a = -0.012, 95% CI = -0.016, -0.008). The indirect effect of self-efficacy at baseline on HbA1c at 12-month follow-up through diabetes distress was not meaningful (ab = -0.001, 95% CI = -0.006, 0.003). Figure B2 in Appendix B displays a path model predicting HbA1c at a 12-month follow-up with overall self-management as the mediator. Participants reporting higher self-efficacy at baseline reported higher overall self-management (a = 0.319, 95% CI = 0.224, 0.414). However, the indirect effect of self-efficacy

at baseline on HbA1c at 12-month follow-up through overall self-management was not statistically significant (*ab* = -0.003, 95% *CI* = -0.008, 0.003). Figure B3 shows that participants reporting higher self-efficacy at baseline reported better medication adherence (i.e., lower medication non-adherence scores), a = -0.053, 95% CI [-0.070, -0.036]. Moreover, participants reporting poorer medication adherence (i.e., higher medication non-adherence scores) at 6-month follow-up reported higher HbA1c at 12-month follow-up (*b* = 0.106, 95% *CI* = 0.025, 0.188). A meaningful indirect path was found from self-efficacy at baseline to HbA1c at 12-month follow-up through medication non-adherence at 6-month follow-up (*ab* = -0.006, 95% *CI* = -0.012, -0.001).

These mediational analyses (Appendix A, Table A16) partially supported our hypothesized models (Figure 1) and were consistent with imputed data analyses.

Chapter IV: Discussion

This study built on previous work and aimed to examine the longitudinal associations among diabetes self-efficacy, overall self-management, medication non-adherence, and glycemic control, as well as mediators linking diabetes self-efficacy to glycemic control in a predominantly socioeconomically disadvantaged Latino population with suboptimally controlled type 2 diabetes. The study indicated several significant bidirectional relationships between diabetes self-efficacy, self-management, and medication nono-adherence. The exploratory mediation model demonstrated that medication non-adherence at mid-study explains an indirect process that underlies a relationship between diabetes self-efficacy at baseline and glycemic control over 12 months.

The first aim of this study was to investigate the impact of telephonic self-management support on diabetes self-efficacy. Consistent with previous studies (Presley et al., 2020; Sadler, et al., 2017), the hypothesized advantage of the telephone intervention over an EUC arm (control group) in self-efficacy was validated. Participants in the intervention group increased diabetes self-efficacy faster than those in the control group, and the difference in the growth rates between these two groups was statistically significant.

A wealth of literature has studied the effect of diabetes self-management education (DSME) on glycemic control in Latino adults with T2DM (Chrvala et al., 2016; Hildebrand et al., 2020; Lorig et al., 2008; Peña-Purcell et al., 2011; Rosal et al., 2011; Vincent et al.,

2007), in addition to research in low-and middle-income countries and primary care clinical settings (Lamptey et al., 2022; Yang et al., 2020). The evidence available suggests that DSME is associated with a reduction in HbA1c. Of note, a recent meta-analysis involving 32 RCTs on the effectiveness of telemedicine in glycemic management among adults with T2DM in primary care found significant improvements in diabetes self-efficacy in the intervention group (Zhang et al., 2022), as corroborated by our study. However, an early RCT study in a predominantly white and highly educated group reported no improvement in self-efficacy in either the intervention or control group over six months (Greenwood et al., 2015). It may be because the intervention ended at three months, and improved results might manifest after continuing the intervention in the longer term (Greenwood et al., 2015).

The current study primarily focused on a sample of predominantly Hispanic adults with low socioeconomic status and found a greater rate of improvement in diabetes self-efficacy in the intervention group. In the parent study, participants in intervention and control groups were provided with print materials focused on the importance of glycemic control, eating a healthy diet, exercise, and other health behaviors (Gonzalez et al., 2024). These intervention components, together with intervention calls in the intervention arm, presumably tapped into sources of self-efficacy, including mastery experience, vicarious experience, social persuasions, and physiological and affective states proposed by Bandura (1997), thus increasing diabetes self-efficacy.

The study's second aim was to examine diabetes self-efficacy at baseline as a predictor of diabetes overall self-management, medication non-adherence, and glycemic control at the end of the study (i.e., 12 months after randomization). Two out of three hypotheses were found. Diabetes self-efficacy at baseline was positively and significantly

associated with better overall diabetes self-management and medication adherence at 12 months. In contrast, the negative association between diabetes self-efficacy at baseline and HbA1c at 12 months was not meaningful.

These results suggest that higher diabetes self-efficacy effectively improves overall diabetes self-management activities, including medication adherence. The literature of cross-sectional studies provided evidence that self-efficacy was positively associated with self-management behaviors among T2DM patients (Jiang et al., 2019a; Luo et al., 2015; Qin et al., 2020; Yao et al., 2019). A systematic review and meta-analysis demonstrated a consistent positive association of self-efficacy with overall diabetes self-management performance, among numerous factors, including overall health beliefs and perceived barriers, on diabetes self-management behaviors (Luo, et al., 2015). Another systematic review comprising eleven cross-sectional studies identified significant and positive associations between diabetes self-efficacy and diabetes self-management in middle-aged and older adults (Qin et al., 2020). Previous longitudinal studies support the findings of the current study. One study collected five repeated assessments spanning 18 months in adults newly diagnosed with T2DM and revealed a significant relationship between self-efficacy and dietary self-management over time (Nouwen et al., 2011). Fisher and colleagues (2014) demonstrated that higher baseline self-efficacy is an independent predictor of improved self-management at 12 months. Hofer and colleagues (2016) concluded that self-efficacy significantly predicts medication adherence with a positive association at 3-month follow-up. Research by Jiang and colleagues (2019b) in their RCT study found better self-efficacy predicts improved self-management behaviors at 6-month follow-up in adults with T2DM, including physical activity, diet plan, self-monitoring of blood glucose, medication adherence, and foot care. Of

note, the association between higher diabetes self-efficacy and better medication adherence runs counter to research by Sarkar and colleagues (2006) in a racially/ethnically diverse population. It may be related to a comparatively higher percentage of "perfect medication adherence" in the study population (Sarkar et al., 2006). In contrast, medication adherence in the current study sample was fairly low. Alternatively, the differential impact of racial/ethnic groups on diabetes self-efficacy is likely to account for the insignificant findings of the early study. The current study included many more Hispanic participants than Sarkar and colleagues (2006), whereas Walker and colleagues (2014) included predominantly non-Hispanic Black participants. Social–cognitive theory postulated that self-efficacy affects task performance (Bandura & Wood, 1989). Therefore, our findings supported the notion that diabetes self-efficacy, a set of beliefs and expectations about self-management behaviors, has proven to be the most consistent predictor of all self-management behaviors (Gonzalez et al., 2016).

The current study found no significant association between diabetes self-efficacy at baseline and HbA1c at 12 months. Previous literature is inconsistent about the association between diabetes self-efficacy and glycemic control, with HbA1c being the proxy. In their cross-sectional study, Walker and colleagues (2014) concluded that increased self-efficacy is significantly associated with improved glycemic control in a predominantly low-income African-American population. However, other studies demonstrated that diabetes self-efficacy is not significantly related to HbA1c (Faridi et al., 2008; Graco et al., 2012; McCarrier et al., 2009; Sousa et al., 2005) in patients with T1DM or T2DM. Of note, the results from the main outcome of New York City Care Calls reported that HbA1c in the intervention group could have improved more if the implementation of the intervention

content were more successful (Gonzalez et al., 2024), a likely contributor to an insignificant relationship between self-efficacy at baseline and HbA1c at 12 months. In addition, the inconsistent findings may be attributable to the failure to consider some psychological constructs, such as diabetes distress or medication non-adherence, that may mediate the association between diabetes self-efficacy and glycemic control. Therefore, the association between diabetes self-efficacy and glycemic control is worth further investigation.

