Relationships Between Sleep and Self-Care in Type 2 Diabetes: An Ecological Momentary Perspective

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LIST OF ABBREVIATIONS

ANOVA	Analysis of Variance
ADA	American Diabetes Association
BMI	Body Mass Index
CPAP	Continuous Positive Airway Pressure
CSD	Consensus Sleep Diary
CSD-M	Consensus Sleep Diary for Morning
DDS	Diabetes Distress Scale
DES-SF	Diabetes Empowerment Scale-Short Form
DSC	Diabetes Symptom Checklist
DSMQ-R	Diabetes Self-Management Questionnaire-Revised
EES	Epworth Sleepiness Scale
EMA	Ecological Momentary Assessment
HPLC	High-Performance Liquid Chromatography
IPAQ-S	International Physical Activity Questionnaire-Short
MET	Metabolic Equivalent
MMAS-8	Morisky Medication Adherence Scale-8
MVPA	Moderate-to-Vigorous Physical Activity
OR	Odds Ratio
PAID	Problem Areas in Diabetes Scale
PI	Principle Investigator
PSG	Polysomnography

LIST OF ABBREVIATIONS (continued)

PSQI	Pittsburgh Sleep Quality Index
RR	Relative Risk
SCI-R	Self-Care Inventory-Revised
SDSCA	Summary of Diabetes Self-Care Activities
SE	Sleep Efficiency
SOL	Sleep Onset Latency
TFEQ	Three-Factor Eating Questionnaire
TST	Total Sleep Time
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
UIC	University of Illinois at Chicago

SUMMARY

Sleep disturbance is widespread, yet is an often ignored complaint among people with diabetes. Sleep disturbance has been related to impairment in optimal glycemic control, which is the key to preventing or delaying chronic diabetic complications. The foundation for optimal glycemic control lies in daily, lifelong, and complex self-care, including regular physical activity, healthy eating behavior, and medication adherence. Several factors have been related to self-care including self-efficacy, distress, fatigue, and daytime sleepiness. Sleep disturbance has been an under-examined risk factor for poor diabetes self-care. Both sleep and self-care are complex behaviors that carry daily fluctuations and contextual variations. Yet, these everyday behaviors are rarely fully captured in current diabetes research that collected cross-sectional data. There is a need to examine whether sleep disturbance is temporally related to diabetes self-care using longitudinal data in the real-world setting.

A correlational, longitudinal study was conducted to examine the temporal relationships between sleep (subjective and objective) and self-care (overall self-care, physical activity, eating behavior, and medication adherence), controlling for covariates. The covariates included age, gender, body mass index, diabetes duration, self-efficacy, distress, fatigue, and daytime sleepiness. A total of 64 adults (51.6% women) between the ages of 50-78 years with type 2 diabetes were recruited for the baseline assessment, and 59 were included in the 8-day assessment. Participants were excluded from the study if they were shift-workers or reported a diagnosis of insomnia, depression, anxiety, uncontrolled pain, or other conditions known to impair their sleep and self-care.

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SUMMARY (continued)

Participants were recruited through flyers posted on campus and throughout the neighborhood. Electronic recruitment flyers were also posted via campus mailing list and online platforms. Baseline data were collected at the University of Illinois at Chicago, College of Nursing diabetes research laboratory. During the baseline visit, health-related data were collected (e.g., fingerstick capillary Hemoglobin A1C, blood pressure, height, and weight). Participants completed a battery of validated instruments to assess their sleep, self-care, self-efficacy, distress, fatigue, and daytime sleepiness. Participants were trained on how to complete the sleep and self-care diaries. They were sent home with a wrist-worn ActiGraph to assess their objective sleep and physical activity. During the following 8-day period, participants were instructed to wear the ActiGraph at all times and fill out electronic daily diaries. Participants returned the ActiGraph after the 8-day assessment. Data were analyzed using multiple linear regression analyses and mixed-effect models.

Participants demonstrated good adherence to the study protocol (missing longitudinal data 1.0%-6.8%). Of the participants, 54.7% had sleep disturbance as measured by the Pittsburgh Sleep Quality Index. We found that that subjective better sleep quality was related to better self-care. The final regression model revealed that six variables explained 51% of the variation in overall self-care. Sleep quality was a strong predictor of overall self-care. The effect of subjective sleep quality on self-care was smaller than that of the commonly reported diabetes distress but larger than that of daytime sleepiness. No strong evidence supported the significant relationship between

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SUMMARY (continued)

sleep and physical activity, except that total sleep time was negatively related to lightintensity physical activity the following day. Analyses using cross-sectional data did not reveal significant relationships between sleep and eating behavior. However, when longitudinal data were used, eating behavior was related to various sleep parameters (e.g., total sleep time, sleep efficiency, and sleep latency). Based on the mixed-effect models, although sleep alone did not predict eating behavior the following day, its interaction with morning fatigue was a significant predictor. These findings suggested that the effect of sleep on eating behavior (e.g., conscious restriction on eating, loss of control over eating, and eating in response of emotional cues) was different for people with different levels of fatigue. Sleep was not associated with medication adherence.

Sleep disturbance in people with diabetes is common and has been underexamined. Findings from this study demonstrated significant relationships between sleep and self-care, particularly eating behavior. Sleep assessment and intervention should be further highlighted as part of the overall diabetes management by the American Diabetes Association diabetes care guideline. In clinical practice, diabetes health providers are encouraged to include comprehensive sleep assessment and sleep-related education. Sleep and fatigue may interact with each other, affecting daytime self-care, such as eating behavior. A detailed evaluation of diabetes symptoms (e.g., fatigue) should also be considered when developing sleep-related interventions. Future studies are needed to further examine the relationships between sleep and selfcare by including fatigue as a mediator or moderator.

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I. INTRODUCTION

A. <u>Background</u>

Diabetes is a major, growing, and costly public health problem. Worldwide, 425 million people were diagnosed with diabetes in 2017.¹ Approximately 12.2% of U.S. adults have been diagnosed with diabetes, and 90% to 95% of them were type 2 diabetes mellitus (T2DM). The prevalence of diabetes in older adults was even higher: 12.7% in those aged between 45 and 64 years; 20.8% in those aged 65 years or over.² Diabetes is the 7th leading cause of death.¹ Every 8 seconds, 1 person dies from diabetes, resulting in 4.0 million deaths in 2017.¹ Diabetes has brought tremendous economic burdens. The direct costs for people with diabetes are estimated to be 2.3 times higher compared to their non-diabetic counterparts.³ In 2017, around 727 billion was spent on diabetes, and the U.S. was the top country for total healthcare expenditure on diabetes (348 billion).¹

Multiple physiological and behavioral factors are considered responsible for the drastic increase in diabetes prevalence, including sleep disturbance.⁴ Unlike sleep disorder (e.g., sleep apnea or insomnia), which requires strict criteria to establish the diagnosis, sleep disturbance is a symptom that might be experienced by anyone. Sleep disturbance in people with diabetes is characterized by impaired sleep quality (e.g., frequent nocturnal awakenings) and/or abnormal sleep duration.⁵ Evidence suggests that sleep disturbance is a risk factor for T2DM.⁶⁻⁹ In people who are diagnosed with T2DM, the prevalence of sleep disturbance ranges from 42% to 76.8%.¹⁰⁻¹² In older adults, sleep disturbance is even more frequent due to physiological changes and age-

related comorbidities.^{13, 14} Diabetes alone is a leading cause of mortality, but when coupled with sleep disturbance, it may pose greater threats to health.

B. <u>Problem Statement</u>

Optimal glycemic control is key to preventing or delaying chronic diabetic complications.¹⁵ A national survey suggests 41.2% adults with diabetes have poor glycemic control,¹⁶ which may lead to complications such as early disability, amputation, and kidney failure. These complications are estimated accounting for 53% of the total amount of diabetes-related expenditure in the U.S.¹⁷ The foundation for optimal glycemic control lies is daily, lifelong, and complex self-care.

Diabetes self-care consists of daily regimen tasks that an individual performs to manage diabetes,¹⁸ such as regular physical activity, healthy eating behavior, and medication adherence. Physical activity is any bodily movements that increase energy use, including planned or incidental.¹⁹ The American Diabetes Association (ADA) has recommended the adoption and maintenance of physical activity to be prescribed to all individuals with diabetes as a fundamental part of the glycemic control and overall wellbeing.²⁰ Similarly, healthy eating behavior, as a key component of diabetes self-care, could have long-term health benefits for people with diabetes.²¹ Meanwhile, effective diabetes treatment involves adhering to the complex medication regimen. Among the 45% T2DM adults that had poor glycemic control (Hemoglobin A1C \geq 7.0%), poor medication adherence was a key risk factor.²² Collectively, those three self-care behaviors constitute the cornerstone of diabetes management.

Several factors have been related to diabetes self-care, including self-efficacy,

diabetes distress, fatigue, and daytime sleepiness. Self-efficacy is one's confidence in performing a particular action and persisting in acting despite barriers.²³ Self-efficacy is a significant and unique predictor of self-care in people with T2DM.^{24, 25} Individuals with low self-efficacy might not be confident enough to take effective actions to manage diabetes. Another important factor affecting self-care is diabetes distress.²⁶⁻²⁸ an emotional burden of self-management, threats of complications, and potential loss of functioning.²⁹ Fatigue,³⁰ a debilitating symptom, is 'the awareness of a decreased capacity for physical and/or mental activity due to an imbalance in the availability, utilization, and/or restoration of resources needed to perform activity. (p.46) Fatigue is pervasive in people with T2DM and has been related to self-care.^{31, 32} A similar yet distinct construct is daytime sleepiness. Daytime sleepiness is one's tendency to fall asleep; it can be experienced as a symptom of medical diseases and a physiological state.³³ People experiencing daytime sleepiness likely lack the energy and motivation to engage in daily behaviors such as physical activity. Significant negative associations between daytime sleepiness and self-care behaviors have been reported.^{34, 35}

Recent evidence indicates that sleep disturbance is related to impaired glycemic control.^{36, 37} Multiple physiological pathways^{6, 7, 38} have been proposed to explain the underlying relationship between sleep disturbance and diabetes. From a behavioral perspective, the presence of sleep disturbance likely impairs diabetes self-care, particularly in older adults whose self-care is further complicated by competing psychosocial and physiological burdens.³⁹ Chasens and colleagues³⁴ reported that sleep disturbance could affect self-care related factors, including diabetes control problems, attitude, and self-care adherence. Sleep disturbance was also suggested to

affect physical, mental and functional outcomes.^{40, 41} In Nefs et al. study,¹¹ no significant relationship between self-reported sleep disturbance and self-care was observed. These studies focused on either T2DM patients with excessive sleepiness or youth with type 1 diabetes mellitus (T1DM). There are also methodological limitations (e.g., secondary analysis, cross-sectional design, or self-reported sleep). Taken together, sleep disturbance has been an under-examined risk factor for poor diabetes self-care. There is a need to examine whether sleep disturbance is related to daily self-care behaviors in the context of older adults with T2DM while addressing those methodological limitations.

Both sleep and self-care are complex behaviors that carry daily fluctuations and contextual variations. Yet, these fluctuations have not been fully captured when data were averaged across time, which may preclude us from drawing a complete picture of their complexity. Traditional cross-sectional measures do not account for day-to-day variations, and also subjects the data to more recall biases.⁴² Ecological Momentary Assessment (EMA) is an innovative method that can collect repeated real-time information on the behaviors of interest; it enables an examination of dynamic processes over time.⁴² EMA allows an examination of the within/between-person variabilities, which provides a more comprehensive and valid delineation of behaviors. An increasing number of studies have used EMA to evaluate behaviors such as physical activity^{43, 44} and eating behavior successfully, supporting the feasibility of using this method. However, using EMA to examine the relationships between sleep disturbance and self-care in older adults with diabetes has rarely been reported.

C. <u>Purpose of the Study</u>

Sleep is a normal physiological process fundamental to an individual's physical and psychological well-being, particularly for those with chronic illness such as T2DM. Increasing evidence support the reciprocal relationship between sleep and diabetes. Nevertheless, to date, whether sleep is related to diabetes from a behavioral perspective has not been thoroughly examined, specifically the relationship between sleep disturbance and self-care, while controlling for potential covariates. Examination of the role sleep plays in diabetes self-care is essential for our overall understanding of the relationship between sleep and diabetes.

Our long-term goal is to help T2DM patients maintain optimal glucose control by performing adequate self-care through understanding the role sleep plays in diabetes self-care. The primary purpose of this study was to examine the temporal relationships between sleep disturbance and self-care using longitudinal EMA data. The rationale is to fill the research gap by examining the central hypothesis: Sleep disturbance is related to impaired self-care behaviors in older adults with T2DM (aged 50 years or over), controlling for potential covariates. The specific hypotheses to be tested are:

1) Sleep disturbance is related to impaired overall self-care, after controlling for potential covariates (e.g., gender, age, body mass index, diabetes duration, self-efficacy, diabetes distress, fatigue, and daytime sleepiness).

2) Sleep disturbance is related to lower levels of physical activity, after controlling for potential covariates (e.g., gender, age, body mass index, diabetes duration, self-efficacy, diabetes distress, fatigue, and daytime sleepiness).

3) Sleep disturbance is related to impaired eating behavior, after controlling for potential covariates (e.g., gender, age, body mass index, diabetes duration, self-efficacy, diabetes distress, fatigue, and daytime sleepiness).

