## Abstract

Daily Self-Reported Sleep Quality and Medication Adherence Among Adults with Type 2 Diabetes: An Ecological Momentary Assessment Approach

**Background:** Medication nonadherence rates are problematically high in adults with type 2 diabetes (T2D). Medication nonadherence is associated with poorly controlled diabetes and is predictive of disease related complications, comorbidities, and negative patient-reported outcomes. Elucidating potential areas for interventions aimed at improving adherence to oral diabetes medications is an important for reducing diabetes burden. Sleep quality is underexamined in relation to diabetes self-management behaviors. Although poor sleep is widely recognized as a risk factor for T2D incidence and disease progression and is implicated in reducing self-regulatory control across populations, there is virtually no research exploring the relationship between sleep quality and medication adherence. Subjective reports of both sleep quality and medication adherence are dynamic in nature and susceptible to psychosocial and contextual factors. Using ecological momentary assessment (EMA) methodology improves ecological validity, reduces the potential impact of cognitive biases, and allows for the examination of between- and within-person relationships among variables. This study evaluated the basic psychometric properties of brief assessment of daily subjective sleep quality delivered via mobile phone application and examined the relationships among subjective sleep quality with both daily self-reported medication adherence and daily electronically monitored medication adherence.

**Methods:** The present study conducted a secondary analysis of a pilot study that evaluated the feasibility and acceptability of a smartphone-based mobile application using EMA methodology to assess the dynamic relationships among reported symptoms and disease self-management

behaviors. Participants were 61 adults with T2D (N = 61; Age = 55.4 (9.9 years); Women = 63.9%; Black = 61%; Latino = 36%; HbA1c = 8.6(2.3)). Data on subjective sleep quality were collected once daily in the morning over a 14-day EMA study period. The Pittsburgh Sleep Quality Index (PSQI) was used to assess retrospective recall of sleep quality and was collected at the follow up lab visit. The basic psychometric properties of a 5-item EMA self-reported sleep quality scale were evaluated. Daily self-reported (SR) medication adherence was measured using a single item that was administered as part of the evening survey administered once daily during the EMA study period, and electronically monitored adherence was captured using Medication Event Monitoring System (MEMS) electronic bottle caps. Multilevel logistic models (MLM) were conducted to evaluate between- and within-person relationships and the role of intraindividual variability in subjective sleep quality and both self-reported and electronically monitored medication adherence.

**Results:** Analyses revealed that the 5-item EMA sleep quality measure had good internal consistency ($\alpha = .86$) and strong convergent validity with the PSQI global score ($\rho = .69, <.001$). Participants had 28% decreased odds of self-reporting 'excellent' medication adherence for every one-unit increase in average daily sleep quality, where higher scores on the sleep quality measure indicated worse sleep quality (OR = 0.72, $p = .006$, 95% CI = [0.57, 0.91]). There was no significant between-person effect of average sleep quality on MEMS adherence. There was no significant within-person effect where sleep quality was associated with adherence at the day level on either self-reported or electronically monitored medication adherence. There was also no significant effect of intra-individual variability in sleep quality on SR medication adherence or MEMS adherence; participants with greater overall variability in sleep quality across the study period did not differ significantly in their self-reported or electronically monitored medication

adherence. Results indicated that self-reported adherence differed significantly from electronically monitored adherence. Chi square test indicated that MEMS adherence was not significantly associated with SR adherence in our sample ($p$ = .284, two-tailed Fisher's Exact Test). A sensitivity and specificity analysis yielded findings of high sensitivity for 'excellent' SR Adherence in reference to 'perfect' MEMS adherence 72.3% (384/531), but low specificity 48.8% (53/121).

**Discussion:** Results showed that the 5-item EMA sleep quality measure had good basic psychometric properties. Our findings lend support for the use of this measure in future EMA studies in a racially diverse, socioeconomically disadvantaged, T2D population. Results also indicated that participants who had better sleep quality on average had greater odds of reporting that they had excellent adherence to their medication, but when someone had a night of better or worse sleep quality than they usually did, there was no influence on their odds of reporting whether they took their medication on the subsequent day. There was no observed relationship between subjective sleep quality and the odds of MEMS adherence. Results also indicated that there was no link between whether participants had consistent sleep quality and their odds of medication adherence. These findings contribute to a foundational understanding of dynamics among sleep quality and medication adherence in this population. The current study's findings provide preliminary support for integrating education on sleep quality into diabetes treatment and highlight the necessity of further research examining dynamics among sleep and medication adherence.

# Daily Self-Reported Sleep Quality and Medication Adherence Among Adults with Type 2 Diabetes: An Ecological Momentary Assessment Approach

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## Dedication

*To Dad and Grammy: My biggest fan, and my first study-buddy*

*For – Rose*

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# Chapter 1: Background and Significance

## Type 2 Diabetes

Diabetes is a group of chronic metabolic diseases affecting insulin production and function (American Diabetes Association Professional Practice Committee, 2021a). Diabetes represents a global public health crisis as the number of cases is expected to reach 693 million by 2045 (Cho et al., 2018). The growing incidence rates of diabetes are of critical concern as diabetes is already the seventh leading cause of death in the United States (Centers for Disease Control and Prevention, 2022). From an economic perspective, diabetes is costly for healthcare systems and patients. The national cost of diabetes was estimated to be $327 billion in 2017 and continues to increase (American Diabetes Association, 2018). Racial and ethnic disparities among individuals with diabetes are striking, with prevalence rates among Non-Hispanic/Latino Blacks (12.1%) and Hispanic/Latinos (11.8%) significantly higher than those among Non-Hispanic/Latino Whites (7.4%) (Centers for Disease Control and Prevention, 2022). Moreover, diabetes increases the risk for developing microvascular and macrovascular complications resulting in life threatening comorbidities such as cardiovascular disease, stroke, nephropathy, retinopathy, and neuropathy, among others (American Diabetes Association Professional Practice Committee, 2021b).

There are two primary types of diabetes: type 1 diabetes (T1D) and type 2 diabetes (T2D). T1D is typically diagnosed in childhood and is characterized by the autoimmune destruction of the insulin secreting pancreatic β-cells, resulting in nearly complete dependence on exogenous insulin (Kahn et al., 2014). In contrast, T2D was traditionally thought to be an adult-onset disease. T2D develops progressively as pancreatic β-cells become ineffective at producing insulin and the body becomes more resistant to insulin that is produced (Stumvoll et

al., 2005). T2D constitutes an estimated 90-95% of diagnosed diabetes cases (Centers for Disease Control and Prevention, 2020).

Decades of research have elucidated an array of factors that contribute to T2D onset and progression (Franks & McCarthy, 2016; Javeed & Matveyenko, 2018). These factors range from prenatal and early life influences to behavioral risk factors like sedentary lifestyle and unhealthful diet, among others (Kahn et al., 2014; Smith & Ryckman, 2015). Poor sleep quality is recognized as a risk factor for T2D incidence, increasing disease severity, and poor patient-reported outcomes (Cappuccio et al., 2010; Spiegel et al., 2009). However, the potential role of sleep quality in T2D self-management remains underexamined.

Disease self-management for T2D includes several time consuming and demanding behaviors, including increasing physical activity, changing and monitoring diet, engaging in foot-checking, regular blood glucose monitoring, and attending regular medical appointments (American Diabetes Association Professional Practice Committee, 2021b). A critical component of T2D self-management is pharmacological intervention targeting glycemic control (American Diabetes Association Professional Practice Committee, 2021c). The general recommendation for otherwise healthy adults is to sustain glycated hemoglobin (HbA1c) values less than 7.0%, with glycemic targets individualized based on patient characteristics and >70% Time-in-Range (70-180 mg/dl) (American Diabetes Association Professional Practice Committee, 2021c). HbA1c is a critical outcome that indicates an individual's average blood glucose levels over the previous three-month period (American Diabetes Association, 2020). Landmark clinical trials demonstrate the importance of maintaining optimal blood glucose levels in reducing the risk for complications and comorbidities (Diabetes Complications and Control Group, 1993; UK Prospective Diabetes Study (UKPDS) Group, 1998). Oral medication is an essential component

of the treatment regimen aimed at reducing HbA1c levels (American Diabetes Association, 2020).

**Medication Adherence and T2D**

Research consistently highlights the effectiveness of adherence to oral diabetes medications in improving glycemic control (Asche et al., 2011; Capoccia et al., 2016; Cramer, 2004). For example, Egede and colleagues (2014) conducted a large, longitudinal cohort study examining veterans' adherence determined by pharmacy refill data, in which the authors found that a 10% increase in medication adherence was associated with a 48% reduced likelihood of having HbA1c levels > 8.0% (Egede et al., 2014). The benefits of adhering to a prescribed oral diabetes medication regimen extend beyond attaining optimal blood glucose levels to reducing more distal health outcomes, such as cardiovascular disease markers, hospitalization rates, and mortality rates (Capoccia et al., 2016; Ho et al., 2006). Despite research outcomes highlighting the imperative role of medication adherence in diabetes management, patient adherence rates remain problematically low.

A comprehensive meta-analysis looking at adherence to oral medications identified a pooled mean medication adherence rate of 75%, with results from included studies reporting adherence rates ranging from 41% to 81% among adults with T2D (Iglay et al., 2015). These results were consistent with previous meta-analyses and systematic reviews, which also highlighted the prevalence of suboptimal adherence in this population (Cramer, 2004; Krass et al., 2015). Discrepant findings between studies, as evidenced by the broad range of adherence rates reported by meta-analyses and systematic reviews, are partially a function of the heterogeneity in adherence measurement approaches (Gonzalez & Schneider, 2011). For example, Cramer (2004) reported that oral medication adherence rates ranged from 36% to 93%

among studies using self-report measures of adherence, and from 67% to 85% for those using electronic monitoring methods (Cramer, 2004). However, there is also evidence that self-reported and objectively measured medication adherence correlate similarly with diabetes outcomes, such as HbA1c, particularly in larger samples (Gonzalez et al., 2013; Hill-Briggs et al., 2005). There is currently no accepted "gold standard" in medication adherence measurement, as each approach has identified weaknesses and strengths (Gonzalez & Schneider, 2011; Hansen et al., 2009). A main weakness of self-report measures is that they capture one's may be influenced by recall bias as well as objective or subjective cognitive dysfunction (Gonzalez & Schneider, 2011; Shapira et al., 2022). In contrast, electronic monitoring methods are subject to device malfunctions and may interfere with established medication taking routines like the use of pillboxes (Gonzalez & Schneider, 2011).

A conceptual framework proposed by Brown and colleagues (2004) demonstrates the pathways through which socioeconomic position (SEP) affects health outcomes among individuals living with diabetes (Brown, 2004). Within this framework, SEP incorporates traditional markers of socioeconomic status such as income level, wealth, education, and occupation at individual and community levels along with critical covariates like race/ethnicity, sex, and age to encapsulate the complexity of this issue (Brown, 2004). The mechanisms though which poor health outcomes are perpetuated are both systemically pervasive and demonstrative of limited access to quality care and barriers to engagement in health behaviors. Walker and colleagues (2014) adapted this framework to account for additional social determinants of health, thus highlighting the role of depression and psychological distress as well as cognitive constructs such as self-efficacy (R. J. Walker et al., 2014).

Barriers to medication adherence occur at the patient level, the provider level, and the system level, many of which are interconnected. Sociodemographic factors including race, ethnicity, age, income level, and education are consistently identified barriers that are resistant to change through typical behavioral medicine interventions (Capoccia et al., 2016; Egede et al., 2011). Results from the Diabetes Prevention Program Outcomes Study conducted by Walker and colleagues (2020) identified significantly lower over rates of adherence to metformin among Black participants relative to White participants, specifically where Black participants demonstrated less consistency in adherence across the 11-year trial duration (Walker et al., 2020). These factors are intertwined with issues of mistrust for physicians and the healthcare system, medication beliefs, limited access to affordable care, low health literacy and numeracy, and poor diabetes knowledge (Osborn et al., 2011; Walker et al., 2016). Exorbitant medication and overall medical care costs are amplified by increasing disease severity and comorbid conditions, which are also more prevalent among socioeconomically disadvantaged individuals (Li et al., 2013). Medication related factors such as regimen complexity (i.e., polypharmacy, dose frequency), insulin use, and perceived adverse effects are also established barriers to adherence (Mann et al., 2009; Rubin, 2005). Thus, identifying any possible additional modifiable barriers is essential to addressing medication nonadherence.

Patient-reported outcomes have been widely explored in the literature as potential modifiable factors. Psychological correlates like depression and disease-related distress have been consistently linked with sub-optimal adherence (Gonzalez et al., 2008, 2015, 2016; Krass et al., 2015). Cognitive impairment has also been shown to impact medication adherence in multiple studies, with consistent evidence highlighting the link between medication adherence and deficits in the domains of executive functioning and memory (Feil et al., 2012; Tran et al.,

2014; Vedhara et al., 2004). Impairments in these cognitive domains also have implications for self-regulation of engagement in health behaviors (Baumeister, 2002; Hagger, 2010b). This is particularly problematic considering the complexity of diabetes self-management regimens and strong evidence that T2D is associated with increased risk for cognitive impairment in these domains (Sadanand et al., 2016; Vincent & Hall, 2015).

Recent T2D literature has placed a greater focus on the potential implications of suboptimal sleep as a factor in general disease self-management (Zhu et al., 2020a; Zhu et al., 2021; Zhu et al., 2018a; Zhu et al., 2018b). However, the extant literature specific to sleep and medication adherence is extremely limited in the T2D population (Marcum et al., 2013). There is substantial evidence supporting the between-person relationship among poor sleep quality and poor engagement in self-care behaviors like diet and exercise among both healthy individuals and those with other chronic diseases (Aga et al., 2019; Best et al., 2019; Hagger, 2010a, 2014). The relatively novel use of experience sampling methods allows for the capture of daily behavioral observations with improved ecological to examine dynamic relationships more thoroughly among health behaviors. As a result, there is now a greater focus on examining within-person relationships among sleep quality and patient reported outcomes including self-care behaviors (Bei et al., 2016, Bei et al., 2017; Danhauer et al., 2019; Tracy et al., 2019). Therefore, elucidating the relationship between sleep and medication adherence among adults with T2D may provide support for further exploring this relationship.

**Sleep Quality Overview**

Poor sleep quality has become a widely recognized public health problem; one-third of U.S. adults report habitually problematic sleep characterized by poor overall sleep quality and/or insufficient duration (Centers for Disease Control and Prevention, 2019). Racial and ethnic

disparities in sleep further complicate this issue as research consistently demonstrates worse reported poor sleep quality among Black and Hispanic/Latino individuals relative to White individuals (Adenekan et al., 2013; Chen et al., 2015; Jackson et al., 2015). Thus, habitually poor sleep patterns affect those who are already at an elevated risk for developing T2D and associated comorbidities and complications. Given the complex and systematic nature of these disparities, interventions that address factors related to poor sleep quality at the individual level are needed to effect more immediate change. The under-explored behavioral pathways linking sleep quality and medication adherence may inform novel research questions and interventions targeting person-level change. To date, research examining the relationship between poor sleep quality and T2D has focused largely epidemiological data and shared biological pathways.

**Sleep Quality Construct and Measurement**

The behavioral medicine literature includes research on distinct, yet overlapping, sleep constructs (Buysse, 2014; Hall, 2010). Sleep quality is perhaps the most widely used term amongst researchers to capture one's experience of sleep (Buysse, 2014). There is currently no agreed upon definition for sleep quality amongst researchers as it may incorporate multiple sleep characteristics that contribute to the ability to fall and stay asleep (Krystal & Edinger, 2008; Ohayon et al., 2017). Sleep quality is typically measured using patient self-report (Hall, 2010). Physiological monitoring devices like polysomnography or actigraphy may also be used to capture objective aspects of sleep quality and other sleep constructs (Hall, 2010; Krystal & Edinger, 2008).

Findings on the agreement between objectively and subjectively measured sleep quality are mixed, with many studies reporting only weak to moderate correlations (Jackson et al., 2018; Kaplan et al., 2017; Lauderdale et al., 2008; Spielmanns et al., 2019). For example, several

validation studies have observed weak to moderate correlations between self-report measures of sleep and actigraphy or polysomnography (Landry et al., 2015; Lauderdale et al., 2008; Matthews et al., 2018; Zhu et al., 2018c). Observed differences based on assessment method may be partially explained by demographics and psychosocial factors like age, depressive symptoms, and self-rated health (Lauderdale et al., 2008; Matthews et al., 2018; Unruh et al., 2008). There is also evidence that depression moderates the magnitude of differences observed between measurement methods, where greater depressive symptom severity is associated with greater discrepancies (Baillet et al., 2016; Matthews et al., 2018). Among individuals with T2D specifically, Zhu and colleagues (2018) demonstrated poor agreement between actigraphy and daily sleep diary data for $N = 32$ adults (Zhu et al., 2018c). This suggests that daily experiences are associated with the perception of sleep quality beyond physiological sleep markers and may provide different information than biological data.