The third aim of this study was to examine baseline diabetes self-management, medication non-adherence, and glycemic control as predictors of diabetes self-efficacy at 12 months. We found that overall self-management or medication non-adherence at baseline independently predicted diabetes self-efficacy at 12 months with a positive and negative association, supporting two out of three hypotheses. However, HbA1c at baseline showed a negative but insignificant association with diabetes self-efficacy at the end of the study.

Our findings support previous systematic reviews and meta-analyses that a consistent and significant association exists between increased diabetes self-efficacy and better self-management activities in individuals with T2DM (Luo et al., 2015; Qin et al., 2020). Although many factors impact diabetes self-management, the effect size was 0.55 (Luo et al., 2015), suggesting a more significant than moderate strength of the relationship between higher self-efficacy and better overall self-management behaviors. However, no longitudinal studies were identified in the review. Hence, the current work contributes to the literature by uncovering bidirectional associations between diabetes self-efficacy, overall self-management, and medication non-adherence in an RCT study. We did not find a significant relationship between glycemic control at baseline and diabetes self-efficacy at 12 months. One possible explanation is that factors other than HbA1c at baseline may be more influential

on diabetes self-efficacy over time for predominantly Hispanic individuals with T2DM. A cross-sectional study in Hispanic patients with uncontrolled HbA1c levels of 8% or greater revealed that self-efficacy depended on the social context, for example, social norms, of diabetes self-management (Mansyur et al., 2016). Additional research is needed to investigate the correlates of diabetes self-efficacy in adults of Hispanic origin who have the poorest glycemic control compared to other racial-ethnic groups in the US (Resnick et al., 2006).

The fourth aim of this study was to explore the hypothesized path model of diabetes self-efficacy at baseline on glycemic control at 12 months that might be mediated by diabetes distress, overall self-management, and medication non-adherence at six months. The data partially supported the hypothesized model: increased diabetes self-efficacy at baseline to improved glycemic control over 12 months was mediated through better medication adherence at six months.

Countering our hypothesis, self-efficacy was not related to HbA1c through diabetes distress, although self-efficacy remained a significant predictor of both diabetes distress and overall self-management. Literature shows inconsistency regarding the correlation between diabetes distress and glycemic control. Numerous previous studies of cross-sectional design highlighted that higher diabetes distress was significantly associated with higher HbA1c (Coccaro et al., 2022; Cummings et al., 2014; Fayed et al., 2022; Fisher et al., 2010; Fouad et al., 2023; Indelicato et al., 2017; Nanayakkara et al., 2018). However, research by Chew and colleagues (2016) in Asian groups with T2DM at the primary care level did not find a significant association between diabetes distress and HbA1c. Furthermore, two cross-sectional studies revealed that an indirect pathway from higher diabetes distress to poorer

glycemic control through nonadherence to medication or treatment regimen was significant (Cummings et al., 2014; Fayed et al., 2021), supported by our findings.

In contrast, limited longitudinal research has examined the relationship between diabetes distress and glycemic control, and the findings were inconsistent. One RCT study reported no consistent prospective association between improved regimen distress, one component of diabetes distress, and better glycemic control at baseline, four months, and 12 months (Hessler et al., 2014). An earlier noninterventional research that collected data at baseline and nine and 18 months did not find a meaningful relationship between diabetes distress and HbA1c in prospective analyses (Fisher et al., 2009). Another observational longitudinal study with two waves of data collection found that diabetes distress was predictive of HbA1c at six months (Aikens, 2012). Gonzalez and colleagues (2024), in their findings of the NYC care calls study, revealed that diabetes distress was positively associated with HbA1c over the course of the study. The discrepancies among these studies might be due to different assessment intervals and data collection time points. Alternatively, the inconsistent findings could represent a measurement issue. How diabetes distress is defined does not match how it is measured (Fisher et al., 2022). Therefore, researchers recommended the new Type 2 Diabetes Distress Assessment System (T2-DDAS), which can disentangle the emotional experience of diabetes distress from diabetes distress sources (Fisher et al., 2022). The current study builds on the limited longitudinal study examining prospective associations of diabetes self-efficacy at baseline with HbA1c at 12 months. The results of our study suggest that attention should be paid to the mediating role of medication non-adherence in the associations between diabetes self-efficacy on the one hand and HbA1c on the other hand. Relatedly, the impact of different self-management behavior components on glycemic

control might vary. It is plausible that some self-management activities, such as medication non-adherence, are more closely related to improvement in glycemic control than others. The current work contributes to the literature and highlights the complicated prospective associations among diabetes self-efficacy, diabetes distress, self-management activities, and glycemic control in adult individuals with T2DM.

Limitations

The findings of this study need to be interpreted with caution in light of several limitations. First, this study was a secondary analysis of a large RCT with an issue of data completeness. A considerable number of participants did not complete follow-up questionnaires with study variables. Approximately 43% of participants were missing values for diabetes self-efficacy, diabetes overall self-management, and medication non-adherence at 12 months. Another 44% of participants were missing values for HbA1c at six months after randomization. The reasons for such a high amount of missing data are likely attributable to 1) a majority of socioeconomically deprived patients in the study sample, who will miss multiple appoints (Ellis et al., 2017); 2) intrinsic drawbacks of the telephonic approach, including losing visual cues for optimizing interview data (Novick, 2008). Multiple imputation (MI) was conducted to manage missing data by estimating and replacing missing values five times. The primary results based on multiple imputation are the same for Aims 2 through 4 as those supplemental analyses based on complete cases. With Aim 1, our hypothesis was supported by analyses based on multiple imputation. In contrast, complete cases revealed a higher but insignificant increase in self-efficacy in the intervention group than in the control group. The literature has established multiple imputation as a preferred method for dealing with missing data over listwise deletion (Carreras et al., 2021; Enders, 2017; Hayati Rezvan et al., 2015;

Jakobsen et al., 2017; Li et al., 2015; Schafer & Graham, 2002; Stavseth et al., 2019). Therefore, we believe the primary results from multiple imputation are valid.

Second, the study's generalizability is an additional limitation. Participants were recruited from primary care practices participating in the Primary Care Information Project, which aims to assist small practices in underserved communities in NYC. Consequently, results may not generalize to other geographic regions and ethnic backgrounds. Moreover, although these participants were similar to those in the population on available EHR data, they may not be representative of patients in the population, given that these participants were people who agreed to participate in the study.

Third, some study methods of the parent RCT study can be considered additional limitations. Although the diabetes self-efficacy scale in this study has been validated in an early study with diverse groups (Sarkar et al., 2006), numerous instruments are available for measuring diabetes self-efficacy (Lee et al., 2020), making it difficult to compare results in the literature.

Fourth, the present study did not assess the impact of tiered telephonic support in the intervention group on diabetes-related results. It is important to emphasize that the findings of our study variables could vary due to a dose-response relationship.

Finally, self-report measures do not allow for real-time evaluation of between-person and within-person changes that could benefit diabetes management for patients, providers, and researchers (Nam et al., 2021). Our study used total DDS scores, including four domains, such as regimen-related distress, which are not closely related to emotional distress (Gonzalez et al.,

2015). Consequently, the emotional burden subscale of the DDS would better represent emotional distress because of managing the daily demands of living with diabetes.

Study strengths include a large sample of predominantly socioeconomically disadvantaged Hispanic individuals with suboptimally controlled T2DM.