4) Sleep disturbance is related to impaired medication adherence, after controlling for potential covariates (e.g., gender, age, body mass index, diabetes duration, self-efficacy, diabetes distress, fatigue, and daytime sleepiness).

D. <u>Significance of the Study</u>

This study is significant in that it will be among the first to examine the temporal relationships between sleep disturbance and diabetes self-care in the context of older adults with T2DM. We will use EMA to evaluate sleep and self-care behaviors using 8-day objective monitoring of sleep and physical activity, and self-reported diaries. This method helps to answer the research question in real time. In this study, we will investigate the relationships between sleep disturbance and self-care, which may contribute to our overall understanding of the complex relationship between sleep and diabetes. We expect the findings from this study will be the important first step in developing future experimental studies that aim to alleviate sleep disturbance, which will potentially lead to better diabetes self-care.

Global expenditure on diabetes and its complications is estimated to be \$727 billion in 2017 and is projected to reach \$776 billion by 2045.¹ While diabetes-related health expenditure for people under 50 years is expected to remain stable in the next decades, it is projected to increase tremendously for older adults (aged 50 years or over). Self-care is crucial in managing diabetes, preventing acute complications, and reducing the risk of long-term, life-threatening complications.⁴⁵ Various factors, such as sleep disturbance, might contribute to impaired self-care behaviors. By understanding the relationships between sleep disturbance and self-care behaviors, we can assist patients to achieve better diabetes management, which will delay complications and reduce diabetes-related physical, emotional, and economic burdens. Findings from this study will provide evidence for the role of sleep disturbance as a potential barrier to optimal self-care. Latest standards of diabetes care have recommended sleep to be included in the comprehensive medical evaluation.⁴⁶ Similarly, national initiatives such as Healthy People 2020⁴⁷ have set clear objectives for sleep health, yet the importance of healthy sleep, especially in people with T2DM, remains under-appreciated. This study is built upon the desperate need for more health-promoting changes in clinical practice, including better sleep evaluation and intervention. Our findings may help to improve current diabetes education guidelines by encouraging the further inclusion of sleep-related assessment and intervention.

II. CONCEPTUAL FRAMEWORK AND RELATED LITERATURE

A. <u>Definition of Sleep Disturbance</u>

Sleep is a normal physiological process that accounts for almost one-third of our life. The absence of sleep disorder or sleep disturbance is fundamental to an individual's well-being. The term "sleep disorder" refers to disorders related to sleep and has been widely used or almost a century.⁴⁸ Meanwhile, the term "sleep disturbance" has frequently been used. Unlike sleep disorder, which can be classified into various categories (e.g., insomnia and sleep apnea) based on diagnostic criteria,⁴⁹ sleep disturbance is a complaint that may be experienced by anyone at some point in life.

Sleep disturbance is complex and likely demonstrates unique characteristics in various populations. People with diabetes are at high risk for sleep disturbance due to physiological and psychological changes that accompany diabetes.⁷ To date, the concept of sleep disturbance in people with diabetes has not been clearly defined, which has hindered effective research and clinical practice. While sleep research in diabetes continues to expand, terms, such as "sleep impairment" and "sleep problem", are often used interchangeably. Inconsistent terminology creates confusion among sleep researchers and healthcare professionals. A recent concept analysis⁵ suggests that sleep disturbance in people with diabetes is "a symptom characterized by impaired sleep quality (e.g., difficulty in initiating or maintaining sleep or frequent nocturnal awakenings) and/or abnormal sleep duration. Sleep disturbance can result from diabetes-related physiological changes and other physical/physiological impairments; it

can exert detrimental effects on daytime functioning, glucose regulation, and quality of life." (p.7) Therefore, the definition described above was used in this study.

B. <u>Relationships Between Sleep Disturbance and Type 2 Diabetes</u>

1. <u>Sleep disturbance as a risk factor for type 2 diabetes</u>

Experimental studies have been conducted to examine the causal relationship between sleep disturbance and diabetes. In a double-blinded randomized clinical trial conducted in 20 healthy men, Buxton et al.⁵⁰ found that 1-week sleep restriction (5h/night) significantly decreased insulin sensitivity. Their findings support the possible effect of sleep disturbance, particularly short sleep duration, on the development of diabetes. In another trial,⁵¹ seven healthy participants were randomized into the normal sleep group (8.5h/night) and sleep restriction group (4.5h/night). The research team examined whether sleep restriction resulted in decreased insulin sensitivity in peripheral adipocytes. They observed a significant reduction in total body insulin sensitivity and cellular insulin sensitivity (p < 0.05). Recently, a research team⁵² examined the effect of sleep condition on glucose homeostasis in 19 healthy participants. They demonstrated that two nights of recovery sleep (10h/night) following four nights of sleep restriction (4.5h/night) improved insulin sensitivity and disposition index (a marker of risk for diabetes) to the levels during normal sleep.

An increasing number of non-experimental studies have investigated the role sleep plays in the development of diabetes. Abnormal sleep duration (\leq 5-6h/night and > 8-9h/night) and impaired sleep quality significantly predicted the risk for T2DM. The pooled relative risk (RR) ranged from 1.28 to 1.84 (p < 0.05).⁵³ Self-reported poor sleep

quality was associated with diabetes with a pooled RR of 1.40 (1.21 to 1.63). The effect size of poor sleep quality was comparable to that of traditional risk factors (e.g., being overweight and physically inactive). Similarly, the pooled RRs of sleeping less than 5h, 6h, and over 9h per night were 1.48 (1.25 to 1.76), 1.18 (1.10 to 1.26) and 1.36 (1.12 to 1.65), respectively.⁹ In a meta-analysis,⁵⁴ there was a U-shaped relationship between self-reported sleep duration and the risk for T2DM. Compared to normal sleep duration (7-8h/night), both short (< 7h/night) and long (> 8h/night) sleep duration were associated with a significantly increased risk for T2DM. The pooled RR for T2DM were 1.09 (1.04 to 1.15) and 1.14 (1.03 to 1.26), respectively. A similar study⁵⁵ examined the relationship between changes in sleep duration over a 5-year period and T2DM incidence rate. The researchers found an increased T2DM incidence rate in people with persistent short sleep duration (\leq 5.5h/night) compared to those with 7h-sleep per night, even after adjusting for confounders (e.g., age and sex). The odds ratio (OR) was 1.59 (1.22 to 20.05). Interestingly, the researchers also found that a 2-hour increase in sleep per night was related to a higher risk of T2DM incidence (OR 1.65). In contrast, Strand et al.⁵⁶ did not find a consistent relationship between sleep disturbance (i.e., insomnia symptoms) and T2DM incidence in older adults over 65 years old. In summary, an accumulating body of evidence suggests that sleep disturbance is a risk factor for T2DM.

2. <u>Sleep disturbance in people with type 2 diabetes</u>

a. Prevalence of sleep disturbance in adults with type 2 diabetes

Sleep disturbance is becoming a common public health issue. Over 50% of U.S. adults complained about poor sleep quality.⁵⁷ The age-adjusted percentage

of adults who had short (\leq 6h) and long sleep duration (\geq 9h) were 29.2% and 8.6%, respectively.⁵⁸ In people with T2DM, sleep disturbance is more widespread. It has been reported that 39.4% and 55.0% adults with T2DM have short sleep duration (< 6.5h per night)⁵⁹ and poor sleep quality.⁶⁰ Compared to healthy controls, more T2DM patients reported poor sleep quality (60% v.s. 47%); the OR for T2DM patients having poor sleep quality was 1.7 (1.04 - 2.78). The effect of diabetes on sleep quality was independent of chronic complications, pain, and nocturia.¹⁰

Older adults are at a higher risk of sleep disturbance due to age-related changes. Older adults usually experience an advanced circadian rhythm, which results in an earlier bedtime and wake-up time. Additionally, changes in sleep architecture accompanying aging can also cause a decreased deep/restorative sleep and increased light sleep, leading to impaired sleep quality.⁶¹ It has been traditionally assumed that the amount of sleep needed per night decreases as we age. However, more evidence^{62, 63} indicates that an individual's ability to obtain sleep is responsible for the reduced amount of actual sleep, rather than aging. The decreased ability usually results from life changes (e.g., retirement) and comorbidities (e.g., diabetes). In healthy older adults, the prevalence of sleep disturbance was 50%.⁶² When adding the layer of diabetes, sleep disturbance is more common, particularly in those with complications.⁶⁴

b. Relationship between sleep disturbance and glycemic control

Emerging evidence indicates that sleep disturbance is associated with glycemic control in people who already have T2DM. Although sleep quality measured by Pittsburgh Sleep Quality Index (PSQI) was not related to Hemoglobin A1C (A1C), a 1-hour increase in sleep duration was associated with a 0.17% (1.4 mmol/mol) decrease in A1C.⁶⁵ A recent large-scale study⁶⁶ conducted in T2DM adults explored the relationship between sleep duration and glycemic control. Weekday sleep duration had a significant U-shaped association with A1C, even after adjusting for confounders. People who slept between 7 and 8 hours per night had the lowest A1C. Also, short sleep duration (< 7h) tended to associated with higher A1C. Recent review findings also support the U-shaped relationship between sleep duration and glycemic control;³⁶ and poor sleep quality was reported related to an increased A1C.^{36, 67} These data further support the potential detrimental effect of sleep disturbance on glycemic control.

3. Mechanisms linking sleep and diabetes

Multiple pathways underlying the relationship between sleep and diabetes have been proposed. Reutrakul and Van Cauter⁶⁸ proposed three potential physiological mechanisms involved in the detrimental effect of sleep disturbance on metabolism. First, short sleep duration and poor sleep quality might cause a decreased brain glucose utilization, which results in hyperglycemia or T2DM. Second, sleep disturbance could induce an increased sympathetic system activity (or alteration in the hypothalamic-pituitary-adrenal axis), increased inflammatory markers (e.g., Interleukin-6 and Tumor Necrosis Factor- α), and abnormal adipocyte function, which can inhibit insulin secretion and promote insulin resistance. Third, an alteration in appetiteregulating hormones caused by sleep disturbance could explain the increased risk of diabetes. Specifically, sleep disturbance promotes the secretion of ghrelin (a hunger hormone) and inhibits the secretion of leptin (a satiety hormone). All those changes are in favor of increased hunger and food intake without an increase in energy expenditure.

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Similar pathways were also proposed by Martins and colleagues.⁶⁹ In addition to the physiological pathways, behavioral mechanisms linking sleep disturbance and diabetes have been suggested. It is possible that diabetes self-care is involved in such a behavioral pathway. Sleep restriction could increase energy intake by increasing the time to eat and decrease energy expenditure by inducing fatigue.⁷⁰ Sleep disturbance also likely leads to increased calorie intake and impaired decision-making (e.g., unhealthy food choices and sedentary behaviors).⁷¹ All those behavioral changes may put people at a higher risk for T2DM.

The relationship between sleep and diabetes seems to be reciprocal. Larcher et al.⁷⁰ indicated that diabetes and sleep disturbance exacerbates each other, forming a vicious cycle. Symptoms related to T2DM (e.g., neuropathic pain and depression) can affect sleep quality, which, in turn, influences glycemic control. The effect of diabetes on sleep was further supported by Surani et al. study.⁷² They illustrated that diabetes could cause nocturia, nocturnal hypoglycemia, depression, and neuropathy, and thereby affect sleep quality. Similarly, Martins et al.⁶⁹ and Barone et al.⁷³ also elucidated the bidirectional relationship between sleep disturbance and T2DM. Figure 1 summarizes possible pathways linking sleep and diabetes based on current evidence.



Figure 1. Pathways underlying the relationship between sleep and diabetes.

C. <u>Diabetes Self-Care</u>

Diabetes self-care are daily regimen tasks that the individual performs to manage diabetes.¹⁸ Ongoing self-care is the cornerstone for maintaining optimal glycemic control and preventing long-term complications (e.g., retinopathy, nephropathy, and neuropathy). Comprehensive diabetes self-care includes adherence to physical activity, healthy eating, and medication regimen. In this chapter, each component of self-care is briefly reviewed. In addition, their relationships with sleep are illustrated.

1. <u>Main components of self-care and their relationships with sleep</u>

a. Physical activity

Physical activity¹⁹ consists of all movements related to energy expenditure, including exercise, which is planned, structured physical activity. Physical activity can be classified into aerobic exercise (e.g., walking, cycling, jogging, and swimming), resistance training (e.g., weight machine or body elastic resistance bands), and other types (e.g., flexibility and balance exercise). The ADA⁷⁴ has recommended that people with T2DM should decrease the time spent in sedentary behavior (i.e., sitting or lying) and interrupt prolonged sitting with bouts of light activity every 30 minutes. Additionally, weekly moderate-to-vigorous intensity physical activity for at least 150 minutes is recommended to enhance insulin action. These activities should be spread over at least three days/week, with no more than two consecutive days to elapse between sessions.

Although regular physical activity is beneficial, it remains challenging for older adults to meet the recommendations. For the general older population, the suggested target is the same for younger adults: ⁷⁵ "150 minutes a week of moderate-intensity activity in bouts of 10 minutes or more. It is often expressed as 30 minutes of brisk walking or equivalent activity five days a week, although 75 minutes of vigorousintensity activity spread across the week, or a combination of moderate and vigorous activity is sometimes suggested. Physical activity to improve strength should also be done at least two days a week". (p.2) This target is difficult to achieve in older adults. Thus, Phillips and colleagues⁷⁵ suggested that reducing sedentary time and increasing light-intensity physical activity may be more feasible and achievable.