Retrospective self-report measures of sleep quality are widely used methods of data capture in intervention and cross sectional studies (Landry et al., 2015). These measures are cost efficient, easily administered, and do not require access to an electronic device (Ibáñez et al., 2018). The most widely used self-report tool to measure overall subjective sleep quality is the Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989; Mollayeva et al., 2016). The PSQI differentiates subjectively 'good' from subjectively 'poor' sleep. This measure assesses several aspects of sleep quality, including sleep efficiency, sleep latency, sleep duration, sleep quality, sleep disturbance, sleep medication use, and daytime dysfunction, as well as an overall sleep quality score (Buysse et al., 1989). The PSQI has consistently been used in studies demonstrating poor sleep quality among individuals with T2D (Chasens et al., 2013; Chasens & Luyster, 2016; Luyster & Dunbar-Jacob, 2011; Tsai et al., 2012). It is widely used in the sleep-health literature

and is often used as a reference point for assessing convergent validity of other sleep quality measures (Fabbri et al., 2021). This measure asks participants to recall several aspects of sleep over the prior month, which increases the potential for recall biases and cognitive impairment (Stone & Shiffman, 1994). To address potential recall inaccuracies and to provide more comprehensive information on day-to-day changes, sleep diaries are often employed in prospective study designs (Ibáñez et al., 2018).

Sleep diaries are considered to be the gold-standard approach for capturing sleep quality over time (Ibáñez et al., 2018). The Consensus Sleep Diary (CSD) is a widely used paper-and-pencil measure that was designed to improve standardization of sleep diaries (Carney et al., 2012). The CSD and other paper-and-pencil sleep diaries have a stronger utility in longitudinal study designs than retrospective recall measures like the PSQI, because in addition to reducing recall bias and the effect of cognitive impairment, they can also capture the daily variability in sleep (Ibáñez et al., 2018). Studies that used electronic data capturing methods have identified benefits of using electronic sleep diary methods over more traditional paper-and-pencil diaries (Tonetti et al., 2016). Electronic sleep diaries improve timing accuracy and reduce what is known as the "parking lot syndrome," in which participants complete multiple entries at the same time and reduce opportunities for human error during the data entry process (Tonetti et al., 2016). These methods also permit the exploration of research questions about both between-person as well as within-person associations to examine granularity in relationships among patient reported outcomes.

While there are limited studies that have examined the agreement between retrospective self-report sleep quality measures, daily diaries, and brief or single-item measures, their findings have generally indicated strong associations among the measures. For example in a sample of

adolescents with T1D, a single-item measure of sleep quality was found to be strongly correlated with the PSQI (Tracy et al., 2019). Another study found a strong correlation between the PSQI and the CSD in a sample of healthy older adults. (Landry et al., 2015)., Daily sleep diaries are preferred to questionnaires as there is evidence that diaries are subject to less bias than questionnaires (Dietch & Taylor, 2021). Thus, additional research on the association between the PSQI and an electronically delivered daily sleep questionnaire specifically among adults with T2D would provide important insight to inform future studies. As research methodologies improve the ability to examine discrete time periods, there is increasing evidence of dynamic relationships among patient-reported outcomes (Shiffman et al., 2008).

**Ecological Momentary Assessment (EMA)**

Ecological momentary assessment (EMA) is an experience sampling methodology that uses the repeated sampling of an individual's experiences in a naturalistic setting (Shiffman et al., 2008; Stone & Shiffman, 1994). EMA is beneficial in that it provides opportunities for: 1) sampling in natural environments, 2) sampling in real-time, and 3) sampling of multiple momentary states (Hamaker, 2012; Reis, 2012; Schwarz, 2012; Stone & Shiffman, 2002). Capturing data about people's experiences within their real-world environment improves ecological validity, thus enhancing the generalizability of study findings beyond the traditional laboratory setting (Reis, 2012). Patient reports of subjective experiences and behavioral processes, such as sleep quality and self-reported medication adherence, are sensitive to contextual factors (Wagner & Miller, 2004). Factors such as social desirability, environmental cues, and current emotional states have been shown to influence participant self-reports (Schwarz, 2012).

Another key benefit of EMA methods is that they reduce the influence of memory limitations by permitting nearly immediate responses about an experience (Stone & Shiffman, 1994). Responses to retrospective self-report measures may be influenced multiple cognitive factors and systematic bias (Hufford & Shiffman, 2002; Shiffman et al., 2008; Smyth & Smyth, 2003). For example, items that ask participants to recall quantitative autobiographical events (i.e., "During the past month, how long has it taken you to fall asleep each night") are cognitively taxing, with participants using fragments of memory to reconstruct an answer (Bradburn et al., 1987). Additionally, individuals' reports may be inaccurate when they are asked about the frequency of an experience over a specified period. If an experience comes to mind easily then an individual may report that it occurs more frequently ("availability heuristic"; Tversky & Kahneman, 1973). Responses are likely to be influenced by an individual's current mood state in addition to emotionally salient memories (Smyth & Smyth, 2003; Solhan et al., 2009). This is particularly relevant in the present sample, as individuals with T2D are at an elevated risk for depression (Anderson et al., 2001). While EMA self-report measures also rely on recall, the potential for bias is reduced due to the significantly shortened time between sleep experience and report.

This approach allows researchers to examine relationships at both within-person and between-person levels (Shiffman et al., 2008; Stone & Shiffman, 1994). Within-person relationships among patient-reported outcomes may be different from between-person relationships, with each analytic approach providing important information. Between-person analyses rely on summary statistics that are best able to answer research questions about averages across individuals, or aggregates (Hamaker, 2012). These analyses are best used to examine constructs that are not expected to change over time or in different situations (Hamaker,

2012). Within-person analyses, however, are best suited to answer questions of changes at the individual level (Curran & Bauer, 2011). These questions are answered by analyzing the variability around the means of individuals, rather than overall sample mean (Hamaker et al., 2007).

EMA methods improve our ability to assess dynamic constructs. This variability is lost when aggregated over several weeks or months, as is common when using traditional self-report measures (Smyth & Smyth, 2003). Behavioral and psychological constructs like medication adherence and sleep quality may differ from day to day and are influenced by contextual events. The concept of "surprise" based on the information theory model considers how even for individuals who may generally be consistent, an unexpected event may occur which then influences other biopsychosocial mechanisms (Turner et al., 2019). These types of anomalies are observable when using within-person analyses. Elucidating relationships among patients' real-time experiences is critical to developing a greater understanding of, and interventions for, the health issues linked with inadequate sleep.

**Sleep Quality and Type 2 Diabetes**

Sleep duration and poor sleep quality have received increasing attention as a risk factor for diabetes incidence (Cappuccio et al., 2010; Spiegel, Tasali, Leproult, & Van Cauter, 2009). For example, a systematic review and meta-analysis reported the pooled relative risk for T2D onset was 1.4 times higher among those reporting poor sleep quality relative to those without (Anothaisintawee et al., 2016). Additionally, this study highlighted that in comparison to the well-established diabetes risk factors like obesity, physical inactivity, and family history, poor sleep was associated greater risk for diabetes onset when compared to the risk associated with physical inactivity (Anothaisintawee et al., 2016). Another source of data elucidating the role of

sleep quality in diabetes onset is research on shift workers. One large Danish cohort study of nurses concluded that nurses who worked night shifts were 1.58 times more likely to develop diabetes than those who worked day shifts, with similar findings in other studies (Gan et al., 2015; Hansen et al., 2016).

Individuals living with diabetes experience poorer sleep quality than those without diabetes (Keskin et al., 2015). The estimated prevalence of sleep problems among those with diabetes ranges from 42% to 77% (Nefs et al., 2015). Common diabetes symptoms, complications, and comorbidities also influence sleep quality (Ogilvie & Patel, 2018; Plantinga et al., 2012; Surani et al., 2015). Sleep disorders such as restless leg syndrome (Harashima et al., 2016), insomnia (Cespedes et al., 2016), and obstructive sleep apnea (Reutrakul & Mokhlesi, 2017) are highly comorbid with diabetes. Nocturia, or waking to urinate during the night, is associated with hyperglycemia and has an established relationship with sleep disturbance (Chang et al., 2017; Surani et al., 2015). Additionally, chronic pain caused by diabetic peripheral neuropathy is associated with increased sleep latency (time to fall asleep) and number of awakenings per night (Ohayon, 2005; Zelman et al., 2006). There is also evidence that diabetes treatment is linked with poor sleep quality. A study published in 2021 by Xue and colleagues investigating the association between oral diabetes medication and self-reported sleep in sample of 11,806 patients with T2D from the UK Biobank study found that individuals taking diabetes medication other than metformin had a 1.24 fold higher odds ratio of reporting sleep difficulties when compared to both untreated patients and those taking metformin (Xue et al., 2021).

At the same time, poor sleep quality is closely associated with impaired glucose metabolism and suboptimal glycemic control (Javeed & Matveyenko, 2018; Lee et al., 2017; Spiegel et al., 2009). As study designs assessing daily experiences become more prevalent, novel

research also indicates that greater variability in daily sleep is also linked with worse glycemic control in T2D (Brouwer et al., 2020; Zhu et al., 2020b) and T1D (Chontong et al., 2016; Perez et al., 2018). Metabolic functioning is also closely tied to hormonal activity throughout the sleep-wake cycle and circadian rhythm (Knutson & Cauter, 2008). Abundant research demonstrates that reductions in certain slow-wave sleep result in decreased insulin sensitivity and increased cortisol levels, both of which are well established correlates of diabetes, obesity, and cardiovascular disease (Buxton & Marcelli, 2010; Spiegel et al., 2009; Tasali et al., 2008). A recent study conducted by Brouwer and colleagues (2020) in a sample of 172 adults with T2D highlighted that patient-reported sleep quality measured using the PSQI had the strongest association with HbA1c levels as compared to other sleep characteristics (Brouwer et al., 2020). Poor sleep quality also contributes to dysregulation of appetite stimulating hormones which promote wakefulness and preferences for high carbohydrate foods and perpetuate the cycle of poor sleep and metabolic consequences (Lin et al., 2020). Bidirectional links between sleep quality and T2D are evident as has been demonstrated both by elevated risk for diabetes onset, worse glycemic control, as well as poorer sleep quality attributed to disease symptoms.

Research examining the relationship between sleep quality and medication adherence among individual with T2D is extremely limited. However, findings from studies assessing relationships among other critical self-managing behaviors and sleep quality in T2D population suggest similar patterns are likely for the link with medication adherence. There is also literature looking at the relationship between sleep quality and medication adherence in other chronic diseases that require a similar level of complex and burdensome self-management. Taken together, there is substantial evidence to support the exploration of the relationship between sleep quality and medication adherence in the T2D population.

**T2D, Sleep Quality, and Self-Management**

The strong evidence of biological relationships among sleep quality and T2D further supports improving our understanding of potential behavioral pathways. However, there are very few studies examining the relationship between sleep and medication adherence to date. Marcum and colleagues (2013) analyzed data from a large study in older adults with heart disease, diabetes, and/or hypertension ($n$ = 897; 37% with diabetes) indicated that individuals with a history of sleep disturbances were at a 1.48 times greater risk for medication nonadherence (Marcum et al., 2013). However, this study assessed sleep disturbances using only one question, not a validated scale. Additionally, this study used only a self-report measure of medication adherence, which is subject to cognitive bias (Gonzalez et al., 2013; Gonzalez & Schneider, 2011). The optimal approach to capturing medication adherence data involves using both a self-report measure and objectively measured adherence, such as an electronic medication bottle (Gonzalez & Schneider, 2011). Telford and colleagues (2018) conducted a secondary analysis on 281 from the baseline of a randomized, controlled trial examining the effects of an educational telemedicine intervention for diabetic kidney disease (Telford et al., 2018). These authors found that a one-point increase on the PSQI global score was associated with a 9% increase in the likelihood of nonadherence, which was measured using an 8-item self-report measure n = 281 Notably, the sleep disturbances and daytime dysfunction subscales of the PSQI were each associated with medication adherence. Their results indicated that medication nonadherence did not mediate the relationship between the sleep disturbance subscale of the PSQI and HbA1c.

Research has consistently identified between-person relationships among poor sleep quality and suboptimal self-management behaviors T2D populations (Chasens et al., 2013; Chasens & Luyster, 2016; Chasens & Olshansky, 2006; Nefs et al., 2020; Zhu et al., 2018a; Zhu

et al., 2018b). A descriptive correlational study including 107 adults with T2D found suboptimal sleep quality to be associated with lower self-rated dietary adherence and general diabetes self-care adherence (Chasens et al., 2013). Additionally, results from a cross-sectional study including 60 adults were similar, with the authors reporting that more severe insomnia symptoms were related to worse self-reported diabetes self-care (Alshehri et al., 2020). Notably, the relationship between problematic sleep and worse self-care remained significant after controlling for known covariates like depression, anxiety, and pain (Alshehri et al., 2020). Wachid and colleagues also published findings that individuals reporting poor overall self-rated sleep quality measured using the PSQI were significantly less likely to adhere to their self-care regimen relative to those reporting good sleep quality (Wachid et al., 2019). Zhu and colleagues reported that self-reported sleep disturbance measured with the PSQI and actigraphy-measured number of awakenings was associated with worse overall self-care (Zhu et al., 2018a). Other important aspects of daily diabetes management such as poor adherence to a healthful diet (Zhu et al., 2019) and poor self-reported daytime functioning (Bani-issa et al., 2018; Chasens et al., 2014; Chasens & Luyster, 2016) are also associated with worse sleep quality.

The literature examining within-person effects of self-reported sleep and self-management in adults with T2D is extremely limited. We identified two studies that looked at between- and within-person associations between sleep and disease self-management in the T2D population. Both of the following studies were secondary analyses of the same parent study, which recruited 64 adults with T2D over the age of 50 (Zhu et al., 2018a). The first study evaluated the relationship between sleep quality and eating behavior in 56 adults with T2D. Sleep quality was assessed using a daily diary completed upon waking about the previous night's sleep quality over a seven-day study period. There were no significant within-person

relationships observed between sleep quality an eating behavior. At between-person level of analysis, poor sleep quality was associated with poor eating habits (Zhu et al., 2020a). A second study conducted by Zhu and colleagues (2021) examined the between- and within-person associations among objective and subjective daily sleep data and physical activity measured with actigraphy. Analyses conducted on a subset of 53 participants from the parent study sample indicated that fluctuations in sleep quality at the within-person level were associated with engagement in moderate-intensity physical activity the following day (Zhu et al., 2021).

Importantly, the aforementioned studies used global measures of diabetes self-care, such as the Diabetes Care Profile (Alshehri et al., 2020; Chasens et al., 2013), and the Diabetes Self-Management Questionnaire-Revised (Wachid et al., 2019; Zhu et al., 2018a). While these well-validated measures provide essential information about diabetes self-care in general as well as some more specific information on diet, physical activity, self-blood glucose monitoring, they do not measure medication adherence specifically. Despite the importance of medication adherence in maintaining glycemic control and the evidence that relationships exist among sleep quality and other aspects of self-care, this line of research is nonexistent in the current literature. Empirical evidence supporting the implications for poor sleep quality in health behavior engagement among healthy adults and those with other chronic diseases is more robust.

### Other Chronic Illnesses, Sleep Quality, and Self-Management

**HIV.** Self-reported sleep quality has received some attention in relation to medication adherence among individuals with HIV at the between-person level. Saberi and colleagues (2011) found that self-reported difficulty falling and staying asleep was associated with a 1.66 times increased risk for self-reported medication nonadherence among a sample of 2,845 HIV-positive adults (Saberi et al., 2011). Although only a few studies have examined this relationship,

results consistently demonstrate an association between poor sleep quality and medication nonadherence (Babson et al., 2013; George Dalmida et al., 2015; Huang et al., 2017).

**Heart Failure.** A prospective study obtained objective medication adherence data from 242 patient with heart failure over six-months and concluded that poor global sleep quality, as measured using the PSQI global scale, is a significant risk factor for nonadherence in this population (Knafl & Riegel, 2014). Results indicated that objectively measured medication adherence may be impacted by poor self-rated sleep, thus highlighting that a relationship among these variables may extend beyond potential cognitive biases and barriers presented with self-report measures.