Implications for Research

Our findings contribute notably to the literature in several areas. Little longitudinal research is available regarding the prospective associations of diabetes self-efficacy, diabetes distress, overall self-management activities, medication non-adherence, and glycemic control, let alone studies in predominantly socioeconomically disadvantaged Hispanic individuals living with uncontrolled T2DM. Self-efficacy, a core construct in Bandura's Social Cognitive Theory (Bandura, 2004), has been conceptualized as the confidence in carrying out self-management activities. Research has shown that self-efficacy positively correlates with treatment adherence in patients living with chronic disease (Farley, 2019). Diabetes self-management (DSM) is pivotal in optimizing glycemic control (Feldman et al., 2014). Studies have revealed low self-efficacy correlates with suboptimal self-management, treatment adherence, and worse glycemic control (King et al., 2010; Walker et al., 2014; Wallston et al., 2007). Thus, an increased understanding of relationships between self-efficacy, self-management activities, and glycemic control contributes significantly to extant literature about individuals with uncontrolled T2DM. In addition, the current study focuses on ethnically diverse and socioeconomically disadvantaged groups disproportionately affected by T2DM (Centers for Disease Control and Prevention, 2020). Our work explores the hypothesized bidirectional relationships between diabetes self-efficacy, overall self-management, medication non-adherence, and glycemic control, as this area lacks research among the

targeted populations. Findings of these relationships in a longitudinal study with a large sample of underrepresented adults living with T2DM support the continuous development of interventions aimed at improving self-management and diabetes distress. Recent studies on self-management interventions have proven to improve diabetes self-efficacy, self-management activities, and glycemic control (Mao et al., 2022; Sayin Kasar et al., 2022).

Our work adds to limited longitudinal research that might shed light on identifying the causal mechanisms underlying the relationships between diabetes self-efficacy, diabetes distress, overall self-management, medication non-adherence, and glycemic control in a prospective model. Only a few studies have examined the pathways of these constructs in either RCT or observational longitudinal analyses. Unsurprisingly, analyses have been exploratory, and more prospective research is needed to corroborate and replicate findings. Our work contributes to the literature on prospectively investigating the impact of psychological constructs on glycemic control in predominantly disadvantaged Hispanic individuals with uncontrolled T2DM, who are vulnerable to health disparities, including access to diabetes management (Haw et al., 2021).

Clinical Implications

One primary clinical implication is that DSE may not directly impact glycemic control. Providers should know that DSE is bidirectionally associated with overall self-management activities (including medication adherence), enriching results with other longitudinal research (Fisher et al., 2014; Hofer et al., 2016; Jiang et al., 2019b). Our research provides robust evidence of this pattern independent of age, BMI, gender, race/ethnicity, primary language spoken, education level, annual household income, duration of diabetes diagnosis, and study groups. In the clinical setting, our findings suggest that

knowledge about the level of diabetes self-efficacy may provide valuable information to the provider, facilitating ongoing support of lifestyle and health behaviors, including eating an appropriate diet, complying with medications, and sustaining an acceptable level of physical activity (Haas et al., 2012). Diabetes self-management activities have been incorporated into glycemic management in T2DM (American Diabetes Association, 2023). Evidence suggests that diabetes self-management activities are essential for optimal glycemic control (Feldman et al., 2014). As such, assessing diabetes self-efficacy is recommended for practitioners to intervene with patients living with uncontrolled T2DM who may benefit from improved overall self-management. By identifying individuals with lower diabetes self-efficacy who may have difficulties managing self-management activities, psychosocial and educational resources can be applied to those who may benefit most. Evidence reveals that diabetes self-management education (DSME) interventions have effectively achieved glycemic control goals in Hispanic individuals with T2DM (Hildebrand et al., 2020). In the meantime, selecting a self-efficacy-focused structured education program and motivational interviewing has effectively improved diabetes self-efficacy (Bilgin et al., 2022; Jiang, et al., 2019b).

Our findings about a pathway from an indirect effect of diabetes self-efficacy on glycemic control through medication non-adherence indicate the complex relationship between an individual's confidence in self-management activities and glycemic outcomes. Providers should be mindful of an inverse association of diabetes self-efficacy with diabetes distress over time because consistent evidence proves a high prevalence of diabetes distress (Dennick et al., 2017; Perrin et al., 2017) and its association with health-related quality of life in individuals living with T2DM (Teli et al., 2023), the latter of which constitutes one of the primary treatment goals of diabetes care (ElSayed et al., 2022). Therefore, identifying

individuals with T2DM with low diabetes self-efficacy during clinical encounters is warranted. This could answer the question of who needs the psychological and behavioral interventions. In sum, we found that diabetes self-efficacy is especially relevant when providers attempt to improve self-management, facilitate emotional well-being, and achieve optimal glycemic control among adults with type 2 diabetes.

Future Directions

Further research is needed to understand the associations of diabetes self-efficacy with self-management activities, medication non-adherence, diabetes distress, and glycemic control. Our work contributed significantly to the literature on longitudinal relationships between these psychological and behavioral constructs that could directly or indirectly correlate with HbA1c. Future research is required to replicate our findings in a prospective study design, preferably studies with more than three waves of data collection with a follow-up time greater than 12 months, which can shed light on causality relationships between constructs of interest. The current study examined the relationship between diabetes self-efficacy, overall self-management, and medication non-adherence within a prospective RCT in predominantly Hispanic individuals with low socioeconomic status and with uncontrolled T2DM. Future studies would benefit from investigating the relationships between other components of self-management activities, including exercise and diet, and the outcomes of diabetes management, which started a decade ago (Nouwen et al., 2011) and has drawn much enthusiasm from recent studies (Gilcharan Singh et al., 2020; Hamidi et al., 2022; Muntis et al., 2023; Ortega et al., 2020). The continual research with associations of these constructs as the primary outcome would allow providers to target specific self-management activities in a resource-constrained environment for disadvantaged groups of patients.

Our work used the Diabetes Distress Scale (DDS) for the assessment of diabetes-related distress (Polonsky et al., 2005), which conflated emotional experience and sources of diabetes distress (Polonsky et al., 2022). Future studies should select a more actionable measure that can tease apart emotional components and contributors to diabetes distress (Polonsky et al., 2022). It would add to our understanding of real-life emotional distress in patients with diabetes and its relationship with psychological and behavioral constructs such as diabetes self-efficacy and self-management activities.

Furthermore, future research is needed regarding the temporal precedence among diabetes self-efficacy, diabetes distress, self-management activities, and outcomes of diabetes care utilizing ecological momentary assessment (EMA) and continuous glucose monitoring (CGM). Intensive longitudinal data with EMA and CGM would help capture the more proximal effects of the interacting constructs in the short term, which a panel data analysis such as the current study can not characterize. In addition, intensive longitudinal data would facilitate a better understanding of the underlying mechanisms in pathway analysis by focusing on within-person differences, eliminating confounding factors that make a cause-and-effect study challenging, if not impossible. It will also allow for testing sources of self-efficacy as laid out in Social Cognitive Theory (Bandura, 1986) in the context of T2DM. This essential step is beneficial to the development of targeted interventions.

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Tables

Table 1

Baseline Demographic Characteristics of Participants after Multiple Imputation **(N = 812)**

Variable	Mean (SD)	N (%)
Age, years	59.2 (10.8)	
Sex		
Female		462 (56.9%)
Male		350 (43.1%)
Race/Ethnicity		
White		123 (15.1%)
Non-Hispanic Black		150 (18.5%)
Hispanic		509 (62.7%)
Non-Hispanic Other		30 (3.7%)
Primary language		
English		179 (22%)
Spanish		633 (78%)
Education		
Less than HS or HS		611 (75.2%)
Above HS		201 (24.8%)
Household income		
Less than $20K		578 (71.2%)
$20K or above		234 (28.8%)
Study variables at baseline		
Self-efficacy		71.4 (20.4)
Overall self-management		76.7 (17.0)
Medication adherence		13.8 (3.5)
Diabetes distress		1.8 (0.7)
HbA1c (%)	9.3 (1.8)	
BMI (kg/m2)	31.2 (6.4)	
DDD, years	12.4 (9.1)	

Note. HS: High school; HbA1c: Hemoglobin A1c; BMI: Body Mass Index; DDD: Duration of Diabetes Diagnosis.