Physiological mechanisms underlying the relationship between sleep and physical activity have been proposed (e.g., thermoregulatory).⁷⁶ Empirical evidence also indicates that sleep may be related to physical activity, but findings are mixed. In a cross-over study,⁷⁷ 15 healthy men underwent two nights of normal sleep (8h/night) and

two nights of sleep restriction (4h/night). The short sleep loss resulted in a significantly decreased amount and intensity of daytime physical activity from baseline (p < 0.05), measured by accelerometer. Mitchell and colleagues⁷⁸ examined the reciprocal relationship between sleep and physical activity in adult women. Wrist-worn and waistworn accelerometers were used to measure the 7-day sleep and physical activity, respectively. They found no significant relationships between moderate-to-vigorous physical activity (MVPA) and sedentary behaviors with total sleep duration and sleep efficiency (and vice versa). In contrast, another group⁷⁹ observed significant temporal relationships between sleep and physical activity. A 1% increase in sleep efficiency was related to a 0.32% and 0.54% increase in daily activity counts and time in MVPA, respectively. Physical activity was not associated with sleep onset latency and sleep duration. In another study,⁸⁰ self-reported sleep duration was obtained. Adjusting for covariates, compared with normal sleepers (7-9h/night), short sleepers (< 7h/night) had an average of 5500 more activity counts, 46.5 and 11.9 more minutes in sedentary behavior and light-intensity physical activity the following day, respectively. Additionally, long sleepers also had reduced odds of engaging in \geq 20 minutes/d of accumulated MVPA the following day (OR = 0.73; 0.67-0.78). In older men (\geq aged 60 years).⁸¹ those with an over 8h of sleep had approximately 80 minutes less sedentary time. A curvilinear relationship between sleep duration and MVPA was also observed. Subjective sleep quality was related to total activity counts ($r^2 = 0.18$, p = 0.05) and MVPA ($r^2 = 0.37$, p = 0.003) in older adults.⁸²

b. Eating behavior

Eating behavior is a multidimensional construct that has been conceptualized in various models including genetic, biological, environmental, psychological, and behavioral variables. From a behavioral perspective, eating behavior has been referred as enjoyment of food, eating in the absence of hunger, reinforcement of food, responsiveness to food stimuli, and self-control over eating.⁸³

Physiological pathways underlying the relationship between eating behavior and sleep have been proposed. "Neurophysiologic and metabolic mechanisms responsible for the control of eating behavior and the control of sleep and wakefulness are coordinated so that hunger and vigilance are paired during the daylight hours, and satiety and sleep are paired during darkness."⁸⁴ (p.S34) Sleep duration or quality is associated with feelings of hunger or eating behavior.⁸⁵ Likewise, short sleep duration could potentially promote reward-driven eating behavior that can lead to food overconsumption.⁸⁶ Lundahl and Nelson⁸⁷ illustrated the mechanism underlying the relationship between sleep and eating behavior. They suggested that sleep disturbance may lead to impaired executive functions and increased reward sensitivity (cognitive pathway), increased negative affect or emotional stress (emotional pathway), and increased impulsivity or impaired decision-making (behavioral pathway). Those changes can further cause increased food intake. They also recommended the incorporation of treating sleep disturbance into the overall diet management so that eating behavior can be indirectly improved. Similarly, Chaput⁸⁸ proposed multiple pathways underlying the connection between sleep and energy balance. The pathways include more time for eating, increased sensitivity to food reward, psychological distress, disinhibited eating,

more energy required for prolonged wakefulness, and changes in appetite-regulating hormones. According to Chaput, sleep disturbance, particularly short sleep duration and poor sleep quality, likely facilitates excessive energy intake by increasing snacking, the number of meals per day, and the preference for energy-rich foods.

Increasing empirical evidence supports the relationship between sleep and eating behavior. People with subjective poor sleep quality demonstrated decreased brain activities involved in cognitive control that might reduce self-regulatory capacity when making immediate decisions, such as eating.⁸⁹ Therefore, it is likely that sleep is related to cognitive control when making decisions, and thereby affecting eating behavior. Interestingly, in a clinical trial⁹⁰ conducted in 50 healthy young adults, a single night sleep restriction resulted in a decrease in both subjective and objective changes in alertness, which was related to total energy intake and consumption of unhealthy food (p < 0.05). In a population-based cohort of adults aged over 45 years,⁹¹ sleep was objectively measured over 7 days, and eating behavior was assessed using a validated questionnaire. Higher sleep fragmentation, lower sleep efficiency, and short sleep duration (< 5h/night) were related to higher energy intake, suggesting a link between sleep disturbance and eating. In sleep-deprived obese adults, objective sleep duration was negatively related to energy intake evaluated by 3-day food records (r = -0.23, p =0.015). A 30-minute short of sleep per day was related to an over 80 kcal increase in energy intake.⁹² Similarly, subjective sleep quality was related to eating behavior in adults at risk for diabetes.⁹³ These findings support the possible negative impact of sleep disturbance on eating behavior.

c. Medication adherence

Adherence is the extent to which a person's behavior, including taking medication, corresponds with agreed recommendations from a health provider.⁹⁴ Similarly, medication adherence is the extent to which the patient confirms to the medication regimen with regard to the timing, dosage, and frequency prescribed by the provider.⁹⁵ Medication adherence focuses on the need for patient agreement while medication compliance lacks patient involvement.^{96, 97} Therefore, medication adherence are used and reviewed in this section.

Limited research has examined the relationship between sleep and medication adherence. In a study³⁵ conducted in 280 adults with chronic heart failure, adults with excessive daytime sleepiness were more likely to experience medication nonadherence (OR = 1.11, 1.05 - 1.19, p < 0.01), even adjusting for confounders such as cognition, age, and gender. Although the direct relationship between sleep and medication adherence was not examined, it is plausible that sleep disturbance could cause excessive daytime sleepiness, and thereby affect medication adherence. Similarly, older adults with poorer subjective sleep quality were at higher risk for poor medication adherence (OR = 3.20, 1.45 - 7.07),⁹⁸ suggesting the possible role sleep plays in medication adherence.

2. Factors related to diabetes self-care

Several factors are related to diabetes self-care behaviors. Specifically, self-efficacy, diabetes distress, fatigue, daytime sleepiness, and other demographics have been reported associated with self-care in people with T2DM.

a. Self-efficacy

Self-efficacy is one's confidence in performing a particular action and persisting in acting despite barriers.²³ Consistent and adequate self-care behaviors are the foundation for diabetes control. Self-efficacy has been proposed as a central concept underlying the behaviors and could serve as the basis for enhancing diabetes self-care.⁹⁹

Evidence supporting the impact of self-efficacy on diabetes self-care is abundant. Mohebi and colleagues¹⁰⁰ suggested a direct relation between self-efficacy and selfcare in a narrative review. "Self-efficacy can induce motivation directly take healthpromoting behavior through efficacy expectations. It also affects motivation, indirectly, through perceived barriers and determining commitment or stability for following function map." (p.1) Similarly, in a mixed method study, self-efficacy was the strongest predictor of self-care (standardized path coefficient = 0.42, p < 0.01).¹⁰¹ Sarkar et al.¹⁰² observed consistent, significant relationships between self-efficacy and self-care across race/ethnicity and health literacy levels. Specifically, controlling for confounders, a 10% increase in self-efficacy was related to 0.14 and 0.09 more days of maintaining optimal diet and exercise during a week, respectively. Self-efficacy and marital status together explained 16.7% of the variation in self-care measured by the Summary of Diabetes Self-Care Activities (SDSCA).²⁴ In a clinical trial,¹⁰³ self-efficacy was a moderator of the relationship between the intervention and self-care behaviors, supporting the important role self-efficacy plays in diabetes self-care.

b. Diabetes distress

Diabetes distress is an emotional burden of self-management, threats of debilitating complications, and potential loss of functioning.²⁹ Distress can be easily confused with depression, which is a different construct identified by the presence, severity, and duration of the symptom.¹⁰⁴ In contrast, diabetes distress is a single, continuous dimension construct defined by the diabetes-related content and severity. Although diabetes distress and depression partly overlap, they are two distinct and uninterchangeable constructs. It was recommended that diabetes distress should be considered when delivering holistic diabetes care.²⁹

Distress is widespread in people with T2DM, with a prevalence of 60.2%.²⁸ Abundant evidence suggests significant relationships between diabetes distress and self-care. Compared to those with a lower level of distress, patients with higher level of distress reported poorer self-care behaviors including physical activity and eating.²⁸ Moderate-to-severe distress was related to poorer medication adherence.²⁶ In a study conducted in 2040 adults with T2DM, compared to those without distress and depressive symptoms, those with moderate-to-severe distress were more likely to have poor self-care, i.e., not meeting physical activity guidelines and having poor eating behavior, even after adjusting for covariates.¹⁰⁵ Controlling for covariates such as age, gender, and diabetes duration, diabetes distress was directly associated with medication adherence, and indirectly through self-efficacy and perceived control.¹⁰⁶ In a longitudinal study,¹⁰⁷ diabetes distress predicted medication adherence, but not physical activity and eating behavior. When diabetes self-care was measured using the SDSCA, medication adherence and general diet were negatively associated with diabetes distress.¹⁰⁸ Consistent curvilinear relationships between diabetes distress and physical activity and diet were also reported.¹⁰⁹

c. Fatigue

Fatigue³⁰ is 'the awareness of a decreased capacity for physical and/or mental activity due to an imbalance in the availability, utilization, and/or restoration of resources needed to perform activity.'(p. 46) In people with diabetes, fatigue is a multidimensional construct that potentially interplays with physiological, psychological, and lifestyle factors (e.g., physical activity).³¹

Fatigue is a common and debilitating symptom and likely impairs an individual's daily self-care behaviors.^{31, 110} In older adults with diabetes (\geq 60 years), fatigue was related to self-care measured by the SDSCA (b = -0.05, SE = 0.02), after controlling for covariates such as age, gender, ethnicity, and diabetes duration.³² Similarly, in patients with chronic heart failure, general fatigue was significantly associated with poor self-care over time (estimate=0.10, p = 0.004), adjusting for covariates including sleep and mood complaints.¹¹¹ In patients under hemodialysis or older adults, fatigue was negatively related to self-care (r = -0.58 - -0.26, p < 0.05).^{112, 113} Evidence is available regarding the relationship between fatigue and self-care behaviors. For instance, physical activity was associated with fatigue in various populations, particularly older adults.¹¹⁴⁻¹¹⁶ Likewise, eating behavior (e.g., emotional eating) was also related to fatigue in healthy young adults. Emotional eating was positively related to the prevalence of fatigue (OR = 3.40, 1.34 - 28.61, p = 0.01).¹¹⁷
d. Daytime sleepiness

Daytime sleepiness is one's tendency to fall asleep; it can be experienced as a symptom of medical diseases as well as a normal physiological state.³³ People experiencing daytime sleepiness likely lack the energy and motivation to engage in adequate daily self-care behaviors.

The prevalence of daytime sleepiness among U.S. adults was 12.7%,¹¹⁸ and approximately one-third T2DM individuals experienced daytime sleepiness.¹¹⁹ Studies have reported significant relationships between daytime sleepiness and self-care behaviors. In particular, Chasens and Olshansky¹²⁰ highlighted the substantial adverse effect of daytime sleepiness on daily self-care in a qualitative study. Participants in their study explicitly stated that "sleepiness affected their daily lives by making the activity more difficult, thereby reducing their functional and social outcomes and their ability to engage in everyday activities that are required to manage their type 2 diabetes."(p. 1148) Daytime sleepiness significantly predicted sedentary behaviors in patients with T2DM, after adjusting for age and body mass index (BMI).¹²¹ Objectively measured physical activity was lower in older adults who reported more daytime sleepiness.⁸¹

e. Potential covariates

Patient demographics (e.g., age, gender, BMI) and diabetes-related factors (e.g., diabetes duration) might play a role in diabetes self-care. Therefore, it is necessary to control for those covariates when examining the relationship between sleep disturbance and self-care behaviors. Older adults with diabetes represent the full spectrum of health status, ranging from good health with an intact function to very poor health with severe functional impairment. Their self-care is further complicated by unique lifestyle requirement, comorbidities, and complications.¹²² All those normal and pathophysiological changes likely impact the self-care. Evidence supporting the significant relationship between age and self-care is available, but findings regarding the direction of the relationship are not consistent. Age was positively related to self-care measured by the SDSCA (r = 0.30, p < 0.01),¹²³ which indicates that older individuals have better self-care. In contrast, older age was also found related to worse self-care (r = -0.30, p = 0.035).¹²⁴ Regardless of the direction, the role age plays in diabetes self-care need to be taken into account.

