Abstract

The Impact of Ecological Momentary Assessment (EMA) in Type 2 Diabetes: Examining study engagement, self-efficacy, self-management and emotional well-being

Objective: To examine the role of self-efficacy, engagement with a smartphone app for ecological momentary assessment (EMA) and depressive symptoms on self-reported self-management behaviors in Type 2 Diabetes, using both quantitative and qualitative methods.
Participants and Methods: This study is a secondary analysis of data from a parent project which used repeated ecological momentary assessment of symptoms, affective states, and self-management behaviors among adults with Type 2 Diabetes, via a phone application known as "MyDay." The sample was comprised of 62 participants with Type 2 Diabetes from the Albert Einstein College of Medicine/Montefiore Medical Center. Participants first completed self-report questionnaires, including self-ratings of oral diabetes medication adherence and blood glucose monitoring adherence, at a baseline study visit. Then, they used the MyDay app for 14 days (completing 3 surveys per day), before returning to the lab for a follow-up visit to complete self-report questionnaires and engage in a semi-structured, audio-recorded exit interview with study staff. First, bivariate correlations were run to evaluate the cross-sectional relationships between baseline study variables of interest. Pearson's r correlational analysis was also run between baseline scores of the self-rating adherence measures and the follow-up self-ratings of adherence. A series of linear mixed effects models were run to evaluate the within-subjects changes in self-management across these two timepoints, examining the potential moderating impact of self-efficacy, depressive symptoms and percentage of completed EMA surveys over the monitoring

period, as an indicator of engagement. Additionally, semi-structured exit interviews were transcribed and analyzed by a team of qualitative coders for themes related to change in self-management across multiple domains (diet, exercise, medication-taking, blood glucose monitoring, and checking one's feet) over the course of study participation.

Results: Baseline self-efficacy was correlated with self-ratings of oral medication adherence and blood glucose monitoring adherence at both the baseline and follow-up timepoints, such that greater self-efficacy was associated with greater adherence. Self-ratings of blood glucose monitoring adherence significantly improved from baseline to follow-up, however oral medication adherence showed no significant change over time. Within the linear mixed effects models, we did not find depressive symptom severity or self-efficacy to be significant moderators of the relationship between baseline and follow-up scores on either of the adherence measures. Survey completion percentage moderated the relationship between baseline and follow-up self-reported blood glucose monitoring adherence, such that participants who completed more surveys showed greater improvements in blood glucose monitoring from baseline to follow-up. Within the qualitative analyses, participants reported change in four of the five hypothesized domains of self-management: taking medications, blood glucose monitoring, adhering to exercise recommendations and adhering to diet recommendations, and participants attributed these changes to their participation in the EMA protocol. We found that these qualitative reports were associated with high self-efficacy, as participants with high self-efficacy scores were more likely to endorse change in self-management behaviors during their exit interview.

Conclusions: Participation in this 2-week EMA app study was associated with significant changes in self-reported diabetes self-management, both adherence to recommended blood

glucose monitoring procedures (identified in the quantitative analyses) as well as adherence to dietary recommendations, exercise regimens, and medication taking (identified in the qualitative analyses). While it is not possible to determine any interventional effect of the EMA app as we did not have a control group in this study, participants who engaged with the app more over the 14 days (by completing more surveys) reported greater improvements in adherence to blood glucose monitoring (in quantitative analysis), as did participants with high baseline self-efficacy (in qualitative analysis). These findings, while limited due to a small sample size, potentially underpowered analyses, and study design without a control group, may have clinical implications for the development of future interventions to improve adherence to important self-management behaviors in this at-risk medical population.

The Impact of Ecological Momentary Assessment in Type 2 Diabetes:

Examining self-management, self-efficacy, study engagement, and emotional well-being

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Dedication

To Pop: How I wish you could have seen me become "the first Dr. Jonas"

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Chapter I: Background

Background on Diabetes

Diabetes Mellitus refers to a group of metabolic diseases related to how the body processes glucose. In diabetes, blood glucose levels in the body rise because blood glucose is not sufficiently metabolized by the cells, either due to problems in the pancreas regarding its ability to produce insulin (a hormone responsible for controlling metabolism), and/or because the cells themselves are unable to effectively use the insulin that is being produced. There are two major chronic, non-reversible diabetes mellitus conditions: Type 1 Diabetes and Type 2 Diabetes. In Type 1 Diabetes (also called insulin-dependent diabetes), the pancreas does not produce sufficient insulin, whereas in Type 2 Diabetes (also called non-insulin dependent diabetes) the body's cells become resistant to insulin that is being produced, and as a result, the pancreas produces less and less insulin over time (Roglic, 2016). Type 1 diabetes is most often diagnosed in children, adolescents and young adults, and is believed to be caused by a combination of genetic components and environmental factors (including viruses), which result in the immune system attacking and destroying cells in the pancreas that are responsible for producing insulin. While the etiology of Type 1 diabetes is not fully understood, there are ongoing research studies which seek to clarify and slow its initiation and progression (Centers for Disease Control and Prevention, 2017). Within Type 2 Diabetes, on the other hand, there are several factors that are believed to contribute to the risk of disease development as well as its progression: as with Type 1, genetics and environmental factors play a role, but lifestyle factors such as obesity, lack of physical activity, and a poor diet are also implicated. It is believed that for people with obesity (characterized as an excess accumulation of body fat which leads to functional impairment across multiple domains of daily living), increased levels of fatty acids, blood sugars, hormones

and proinflammatory biological markers in the body contribute to the development of insulin resistance and consequently, Type 2 diabetes (Al-Goblan et al., 2014). Obesity itself is considered an epidemic, and its relationship to the development of Type 2 Diabetes underscores the urgency of responding to this major global health concern (Jaacks et al., 2019).

Type 2 diabetes has become a major public health challenge, and together with other non-communicable diseases such as cardiovascular disease, cancer, and chronic respiratory illnesses, has been targeted as a serious public health problem by the World Health Organization (WHO) (Roglic, 2016). Globally, Type 2 Diabetes was found to be the tenth leading cause of death in 2017 (Williams & Loeffler, 2019). Type 2 Diabetes makes up the vast majority of diagnosed cases of diabetes amongst adults living in the United States – between 90-95% – and constitutes a growing problem. At present, 415 million people worldwide have diabetes, and this statistic is reported to have doubled over the past twenty years (Zimmet et al., 2014). It is projected by the Centers for Disease Control and Prevention that by the year 2040, nearly half a billion people globally will have diabetes (Sun et al., 2022).

Diabetes Mellitus is prevalent in the United States, with a reported estimate that nearly 35 million people (10.5% of the United States population) have diabetes (Centers for Disease Control and Prevention, 2017). Of note, there are significant differences in diabetes mellitus prevalence among racial and ethnic groups in the United States, indicating a relationship between diabetes and sociocultural factors of oppression and marginalization. Reports have found that among U.S. adults aged 18 or older, prevalence of diagnosed diabetes was highest among American Indians/Alaska Natives (14.7%), followed by people of Hispanic/Latinx origin (12.5%), non-Hispanic Black individuals (11.7%), non-Hispanic Asian individuals (9.2%) and lastly non-Hispanic White people (7.5%). Looking only at New York State (NYS), prevalence of

diabetes mellitus is similar to national reports: in NYS, an estimated 1.6 million people (10.5% of the population) have been diagnosed with diabetes (New York City Department of Health and Mental Hygiene, 2016). Within NYS, Bronx County has the highest reported prevalence of diabetes mellitus of all 57 counties, with 16% of adults being diagnosed with diabetes (New York City Department of Health and Mental Hygiene, 2016). Understanding differences in county-specific incidence and prevalence of chronic conditions such as diabetes is important for identifying specific communities of high risk for this disease, and for the development and evaluation of targeted interventions to reduce this risk. On both a global and national level, the growing burden of diabetes mellitus disproportionately affects socially disadvantaged groups of people.

Diabetes is often diagnosed following the presence of symptoms such as increased urine output, fatigue, and decreased appetite, and diagnosis is determined following a routine laboratory blood test. However, according to the National Diabetes Statistics Report 2020, 7.3 million adults aged 18 or older (2.8% of all U.S. adults, and 21.4% of all U.S. adults with diabetes) who met laboratory criteria for diabetes were not previously aware of or did not report having diabetes. Both Type 1 and Type 2 Diabetes Mellitus diseases are manageable with treatment, which includes medication and routine monitoring by physicians. However, undiagnosed and consequently untreated diabetes poses a very serious health concern: complications from diabetes can include kidney disease, vision disability, and death (Ahola & Groop, 2013). As such, screening and detection of diabetes and prediabetes via diagnostic blood tests – to identify individuals in need of treatment or even primary prevention – has been identified as an increasingly important goal for providers across medical disciplines, especially for patients with multiple risk factors (Lawrence et al., 2001; Genco et al., 2014).

Given the aforementioned confluence of genetic, environmental and lifestyle factors which contribute to the etiology of Type 2 Diabetes, as well as the disproportionate number of socially disadvantaged and marginalized people impacted by this specific condition within the family of diabetes mellitus diseases, this study focused on adults with Type 2 Diabetes. This study, and the following review of the literature, seeks to elucidate the complex relationships between psychosocial factors and diabetes self-management outcomes in this underserved and at-risk medical population of individuals with Type 2 Diabetes.

Diabetes Treatment and Self-Management

Diabetes is considered manageable with the proper treatment. However, diabetes requires intense efforts at self-care, often completed by patients in their own environment, rather than treatment comprised of interventions or monitoring that is administered or completed only in a doctor's office. Research has identified that people with diabetes can find this responsibility and the many tasks associated with self-management of diabetes to be burdensome, overwhelming and frustrating. This is compounded by the fact that at times, despite a patient's best efforts, diabetes outcomes such as blood glucose levels or reduced experience of uncomfortable complications of diabetes (such as peripheral neuropathy) do not necessarily change – or if they do, they may not change as quickly as a patient desires or expects (Polonsky, 2002).

Self-management of diabetes includes tasks such as increasing one's level of physical activity, maintaining adherence to dietary recommendations (many of which are contrary to the way an individual had already been eating, or their cultural or socioeconomic expectations of food and diet; Booth et al., 2013), taking medications, checking one's blood glucose levels with their own monitors, and injecting oneself with exogenous insulin in response to out-of-range blood glucose levels (Safford et al., 2005). Additionally, due to increased risk of peripheral

neuropathy (most often experienced in the hands or feet), people with diabetes are advised to check their feet for wounds or sores (also called ulcers) which may not be detected through sensation as it would for someone without peripheral neuropathy. Checking one's feet for ulcers and subsequently practicing fastidious infection prevention is a primary method to prevent neuropathy-related amputations (Bartus & Margolis, 2004).

In order to maintain awareness of blood glucose levels, which can rapid shift and change minute-to-minute based on metabolic and environmental factors such as physical activity and food intake, people with diabetes are responsible for regularly monitoring their own blood glucose levels via finger-sticks to obtain a blood sample to be analyzed with portable blood glucose monitors. The use of blood glucose monitors can help individuals with diabetes to adequately assess risk for hyperglycemia (blood glucose levels that are too high) or hypoglycemia (blood glucose levels that are too low) and adjust their self-management accordingly. Using blood glucose monitors can be physically uncomfortable or even bring up feelings of embarrassment (Cradock & Hawthorn, 2002). As such, there have been technological advancements aimed at reducing the burden of blood glucose monitoring: continuous glucose monitors (CGM) are one example of this. CGM are temporarily-implanted devices that use a subcutaneous needle to test a wearer's blood glucose consistently throughout the day and provide real-time data about blood glucose values to the patient, often via a smartphone app. CGMs have been shown to be associated with reduced episodes of hypoglycemia in wearers with diabetes (Beck et al., 2017), and some wearers have reported feeling more secure, more informed about their metabolism, and less burdened by diabetes self-management (Huhn et al., 2022). However, there are significant barriers to adopting this technology, which leaves the majority of individuals with diabetes continuing to use standard self-monitoring of blood-glucose via finger-sticks:

CGM is not often covered by health insurance, and as such, costs to patients can range from $2,500 to $6,000 annually (Robertson, Shaughnessy & Slawson, 2020). This is prohibitive for many people with diabetes, and should be considered in the context of what is known about how Type 2 Diabetes disproportionately impacts socioeconomically or otherwise disadvantaged communities. As such, while standard self-monitoring of blood glucose remains the primary system for many patients with diabetes in the United States, it is important to identify ways that this vital diagnostic and treatment tool can be made more adaptable and less burdensome for patients tasked with the self-management of a chronic illness like Type 2 Diabetes.

Other elements of diabetes self-management are also known to be burdensome and challenging for people with Type 2 Diabetes. Some individuals with diabetes require exogenous insulin administered via injection to compensate for hyperglycemic levels. As with the advent of CGM, there are technologies which aim to use continuous subcutaneous insulin infusions (CSII) to make this process easier and safer for patients. One example of CSII is wearable insulin pumps, which both reduce patient burden of injecting oneself multiple times a day as well as deliver a continuous infusion of insulin which more effectively mimics the physiologic insulin production that is dysfunctional for people with diabetes (Zhang et al., 2021). However, insulin pumps must be changed every few days, and patients are instructed to choose new infusion sites on their body each time, to avoid skin problems like infections or dermatitis (Heinemann & Krinelke, 2012). Additionally, some insulin pump users have expressed dissatisfaction with the technology, ranging from issues like pain, difficulty with insertion, and product malfunctions (Klonoff et al., 2017). Also, the cost of insulin – either administered via self-injection, or via CSII technology – can pose as another barrier to effective self-management of diabetes via insulin therapy in this population. The price of insulin has increased by 1000% in the past 20

years (Prasad, 2019). Insulin's exorbitant pricing has resulted in many patients engaging in the dangerous behavior of self-titrating insulin therapy in order to stretch their doses (and, their dollars) for longer. In one study, 51% of surveyed participants (with both type 1 and Type 2 Diabetes) endorsed under-using their prescribed insulin to save money; these patients were more likely to have poor glycemic control (Herkert et al., 2019).

Taking medications aimed at maintaining glycemic control is another major task associated with the self-management of diabetes, and one that can pose a marked burden to patients. There are eleven classes of drugs used in the treatment of diabetes: some of these aim to decrease insulin resistance (such as Metformin), whereas others increase insulin secretion by way of stimulating pancreatic cells (sulfonylureas) (Alexander et al., 2018). While oral medications have been shown to be an effective way to manage Type 2 Diabetes, there are significant barriers to medication adherence. A systematic review of the literature revealed that patients identified fear about potential side effects, worry about knowledge or skill in their taking medications, depressive symptoms, a lack of confidence in the immediate or future benefit of the medication, as well as difficulty remembering to take medications all as factors which can interfere with their adherence to prescribed medication regimens for their diabetes (Odegard & Capoccia, 2007). Medication non-adherence has been associated with adverse outcomes including increased risk of vascular side effects (such as stroke and high blood pressure), poor cholesterol, hospitalizations and death (Ho et al., 2006). Taken together, there appear to be many barriers to effective self-management of diabetes, including patient-related factors such as fear and worry, as well as external factors such as medication, insulin or device costs. This identifies a need for interventions or tools that can improve adherence to the range of self-management

behaviors required of this patient population to maintain optimal control of diabetes outcomes, such as blood glucose levels, and avoid dangerous and even life-threatening side effects.