Table 2

Pearson Correlation Coefficients between Continuous Variables at Baseline

	Age	BMI	DoDD	A1c	DSE	DSM	MNA	DDS
		Correlation (CI)	Correlation (CI)	Correlation (CI)	Correlation (CI)	Correlation (CI)	Correlation (CI)	Correlation (CI)
Age		**-.19** (-0.25,-0.12)	**.31** (0.25,0.37)	**-.24** (-0.30,-0.17)	.07 (-0.00,0.13)	**.21** (0.15,0.28)	**-.19** (-0.25,-0.12)	**-.14** (-0.21,-0.08)
BMI			-.05 (-0.11,0.02)	.01 (-0.06,0.08)	-.05 (-0.12,0.02)	**-.17** (-0.23,-0.10)	.02 (-0.05,0.09)	.03 (-0.03,0.10)
DoDD				**-.08** (-0.14,-0.01)	-.04 (-0.11,0.03)	.07 (-0.00,0.13)	-.001 (-0.07,0.07)	**.09** (0.02,0.15)
A1c					-.07 (-0.14,0.00)	**-.10** (-0.17,-0.03)	**.11** (0.04,0.17)	**.08** (0.01,0.15)
DSE						**.55** (0.50,0.59)	**-.31** (-0.37,-0.24)	**-.47** (-0.52,-0.41)
DSM							**-.33** (-0.39,-0.27)	**-.41** (-0.46,-0.35)
MA								**.33** (0.27,0.39)

Note. CI: 95% CI; BMI: Body Mass Index; DDD: Duration of Diabetes Diagnosis; DSE: Diabetes Self-Efficacy as measured by the 8-item questionnaire; DSM: Diabetes Self-Management as measured by the 5-item questionnaire; MNA: Medication Non-Adherence as measured by the 11-item ARMS-D questionnaire; DDS: Diabetes Distress Scale as measured by the 17-item questionnaire.

Bold correlations are statically significant ($p < .05$).

Table 3

Mean Difference in Study Variables for Categorical Variables at Baseline

		HbA1c		DSE		DSM		MNA		DDS	
		Mean Difference	P	Mean Difference	P	Mean Difference	P	Mean Difference	P	Mean Difference	P
Sex	Female Male	-0.25(0.12)	**.047**	-5.38(1.43)	**<.001**	-0.25(1.21)	.83	0.02(0.25)	0.93	0.09(0.05)	.086
R/E	Hispanic Non-His	0.17(0.13)	.17	-3.97(1.47)	**.007**	0.07(1.24)	.96	-0.01(0.25)	.98	0.07(0.05)	.21
Lan	Spanish English	-0.02(0.15)	.89	-5.90(1.71)	**<.001**	0.60(1.44)	.68	-1.16(0.29)	**<.001**	0.17(0.06)	**.003**
Edu	<=HS >HS	-0.04(0.14)	.78	-0.99(1.66)	.55	2.20(1.39)	.11	-0.62(0.33)	.07	-0.03(0.06)	.64
A.I.	<$20K >=$20K	-0.42(0.14)	**.002**	-9.03(1.52)	**<.001**	1.69(1.30)	.19	0.24(0.27)	.37	0.17(0.05)	**.002**

Note. R/E: Race/Ethnicity; Non-His: Non-Hispanic; Lan: Language; Edu: Education; HS: High School; A.I.: Family Annual Income; DSE: Diabetes Self-Efficacy as measured by the 8-item questionnaire; DSM: Diabetes Self-Management; MNA: Medication Non-Adherence; DDS: Diabetes Distress Scale; Standard Errors are in parentheses.

Bold *P* values are statistically significant.

Table 4

Mean DSE Scores in the Intervention and Control Groups at Baseline and Follow-up

	No of Participants	Baseline			Mid-study			End-study		
		MDSE(SD)	p	95% CI	MDSE(SD)	p	95% CI	MDSE(SD)	p	95% CI
Intervention	409	71.7(20.0)	.73	-2.3, 3.3	76.9(16.2)	**.003**	1.2, 6.0	75.9(16.3)	**<.001**	1.9, 6.6
Control	403	71.2(20.8)			73.3(18.5)			71.7(18.4)		

Note. MDSE: Mean Diabetes Self-Efficacy as measured by the 8-item questionnaire; SD: Standard Deviation.

Bold *P* values are statistically significant.

Table 5

Model Results of Multilevel Regression Analysis

	Estimate	SE	Est./SE	P Value
Within Level				
Residual variances				
DSE	152.01	8.33	18.24	< **.001**
Between Level				
Regression of random slope on study groups	1.87	0.69	2.72	.**006**
Regression of the random intercept on study groups	2.78	1.06	2.63	**.009**
Intercepts				
Regression of DSE on study groups	72.04	0.79	90.72	< .**001**
Regression of random slope on study groups	0.23	0.49	0.47	.64

Note. DSE: Diabetes Self-Efficacy as measured by the 8-item scale.

Bold *p* values are statistically significant.

Table 6

Multivariate Linear Regression Analysis for DSE at Baseline Predicting Overall Self-management, Medication Non-Adherence, and Glycemic Control at 12 Months

	DSM at 12 Months				MNA at 12 Months				HbA1c at 12 Months			
	b	SE	95% CI		b	SE	95% CI		b	SE	95% CI	
DSE[a]	**0.274**	0.024	0.228	0.320	**-0.027**	0.005	-0.037	-0.018	-0.004	0.003	-0.010	0.002
Groups	0.158	0.920	-1.648	1.963	0.003	0.191	-0.373	0.379	-0.152	0.115	-0.377	0.074

Note. DSE: Diabetes Self-efficacy as measured by the 8-item questionnaire; DSM: Diabetes Self-Management as measured by the 5-item questionnaire; MNA: Medication Non-Adherence as measured by the 11-item ARMS-D questionnaire; Groups: treatment group, including intervention and control groups.

[a]Adjusted for sociodemographic factors (e.g., sex, age, language spoken, education, household annual income, and race/ethnicity), clinical characteristics (e.g., Body Mass Index and duration of diabetes diagnosis), and study group (intervention vs control).

DV: DSM at 12 months $F(12,799) = 18.10$, $p < .001$ $R^2 = .214$

DV: MNA at 12 months $F(12, 799) = 6.48$, $p < .001$ $R^2 = .089$

DV: HbA1c at 12 months $F(12, 799) = 5.28$, $p < .001$ $R^2 = .073$

Table 7

Multiple Linear Regression Analysis for Overall Self-management, Medication Non-Adherence, and Glycemic control at Baseline Predicting DSE at 12 Months

	b	SE	95% CI	
Overall self-management[a]	**0.351**[b]	0.034	0.284	0.418
Medication non-adherence[a]	**-1.001**[b]	0.167	-1.328	-0.673
HbA1c[a]	-0.257[c]	0.315	-0.876	0.362
Groups	**3.582**[b]	1.067	1.487	5.676

Note. DSE: Diabetes Self-efficacy; Groups: treatment group (intervention vs control groups).

[a]Adjusted for sociodemographic factors (i.e., age, gender, education, household annual income, language spoken, and race/ethnicity), clinical characteristics (e.g., Body Mass Index and duration of diabetes diagnosis), and study group (intervention vs control).

b$p < .001$

c$p = .415$

$F(14, 797) = 20.55$, $p < .001$, $R^2 = .265$.

Table 8

Mediation Analysis Summary

Total Effect (se)	Direct Effect (se)	Relationship	Indirect Effect(se)	95% Confidence Interval	
				Lower Bound	Upper Bound
DSE_0 -> $HbA1c_2$ -0.004(0.003)	DSE_0 -> $HbA1c_2$ -0.002(0.003)	H:DSE_0->DDS_1->$HbA1c_2$	-0.002(0.001)	-0.004	0.001
DSE_0-> $HbA1c_2$ -0.004(0.003)	DSE_0->$HbA1c_2$ -0.002(0.003)	H:DSE_0->DSM_1->$HbA1c_2$	-0.002(0.002)	-0.005	0.001
DSE_0-> $HbA1c_2$ -0.004(0.003)	DSE_0->$HbA1c_2$ 0.001(0.003)	H:DSE_0->MNA_1->$HbA1c_2$	**-0.005**(0.001)	-0.007	-0.003

Note. se: Standard Error; H: Hypothesis; DSE: Diabetes Self-Efficacy; DSM: Diabetes Self-Management; MNA: Medication Non-Adherence; DDS: Diabetes Distress Scale.