Consistent evidence indicates women had poorer self-care than man. In a qualitative study,¹²⁵ women struggled more with a healthy diet and relied on a wider social support network. In contrast, men faced fewer diet challenges and disclosed larger familial support in adopting healthier lifestyle including eating behavior. Socio-cultural factors might facilitate men's self-care, but likely hamper women's ability. Those challenges could help to explain the gender difference in self-care. Quantitatively, women reported more barriers, received less support, and had lower levels of self-care.¹²⁶ Compared to their male counterparts, females were more likely to have difficulties in engaging in self-care activities¹²⁷ and had significantly lower self-care.¹²⁸ It was also suggested that women should be targeted regarding healthy diet recommendations.¹²⁹

Body mass index may be related to diabetes self-care, particularly physical

activity and eating behavior. People with a higher BMI might be more likely to engage in physical activity or healthy eating to control their weight. However, it is also possible that physical and psychological burdens associated with higher BMI may be a barrier for an individual to engage in adequate self-care. Ausili and colleagues¹³⁰ conducted a cross-sectional study that recruited 302 randomly selected T2DM patients. Self-care behaviors were assessed by the SDSCA. They found that physical activity was associated with BMI (p = 0.007), controlling for other covariates. In another large-scale study,¹³¹ diabetes self-care was measured by the Diabetes Self-care Inventory-Revised. The researchers found that those who were more obese (BMI \geq 35 kg/m²) were less likely to meet physical activity and healthy eating recommendations, and reported higher burdens related to these recommendations than those who were less obese (BMI < 35 kg/m²).

Diabetes duration might be related to self-care. As a chronic and progressive disease, diabetes can have physiological and psychological impacts on an individual. Thus, people with longer diabetes duration might experience more emotional distress or physiological burden, which might impair their self-care. However, as diabetes progresses, an individual's knowledge, ability, and self-efficacy to perform self-care activities may increase. Findings regarding the relationship between diabetes duration and self-care are inconsistent. Diabetes duration was positively related to self-care mediated by self-efficacy.¹⁰¹ In contrast, participants with longer diabetes duration (> 3 years) had lower levels of self-care regarding physical activity and eating, compared to those with shorter diabetes duration (< 1 year).¹³²

D. <u>Conceptual Framework</u>

Based on the literature reviewed in the above section, the following conceptual framework (Figure 2) was proposed to delineate the relationships between sleep disturbance and self-care behaviors in people with T2DM. The framework also includes potential covariates, such as age, gender, BMI, diabetes duration, self-efficacy, diabetes distress, fatigue, and daytime sleepiness.



Figure 2. Conceptual framework.

E. <u>Overview of Ecological Momentary Assessment</u>

Ecological Momentary Assessment (EMA)⁴² is a method where repeated data on participants' states in the natural setting is collected over time. The EMA is derived from several preexisting methods that involve real-time data collection. The commonly used methods include diaries, which typically combine with physiological function assessment, behavioral observation, self-monitoring, experience sampling (e.g., beeping), and ambulatory monitoring (e.g., continuous glucose monitoring). Each of these methods was developed for particular disciplines to meet specific research needs and with little systematic integration across disciplines. EMA provides a unifying structure for these methods by recognizing the common aspects and systematizing the methodological issues within each method. Thus, EMA is a more comprehensive method that can be used across disciplines.

Ecological Momentary Assessment has been used widely across disciplines due to its inherent strengths.⁴² Compared to the traditional cross-sectional methods, EMA can reduce recall bias by collecting data on momentary states. When assessing a behavior or experience retrospectively, availability of that event could bring recall bias. For example, people are more likely to remember more severe, recent, and unusual events, which might not be representative of the behavior of interest. People tend to reconstruct so that the event is consistent with the subsequent one. Additionally, repeated data collection within the MEA protocol can increase the reliability of measures and enable the analysis of dynamic processes over time. Both the within-person variability and between-person relationships can be examined. EMA can also enhance external validity of the study by collecting data in the real world setting. Although EMA has multiple advantages, it has limitations. For instance, EMA is not optimal for the assessment of rare or important experiences (e.g., surgery or giving birth). EMA also requires the participants' willingness to use technology embedded in the protocol or enroll in studies with intensive assessments.

One major challenge when using EMA is participant adherence, the extent to which participants follow the study protocol.¹³³ Data collection in an EMA study can be intensive and burdensome, which could result in poor adherence. Multiple reasons could cause non-adherence.⁴² In the case of a desire to please, non-adherence is related to whether participants know the researcher is tracking their adherence. There are instances where participants forget. Lack of feedback from the researcher might also lead to nonadherence. Given the mechanisms involved in non-adherence, built-in strategies can help increase participant adherence.⁴² Specifically, participant training at baseline is necessary for them to understand and adhere to the protocol. Reminders can minimize missing data due to poor recall by the participants. It is recommended that the reminders be consistent with the lifestyle. E.g., avoid beeping while sleeping. In addition, timely feedback is crucial for adherence. During the data collection, participants might experience technical difficulties that might cause unintentional missing data. Researcher feedback is, thus, very crucial so that any problems the participants might encounter can be resolved during data collection. Creating a sense of accountability could also be a good strategy. The researchers can do so by telling the participants their adherence is monitored, emphasizing the importance of complying with the protocol, and demonstrating the contribution they make to science.

The core of EMA is repeated assessments of behaviors of interest. Therefore, the key issue in an EMA study is developing a detailed protocol for data collection.⁴² Real-time data relies on episodic memory characterized by a specific memory tied to a particular event. It tends to decay rapidly and is very time-dependent or prone to forgetting. The employment of EMA depends on the research question. EMA is applied when the attribute being assessed varies over time, and the assessments are conceptualized as sampling the person's condition over time. EMA aims to produce reliable and representative data. That is most clear when EMA measures are used to assess participants' immediate momentary state at random times throughout the day. Thus, each assessment is a sample from the population of moments in that person's experience. One major issue in developing an EMA protocol is the sampling scheme, including frequency and intensity. There are two types of sampling scheme: eventbased and time-based sampling. Event-based sampling is suitable when the phenomenon under study is conceptualized as occurring in discrete episodes (e.g., meals and taking medication). Typically, sampling an event in real-time requires the researcher to understand the base rate of the event under study. In that way, the wrong conclusion is not drawn because one infers from the absence of evidence that there is evidence of absence. The construct should be amenable to the sampling density of the EMA protocol. The event should be clearly defined a priori. A major challenge in eventbased sampling is participant non-adherence. In time-based sampling, the assessments are scheduled at regular (e.g., daily diaries) or random intervals (more representative of the behavior). It is particularly suitable if the phenomenon is continuous, and expected to vary in intensity (e.g., pain, fatigue, and blood glucose).

III. METHODS

A. <u>Design</u>

This study is a quantitative descriptive study. Specifically, a longitudinal, associational design was used. Real-time data about sleep and self-care behaviors were collected over an 8-day period in the free-living setting.

Using a quantitative approach, we can make inferences about the target population from a small selected population. The choice of the associational design was based on the specific aim, which was to examine the relationships between sleep disturbance and self-care. The primary constructs of interest (i.e., sleep and self-care) were repeatedly evaluated using EMA. This method helps to minimize recall bias and maximize external validity of the study. EMA also enables a delineation of the dynamic nature of daily sleep and self-care. A time-based sampling scheme was used. Both sleep and self-care were evaluated on a daily basis for eight days. The choice of a day as a natural unit was dependent on that sleep is an intact physiological process over a 24h period. Although a summary of a day's experience in self-care still introduces recall bias, it is assumed that self-care behaviors do not vary meaningfully within a day. Moreover, sampling once a day is less demanding, which could result in better adherence. The 8-day sampling window was chosen to better estimate sleep-wake patterns,⁴⁹ capture day-to-day variations, and reduce measurement errors.¹³⁴ Intensive sampling might cause reactivity. However, assessment once a day is expected to have minimal influences on one's behaviors. Importantly, reactivity might affect variable means but has little effect on the relationships of variables under investigation.¹³⁵

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B. <u>Setting and Sample</u>

1. <u>Study population</u>

The target population was older adults with T2DM. However, the accessible source was limited to volunteers who have access to online and physical flyers. Therefore, a convenience sample method was used. Both men and women were recruited in this study. There was no restriction on ethnicity. People from different ethnic groups had an equal chance of being selected. The physiological, social, and behavioral pathways influencing both sleep and diabetes in children are different from that in adults.^{136, 137} Therefore, the study population was limited to adults.

2. Inclusion and exclusion criteria

In this study, people who were 50 years or over and had T2DM for over a year were included. Newly diagnosed patients (within one year) typically have not achieved a stable glycemic control or acquired self-care skills. We limited our recruitment to T2DM patients because there are physiological and treatment differences between those with T1DM and T2DM. The inclusion of both types of diabetes may confound the relationships between variables of interest. Detailed exclusion criteria and corresponding rationales are listed in Table I.

Exclusion criteria (self-reported)	Rationale
On anti-depressant, anxiolytic agents, and antipsychotics, or with other physical disabilities (e.g., amputation and paralysis)	These conditions could limit self-care abilities, which might confound the findings
Gestational diabetes	Pregnancy-related changes could influence one's sleep, making the sleep during pregnancy incomparable to the sleep in the general population
Acute diabetic complications or other comorbidities including chronic arthritis with uncontrolled pain, cancer within the past year, heart failure, liver disease, chronic obstructive pulmonary disease, and kidney failure	These conditions might affect sleep
Using prescription sleep medications for insomnia or diagnosed with restless leg syndrome	Sleep in these patients is different
Shift-workers	They have different sleep-wake schedules, incomparable with regular sleep schedules
Non-English speakers	All instruments and communication with the investigator were in English

TABLE IEXCLUSION CRITERIA AND RATIONALES

3. <u>Sample size</u>

Three methods have been commonly used to run a power analysis:¹³⁸ a robust estimation of the effect size from the literature; Cohen's recommendations; and pilot testing. Robust estimation was difficult at this stage given limited evidence on the same topic was available. Preliminary power calculation was conducted based on the following parameters: Cohen's recommendations for a medium effect size ($f^2 = 0.15$),¹³⁹ two-tailed α level at 0.05 and power at 0.80, and controlling for eight covariates (gender, age, BMI, diabetes duration, self-efficacy, diabetes distress, fatigue, and daytime

sleepiness). Approximately 85 participants were needed to detect a significant increase in the variation of self-care explained by sleep. G*Power 3.1 (Franz Faul, Germany) was used to calculate the sample size. The sample size was calculated to accommodate the most stringent criteria. Thus, the estimate of 85 was sufficient to detect significance.

Pilot data were used to run a simulation-based power analysis to get a more robust estimation. The simulation¹⁴⁰ includes iterative procedures such as generating simulated datasets and using regression modeling to calculate model fitness and power. The information then is aggregated across all simulated datasets. The statistical power is the proportion of p values lower than a specified α level. In this study, baseline data from 50 participants were used to establish the simulation model. The dependent variable was overall self-care. The independent variables were subjective sleep quality and the eight covariates (i.e., gender, age, BMI, diabetes duration, self-efficacy, diabetes distress, fatigue, and daytime sleepiness). The simulation results suggested that with a sample size of 50, the power of detecting a significant relationship between sleep quality and self-care was 0.78. When the sample size is increased to 60, the anticipated power is 0.88, suggesting that a sample size of 60 should be large enough to detect a significance and avoid type 1 error.

C. Variables and Measurement

1. <u>Study concept and operationalization</u>

Study concepts, their definitions, variables of interest, and operational measures are outlined in Table II. The role of each variable (i.e., dependent variable, independent variable, and covariates) is also listed.

 TABLE II

 STUDY VARIABLES AND OPERATIONAL MEASURES

Concept	Variable	Operational measure
	Independent variable	
Sleep disturbance		
Impaired sleep quality and/or	Objective sleep	
abnormal sleep duration ⁵	TST, SE, SOL, WASO	^a ActiGraph wGT3X
	Number of awakenings	
	Subjective sleep	
	Sleep quality	Pittsburgh Sleep Quality
		Index
	TST, SE, SOL, WASO	^a Sleep Diary
	Dependent variable	
Self-care		
Daily regimen tasks that the	Self-care	Diabetes Self-Management
individuals perform to manage		Questionnaire-Revised
diabetes (e.g., physical		
activity, eating behavior, and	Physical activity ¹⁴¹	
medication adherence) ¹⁸	Objective	^a ActiGraph wGT3X
	Sedentary behavior (< 100	
	count/minute)	
	Light-intensity activity (100-	
	1951 count/minute)	
	Moderate-intensity activity	
	(1952-5724 count/minute)	
	Subjective (weekly MFT)	International Physical Activity
		Questionnaire-Short
	Eating behavior	Three-Factor Eating
	ç	Questionnaire -R18V2
		^a Self-care Diary
		-
	Medication adherence	Morisky Medication
		Adherence Scale
		^a Self-care Diary

TABLE II (continued)STUDY VARIABLES AND OPERATIONAL MEASURES

Concept	Variable	Operational measure
	Covariate	
Self-efficacy		
One's confidence in taking	Self-efficacy	Diabetes Empowerment
particular actions and		Scale-Short Form
persisting in acting despite		
barriers ²³		
Diabetes distress		
Emotional burden of self-care,	Diabetes distress	Diabetes Distress Scale
threats of complications, and		
potential loss of functioning		
related to diabetes ²⁹		
Fatigue		
Awareness of a decreased	Fatigue	Diabetes Symptom Checklist-
capacity for physical and/or		Revised
mental activity due to an		
imbalance in the availability,		
utilization, and/or restoration		
or resources needed to		
Deutime cleaninges		
Daytime sleepiness		
that can be experienced as a	Daytime sleepiness	Epworth Sleepiness Scale
that can be experienced as a		
discassos, as well as a normal		
obveiological state ³³		
Demographic and	Age gender DML and	Deceline questionneire
bemographic and	Aye, yenuer, Divil, and	
		Rever A1CNow+™
	Obstructive algon anneg rick	
	Obstructive sleep apried risk	SIOP-Bang

^a 8-day data collection.