**T1D.** Among adolescents with T1D suboptimal sleep is associated with decreased engagement self-reported regimen and insulin adherence (Hazen et al., 2015; McDonough et al., 2017). Another study found that blood glucose monitoring frequency mediated the relationship between actigraphy measured sleep duration and HbA1c levels and that self-reported sleep quality was associated with less engagement in self-care behaviors in a sample of adolescents with T1D (Frye et al., 2019). Notably, EMA studies looking at intra-individual variability in sleep in relation to self-management behaviors have begun to highlight the importance of not just poor sleep quality, but also inconsistent sleep quality in predicting diabetes outcomes. Turner and colleagues (2016) analyzed daily sleep quality and self-management data from 236 older adolescents with T1D collected over a 2-week period via daily diary (Turner et al., 2016). Analyses examined both between-person and within-person differences in sleep quality in relation to daily self-regulatory failures, which was captured by an eight-item measure item capturing issues related to blood glucose monitoring. These authors found that better average sleep quality across individuals was associated with fewer self-regulatory failures, and that

individuals reporting better sleep quality had self-regulatory failures the following day at a within-person level. Additionally, those with better sleep quality consistently over the 2-week periods demonstrated a lower risk for elevated blood glucose levels. Results from this study provide strong support for examining the dynamic relationship among sleep quality and critical aspects of diabetes self-management at the day-level. Tracy and colleagues (2019) expanded upon these findings by demonstrating that not only is better sleep quality associated with higher engagement in self-care behaviors among adults those with T1D at both a between-person and within-person basis, but the relationship between sleep quality and blood glucose levels is mediated by self-management behaviors (Tracy et al., 2019). While these findings are not generalizable to adults with T2D, they clearly demonstrate ties among sleep quality and engagement in burdensome self-management behaviors that may be demonstrated in T2D as well. These findings also highlight the value of assessing both within-person and between-person relationships among these variables.

**Sleep, Self-Regulatory Capacity, and Medication Adherence**

Self-regulation is a critical factor in health behavior engagement and has been targeted in intervention trials aimed at improving adherence to chronic disease self-management regimens (Hagger, 2010b; Wilson et al., 2020). Self-regulation refers to the effortful process of modifying behavior to reach a goal by exercising control over cognitions, affect, and behaviors that would impede one from attaining the desired outcome (Baumeister & Heatherton, 1996a; Baumeister & Vohs, 2016). The self-regulatory strength model is a widely applied perspective that seems to explain how engaging in certain cognitively taxing activities influences the capacity for subsequent self-regulatory demands (Baumeister et al., 1998; Muraven & Baumeister, 2000).

Specifically, preventing self-regulatory failures in part depends upon attention and executive functioning abilities to self-monitor behavior, inhibit impulses, and set shift away from behavior that is incongruent with the identified goal (Baumeister, 2002; Vohs & Heatherton, 2000). This model proposes that self-regulatory ability is dependent upon a limited internal energy resource that deplete over time and with repeated exertion (Baumeister & Heatherton, 1996b; Baumeister & Vohs, 2016). While Baumeister's work has received some critiques in its ability to be replicated over time, it serves as a conceptual basis for hypothesizing the link between self-regulation and engagement in important health behaviors (Drummond & Philipp, 2017).

The self-regulatory strength model has been applied to explain lapses in adherence to health behaviors like diet and exercise (Hagger, 2010a; Hagger, 2014). Within the T2D population, Wang and colleagues (2018) sought to examine the relationship between self-regulation failures and engagement in self-care behaviors in adults with T2D (Wang et al., 2018). Specifically, they used a sequential-task paradigm to test the effect of self-regulatory resource depletion on self-care behaviors like diet and exercise. Their findings were consistent with the self-regulatory strength model, in that reduced self-regulatory resources were association with worse engagement in self-care behaviors. The sequential-task paradigm used in the Wang et al. (2018) study is frequently used laboratory experiment used to test the self-regulatory strength model as they are designed to place demands on executive functioning to reduce self-regulatory resources (Arber et al., 2017; Hagger et al., 2010). This study is one of many that used an experimental design to demonstrate the role of executive functioning and impulse control in self-regulation (Hagger, 2010b).

Castonguay and colleagues (2018) developed a model to demonstrate the hypothesized ways in which various self-regulatory depleting factors in T2D contribute to a lack of engagement in physical activity (Castonguay et al., 2018). As demonstrated in Figure 1, Castonguay, Miquelon, and Boudreau (2018) hypothesized that the burden of an already complex self-care regimen, higher likelihood of mood-related symptoms, increased risk for cognitive impairment, and T2D-related symptoms accumulate to deplete self-regulatory capacity. While these authors and Wang and colleagues (2018) focused on the impact of physical activity component of the T2D self-management regimen, we believe this model could be applied wherein medication adherence is the behavior impacted by reduced self-regulatory resources.

Beyond self-regulatory resource depletion, the self-regulatory strength model has been expanded upon to hypothesize how these resources are replenished and ways in which they can be strengthened (Muraven et al., 2006; Muraven & Baumeister, 2000). Akin to overuse of a muscle, self-regulatory capacity is replenished with rest (Baumeister & Heatherton, 1996a; Muraven & Baumeister, 2000). Specifically, sleep has been identified as a way to replenish self-regulatory resources based in part on the abundant literature demonstrating the role of sleep in optimal cognitive performance and the deleterious effects of insufficient and inconsistent sleep on self-regulatory behaviors (Hagger, 2014; Pilcher et al., 2015)

The relationship between sleep and cognitive domain of executive functioning is well established in the literature (Barkley, 2001). Findings consistently indicate that sleep disturbances are linked with executive dysfunction in healthy participants (Wilckens et al., 2014) those with sleep disorders (Bucks et al., 2013), and those with T2D (Titova et al., 2020). Between person studies consistently highlight the relationship between sleep issues and cognitive impairment in both cross sectional (Kohn et al., 2020; Li et al., 2022; Nebes et al., 2009) and

prospective studies (Gildner et al., 2019; Wang et al., 2021). There is also evidence of an association between poor sleep and reduced cognitive functioning at the within-person level both globally and in the domain of executive functioning (Gamaldo et al., 2010; Lücke et al., 2022). Given that individuals with T2D are already at an elevated risk for cognitive impairment, sleep disorders, and both objective and subjectively demonstrated poor sleep, it is likely that executive dysfunction and poor impulse control play a critical role in the relationship between not only sleep and self-regulatory capacity, but also the proposed relationship between sleep quality and medication adherence.

Additionally, research conducted by Barber and colleagues (2010) highlights the role of both consistent and sufficient sleep together in self-regulatory control and replenishment (Barber et al., 2010; Barber & Munz, 2011). These authors proposed that sleep consistency prevents resource depletion by improving self-regulatory resources based on research that variation in sleep onset predicts fatigue the subsequent day (Dahl & Lewin, 2002). To examine this notion, Barber and colleagues (2010) conducted a study in which 88 undergraduate students completed a daily sleep diary over five consecutive days and also completed a measure indicating their daily perceived level of stress. Findings indicated a within-subject significant interaction between sleep insufficiency and sleep inconsistency on perceived stress. These findings provide support for looking an intra-individual variability in sleep, in addition to examining within-person and between-person effects.

**Study Rationale/Innovativeness**

The current study sought to assess the relationship between subjective sleep quality and medication adherence among a diverse, urban sample of adults with T2D using an EMA approach. Specifically, we first evaluated the basic psychometric properties of an unvalidated 5-

item subjective sleep quality measure delivered via mobile phone application. Assessing these properties aimed to inform the utility of a brief, easily administered measure to capture real-time perceptions of sleep quality that can be easily added to research protocols without adding unnecessary participant burden and can then allow for examination of dynamic processes among sleep quality and psychosocial constructs.

Our study next sought to examine the between- and-within person relationships and intra-individual associations among subjective sleep quality and both self-reported and electronically monitored adherence to one oral diabetes medication. There is evidence that traditional self-report measures measure somewhat different constructs than real-time assessments delivered via EMA methods as a result of a variety of factors ranging from issues with ecological validity, recall bias and cognitive limitations, and reduction of granularity of psychological and behavioral processes due to aggregation (Hoffman, 2007; Hufford & Shiffman, 2002; Smyth & Smyth, 2003; Stone & Shiffman, 2002). By evaluating the hypothesized relationships between sleep quality and medication adherence using real-time, multi-level data, we may better understand the nature of these relationships and whether sleep quality is an important variable to examine further in this context.

This study addressed novel questions about the potential relationship between sleep quality and medication adherence in the T2D population. The two previous studies that examined the relationship between sleep and medication adherence in a T2D sample used a cross-sectional study design and measured medication adherence only by self-report, which are critical limitations (Marcum et al., 2013; Telford et al., 2018). The relationship between sleep quality and medication adherence presents a crucial area for research growth and clinical application. To date much of our understanding of the relationship between poor sleep quality and T2D focuses

on shared biological pathways and epidemiological data. Overall, this study aimed to address gaps in our understanding of a relationship between sleep quality and medication adherence with a goal of yielding novel information to inform future research and clinical care in a socioeconomically disadvantaged population already at an elevated risk for poor diabetes-related outcomes.

**Specific Aims**

**Aim 1:** To evaluate the basic psychometric properties of the EMA daily sleep quality measure

- H1A: The daily sleep measures will have an acceptable level of reliability
- H1B: The daily sleep measure will have acceptable convergent validity

**Aim 2:** To evaluate the within- and between-person effects of daily sleep quality on daily medication adherence.

- H2A: Individuals with lower sleep quality will have reduced odds of MEMS adherence.
- H2B: Individuals with lower sleep quality will have poorer daily self-reported medication adherence.
- H2C: When a person reports poorer sleep from the previous night (relative to their average), their odds of same-day MEMS adherence will be reduced.
- H2D: When a person reports poorer sleep from the previous night (relative to their average), they will have poorer self-reported medication adherence.

**Aim 3:** To assess the relationship between daily sleep quality consistency and daily medication adherence.

- H3A: Greater intra-individual variability will be associated with increased odds of MEMS non-adherence.

- H3B: Greater intra-individual variability will be associated with poorer self-reported medication adherence.

# Chapter II: Design and Methods

## Description of the Study

This project conducted a secondary analysis using data from a pilot study, entitled "Daily assessment of patient-reported symptoms and diabetes self-care in T2D" (IRB 2017-8241, PI: Gonzalez, Co-I: Hoogendoorn and Crandall). The parent study focused on assessing the feasibility and acceptability of a smartphone-based mobile application using EMA methodology to assess the dynamic relationships among reported symptoms and disease self-management behaviors in a sample of urban-dwelling adults with T2D. The parent study used a prospective design that involved a baseline lab visit, a two-week period of daily assessments, and a follow-up lab visit. The present study used demographic data collected during the baseline visit, one measure collected from the follow-up visit, and intensive longitudinal data collected throughout the observational study period. The aims of the current study were to evaluate the basic psychometric properties of brief measure assessing daily sleep quality; additionally, this study examines the association between daily self-reported sleep quality and daily medication adherence. This work builds upon the foundation of the pilot study to evaluate more comprehensively specific relationships among critical components of diabetes self-care.

## Participants and Recruitment

Participants were recruited from the Albert Einstein College of Medicine/Montefiore Clinical Diabetes Program in Bronx, NY. Lab members of the Principal Investigator, Dr. Jeffrey Gonzalez, sent opt-out letters, conducted in-clinic screenings, and made recruitment calls using referral lists provided by primary care and specialty care clinics within the healthcare network. Study staff also conducted in-person screenings in the Einstein and Montefiore clinics. Additionally, IRB-approved flyers were posted throughout the Ferkauf Graduate School of

Psychology and at select medical clinics. Recruitment began in July 2018 and was completed in March 2020. Eligible participants signed an informed consent form approved by the human subjects committee of the Albert Einstein College of Medicine.

**Eligibility and Exclusion Criteria.** Individuals were considered eligible to participate if they were 18 years or older, had a diagnosis of T2D for at least one year, were prescribed one or more oral hypoglycemic medication, owned a smart phone, and owned and regularly used a blood glucose meter and test strips. Individuals were considered ineligible if they were unable to read or consent in English, or if they were pregnant. Participants were also considered ineligible to participate if they were unable to download and engage with the smartphone application.

## Procedure

**Enrollment Screen.** Study staff contacted potential participants either in-person or via phone to conduct a brief screen. If eligible, participants were scheduled for two lab visits that were 14-days apart (see Figure 2 for study flow).

**Baseline Visit.** Informed consent was obtained from eligible participants. Participants were then asked to complete a battery of self-report measures that included demographic information, disease-specific information, and psychosocial symptom reports. Participants were also asked to provide a list of current medications. Participants transferred their selected oral diabetes medication into a new medication bottle with a MEMS electronic bottle cap (AARDEX Group, Zurich, Switzerland) and downloaded a phone application called MyDay (Mulvaney et al., 2018; Mulvaney et al., 2019) onto their devices. Study staff provided educational materials and trained participants in using each device. Participants were asked to provide three convenient times per day (morning, afternoon, evening) to receive a phone notification to complete the EMA surveys.

**Observational Period.** For the next 14 days, participants were prompted at three times each day via smartphone notification to complete the EMA surveys using the MyDay application for a total of 42 momentary assessments. To standardize response times, participants received a second notification one hour later if they had not yet completed their survey. Participants were encouraged to call and/or email study staff if they experienced any technological challenges with the MyDay app. Participants were instructed to take their selected oral diabetes medication only from the medication bottle with the MEMS monitoring cap for the duration of their study participation. Participants were also asked to use their blood glucose meter upon waking to get a fasting blood glucose reading. Study staff called participants within the first week of study participation to provide an opportunity for participants to report any problems. Study staff also monitored EMA survey data transmitted through the MyDay online portal.

**MyDay Mobile Application.** MyDay is a mobile application written in Ruby On Rails (v4.1) with a PostgreSQL database background (Mulvaney et al., 2018). MyDay was developed specifically for use in the T1D population and was adapted for use in the parent study. MyDay was developed to operate using both iOS and Android platforms. It provides a secure web interface for administering surveys and collecting data. The application and database servers are managed through the Vanderbilt University Information Technology department protected by the Vanderbilt University firewall.

**EMA Data Collection.** EMA data were collected and stored using Research Electronic Data Capture (REDCap), which is a HIPAA compliant web-based application for data collection and storage (Harris et al., 2009).

**Follow-Up Visit.** Participants returned to the lab after 14 days to complete the psychosocial self-report battery and download MEMS data. Study staff reviewed the MEMS

reports with each participant to clarify any possible discrepancies. Blood glucose values from the 14-day study period were downloaded from the participants' blood glucose meters. Study staff conducted a brief, audio-recorded interview in which participants provided feedback to study staff on their experience and satisfaction with the study.

**Participant Incentives.** All participants received payment with a credit card-gift card at the end of their follow-up visit. Participants received $25 for each lab-visit, for a total of up to $50. Additionally, participants received up to $75 for completion of the EMA assessments and daily glucose monitoring based on adherence to the protocol. Participants received the full $75 if they completed ≥ 70% of all daily assessments, $50 if adherence to EMA assessments was less than 70% but above 20%, and no additional incentive if adherence rates were below 20%. Participants received up to $125 total (lab visits and EMA assessments).

## Measures

**Demographic Information.** Information on age, race, ethnicity, sex, was collected using a basic demographic questionnaire. Participants also provided information specific to their medical treatment including a list of their current medications.

**Glycosylated Hemoglobin (HbA1c).** HbA1c values were collected at the baseline visit from participant medical records. All HbA1c values were recorded within six months of the baseline visit.

**Pittsburgh Sleep Quality Index (PSQI).** The Pittsburgh Sleep Quality Index (PSQI) was used to measure sleep quality at the baseline and follow up visits (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). For the follow up measure, participants were asked to consider their sleep quality over the two weeks that corresponded with their study participation. The current study uses the PSQI collected at the follow up visit, as it most closely matches the time frame for

EMA data collection. The PSQI is a widely used self-report measure that contains 19 items, seven component scores, and a global score. The component scores are: 1) Subjective Sleep Quality, 2) Sleep Latency, 3) Sleep Duration, 4) Habitual Sleep Efficiency, 5) Sleep Disturbances, 6) Use of Sleep Medication, and 7) Daytime Dysfunction. Each component score is weighted on a Likert scale ranging from 0-3. The global score is a sum of the component scores, with possible scores ranging from 0-21, where higher scores indicate worse sleep quality. The PSQI has strong psychometric properties ($\alpha = 0.80$) across populations (Carpenter & Andrykowski, 1998). A global score of >5 has been reported is reflective of poor sleep quality (Buysse et al., 1989).

**EMA 5-Item Sleep Survey.** Participants responded to questions about sleep quality as part of the morning EMA assessment. These questions asked participants to reflect on their sleep from the previous night (e.g., participants answered questions on Tuesday morning about their sleep quality from Monday night). The following symptom severity items were included: "Trouble falling asleep?" (0 = not at all, 1 = a little, 2 = quite a bit, 3 = extremely), "Do you feel well rested?" (Reverse coded; 0 = not at all, 1 = a little, 2 = quite a bit, 3 = extremely), "Number of awakenings" (0 = none, 1 = 1 - 2, 2 = 3 - 5, 3 = >5), "Rate how well you slept" (0 = very well, 1 = well, 2 = okay, 3= poorly, 4 = very poorly), and "How tired do you feel right now?" (0 = not at all, 1 = a little, 2 = quite a bit, 3 = extremely). This measure has strong reliability ($\alpha = .78$) for use as a single-factor scale (Shiffman et al., 2006). A daily total score was calculated for each participant, where a higher score indicates worse sleep quality (McCarthy et al., 2016; Shiffman et al., 2006). This measure was used in previous studies conducted by Shiffman and colleagues (2006) and McCarthy and colleagues (2016), although the psychometric properties were not previously assessed (McCarthy et al., 2016; Shiffman et al., 2006).