Subscripts (0, 1, and 2) refer to baseline, 6-month follow-up, and 12-month follow-up, respectively.

Figures

Figure 1

Hypothesized Path Model Predicting HbA1c Levels with Overall Self-management, Medication Non-Adherence, and Diabetes-Related Distress as Mediators

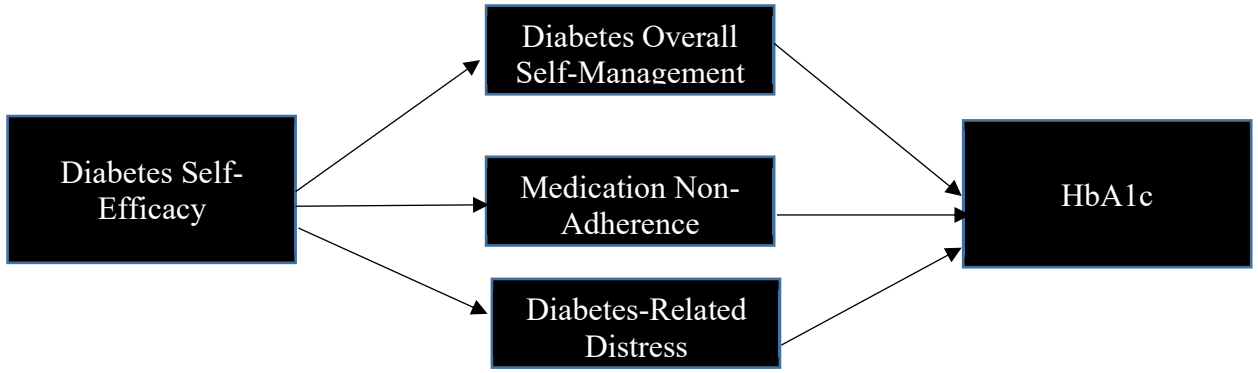


Figure 2

Path Model Predicting HbA1c at 12-month Follow-up with Diabetes Distress at 6-month Follow-up as the Mediator

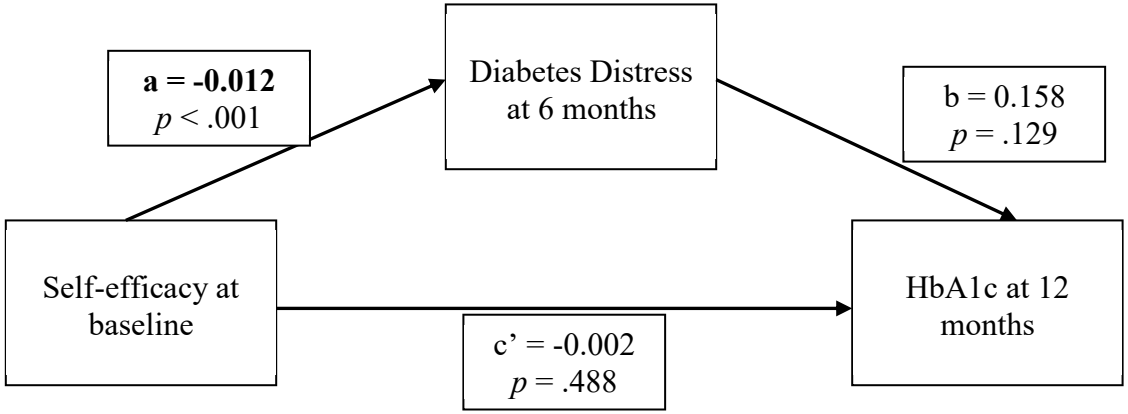


Figure 3

Path Model Predicting HbA1c at 12-month Follow-up with Overall Self-management at 6-month Follow-up as the Mediator

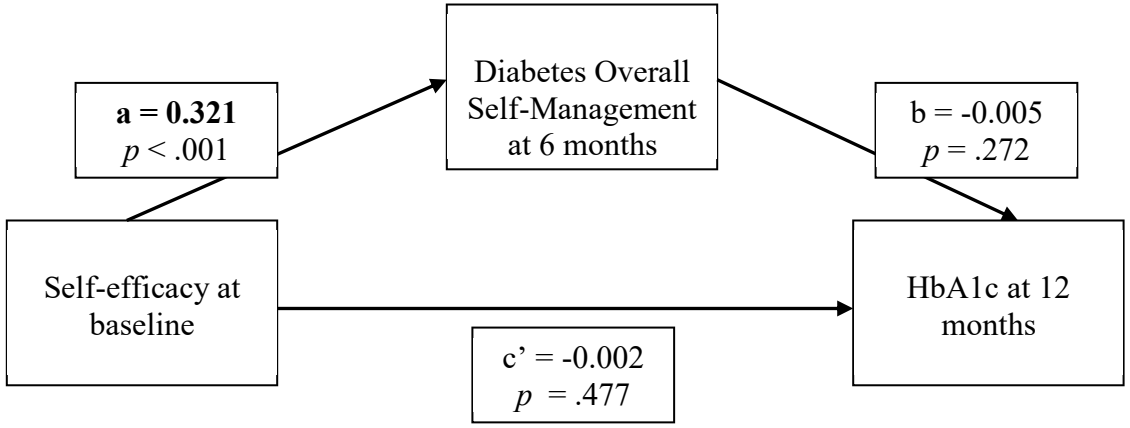
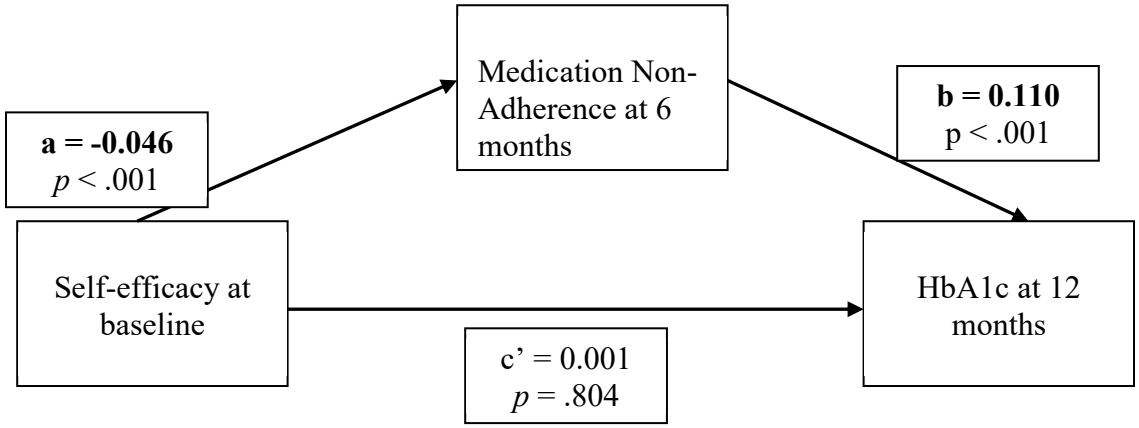


Figure 4

Path Model Predicting HbA1c at 12-month Follow-up with Medication Non-Adherence at 6-month Follow-up as the Mediator



Appendix A

Table A1

Missingness for Demographic Factors (N = 812)

Variable	Valid	% Missing
Treatment group	811	0.1%
Gender	812	0
Education	806	0.7%
Household income	520	36%
Primary language	812	0
Hispanic ethnicity	808	0.5%
Race	646	20.4%
Marital Status	797	1.8%

Missingness for Continuous Variables (N = 812)

Variable	Valid	% Missing
Age	812	0
Duration of Diabetes	801	1.4%
BMI at baseline	749	7.8%
BMI at 6 months	502	38.2%
BMI at 12 months	529	34.9%
A1c at baseline	806	0.7%
A1c at 6 months	453	44.2%
A1c at 12 months	611	24.8%
DDS at baseline	812	0
DDS at 6 months	582	28.3%
DDS at 12 months	519	36.1%
DSE at baseline	812	0
DSE at 6 months	543	33.1%
DSE at 12 months	460	43.3%
DSM at baseline	799	1.6%
DSM at 6 months	537	33.9%
DSM at 12 months	458	43.6%
MNA at baseline	811	0.1%
MNA at 6 months	540	33.5%
MNA at 12 months	456	43.8%

Note. BMI: Body Mass Index; DDS: Diabetes Distress Scale; DSE: Diabetes Self-Efficacy; DSM: Diabetes Self-Management; MNA: Medication Non-Adherence.