2. <u>Validity and reliability of the instruments</u>

Instruments used to measure study variables are described below. Psychometric properties of each instrument and the rationales for choosing them are also outlined.

a. Objective sleep

Objective sleep was measured using an accelerometer ActiGraph wGT3X.¹⁴² ActiGraph wGT3X is a small wristwatch-like device that records highresolution activity information using a solid state tri-axial accelerometer. Compared to the gold standard of polysomnography (PSG), the accelerometer (e.g., ActiGraph) is portable, less expensive, less invasive and burdensome, and thus is preferred in clinical research.¹⁴³ ActiGraph is typically worn on the non-dominant wrist to provide more valid estimates of sleep. ActiGraph wGT3X worn on the wrist worked better than worn on the hip in measuring sleep.^{144, 145} Actigraphy data can be collected in the 30s or 60s epoch, and each epoch of data is evaluated as sleep or wake, based on computerized scoring algorithms.¹⁴⁶ In this study, data were collected in the 30s epoch. Data were scored using the Cole-Kripke algorithm,¹⁴⁷ which had a medium sensitivity setting (cut-off of 40 activity count per minute, for 10 minutes of immobile/mobile for sleep onset and sleep offset) was used for data scoring. This algorithm was developed in people aged between 35 and 65 years and thus is appropriate for use with adult populations. Variables reflecting both sleep duration and sleep quality were obtained. These sleep variables included total sleep time (TST), sleep efficiency (SE), sleep onset latency (SOL), wake after sleep onset (WASO), and the number of awakenings.

Validity and reliability: The ActiGraph was comparable to PSG in detecting sleep patterns and sleep disturbance.¹⁴⁸ It can provide a reasonably accurate estimate of sleep patterns in healthy adults and people with insomnia.¹⁴⁹⁻¹⁵¹ When tested against PSG in healthy adults, the wrist-worn ActiGraph wGT3X had a high sensitivity (90%) and accuracy (84%), whereas low specificity (46%),¹⁴⁴ suggesting its limited ability in detecting awakenings. When compared to other eight wearable devices, ActiGraph GT3X had the closest measure of sleep.¹⁵² It also showed good agreement with the Actiwatch for sleep assessment.¹⁵³ Actigraphy sleep measures had reasonable test-retest reliability. However, the night-to-night variability in sleep patterns needs to be taken into consideration. An extended monitoring (5 days or longer) can reduce the inherent measurement errors and increases reliability.¹⁴⁶ A minimum of 7-day monitoring has been recommended.^{49, 154, 155}

b. Subjective sleep

Subjective sleep was measured using a sleep diary developed from the **Consensus Sleep Diary for Morning (CSD-M)**.¹⁵⁶ A sleep diary is the gold standard for subjective sleep measures and is recommended as an addition to objective measures.¹⁵⁷ A sleep diary is a useful supplement to help identify invalid data and nonadherent participants¹⁵⁵ and interpret actigraphy data.¹⁵⁸ The CSD-M¹⁵⁶ was developed from the core 9-item CSD by a panel of 25 sleep experts. It consists of additional items asking about an individual's sleep, such as early awakening, refreshing quality of sleep, and daytime nap. The CSD-M can be used to record daily sleep across multiple days. An example question is "What time did you get into bed?" In this study, variables derived from the sleep diary included TST, SE, SOL, and WASO. In addition, one question about morning fatigue was added to the sleep diary by asking "how tired you are upon awakening (0-not at all, 10-the most possible)?"

<u>Validity and reliability</u>: In older adults, the CSD was more sensitive in identifying insomnia compared to actigraphy.¹⁵⁹ In people with insomnia,¹⁶⁰ the CSD was able to differentiate good sleepers from those with insomnia; CSD-derived sleep variables were associated with Actiwatch-measured sleep variables (r = 0.31-0.41). Additionally, the predictive validity of the CSD was supported by significant relationship between improvement in insomnia symptom and CSD parameters. Completion rate of the CSD across all 14 days was 99.8%, supporting its usability.

c. Sleep quality

Subjective sleep quality over the past month was measured by the **Pittsburgh Sleep Quality Index (PSQI)**.¹⁶¹ PSQI is composed of 19 items, which form seven factors, including subjective sleep quality, sleep duration, sleep latency, sleep efficiency, sleep disturbance, use of sleep medication, and daytime dysfunction. The PSQI global score ranges from 0 to 21, and a higher score indicates poorer sleep quality. A PSQI global score of over 5 suggests poor sleep quality.

<u>Validity and reliability</u>: In the original validation study¹⁶¹ conducted in 148 healthy participants and those with psychiatric or sleep disorder, PSQI has an acceptable internal consistency coefficient (Cronbach's α = 0.83) and test-retest reliability. It also showed high sensitivity (89.6%), specificity (86.5%), and accuracy (88.5%) when a cut-

off point was set at 5, supporting its ability to discriminate good and poor sleep quality. Chasens et al.³⁴ and Cole et al.¹⁶² found that the three-factor model performed better in their study populations (adults with diabetes, older adults) than the original one-factor.

d. Self-care (overall)

Participant overall self-care was measured using the **Diabetes Self-Management Questionnaire-Revised (DSMQ-R)**.¹⁶³ The DSMQ-R was developed from the original DSMQ, which assesses diabetes self-care over the past two months. The DSMQ-R consists of four subscales: glucose management, dietary control, physical activity, and physician contact. Seven optional items in the DSMQ-R was used only for patients using intensive insulin treatment. Each item evaluates an individual's perception of his/her self-care behaviors. Respondents rate the extent to which the description applies to them on a 4-point Likert scale (0-does not apply to me, 3-applies to me very much). The scale score is the sum of item scores and is transformed to a scale ranging from 0 to 10. Higher scores indicate better self-care.

<u>Validity and Reliability</u>: In the original validation study,¹⁶³ the DSMQ has acceptable internal consistency reliability in adults with T2DM. Average Cronbach's α for the four subscales was 0.68, and the Cronbach's α coefficient for the sum scale was 0.82. Reliability was also supported by significant inter-item, item-to-subscale correlations (r = 0.20-0.50, p < 0.01). The validity of the DSMQ was supported by its ability to differentiate people with good, medium, and poor glycemic control. The DSMQ scales showed significant convergent correlations with the widely used Summary of Diabetes Self-Care Activities (r = 0.52-0.57, p < 0.01). Additionally, the DSMQ correlated strongly with A1C levels in T2DM (r = -0.46, p < 0.01).¹⁶⁴

e. Objective physical activity

Objective physical activity was evaluated using the ActiGraph wGT3X. ActiGraph¹⁶⁵ uses a Microelectromechanical System based tri-axial accelerometer that can detect movement in the vertical, anteroposterior and lateral planes. Thus, it may provide a better estimation of nonambulatory and sedentary activities. ActiGraph integrates digitized acceleration signal during a specified time interval to an epoch, which is then summed into activity count. The count in a given time is linearly related to the physical intensity during that period.¹⁶⁵ The 60s epoch length is commonly used and is suggested to have minimal impact on activity assessments in adults.^{165, 166} The large storage capacity of modern device and precision of a shorter epoch also makes the 30s epoch favorable. ActiGraph can detect acceleration resulting from physical activity related body movement at a fixed body position (e.g., wrist, thigh, and hip). When worn in the hip, the ActiGraph wGT3X can differentiate off, lying, and standing positions, which provides more detailed and accurate classification of physical activity. It is recommended that the accelerometer should be placed as close as possible to the trunk such as hip.¹⁶⁵ Studies found that total step counts per day correlated highly between hip and wrist placement (r = 0.73) in older, free-living women.¹⁶⁷ However, compared to hip placement, wrist placement has lower sensitivity and specificity for determining sedentary (53% and 76%) and moderate-to-vigorous physical activity (30% and 69%).¹⁶⁸ Wrist placement is preferred considering study feasibility and participant adherence. Indeed, the National Health and Nutrition Examination Survey changed the

placement from waist to wrist to increase participant adherence.¹⁶⁹ Innovative algorithms have been proposed to translate the raw data from wrist-worn accelerometer to activity classification.^{170, 171} In this study, ActiGraph was worn on the non-dominant wrist to better estimate sleep and enhance participant adherence. Data were collected using the 30s epoch. Different types of physical activity were defined by the Freedson cut-off points,¹⁴¹ which were tested in healthy adults. Detailed descriptions of the cut-off points are listed in Table II.

<u>Validity and reliability</u>: The tri-axial accelerometer has high validity and sensitivity. Its positive predictive values for sitting/lying and walking/jogging were over 85% and 90%, respectively.¹⁷² Activity counts per minute for the ActiGraph GT3X correlated highly with oxygen consumption (r = 0.81, p < 0.01),¹⁷³ indicating its validity in measuring physical activity. The ActiGraph GT3X demonstrated good inter-instrument reliability across all planes.¹⁷⁴ The intra-class correlation for activity counts for all planes was 0.97, suggesting that the ActiGraph GT3X was reliable within common frequencies for most types of daily activities.¹⁷⁵

f. Subjective physical activity

Subjective physical activity was assessed using the self-administered **International Physical Activity Questionnaire-Short (IPAQ-S)**.¹⁷⁶ The IPAQ-S evaluates health-related physical activity over the past seven days. It was designed to be used in people aged between 15 and 69 yrs. The IPAQ-S consists of 7 items that evaluate four categories of physical activity: vigorous, moderate, walking, and sitting. Responses were scored using established data screening and weighting procedures.

Weekly metabolic equivalent (MET) expenditure is obtained by summing the MET energy expenditure estimate corresponding to each category.

<u>Validity and reliability</u>: In the validation study¹⁷⁶ conducted in 12 countries, the self-administered IPAQ-S showed good test-retest reliability (Spearman r = 0.66-0.89). The pooled correlation between the IPAQ-S and the long form was 0.67, indicating reasonable concurrent validity. When tested against accelerometer measures, the IPAQ-S showed fair agreement (r = 0.30), suggesting acceptable criteria validity.

g. Eating behavior

Eating behavior was measured using the **Three-Factor Eating Questionnaire-R18V2 (TFEQ-R18V2).**¹⁷⁷ The TFEQ-R18V2 was developed from the original 51-item TFEQ,¹⁷⁸ which was later revised into the TFEQ-R18. The TFEQ-R18 consists of 18 items and three subscales: Cognitive Restraint, Uncontrolled Eating, and Emotional Eating. They measure conscious restriction of food intake to control weight, tendency to eat more due to a loss of control accompanied by feelings of hunger, and inability to resist emotional cues, respectively.¹⁷⁹ Three additional items were added to the emotional eating domain to minimize floor and ceiling effects, which resulted in the 21-item version (TFEQ-R21). The TFEQ-R21 showed improved psychometric properties.¹⁸⁰ Later, three items were removed from the TFEQ-R21, producing the revised version TFEQ-R18V2.¹⁷⁷ Items are scored on a 4-point Likert scale (definitely true, mostly true, mostly false, and definitely false). The score of the subscale is the sum of the items included in that scale. Raw scores are transformed to a 0-100 scale; higher score indicates more eating behavior measured by the corresponding subscale. <u>Validity and reliability</u>: In a sample of obese and non-obese participants,¹⁷⁷ the factor analysis confirmed the robust three-factor structure of TFEQ-R18V2. It also showed good internal consistency: Cronbach's α for the three domains Uncontrolled Eating, Cognitive Restraint, and Emotional Eating were 0.89, 0.78, and 0.94, respectively.

h. Medication adherence

Medication adherence was measured using the **Morisky Medication Adherence Scale-8 (MMAS-8)**.¹⁸¹ The MMAS-8 is an 8-item scale developed from the validated MMAS-4¹⁸² by adding four additional items to account for reasons for nonadherence. The MMAS-8 assesses different medication adherence behaviors. Each item is dichotomized/scored as 0 (yes) or 1 (no), except the last item is scored on a 5point Likert scale (0, 0.25, 0.50, 0.75, and 1). The sum of the eight items results in a total score ranging from 0 to 8. A higher score indicates better medication adherence. Adherence can be categorized into three groups: high (MMAS-8 = 8), medium (MMAS-8 = 6-7), and low (MMAS-8 = 1-5).

<u>Validity and reliability</u>: When the MMAS-8 was initially tested in patients with hypertension,¹⁸¹ it showed good reliability (Cronbach's α = 0.83). Sensitivity and specificity of the MMAS-8 were 93% and 53% when a cutoff point of less than 6 was used. In people with T2DM,¹⁸³ the MMAS-8 demonstrated good predictive validity, supported by significant correlations with the A1C level.

i. Self-care (daily)

Daily self-care behaviors were measured using a self-care diary. The diary consists of items assessing the three main components of self-care: physical activity, eating behavior, and medication adherence. The items were derived and revised from existing questionnaires.