Diabetes, Depression and Self-Management

Adults with diabetes are not only at a greater risk for physical health problems, such as diabetic neuropathy, nephropathy, glaucoma, and cardiovascular disease, but also experience increased prevalence of mental health comorbidities such as depression, compared to those without diabetes (Stolar, 2010; Anderson et al., 2001; Cohen et al., 1997; de Groot et al., 2001). There appears to be a bidirectional relationship between diabetes and depression, such that individuals with Type 2 Diabetes are nearly twice as likely to develop depression (Chireh et al., 2019; van Sloten & Schram, 2018; Ali, Stone & Peters, 2006; Anderson et al., 2001), and longitudinal studies have shown that individuals with depression have a 1.5-times higher risk of later developing diabetes (Rotella & Mannucci, 2013). Psychological factors related to chronic illness like shame, social isolation, worry, and emotional distress may contribute to the development of depressive symptoms (De Ridder et al., 2008; Williamson et al., 2020). There is also evidence that depression and diabetes are linked by biological mechanisms. These shared biological mechanisms between depression and diabetes may serve to better explain the bidirectionality of these constructs. One such mechanism may be vascular dysfunction: in the "vascular depression" hypothesis, it is proposed that vascular damage to various parts of the brain is responsible for dysfunction in mood and emotion regulation and can lead to the development of depression (Taylor et al., 2013). Notably, Type 2 Diabetes is closely linked with cerebrovascular damage, including cortical infarctions (Luitse et al., 2012) and white matter hyperintensities (Moulton et al., 2015). Another shared biological mechanism between depression and diabetes relates to hyperglycemia. Prolonged hyperglycemia (or an excess of

blood sugar) is associated with the development of Type 2 Diabetes (Sima et al., 2004) as well as depression, as hyperglycemia appears to be related to neuronal damage that can lead to depression (Moulton et al., 2015; Nefs et al., 2012).

Among mental health comorbidities associated with diabetes, research on depression has been the most extensive, and depression has been shown to be the most consistently related with difficulties maintaining many vital, patient-directed self-management behaviors for Type 2 Diabetes patients (Lin et al., 2004; Ducat et al., 2014; Egede & Ellis, 2008; Bell et al., 2010; Gonzalez et al., 2008b; Gonzalez et al., 2007). In particular, the presence of depression symptoms is a significant risk factor for medication nonadherence, less adherence to dietary recommendations, and can also lead to poorer physical and mental functioning as well as greater healthcare costs (Gonzalez et al., 2008a; Ciechanowski et al., 2000). Depressive symptoms have also been shown to be associated with reported difficulty coping with stressors related to disease management in various illness populations (DiBenedetto et al., 2014; Fleishman & Fogel, 1994; Klein et al., 2007). Individuals who have Type 2 Diabetes and depression have a higher risk of developing both micro- and macro-vascular complications of diabetes and have a 50% higher mortality risk compared to counterparts who have diabetes without comorbid depression (van Dooren et al., 2013).

Because poor diabetes self-management itself has many negative health-related consequences, this creates a challenging and dangerous cycle for people with Type 2 Diabetes who are coping with comorbid mental health problems such as depression symptoms; depressive symptoms beget worse self-management, which can lead to detrimental physical effects, the presence of which may serve to worsen a person's depression related to their illness experience (Ahola & Groop, 2013; Lipman & Sherr, 2013; Klein & Lippa, 2008). Interventions have been

designed to address depression in diabetes, and some of these have been found to improve health outcomes related to diabetes as a secondary effect. Treatments for depression typically fall within three categories: psychosocial (such as cognitive-behavioral therapy), pharmacologic (such as the use of SSRIs, which are recommended for people with depression and diabetes due to their secondary effects of lowering blood sugar and weight loss), and collaborative care (typically in a primary care setting.) In a meta-analysis which examined studies of treatments for depression in diabetes across all three of these categories and within both Type 1 and Type 2 Diabetes populations, researchers found that while these treatments were generally effective for the treatment of depression, findings were mixed regarding secondary health outcomes such as treatment adherence and glycemic control (McKellar et al., 2004). In one meta-analysis, pharmacological diabetes treatments were examined for their potential impact on co-occurring depressive symptoms in patients with diabetes, which revealed mixed findings such that some commonly prescribed drug class treatments but not others were found to reduce symptoms of depression in this population – though, by nature of their initial purpose, all reduced other diabetes-related health outcomes such as glycosylated hemoglobin (HbA1c) (Moulton et al., 2018). Other research has found that psychotherapeutic treatments specifically, such as mindfulness-based cognitive therapy and standard cognitive-behavioral therapy, are helpful for reducing depressive symptoms in people with diabetes, but did not have an impact on HbA1c (Tovote et al., 2014). In some studies, diabetes-related health outcomes actually got worse after engaging in a treatment for depression (Lustman et al., 1998; Katon et al., 2004). One hypothesis for why this occurred is that perhaps patients were overwhelmed by engaging in an additional treatment protocol along with the tasks necessary to self-manage their diabetes (Lin et al., 2006). This provides support for the continued importance of understanding the role of depression on

diabetes outcomes such as self-management, and for the future development of interventions that may seek to address these two important constructs concurrently, without further burdening patients.

Self-Efficacy, Depression and Diabetes Self-Management

Self-efficacy – the belief that one can successfully execute the behavior required to produce a given outcome (Bandura, 1997) – also likely plays a role in outcomes related to diabetes self-management, and even the relationship between depression and diabetes self-management. First, research has identified the presence of a bidirectional relationship between low self-efficacy and increased prevalence of disease and symptoms in chronic illness (Devellis & Devellis, 2001; Penninx et al., 1998; Chao et al., 2005). Greater self-efficacy has been shown to be associated with improved self-management behaviors in diabetes including diet, exercise, and blood glucose monitoring (Aljasem et al., 2001) as well as exercise (Sarkar et al., 2006). In particular, one study found that with each 10% increase in scores on a self-report self-efficacy questionnaire, individuals with Type 2 Diabetes were more likely to report a more-adherent diet 0.14 days/week, more exercise 0.09 days/week, and had improved self-monitoring of blood glucose as well as foot care, when adjusting for duration of diabetes, insulin use, race, ethnicity, and level of literacy (Sarkar et al., 2006). There appear to be multiple factors that may contribute to improved self-efficacy in this population, and as such should be considered for the development of interventions that may aim to improve self-efficacy: higher self-efficacy has been associated with having higher levels of health literacy, more diabetes-related education, and being currently employed (Bohanny et al., 2013). In a study of individuals with both Type 1 and Type 2 Diabetes, who were being treated with complex insulin regimens, self-efficacy was predictive of later engagement in self-care behaviors, independent of demographic or diabetes-

related variables (Hurley & Shea, 1992). Other research with end-stage renal disease patients, has demonstrated that higher self-efficacy was correlated with improved self-management behaviors, more so than demographic or other variables (Curtin et al., 2008).

There also appears to be a relationship between higher levels of self-efficacy and lower levels of reported depression symptoms in chronic illness, as well as low self-efficacy predicting the later development of depression. In a sample of chronic heart failure patients, those with lower self-efficacy were shown to have greater depression, even when controlling for disease severity (Tsay & Chao, 2002). In another study which looked at chronic pain patients, self-efficacy was found to contribute to the development of depression, along with pain intensity (Arnstein et al., 1999).

Research has identified independent roles of high self-efficacy and low depression on improved chronic illness self-management (Schinckus et al., 2018; Wu et al., 2013). Whereas self-efficacy has demonstrated a relationship with diabetes self-management, it appears that those with greater depression symptom severity may experience a weaker relationship between these two factors, as depression symptoms could prevent individuals from fully engaging with psychological resources in such a way that might help with the management of their disease (Jacobson & Weinger, 1998; Adam & Folds, 2014). As such, those with greater depression symptom severity may be less likely to benefit from interventions that seek to improve either self-efficacy or self-management in chronic illness. Further exploring the roles of depression symptom severity and self-efficacy on diabetes self-management (and how depression symptom severity may interfere with factors that improve these outcomes, and how self-efficacy may be beneficial) may strengthen the development of behavioral interventions for diabetes self-

management, or even better predict patient success in existing interventions that require patient-initiated participation.

Illness Experience Awareness and Feedback in Type 2 Diabetes

Research across a spectrum of chronic illnesses has shown that bringing awareness to one's illness experience (either through symptom-tracking via the use of daily diaries or other protocols) is associated with improved self-management behaviors, though this relationship is not well-explained. In one study, children with chronic asthma who tracked their asthma symptoms over 90 days showed improved self-care behaviors compared to peers who did not track symptoms (Guendelman et al., 2002). In a study that examined symptom diaries and self-management in three separate chronic illness populations (Type 2 Diabetes, irritable bowel syndrome, and chronic widespread pain), researchers found that the use of web-based self-monitoring symptom tracking diaries was feasible for supporting daily self-management behaviors (Nes et al., 2013). Researchers posit that one reason why bringing awareness to the illness experience, via symptom-tracking or other protocols, may improve self-management is due to increases in self-efficacy as a result of patients feeling empowered by autonomously collecting their own health data, leading to greater engagement in actual health behaviors (Van Woensel et al., 2015; Funnell & Anderson, 2004).

These relationships can also be explored in a body of work examining blood glucose awareness training, a psychoeducational intervention initially designed for Type 1 diabetes, wherein patients are trained to more accurately recognize fluctuations in their blood glucose using biofeedback (Gonder-Frederick et al., 2000). Unlike symptom-tracking diaries, blood glucose awareness training uses feedback to either discourage or reinforce patient behaviors. Blood glucose awareness training protocols call upon patients to purposefully draw attention to

their physical experiences of illness and record their symptoms with the goal of using this awareness to prevent extreme blood glucose values (Cox et al., 2006). These protocols have been associated not only with improved physical health outcomes, but also with improved psychological functioning, including less worry about one's diabetes, improved patient-reported quality of life, and less depression symptoms for those with at least mild depression at baseline (Cox et al., 2001; Schachinger et al, 2005). Compared to other interventions such as cognitive-behavioral therapy for adherence in diabetes (which does not specifically require patients to direct their attention towards symptom experiences or to record their symptoms), blood glucose awareness training has been shown to effectively reduce both the fear and worry associated with diabetes complications like extreme blood glucose values, but also reduce the actual frequency of these complications occurring (Wild et al., 2007).

Blood glucose awareness training is one example of an intervention that effectively improves the patient's perception and experience of their illness on multiple facets: both their self-management behaviors, as well as their reported emotional experiences such as worry. Notably, blood glucose awareness training protocols draw heavily from Bandura's social cognitive theory, which stresses the importance of both a personal sense of control as well as outcome expectancies (an understanding of the consequences of one's actions) as being integral to longstanding behavior change (Bandura, 1988; Schwarzer & Luszczynska, 2005). Thus, one explanation for the effectiveness of blood glucose awareness training may be the secondary improvement of diabetes self-efficacy through empowering patients to use their awareness of illness experience as a tool to prevent diabetes complications. While no studies were found that explore diabetes self-efficacy as an outcome of blood glucose awareness training, one meta-analysis identified that from eight different categories of psychoeducational and psychosocial

interventions for diabetes, interventions that utilize social cognitive theory (including those that used biofeedback about blood glucose, such as blood glucose awareness training) were among the strongest, providing further support for the role of self-efficacy to impact long-term health outcomes related to diabetes (Padgett et al., 1988). Taken together, this work provides support for self-efficacy as a potential explanation for why bringing awareness to one's illness experience (via symptom-tracking, daily diaries, biofeedback-oriented interventions such as blood glucose awareness training, or other tools) might improve self-management behaviors or other outcomes in chronic illness patients.

Background on Ecological Momentary Assessment (EMA)

Another tool which draws patients' awareness to their experience of illness is ecological momentary assessment (EMA; Shiffman et al., 2008), a methodology which seeks to assess individuals' ongoing experiences in naturalistic settings. EMA offers considerable advantages – especially in health psychology research – compared to patient-reported, retrospective data (Schuz et al., 2015), and is believed to reduce "recall bias," or, inaccuracies in retrospective self-report answers to questions (Nam et al., 2021). With EMA, participants are able to record symptoms, feelings, or observations about their experience of their illness in the moment they occur, as opposed to reflecting on their experience when being asked about it later. With this dynamic and technologically advanced methodology, researchers may be able to glean insight into the time-based unfolding of symptoms or other disease-related variables that are not able to be captured otherwise (Shiffman et al., 2008). EMA allows greater sensitivity for connecting emotional experiences with behavioral and biological process, and as such allows for the evaluation of temporal relationships with these variables both within-subjects and between

subjects, in a way that other measurement techniques (such as patient retrospective self-report) do not (Anestis et al., 2010; Kuerbis et al., 2013).

EMA methodologies have been well-validated in chronic illness populations including diabetes (Nam et al., 2021). In one study, in which EMA was used to measure blood glucose monitoring and insulin administration in adolescents with Type 1 Diabetes, EMA (delivered via mobile phone) was deemed feasible in this population (Mulvaney et al., 2012). In another study of adults with Type 2 Diabetes, an EMA mobile phone app was used to assess patient progress towards achieving the goal of a lower glycemic index diet (recommended by their physician for diabetes treatment and control): the EMA phone app was found to be feasible, and collected nuanced datapoints indicating intraindividual variability in goal progress that researchers believe may be helpful for the development of personalized recommendations or treatment, moving forward (Miller et al., 2016). Very recent research using meta-analytic procedures to assess a breadth of EMA studies within diabetes populations revealed that EMA may have significant clinical utility for assessing diabetes self-management (such as blood glucose monitoring, dietary adherence and exercise) as well as in developing individualized diabetes interventions, by way of personalizing treatment to each patient based on data captured via EMA (Nam et al., 2021).

In this study, we hypothesize that exposure to an EMA protocol that includes 3x-daily recording of illness experience (of both physical and emotional symptoms, affective state, as well as sleep quality) will improve patient-reported self-management behaviors. Critically exploring whether bringing awareness to one's illness experience through exposure to an EMA protocol may be associated improved patient-reported diabetes self-management is an important and potentially impactful next step for this body of research. Taken with the prevalence of depression symptoms in this population (which has been associated with both poorer self-

management as well as worse mental functioning) it is possible that depression symptom severity is a factor that may disrupt the hypothesized positive relationship between illness experience awareness through exposure to the EMA protocol, and improved diabetes self-management. Based on a review of the literature, it is also possible that self-efficacy may be one factor that strengthens an individual's likelihood of self-management improvements after engaging in an EMA protocol. Thus, examining the roles of depression symptom severity and self-efficacy on patients' ability to benefit by way of improved self-management from drawing awareness to their illness experience, in the context of an EMA protocol, is one way of further elucidating some relationships between psychosocial variables in chronic illness. Both exposure to the EMA protocol, as well as engagement with the EMA protocol, are two constructs being examined in this study. Exposure to the EMA protocol was experienced by all enrolled participants who were trained in using EMA, and subsequently completed surveys about their illness experience 3x per day over the two-week study. Engagement with the EMA protocol is measured by the percentage of surveys completed by these participants, over the course of the study.