Table A2

Mean Diabetes Self-Efficacy Differences in Two Groups at Baseline and End-Study

	N	Mean Difference	SD	SE	95% CI of the Difference		P Value
					Lower	Upper	
Control	403	-0.46	19.66	.98	-2.39	1.46	.64
Intervention	409	-4.19	19.43	.96	-6.08	-2.30	< .001

Note. SE = Standard Error Mean; Mean Difference = Diabetes Self-Efficacy Score at Baseline – Diabetes Self-Efficacy at End-Study.

Table A3

Pearson Correlation Coefficients between Main Study Variables and Dichotomous Variables at Baseline

	A1c	95%CI	DSE	95%CI	DSM	95%CI	MNA	95%CI	DD	95%CI
Gender	**.070**	0.001,0.138	**.131**	0.063,0.198	.007	-0.061,0.076	-.003	-0.072,0.066	-.060	-0.129,0.009
Edu	.010	-0.059,0.079	.021	-0.048,0.090	-.056	-0.124,0.013	**.076**	0.007,0.144	.017	-0.052,0.085
HAInc	**.112**	0.043,0.179	**.205**	0.138,0.270	-.046	-0.114,0.023	-.031	-0.100,0.038	**-.106**	-0.174,-0.038
Lang	.005	-0.064,0.073	**.120**	0.052,0.187	-.015	-0.083,0.054	**.137**	0.069,0.204	**-.095**	-0.163,-0.027
RaEth_W	-.020	-0.088,0.049	.001	-0.067,0.070	-.021	-0.089,0.048	-.054	-0.122,0.015	.044	-0.025,0.113
RaEth_H	.048	-0.021,0.116	**-.094**	-0.162,-0.026	.002	-0.067,0.071	-.001	-0.070,0.068	.045	-0.024,0.113
RaEth_B	.003	-0.066,0.071	**.100**	0.032,0.168	.002	-0.067,0.071	.051	-0.018,0.120	**-.082**	-0.150,-0.013
RaEth_O	**-.091**	-0.159,-0.023	.033	-0.036,0.101	.030	-0.039,0.098	-.001	-0.070,0.068	-.030	-0.099,0.039

Note. A1c: HbA1c; DSE: Diabetes Self-Efficacy; DSM: Diabetes Self-Management; MNA: Medication Non-Adherence; DD: Diabetes Distress; Edu: Education; HAInc: Household Annual Income; Lang: Language; RaEth_W: Race/Ethnicity_White; RaEth_H: Race/Ethnicity_Hispanic; RaEth_B: Race/Ethnicity_NonHispanic_Black; RaEth_O: Race/Ethnicity_NonHispanic_Other.

Bold coefficients are statistically significant ($p < .05$).

Table A4

Multiple Linear Regression Analysis for DSE at Baseline Predicting Overall Self-Management at 12 Months

	b	SE	95% CI		P Value
Age	0.277	0.048	0.184	0.370	**<.001**
BMI	-0.121	0.076	-0.269	0.027	.110
Gender	0.976	0.962	-0.911	2.864	.310
Language	-2.815	1.352	-5.468	-0.161	**.038**
Income	-2.949	1.074	-5.057	-0.841	**.006**
DoDD	-0.083	0.053	-0.187	0.021	.118
Edu	0.897	1.107	-1.275	3.070	.418
RaEth_W	-0.849	1.322	-3.445	1.746	.521
RaEth_B	-0.882	1.427	-3.682	1.919	.537
RaEth_O	-0.759	2.474	-5.615	4.096	.759

Note. A significant linear regression was found, $F(12, 799) = 18.10$, $p < .001$, with an R^2 of .214. DSE: Diabetes Self-efficacy; BMI: Body Mass Index; HAincome: Household Annual Income; DoDD: Duration of Diabetes Diagnosis; Edu: Education; RaEth_W: Race/Ethnicity_White; RaEth_B: Race/Ethnicity_NonHispanic_Black; RaEth_O: Race/Ethnicity_NonHispanic_Others; Race/Ethnicity_Hispanic is the reference group; DSM_0: Overall Self-management at baseline.

Bold *p* values are statistically significant.

Table A5

Multiple Linear Regression Analysis for DSE at Baseline Predicting Medication Non-Adherence at 12 Months

	b	SE	95% CI		P Value
Age	-0.046	0.010	-0.065	-0.026	**<.001**
BMI	0.008	0.016	-0.023	0.038	.629
Gender	0.401	0.200	0.008	0.794	**.046**
Language	0.821	0.281	0.269	1.374	**.004**
Income	-0.293	0.224	-0.732	0.146	.190
DoDD	0.007	0.011	-0.015	0.028	.556
Edu	-0.275	0.230	-0.728	0.177	.232
RaEth_W	0.025	0.275	-0.515	0.565	.928
RaEth_B	-0.039	0.297	-0.622	0.544	.896
RaEth_O	-0.364	0.515	-1.375	0.647	.480

Note. A significant linear regression was found, $F(12, 799) = 6.48$, $p < .001$, with an R^2 of .089. DSE: Diabetes Self-efficacy; BMI: Body Mass Index; HAincome: Household Annual Income; DoDD: Duration of Diabetes Diagnosis; Edu: Education; RaEth_W: Race/Ethnicity_White; RaEth_B: Race/Ethnicity_NonHispanic_Black; RaEth_O: Race/Ethnicity_NonHispanic_Others; Race/Ethnicity_Hispanic is the reference group; MNA_0: Medication Non-Adherence at baseline.

Bold *p* values are statistically significant.

Table A6

Multiple Linear Regression Analysis for DSE at Baseline Predicting Glycemic Control at 12 Months

	b	SE	95% CI		P Value
Age	-0.034	0.006	-0.046	-0.022	**<.001**
BMI	-0.028	0.009	-0.047	-0.010	**.003**
Gender	0.326	0.120	0.090	0.562	**.007**
Language	0.030	0.169	-0.301	0.362	.857
Income	-0.215	0.134	-0.479	0.049	.110
DoDD	0.019	0.007	0.006	0.032	**.005**
Edu	-0.024	0.138	-0.296	0.247	.861
RaEth_W	-0.274	0.165	-0.599	0.051	.098
RaEth_B	0.219	0.178	-0.132	0.569	.221
RaEth_O	-0.460	0.309	-1.067	0.148	.138

Note. A significant linear regression was found, $F(12, 799) = 5.28$, $p < .001$, with an R^2 of .073. DSE: Diabetes Self-efficacy; BMI: Body Mass Index; HAincome: Household Annual Income; DoDD: Duration of Diabetes Diagnosis; Edu: Education; RaEth_W: Race/Ethnicity_White; RaEth_B: Race/Ethnicity_NonHispanic_Black; RaEth_O: Race/Ethnicity_NonHispanic_Others; Race/Ethnicity_Hispanic is the reference group; $A1c_0$: HbA1c at baseline.

Bold *p* values are statistically significant.