Physical activity: The self-reported physical activity diary was used as a complement to the ActiGraph, which could facilitate interpretation of objective physical activity. The IPAQ-S¹⁷⁶ was revised to assess daily physical activity by replacing the original "past 7 days" with "today". Although no studies were found to validate these revisions, they were made based on recommendations by Matthews et al. to shorten the recall period to a single day and thus increase validity.¹⁸⁴ Previous studies have used the revised version successfully.¹⁸⁵

Eating behavior: The Automated Self-Administered 24h dietary recall¹⁸⁶ is a valid tool to estimate total energy intakes. However, the average time to complete the dietary recall is about 30 minutes, which is time-consuming and may undermine adherence if used on a daily basis. Our primary goal was to examine the relationship between sleep disturbance and eating behavior rather than the actual energy intake. Thus, items from the TFEQ-R18V2¹⁷⁷ were used to assess daily eating behavior. To minimize participant burden and increase adherence, we used two items from each subscale (i.e., cognitive constraint, uncontrolled eating, and emotional eating). The items were chosen because they had the largest loading on each subscale.¹⁷⁷ Selected items were reworded to reflect "today". Two more questions were added to evaluate

daily variations in the main meal and snack eating behavior. Each item was scored on a 5-point Likert scale (1-not at all agree, 5-extremely agree). The two items within each subscale derived from TFEQ-R18V2 were averaged, and the two items regarding eating variations were averaged. A higher score indicates more of the eating behavior measured by the subscale.

Medication adherence: Items from the Self-Care Inventory-Revised (SCI-R)¹⁸ was used to assess daily medication adherence. The SCI-R consists of 15 items reflecting current diabetes practice. The three items that address medication adherence were used and reworded to reflect the daily behavior. The original items are scored on a 5-point Likert scale. In this study, the answers were dichotomized as yes/no. Although the medication subscale of SCI-R moderately correlated with subscale in another instrument (r = 0.38), no studies were found validating the revised items.

j. Self-efficacy

Self-efficacy was measured using the **Diabetes Empowerment** Scale-Short Form (DES-SF).¹⁸⁷ The SE-SF is an 8-item scale assessing the overall diabetes-related psychosocial self-efficacy. It was derived from the original DES,¹⁸⁸ which consists of three subscales that evaluate eight conceptual domains. Items having the highest item-to-subscale correlation from the eight domains were chosen to composite the DES-SF. Each item is rated on a 5-point Likert scale (1-strongly disagree, 5-strongly agree). Average of all eight items results in the total score. A higher score indicates a higher level of self-efficacy. <u>Validity and reliability</u>: The internal consistency reliability of the DES-SF was tested in two independent samples.¹⁸⁷ The Cronbach's α was over 0.84, indicating good reliability. Content validity was supported by similar, positive changes in the DES-SF score and A1C after an intervention program. A review¹⁸⁹ indicated that the DES-SF was psychologically sound regarding its reliability, validity, feasibility, and suitability.

k. Diabetes distress

Diabetes distress was measured using the **Diabetes Distress Scale** (**DDS**).¹⁹⁰ The DDS is a self-administered 17-item scale. It was developed partially based on the Problem Areas in Diabetes (PAID) Scale, which is a commonly used tool. Compared to PAID, the DDS was more reflective of self-care-related distress.¹⁹¹ It measures four domains of diabetes-related emotional distress over the past month: Emotional Burden, Physician-related Distress, Regimen-related Distress, and Diabetes-related Intrapersonal Distress. Each item is scored on a 6-point Likert scale (1-not a problem, 6-a very serious problem). A higher score indicates a higher level of distress. The DDS total score can be used to categorize people into three groups: little or no distress (< 2.0), moderate distress (2.0-2.9), and high distress (\geq 3.0).¹⁰⁹

<u>Validity and reliability</u>: In the validation study conducted at four different sites,¹⁹⁰ the DDS demonstrated high internal consistency reliability (Cronbach's $\alpha > 0.87$). Significant correlations between DDS and depression, meal planning and exercise provided evidence for the convergent validity. The ability of the DDS to differentiate insulin-users and diet-controlled participants also supported its criterion validity. In a study comparing the psychometric properties of the DDS and PAID, DDS showed a more precise and consistent four-factor structure in the factor analysis. Cronbach's α for the overall scale and four subscales were 0.89 (total scale), 0.87(Emotional Burden), 0.84(Physician-related Distress), 0.84(Regimen-related Distress), and 0.71(Interpersonal Distress). The split-half coefficient ranged from 0.73 to 9.91, indicating acceptable reliability.¹⁹¹ Another large-scale study¹⁹² reported that the DDS has good convergent and criterion validity in people with T2DM.

I. Fatigue

Fatigue was measured using the fatigue subscale of the **Diabetes Symptom Checklist-Revised (DSC-R)**.¹⁹³ DSC-R was derived from the DSC,¹⁹⁴ which measures perceived occurrence and burden of T2DM-related physical and psychological symptoms during the past month. DSC-R consists of 34 items that measure eight domains: hyperglycemic, hypoglycemic, cardiovascular, polyneuropathic sensory, polyneuropathic pain, psychological fatigue, psychological/cognitive, and ophthalmologic. Each item is rated on a 5-point Likert scale (1-not at all, 5-extremely). Domain score is the sum of domain items and the sum of all eight domain scores results in the total score. A Higher score indicates greater symptom burden. Fatigue also carries contextual variations. Therefore, daily morning fatigue was evaluated by asking "how tired you are upon awakening (0-not at all, 10-the most possible)?" This item was incorporated in the daily sleep diary.

<u>Reliability and Validity</u>: In a multi-country trial¹⁹³ consisting of approximately 4000 participants with T2DM, confirmatory factor analysis and multitrait analysis demonstrated acceptable construct validity of the DSC-R. Cronbach's α of the overall

scale and fatigue subscale was 0.94 and 0.87, respectively, supporting the internal consistency reliability. Item-domain correlations of the fatigue subscale ranged from 0.64 to 0.78, supporting its validity. The fatigue subscale also showed high correlation with the Short Form Health Survey (SF-36) Vitality scale (r = -0.69), supporting its convergent validity. Validity was further supported by significant differences in fatigue severity between participants with different A1C levels.

m. Daytime sleepiness

Daytime sleepiness was measured using the **Epworth Sleepiness Scale (ESS)**.¹⁹⁵ The ESS contains eight items that assess one's tendency to fall asleep in eight situations. Each item is rated on a 4-point Likert scale (0-no chance of dozing, 3-high chance of dozing). The sum of all items results in a total score, ranging from 0 to 24. Higher scores indicate higher levels of sleepiness. The total score can be classified into four categories (0-7 unlikely abnormal sleep; 8-9 average amount of sleepiness; 10-15 excessively sleepy; 16-24 should seek medical attention).

<u>Validity and reliability</u>: In two validation studies,^{195, 196} the validity of the ESS was supported by its capacity to discriminate healthy participants and patients with sleep disorders. ESS score also had significant correlations with the multiple sleep latency test and PSG measures. Factor analysis supported the single-factor model. Reliability of ESS was supported by high internal consistency (Cronbach's α = 0.88) and test-retest correlation (r = 0.82). The ESS can be used to distinguish normal daytime sleepiness and excessive daytime sleepiness. It demonstrated high sensitivity (93.5%) and specificity (100%) when a cut-off score of 10 was used.¹⁹⁷

n. Glycemic control

Bayer A1CNow+[™] was used to measure A1C, which reflects the overall glycemic control over the past three months.¹⁹⁸ A1C correlates strongly with mean plasma glucose. Compared to fasting and 2-hour postprandial glucose monitoring, A1C has greater pre-analytical stability and less day-to-day fluctuation during stressful events.¹⁹⁹ The Bayer A1CNow+^{™200} is a Clinical Laboratory Improvement Amendments-waived and National Glycohemoglobin Standardization Program-certified device. It is a portable A1C point-of-care analyzer that can provide A1C level in five minutes without calibration. A small blood sample (5 µL) was used and mixed with a reagent provided with the test kit. It has been widely used as a substitution of highperformance liquid chromatography (HPLC) because of its high efficiency and portability.

<u>Validity and reliability</u>: Studies have shown that A1C levels measured with the A1CNow⁺ were almost equivalent to the results from the laboratory method.^{201, 202} The sensitivity and specificity of the A1CNow+ kit compared to the HPLC method were 100% and 82.4% in identifying individuals with diabetes (A1C \geq 6.5%).²⁰³

o. Sleep apnea risk

Sleep apnea risk was evaluated using the **STOP-Bang**.²⁰⁴ The STOP-Bang is an 8-item questionnaire that assesses the risk of obstructive sleep apnea. Each item is scored as 1 (yes) or 0 (no). Sum of the eight items results in a total score (0 to 8). Participants can be classified into three groups: low (0-2), intermediate (3-4), and high (5-8) risk of sleep apnea based on the total score. <u>Validity and reliability</u>: In a perioperative population,²⁰⁴ a score of 3 and over had a high sensitivity for detecting moderate (sensitivity = 93%) and severe (sensitivity=100%) sleep apnea. A meta-analysis²⁰⁵ also supported the high performance of STOP-Bang for the screening for sleep apnea. In people with T2DM,²⁰⁶ the performance of STOP-Bang was different in males and females: sensitivity being 74% and 29%; specificity being 56% and 82%.

D. <u>Procedures</u>

1. <u>Recruitment</u>

The study was approved by the Institutional Review Board of the University of Illinois at Chicago (UIC). Participants were recruited through flyer distribution throughout the campus and neighborhoods. Additionally, electronic flyers were posted through the UIC mailing list and internet (e.g., Craigslist and ResearchMatch.org). Meanwhile, Dr. Cynthia Fritschi and Dr. Lauretta Quinn kept a database of participants with T2DM who have given permission to be contacted for future research. They were contacted by the principal investigator (PI).

2. <u>Screening</u>

In response to flyers and invitation to participate, all potential participants called into the PI's telephone. The PI described the study briefly and screened the participants according to the eligibility checklist developed from the inclusion and exclusion criteria. The entire telephone screening took approximately 10 minutes. All eligible participants were invited to participate, and the baseline assessment was

scheduled. No further contact was made with those who did not meet inclusion criteria, and their information was destroyed at the end of the study.

3. Data collection

Data were collected during the baseline interview, 8-day free-living period, and post-interview. The interviews were conducted at the College of Nursing diabetes research laboratory by the PI. An overview and detailed description of study procedures are presented in Figure 3 and Table III.



Figure 3. Overview of study procedures.

a. Baseline interview

Prior to data collection, written informed consent was obtained.

Participants were informed of their right to withdraw at any phase of the study.

Fingerstick capillary A1C was collected using Bayer A1CNow+™. Height and weight

were measured using a wall-mounted stadiometer and upright, balanced scale, respectively. Neck and waist circumference were measured using a tape measure. Questionnaires were administered in paper-and-pencil format. The PI was present to answer any pertinent questions.

Non-adherence, a systematic bias, might be present due to reasons such as the desire to please, forgetting, monitoring burden, and lack of feedback.¹³³ Multiple strategies were used to increase participant adherence in this study. After baseline data collection, participants were trained on how to use the ActiGraph. They were guided to wear the ActiGraph on the non-dominant wrist for eight consecutive days. The only time they need to take it off is when they take a bath or swim longer than 30 minutes. The PI instructed on how to address issues such as skin irritation. Participants were asked whether they had any concerns about wearing the ActiGraph. The PI emphasized the importance of wearing the ActiGraph at all times and the contributions they would make to this study. This strategy would help to create a sense of accountability.

Compared to paper-and-pencil format, the electronic diary has several advantages. It can be completed using various electronic devices such as a computer, tablet, or smartphone. Customized format and skip patterns can save time and space. Additionally, the electronic diary helps to strengthen data entry, storage, and transfer. Data obtained from electronic diary are time-stamped, which can be used to objectively and accurately evaluate adherence.^{207, 208} Evidence ²⁰⁹ indicates that patient-reported outcomes collected electronically had good data quality: age, computer experience, and education had no effect on the results. Compared to paper-and-pencil format, the

electronic format was easier to use and less time-consuming. Even in older adults with cognitive difficulties, the use of electronic assessment was feasible.²¹⁰ Furthermore, electronic diary yielded psychometrically equivalent data with the paper-and-pencil diary.²¹¹⁻²¹³ One of the challenges of using electronic diary is the ownership of an electronic device and internet connection. However, data showed that among adults aged 50-64 years, 70% and 81% of them owned a computer and had an internet connection, respectively. Among those aged 65 years or over, 55% and 58% of them owned a computer and had an internet connection, respectively. Among those aged 65 years or over, 55% and 58% of them owned a computer and had an internet connection, respectively.^{214, 215} Thus, the electronic diary was used as the first choice in this study. Only in those who did not own an electronic device were the paper diaries provided. Participants were trained on how to complete the diaries. They were asked to fill out a diary sample so that any questions were resolved in time. The entire baseline assessment took approximately 1.5 hours. Before leaving, participants received \$20 in cash for compensation of their time.

b. Eight-day data collection

During the 8-day period, participants were asked to continue their usual routines while wearing the ActiGraph. They were encouraged to be open about the ActiGraph while around family and friends so that they can habituate to wearing the ActiGraph more quickly, and thereby reducing reactivity.²¹⁶ Electronic links containing the diaries and instructions were sent to participants on a daily basis via REDCap electronic data capture tools hosted at UIC.²¹⁷ The time preference to receive the diaries was tailored for each individual. The diaries can be completed through any device with internet connection. Participants were instructed to fill out the self-care diary within an hour before bedtime and the sleep diary within one hour upon awakening.

During the 8-day period, the PI had a weekly follow-up with the participants. Participants were asked about their preference in ways (e.g., phone call, e-mail, or text) to receive the follow-up during the baseline interview. The PI contacted the participants and asked about concerns regarding filling out the diaries and wearing the ActiGraph. For those who did not complete the diaries in time, the PI contacted them as a reminder. A wear time sensor on the back of the ActiGraph uses capacitive touch technology to detect when a wrist-worn device is removed automatically. This technology further facilitated adherence monitoring.

c. Post-interview

After the 8-day period, participants came back to the laboratory and returned the ActiGraph. Participants completed a 3-minute post-study survey, which asked their experience in participating in this study. A compensation of \$40 in cash was given to the participants before they left.