Reactivity to EMA (the extent to which change is thought to occur as a direct result of engaging with the EMA protocol itself) has been examined as a factor which may lessen the validity of EMA studies that seek to capture reliable in-vivo data about health or illness experiences (Litt et al., 1998; Stone et al., 2003; Cruise et al., 1996). However, in this study, the presence of EMA reactivity would be considered a positive implication for the potential use of an EMA smartphone app as a tool to improve psychosocial or physical health outcomes, in the future. EMA reactivity studies often explore either behavioral reactivity (the extent to which behavior changes as a result of self-monitoring), or motivational reactivity (the extent to which one's readiness to change a behavior may change as a result of self-monitoring.) In one study

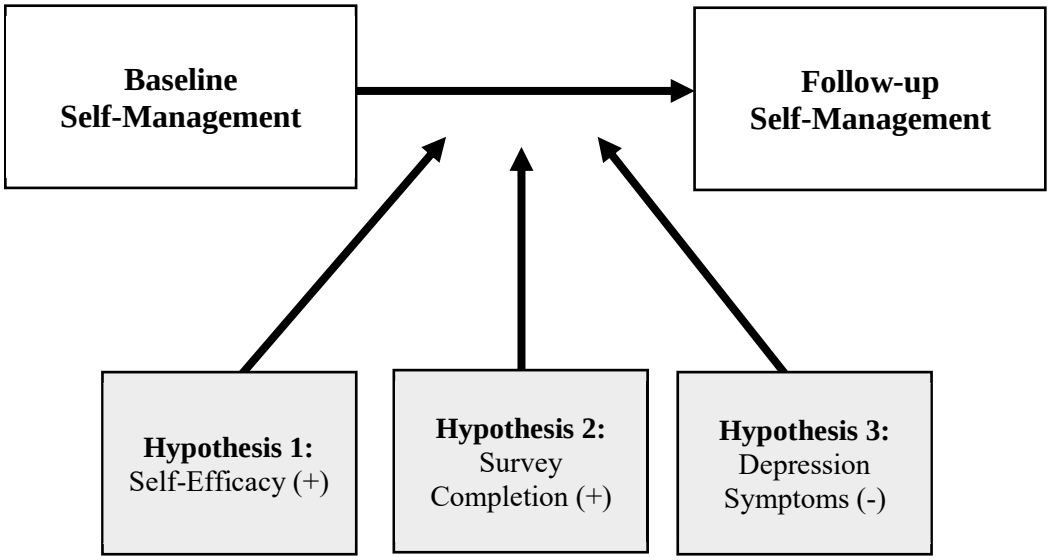
which examined EMA reactivity over two weeks regarding the drinking behaviors of undergraduate college students, researchers concluded that EMA survey completion did not impact behavioral nor motivational reactivity (Hufford et al., 2002). In another study of smoking cessation – which notably used a control group that did not engage in EMA, unlike many other studies—there was evidence for EMA reactivity, specifically impacting smoking-related phenomena (such as the presence of withdrawal symptoms) as well as emotional phenomena such as self-efficacy for smoking cessation (Rowan et al., 2007). These mixed findings identify that the role of exposure to — or engagement with — an EMA protocol to impact either behavior change or patients' feelings about behavior change is not well understood. This provides support for the innovativeness of this study, which seeks to examine not only exposure to, but also levels of engagement with an EMA protocol, and whether the mechanisms of participating in this protocol (in particular, the drawing of awareness to one's illness experience of Type 2 Diabetes) may be associated with improved patient-reported self-management over a short time period, as well as whether this relationship is stronger for participants who engaged with the study more, assessed as having completed a higher percentage of surveys.

Rationale/Hypotheses

While there have been a number of reviewed studies that have explored the prevalence and predictors of self-efficacy, self-management, and depression in chronic illness populations, few studies have examined these variables together. This study first seeks to identify whether drawing awareness to one's illness experience (through using the EMA app over two weeks) may be associated with improved patient-reported self-management. This will be examined in two ways: first, by exploring if there is a difference between scores on self-ratings of self-management from baseline to follow-up timepoints, and then by identifying whether participants

who engaged with the EMA protocol more (by completing a higher number of the assigned, prompted 3x per day surveys) had a greater difference between these scores. We also seek to explore whether self-efficacy plays a role in this change. If self-efficacy is found to strengthen this change in self-management, this may have implications for the development of interventions that aim to improve self-management, as researchers may consider ways to first build self-efficacy. There have been a number of effective, identified techniques for improving patient self-efficacy regarding various health tasks such as physical exercise (Williams & French, 2011) and overall, self-efficacy is understood as a malleable and flexible psychological construct that is likely susceptible to interventions (Gist & Mitchell, 1992; Gerhardt & Brown, 2006.) This study also seeks to explore if depression symptom severity plays a role in these relationships, such that we hypothesize depressive symptoms will interfere with the hypothesized benefits of EMA and those with greater depression symptom severity will notice less of a change in self-management from baseline to follow-up timepoints. If depression symptom severity is found moderate the purported helpfulness of an EMA app, this has implications for identifying which patients may be best suited for such interventions going forward, as well as provide more clarity as to the specific detrimental nature of depressive symptoms in this population. Figure 1, below, illustrates the proposed relationships between baseline and follow-up self-rated self-management, as well as the expected moderators.

Figure 1. Conceptual Diagram of Moderation Hypotheses



Of note, this project targets a minority population, those with Type 2 Diabetes living in the Bronx, New York. In the Bronx, 43% of residents are non-Hispanic black, 56% are Hispanic or Latino (primarily from Puerto Rico and the Dominican Republic), and 28% of residents are below the poverty line (United States Census Bureau, 2020). This project targeted minorities specifically because there is a critical need to serve this population: research has shown that individuals living in low-income, urban communities, such as the Bronx, are at a higher risk of being diagnosed with a chronic illness such as diabetes, and are at a greater risk of experiencing complications subsequent to this diagnosis (Agardh et al., 2011; Robbins et al., 2001; Karter et al., 2002). While there are significant efforts to expand upon existing healthcare resources for diabetes patients in New York City, there is still a need to further develop cost-effective, accessible resources for low-income, chronically ill individuals (NYC DOMH, 2016). This study

seeks to determine whether engaging in a low-cost, accessible research protocol such as using a smartphone app over two weeks may be associated with some improved outcomes (such as patient-reported self-management) in Type 2 Diabetes. By targeting recruitment in diverse communities of New York City, such as the Bronx, the results of this study may have important implications for how future health interventions may best serve these at-need communities going forward.

The parent study for these secondary analyses (IRB #2017-8241) used the innovative methodological approach of EMA, delivered via smartphone app, to better understand the within-person and temporal relationships between psychological symptoms (including depression and diabetes distress) and treatment nonadherence. This study used self-report measures captured at a baseline lab visit, and then a follow-up lab visit 14 days later. Self-management was measured with two self-report measures, which are scored and analyzed independently: the Oral Medication Adherence Measure and the Blood Glucose Monitoring Adherence Measure. Self-Efficacy was measured using the Diabetes Self-Efficacy Scale. Depressive symptoms were measured using the 9-item Patient Health Questionnaire (PHQ-9). Additionally, engagement with the EMA app was calculated as the percentage of completed surveys out of those that were required (3x per day) across the 14 days of study participation. Also, during their follow-up lab visit, participants engaged in a semi-structured exit interview which was audio-recorded, then transcribed and qualitatively analyzed for the presence of themes determined *a priori*, related to change in self-management across five domains throughout study participation. The following specific aims were designed to achieve the goal of this dissertation.

Specific Aims

Aim 1: The first aim evaluated the role of diabetes self-efficacy (assessed at baseline) on the change in within-subjects, patient-reported diabetes self-management (assessed at baseline and follow-up). The specific hypotheses regarding the relationship between diabetes self-efficacy and diabetes self-management were evaluated using the following mixed methods approach:

- **Hypothesis 1(a):** Participants would demonstrate improved self-management over the course of the two-week study. Using a within-subjects design, participants' total scores on the Oral Medication Adherence Measure obtained at follow-up were compared to their total scores at baseline. This analysis was then be repeated with the Blood Glucose Monitoring Adherence Measure scores from baseline and follow-up.
- **Hypothesis 1(b):** It was hypothesized that baseline diabetes self-efficacy scores would strengthen the relationship between baseline and follow-up patient-reported diabetes self-management, such that those with greater self-efficacy scores at baseline would demonstrate a greater difference between baseline vs. follow-up self-rated adherence measure total scores. See Figure 1, a conceptual diagram of the expected moderation effects for this hypothesis and all the moderation hypotheses that follow.
- **Hypothesis 1(c):** At least one participant would report, via qualitative feedback obtained from audio-recorded semi-structured exit interview at follow-up, that they felt their diabetes self-management improved after EMA study participation. We expected that participant exit interviews for those with high baseline self-

efficacy would demonstrate greater presence of this theme compared to participant exit interviews for those with low self-efficacy.

Aim 2: The second aim evaluated the role of engagement with the EMA protocol (survey completion percentage) on the change in within-subjects, patient-reported diabetes self-management (assessed at baseline and follow-up). The specific hypotheses regarding the relationship between engagement with the EMA protocol and diabetes self-management were evaluated using the following mixed methods approach:

- **Hypothesis 2(a):** It is hypothesized that total percentage of EMA survey completion over the two-week study (calculated at the end of the study) would strengthen the relationship between baseline and follow-up patient-reported diabetes self-management, such that those with greater survey completion would demonstrate a greater positive difference between baseline vs. follow-up self-rated adherence measure total scores.
- **Hypothesis 2(b**): Participant exit interviews for those with high survey completion percentage would demonstrate greater presence of the theme, improvement in self-management, compared to participant exit interviews for those with low survey completion percentage.

Aim 3: The third aim seeks to evaluate the role of depressive symptom severity (assessed at baseline) on the change in within-subjects, patient-reported diabetes self-management (assessed at baseline and follow-up). The specific hypotheses regarding the relationship between depression symptom severity and diabetes self-management were evaluated using the following mixed methods approach:

- **Hypothesis 3(a):** It is hypothesized that baseline depression symptom severity would weaken the relationship between baseline and follow-up patient-reported diabetes self-management, such that those with greater depression symptom severity at baseline would demonstrate less difference between baseline vs. follow-up self-rated adherence measure total scores.
- **Hypothesis 3(b):** Participant exit interviews for those with high depressive symptom severity would demonstrate less presence of the theme, improvement in self-management, compared to participant exit interviews for those with low depressive symptom severity.

Innovation

Technological Advancement. The technological element of this project seeks to remain both accessible and cost-effective. It is estimated that 81% of individuals living in the United States own a smartphone; while there is some variation across socioeconomic groups, research has identified that the vast majority of individuals are smartphone users even in low-income communities (Pew Research Center, 2019). Therefore, identifying the role of smartphone applications, such this EMA application, to draw patients' awareness to the illness experience and in turn, potentially impact outcomes such as patient-reported self-management, is an important next step for the field of health psychology. This work may provide support for the future development of accessible and low-cost options for health interventions across the spectrum of chronic illness.

Analytic Approach. This study includes both quantitative analyses as well as qualitative analyses using the data collected. This mixed-methods approach has the potential to provide nuanced, unique contributions to research (Curry et al., 2009; Mays & Pope, 2000; Greenhalgh

& Taylor, 1997). By taking a mixed-methods approach to these research questions, we will potentially be able to detect nuances related to patient perception of improvement in self-management over the course of this study that may be difficult to identify with only quantitative analyses in a relatively small sample.

Chapter II: Methods

Participants and Recruitment

The study was conducted with Albert Einstein College of Medicine/Montefiore Clinical Diabetes Program, and Yeshiva University's Ferkauf Graduate School of Psychology in the Bronx, New York. Participants were recruited at the Albert Einstein College of Medicine/Montefiore Clinical Diabetes Program through opt-out letters, in-clinic screenings, and direct referral by physicians. The Einstein/Montefiore system is estimated to include over 3,500 Type 2 Diabetes patients in active clinical care. All participants who were interested were asked exclusion/inclusion questions by study staff, either in person or over the phone, depending on referral source. Proper care was taken to obtain informed consent during both the recruitment and screening processes to ensure HIPPA guidelines were met. Recruitment in this manner lasted for 1.5 years before the final sample was comprised. To be included, all participants were required to be aged 18 years or older, have had Type 2 Diabetes for at least one year, be instructed by their doctor to regularly test their blood glucose, be prescribed at least one oral hypoglycemic medication, and own a smartphone with internet access with which they are proficient. Exclusion criteria included the inability to participate in the study in English. While this study was only conducted in English, efforts were made to recruit individuals who spoke

both English and Spanish, so as to better and more accurately capture the demographic makeup of the target population in the Bronx.

Procedures

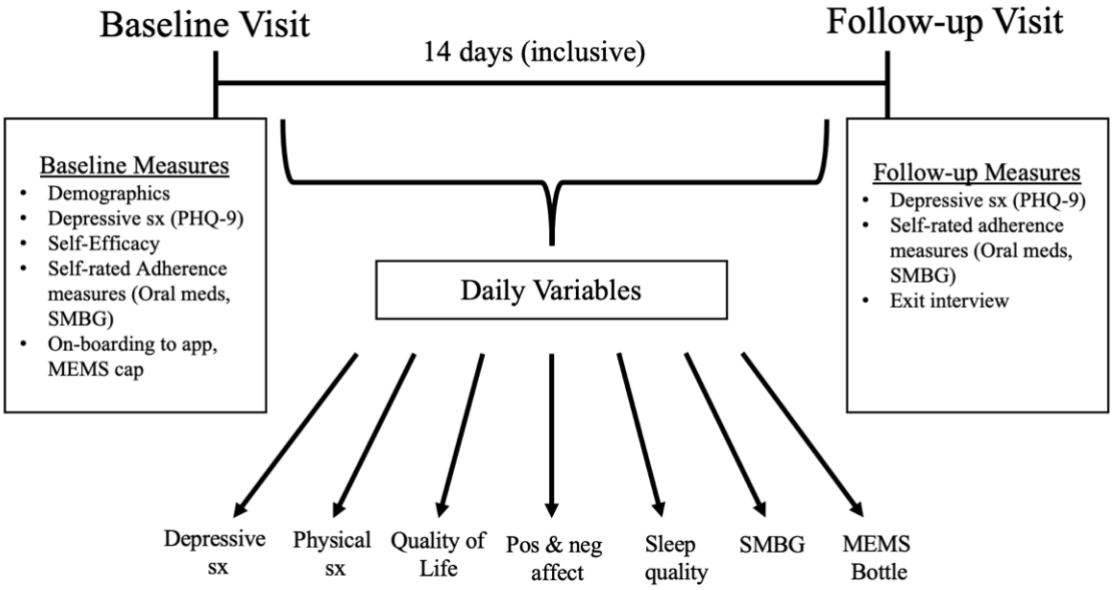
Once deemed eligible, participants were scheduled for two in-lab sessions, spaced two weeks apart. The first visit ("Baseline") began with informed consent and screening questions to ensure that participants still met eligibility, followed by the administration of self-report measures. After all self-report measures were completed, study staff assisted the participant with downloading and learning how to use the smartphone application for EMA. Study staff also provided each patient with an electronically-monitored medication adherence bottle cap, which tracked adherence for one of the patient's oral medications throughout the study; the electronically-monitored medication adherence bottle cap did not provide feedback to participants. Participants were also instructed to monitor their blood glucose daily with their own glucose monitor, though it was made clear that they were not compensated based on how many blood glucose readings were captured (as they were for EMA survey completion.)

The second visit ("Follow-up") was scheduled for 14 days after baseline, and during this visit, participants completed additional self-report measures, return their electronically-monitored bottle cap, and provided study staff with their blood glucose monitor so that readings could be transcribed. At this visit, participants also provided feedback about their study experience of using the smartphone application for EMA surveys, via a short, audio-recorded semi-structured individual exit interview with study staff.

Participants received $25 for each in-lab visit, and up to an additional $75 if they completed at least 70% of app-based surveys; if participants completed less than 20% of the daily surveys they were not compensated for this portion of the study. In total, a participant could

receive up to $125 in total for participation in this study. Survey completion percentage was calculated by measuring the number of surveys that were successfully completed throughout the study, out of the total that were prompted through the application (3 times a day, for 14 days). Figure 2 illustrates the flow of this study, with relevant measures collected at baseline and follow-up highlighted.

Figure 2. Study Flow



SMBG = Self-monitoring of blood glucose (using own monitor)
MEMS = Medication Event Monitoring System, the electronically-monitored medication bottle cap

Measures/Instruments

All self-report measures were administered by study staff. The baseline and follow-up self-report measures were administered in two respective single sessions with study staff present. See Appendix B for source documentation of all administered measures relevant to the current study. At the baseline visit, study staff also provided training and information about how to

download and use the EMA smartphone application. Over the two-week study, participants were prompted to complete EMA surveys on their smartphone (including questions about physical and emotional symptoms, and sleep quality) 3 times per day. After 14 days of completing EMA surveys on their own at home, participants returned to the lab for their Follow-up visit, during which study staff administered additional self-report measures.

Demographics. Participant demographic data, which included age, gender, race, ethnicity, and educational attainment were captured at the baseline lab visit through questionnaires with study staff present.

Glycosylated Hemoglobin Level (HbA1c). HbA1c levels were extracted for each participant from their medical records at the baseline visit. All HbA1c were from within the past 6 months; for participants with multiple HbA1c values on file, we selected the most recent value.