Table A7

Multiple Linear Regression Analysis for Overall Self-management, Medication Non-Adherence, and HbA1c at Baseline Predicting DSE at 12 Months

	b	SE	95% CI		P Value
Age	-0.042	0.057	-0.154	0.071	.467
BMI	0.126	0.089	-0.049	0.300	.157
Gender	1.499	1.109	-0.678	3.677	.177
Language	6.729	1.580	3.628	9.830	**<.001**
Income	3.109	1.234	0.686	5.531	**.012**
DoDD	-0.084	0.062	-0.204	0.037	.174
Edu	0.900	1.286	-1.624	3.424	.484
RaEth_W	-2.642	1.537	-5.659	0.374	.086
RaEth_B	2.971	1.653	-0.273	6.215	.073
RaEth_O	-0.703	2.875	-6.347	4.941	.807

Note. A significant linear regression was found, $F(14, 797) = 20.55$, $p < .001$, with an R^2 of .265. DSE: Diabetes Self-efficacy; BMI: Body Mass Index; Icome: Household Annual Income; DoDD: Duration of Diabetes Diagnosis; Edu: Education; RaEth_W: Race/Ethnicity_White; RaEth_B: Race/Ethnicity_NonHispanic_Black; RaEth_O: Race/Ethnicity_NonHispanic_Others; Race/Ethnicity_Hispanic is the reference group; DSE_0: DSE at baseline.

Bold *p* values are statistically significant.

Table A8

Baseline Demographic Characteristics of Participants before Multiple Imputation *(N = 812)*

Variable	Mean (SD)	N (%)
Age, years	59.2 (10.8)	
Sex		
Female		462 (56.9%)
Male		350 (43.1%)
Race/Ethnicity		
White		123 (15.1%)
Non-Hispanic Black		150 (18.5%)
Hispanic		509 (62.7%)
Non-Hispanic Other		30 (3.7%)
Primary language		
English		179 (22%)
Spanish		633 (78%)
Education		
Less than HS or HS		607 (75.3%)
Above HS		199 (24.7%)
Household income		
Less than $20K		343 (66%)
$20K or above		177 (34%)
Study variables at baseline		
Self-efficacy		71.4 (20.4)
Overall self-management		76.8 (17.1)
Medication non-adherence		13.8 (3.5)
Diabetes distress		1.8 (0.7)
HbA1c (%)	9.3 (1.8)	
BMI (kg/m2)	31.3 (6.5)	
DDD, years	12.4 (9.2)	

Note. HS: High school; HbA1c: Hemoglobin A1c; BMI: Body Mass Index; DDD: Duration of Diabetes Diagnosis.

Table A9

Model Results of Multilevel Regression Analysis (Completer Analysis)

	Estimate	SE	Est./SE	P Value
Within Level				
Residual variances				
DSE	187.33	13.67	13.70	**< .001**
Between Level				
Regression of random slope on Study groups	1.42	0.89	1.59	.112
Regression of the random intercept on Study groups	2.01	1.22	1.65	.100
Intercepts				
Regression of DSE on study groups	73.25	0.91	80.84	**< .001**
Regression of random slope on study groups	1.96	0.65	3.03	**.002**

Note. DSE: Diabetes Self-Efficacy as measured by the 8-item scale.

Table A10

Multiple Linear Regression Analysis with Missingness for DSE at Baseline Predicting Overall Self-Management, Medication Non-Adherence, and Glycemic Control at 12 Months

	DSM at 12 Months				MNA at 12 Months				HbA1c at 12 Months			
	B	SE	95% CI		B	SE	95% CI		B	SE	95% CI	
DSE[a]	**0.304**	0.046	0.214	0.394	**-0.031**	0.009	-0.049	-0.013	-0.008	0.005	-0.017	0.002
Groups	1.057	1.721	-2.331	4.445	0.077	0.343	-0.598	0.752	-0.150	0.182	-0.507	0.208

Note. DSE: Diabetes Self-efficacy as measured by the 8-item questionnaire; DSM: Diabetes Self-Management as measured by the 5-item questionnaire; MNA: Medication Non-Adherence as measured by the 11-item ARMS-D questionnaire; Groups: treatment group, including intervention and control groups.

[a]Adjusted for sociodemographic factors (e.g., age, gender, language spoken, education, household annual income, and race/ethnicity), clinical characteristics (e.g., Body Mass Index and duration of diabetes diagnosis), and study groups (intervention vs control).

DV: DSM at 12 months $F(12, 269) = 7.718$, $p < .001$, $R^2 = .256$

DV: MNA at 12 months $F(12, 268) = 3.544$, $p < .001$, $R^2 = .137$

DV: HbA1c at 12 months $F(12, 348) = 2.121$, $p = .015$, $R^2 = .068$

Table A11

Multiple Linear Regression Analysis for DSE at Baseline Predicting Overall Self-management at 12 Months (Completer analysis N = 282)

	b	SE	95% CI		P Value
DSE	0.304	0.046	0.214	0.394	**<.001**
Age	0.384	0.091	0.204	0.564	**<.001**
BMI	-0.078	0.134	-0.342	0.187	.563
Gender	3.812	1.760	0.346	7.278	**.031**
HAincome	-2.329	1.915	-6.099	1.441	.225
Language	-5.025	2.353	-9.658	-0.392	**.034**
DoDD	0.019	0.102	-0.181	0.220	.851
Edu	0.803	1.985	-3.106	4.712	.686
RaEth_W	1.285	2.477	-3.591	6.161	.604
RaEth_B	1.209	2.482	-3.678	6.095	.627
RaEth_O	4.185	4.276	-4.234	12.604	.329

Note. A significant linear regression was found, $F(12, 269) = 7.718$, $p < .001$, with an R^2 of .256. DSE: Diabetes Self-efficacy; BMI: Body Mass Index; HAincome: Household Annual Income; DoDD: Duration of Diabetes Diagnosis; Edu: Education (0: high school or less than high school; 1: above high school; RaEth_W: Race/Ethnicity_White; RaEth_B: Race/Ethnicity_NonHispanic_Black; RaEth_O: Race/Ethnicity_NonHispanic_Others; Race/Ethnicity_Hispanic is the reference group.

Bold *p* values are statistically significant.

Table A12

Multiple Linear Regression Analysis for DSE at Baseline Predicting Medication Non-Adherence at 12 Months (Completer Analysis N = 281)

	b	SE	95% CI		P Value
DSE	-0.031	0.009	-0.049	-0.013	**<.001**
Age	-0.058	0.018	-0.094	-0.023	**.001**
BMI	0.005	0.027	-0.047	0.058	.850
Gender	0.194	0.351	-0.497	0.884	.581
HAincome	-0.389	0.382	-1.141	0.363	.310
Language	1.255	0.473	0.324	2.186	**.008**
DoDD	-0.011	0.020	-0.051	0.029	.589
Edu	-0.497	0.398	-1.280	0.287	.213
RaEth_W	0.014	0.492	-0.954	0.982	.977
RaEth_B	-0.605	0.496	-1.583	0.372	.224
RaEth_O	-1.676	0.849	-3.348	-0.005	**.049**

Note. A significant linear regression was found, $F(12, 268) = 3.544$, $p < .001$), with an R^2 of .137. DSE: Diabetes Self-efficacy; BMI: Body Mass Index; HAincome: Household Annual Income; DoDD: Duration of Diabetes Diagnosis; Edu: Education (0: high school or less than high school; 1: above high school; RaEth_W: Race/Ethnicity_White; RaEth_B: Race/Ethnicity_NonHispanic_Black; RaEth_O: Race/Ethnicity_NonHispanic_Others; Race/Ethnicity_Hispanic is the reference group.

Bold *p* values are statistically significant.

Table A13

Multiple Linear Regression Analysis for DSE at Baseline Predicting HbA1c at 12 Months (Completer Analysis N = 361)

	b	SE	95% CI		P Value
DSE	-0.008	0.005	-0.017	0.002	.118
Age	-0.034	0.010	-0.053	-0.015	**<.001**
BMI	-0.026	0.016	-0.056	0.005	.097
Gender	0.328	0.187	-0.040	0.695	.080
HAincome	-0.106	0.206	-0.510	0.299	.608
Language	-0.258	0.251	-0.752	0.235	.304
DoDD	0.023	0.011	0.002	0.043	**.034**
Edu	0.159	0.211	-0.255	0.573	.451
RaEth_W	-0.048	0.262	-0.563	0.467	.855
RaEth_B	0.328	0.267	-0.197	0.852	.220
RaEth_O	-0.273	0.422	-1.104	0.558	.518

Note. A significant linear regression was found, $F(12, 348) = 2.121$, $p = .015$, with an R^2 of .068. DSE: Diabetes Self-efficacy; BMI: Body Mass Index; HAincome: Household Annual Income; DoDD: Duration of Diabetes Diagnosis; Edu: Education (0: high school or less than high school; 1: above high school; RaEth_W: Race/Ethnicity_White; RaEth_B: Race/Ethnicity_NonHispanic_Black; RaEth_O: Race/Ethnicity_NonHispanic_Others; Race/Ethnicity_Hispanic is the reference group.