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Measures	Baseline	8-day	Post-
	interview		interview
Baseline questionnaire			
A1C			
Pittsburgh Sleep Quality Index	\checkmark		
Diabetes Self-Management Questionnaire-Revised	\checkmark		
International Physical Activity Questionnaire-Short	\checkmark		
Three-Factor Eating Questionnaire-R18V2	\checkmark		
Morisky Medication Adherence Scale-8	\checkmark		
Diabetes Empowerment Scale-Short Form	\checkmark		
Diabetes Distress Scale	\checkmark		
Diabetes Symptom Checklist-Revised	\checkmark		
Epworth Sleepiness Scale	\checkmark		
STOP-Bang	\checkmark		
ActiGraph wGT3X (non-dominant wrist)		\checkmark	
Sleep diary		\checkmark	
Self-care diary		\checkmark	
Follow-up		\checkmark	
Post-study survey			\checkmark
Returning ActiGraph wGT3X			\checkmark

TABLE IIIDETAILED STUDY PROCEDURES

E. Data Analysis

1. Data management

The survey data were procured in paper-and-pencil and entered into REDCap. REDCap²¹⁷ has multiple functions including data entry, data backup, encryption, and monitoring. The built-in rules in REDCap, such as detecting missing value, field validation error, outliers, and invalid values, allows efficient and accurate data quality monitoring. In additional, REDCap has a "data dictionary" which contains coding of each variable. Survey data was checked immediately upon completion. Thus, missing was minimized. Each participant was assigned an ID after they signed the informed consent form. Only the ID was used in both the surveys and diaries. After the

post-interview, the actigraphy data was downloaded to the PI's password-protected laptop. Dr. Bronas reviewed the actigraphy data for missing or non-wear. All other electronic data was stored on the same encrypted laptop. Paper questionnaires were stored in a locked cabinet in the PI's office. The statistician Dr. Park has access to the de-identified dataset for statistical consultation. The coding sheet was destroyed at the conclusion of the study.

2. Longitudinal data reduction

Actigraphy data were processed using Actilife 6.8 (ActiGraph, Pensacola, FL). Physical activity data were scored following Freedson and colleagues' ¹⁴¹ definitions of sedentary behavior, light-intensity, and moderate-intensity physical activity. The Cole-Kripke algorithm¹⁴⁷ embedded in the Actilife software was used to score the sleep data following standard procedures.¹⁴³ A medium sensitivity setting was used (cut-off of 40 activity count per minute, for 10 minutes of immobile/mobile for sleep onset and sleep offset). Calculations of each sleep variable from the actigraphy and diaries are shown in Table IV.

TABLE IV

DEFINITIONS/CALCULATIONS OF SLEEP VARIABLES FROM ACTIGRAPHY AND SLEEP DIARIES

Measures	Actigraphy	Sleep diary
Bedtime/rise time	Determined by the researcher based on a combination of sleep diary, sharp decrease or spike in activity count of the actigraphy, and ambient light measurements	"What time did you get into bed"
		"What time did you get out of bed for the day"
Sleep onset/offset	Based on the Cole-Kripke algorithm	NA
Time in bed (TIB)	Period between bedtime and rise time	Period between bedtime and rise time
TST	Amount of time scored as sleep between sleep onset and offset	"What time was your final awakening" - "What time did you try to go to sleep" - SOL - WASO
SOL	Amount of time between bedtime and sleep onset	"How long did it take you to fall asleep"
SE	(TST/TIB)*100%	(TST/TIB)*100%
WASO	Amount of time scored as awake between sleep onset and offset	"In total, how long did those awakenings last"
Number of awakenings	The number of different awakening episodes as scored by the algorithm	"How many times did you wake up"

Adherence is the extent to which participants following the protocol.¹³³ Participant adherence to filling out the daily diaries and wearing the ActiGraph were calculated. Physical activity data from the ActiGraph and self-care data from the two days participant visited us were excluded. Therefore, only 7-day data were used. Eight-day sleep data were available and thus were used to calculate the adherence rate. Diary adherence was defined as the number of days that the dairy was completed divided by 7. At least 50% of the responses need to be recorded for that day to be valid. Response to the self-care diary was considered timely if completed within one hour before bedtime. However, the response window was allowed to be delayed until the following morning upon awakening. Similarly, the response to sleep diary was considered timely if completed within one hour upon awakening. The sleep diary was allowed to be delayed until bedtime on the following day. Both timely and delayed responses were used to calculate the diary adherence rate. For the participant to be adherent to physical activity monitoring, the number of days required was four and over, including at least one weekend day. The number of hours required per day was 10 and over, which is considered representative of a day's physical activity.²¹⁸ Automated wear time estimates were obtained using the algorithm developed by Choi and colleagues. Their definition for the non-wear time was used: 90-minute time window for consecutive zero counts, with an allowance of a 2-minute interval of non-zero counts with the up/downstream 30-minute consecutive zero counts window for detection of artifactual movements.²¹⁹ In line with the definition of physical activity adherence, sleep monitoring for four days and over is required.

3. <u>Statistical analysis</u>

Stata 13.0 (StataCorp LP, College Station, Texas) and SPSS 22.0 (SPSS Inc., Chicago, IL) were used for all analyses. Data were checked for missing, outliers, and normal distribution prior to analyses. Missing data were imputed based on the amount and pattern of missing; mean substitution was used if missing was less than 5%.²²⁰ Descriptive statistics were calculated (i.e., frequency and $\bar{x} \pm$ SD). Based on the distribution of the data, independent-sample t-tests (normal distribution) or Wilcoxon-Mann-Whitney tests (non-normal distribution) were conducted to compare the difference between two groups. Bivariate Pearson or Spearman correlation analyses were used to examine the relationship between two continuous variables, such as age, BMI, diabetes
duration, self-efficacy, distress, daytime sleepiness, fatigue, and sleep quality.

a. Multiple linear regression analysis

Separate multiple linear regression analyses were conducted to test the hypotheses using cross-sectional data. Specifically, the dependent variables included overall self-care, physical activity, eating behavior, and medication adherence. The independent variables, which entered into the multiple linear regression model, were chosen based on the conceptual framework and bivariate results. Besides sleep quality, only those predictors significant at p < 0.2 were included in the model. Model statistics were compared, and the more parsimonious one was presented. Once the final model was obtained, a series of regression diagnostics were run. Influential data were checked first and excluded if warranted. The following four assumptions were examined: model specification, homoscedasticity, multicollinearity, and normal distribution of residuals.

b. Mixed-effect models

Mixed-effect models were used to further test the relationships between sleep and self-care behaviors (i.e., physical activity, eating behavior, and medication adherence) using longitudinal data. Repeated measure ANOVA is frequently used in longitudinal data analysis. It requires the same number of measurements per participant, which is rarely achieved in EMA design. Additionally, EMA data typically involves serial autocorrelation where the closer in time two assessments are made; the more similar the values are likely to be for each individual. That is particularly a problem when using least square analysis.^{72, 73} In contrast to the repeated measure ANOVA, multilevel mixed-effect models can handle issues like unbalanced design and serial autocorrelations from a within/between-person level. For exploration, weekly averages of sleep and self-care were calculated. Pearson correlation analyses were used to assess the bivariate relationships among covariates and weekly averages of sleep and self-care. However, using aggregated data from the 7-day period has limitations.^{221, 222} Specifically, the homoscedasticity assumption for regression analysis might be violated if different numbers of evaluation per participant are used for the aggregation. Thus, type 1 or 2 error might be inflated. Therefore, the multilevel mixed-effect model with a restricted maximum likelihood estimation method was used. The first-order autoregressive structure with homogeneous variances (AR1) was chosen for the fixed effect. The unstructured covariance was used for the random effect. Models with only fixed effect were compared with those with a random effect. If the model fitness did not improve significantly, the more parsimonious one was used. Separate models were run to test the relationship between each sleep variable (i.e., TST, SE, SOL, WASO, and number of awakenings) and self-care variables the following day (i.e., physical activity, eating behavior, and medication adherence). Daily morning fatigue and its interaction with sleep were added in the model. All models were adjusted for individual-level covariates (age, gender, BMI, diabetes duration, self-efficacy, distress, and daytime sleepiness). ActiGraph wear time was included as a covariate to control for variations in accelerometer wear time among participants. Although there were no apparent time trends in the data, we included day in the model.

Mathematical equations used to express the mixed-effect models are presented

below. y_{it} (with i indexing persons and t indexing the momentary assessments of the ith person); J person-level predictor variables, x_{ji} , K moment-level predictor variables, z_{kit} . Level 1 equation describes the within-person relationship between dependent and independent variables.

Level 1 (within-person level). Momentary outcome is predicted by momentary predictors: predicting self-care from night sleep (TST, SE, SOL, WASO, and number of awakenings)

$$y_{it} = \pi_{0i} + \sum_{k=1}^{K} \pi_{ki} z_{kit} + \varepsilon_{it}$$
 (1)

The π_k 's are regression coefficients and "i" subscript in each coefficient indicates that each coefficient is free to vary from person to person, and thus each person has her/his own equation.

Level 2 (between-person level). People's intercepts are predicated by personlevel predictors: predicting self-care from person-level covariates.

$$\pi_{0i} = \beta_{00} + \sum_{j=1}^{J} \beta_{0j} x_{ji} + \delta_{0i}$$
(2a)

$$\pi_{ki} = \beta_{k0} + \sum_{j=1}^{J} \beta_{kj} x_{ji} + \delta_{ki}$$
 (2b)

Intercepts from (1) are the linear function of the person-level predictors plus a residual term δ_{0i} (2a). The residual term is to account for that portion of the individual differences in intercepts that cannot be accounted for by the measured person-level variables. Individual differences in the effect of the momentary independent variable on the dependent variable are predicted by person-level predictors (2b).

Integrated equation:
$$y_{it} = \beta_{00} + \sum_{j=1}^{J} \beta_{0j} x_{ji} + \sum_{k=1}^{K} \beta_{k0} z_{kit} + \delta_{0i} + \varepsilon_{it}$$

The aim of this study was to examine whether sleep was related to self-care from both a between-person and within-person level while accounting for baseline covariates. Thus, the following equations were formulated.

Begin with a fixed effect: assuming that sleep has the same effect on self-care for everyone.

Level 1: Self-care_{it} = π_{0i} + π_{1i} sleep_{it} + ϵ_{it}

Level 2: $\pi_{0i} = \beta_{00} + \delta_{0i}$; $\pi_{1i} = \beta_{10}$

<u>Continue with a random effect:</u> assuming that sleep does not have the same effect on self-care for everyone.

Level 1: Self-care_{it} = π_{0i} + π_{1i} sleep_{it} + ϵ_{it}

Level 2: $\pi_{0i} = \beta_{00} + \delta_{0i}$; $\pi_{1i} = \beta_{10} + \delta_{1i}$

Final model: assuming that sleep is related to self-care, controlling for covariates.

Level 1: Self-care_{it} = π_{0i} + π_{1i} sleep_{it} + ϵ_{it}

Level 2: $\pi_{0i} = \beta_{00} + \beta_{01} \text{ age}_i + \beta_{02} \text{ gender}_i + \beta_{03} \text{ duration}_i + \beta_{04} \text{ BMI}_i + \beta_{05} \text{ daytime}$ sleepiness_i + β_{06} self-efficacy_i + β_{07} distress_i + β_{08} fatigue_i + δ_{0i} ; $\pi_{1i} = \beta_{10} + \delta_{1i}$

IV. RESULTS

This chapter presents study findings. They include participant recruitment process, psychometric properties of the instruments, participant characteristics, and results for the four study hypotheses.

A. <u>Participant Recruitment Process</u>

A total of 126 participants were contacted by phone, of which 102 underwent the full screening. Eighty participants were eligible, and 64 were enrolled. Among the 64 participants, five were excluded from the 8-day assessment based on reasons listed below. The eligibility and response rate was 78.4% and 80.0%, respectively. The recruiting process is shown in Figure 4.



Figure 4. Participant recruitment process.

B. <u>Reliability and Validity of the Instruments</u>

Internal consistency reliability and validity of the instruments is presented below.

Cronbach's α of each instrument for this study and reference study is listed in Table V.

Construct (Instrument)	Cronba	ach's α
	Current study	Reference
Sleep quality (PSQI)	0.71	0.83 ¹⁶¹
Self-care (DSMQ-R)	0.79	0.84 ¹⁶³
Eating behavior (TFEQ-R18V2)		
Cognitive Restraint	0.66	0.78 ¹⁷⁷
Uncontrolled Eating	0.81	0.89
Emotional Eating	0.91	0.94
Medication adherence (MMAS-8)	0.77	0.83 ¹⁸¹
Self-efficacy (DES-SF)	0.83	0.84 ¹⁸⁷
Diabetes distress (DDS)	0.94	0.93 ¹⁹⁰
Fatigue (DSC-R)	0.83	0.87 ¹⁹³
Daytime sleepiness (ESS)	0.73	0.88 ¹⁹⁶

TABLE VINTERNAL CONSISTENCY OF INSTRUMENTS

1. <u>Pittsburgh Sleep Quality Index</u>

In this population, the PSQI demonstrated adequate internal consistency reliability, with a Cronbach's α of 0.71. Theoretically, people with poorer sleep may have more daytime sleepiness or fatigue. Thus, the convergent validity of PSQI was examined by correlating PSQI global score with daytime sleepiness measured by ESS and fatigue measures by the DSC-R fatigue subscale. The respective correlations were 0.15 (p = 0.25) and 0.34 (p = 0.007), supporting the convergent validity.