Smartphone application for ecological momentary assessment (EMA App). All participants downloaded the smartphone application known as "MyDay," and were trained on how to use the application for ecological momentary assessments of their daily experience living with Type 2 Diabetes. MyDay is a cross-platform (iOS/Android) mobile application designed by a team at Vanderbilt University to collect, integrate and provide feedback on a wide range of individual data relevant for diabetes self-management. MyDay is specifically intended for use by individuals with diabetes, enabling the assessment of factors that are potentially critical for patient health behavior decision-making (Mulvaney et al., 2019). For the purpose of the parent study, the feasibility and efficacy of MyDay was piloted by patients with Type 2 Diabetes as they completed a small battery of self-report questions 3 times per day, for a two-week duration. The survey battery included questions about emotional symptoms, physical symptoms, as well as sleep quality, and takes approximately between 5-10 minutes to complete each time, for a total

maximum of 30 minutes per day. At their first visit, participants were prompted to select their three timepoints, representing morning (immediately upon waking, before they have checked their fasting blood glucose), afternoon, and evening (before bed, after having completed the majority of their daily routines).

Depression. Depression symptom severity was assessed with the 9-Item Patient Health Questionnaire (PHQ-9), which was collected at both baseline and follow-up visits. For this study's analyses, only the baseline PHQ-9 score was used. The PHQ-9 is a brief self-report depression screening measure that assesses the frequency of depression symptoms over the past 2 weeks, with higher scores indicating more severe depression symptoms (Kroenke et al., 2001). The PHQ-9 assesses four somatic symptoms (sleep, fatigue, appetite and psychomotor retardation) and five cognitive-affective symptoms (lack of interest, depressed mood, negative self-feelings, concentration problems and suicidal ideation), all part of the DSM-5 diagnostic criteria for major depressive disorder (MDD; American Psychiatric Association, 2013). This measure has been validated and found to be reliable in both Type 2 Diabetes and the general population (van Steenbergen-Weijenburg et al., 2010; Barbic et al., 2015). The scores on the PHQ-9 are split as follows: 0-4=no depression; 5-9=mild depression; 10-14=moderate depression; 15-19=moderately severe depression; 20-27=severe depression; total scores greater than or equal to 10 are considered a positive screen for MDD (Kroenke et al., 2001). Depression symptom severity was treated as a continuous variable based on the total score (Whitney et al., 2010). In the current sample, the PHQ-9 collected at baseline demonstrated very good internal reliability (Cronbach's alpha = .82).

Self-Efficacy. Self-efficacy for diabetes self-management was assessed with the Diabetes Self-Efficacy Scale, an 8-item scale, collected only at baseline. This scale was developed

specifically for Type 2 Diabetes and has been well-validated in this population (Sarkar et al., 2006). Questions on this measure asked, *"at the present time, how sure are you that you can… take care of your health/get medical attention when you need it/take all your diabetes medications correctly,*" etc. Participants are asked to respond on a Likert scale ranging from 1 (not at all sure) to 4 (very sure). The items are summed to compute a total score, lower scores indicating poorer self-efficacy and higher scores indicating greater self-efficacy. Internal reliability for the Diabetes Self-Efficacy scale in this sample was found to be acceptable (Cronbach's alpha = .76).

Self-Management. Diabetes self-management was measured at baseline and follow-up lab visits using both the Oral Medication Adherence Measure as well as the Blood Glucose Monitoring Adherence Measure. The original version of these measures were initially developed to measure aspects of illness self-management in people with HIV but in this study, the adherence questions have been adapted for use in diabetes populations (Wilson et al., 2016; Wilson et al., 2014). The self-rated adherence measures each include three questions - *"In the last 30 days, on how many days did you miss at least one dose of any of your oral diabetes medications/miss a day of monitoring blood glucose?*", "*In the last 30 days, how good a job did you do at taking your diabetes medications/monitoring your blood glucose in the way you were supposed to?"* and, "*In the last 30 days, how often did you take your oral diabetes medications/monitor your blood glucose in the way that you were supposed to?*", with the last 2 questions rated on a 6-point Likert Scale, where 1 = Very Poor, 2 = Poor, 3 = Fair, 4 = Good, 5 = Very Good, and 6 = Excellent. At follow-up, language for these measures was updated to state, "since your last visit," rather than "in the last 30 days." In terms of scoring this measure, first, the first item of the scale is changed to reflect the number of days that the individual did not miss

medication (by subtracting the number they provided from 30 for the version of this measure collected at baseline, to reflect "in the past month…", and 14 from the measure collected at follow-up, to reflect "since your last visit.") Then, each individual item on the measure is transformed to use a 0-100 scale, as opposed to a 0-30, 0-14, or 1-6 scale. Finally, the average of all three items is taken to compute a total score for the measure. Possible scores on these measures range from 0-100, with higher scores indicating better self-management across each domains. The internal reliability of the Oral Medication Adherence Measure from both baseline and follow-up was good (Cronbach's alpha = .82 and .83, respectively). The internal reliability of the Blood Glucose Adherence Measure from both baseline and follow-up was also good (Cronbach's alpha = .93 and .89, respectively.)

Semi-Structured Individual Exit Interview. All study participants engaged in an audio-recorded, semi-structured individual exit interview with study staff upon the conclusion of their participation, at the follow-up visit. The exit interview was created to capture qualitative data on participants' overall experience in the study, and asks targeted questions about participants' opinions on the app interface and function, technical difficulties that may have arisen throughout the study, their experience at both in-lab visits (baseline and follow-up) as well as any impact that study participation may have had on their experience of diabetes. Study staff were also instructed to adjust questions as needed and maintain a conversational flow to the interview, to capture as much data about the participants' experience in the study as possible. The audio-recorded exit interviews were then transcribed by study staff and assessed for content related to changes in self-management over the course of the two-week study (see Data Analysis Plan, Qualitative Analysis for more information on this procedure.)

Data Analysis Plan

Quantitative Analysis. For the quantitative analyses (Hypotheses 1a & 1b, 2a & 3a) all data was analyzed using IBM SPSS Software version 27. The data was first examined and visually inspected with histograms and frequency tables for skewness and kurtosis. Descriptive statistics, including mean and standard deviation, were inspected to determine the distribution of the data. Statistical techniques were chosen in accordance with variable distributions. Bivariate correlations revealed that demographic variables age and gender were not associated with any other study variables of interest. Cronbach's alpha was calculated to determine internal consistency and reliability of all relevant measures. For the linear mixed effects models, visually inspecting information criterion statistics determined the best fitting covariance structure for each model, and as such all models were run with a diagonal covariance structure (Littell et al., 2000). For the proposed linear mixed effects models, interaction effects were plotted even for those that did not yield significant findings, to allow for visual comparison between them.

Aim 1a: Evaluated the relationship between baseline and follow-up scores on measures of diabetes self-management: the Oral Medication Adherence Measure and the Blood Glucose Monitoring Adherence Measure.

Hypothesis 1a: Using a within-subjects analysis, participants will report higher scores on both Oral Medication Adherence at the follow-up timepoint, compared to the baseline timepoint as well as Blood Glucose Monitoring Adherence. To evaluate this, follow-up total scores on each measure were subtracted from baseline total scores using a paired-samples t-tests for normally distributed data and examining the mean and the standard error of this difference.

Aim 1b: Evaluated the role of self-efficacy on the change in patient-reported diabetes self-management.

Hypothesis 1b: Baseline diabetes self-efficacy scores will strengthen the relationship between baseline and follow-up patient-reported diabetes self-management, such that those with greater self-efficacy scores at baseline will demonstrate a greater positive difference between baseline vs. follow-up self-rated adherence measure total scores. This was assessed using a mixed-model linear regression, wherein the outcome variable is self-management total score (Oral Medication Adherence and Blood Glucose Monitoring Adherence scores each run separately), and the main predictor variables are a variable indicating baseline vs. follow-up, and an interaction term of the baseline vs. follow-up variable x self-efficacy, with a random intercept at the person level.

Aim 2a: Evaluated the role of engagement with the EMA protocol (survey completion percentage) on the change in patient-reported diabetes self-management.

Hypothesis 2a: Higher survey completion percentage will strengthen the relationship between baseline and follow-up scores on both self-management measures, such that those with higher survey completion will demonstrate a greater difference between baseline vs. follow-up self-rated adherence measure total scores. This was assessed using a mixed-model linear regression, wherein the outcome variable is self-management total score (Oral Medication Adherence and Blood Glucose Monitoring Adherence scores each run separately), and the main predictor variables will be a variable indicating baseline vs. follow-up, and an interaction term of the baseline vs. follow-up variable x survey completion, with a random intercept at the person level.

Aim 3a: Evaluated the role of depressive symptom severity (PHQ-9 from baseline visit) on the change in diabetes self-management.

Hypothesis 3a: Baseline PHQ-9 score will weaken the relationship between baseline and follow-up patient-reported diabetes self-management, such that those with higher PHQ-9 at baseline will demonstrate less difference between baseline vs. follow-up self-rated adherence measure total scores. This will be conducted using a mixed-model linear regression, wherein the outcome variable will be total self-management score, and the main predictor variables is a variable indicating baseline vs. follow-up and an interaction term of the baseline vs. follow-up variable x depression symptom severity, with a random intercept at the person level.

Qualitative Analysis. Qualitative research is a standardized form of inquiry designed to gather detailed, thorough information about the experience of individuals from their own perspective. For the qualitative component of these analyses (Hypotheses 1c, 2c and 3c), the qualitative data from semi-structured individual exit interviews obtained at follow-up were analyzed by a team of coders, a technique with a basis in the grounded theory approach to qualitative research (Bryant & Charmaz, 2012). While traditionally, qualitative analyses have been considered primarily suitable for hypothesis-generating rather than hypothesis-testing (Maudsely, 2011; Ritchie et al., 2013; Sullivan & Sargeant, 2011), there is a body of research that argues for a post-positivist and hypothesis-testing use of qualitative data, especially in a mixed-methods context such as this study (Flyvbjerg, 2006; Kvale, 1994; Avis, 2003). And, there is a standard of other studies examining qualitative interview data in individuals with diabetes that have used qualitative codebooks which are determined *a priori*, as opposed to using codes which are emergent only after reading through interviews (Stuckey, 2015; Goldenhar &

Kues, 2006; Franklin & Ballan, 2001). This is known as the confirmatory approach to qualitative analysis (compared to an exploratory approach) and is the methodology being used in this study (Bernard & Ryan, 1998).

In this study, the qualitative data collected from the exit interviews at follow-up was analyzed using a codebook of specific, hypothesized themes of interest related to improvement in diabetes self-management. The supraordinate theme, improvement in diabetes self-management, had 5 subthemes based on measures of self-management used in this population such as the Heisler Self-Care Scale (Heisler, 2003). See Appendix A for the codebook. A coding team of two clinical health psychology graduate students systematically assessed each interview for the presence of these themes, using what is known as the "template approach" to tag specific sections of text, and then sorted text into separate categories based on theme, to be then analyzed for the strength of the presence of each theme as well as to have specific quotes distilled, illustrating findings (Miles & Huberman, 1994; Silverman, 2015; DiCicco-Bloom & Crabtree, 2006). The coders each assessed the interviews simultaneously, blinded to the other coder's assessment of themes. The coders then compared their assessments and reached a consensus about whether or not each interview contains the themes of interest; discrepancies were first resolved through discussion, along with a third team member (also a clinical health psychology graduate student) who was available to serve as a tie-breaker if there was irreconcilable disagreement. Using a coding team in this way enabled investigator triangulation to support the credibility of this work (Patton, 1999) and similar methods have been used before in qualitative analyses of exit interviews in the Type 2 Diabetes population (Tanenbaum et al., 2016). We hypothesized that at least one of the interviews would affirmatively contain the supraordinate theme, improvement in self-management; given the qualitative nature of this data,

generalizability to a much greater population is not possible and instead, this work seeks to examine only the particular experiences of the participants in this study (Hyde, 2000). NVivo software was used to organize coding and assess the strength of the presence of the supraordinate theme (improvement in diabetes self-management) as well as its subthemes in the exit interviews (Welsh, 2002). Secondary analyses of this data included breaking the participants' interviews into dichotomized groups: high vs. low baseline self-efficacy, high vs. low survey completion, and high vs. low baseline depression symptom severity. For these analyses, we hypothesized that the participant interviews for those that have higher survey completion percentage would demonstrate greater themes of improvement in diabetes self-management than those with lower survey completion percentage. We also hypothesized that the participant interviews for those with greater depression symptom severity at baseline would demonstrate less themes of improvement in diabetes self-management, than participants with less depression symptom severity at baseline. We also hypothesized that the participant interviews for those with greater diabetes self-efficacy at baseline would demonstrate greater themes of improvement in diabetes self-management, than participants with less diabetes self-efficacy at baseline. Overall, data reported includes the percentage of interviews that contain each subtheme of interest, an analysis of the strength of the presence of these themes throughout the interviews based on the aforementioned dichotomization of the participants' interviews, and selected quotes that serve to illustrate these findings.

Power Analysis Plan

Given the exploratory nature of these secondary analyses to the parent study, it was deemed not appropriate to use power analyses to determine an ideal sample size. At the time of proposal for analyses, recruitment for this study was complete, and has resulted in a sample size

of 62 participants. Given this fixed, unalterable sample size, the standardized effect size that was detectable, using G*Power (Faul et al., 2009), at the .05 level with 90% power for the linear mixed effects models (H1b, H2b, H3a and H3b) is $f^2 = .21$, representing a medium effect size (Cohen, 1988). As such, this study is likely to be underpowered to detect moderation effects except for relatively large differences.

Ethics

The current study is included under the larger parent study, which was approved by the Institutional Review Board at the Albert Einstein College of Medicine of Yeshiva University (IRB #2017-8241). All study personnel received Collaborative Institutional Training Initiative (CITI) training. The PI of the parent study, Dr. Jeffrey Gonzalez, is a licensed clinical psychologist who supervised all study personnel interacting with participants during the study. The risks and benefits of the study are outlined in the informed consent and in the below Risks and Benefits section.

Risks and Benefits

This study did not involve any invasive physical procedures, and as such the risks to participants are essentially none. A possible risk is the burden of completing questionnaires three times per day on the phone app, as well as completing paper-and-pencil questionnaires during lab visits. However, all participants in the parent study were told that they have the option of terminating participation at any time and not answering any questions that they do not want to answer. Additionally, there was the risk of loss of confidentiality. Steps to reduce this risk were taken, such as keeping paper data in locked file cabinets in locked offices, maintaining password-protected computer records, and only including participant IDs (no identifying information) with data.

While this research study does not provide any direct benefits to participants, the benefits to others are potentially quite large. This study may provide support for the role of bringing awareness to one's illness experience (via a low-cost, accessible phone app) to improve health outcomes in a diverse population of Type 2 Diabetes patients. And, this work could help build the evidence base for the development of future behavioral interventions that could improve diabetes outcomes.

Chapter III: Results

Participant Characteristics

Descriptive statistics including mean, median, range, frequencies, skewness and kurtosis were examined for each variable in the analyses. Scatter plots and histograms were generated for variables of interest to evaluate whether variables were normally distributed. All variables indicated relatively normal levels of skewness and distribution based on guidelines for these values in the literature (George & Mallery, 2009; Tabachnik & Fidell, 2007). Furthermore, evidence demonstrates that the robustness of the proposed analytic models remains unaffected even in the context of moderate skewness (Arnau et al., 2003). As such, no transformations were applied. To test for multivariate outliers within the pairs of self-management variables of interest (baseline blood glucose monitoring/follow up blood glucose monitoring, and baseline oral medication adherence/follow up oral medication adherence), data were assessed using a Mahalanobis Distance Test (Tabachnik & Fidell, 2013). This revealed two multivariate outliers for each pair. All multivariate analyses were run both with and without the outliers, and results remained unchanged. And, close examination of the outliers revealed that they were not data error, but rather true values. As such – and, in an effort to preserve the full sample size – they remained in the sample and all reported results are inclusive of the identified outliers.