**EMA Medication Adherence Survey (SR Adherence).** Participants were asked to respond to a one item question about their adherence to diabetes medication as part of the evening survey prior to going to sleep. Participants were asked "Today, how did you do at taking your diabetes medicines?" with responses rated on a five-point Likert scale including the following options: excellent, very good, good, fair, and poor. This variable was dichotomized where "excellent" = 1 and "very good," "good," "fair," and "poor" = 0.

**Medication Event Monitoring System (MEMS).** Each participant was given a Medication Event Monitoring System (MEMS) bottle cap (AARDEX Group, Zurich, Switzerland) at the baseline visit to monitor adherence for their selected oral diabetes medication for the two-week study period. If participants were prescribed multiple oral diabetes medications, they were asked to choose the medication they take most often or find most burdensome. Participants were asked to bring back their MEMS caps to their follow-up visit, and data were downloaded using a MEMS cap reader. MEMS readings were recorded at the follow-up visit and reports were reviewed with each participant to address any potential discrepancies. Percentage adherence was calculated at a day-level for each participant. For example, if a participant's prescribed regimen requires two doses per day, the participant was considered 100% adherent if they opened their medication bottle twice in a day. If they opened the medication bottle once in a day, they were 50% adherent, and if they opened the bottle three times in one day, they were 150% adherent. For the current study, daily adherence was considered dichotomous, wherein any participant with 100% adherence = 1 and any degree of nonadherence = 0. Participants with <100% adherence or >100% adherence were considered nonadherent for the purposes of these analyses. This coding is consistent with the use of MEMS data in the literature, in which "perfect" adherence is compared to "imperfect" adherence (Berg et al., 2012). Additionally,

inspection of the distribution of the categorical MEMS variable indicated that a large majority of the observations were 100% adherent with significantly fewer observations being greater than or less than 100% (Supplemental Figure 1).

**Data Analysis**

Statistical analyses were conducted using SPSS software version 27.0 (IBM Corp., Armonk, NY). Continuous variables were assessed for normality using measures of skewness and kurtosis (Supplemental Table 1) and data were visually inspected using histogram plots. Dichotomous and categorical variables were visually inspected using histogram plots. Statistical techniques were chosen in accordance with variable distributions. Data cleaning and screening procedures inspected for outliers and missing values. Descriptive statistics were conducted for each of the study variables and demographic variables to characterize the sample. Bivariate relationships among outcome variables. Age, race, ethnicity, sex, and HbA1c were evaluated as potential covariates to be included in the multilevel models.

**Missing Data and Data Cleaning**

There were 15 participants with missing data on one item of the PSQI (i.e., item 5j, “How often since your last visit have you had trouble sleeping because of this”; Appendix C). This item contributed to the PSQI Sleep Disturbance component score as well as to the PSQI Global Score. Data were likely missing due to the form set up, which was structured so that this item was easily overlooked. Therefore, missingness was likely not associated with the item content. To address this issue, a sensitivity approach was taken to ensure robustness of the results. To compute the corrected PSQI Sleep Disturbance component score, an average score rather than a total score was conducted using available data from the items that compose the component score, thus the component score range remained 0-3. Next, this corrected component score was included in the

calculation of a corrected PSQI global score, where the possible scores ranged from 0-21. A sensitivity analysis was conducted using the original PSQI Sleep Disturbance component score and original PSQI Global score, which yielded findings consistent with those presented in the main analyses (Supplemental Table 2).

The SR adherence variable was found to be moderately positively skewed (Skewness = .63 *SE* = .09, Kurtosis = -.56 *SE* = .19) with too few data points in the fifth category (5/680; see Supplemental Figure 3 for histogram of raw categorical SR adherence variable). Therefore, it was not appropriate to treat this as a continuous variable and modeling approaches for ordinal outcomes are inappropriate due to category sparseness without collapsing categories. To address this issue, and for ease of interpretation of the results, the EMA medication adherence variable was recoded from a categorical variable to a dichotomous variable used in the main analysis (Supplemental Table 3 depicts descriptive statistics of SR adherence variables created for sensitivity analyses; see Supplemental Figure 4 for variable distribution of "excellent" cut point and Supplemental Figure 5 for variable distribution of "very good" cut point).

Prior studies consistently indicate that data tend to be inflated on self-report measures of adherence and thus dichotomization of self-report measures around the 100% mark is recommended (Stirratt et al., 2015). The main analyses presented in the current project were conducted using a dichotomized variable, where participants who endorsed "excellent," adherence were recoded as 1, while "very good," "good," "fair," and "poor" ratings were recoded as 0. This approach was reported in the main analyses as it is consistent with the MEMS dichotomization of 'perfect' and 'imperfect' adherence, as well as the previously mentioned recommendations in the medication adherence literature (Berg et al., 2012; Stirratt et al., 2015). A sensitivity analysis was conducted using the original categorical SR adherence variable in the

multilevel models (Supplemental Table 4), which yielded no significant changes from those results reported in the main analysis section. Regarding the consideration of where the cut was made to dichotomize the SR adherence variable, we considered dichotomizing the at the "very good" score (where "excellent" and very good = 1, and "good," "fair," and "poor" = 0), although the distribution was like that of the variable used in the main analysis. Sensitivity analyses were conducted using variables dichotomized both at the "very good" cut point and the "excellent" cut point and yielded no significant changes.

For the multilevel data, single imputation was considered unnecessary given the low percentage of missing data and the application of multilevel modeling, which assumes data may be missing at random (Hox, 2002).

**Aim 1:** To evaluate the basic psychometric properties of the EMA daily sleep quality measure

- H1A: The daily sleep measures will have an acceptable level of reliability
- H1B: The daily sleep measure will have acceptable convergent validity

To circumvent concerns of non-independence of observations due to the repeated administration of the EMA daily measures, one observation per participant was randomly selected from daily sleep quality data for the correlation analyses. To evaluate the basic psychometric properties of the EMA sleep quality scale, item-level descriptive statistics, including the mean and standard deviation, and Pearson correlations were first calculated for the EMA sleep quality measure at the participant level. Cronbach's alpha was computed to evaluate internal consistency (Cronbach, 1951). Next, the intraclass correlation coefficient (ICC) was calculated to evaluate the test-retest reliability based on an unconditional multilevel model (no predictors) with a random subject intercept effect (Hox, 2002)

To examine the second hypothesis of Aim 1, Spearman's rank-order correlation coefficients were calculated to evaluate the convergent validity of the EMA sleep quality measure with the follow-up PSQI Global and Component scores. No prior study (to the best of our knowledge) has assessed the correlation between the 5-item EMA sleep survey used in the present study and the PSQI. However, previous research using a single item to assess sleep quality reported a strong with the PSQI global score ($r$ = .83) in a sample of adolescents with T1D (Turner et al., 2016). We hypothesized that EMA sleep quality survey would demonstrate a strong, positive correlation with the PSQI global score in our population ($r > 0.5$). In line with previous research in which a one-item sleep quality measure demonstrated moderate to strong correlations with PSQI component scores in a population with insomnia and depression (Snyder et al., 2018), we hypothesized a moderate (r >.30) to strong correlation ($r > 0.5$) among PSQI component scores across participants and EMA sleep quality total scores (Cohen, 1988).

**Aim 2:** To evaluate the within- and between-person effects of daily sleep quality on daily medication adherence.

- H2A: Individuals with lower sleep quality will have reduced odds of MEMS adherence.
- H2B: Individuals with lower sleep quality will have poorer daily self-reported medication adherence.
- H2C: When a person reports poorer sleep from the previous night (relative to their average), their odds of same-day MEMS adherence will be reduced.
- H2D: When a person reports poorer sleep from the previous night (relative to their average), they will have poorer self-reported medication adherence.

To evaluate the between- and within-person effects of the sleep quality on medication adherence, the EMA daily sleep measure was used to predict both electronically monitored and

subjective medication adherence using logistic multilevel models (binary outcome variables). The multilevel models accounted for the nested structure of the data (study day number nested within participants), in which with daily observations constituted Level-1 (daily sleep total score, MEMS adherence, and SR adherence) and participant-level variables that varied between persons constituting Level-2. Separate multilevel models were fitted using a link logit function with a binomial response distribution and included a random-subjects effect to account for the nesting of repeated observations within subjects (Bolger & Laurenceau, 2013; Hox, 2002). These models evaluated the effects of EMA sleep quality on MEMS adherence (Aim 2A and Aim 2C), and to evaluate the effects on SR adherence (Aim 2B and Aim 2D).

Between-and within-person effects were analyzed using the recommended approach of person-mean centering (Bolger & Laurenceau, 2013). For each participant, a mean sleep quality score was computed across the available study days to represent the between-person effect [$MnSQ_i$]. Then, a person-centered within-subject variable was created by subtracting each person's respective mean score from the observed daily sleep quality score [$(SQ_{di} – MnSQ_i)$]. These variables were then added as predictors in the models fit for each hypothesis, thus allowing for examination of whether, 1.) individuals that have overall poorer sleep quality have decreased odds of medication adherence (between-person effect), and 2.) on days where individuals report worse sleep quality from the previous night than normal, they have decreased odds of medication adherence on same day (within-person effect).

Next, we describe the steps taken to estimate the models. First an unconditional model was constructed, to test whether there is significant individual variability in the outcome variable specified in each model (either SR adherence or MEMS adherence). The equations below depict the unconditional model specification for the *i* Level-1 observations nested within the *j* Level-2

participants. At Level-1, within-person, adherence ($y_{ij}$) is a function of the random intercept ($\beta_{0i}$) (there is not a error/residual terms because the outcomes are binary). At Level-2, $\beta_{0i}$ (random intercept) is modeled as a function of the fixed intercept effect ($\gamma_{00}$) and subject-level residual, or error ($u_{0i}$). The unconditional models are depicted below (Hox, 2002; Raudenbush & Bryk, 2002).

$$\text{Level 1: } y_{ij} = \beta_{0i}$$

$$\text{Level 2: } \beta_{0i} = \gamma_{00} + u_{0i}$$

Next, a series of conditional mulilevel models were fitted to the specific research questions. First, the between-person sleep quality effect was evaluated (referred to as Model 1a (MEMS adherence) and Model 2a (SR adherence) in text that follows). This involved adding the between-person variable ($\text{MnSQ}_i$) as a Level-2 fixed effect predictor ($\gamma_{01}$):

$$\text{Level 1: } y_{ij} = \beta_{0i}$$

$$\text{Level 2: } \beta_{0i} = \gamma_{00} + \gamma_{01}\text{MnSQ}_i + u_{0i}$$

To address Aim 2C and Aim 2D, the person-centered within-subject predictor variable ($\text{SQ}_{ij} - \text{MnSQ}_i$) was added as a Level-1 fixed effect predictor ($\beta_1$) (referred to as Model 1b (MEMS adherence) and Model 2b (SR adherence) in the following text):

$$\text{Level 1: } y_{ii} = \beta_{0i} + \beta_1(\text{SQ}_{ij} - \text{MnSQ}_i)$$

$$\text{Level 2: } \beta_{0i} = \gamma_{00} + \gamma_{01}(\text{MnSQ}_i) + u_{0i}$$

Thus, within-person daily adherence (Level-1, $y_{ij}$) is a function of random intercept effect ($\beta_{0i}$) and the within-person daily sleep quality effect ($\beta_1$) while between-person adherence (i.e., Level-2 random intercept) is a function of the fixed intercept effect ($\gamma_{00}$), the fixed between-person sleep quality effect ($\gamma_{01}$), and participant-level or error ($u_{0i}$).

**Aim 3:** To assess the relationship between daily sleep quality consistency and daily medication adherence.

- H3A: Greater intra-individual variability will be associated with increased odds of MEMS non-adherence.
- H3B: Greater intra-individual variability will be associated with poorer self-reported medication adherence.

To assess the relationship between daily sleep consistency and daily medication adherence, a within-person sleep quality variance estimate was calculated for each participant ($SQVar_i$). By adding each participant's estimated within-person sleep quality variance as a Level-2 fixed effect predictor of medication adherence, inferences can be made as to whether people who tend to have greater intra-individual variability in sleep quality across the study period tend to have better, or worse, medication adherence. The model is depicted below, where $\gamma_{02}$ is the sleep variability effect at Level-2 (referred to as Model 1c (MEMS adherence) and Model 2c (SR adherence) in the following text):

$$\text{Level 1: } y_{ij} = \beta_{0i} + \beta_1(SQ_{ij} - MnSQ_i)$$

$$\text{Level 2: } \beta_{0i} = \gamma_{00} + \gamma_{01}(MnSQ_i) + \gamma_{02}(SQVar_i) + u_{0i}$$

**Power Analysis**

The current project is a secondary analysis using data previously collected for a pilot study. Recruitment for the parent study had been completed prior to completing the current study, and thus it was not possible to conduct an a priori power analysis. Simulation studies are commonly used methods to estimate power and necessary sample size (Hox, 2002). To the best of our knowledge, there are no published studies that have included repeated-measures assessments of sleep quality and medication adherence and thus many of the parameters cannot

be estimated to complete a simulation study. However, guidelines suggest that the highest level in a multilevel model design, in this case the participant level (level 2), is the most restrictive (Hox, 2002; Maas & Hox, 2005). A study conducted by Maas and Hox (2005) aimed at estimating sufficient sample sizes for multilevel model designs with results indicating that a sample size of less than 50 at level 2 may lead to biased estimates of standard errors (Maas & Hox, 2005). An average of 13.26 EMA sleep quality surveys were completed per participant, and we have a sample size of 61 participants for the current study. There are 808 observations at level 1, and we have more than 50 unique observations at level 2 which is sufficient for a study using a multilevel modeling approach (Hox, 2002; Maas & Hox, 2005).

**Ethics**

This study was approved by the Institutional Review Board of the Albert Einstein College of Medicine (IRB 2017-8241).

**Risks and Benefits**

There were few risks associated with participation in this research study. This study did not involve invasive physical procedures. Participants were informed of possibility of experiencing psychological discomfort when answering questions. There was also a possible risk of feeling burdened by completing the three-time-daily app-based questionnaires for two weeks. Participants were informed during the consent process that they could discontinue their study participation at any time or decline to answer questions that caused discomfort. Referrals were made to the Max and Celia Parnes Family Psychological and Psychoeducational Services Clinic as needed.

Additionally, there was a potential risk of the loss of confidentiality and personal health information. To minimize this risk, study materials were deidentified, and participants were

assigned study identification codes. Data were stored in locked filing cabinets and any information containing identifiers (i.e., signed consent) were stored separately from data containing identification codes. Data collected via phone-based app and electronic medication caps contained only de-identified study codes.

There were no direct benefits to participants from participating in this study. However, this study may benefit others by increasing our knowledge about the factors associated with diabetes medication adherence and could help provide improved measurement tools for future studies targeting improved diabetes outcomes.

# Chapter III: Results

## Descriptive Statistics

Descriptive statistics including mean, median, range, frequencies, skewness, and kurtosis, were examined for each of the main continuous study variables. All categorical participant demographic and disease-related variables are summarized using the appropriate summary statistic (i.e., sample size [n] and percentages [%]). A total of 62 participants completed the baseline and follow-up assessments of the study. One participant was excluded from the analyses for completing <5 days of daily surveys, resulting in a sample size of 61 participants. Table 1 displays descriptive statistics for variables collected at baseline or follow-up visits, including characteristics of the full sample and follow-up PSQI global and component scores. Participants were predominantly Black (*n* = 38, 62.3%), women (*n* = 39, 63.9%), with a mean age of 55.4 years (*SD* = 9.9). Just over a third of the sample identified ethnically as Hispanic or Latino (*n* = 22, 36.1%). The average HbA1c was 8.5 (*SD* = 2.40). Participants reported poor overall sleep quality on average (*n* = 45, mean = 8.36, *SD* = 4.83) at the follow-up visit as measured by the global PSQI score (Buysse et al., 1989).

Table 2 shows aggregated person-level descriptive statistics for the day-level study variables. The average number of EMA sleep quality surveys completed per subject was 13.26 (*SD* = 2.38) and the average person-level sleep quality score was 5.91 (*SD* = 2.57, Min = 0.69, Max = 11.93). Similarly, an average of 12.43 [*SD* = 2.22] MEMS adherence observations were collected at the day-level per person. Participants were adherent to their diabetes medication about 77% of the time based on objective MEMS measurement, though 68% of participants reported “excellent” adherence per the self-report EMA measure (Mean [*SD*] observations per subject: 10.87 [3.25]).

**Bivariate Relationships**

Bivariate relationships between person-level characteristics (i.e., race, ethnicity, and HbA1c) and adherence were evaluated. For each adherence variable, one observation per participant was randomly selected to account for the non-independence of observations. Sensitivity analyses were conducted to ensure the robustness of the results. Sensitivity analyses involved conducting a second set of demographic analyses using a second, randomly selected observation per participant; these analyses yielded no differences in results.