Bold *p* values are statistically significant.

Table A14

Multiple Linear Regression Analysis with Missingness for Overall Self-management, Medication Non-Adherence, and Glycemic control at Baseline Predicting DSE at 12 Months (Completer analysis N = 282)

	B	SE	95% CI	
Overall self-management	**0.427**	0.068	0.293	0.561
Medication non-adherence	**-1.452**	0.378	-2.197	-0.707
HbA1c	0.230[a]	0.632	-1.014	1.474
Groups	2.438[b]	2.043	-1.585	6.461

Note. A significant linear regression was found, $F(14, 267) = 7.385$, $p < .001$, with an $R^2 = .279$. DSE: Diabetes Self-efficacy; Groups: study groups, including intervention and control groups.

[a]$p = .716$

[b]$p = .234$

Bold values are statistically significant ($p < .001$).

Table A15

Multiple Linear Regression Analysis for Overall Self-management, Medication Non-Adherence, and HbA1c at Baseline Predicting DSE at 12 Months (Completer Analysis N = 282)

	b	SE	95% CI		P Value
DSM	0.427	0.068	0.293	0.561	**<.001**
MA	-1.452	0.378	-2.197	-0.707	**<.001**
A1c	0.230	0.632	-1.014	1.474	.716
Age	-0.141	0.112	-0.361	0.080	.210
BMI	0.029	0.163	-0.291	0.350	.856
Gender	2.948	2.102	-1.190	7.086	.162
Language	5.902	2.819	0.351	11.453	**.037**
HAincome	2.560	2.246	-1.863	6.982	.256
DoDD	0.137	0.121	-0.101	0.376	.258
Edu	5.632	2.384	0.938	10.325	**.019**
RaEth_W	1.358	2.916	-4.384	7.099	.642
RaEth_B	4.734	2.952	-1.078	10.546	.110
RaEth_O	1.295	5.119	-8.784	11.373	.801

Note. A significant linear regression was found, $F(14, 267) = 7.385$, $p < .001$), with an R^2 of .279. DSE: Diabetes Self-efficacy; DSM: Overall Diabetes Self-management; MNA: Medication Non-Adherence; A1c: HbA1c; BMI: Body Mass Index; HAincome: Household Annual Income; DoDD: Duration of Diabetes Diagnosis; Edu: Education; RaEth_W: Race/Ethnicity_White; RaEth_B: Race/Ethnicity_NonHispanic_Black; RaEth_O: Race/Ethnicity_NonHispanic_Others; Race/Ethnicity_Hispanic is the reference group.

Bold *p* values are statistically significant.

Table A16

Mediation Analysis Summary (Completer Analysis)

Total Effect (se)	Direct Effect (se)	Relationship	Indirect Effect(se)	95% Confidence Interval	
				Lower Bound	Upper Bound
DSE_0 -> $HbA1c_2$ -0.007(0.005)	DSE_0 -> $HbA1c_2$ -0.005(0.006)	H:DSE_0->DDS_1->$HbA1c_2$	-0.001(0.002)	-0.006	0.003
DSE_0-> $HbA1c_2$ -0.009(0.006)	DSE_0->$HbA1c_2$ -0.006(0.006)	H:DSE_0->DSM_1->$HbA1c_2$	-0.003(0.003)	-0.008	0.003
DSE_0-> $HbA1c_2$	DSE_0->$HbA1c_2$	H:DSE_0->MNA_1->$HbA1c_2$	**-0.006**(0.003)	-0.012	-0.001

Note. se: Standard Error; H: Hypothesis; DSE: Diabetes Self-Efficacy; DSM: Diabetes Self-Management; MNA: Medication Non-Adherence; DDS: Diabetes Distress Scale; Ind/IND: Indirect path; Subscripts (0, 1, and 2) refer to baseline, 6-month follow-up, and 12-month follow-up, respectively.

Appendix B

Figure B1

Path Model Predicting HbA1c at 12-month Follow-up with Diabetes Distress at 6-month Follow-up as the Mediator (Completer Analysis N = 277)

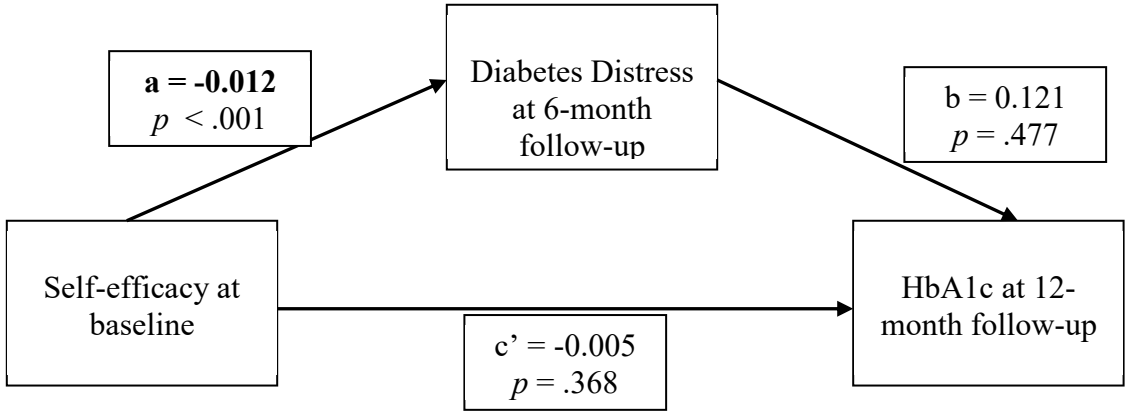


Figure B2

Path Model Predicting HbA1c at 12-month Follow-up with Overall Self-management at 6-month Follow-up as the Mediator (Completer Analysis N = 256)

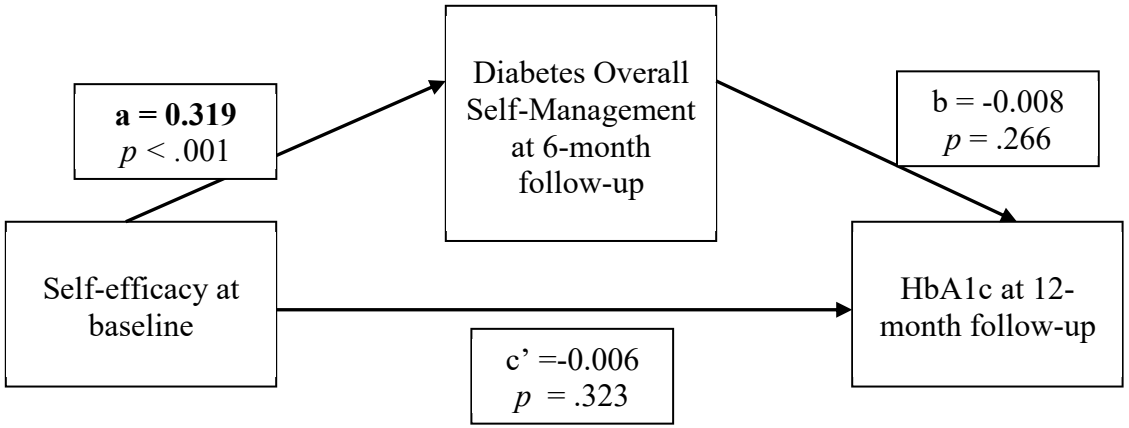


Figure B3

Path Model Predicting HbA1c at 12-month Follow-up with Medication Non-Adherence at 6-month Follow-up as the Mediator (Completer Analysis N = 259)