Table 1 provides descriptive statistics regarding participant characteristics for the 62 adults with Type 2 Diabetes who were included in this study. The sample was 61% Black/African American race, 65% male and the average age was 55 years old. The average glycosylated hemoglobin level (HbA1C) % was 8.4, indicating suboptimal control of diabetes (Centers for Disease Control and Prevention, 2018). At baseline, participants reported an average score of 6.72 on the PHQ-9, indicating mild depressive symptoms (Kroenke et al., 2001).

Educational attainment was collected for 61 participants using a drop-down menu of several options and ranged from “some high school,” to “graduate degree” and most participants (64.6%) had less than a college degree.

Average scores on the blood glucose monitoring adherence measure were 69.74 at baseline (range: 0 – 100) and 78.99 at follow-up (range: 6.67 – 100). Average adherence scores for oral medication were 81.70 at baseline (range: 17.78 – 100) and 83.70 at follow-up (range: 6.67 – 100). Participants had been told they needed to complete a minimum of 70% of all prompted surveys (42 in total, across the 14 days) to receive full participation compensation and the average completion of assigned EMA surveys was 83%, indicating good adherence to the study protocol overall.

Excluded participants. Two participants did not complete the measure of blood glucose monitoring adherence collected at baseline, as prior to participating in this study they reported they had not been regularly testing their own blood glucose at all though per study eligibility requirements, they had been instructed to do so by their doctor. For these participants, “30” was imputed for the “days missed” question on this measure, and “1” (“Very Poor”/“Never”) was imputed for the two questions regarding how well they had been adhering to blood glucose self-management and how often they monitored their blood glucose the way they had been instructed to by their doctor. Two additional participants did not complete the measure of blood glucose monitoring adherence collected at follow-up due to data collection issues; these participants were excluded from analyses using these measures. One participant was excluded from analyses using survey completion percentage due to not having been able to complete surveys using the app due to reported technological problems with their phone during their study participation. This participant instead completed printed surveys using pen-and-paper throughout the two weeks,

and as such their responses were included in all other analyses besides those which required the direct measurement of how many surveys were completed each day.

Quantitative Analyses

Bivariate Correlations. The relationships between continuous study variables (age, gender, self-efficacy, depressive symptoms, survey completion percentage, and both baseline and follow-up scores on the blood glucose monitoring adherence measure and the oral medication adherence measure) were examined using Pearson product-moment correlations (Table 2). Self-efficacy was found to be correlated with all aspects of self-management: both oral medication adherence at baseline and follow-up ($p < .001$; $p = .001$) as well as blood glucose monitoring adherence at baseline and follow-up ($p < .001$; $p = .001$), such that higher self-efficacy was associated with greater self-management scores. Self-efficacy was also found to be negatively correlated with depressive symptoms ($p = .003$) such that lower self-efficacy was associated with higher depression. Age, gender and survey completion percentage were not found to be associated with any study variables.

Within-Subjects Comparison of Baseline vs. Follow-up Diabetes Self-Management Scores. For Aim 1a, paired-samples t-tests were run to compare participants' scores on both the oral medication self-management adherence measure and the blood glucose monitoring adherence measure, collected at baseline and then again at the follow-up visit for this study; results are shown in Table 3. Scores on the oral medication adherence measure at follow-up were not any significantly greater than scores on the same measure from baseline. However, scores on the blood glucose monitoring adherence measure were significantly greater than scores on the same measure from baseline ($p = .01$).

Within-Subjects Moderation Analyses. For Aim 1b, two linear mixed effects models were run, examining the role of self-efficacy in the relationship between baseline and follow-up scores on the self-management measures (both oral medication and blood glucose monitoring adherence, run separately).

Blood Glucose Monitoring Adherence*Self-Efficacy: The linear mixed effects model for blood glucose monitoring, did not show a significant interaction of baseline blood glucose monitoring with baseline self efficacy (B = -1.65, t = -1.83, 95% CI = -3.4, .15) in predicting follow-up blood glucose monitoring, which demonstrates that self-efficacy did not moderate the change in blood glucose monitoring adherence from baseline to follow-up (Table 4; Figure 3).

Oral Medication Adherence*Self-Efficacy: The linear mixed effects model for oral medication adherence, also did not show a significant interaction of baseline oral medication adherence with baseline self-efficacy (B = -.53, t = -1.10, 95% CI = -1.49, .43) in predicting follow-up medication adherence, which demonstrates that self-efficacy did not moderate any difference between oral medication adherence scores from baseline to follow-up. (Table 5; Figure 4).

For Aim 2a**,** the linear mixed effects models were repeated, examining survey completion as a potential moderator of the relationships between baseline and follow-up self-management scores (both oral medication and blood glucose monitoring adherence, run separately).

Blood Glucose Monitoring*Survey Completion: The linear mixed effects model for blood glucose monitoring showed a significant interaction of baseline blood glucose monitoring with survey completion (B= 43.57, = *t* = 2.59, 95% CI = 10.00, 77.14) in predicting follow-up blood glucose monitoring, such that those with higher survey

completion percentage demonstrated greater change in scores on blood glucose monitoring adherence from baseline to follow up. (Table 6; Figure 5).

Oral Medication Adherence*Survey Completion: The linear mixed effects model for oral medication adherence did not show a significant interaction of baseline oral medication adherence with survey completion (B = 12.24, *t* = 1.42, 95% CI = -5.01, 29.49) in predicting follow-up oral medication adherence, indicating that survey completion percentage did not moderate any change in oral medication adherence from baseline to follow-up. (Table 7; Figure 6).

For Aim 3a, the linear mixed effects models were repeated, examining depressive symptoms as a potential moderator of the relationships between baseline and follow-up self-management scores (both oral medication and blood glucose monitoring adherence, run separately).

Blood Glucose Monitoring*PHQ-9: The linear mixed effects model for blood glucose monitoring did not show a significant interaction of Blood Glucose Monitoring*PHQ-9 (B = -.01, *t* = -.02, 95% CI = -1.35, 1.32) which demonstrates that depressive symptoms did not moderate any difference in blood glucose monitoring adherence from baseline to follow-up (Table 8; Figure 7).

Oral Medication Adherence*PHQ-9: The linear mixed effects model for oral medication adherence did not show a significant interaction of Oral Medication Adherence*PHQ-9 (B= .64, *t* = 1.89, 95% CI = -.03, 1.32), which demonstrates that depressive symptoms did not moderate any difference in oral medication adherence from baseline to follow up (Table 9; Figure 8).

Qualitative Analyses

For Aims 1c, 2b and 3b: After a team of two coders used the "template approach" to tag specific sections of text that were later sorted into categories based on subtheme using nVivo

software (Miles & Huberman, 1994), we found that 71% (n = 44) of the 62 exit interviews were deemed to contain themes related to improvement of self-management of diabetes. Four of the five sub-themes related to improvement of diabetes self-management over the two week-study were found to be present across the interviews. Table 10 illustrates the prevalence of the themes throughout the interviews.

Improvements in Taking Medications. Reported improvements in taking medications were found in 52% (n =32) of interviews. The following are excerpts from conversations between an interviewer and research participant, about how participating in this study influenced their diabetes self-management medication-taking:

Participant 1:

> ***Participant 1:*** *It's been helping me keep track of my diabetes medication and the timing that I take it, because before I was just taking it when I wake up or whenever I decided to take it. But this was on schedule and I had to take it.*
>
> ***Interviewer:*** *So you felt like it was like a reminder?*
>
> ***Participant 1:*** *Yes, it kept me on regimen, and now hopefully I can keep on with this regimen… I shouldn't take it whenever I feel like it, I should take it every morning at the same time.*
>
> ***Interviewer:*** *Did you find that was helpful in terms of feeling different? Like, in terms of how you felt physically, in terms of taking your medication at that time?*
>
> ***Participant 1:*** *Physically, no. But it gave me the mindset of, you need to be responsible to take it at the same time and not taking it 2-3 hours later after you wake up.*

Participant 2:

> ***Participant 2:*** *It reminded me to take my medication more, even [though] it didn't say to… I [did] skip Metformin sometimes before the app. With the app, it reminded me to take my medication and how many times I got to, you know, utilize the insulin… but it did not help me how to take my, to remind me to take my blood sugar, because that doesn't apply. Only applies how much I ate… if I felt more appetite.*

Improvements in Exercise. A small number of participants spontaneously discussed improvements in exercising (5% of interviews, n = 3). The following excerpt is from a conversation between an interviewer and research participant regarding perceived change in diabetes self-management exercise behaviors from participating in this study:

> ***Participant:*** *When it says, 'how frequently do you urinate every day,'… I was like 'yeah, I do urinate a lot, and I urinate a more a lot when my sugar is high and when its low.' And I was like, you know what, I just realized that. I use that bathroom a lot when my sugar is high. And when it is normal, I don't go to the bathroom as much.*
>
> ***Interviewer:*** *Did you change anything about the way you take care of yourself by realizing these different things about yourself?*
>
> ***Participant:*** *I force myself to like, to get up and do more exercises, walk around. Walk across outside. And also motivates me to talk more frequently, to open up, to talk to other people… when I was at my sister's gathering, get together, for a birthday… we went to her house and my brother's girlfriend, you know, she has Type 1 and she also takes shots, so she's taking the insulin… and she was like, the*

pills that they gave her, it is not helping. So, I was like, 'well you know, you should do a lot more exercising.'

Improvements in Dietary Adherence. Reported improvements in dietary adherence were found in 24% (n = 15) of interviews. The following quote is from a participant, regarding perceived change in adherence to dietary recommendations from participating in this study:

Participant: [*By] Asking me the questions… like when I was feeling, it makes me think that I've gotta change a lot of things. I started taking some books that I got for diabetics. And the one that he [the doctor] told me for diabetics. The recipes. Those questions, you know, it was like something new for me. So, yeah, it made me have to change... to cook diabetic recipes. And it got me to do exercises.*

Improvements in Self-Monitoring of Blood Glucose. Reported improvements in checking blood glucose were found in 45% (n = 28) of the interviews. The following quote represents a conversation between participant and interviewer regarding perceived change in blood glucose monitoring from participating in this study:

Participant 1:

Interviewer: *Did using the phone app influence or change how you took care of yourself over the two weeks?*

Participant 1: *Influence.*

Interviewer*: How so?*

Participant 1: *Because it forced me to check my sugar like I am supposed to. It forced me to keep like a daily, I don't know what you call it, it's not a ritual, that's not the word for it, but it's like a daily, you know…*

Interviewer: *Like a routine?*

> ***Participant 1:*** *Routine, yeah that's the word. It forced me to keep a daily routine. Before, maybe I would halfway do it, or I would do it for three days in a row and then I wouldn't do it one day or I would have way do it the next day. Then, I would go back and start doing it again.*

Participant 2:

> ***Interviewer:*** *Do you feel like when you were using the app, it changed how often you were taking your blood sugar…testing it?*
>
> ***Participant 2:*** *I was testing it three times.*
>
> ***Interviewer:*** *So, you were doing it more consistently three times a day.*
>
> ***Participant 2:*** *Yeah.*

Improvement in Checking Feet. None of the interviews contained the sub-theme related to improvements in checking one's feet.

Overall, participants endorsed in these interviews that participating in the two-week EMA app study influenced positive changes in their self-management of diabetes across multiple domains. Additional relevant quotes distilled from these interviews related to each theme of self-management change can be found in Table 11.

Next, we sought to examine the relationships between variables of interest – depressive symptoms, self-efficacy, survey completion, as well as demographic variables age and gender – with the presence of themes related to improvement in self-management in the interviews. Chi-squares tests were used to test the relationships between dichotomized (median-split) variables high baseline depression, high self-efficacy, high survey completion, and the dichotomous (yes/no) presence of themes related to improvement in self-management in qualitative interviews; gender was included here, too (Table 12). Pearson correlations were used to test

associations between age and the dichotomous presence of themes related to improvement in self-management (Table 13). These results revealed that high baseline depression, high survey completion, gender and age were not correlated with the presence of themes related to changes in self-management in qualitative interview. However, high baseline self-efficacy was positively correlated with the presence of themes related to self-management in the qualitative interview ($X^2 = 7.50$, $p < .01$). This relationship was further probed by conducting an independent samples t-test, comparing continuous scores on self-efficacy in the presence of theme improvement in self-management in exit interview vs. no presence of the theme. This revealed a significant difference between the scores for baseline self-efficacy for the presence of the theme in exit interviews ($M = 25.61$, $SD = 3.81$) and no presence of the theme ($M = 27.83$, $SD = 3.79$) ($t = -2.08$, $p = .04$) such that higher scores on self-efficacy were associated with a greater likelihood of the supraordinate theme, improvement in self-management, being present in the interview (Table 14).

Chapter IV: Discussion

This secondary analysis of a parent study testing the feasibility of an ecological momentary assessment (EMA) app for people with Type 2 diabetes sought to explore the roles of self-efficacy, engagement with EMA, and depressive symptoms on improvement in self-reported self-management behaviors, using both quantitative and qualitative methods. Participants in this study first completed various self-report measures at their "baseline" visit, then used the EMA app for two weeks, before returning to the lab for their "follow-up" visit where they completed more self-report measures and participated in a semi-structured exit interview with study staff which was audio-recorded, transcribed and analyzed qualitatively.

Within the quantitative analysis component of this project, we found that greater baseline self-efficacy was associated with both higher self-rated oral medication adherence and higher self-rated blood glucose monitoring adherence at both the baseline and follow-up visits. We also found that self-ratings of adherence to blood-glucose monitoring recommendations significantly improved from baseline to follow-up, however, self-ratings of oral medication adherence showed no significant change over time. Contrary to our hypothesis, we did not find depressive symptom severity or self-efficacy to be significant moderators of the relationship between baseline and follow-up scores on either of the adherence measures. However, survey completion percentage moderated the relationship between baseline and follow-up self-reported blood glucose monitoring adherence, such that participants who completed more surveys showed greater improvements in self-rated adherence to blood glucose monitoring. The qualitative analyses supported many of the results from the quantitative analyses and provided additional findings: participants reported change in four of the five domains of self-management – taking medications, blood glucose monitoring, adhering to exercise recommendations and adhering to

diet recommendations, and participants attributed these changes to their participation in the EMA protocol. We found that these qualitative reports were associated with higher baseline self-efficacy, as participants with high self-efficacy scores were more likely to endorse change in self-management behaviors during their exit interview. The results of this study provide preliminary evidence that participating in a two-week study involving an EMA app (which draws one's awareness to symptoms and illness experience 3x per day) may have an impact on various domains of self-management behaviors for people with Type 2 Diabetes. To our knowledge, this project is the first to evaluate self-rated self-management as a mechanism of change in the context of a short-term EMA study, essentially attempting to capture whether reactivity to EMA may be a beneficial side-effect in the context of behaviors that are vital for maintaining health and wellness with a chronic illness such as Type 2 Diabetes.

Our finding that self-efficacy was associated with higher self-management scores on two domains of self-management, oral medication adherence and blood glucose monitoring, at baseline and follow-up, is consistent with the literature on this topic. A breadth of earlier research has found that patient self-efficacy, or the belief that one has the correct tools and skills to complete a certain task, is associated with better self-management behaviors in chronic illness, including Type 2 Diabetes (Aljasem et al., 2001; Sarkar et al., 2006; Hurley & Shea, 1992; Curtin et al., 2008). As previously mentioned, the spectrum of self-management behaviors – including blood glucose monitoring and adhering to a complex medication regimen – is necessary for reaching and maintaining wellness with a chronic disease such as Type 2 Diabetes. Self-management tasks such as these are vital for avoiding extremely detrimental side effects such as glaucoma, neuropathy and even death (Ahola & Groop, 2013). Patients have reported that self-management tasks can be stressful, burdensome, and contribute to anxiety and

depression. As such, it is encouraging that this study was able to identify psychosocial variables such as self-efficacy that appear to be associated with greater engagement with these important behaviors, and that this finding is consistent with earlier findings within the literature.