There was a significant association between race (Black vs. Non-Black) and SR adherence, $\chi^2$ (1, $n$ = 49) = 6.27, $p$ = .012, phi = .40; however, this association was not observed for the relationship between race and MEMS adherence, $\chi^2$ (1, $n$ = 55) = 1.76, $p$ = .19, phi = -.22. A similar pattern was observed for the associations between adherence and ethnicity, where SR adherence was associated with ethnicity (Hispanic vs. Non-Hispanic/Latino), $\chi^2$ (1, $n$ = 49) = 4.73, $p$ = .03, phi = -.35, while MEMS adherence was not, $\chi^2$ (1, $n$ = 55) = 1.05, $p$ = .31, *phi* = .18. There were no significant relationships between SR adherence and sex ($p$ = 1.00, two-tailed Fisher's Exact Test) or MEMS adherence and sex ($p$ = 1.00, two-tailed Fisher's Exact Test).

A Chi square test indicated that MEMS adherence was not significantly associated with SR adherence ($p$ = .284, two-tailed Fisher's Exact Test). Analyses were also conducted to examine the sensitivity and specificity of a self-report of "excellent" adherence in identifying participants who missed at least one dose of their MEMS medication. Sensitivity was defined as the probability of self-reporting "excellent" medication adherence when no doses were missed, based on MEMS data. Specificity was defined the probability of self-reporting reporting less than excellent adherence (i.e., "very good" "good" "fair" or "poor) when one or more doses were missed based on MEMS data (i.e., < 100% or >100% adherence). Notably, MEMS adherence

was not significantly associated with SR adherence ($p$ = .284, two-tailed Fisher's Exact Test). Sensitivity and specificity were examined for SR adherence with MEMS adherence as the reference using all available observations (Table 3). Sensitivity for the SR Adherence measure was high; 72.3% (384/531) of the observations where participants electronically monitored medication adherence was 100%, were consistent with EMA self-reports of 'excellent' adherence. However, only 48.8% (53/121) of the observations where participants were non-adherent based on MEMS data also self-reported less than 'excellent' medication adherence on EMA survey, indicating low specificity. Sensitivity analyses were conducted using the "very good" cut point, yielding no differences from the those reported above.

Non-parametric approaches were used to evaluate the relationships among HbA1c and study variables, as the HbA1c distribution violated the assumption of normality. HbA1c was moderately correlated with daily subjective sleep quality, where higher HbA1c levels were associated with worse reported sleep quality ($\rho$ = .26, $p < .05$). HbA1c was not associated with age ($\rho$ = -.025, $p$ = .85). There were no significant differences in the HbA1c levels of participants with regards to 100% MEMS adherence ($Md$ = 7.35, $n$ = 50) and non-adherence ($Md$ = 8.05, $n$ = 14), U = 218, $z$ = -1.23, $p$ = .22. There were also no significant differences in HbA1c between those self-reporting excellent adherence via EMA ($Md$ = 7.60, $n$ = 29) and those reporting less than excellent adherence ($Md$ = 7.75, $n$ = 20), U = 287, $z$ = -.061, $p$ = .95. A sensitivity analysis was conducted assessing HbA1c and SR Adherence using "very good" as a cut point, which yielded no differences from those using the "excellent" cut point.

## Main Analyses

### Aim 1

To evaluate the basic psychometric properties of the EMA sleep quality measure, descriptive statistics along with inter-item correlations, Cronbach's alpha, and ICC were conducted (Table 4). Results showed moderate to strong inter-item correlations among the items (range: $r = .28$ to $r = .77$ $p < .05$ for all). The scale also demonstrated a high level of internal consistency ($\alpha = .86$). An unconditional multilevel linear model was constructed to evaluate the ICC using all available data. The ICC was estimated to be .50, which is considered moderate based on common recommendations (Cicchetti, 1994). Overall, these findings show good psychometric support for this measure.

Spearman's rank-order correlations were conducted due to the violation of the normality assumption by the EMA sleep quality and the PSQI. The following results are based on the corrected PSQI global score and the corrected PSQI Sleep Disturbance component score (Table 5). Correlations conducted using the raw PSQI data for sensitivity purposes did not yield any significant differences. The PSQI Global score was strongly correlated with the EMA Sleep Quality measure ($\rho = .69$, $p < .001$) indicating strong convergent validity between the measures. The EMA sleep quality measure was significantly associated with each of the PSQI component scores (Sleep Quality: $\rho = .58$, $p < .001$; Sleep Latency: $\rho = .47$, $p < .001$; Sleep Duration: $\rho = .50$, $p < .01$; Sleep Efficiency: $\rho = .54$, $p < .001$; Sleep Disturbance: $\rho = .39$, $p = .002$; Daytime Dysfunction: $\rho = .77$, $p < .001$). There was not a significant association between the EMA sleep quality measure and the PSQI Use of Sleep Medication component score ($\rho = .16$, $p = .22$).

**Aim 2**

Multilevel logistic models were constructed to test the between and within-person effects of daily sleep quality on the likelihood of MEMS adherence (Table 6). Unconditional (null) models were used to evaluate whether the subject level random intercept effect variance was equal to zero, and if not, then how much of the variance in the dependent variable occurred at the between-person level. In the unconditional model, there was a significant amount of between-person variability in MEMS adherence (random intercept variance = 2.00, $p$ <.001) with 38% of the total variability in MEMS adherence being attributed to between-person differences (ICC = .38).

For analyses examining relationships between show Daily Sleep Quality and MEMS adherence, participants needed to have observations for both the daily sleep quality measure and MEMS adherence collected on the same day (758 total observations). Daily Sleep Quality did not have significant between-person or within-person effects on MEMS adherence. This indicated that individuals with better overall sleep quality did not have increased odds of objective medication adherence (between-person effect) and, when individuals had better sleep quality than normal, they did not have increased odds of medication adherence the next day based on the MEMS (within-person effect). These findings remained the same in sensitivity analyses that controlled for of race and ethnicity as covariates (Between-Person [Model 1d]: OR = 1.13, $p$ = .17, 95% CI = 0.95 – 1.34).

Separate models were constructed to examine the SR adherence outcome (652 total observations) (Table 7). In the unconditional model, there was a significant amount of between-person variability in SR adherence (random intercept variance = 4.40, $p$ <.001 with 57% of the total variability in SR adherence being attributed to between-person differences (ICC = .57).

There was a significant between-person effect of Sleep Quality on SR Adherence such that participants with worse average sleep quality had decreased odds of endorsing SR adherence (Model 2a: OR = 0.72, $p$ = .006, 95% CI = [0.57, 0.91]). Specifically, for every one-unit increase in average daily sleep quality (worse sleep quality), individuals were 28% less likely to report that they were good at taking their diabetes medication. However, there was not a significant within-person effect of Sleep Quality on SR Adherence (Model 2b: OR = 0.97, $p$ = .51, 95% CI = [0.89, 1.06]). In other words, an individual having better or worse sleep quality than usual did not significantly predict SR adherence the next day. These findings remained the same in supplemental sensitivity analyses that controlled for of race and ethnicity as covariates, where the between-person relationship was significant, but the within person relationship was not significant (Between-Person [Model 2d]: OR = 0.73, $p$ = .006, 95% CI = 0.58 – 0.91; Within-Person [Model 2e]: OR = 0.97, $p$ = .48, 95% CI = 0.89 – 1.06).

**Aim 3**

Models evaluating whether individual variability in subjective sleep quality predicted better or worse medication adherence are shown depicted in Table 6 (Model 1c) and Table 7 (Model 2c) for objective medication adherence and self-reported medication adherence, respectively. Results again showed that the within-person variability in sleep quality was not predictive of either MEMS Adherence (Model 1c OR= 1.01, $p$ = 0.82, 95% CI = [0.93, 1.10]) or SR Adherence (Model 2c, OR = 1.02, $p$ = 0.80, 95% CI = [0.89, 1.16]). This indicated individuals that reported more variable sleep quality from night-to-night did not tend to have worse medication adherence. These findings also remained the same in supplemental sensitivity analyses that controlled for race and ethnicity as covariates both for MEMS adherence (Model

1d: OR = 1.01, $p$ = .82, 95% CI = 0.92 – 1.12) and SR adherence (Model 2d: OR = 0.99, $p$ = .86, 95% CI = 0.87 – 1.12).

## Chapter IV: Discussion

The purpose of this study was to examine whether a 5-item subjective sleep quality measure delivered via mobile phone application had good basic psychometric properties, and to explore relationships among daily sleep quality and daily medication adherence (both electronically measured and self-reported) in adults with T2D. EMA methodology, a relatively novel approach for real-time data collection, was used to capture data and allow for analysis of between- and within-subject dynamics. This study was innovative in its assessment of the virtually unexplored relationship between sleep quality and medication adherence. We based our hypotheses that there would be between-person, within-person, and intraindividual effects of sleep quality on both subjectively and objectively reported medication adherence based on evidence from literature elucidating links between sleep and self-care behaviors in other chronic illnesses, as well as biological underpinnings of sleep and diabetes etiology, and a conceptual model of self-regulation. Our study adds to the limited existing evidence by disaggregating the between- and within-person effects of sleep quality on medication adherence, and more broadly, on sleep quality and diabetes self-management.

Results indicated that the EMA sleep quality survey demonstrated good internal consistency, indicating that the items composing the measure were related (Mollayeva et al., 2016; Streiner, 2003). Items on the scale were moderately to strongly correlated with one another. We hypothesized that the 5-item EMA sleep quality measure would demonstrate good internal consistency as well as good convergent validity with the PSQI. As expected, there were moderate-to-strong associations among the EMA sleep quality total score and six of the seven PSQI component scores. The Use of Sleep Medication component was not significantly

correlated with the EMA sleep quality total score. These results support continued applications of this 5-item EMA sleep quality measure in adults with T2D.

Notably, the use of sleep medication component was only significantly related to the PSQI Sleep Disturbance component, but it was not associated with the global score or any other component score. It is possible that participants in our sample did not use sleep medication despite having difficulty sleeping; this would result in elevated scores on other PSQI component scales, but not with elevation on the sleep medication component score. This pattern of results in which the use of sleep medication component score was not correlated with many of the other PSQI component scores has been demonstrated in studies validating other measures against the PSQI as a gold standard. For example, a study validating the PSQI in community dwelling Black and White women over age 65 found that the PSQI sleep medication subscale had insufficient internal consistency (Beaudreau et al., 2012). Several studies in various patient populations including T2D (Zhu et al., 2018c) have found that psychometric properties improve when the sleep medication component score is removed (Mollayeva et al., 2016; Spira et al., 2012; Tomfohr et al., 2013). These findings were consistent with a previous EMA study that found a strong correlation between the PSQI and a single-item measure of subjective sleep quality or single-item measures of subjective sleep quality (Tracy et al., 2019). Therefore, findings from the current study are congruent with the larger PSQI literature.

Regarding our second aim, results indicated a significant between-person effect for daily sleep quality on average SR adherence. In contrast, within-person fluctuations in daily sleep quality were not predictive of greater odds of daily SR adherence at the day-level. This suggests that participants who had better sleep quality on average had higher odds of adhering to their medication, but when someone had a night of better or worse sleep quality than they usually did,

there was no influence on their odds of taking their medication on the subsequent day. These findings highlight that subjective sleep quality is a contributing factor to whether someone reports their adherence behavior as "excellent" in our sample. Interestingly, this was not true at the individual level. A strength of the present study design is the use of EMA methods and multilevel modeling to disaggregate between- and within-person effects. Thus, this study assessed not only whether we observed a relationship between average sleep quality and average medication adherence at the person-level, but also whether sleep quality reported on one morning was associated with the likelihood of reporting excellent adherence on days where a participant's sleep quality was poor relative to their person-centered mean. Our findings suggest the possibility that covariates contribute to the relationship observed between people, is possible that other factors contribute to the relationship observed across people. For example, factors that may vary at the individual-level, but not the day-level, such as depression, which has an established relationship with medication adherence in the T2D population may moderate or mediate this relationship (Gonzalez et al., 2016).

Contrary to our hypotheses, sleep quality was not associated with MEMS adherence at the between-person level or the within-person level. This suggests that there was no link between whether good sleepers or poor sleepers were more or less likely to take their diabetes medication monitored by the electronic pill cap in our sample, which differed from our findings for SR adherence. As this was the first study to our knowledge that examined the relationship between subjective sleep quality and objectively measured medication adherence, these findings contribute significantly to a foundational understanding of the dynamics among these variables in our sample of adults with T2D. Given the inconsistency in the between-person findings for SR adherence and MEMS adherence outcomes, we sought to further characterize the relationship

among these variables by examining the sensitivity and specificity of SR adherence relative to MEMS adherence. In the present sample, the SR adherence measure had high sensitivity, but low specificity in reference to MEMS. In most cases, participants tended to self-report "excellent" adherence when their adherence data from the MEMS cap indicated they opened the medication bottle. However, there were many cases in which participants did not report suboptimal adherence when MEMS data indicated nonadherence (<100% or >100%).

It is important to note that the current study is underpowered for evaluating between-person relationships. Medication adherence is affected by a variety of factors that were not examined as part of the current project. One consideration is that sleep quality may account for a small portion of the variance in medication adherence at the between-person level, as was demonstrated by the SR adherence findings, which may be undetectable in an underpowered sample. Literature elucidating associations between medication adherence and HbA1c in well powered samples highlights that both objectively measured medication adherence and self-reported medication adherence are associated with glycemic control, though the magnitude of these relationships is modest (Gonzalez et al., 2013; Hood et al., 2009; Schectman et al., 2002). Future studies with larger sample sizes are necessary to continue to elucidate the relationship between medication adherence and sleep quality with the consideration that both SR adherence and objectively measured adherence are associated with other well-established diabetes outcomes.

Our findings also add to the literature on the methodological differences in medication adherence measurement. There is no measurement approach currently considered to be the "gold standard" for assessing adherence, as each approach presents different strengths and weaknesses (Hansen et al., 2009; Karve et al., 2008). Thus, a strength of the present study is the use of both

electronic monitoring and self-report. Benefits of MEMS electronic monitoring include the minimization of recall bias and social desirability (Cook et al., 2005; Gonzalez & Schneider, 2011). In contrast, benefits of self-report measures include cost effectiveness, ease of administration, and that they provide information about participant's subjective experiences (Farmer, 1999; Gonzalez & Schneider, 2011).

Multiple psychosocial factors have been shown to contribute to the observed differences between self-reported adherence and electronically measured adherence. One possible factor explaining a lack of concordance among SR adherence and MEMS adherence for some participants could be objective or subjective cognitive impairment (Shapira et al., 2022). A recent study by Shapira and colleagues (2022) found that memory complaints moderated the relationship between self-reported and electronically monitored medication adherence, whereby people with more memory complaints had less concordance between their self-reported and electronically monitored medication adherence in a sample of adults with T2D. Depressive symptoms have also been identified as contributory to disagreements between self-reported and electronically monitored adherence among adults with T2D (Hansen et al., 2009). The current findings provide support for the exploration of correlates of the disagreement between subjective and objective measures of adherence in relation to sleep and as potential moderators of these relationships.

Findings about the relationships among sleep quality and SR adherence were consistent with findings from the two previously identified studies in T2D that assessed between-person links between these variables. Marcum and colleagues (2013) found that the presence of sleep disturbances was associated with medication adherence based on a four-item self-report measure assessed as part of a observational study (Marcum et al., 2013). Telford and colleagues (2018)

identified that good sleepers relative to bad sleepers, as classified by the PSQI, were more likely to report medication nonadherence as was captured via self-report questionnaire (Telford et al., 2018). Our findings are also are congruent with those from one of few published studies using ambulatory methods to evaluate relationships among sleep quality and self-management behaviors in adults with T2D (Zhu et al., 2020a). Zhu and colleagues (2020) found that poor sleep quality captured by a daily sleep diary predicted uncontrolled eating and emotional eating on the next day across participants, but as was true for our study, this relationship was not observed within participants. While medication adherence differs from other aspects of disease self-management like diet and exercise, these are all behaviors that require significant self-regulatory resources, and are thus susceptible to self-regulatory failure when depleted (Castonguay et al., 2018; Muraven & Baumeister, 2000).

Analyses for our third study aim, which evaluated the link between intraindividual variability in sleep quality and medication adherence yielded nonsignificant results. Participants who had more variable sleep quality over the 14-day study period did not have increased odds of either self-reporting medication adherence or 100% adherence using MEMS bottle caps. The present study contributes to the extremely limited research on intra-individual variability in sleep in this population. When considered alongside the results from the one other identified study that examined intra-individual variability in sleep in relation a T2D outcome variable in which Zhu and colleagues (2020) identified that greater intra-individual variability in sleep duration and mid-sleep time was associated with higher A1C values, we consider that variability in subjective sleep quality may be less important than variability in objective sleep characteristics in relation to diabetes outcomes. It is also worth noting that medication adherence is a behavioral outcome, while A1C is a biological marker, although they are highly related. Further exploration of the

role of medication adherence as potential mediator, or moderator, in relationships between objective and subjective measures of sleep quality and glycemic control is important to parse out the connections among these variables.

**Limitations**

The study findings must be interpreted in the context of the study's limitations. There are several implications of the present study being a secondary analysis of a pilot study that was using already collected data. One significant limitation is that we do not have information on whether the participants were diagnosed with a comorbid sleep disorder. Obstructive sleep apnea and insomnia are prevalent in the T2D population, are well-known correlates of poor glycemic control and poor health outcomes and may account for poor sleep quality in a portion of our sample (Cespedes et al., 2016; Reutrakul & Mokhlesi, 2017). Due to the pilot study nature of the parent-study, there were several instances of technological failures with the MyDay application throughout the EMA study period, which resulted in some missing data.

Another limitation is the small sample size; while the sample size was sufficient for testing the main hypotheses, it is possible that significant relationships would be strengthened by a larger sample size. The study was underpowered for between-person relationships such as those looking at correlations among adherence variables. Having a longer data collection period for the EMA measures would allow for observation of potentially greater variability in adherence and in sleep quality to perhaps capture potential covariations over a longer period. An additional limitation is that we are unable to determine causality within the relationships.

A limitation specific to our understanding of medication adherence is that the question used to assess SR adherence did not specify which specific diabetes medication to consider when responding. Patients with T2D may be treated with multiple oral medications, so it is possible

that the EMA question and MEMS were not capturing adherence specific to the same medication. Further, while the benefits of self-report and electronically monitored medication adherence are described above, there are limitations to these methods. As has been highlighted throughout this study, self-report measures are subject to recall bias and other cognitive and contextual phenomena. While EMA methodology reduces this impact, it is still important to note when considering the findings. Additionally, a limitation of MEMS caps is that while they track when the cap has been removed from the medication bottle, they cannot record whether a participant took their medication as prescribed.

Generalizability of the study findings is another potential limitation. The population of our study consisted of majority Black, middle-aged, socioeconomically disadvantaged participants living in an urban community. Therefore, while this study adds important findings to the literature of underrepresented sociodemographic population, the findings cannot be generalized beyond this. Replicating this study within different cultural groups and among individuals of varying socioeconomic statuses is needed.

Additional limitations of this study relate to the completeness of the data. For the analyses evaluating basic psychometric properties of the EMA sleep quality survey using person-level data, there were responses missing for one item of the PSQI for 15/62 participants. Based on review of the physical study questionnaire, we surmised that the missingness was not related to the item context, but rather to the position of the question on the page. Sensitivity analyses were conducted using the raw data, as well as corrected data using an average of the available data at the component level for the missing item. Our analyses showed no differences between using the raw data and the corrected data. However, we cannot determine with certainty whether the data were missing at random. Another potential methodological limitation is that we dichotomized the

SR adherence variable due to data sparseness in one of the categories and skewness of the distribution, which may result in loss of power and loss of information about individual difference (MacCallum et al., 2002).

This study only examined self-reported sleep quality, which provides a limited perspective. Self-report measures of sleep quality capture the subjective experience of sleep but does not describe objective aspects of sleep and are influenced by recall bias and contextual factors. Substantial evidence indicates that objective measures of sleep, such as actigraphy and polysomnography, have only a weak to mode rate correlation with self-reported sleep quality measures including both retrospective self-reports and daily diaries (Baillet et al., 2016; Landry et al., 2015; Lauderdale et al., 2008; Matthews et al., 2018; Unruh et al., 2008). Using multiple methods to assess aspects of sleep such as sleep latency, total sleep time, and sleep efficiency would provide additional information on the aspects of sleep that are associated with medication adherence and should be integrated into future studies.

**Implications for Research**

Despite its limitations, the present study offers a critical contribution to the existing body of literature on sleep quality and medication adherence in adults with T2D. This is a novel study that extends the literature in many ways; to our knowledge this is the first that examined the between- and within-person relationships among sleep quality and medication adherence in T2D patients. Findings from the present study extend the literature from a methodological perspective by identifying that the 5-item EMA sleep quality survey is appropriate to use in future EMA studies in a racially diverse T2D sample. As the focus on sleep characteristics continues to grow in studies capturing daily experiences as it now widely recognized as both an essential patient reported outcome and a correlate of disease-related outcomes. This measure may reduce

participant burden by capturing a similar construct to the widely used and well validated PSQI, though dramatically reducing cognitive demand and time requirements so that sleep quality can easily be measured daily basis with the ease of a mobile phone application.

To date, much of the literature on T2D and sleep has focused on understanding the etiology of higher incidence rates of T2D among people with poor sleep and shared biological mechanisms, which is crucial for public health. Research extending into behavioral mechanisms is limited and has focused on other self-management and self-care behaviors such as physical activity and eating behaviors (Chasens et al., 2013; Chasens & Luyster, 2016; Chasens & Olshansky, 2006; Nefs et al., 2015; Wachid et al., 2019; Zhu et al., 2020a; Zhu et al., 2019; Zhu et al., 2018a). Our study built upon these existing studies that consistently identified between-person level associations between sleep and T2D self-management behaviors by identifying that this relationship remains true for medication adherence as well, which is another aspect of diabetes self-management that has consistently been problematic within this population. Between-person effects for the relationship between subjective sleep quality and subjective medication adherence suggest that people who generally have better sleep quality also generally report that they do a better job taking their medication.

Notably, this first study that evaluated the relationship between subjective sleep quality and medication adherence at the within-person level of analysis. It employed a relatively novel methodological approach as it captures these variables at the day-level within a naturalistic setting. Though we did not find significant relationships among sleep quality and medication adherence at the day-level of analysis, this adds a meaningful contribution to the literature by providing a foundation for which other studies may build upon this question. This also is the first study to examine intra-individual variability in sleep quality in the T2D population in relation to

medication adherence, which contributes significantly to a new and growing area of the literature on intra-individual variability in sleep in this population.

**Clinical Implications and Future Directions**

The results of the current study may guide clinical considerations related to sleep quality for adults with T2D. Our results provide preliminary evidence that improving sleep quality may have positive outcomes on improving medication adherence, and therefore may improve patient care efforts by providers. Physicians, health psychologists, and other healthcare professionals providing diabetes education should inform patients about the importance of good quality sleep in maintaining their self-management regimen, including adhering to their oral diabetes medications. Further, providers should inquire about patients sleep quality and provide appropriate interventions to improve sleep, such as cognitive behavioral therapy for insomnia (CBT-I), which is a gold standard treatment for sleep problems and has been shown to significantly improve sleep quality for those with diabetes (Kothari et al., 2021).

Findings from this secondary analysis highlight the need for further evaluation of the dynamic relationships among sleep quality and medication adherence. This present study provides support for looking more closely at dynamic relationships among sleep, medication adherence, and other psychosocial and contextual factors at the day-level to develop individually tailored interventions for improving quality of life and disease-specific outcomes for adults with T2D. One possible direction for future research is to examine lagged and curvilinear relationships among these variables, ideally over a longer EMA study period. This is based on evidence that the effects of changes in sleep characteristics on eating behaviors, another behavior that relies heavily on self-regulatory control, were observed to vary from week-to-week, but not from day-to-day (Parker et al., 2022). It is possible that there may be an accumulation effect of

poor sleep that was not observed by looking at the relationship between sleep quality and medication adherence on the same day. There is an overall need for greater understanding of how various aspects of sleep, both objectively and subjectively measured, are related to critical behaviors of diabetes self-management.

Despite the lack of significant findings at the within-person level, further exploration of individual time and/or context specific factors, these authors believe it is important to examine these dynamics further. Future research should focus on parsing out whether these relationships simply do not exist at the individual level, or whether there are factors we were not able to account for in the current project. Future research questions may focus on incorporating psychosocial variables that are already identified as having dynamic, temporal relationships with subjective sleep, such as affect, cognitive functioning, fatigue, and glycemic variability among others (Brandt et al., 2021; Mccrae et al., 2008; Patel et al., 2018; Zhu et al., 2019). EMA is a relatively novel methodological approach that allows for the examination of multiple sources of data. Our findings lend support to integrating objective sleep measurement tools like actigraphy into analyses to perhaps examine the agreement with EMA self-report sleep surveys and the relationships among measures of other sleep constructs with medication adherence. It would also be beneficial for future studies to track weekend versus weekday sleep data, as well as other potential anomalies or unexpected contextual circumstances to see whether changes are associated with medication adherence behaviors.

In sum, this project was a secondary analysis of a pilot study assessing the feasibility and acceptability of mobile phone application (MyDay) for capturing daily psychosocial and disease related symptoms in adults with T2D using ecological momentary assessment methods. Our

study findings provide novel insights into the ways in subjective sleep quality is related to medication adherence in a small, urban, middle-aged, mostly Black group of adults with T2D.

## Tables

Table 1
*Descriptive Statistics for Demographic and Follow-up Study Variables*

| Variable | | Mean (SD) or N (%) |
|---|---|---|
| Age | | 55.44 (9.90) |
| # of Observations per subject | | 12.74 (1.68) |
| Sex | | |
| | *Female* | 39 (63.9%) |
| | *Male* | 22 (36.1%) |
| Ethnicity | | |
| | Not Hispanic | 34 (55.7%) |
| | Hispanic | 22 (36.1%) |
| | No Answer | 5 (8.2) |
| Race | | |
| | White | 6 (9.8%) |
| | Native Hawaiian or Pacific Islander | 1 (1.6%) |
| | Black | 38 (62.3%) |
| | Asian | 2 (3.3%) |
| | Other | 3 (4.9%) |
| | Declined to answer | 11 (18.0) |
| HbA1c ($n$ = 60) | | 8.5 (2.4) |
| PSQI | | |
| | Global Score | 8.36 (4.82) |
| | Sleep Quality | 1.34 (0.96) |
| | Sleep Latency | 1.54 (1.07) |
| | Sleep Duration | 1.33 (1.06) |
| | Sleep Efficiency ($n$ = 60) | 1.22 (1.15) |
| | Sleep Disturbance | 1.67 (0.87) |
| | Use of Sleep Medication | 0.67 (1.12) |
| | Daytime Dysfunction | 0.72 (0.80) |

Note. Pittsburgh Sleep Quality Index (PSQI); glycosylated hemoglobin (HbA1c); standard deviation (SD)

Table 2

*Descriptive Statistics for Day-Level Main Study Variables*

| Variable | M(SD) | Min | Max |
|---|---|---|---|
| EMA Sleep Quality Total Score (*n* = 61) | 5.91(2.57) | 0.69 | 11.93 |
| MEMS Adherence Proportion 'Perfect' (*n* = 61) | 0.77(0.25) | 0.00 | 1.00 |
| SR Adherence Proportion 'Excellent' (*n* = 60) | 0.68(1.75) | 0.00 | 8.00 |

Note. Medication Event Monitoring System (MEMS); SR Adherence (EMA Self-Reported Adherence); Standard deviation (SD)

Table 3
*Sensitivity and Specificity of Self-Reported Adherence Relative to MEMS Adherence*

| | MEMS Adherent | MEMS Non-Adherent |
|---|---|---|
| SR Adherent | 48.8%* | 51.2% |
| SR Non-Adherent | 27.7% | 72.3%** |

Note. *Specificity; **Sensitivity

Table 4

*Inter-item Correlations Among EMA Sleep Quality Variables*

| | | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| 1 | Trouble falling asleep? | 1.00 | | | | |
| 2 | Do you feel well rested? | 0.55 | 1.00 | | | |
| 3 | Number of awakenings. | 0.48 | 0.37 | 1.00 | | |
| 4 | Rate how well you slept. | 0.63 | 0.74 | 0.50 | 1.00 | |
| 5 | How tired do you feel right now? | 0.43 | 0.77 | 0.28 | 0.69 | 1.00 |
| | *Mean* | 0.67 | 1.61 | 1.03 | 1.52 | 0.85 |
| | *SD* | 0.77 | 0.95 | 0.71 | 1.12 | 0.85 |
| | *Cronbach's Alpha* | 0.86 | | | | |
| | *Intraclass Correlation (ICC)* | 0.50 | | | | |

Note. SD = standard deviation. All correlations are statistically significant at $p < .05$.

Table 5
*Spearman Correlation Coefficients Between PSQI and EMA Daily Sleep Measure*

| | Variable | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | PSQI Sleep Quality | 1.00 | | | | | | | | |
| 2 | PSQI Sleep Latency | 0.38* | 1.00 | | | | | | | |
| 3 | PSQI Sleep Duration | 0.62** | 0.36* | 1.00 | | | | | | |
| 4 | PSQI Sleep Efficiency | 0.58** | 0.28* | 0.54** | 1.00 | | | | | |
| 5 | PSQI Sleep Disturbance | 0.33** | 0.46** | 0.34** | 0.22 | 1.00 | | | | |
| 6 | PSQI Sleep Medication | 0.18 | 0.30* | 0.17 | 0.11 | 0.25 | 1.00 | | | |
| 7 | PSQI Daytime Dysfunction | 0.48** | 0.45** | 0.35* | 0.28 | 0.51* | 0.41* | 1.00 | | |
| 8 | PSQI Global Score | 0.77** | 0.68** | 0.74** | 0.66* | 0.62* | 0.49* | 0.71* | 1.00 | |
| 9 | EMA Daily Sleep Quality | 0.58** | 0.47** | 0.50** | 0.54* | 0.39 | 0.16 | 0.47* | 0.69* | 1.00 |

Note. *$p < .05$, 2-tailed; **$p < .01$, 2-tailed; Pittsburgh Sleep Quality Index (PSQI)

Table 6

*Multilevel Logistic Regression Models (MLM) Where EMA Sleep Quality Predicted MEMS Adherence*

| | Unconditional Model | | | | | | Model 1a | | | | | | Model 1b | | | | | | Model 1c | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Fixed Effects* | Est | SE | Test Stat | p | OR | 95% CI | Est | SE | Test Stat | p | OR | 95% CI | Est | SE | Test Stat | P | OR | 95% CI | Est | SE | Test Stat | P | OR | 95% CI |
| Intercept | 1.56 | 0.21 | 7.37 | <.001 | -- | -- | 0.90 | 0.54 | 1.68 | 0.4 | -- | -- | 0.90 | 0.54 | 1.68 | 0.09 | -- | -- | 0.86 | 0.58 | 1.48 | 0.14 | -- | -- |
| EMA Sleep Quality (Between-Person) | | | | | | | 0.11 | 0.08 | 1.34 | 0.18 | 1.12 | [0.95, 1.32] | 0.11 | 0.08 | 1.34 | 0.18 | 1.12 | [0.95, 1.32] | 0.11 | 0.09 | 1.25 | 0.21 | 1.12 | [0.94, 1.32] |
| EMA Sleep Quality (Within-Person) | | | | | | | | | | | | | 0.01 | 0.04 | 0.23 | 0.82 | 1.01 | [0.93, 1.09] | 0.01 | 0.04 | 0.23 | 0.82 | 1.01 | [0.93, 1.09] |
| Sleep Quality (Variability) | | | | | | | | | | | | | | | | | | | 0.01 | 0.05 | 0.24 | 0.81 | 1.01 | [0.92, 1.12] |
| *Random Effects:* | | | | | | | | | | | | | | | | | | | | | | | | |
| Intercept Variance | 2 | 0.54 | 3.73 | <.001 | -- | -- | 1.98 | 0.54 | 3.67 | <.001 | -- | -- | 1.98 | 0.54 | 3.67 | <.001 | -- | -- | 2.04 | 0.56 | 3.66 | <.001 | -- | -- |

Note. Est = estimate. SE = standard error, Test Stat = test statistic. p = p-value. OR = odds ratio. 95% CI = 95% confidence interval. All models: 758 observations

Table 7
*Multilevel Logistic Regression Models (MLM) Where EMA Sleep Quality Predicted SR Adherence*

| | Unconditional Model | | | | | | Model 1a | | | | | | Model 1b | | | | | | Model 1c | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Fixed Effects* | Est. | SE | Test Stat | p | OR | 95% CI | Est | SE | Test Stat | p | OR | 95% CI | Est | SE | Test Stat | p | OR | 95% CI | Est | SE | Test Stat | p | OR | 95% CI |
| Intercept | 1.174 | 0.3 | 3.87 | <.001 | -- | -- | 3.12 | 0.78 | 4.01 | <.001 | -- | -- | 3.12 | 0.78 | 4.01 | <.001 | -- | -- | 3.06 | 0.85 | 3.61 | <.001 | -- | -- |
| Sleep Quality (Between-Person) | | | | | | | -0.33 | 0.12 | -2.75 | ***0.01*** | 0.72 | [0.57, 0.91] | -0.33 | 0.12 | -2.74 | ***0.01*** | 0.72 | [0.57, 0.91] | -0.33 | 0.12 | -2.73 | ***0.01*** | 0.72 | [0.57, 0.91] |
| Sleep Quality (Within-Person) | | | | | | | | | | | | | -0.03 | 0.04 | -0.66 | 0.51 | 0.97 | [0.89, 1.06] | -0.03 | 0.04 | -0.66 | 0.51 | 0.97 | [0.89, 1.06] |
| Sleep Quality (Variability) | | | | | | | | | | | | | | | | | | | 0.02 | 0.07 | 0.25 | 0.80 | 1.02 | [0.89, 1.16] |
| *Random Effects:* | | | | | | | | | | | | | | | | | | | | | | | | |
| Intercept Variance | 4.41 | 1.09 | 4.06 | <.001 | -- | -- | 4.02 | 1.01 | 3.98 | <.001 | -- | -- | 4.04 | 1.01 | 3.98 | <.001 | -- | -- | 4.14 | 1.05 | 4.00 | <.001 | -- | -- |