Across both quantitative and qualitative analyses, we also identified a positive change in patient self-reported self-management behaviors across at least two domains (blood glucose monitoring and oral medication adherence), after drawing awareness to one's illness experience after two weeks of an EMA app. Specifically, quantitative analyses demonstrated that blood glucose monitoring adherence scores significantly improved from baseline to follow-up. Within a qualitative analysis of semi-structured exit interviews completed at the patients' follow-up visit with the study, which examined more domains of self-management than were able to be captured by the self-report adherence measures, we identified that patients reported change in four domains of diabetes self-management (oral medication adherence, blood glucose monitoring, adherence to exercise recommendations, and adherence to diet recommendations), which they attributed to their participation in this study. However, no participants in this study indicated that they experienced any improvement in checking their feet, throughout the course of participating in this study. Foot checking, as a response to diabetic neuropathy, is considered an important self-care activity for all people with diabetes, as foot ulcers and resulting amputations are a major cause of morbidity and disability in people with diabetes (Mayfield et al., 2004). Yet, it is widely understood that even after receiving foot care education from providers, many people with diabetes do not engage in this self-care behavior, with reports that two-thirds of patients check their feet "rarely, if at all" (Pollock et al., 2004; McInnes et al., 2011). And, while foot care should ideally be performed as a preventative measure in diabetes, research also indicates that healthcare providers are significantly more likely to administer foot checks and provide

education about foot self-care to patients who already have foot lesions as opposed to those who do not, but may be at risk (Del Aguila et al., 1994). It remains an important goal for the field to increase access to foot care education for all people with diabetes, and develop tools or interventions that can improve patient adherence to this potentially life-saving self-management task. Nonetheless, given this background, it is not surprising that of all self-management behaviors queried in the exit interview qualitative analysis, improvement in checking one's feet was not endorsed by any of our participants.

One possible reason why we noticed quantitative changes across blood glucose monitoring adherence, but not oral medication taking adherence, was that scores on blood glucose monitoring were lower on average at baseline than oral medication taking, indicating lower initial adherence in this participant population. Blood glucose monitoring is one of the most burdensome self-management tasks for patients with diabetes, as it requires self-administering finger pricks, and barriers to this can include fear of needles and pain, stigma about taking one's own blood glucose in front of others, and feelings of frustration about high readings (Ong et al., 2014). From this, it may be inferred that one reason why patients with diabetes can be poorly adherent to self-monitoring of blood glucose is to avoid drawing their awareness to their illness experience any more than they feel they must: as such, by using the EMA app for two weeks and automatically drawing their attention to their diabetes, perhaps patients were influenced to adhere more to self-monitoring of blood glucose recommendations. This is aligned with what we saw in the qualitative analysis of some exit interviews, wherein some participants shared that completing EMA surveys 3 times per day piqued their curiosity about other diabetes-related data they might collect on their own.

The mixed-methods approach to this research question has allowed for a nuanced understanding of the patient experience engaging with the EMA app in this study, and more broadly, an exploration of how patients feel that their self-management even improved as a result of their participation. These findings provide tentative evidence that a low-cost and highly adaptive tool such as the smartphone app developed for the parent study may contribute to improvements in adherence to fundamental and impactful health behaviors in the context of a chronic illness like Type 2 Diabetes. While it must be noted that we did not have a control group and thus, cannot infer causation regarding any changes being due directly to engaging with the EMA app itself, the qualitative analysis of exit interviews certainly provides additional depth to our understanding of quantitative findings.

This mixed-methods approach has also provided context and detail to a study which is limited by a relatively small sample size. For example, within the quantitative analyses, we were unable to detect a change in the self-management related to oral medication adherence from baseline to follow-up, however qualitative analyses illuminated that the participants in this study did report a change within this domain, in multiple cases stating explicitly that by completing the EMA questions 3x per day they felt that they were in a more structured routine of self-care for their diabetes and as such were able to maintain adherence to medication regimens, as well. Participants also noted that the EMA app's queries about their current symptoms, mood and activities allowed them to make connections between their experience of diabetes and the behaviors they engage in to maintain wellness in the context of diabetes, such as blood glucose monitoring and taking medication. These identified nuances, which were not possible to capture by the self-report measures collected at the baseline and follow up visits, may be because the semi-structured interview itself was a more sensitive measure of self-management changes than

the self-report questionnaires that were administered. Previous research has established structured or semi-structured clinician-administered interviews as a "gold standard" for collecting health behavior information from a variety of patient populations, including those with Type 2 Diabetes, across symptom presentations such as depression and post-traumatic stress disorder (PTSD) (Tanenbaum & Gonzalez, 2012; Shapira et al., 2018; Forbes et al., 2001). While this study's exit interview was not a validated, clinician-administered measured of self-management behaviors, it is possible that it was indirectly able to capture more – or simply different – elements of the patient experience in this study related to self-management than the pen-and-paper questionnaires.

Of note, we also found that survey completion moderated the change in scores on blood glucose monitoring adherence from baseline to follow-up, such that those with higher survey completion demonstrated a greater difference in their scores. While this study was not designed to be an intervention (and as such there was no control group that did not receive the EMA app, against whom we might compare these changes), this provides evidence for the role of the EMA app itself to have contributed to these changes in self-management for patients, as patients who used the app more had greater improvements. This provides support for the impact of drawing awareness to one's illness experience on better performance of behaviors associated with illness: earlier research has identified that bringing awareness to one's experience of illness through symptom-tracking (like that which was performed within the EMA app use-protocol for this study) or the use of daily diaries has been associated with improved self-management behaviors (Guendelman et al., 2002; Nes et al., 2013). Of note, the daily EMA app surveys also required participants to report on their medication taking, assess their sleep among other aspects of day-to-day functioning, and record their mood. As such, while the results from this study tentatively

point to some aspect of EMA app engagement being associated with improvements in self-management, it is not possible to identify exactly which elements of the app (or, study protocol more broadly) may be responsible. The EMA app protocol was short-term, across only 2 weeks, and was not designed as an intervention. In this protocol, we required participants draw their attention to their diabetes illness experience in nuanced ways (from symptom recording to assessment of their mood) – and it appears that those who did this more so, by completing more of the surveys that were prompted through the app, noticed more of a difference in their self-management than those who completed less surveys.

Contrary to what was initially expected, neither baseline self-efficacy nor baseline depression were found to be moderators of change in either direction in self-management domains over the two-week study, across both blood glucose monitoring as well as oral medication adherence, within the quantitative exploration of this hypothesis. The finding that depression was not related to change in self-management behaviors was replicated within the qualitative analyses, as participants with high baseline scores on the measure of depressive symptom severity were not found to have more or less change in self-management behaviors reported in their exit interviews. This may be an especially helpful contribution to the literature, given the well-established high rates of depression and distress in this population (Ali et al., 2013; Ali et al., 2006; Perrin et al., 2017). This finding, or lack thereof, also has implications for our understanding of EMA reactivity. Previous research using EMA in many different populations (such as those who are monitoring smoking and drinking behaviors, or individuals who are homeless) have reported mixed findings in terms of whether or not there is reactivity to EMA (the phenomenon in which being monitored or self-monitoring through a process like EMA may actually impact outcomes or behavior) (Hufford et al., 2008; Rowan et al., 2007;

Semborski et al., 2022). Our study sought to identify person-level moderators of the potential for EMA reactivity, and we identified that depressive symptoms and self-efficacy are two factors which do not appear to play a role. As such, if there is the potential for reactivity in EMA, it appears that it would not be different for those with pre-existing mental health concerns such as depression, or varying levels of psychological resources like self-efficacy. This is congruent with research that has found EMA to be an acceptable and feasible measurement tool even in at-risk psychiatric populations (Glenn et al., 2022), or for those with chronic illness like Type 2 Diabetes (Wooldridge et al., 2022). While contrary to what we expected, this finding may point to the acceptability and feasibility of EMA measurement for diverse patient populations.

While – as previously mentioned – we identified a cross-sectional relationship with self-efficacy and self-management behaviors at both baseline and follow-up timepoints, self-efficacy was not found to moderate any change in patient-reported blood glucose monitoring nor medication-taking. Of note, however, is that self-efficacy did appear to play a role within the qualitative analyses of patient-reported changes in self-management: within the exploration of the exit interviews, we found that participants with high scores on the measure of self-efficacy collected at baseline were more likely to report change in self-management behaviors attributable to their participation in this study. The difference in the results for this research question across quantitative and qualitative methods of inquiry points to the innovativeness and sensitivity of a mixed-methods research approach: it is possible that the exit interview picked up on changes that were not detectable by pen-and-paper self-report measures. Further exploration of these research questions within a larger and more diverse sample is necessary to continue to parse out these complicated relationships.

Clinical Implications

The current study's findings provide significant considerations for potential clinical applications. This research highlights the potential impact of a short-term and highly adaptable protocol, using an EMA app for symptom recording across two weeks, to change participants' self-management behaviors. In particular, our qualitative finding that higher self-efficacy was associated with greater change in self-reported self-management behaviors – as well as the quantitative finding that cross-sectionally, greater self-efficacy was associated with greater oral medication adherence and blood glucose monitoring adherence across both collected timepoints – may have clinical relevance for providers seeking to improve patient adherence to self-management behaviors. Self-efficacy is widely considered a malleable and sensitive construct that can be improved or changed with relatively short-term interventions (Bandura, 1977; Gist & Mitchell, 1992; Hyde et al., 2008; Unrau et al., 2018). Improving self-efficacy can happen through demonstrated techniques such as helping patients to increase their sense of mastery, manage stress related to task performance, and providing feedback on performance (Prestwich et al., 2014). These techniques would likely be very impactful for individuals with Type 2 Diabetes, given this study's finding that higher self-efficacy may be associated with better adherence to self-management behaviors, both at baseline and over time.

It is also clinically relevant that we were not able to confirm the hypothesis that depressive symptom severity would interfere with any purported helpfulness of symptom-recording and illness experience awareness from engaging with the EMA app, either as a moderator of the change in self-management over time, nor as having any cross-sectional association with any other study variables, including self-management scores. Aligned with this, our visual representations of these analyses (in Figures 7 and 8) do not show much of a trending

change between high and low depressive symptoms across the two timepoints of self-management measures that were captured. This perhaps identifies that people with Type 2 Diabetes would be similarly likely to potentially benefit from a tool that draws their awareness to their illness experience, such an EMA app, regardless of their mental health when they begin app use. This finding should be taken within an understanding that our sample, on average, did not have high depression symptoms – thus, it is challenging to confidently conclude that depression did or did not play a role. Overall, mental health comorbidities such as depression and anxiety are higher in populations with Type 2 Diabetes than the general population (Ali et al., 2006; Ali et al., 2013) and it is vital that providers who treat people with diabetes are screening for depressive symptoms, either via self-report measures, or clinical interview (Young-Hyman et al., 2016) – however, it is encouraging that the presence of these symptoms do not seem to play a role here. Given the aforementioned low power of our moderation effects, however, future research is necessary to explore this hypothesis further, in a broader context and with a larger sample size.

Limitations

There are several limitations to consider within the current study. The most significant limitation to this study is the lack of control group that was not using the EMA smartphone application over the course of two weeks. As such, given that the design of the parent study is not that of a true intervention, we are unable to determine if any significant changes noted in diabetes self-management (quantitatively across self-monitoring of blood glucose) from baseline to follow-up can be attributed to illness awareness experience via exposure to the EMA protocol, or representative of reactivity of the EMA smartphone application, or indicates some other external factor. However, the qualitative data analyzed from the semi-structured individual exit

interviews upon completion of the study complements these findings well, by identifying that as a whole, patients do attribute improvements in their diabetes-related behaviors across four domains (oral medication taking, testing blood glucose, dietary adherence, and exercising) to their participation in the study. Future studies may seek to explore the impact of tools that increase awareness of one's illness experience (such as the EMA app) on psychosocial and physical health outcomes of diabetes in a true interventional context.

There are also limitations associated with the analytic approach to this project. Research in social science statistics has demonstrated that even studies that use very large sample sizes are at risk for being underpowered to detect moderation effects, even if they have sufficient power for detecting main effects (Blake & Gangestad, 2020). In particular, the use of a normally distributed continuous moderator variable (such as all three tested moderators in this study) can be associated with an eight-fold decrease in statistical power (McClelland & Judd, 1993). While we did not find it appropriate to estimate this study's power *a priori*, it should be noted that this study is likely also underpowered to confidently stand by the significant moderation effect that we identified (survey completion as a moderator of the change in score on blood glucose monitoring adherence from baseline to follow-up.) That said, this limitation is ameliorated by our interesting main effects, as well as the complementary qualitative analyses.

Generalizability of this study may be another limitation. This study, using data collected as part of a parent study, had a small sample size and resulting potentially underpowered analyses. As such, while this study may not be exceedingly generalizable to a greater population, these findings may contribute to the development of future research projects that are able to recruit a larger sample size. Within our small sample, the majority of participants in this study identified their race as Black/African American (61%) and other racial groups were not very

highly represented (Asian: 5%, White: 10%, Other: 10%, Did not answer: 14%). Also, this study was only conducted in English, whereas we know from community census data that within the Bronx, almost 50% of the population speaks Spanish (either in addition to English, or as their primary language) (United States Census Bureau, 2020) As such, the findings of this study may have had wider applicability and more nuance should it have been conducted in languages other than English, specifically Spanish, given the demographic breakdown of the community wherein the study was conducted. Future work on this topic may consider adapting an EMA app for symptom-recording in diabetes for different languages, as well as adapting the relevant self-report measures for this study to different languages. Taken together, these findings are not representative of the full range of individuals with Type 2 Diabetes in the United States, though it is important to note that it was conducted within one of the most at-risk communities with this illness, who would be likely to benefit from low-cost, adaptable interventions to improve the illness experience of diabetes as well as vitally important self-management behaviors. Also, this study design and the population of this sample was limited to people with Type 2 Diabetes – as such, it is possible that the relationships between study variables may be different for people with Type 1 Diabetes, or other medical conditions or chronic illnesses that also necessitate involvement in complex and burdensome self-management tasks.

Another limitation lies within the variables that we did not measure within this sample. Other psychosocial variables, such as personality factors (in particular, conscientiousness) have been shown to be related to both high self-efficacy (Lee & Klein, 2002), as well as better outcomes in chronic illness populations, compared to other personality factors (Jerant et al., 2010). Capturing personality factors or other underlying individual features of our participant sample may have aided in understanding which findings can be attributed to intrinsic motivation

vs. extrinsic motivation, such as being compensated for study participation, and should be considered in future research.

Future Directions

This study provides potential jumping-off points for a number of future directions for the research. First, given some of the aforementioned limitations of this study design, future research may consider exploring the associations between these variables of interest in a broader, cross-cultural and multilingual context, to better capture the potential global impact of these findings. This includes exploring these same relationships within a larger sample size, to more accurately detect changes such as potential moderation effects. Additionally, the major limitation of this study and its findings was that the parent study was not designed as an EMA intervention, but rather a feasibility and acceptability pilot for this type of methodology in Type 2 Diabetes. As such, future studies should examine this potential change in a truly interventional context (some participants engaging with an EMA app, others receiving enhanced treatment as usual or no treatment, or a similarly multi-armed approach). Also, the mixed-methods approach of this study resulted in contrary findings across quantitative and qualitative explorations of the same hypothesis: while certainly unexpected, this may point to the increased sensitivity of a semi-structured interview approach to capturing patient health behavior data compared to pen-and-paper questionnaires. Based on this perceived sensitivity, one future direction for the research may be to develop a semi-structured clinical interview meant specifically to capture information about self-management for people with chronic illness, as presently no such interview exists.