Note. Est = estimate. SE = standard error, Test Stat = test statistic. P = p-value. OR = odds ratio. 95% CI = 95% confidence interval. 652 total observations in all models

## Figures

Figure 1

How Diabetes Management Related Tasks Influence Self-Regulation Resources and PA Among T2D Adults (Castonguay, Miquelon, & Boudreau, 2018)

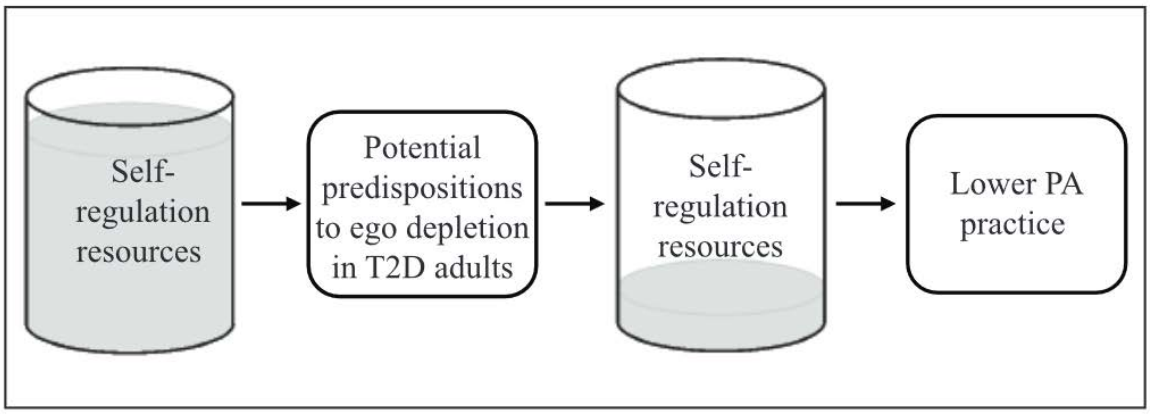
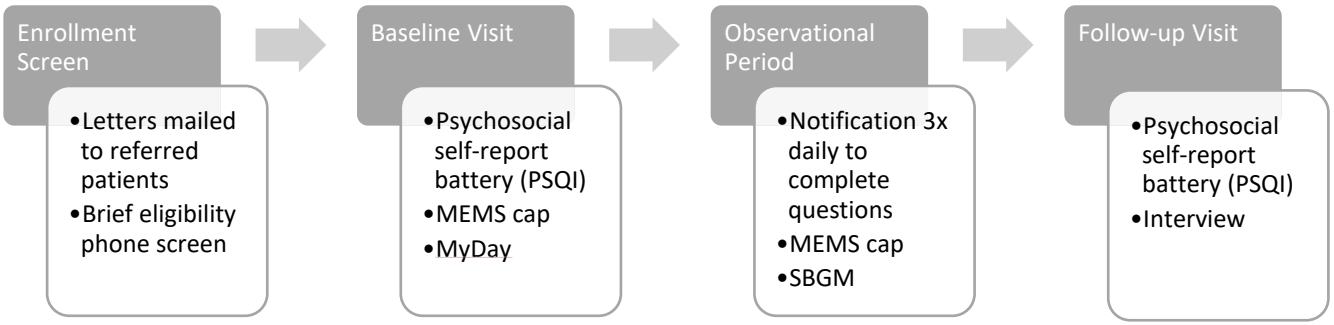



**Figure 1.** How diabetes management related tasks influence self-regulation resources and PA practice among T2D adults.

Figure 2

*EMA Parent Study Flow*



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# Appendices

## Appendix A. Supplemental Tables and Figures

Supplemental Table 1

*Normality Statistics for Continuous Main Study Variables and Continuous Demographic and Disease Specific Variables*

| Variable (n) | Skewness | | Kurtosis | | Shapiro Wilk Test Statistic | | |
|---|---|---|---|---|---|---|---|
| | Statistic | SE | Statistic | SE | Statistic | df | p |
| EMA Daily Sleep Quality | .481 | .102 | -.232 | .203 | .971 | 575 | <.001 |
| PSQI Global Score | .286 | .102 | -.622 | .203 | .967 | 575 | <.001 |
| PSQI Sleep Quality | .271 | .102 | -.883 | .203 | .864 | 575 | <.001 |
| PSQI Sleep Latency | -.067 | .107 | -1.27 | .203 | .865 | 575 | <.001 |
| PSQI Sleep Duration | .491 | .102 | -1.04 | .203 | .833 | 575 | <.001 |
| PSQI Sleep Efficiency | .569 | .102 | -1.15 | .203 | .798 | 575 | <.001 |
| PSQI Sleep Disturbance | -.144 | .102 | -.815 | .203 | .864 | 575 | <.001 |
| PSQI Sleep Medication | 1.41 | .102 | .198 | .203 | .567 | 575 | <.001 |
| PSQI Daytime Dysfunction | .503 | .102 | -.897 | .203 | .776 | 575 | <.001 |
| Age | -.213 | .086 | .374 | .172 | .966 | 809 | <.001 |
| HbA1c | .963 | .087 | -.068 | .173 | .885 | 795 | <.001 |

Note. Pittsburgh Sleep Quality Index (PSQI); glycosylated hemoglobin (HbA1c) standard error (SE); degrees of freedom (df); n = 61

Supplemental Table 2

*Spearman Correlations Between Original PSQI Variables and Daily Sleep Quality*

| | Variable | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | PSQI Sleep Quality | 1.00 | | | | | | | | |
| 2 | PSQI Sleep Latency | 0.38* | 1.00 | | | | | | | |
| 3 | PSQI Sleep Duration | 0.62** | 0.36* | 1.00 | | | | | | |
| 4 | PSQI Sleep Efficiency | 0.58** | 0.28* | 0.54** | 1.00 | | | | | |
| 5 | PSQI Sleep Disturbance (n=45) | 0.30* | 0.47** | 0.32* | 0.26 | 1.00 | | | | |
| 6 | PSQI Sleep Medication | 0.18 | 0.30* | 0.17 | 0.11 | 0.24 | 1.00 | | | |
| 7 | PSQI Daytime Dysfunction | 0.48** | 0.45** | 0.35* | 0.28 | 0.48** | 0.41* | 1.00 | | |
| 8 | PSQI Global Score (n=45) | 0.73** | 0.71** | 0.69** | 0.67** | 0.64* | 0.50** | 0.73** | 1.00 | |
| 9 | EMA Daily Sleep Quality | 0.58** | 0.47** | 0.50** | 0.54* | 0.49** | 0.16 | 0.47* | 0.77** | 1.00 |

Note. *$p < .05$, 2-tailed; **$p < .01$, 2-tailed; Pittsburgh Sleep Quality Index (PSQI)

Supplemental Table 3

*Descriptive Statistics of Self-Reported Medication Adherence Variables Used in Sensitivity Analyses*

| Variable | M(SD) | Min | Max |
|---|---|---|---|
| SR Adherence* Proportion 'Excellent' | 0.68(0.35) | 0.00 | 1.00 |
| SR Adherence** Proportion 'Excellent' and 'Very Good' | 0.91(0.19) | 0.00 | 1.00 |
| SR Adherence Raw*** | 1.05(0.79) | 0.00 | 4.00 |

Note. *Self-Reported Adherence variable used in main analyses dichotomized where 0 = 'very good,' 'good,' 'fair, 'and 'poor' and 1 = 'excellent;' **Self-reported Adherence variable used in sensitivity analyses dichotomized where 0 = 'good,' 'fair,' and 'poor,' and 1 = 'excellent' and 'very good;' ***Self-Reported Adherence Raw variable was original categorical variable where 0 = 'excellent,' 1 = 'very good,' 2 = 'good,' 3 = 'fair,' and 4 = 'poor,' used in sensitivity analyses

Supplemental Table 4

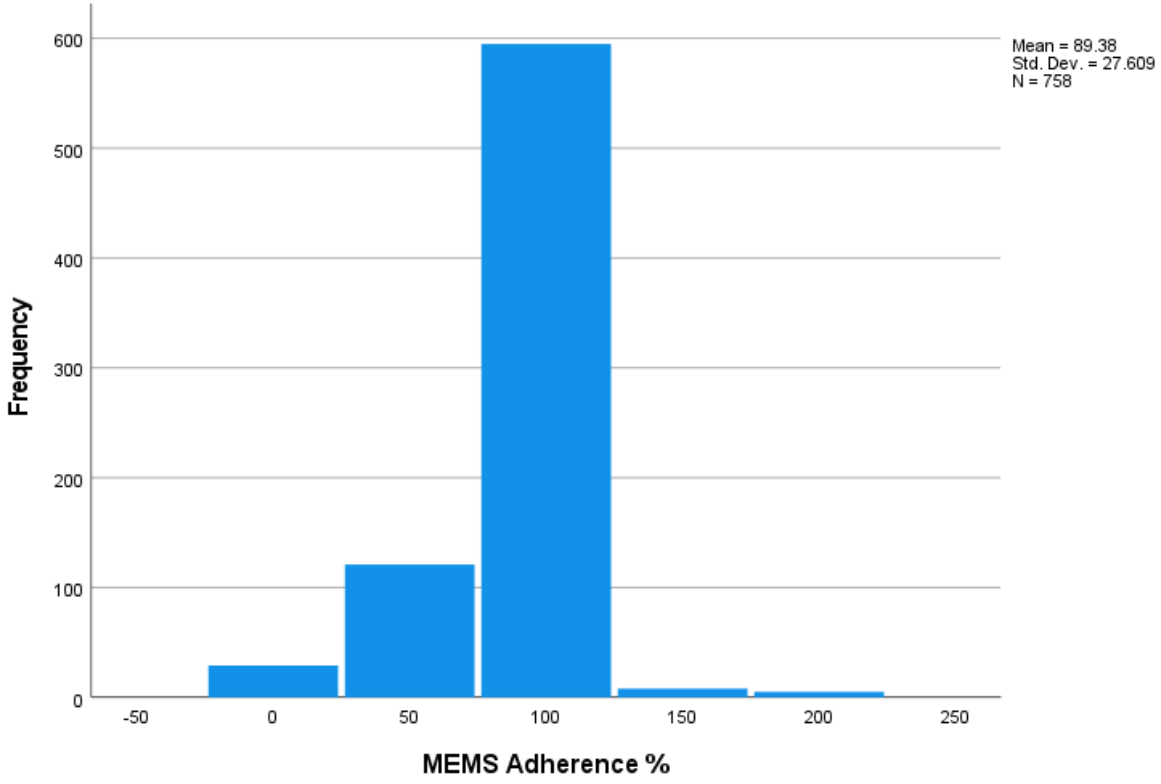
*Multilevel Logistic Regression Models (MLM) Where EMA Sleep Quality Predicted SR Adherence Dichotomized at "Very Good"*

| | Unconditional Model | | | | | | Model 1a | | | | | | Model 1b | | | | | | Model 1c | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Fixed Effects* | Est. | SE | Test Stat | p | OR | 95% CI | Est | SE | Test Stat | p | OR | 95% CI | Est | SE | Test Stat | p | OR | 95% CI | Est | SE | Test Stat | p | OR | 95% CI |
| Intercept | 2.87 | 0.81 | 3.54 | <.001 | -- | -- | 4.48 | 0.78 | 5.44 | <.001 | -- | -- | 4.48 | 0.82 | 5.44 | <.001 | -- | -- | 4.59 | 0.90 | 5.10 | <.001 | -- | -- |
| Sleep Quality (Between-Person) | | | | | | | -0.25 | 0.12 | -2.08 | ***0.04*** | 0.78 | [0.62, 0.99] | -0.25 | 0.12 | -2.08 | ***0.04*** | 0.78 | [0.62, 0.99] | -0.24 | 0.12 | -1.99 | ***0.047*** | 0.78 | [0.62, 1.00] |
| Sleep Quality (Within-Person) | | | | | | | | | | | | | -0.01 | 0.06 | 0.22 | 0.83 | 1.01 | [0.90, 1.15] | -0.01 | 0.06 | 0.22 | 0.82 | 1.01 | [0.90, 1.15] |
| Sleep Quality (Variability) | | | | | | | | | | | | | | | | | | | -0.17 | 0.07 | -0.26 | 0.79 | 0.98 | [0.86, 1.12] |
| *Random Effects:* | | | | | | | | | | | | | | | | | | | | | | | | |
| Intercept Variance | 4.41 | 1.09 | 4.06 | <.001 | -- | -- | 4.02 | 1.01 | 3.98 | <.001 | -- | -- | 4.04 | 1.01 | 3.98 | <.001 | -- | -- | 4.14 | 1.05 | 4.00 | <.001 | -- | -- |

Note. Est = estimate. SE = standard error, Test Stat = test statistic. P = p-value. OR = odds ratio. 95% CI = 95% confidence interval. 652 total observations in all models