Additionally, while our finding that the EMA app study protocol may be associated with changes in self-management is very tentative, it is also incomplete in that we were not able to assess which elements of the EMA app itself may be responsible for any of these detected

changes. The EMA app required participants to self-monitor their diabetes in specific and targeted ways – through both symptom recording as well as calling attention to their experiences of their diabetes symptoms (i.e., mood and affect) – and this type of self-monitoring is markedly different from other types of necessary self-monitoring within Type 2 Diabetes or chronic illness at large. Research on other types of self-monitoring in diabetes, such as blood glucose awareness training or studies that use continuous glucose monitoring (CGM), have shown that the self-monitoring of objective health data like blood glucose levels may also be implicated in actual self-management changes (Cox et al., 2001; Schachinger et al, 2005; Lawton et al., 2018; Gal et al., 2020). Thus, future studies may explore EMA reactivity within a nuanced assessment of which types of EMA questions or surveys are most effective for drawing participants' awareness to their illness experience in such a way that may improve outcomes like self-management, or intermediary factors like self-efficacy or mood symptoms. These studies might also consider comparing and contrasting the impact of EMA questions or surveys as a tool for calling awareness to one's illness experience, with objective health data collection like blood glucose awareness training or CGM. Future studies should consider exploring the impact of EMA in an interventional, and nuanced context. Of note, participants in this study were incentivized to complete surveys by a tiered compensation model in which they received more payment for completing more surveys. This is a limitation in that it may have muddied our ability to capture participants' intrinsic motivation (including the relationship with factors such as self-efficacy or depressive symptoms) to engage with the EMA app. Future studies might consider other compensation models which serve to reduce extrinsic motivation to participate in an intervention like this.

Conclusions

This project was a secondary analysis to a parent study testing the acceptability and feasibility of an ecological momentary assessment (EMA) phone app for survey completion (specifically, symptom recording) in Type 2 Diabetes. We sought to evaluate whether patient-reported adherence to a range of diabetes self-management tasks were improved after engaging with the EMA app for the 14-day study, as well as whether patient-reported diabetes-related self-efficacy, depressive symptoms, and the amount that participants actually engaged with the app were factors that impacted the strength of that improvement, using both quantitative and qualitative methods. Within both quantitative and qualitative explorations of the data available, we found that overall patient-reported levels of self-management did improve between the participants' first visit in the lab, and their second visit 14 days later, two appointments that bookended their 3x-daily survey completion with the EMA phone app. In quantitative analyses, we found that the amount that participants engaged with the app (percentage of survey completion) moderated the relationship between baseline and follow-up captures of self-rated blood glucose monitoring adherence, such that participants who completed more surveys across the 14 days noticed a greater improvement in their self-rated adherence to at-home blood glucose monitoring. Qualitative exploration of audio-recorded exit interviews from the follow-up visit revealed that participants with higher self-efficacy were more likely to report change in self-management across four hypothesized domains of self-care tasks: medication adherence, blood glucose monitoring, diet, and exercise.

Overall, while this research study is limited by a small sample size, and subsequent lack of generalizability to the greater diabetes population as well as limitations related to our analytic approach, these are important preliminary findings that contribute to a broader literature on

diabetes self-management. Diabetes requires a high level of patient engagement in their own care - people with diabetes must monitor their symptoms, collect their own health data such as blood glucose levels at home and medicate accordingly using oral medications or insulin, and engage in preventative health care behaviors that may be highly burdensome such as diet changes, exercise, and foot checks. Identifying factors that may be associated with greater patient adherence to any of these vital self-management tasks (such as self-efficacy), or even recognizing if there are elements of a relatively low-cost and highly adaptable tool like an EMA phone app that may be related to improvements in self-management, can inform the development of interventions to help this at-risk population achieve better health outcomes.

Tables.

Table 1: Descriptive Statistics for Study Variables

	Mean (SD) or Percent n = 62
Age	55.44 (9.81)
Race	
Black/African American	61%
Asian	5%
White	10%
Other	10%
Did not answer	14%
Ethnicity	
Hispanic/Latinx	36%
Not Hispanic/Latinx	56%
Did not answer	8%
Male gender	64.5%
HbA1c (%)	8.6 (2.4%)
Education (n=61)	
Some high school	19.4%
High school diploma	24.2%
Some college	21%
College degree	17.7%
Some graduate school	3.2%
Graduate degree	12.9%
Baseline Depression (PHQ-9)	6.72 (5.45)
Diabetes Self-Efficacy	26.25 (3.90)
Survey Completion % (n=61)	83%
Diabetes Self-Management Measures	
Oral Medication Adherence	
Baseline (n=62)	81.70 (19.26)
Follow-up (n=62)	83.55 (19.73)
Blood Glucose Testing Adherence	
Baseline (n =62)	69.74 (29.04)
Follow-up (n =60)	78.99 (22.14)

Table 2: Bivariate correlations

	Self-Efficacy	Oral Med (Baseline)	Oral Med (Follow up)	BG Monitoring (Baseline)	BG Monitoring (Follow up)	PHQ-9	Age	Survey completion
Self-Efficacy	--	--	--	--	--	--	--	--
Oral Med (Baseline)	.55**	--	--	--	--	--	--	--
Oral Med (Follow up)	.43**	.71**	--	--	--	--	--	--
BG Monitoring (Baseline)	.55**	.41**	.40**	--	--	--	--	--
BG Monitoring (Follow up)	.43**	.41**	.53**	.43**	--	--	--	--
Depressive symptoms (PHQ-9)	-.37**	-.27*	-.08	-.07	-.09	--	--	--
Age	-.11	.13	.12	-.14	.05	-.10	--	--
Survey Completion	.01	.03	.16	-.12	.25	.01	.24	--
Gender	-.10	.001	.11	-.05	-.05	-.08	.12	-.11

*p<.05 (2-tailed)
**p<.01 (1-tailed)

Table 3. Paired Samples Test for self-rated adherence measures of diabetes self-management

	Mean	SD	Std. Error Mean	95% CI of Difference Lower	Upper	t	df	Sig. (2-tailed)
Pair 1: Oral Med Follow up – Oral Med Baseline (n=62)	1.85	14.76	1.87	-1.89	5.60	.98	61	.327
Pair 2: BG Follow up –BG Baseline (n=60)	9.75	28.21	3.64	2.46	17.04	2.67	59	.010

Table 4: Linear Mixed Effects Model, Changes in Self-Rated Blood Glucose Monitoring over time with Self-Efficacy

Fixed Effects	**Estimate**	**SE**	**Significance**
Intercept	-91.12	41.72	.033
BG	53.09	23.98	.031
Self-Efficacy	5.76	1.57	.001
BG*Self-Efficacy	-1.65	0.90	.072

BG = Blood glucose monitoring adherence

Table 5: Linear Mixed Effects Model, Changes in Self-Rated Oral Medication Adherence over time with Self-Efficacy

Fixed Effects	**Estimate**	**SE**	**Significance**
Intercept	-4.87	22.01	.825
OralMed	15.86	12.81	.221
Self-Efficacy	3.22	.82	.000
OralMed*Self-Efficacy	-.53	.48	.273

OralMed= Oral medication adherence

Table 6: Linear Mixed Effects Model, Changes in Self-Rated Blood Glucose Monitoring over time with Survey Completion

Fixed Effects	**Estimate**	**SE**	**Significance**
Intercept	110.27	27.86	.000
BG	-26.31	14.74	.074
Survey Completion	-60.90	32.41	.065
BG*Survey Completion	43.57	16.78	.012

BG = Blood glucose monitoring adherence

Table 7: Linear Mixed Effects Model, Changes in Self-Rated Oral Medication Adherence over time with Survey Completion

Fixed Effects	**Estimate**	**SE**	**Significance**
Intercept	87.14	15.03	.000
OralMed	-7.67	7.40	.304
Survey Completion	-9.60	17.51	.586
OralMed*Survey Completion	12.24	8.62	.161

OralMed = Oral medication adherence

Table 8: Linear Mixed Effects Model, Changes in Self-Rated Blood Glucose Monitoring over time with Depressive Symptoms

Fixed Effects	**Estimate**	**SE**	**Significance**
Intercept	62.69	10.77	.000
BG	9.50	5.78	.106
PHQ-9	-.35	1.24	.779
BG*PHQ-9	-.01	.66	.985

BG = Blood glucose monitoring adherence
PHQ-9 = 9-Item Patient Health Questionnaire, measure of depressive symptoms

Table 9: Linear Mixed Effects Model, Changes in Self-Rated Oral Medication Adherence over time with Depressive Symptoms

Fixed Effects	**Estimate**	**SE**	**Significance**
Intercept	90.48	5.45	.000
OralMed	-2.46	2.92	.403
PHQ-9	-1.58	.63	.015
OralMed*PHQ-9	.64	.34	.063

OralMed = Oral medication adherence
PHQ-9 = 9-Item Patient Health Questionnaire, measure of depressive symptoms

Table 10: Qualitative improvement in self-management themes, prevalence in exit interviews

Qualitative Themes	Interviews (%) mentioning theme
Improvement in Self-Management	44 (71%)
Improvement in taking medication	32 (51%)
Improvement in exercise	3 (4%)
Improvement in dietary adherence	15 (24%)
Improvement in checking blood sugar	28 (45%)
Improvement in checking feet	0 (0%)

Table 11: Selected quotes from qualitative analysis of exit interviews

Subtheme of Change in Self-Management	Quote
Taking medication	"[Using the app] helped a lot… like, a little reminder of the pills, because sometimes I would forget. It was a good reminder."
	"What I liked was that it made me more attentive to taking my medication. You know, where in the past I may have not paid it too much mind, since I had to do this, it made it more on schedule."
	"I think it enlightened me to remind me that I am diabetic and that medication taken at a timely manner are important."
Exercising Regularly	"[Using the app influenced me] by watching what I ate, and trying to exercise."
	"[By] asking me questions about what I was feeling, it makes me think I've gotta change a lot of things. It got me to do exercises."
Dietary adherence	"It made me eat three times a day… at noontime, I was like, oh, it's lunchtime, let me do the app – then I would get up and eat something. It made me keep an eye on my regimen, my food diet."
	"[I learned] how important it is for me to take care of my diet."
Checking blood sugar	"[Using the app] kept me abreast of my testing… testing my blood sugar on time, daily."
	"[Using the app] helped me to take care of myself more. I'm gonna be more aware of what I'm eating and doing my blood in the morning."
	"[Using the app] forced me to check my sugar like I'm supposed to. It forced me to keep a daily… routine. Before, maybe I would halfway do it, or I would do it for three days in a row and then I wouldn't do it one day or I would have way do it the next day. Then, I would go back and start doing it again."
	"It was helping me to pay more attention to taking and checking my sugar every morning. Which I wasn't doing it… I think the study helped me a lot in that way."

Table 12. Correlations between High self-efficacy, High Depression, and High Survey Completion with the Presence of theme *improvement in self-management in exit interviews*

	High Self Efficacy	**High Depression Sx**	**High Survey Completion**	**Gender**
Presence of Theme, *Improvement in Self-Management*	7.50**	.00	.00	.05

Pearson Chi-Squares, each computed for 2x2 Table (all variables dichotomous)
* $p < .05$
** $p < .01$

Table 13. Correlation between Age with the Presence of theme *improvement in self-management in exit interviews*

	Age
Presence of Theme, *Improvement in Self-Management*	.13

Pearson product-moment coefficients shown
* $p < .05$
** $p < .01$

Table 14. Independent samples t-test, examining continuous self-efficacy score with the presence of improvement in self-management theme in exit interview

	t	***df***	***Sig.* (2-tailed)**	**Mean difference**	**Std. Error Difference**	**95% CI**
Self-Efficacy	-2.08	60	.04*	-2.22	1.06	-4.43, -.08

T-test for equality of means, equal variances assumed, computed for both groups (yes/no presence of theme improvement in self-management)
* $p < .05$
** $p < .01$

Figure 3. Changes in Self-Rated Blood Glucose Monitoring over time with Self-Efficacy

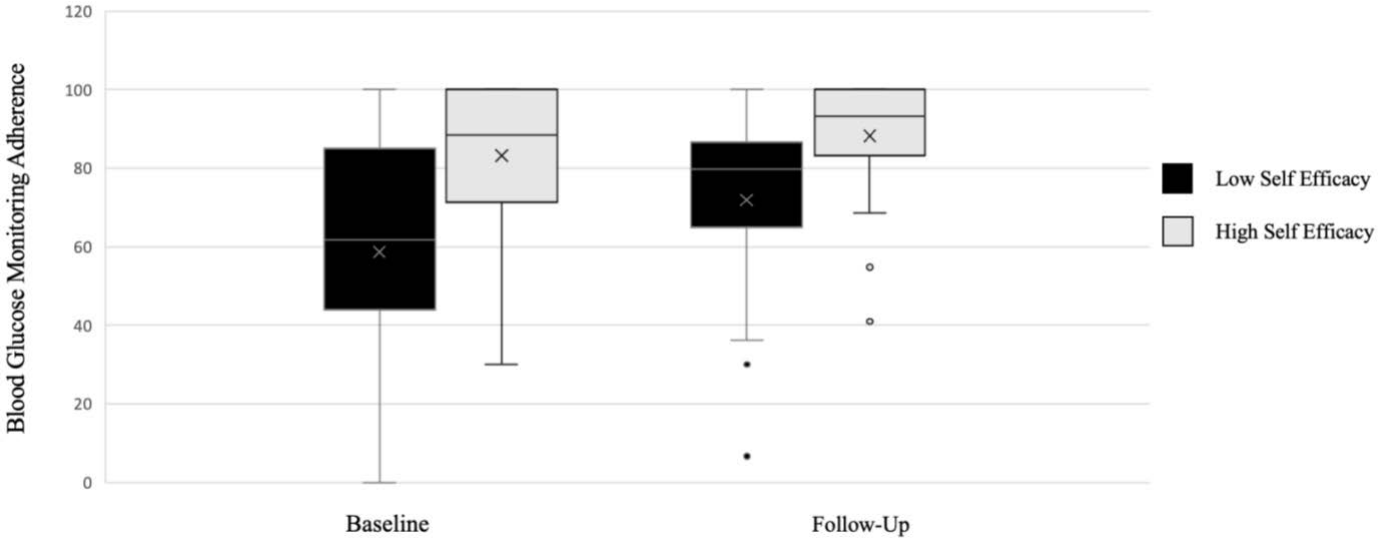


Figure 4. Changes in Self-Rated Oral Medication Adherence over time with Self-Efficacy

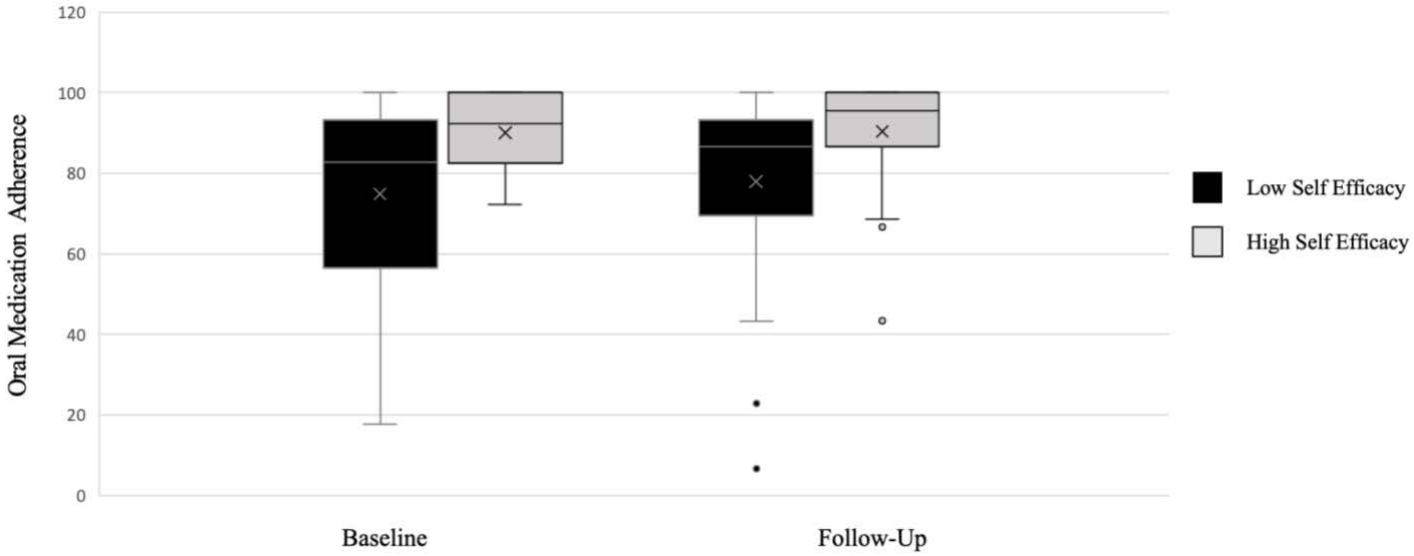


Figure 5. Changes in Self-Rated Blood Glucose Monitoring over time with Survey Completion

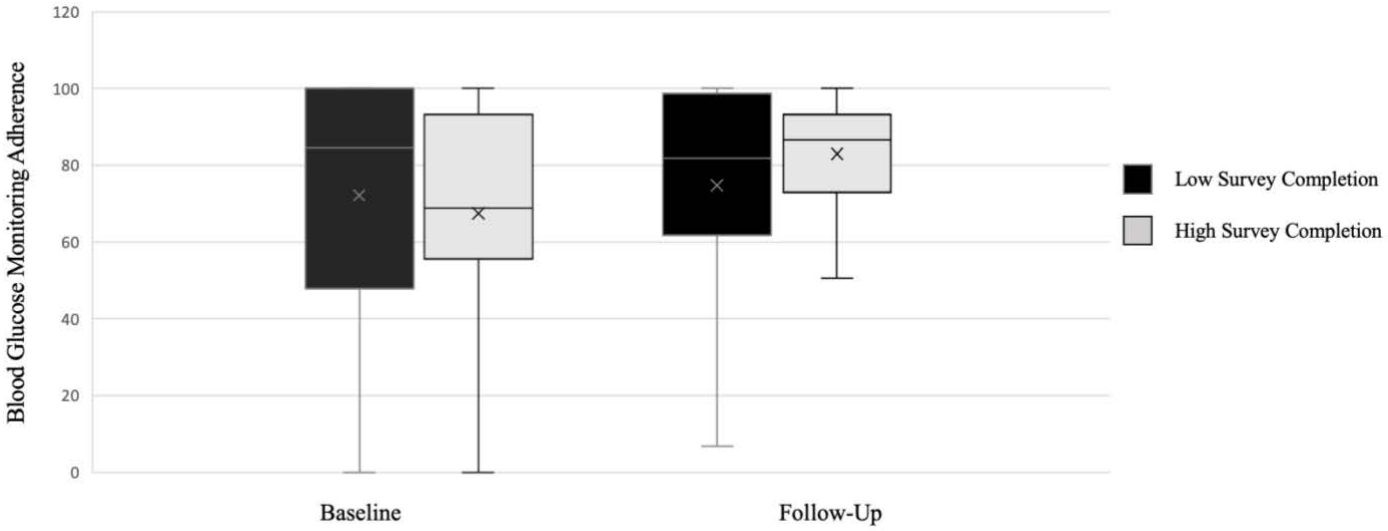


Figure 6. Changes in Self-Rated Oral Medication Adherence with Survey Completion

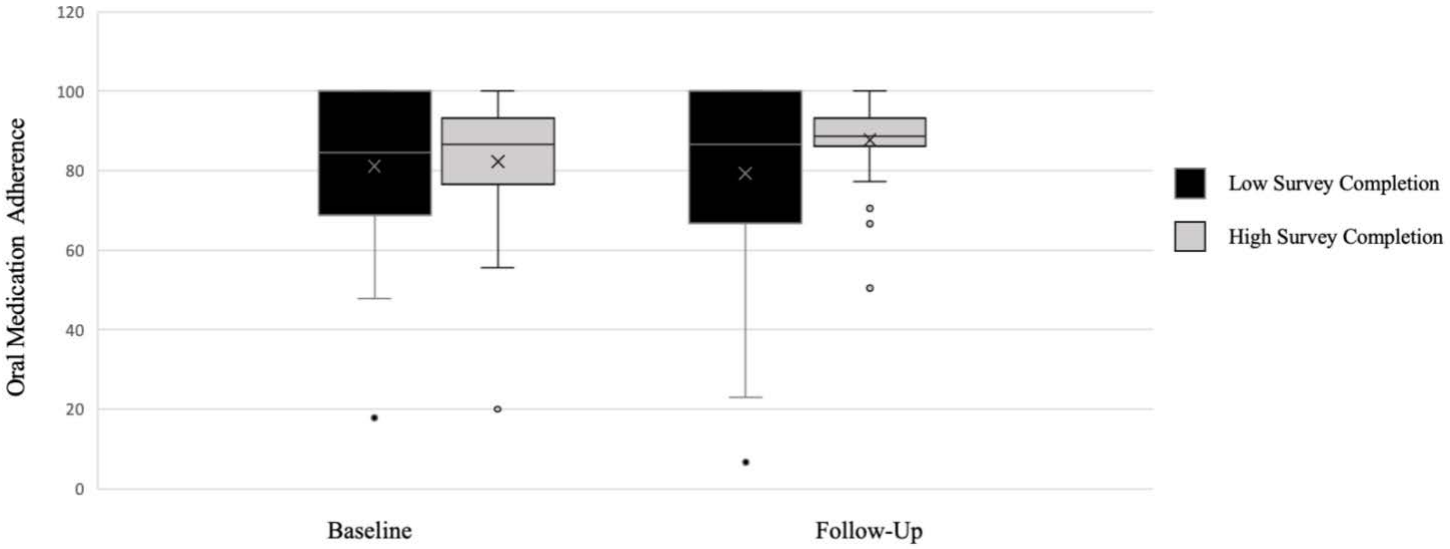


Figure 7. Changes in Self-Rated Blood Glucose Monitoring with Depressive Symptoms

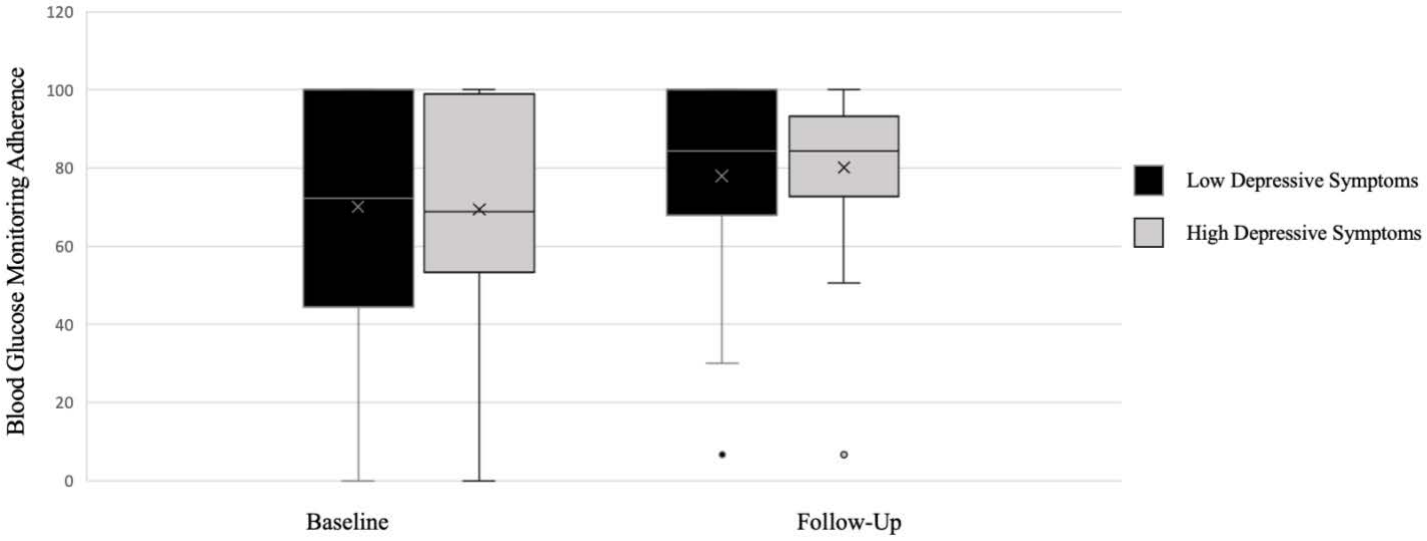
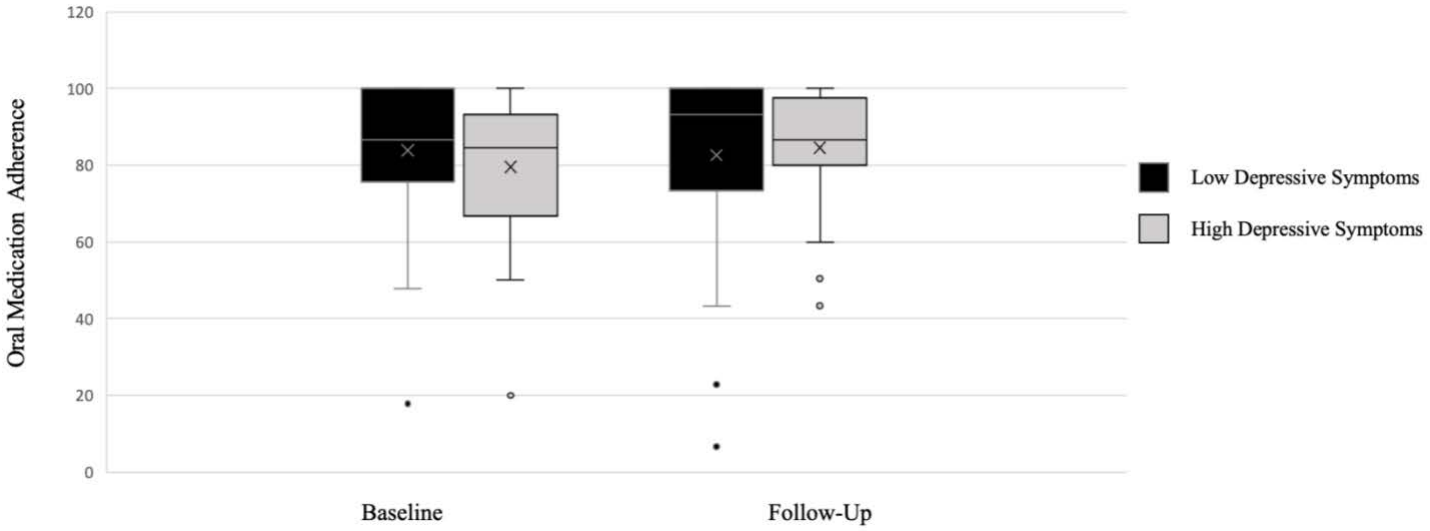


Figure 8. Changes in Self-Rated Oral Medication Adherence with Depressive Symptoms



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Appendices.

Appendix A: Qualitative Analysis Codebook

1) Improvement in Self-Management:

    1a. Improvement in Taking medications

    1b. Improvement in Engaging in exercise

    1c. Improvement in Maintaining diet

    1d. Improvement in Checking own blood glucose

    1e. Improvement in Checking own feet

Appendix B: Study Questionnaires

Oral Medication Adherence Measure:

Baseline _____

Wilson – Oral Diabetes Medication

In the last 30 days, on how many days did you miss at least one dose of any of your **oral diabetes medications**? _____ (0-30)

In the last 30 days, how good a job did you do at taking your **oral diabetes medications** in the way you were supposed to?

Very Poor Poor Fair Good Very Good Excellent

Since your last visit, how often did you take your **oral diabetes medications** in the way that you were supposed to?

Never Rarely Sometimes Usually Almost Always Always

Follow up_____

Wilson – Oral Diabetes Medication

Since your last visit, on how many days did you miss at least one dose of any of your **oral diabetes medications**? _____ (0-14)

Since your last visit, how good a job did you do at taking your **oral diabetes medications** in the way you were supposed to?

Very Poor Poor Fair Good Very Good Excellent

Since your last visit, how often did you take your **oral diabetes medications** in the way that you were supposed to?

Never Rarely Sometimes Usually Almost Always Always

Blood Glucose Monitoring Adherence Measure:

Baseline _____

Wilson - Blood Glucose Monitoring

☐ If you do NOT monitor your blood glucose for your diabetes, please check this box and skip to the next questionnaire

In the last 30 days, on how many days did you miss at least one time of **monitoring your blood glucose**? _____ (0-30)

In the last 30 days, how good a job did you do at **monitoring your blood glucose** in the way you were supposed to?

Very Poor Poor Fair Good Very Good Excellent

Since your last visit, how often did you **monitor your blood glucose** in the way that you were supposed to?

Never Rarely Sometimes Usually Almost Always Always

Follow up_____

Wilson - Blood Glucose Monitoring

Since your last visit, on how many days did you miss at least one time of **monitoring your blood glucose**? _____ (0-14)

Since your last visit, how good a job did you do at **monitoring your blood glucose** in the way you were supposed to?

Very Poor Poor Fair Good Very Good Excellent

Since your last visit, how often did you **monitor your blood glucose** in the way that you were supposed to?

Never Rarely Sometimes Usually Almost Always Always

Diabetes Self-Efficacy Scale:

Some people are not sure that they can do all of the things they need to do to control their diabetes.

At the present time, how sure are you that you can…

	Not sure at all	Just a little sure	Fairly sure	Very sure
1. Take care of your health?	(1)☐	(2)☐	(3)☐	(4)☐
2. Get medical attention when you need it?	(1)☐	(2)☐	(3)☐	(4)☐
3. Make and stay with changes in your diet?	(1)☐	(2)☐	(3)☐	(4)☐
4. Make and stay with regular exercise plan?	(1)☐	(2)☐	(3)☐	(4)☐
5. Test your blood sugar regularly?	(1)☐	(2)☐	(3)☐	(4)☐
6. Take all your diabetes medicine regularly?	(1)☐	(2)☐	(3)☐	(4)☐
7. Get people around you to help with your diabetes when needed?	(1)☐	(2)☐	(3)☐	(4)☐
8. Get all the information you need to take care of your diabetes?	(1)☐	(2)☐	(3)☐	(4)☐

9-Item Patient Health Questionnaire (PHQ-9):

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
☐	☐	☐	☐

Appendix C: Semi-Structured Exit Interview

Overall Study Participation

1. When you think about the past 2 weeks and your study participation, what comes to mind?
    a. What parts of study participation did you like best? Worst?
    b. Did you have any issues with measuring your fasting blood glucose every morning?
    c. Would you recommend participation in this study to others?

Lab Component of Study

2. How did you feel about the questionnaires and tasks that you completed at baseline and follow-up, while you were here with us in the lab?
    a. Would you say that there was too little or too much to do?
    b. Did you find any aspects overwhelming or difficult?
    c. What aspects did you like best? Worst?
    d. Do you have any suggestions for study staff to make participation better or easier?

App Component of Study

3. How user-friendly or challenging did you find the phone app to be?
    a. What did you think about font size, interface, and function?
    b. How long did it take for you to feel comfortable using the phone app?
    c. Did your feelings about the phone app change over the 2-week period?
    d. What parts of using the phone app did you like best? Worst?
    e. Did using the phone app influence or change how you took care of yourself over the 2 weeks?
4. Can you describe a time when the phone app was particularly challenging?
    a. How did you deal with that situation?
    b. Was there anything study staff could have done to help with this situation?
5. What did you think about the amount and frequency of questions asked throughout the course of the day?
    a. Were there too many questions? Too few?
    b. Would you be willing to answer questions at more timepoints throughout the day? (probe: You're currently completing 3 times, would you be willing to do 5 or 7 times a day?)

In Closing

6. Is there anything you would like to add to describe your participation over the past 2 weeks that would help us make the study better for future participants?