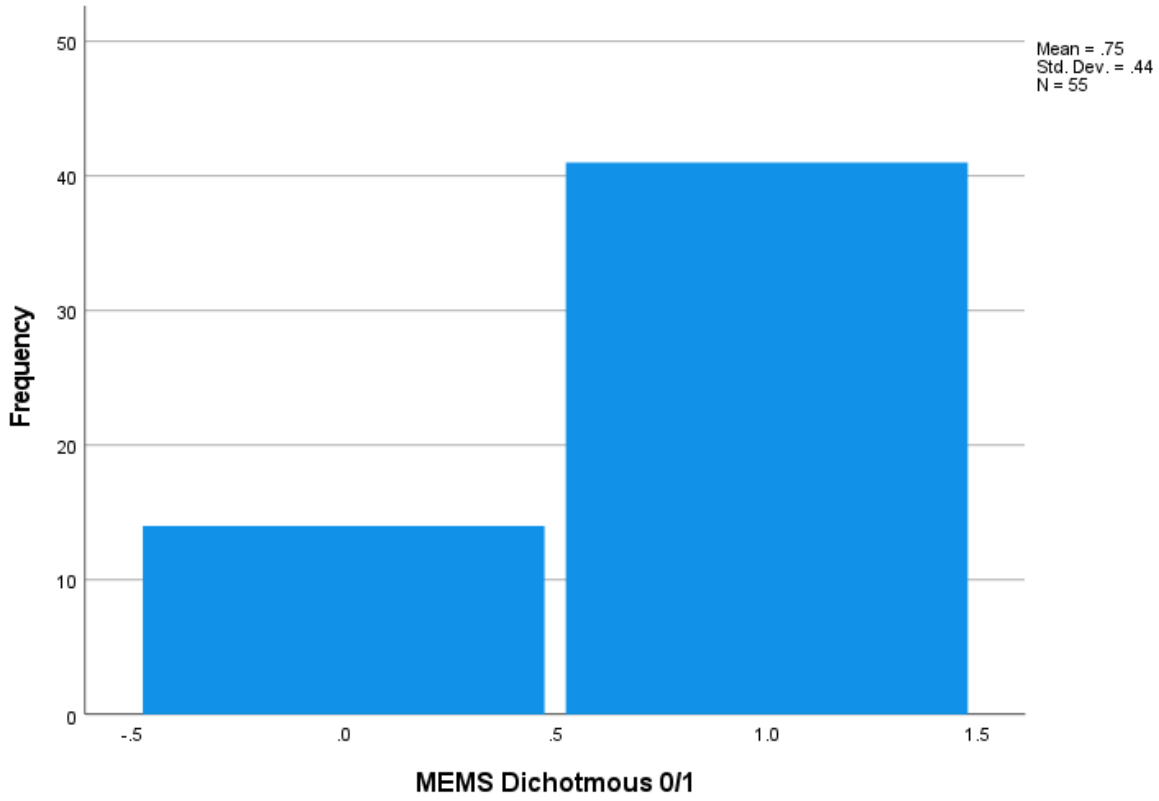
Supplemental Figure 1

*Histogram of MEMS Adherence by Percent Variable Distribution*



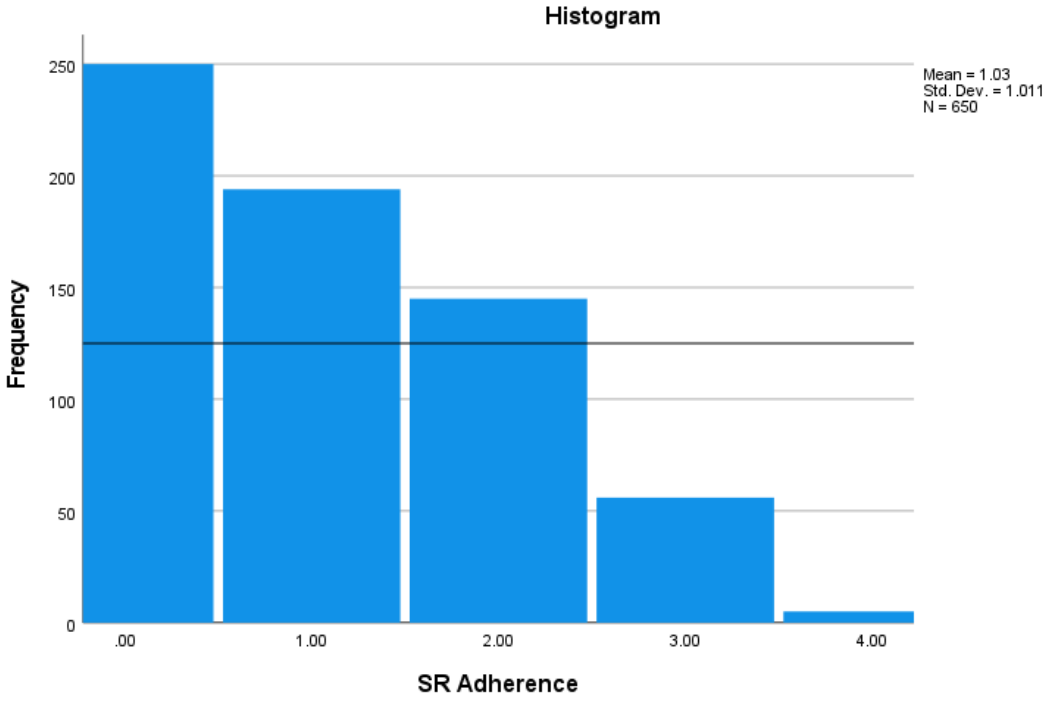
Supplemental Figure 2

*Histogram of Dichotomous MEMS Adherence Variable Distribution*



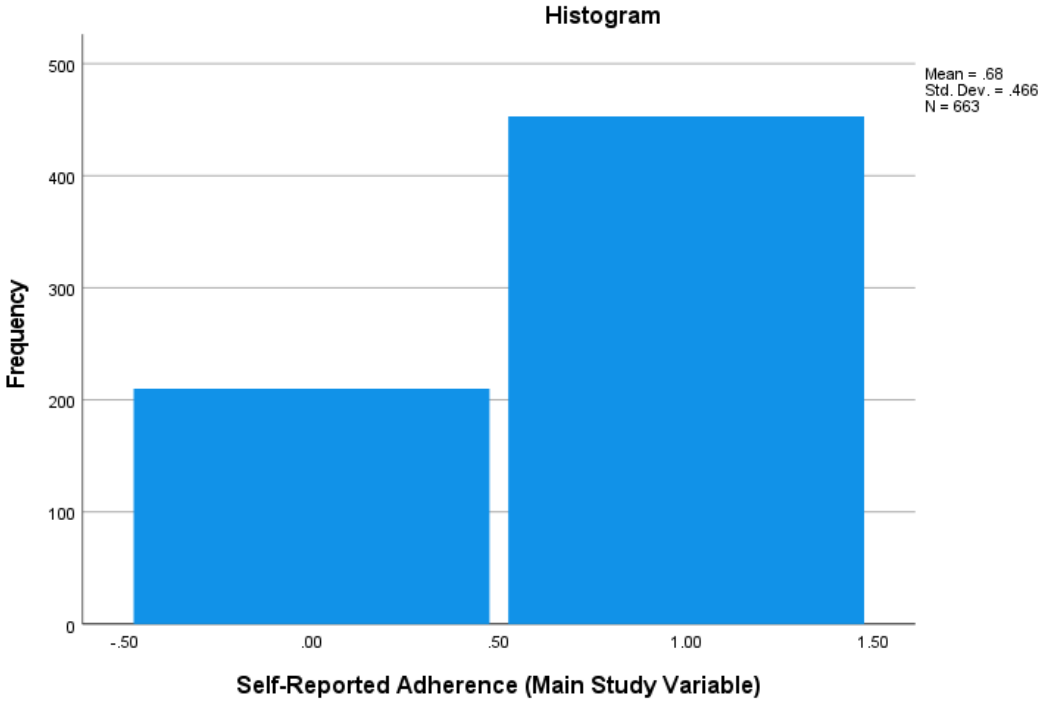
Supplemental Figure 3

*Histogram of Raw Self-Reported Adherence Variable Distribution*



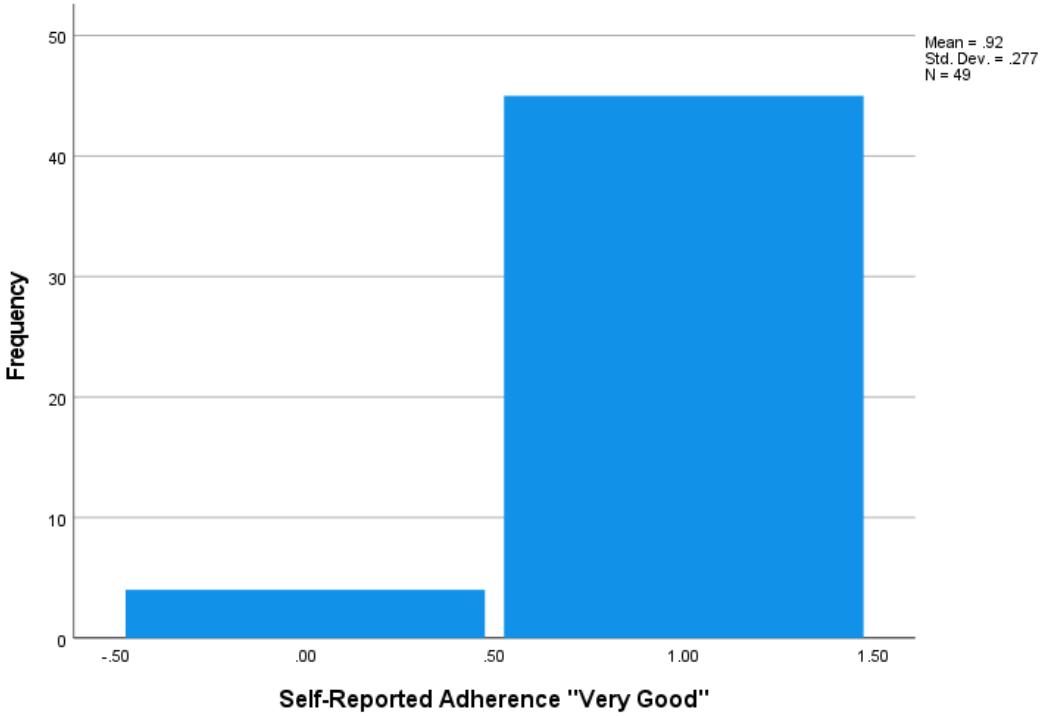
Supplemental Figure 4

*Distribution of Self-Reported Adherence Variable Used in Main Analyses*



Supplemental Figure 5

*Distribution of Self-Reported Adherence Variable "Very Good" Cut Point*



## Appendix B

Daily Questions as Appearing in MyDay Mobile Application

5-Item EMA Daily Sleep Survey

3. **Question Set: Sleep (Morning Only)** **[5 items]**
    a. ABOUT LAST NIGHT – Trouble falling asleep?
        i. Not At All
        ii. A Little
        iii. Quite A Bit
        iv. Extremely
    b. ABOUT LAST NIGHT – Do you feel well rested?
        i. Not At All
        ii. A Little
        iii. Quite A Bit
        iv. Extremely
    c. ABOUT LAST NIGHT – Number of awakenings?
        i. None
        ii. 1-2
        iii. 3-5
        iv. >5

    d. ABOUT LAST NIGHT – Rate how well you slept
        i. Very well
        ii. Well
        iii. Okay
        iv. Poorly
        v. Very Poorly
    e. How tired do you feel RIGHT NOW?
        i. Not At All
        ii. A Little
        iii. Quite A Bit
        iv. Extremely

EMA Self-Reported Medication Adherence Item

c. **Question Set: End of Day [4 items]**
    a. TODAY, how did you do at Taking your Diabetes Medicines?
        i. Excellent
        ii. Very Good
        iii. Good
        iv. Fair
        v. Poor

# Appendix C

## PITTSBURGH SLEEP QUALITY INDEX (PSQI)

**INSTRUCTIONS:** The following questions relate to your usual sleep habits since your last visit only. Your answers should indicate the most accurate reply for the majority of days and nights since your last visit. Please answer all questions.

1. Since your last visit, when have you usually gone to bed at night?

   USUAL BED TIME _____

2. Since your last visit, how long (in minutes) has it usually take you to fall asleep each night?

   NUMBER OF MINUTES _____

3. Since your last visit, when have you usually gotten up in the morning?

   USUAL GETTING UP TIME _____

4. Since your last visit, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed.)

   HOURS OF SLEEP PER NIGHT _____

**INSTRUCTIONS:** For each of the remaining questions, check the one best response. Please answer all questions.

5. Since your last visit, how often have you had trouble sleeping because you...

| | Not since your last visit | Less than once a week | Once or twice a week | Three or more times a week |
|---|---|---|---|---|
| (a) ...cannot get to sleep within 30 minutes | ☐ | ☐ | ☐ | ☐ |
| (b) ...wake up in the middle of the night or early morning | ☐ | ☐ | ☐ | ☐ |
| (c) ...have to get up to use the bathroom | ☐ | ☐ | ☐ | ☐ |
| (d ...cannot breathe comfortably | ☐ | ☐ | ☐ | ☐ |
| (e) ...cough or snore loudly | ☐ | ☐ | ☐ | ☐ |
| (f) ...feel too cold | ☐ | ☐ | ☐ | ☐ |
| (g) ...feel too hot | ☐ | ☐ | ☐ | ☐ |
| (h) ...had bad dreams | ☐ | ☐ | ☐ | ☐ |
| (i) ...have pain | ☐ | ☐ | ☐ | ☐ |
| (j) Other reason(s), please describe _____ _____ | | | | |
| How often since your last visit have you had trouble sleeping because of this? | ☐ | ☐ | ☐ | ☐ |

| | Very good | Fairly good | Fairly bad | very bad |
|---|---|---|---|---|
| 6. Since your last visit, how would you rate your sleep quality overall? | ☐ | ☐ | ☐ | ☐ |

| | Not during the past month | Less than once a week | Once or twice a week | Three or more times a week |
|---|---|---|---|---|
| 7. Since your last visit, how often have you taken medicine (prescribed or "over the counter") to help you sleep? | ☐ | ☐ | ☐ | ☐ |
| 8. Since your last visit, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity? | ☐ | ☐ | ☐ | ☐ |

| | No problem at all | Only a very slight problem | Somewhat of a problem | A very big problem |
|---|---|---|---|---|
| 9. Since your last visit, how much of a problem has it been for you to keep up enough enthusiasm to get things done? | ☐ | ☐ | ☐ | ☐ |

| | No bed partner or roommate | Partner/ roommate in other room | Partner in same room, but not same bed | Partner in same bed |
|---|---|---|---|---|
| 10. Since your last visit, how much of a problem has it been for you to keep up enough enthusiasm to get things done? | ☐ | ☐ | ☐ | ☐ |

If you have a roommate or bed partner, ask him/her how often since your last visit you have had...

| | Not since your last visit | Less than once a week | Once or twice a week | Three or more times a week |
|---|---|---|---|---|
| (a) ...loud snoring | ☐ | ☐ | ☐ | ☐ |
| (b) ...long pauses between breaths while asleep | ☐ | ☐ | ☐ | ☐ |
| (c) ...legs twitching or jerking while you sleep | ☐ | ☐ | ☐ | ☐ |
| (d) ...episodes of disorientation or confusion during sleep | ☐ | ☐ | ☐ | ☐ |
| (e) Other restlessness while you sleep; please describe | ☐ | ☐ | ☐ | ☐ |

_____

_____

**SCORING INSTRUCTIONS FOR THE PITTSBURGH SLEEP QUALITY INDEX:**

The Pittsburgh Sleep Quality Index (PSQI) contains 19 self-rated questions and 5 questions rated by the bed partner or roommate (if one is available). Only self-rated questions are included in the scoring. The 19 self-rated items are combined to form seven "component" scores, each of which has a range of 0-3 points. In all cases, a score of "0" indicates no difficulty, while a score of "3" indicates severe difficulty. The seven component scores are then added to yield one "global" score, with a range of 0-21 points, "0" indicating no difficulty and "21 " indicating severe difficulties in all areas.

Scoring proceeds as follows:

**Component 1: Subjective sleep quality**

Examine question #6, and assign scores as follows:

| Response | Component 1 score |
|---|---|
| "Very good" | 0 |
| "Fairly good" | 1 |
| "Fairly bad" | 2 |
| "Very bad" | 3 |

***Component 1 score:_____***

**Component 2: Sleep latency**

1. Examine question #2, and assign scores as follows:

| Respo\nse | Score |
|---|---|
| ≤15 minutes | 0 |
| 16-30 minutes | 1 |
| 31-60 minutes | 2 |
| > 60 minutes | 3 |

*Question #2 score:* _____

2. Examine question #5a, and assign scores as follows:

| Response | Score |
|---|---|
| Not during the past month | 0 |
| Less than once a week | 1 |
| Once or twice a week | 2 |
| Three or more times a week | 3 |

*Question #5a score:* _____

3. Add #2 score and #5a score

*Sum of #2 and #5a:* _____

4. Assign component 2 score as follows:

| Sum of #2 and #5a | Component 2 score |
|---|---|
| 0 | 0 |
| 1-2 | 1 |
| 3-4 | 2 |
| 5-6 | 3 |

***Component £ score:_____***

### Component 3: Sleep duration

Examine question #4, and assign scores as follows:

| Response | Component 3 score |
|---|---|
| > 7 hours | 0 |
| 6-7 hours | 1 |
| 5-6 hours | 2 |
| < 5 hours | 3 |

***Component 3 score:*** _____

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### Component 4: Habitual sleep efficiency

1. Write the number of hours slept (question #4) here: _____
2. Calculate the number of hours spent in bed:

   Getting up time (question #3): _____

   Bedtime (question #1): _____

   _____

   *Number of hours spent in bed:* _____

3. Calculate habitual sleep efficiency as follows:

   (Number of hours slept/Number of hours spent in bed) X 100 = Habitual sleep efficiency (%)

   (_____/_____) X 100 = %

4. Assign component 4 score as follows:

| Habitual sleep efficiency % | Component 4 score |
|---|---|
| > 85% | 0 |
| 75-84% | 1 |
| 65-74% | 2 |
| < 65% | 3 |

***Component 4 score:*** _____

## Component 5: Step disturbances

1. Examine questions #5b-5j, and assign scores for each question as follows:

| Response | Score |
|---|---|
| Not during the past month | 0 |
| Less than once a week | 1 |
| Once or twice a week | 2 |
| Three or more times a week | 3 |

*5b score:* _____

*5c score:* _____

*5d score:* _____

*5e score:* _____

*5f score:* _____

*5g score:* _____

*5h score:* _____

*5i score:* _____

*5j score:* _____

2. Add the scores for questions #5b-5j:

*Sum of #5b-5j:* _____

3. Assign component 5 score as follows:

| Sum of #5b-5j | Component 5 score |
|---|---|
| 0 | 0 |
| 1-9 | 1 |
| 10-18-4 | 2 |
| 19-27 | 3 |

***Component 5 score:*** _____

## Component 6: Use of sleeping medication

Examine question #7 and assign scores as follows:

| Response | Component 6 score |
|---|---|
| Not during the past month | 0 |
| Less than once a week | 1 |
| Once or twice a week | 2 |
| Three or more times a week | 3 |

***Component 6 score:*** _____

## Component 7: Daytime dysfunction

1. Examine question #8, and assign scores as follows:

| Response | Score |
|---|---|
| Never | 0 |
| Once or twice | 1 |
| Once or twice each week | 2 |
| Three or more times each week | 3 |

*Question#8 score:* _____

2. Examine question #9, and assign scores as follows:

| Response | Score |
|---|---|
| No problem at all | 0 |
| Only a very slight problem | 1 |
| Somewhat of a problem | 2 |
| A very big problem | 3 |

*Question #9 score:* _____

3. Add the scores for question #8 and #9:

*Sum of #8 and #9:* _____

4. Assign component 7 score as follows:

| Sum of #8 and #9 | Component 7 score |
|---|---|
| 0 | 0 |
| 1-2 | 1 |
| 3-4 | 2 |
| 5-6 | 3 |

***Component 7 score:*** _____

## Global PSQI Score

Add the seven component scores together:

***Global PSQI Score:*** _____