2. <u>Diabetes Self-Management Questionnaire-Revised</u>

The DSMQ-R overall scale demonstrated adequate internal consistency (Cronbach's $\alpha = 0.79$). Theoretically, better self-care should be related to better glycemic control. Thus, convergent validity of the DSMQ-R was examined by correlating the DSMQ-R total score with A1C level. The correlation coefficient was -0.27 (p = 0.04), supporting its convergent validity.

3. <u>Three-Factor Eating Questionnaire-R18V2</u>

The TFEQ-R18V2 consists of three subscales: Cognitive Restraint, Uncontrolled Eating, and Emotional Eating. In this sample, the Cronbach's α s for the three subscales was 0.66, 0.81, and 0.91. The Uncontrolled Eating and Emotional Eating subscales demonstrated good internal consistency, while the Cognitive Restraint subscale showed suboptimal reliability. Concurrent validity of the TFEQ-R18V2 was examined by correlating each subscale with the dietary control subscale of DSMQ-R. The correlation coefficients were 0.41, -0.39, and -0.29 (p < 0.05), supporting the validity of TFEQ-R18V2.

4. Morisky Medication Adherence Scale-8

The MMAS-8 had adequate internal consistency reliability (Cronbach's α = 0.77). Concurrent validity of the MMAS-8 was supported by its significant correlation with glucose management subscale of the DSMQ-R (r = 0.49, p < 0.01).

5. <u>Diabetes Empowerment Scale-Short Form</u>

The DES-SF demonstrated adequate internal consistency (Cronbach's α = 0.83). Theoretically, people with higher self-efficacy should have better self-care. Thus, convergent validity of the DES-SF was examined by correlating the DES-SF score with self-care measured by the DSMQ-R. Results supported the convergent validity (r = 0.33, p < 0.01).

6. <u>Diabetes Distress Scale</u>

Only the DDS total score was used in this study. The DDS demonstrated excellent internal consistency reliability (Cronbach's α = 0.94). The convergent validity of the DDS was examined by correlating distress with related constructs, such as diabetes symptom. It was hypothesized that people with higher distress might be related to higher diabetes symptom. In this population, the DSC-R total score and DDS were moderately correlated with each other (r = 0.49, p < 0.01).

7. Diabetes Symptom Checklist-Revised

For this study, the score for the DSC-R fatigue subscale was calculated. The Cronbach's α was 0.83, supporting the internal consistency reliability of the DSC-R fatigue subscale. It was hypothesized that diabetes symptoms (e.g., fatigue) would be related to diabetes distress. In this study, the DSC-R fatigue subscale was significantly related to diabetes distress measured by the DDS (r = 0.44, p < 0.01), supporting the convergent validity.

8. <u>Epworth Sleepiness Scale</u>

The ESS had adequate internal consistency reliability (Cronbach's α = 0.73). Daytime sleepiness is a distinct construct from fatigue. Thus, it was hypothesized that daytime sleepiness measured by ESS would not be related to fatigue measured by the DSC-R fatigue subscale. In this study, their correlation coefficient was 0.05 (p = 0.70), supporting the discriminate validity of ESS. Additionally, both ESS and STOP-Bang have been used to screen sleep apnea. In this study, the concurrent validity of

ESS was supported by its significant correlation with STOP-Bang (r = 0.37, p < 0.01).

9. STOP-Bang

Because questions in the STOP-Bang questionnaire reflect different dimensions of sleep apnea, internal consistency reliability cannot be obtained. This instrument should be able to identify those with diagnosed sleep apnea. In this study, the contrasting-group method was used to examine the construct validity of STOP-Bang. People with self-reported diagnosed sleep apnea had a higher STOP-Bang score (p < 0.01), supporting its validity.

C. <u>Participant Demographic Characteristics</u>

Demographic characteristics of the 64 participants are presented in Table VI. Participants age ranged from 50 to 78 years, with a mean of 60.4 years (SD 6.8). Women constituted 51.6% of the sample, and 53.1% were non-Hispanic Black, representative of the neighborhood.

Variables	n (%)/	Range
Age (years)	60.4 ± 6.8	50 - 78
Gender (female)	33 (51.6)	
Race		
Hispanic	12 (18.8)	
Non-Hispanic White	17 (26.5)	
Non-Hispanic Black	34 (53.1)	
Other (Asian)	1 (1.6)	
Education (years)	14.4 ± 2.8	4 - 20
Marital status		
Married and not separated	15 (23.4)	
Single	22 (34.4)	
Other	27 (42.2)	
Work status		
Not working	37 (57.8)	
Part-time	13 (20.3)	
Full-time	14 (21.9)	

TABLE VIDEMOGRAPHIC CHARACTERISTICS

D. <u>Health-Related Characteristics</u>

Health-related characteristics of the 64 participants are shown in Table VII. Participant had a mean BMI of 33.8 kg/m² (SD 8.7), ranging from 19.2 to 56.3 kg/m². Mean diabetes duration was 11.2 years (SD 8.8), ranging from 1 to 40 years. Glycemic controlled measure by A1C was 7.9% (SD 2.0), slightly higher than the ADA recommended goal (A1C < 7.0%).¹⁵ Over half of the participants (61.9%) were using oral medication only as their treatment regimen. In this sample, 28.1% participants had a self-reported diagnosis of sleep apnea, among which 55.6% were receiving continuous positive airway pressure (CPAP) treatment.

Variables	n (%)/ <i>x</i> ± SD	Range
BMI (kg/m ²)	33.8 ± 8.7	19.2 - 56.3
Smoking status		
Never smoker	32 (50.0)	
Former smoker (quit over 1 yr.)	19 (29.7)	
Current smoker	13 (20.3)	
Waist circumference (cm)	112.0 ± 19.2	77.1 - 148.5
Neck circumference (cm)	40.3 ± 5.4	31 - 54.5
Resting blood pressure (mmHg)		
Systolic	135.1 ± 19.6	91 - 185
Diastolic	79.6 ± 11.0	59 - 114
Diabetes duration (yr.)	11.2 ± 8.8	1 - 40
A1C (%)	7.9 ± 2.0	4.6 - 13.0
Poor glycemic control (A1C ≥ 7.0%)	39 (61.9)	
Diabetes treatment regimen		
Insulin only	8 (12.5)	
Oral medication only	37 (57.8)	
Insulin and oral medication	14 (21.9)	
Exercise/diet control	5 (7.8)	
Hypertension (yes)	38 (59.4)	
Sleep apnea (yes)	18 (28.1)	
Current use of CPAP	10 (55.6)	

 TABLE VII

 HEALTH-RELATED CHARACTERISTICS

E. <u>Descriptions of Main Study Variables</u>

Descriptions of main study variables obtained from baseline data are presented in Table VIII. Participants mean PSQI global score was 7.0 (SD 3.7), with a range of 2 to 20. Approximately 54.7% had poor sleep quality (PSQI > 5). Overall, participants in this study had adequate self-care. Specifically, the average DSMQ-R total score was 6.9 (SD 1.5), ranging from 2.5 to 10. Mean MMAS-8 score was 6.3 (SD 1.9), and 33.9% had poor medication adherence (MMAS-8 < 6).

Variables	n (%)/x̄±SD	Range
Sleep quality (PSQI global)	7.0 ± 3.7	2 - 20
Poor sleep quality (PSQI global > 5)	35 (54.7)	
Self-care (DSMQ-R)	6.9 ± 1.5	2.5 - 10
Physical activity: weekly MET (IPAQ-S)	1455.8 ± 1439.3	0 - 5158
Eating behavior (TFEQ-R18V2)		
Cognitive restraint	47.0 ± 25.6	0 - 100
Uncontrolled eating	34.9 ± 18.8	0 - 81.5
Emotional eating	34.0 ± 25.4	0 - 100
Medication adherence (MMAS-8)	6.3 ± 1.9	1.5 - 8
Poor adherence (MMAS-8 < 6)	20 (33.9)	
Self-efficacy (DES-SF)	4.1 ± 0.8	2.3 - 5
Diabetes distress (DDS)	2.0 ± 1.0	1 - 4.7
High-to-moderate distress (DDS > 2)	26 (40.6)	
Fatigue (DSC-R)	1.6 ± 1.2	0 - 4.3
Daytime sleepiness (ESS)	8.7 ± 4.5	0 - 24
Sleep apnea risk (STOP-Bang)	3.8 ± 1.7	1 - 8

 TABLE VIII

 DESCRIPTIVE ANALYSES OF MAIN STUDY VARIABLES

F. <u>Participant Adherence and Reactivity</u>

A total of 59 participants were included for the 8-day EMA assessment. One participant was hospitalized the third day after enrollment and therefore was not included in further analyses. Among the remaining 58 participants, 46 (79.3%) used the electronic diary, and 12 used the paper diary. Comparison of those participants is presented in Table IX.

TABLE IX COMPARISONS BETWEEN PARTICIPANTS USING ELECTRONIC AND PAPER DIARIES

Variables	Electronic diary	Paper diary	р
	n = 46	n = 12	
Age (years)	59.3 ± 6.2	65.8 ± 6.6	0.003
Gender (female)	22(47.8)	11(91.7)	0.006
Education (years)	15.1 ± 2.2	12.3 ± 3.8	0.002
Diabetes duration (years)	10.5 ± 8.2	13.3 ± 9.7	0.33
Ethnicity (Non-Hispanic)	41(89.1)	8(66.7)	0.056
A1C	8.1 ± 2.2	7.2 ± 1.3	0.23
Sleep quality (PSQI)	6.8 ± 3.5	8.3 ± 4.8	0.25
Self-care (DSMQ-R)	6.9 ± 1.4	6.7 ± 1.9	0.71
Eating behavior (TFEQ-R18V2) ^a			
Uncontrolled Eating	33.8 ± 19.9	37.7 ± 15.0	0.54
Cognitive Restraint	49.5 ± 24.6	37.0 ± 31.9	0.15
Emotional Eating	34.9 ± 25.8	29.2 ± 26.6	0.50
Medication adherence	6.1 ± 2.0	6.5 ± 1.8	0.55
Physical activity (IPAQ-S)	1592.2 ± 1440.0	1236.8 ± 1543.6	0.46

^a n = 53

Participant adherence to the diaries and ActiGraph is presented in Figure 5. Overall, the 58 participants had good adherence to study protocol. Mean daily ActiGraph wear time was 1426 minutes (SD 51), ranging from 1079 to 1440 minutes. After excluding unreasonable data and missing days, 87.9% and 94.8% participants had at least seven days sleep data from the diaries and actigraphy, respectively. A respective of 81.0% and 82.8% participants had 7-day self-care and actigraphy physical activity data. One participant had 3-day valid data and thus was excluded from analyses. Therefore, data from 57 participants were used for the mixed-effect models.



Figure 5. Participant adherence.

5A: sleep diary; 5B: actigraphy sleep assessment; 5C: self-care diary; 5D: actigraphy physical activity assessment (numbers within the figure are the numbers of participants).

Participant reactivity was briefly assessed during the post-study interview. They were asked the degree to which they changed their sleep and self-care behaviors by participating in this study. Data from 52 participants who completed the post-study survey are presented in Table X.

Measures	Not at all	A little	Moderately	Very	Extremely
Changes in sleep behaviors					
Diary	31(59.6)	13(25.0)	7(13.5)	1(1.9)	0
Wearing ActiGraph	37(72.6)	8(15.7)	5(9.8)	1(2.0)	0
Changes in self-care					
Eating behavior	19(36.5)	13(25.0)	15(28.9)	5(9.6)	0
Taking medication	33(63.5)	9(17.3)	6(11.5)	2(3.9)	2(3.9)
ActiGraph physical activity	33(64.7)	8(15.7)	10(19.6)	0	0

TABLE XPARTICIPANT REACTIVITY

G. <u>Summary of Longitudinal Data</u>

Averages of sleep and self-care variables across the seven days from the 57 participants are shown in Table XI. Missing for the 7-day data was small, ranging from 6.8% to 1.0%. On average, participant TST and SE were around 400min and 80%, respectively. Time spent in sedentary, light-intensity and moderate-intensity physical activity was 315.9 minutes (SD 114.4), 510.6 minutes (SD 90.9), and 133.7 minutes (SD 67.7), respectively. No participant engaged in vigorous physical activities.

Variables	$\overline{x} \pm SD$	Range
Diary sleep		
TST (min)	402.8 ± 77.1	235.6 – 572.5
SE (%)	80.6 ± 10.5	51.8 – 97.3
SOL (min)	24.5 ± 20.7	2.6 - 86.7
WASO (min)	19.7 ± 15.3	1.0 – 61.0
Morning fatigue	3.0 ± 1.9	0 – 8.8
Actigraphy sleep		
TST (min)	394.6 ± 70.4	250.5 – 572.4
SE (%)	80.9 ± 8.1	58.5 – 94.4
SOL (min)	7.3 ± 3.0	4 – 20.2
WASO (min)	87.6 ± 43.5	21.6 – 239
Number of awakenings	18.7 ± 7.2	6.9 – 34.4
Actigraphy physical activity		
Sedentary (min/d)	315.9 ± 114.4	139.7 – 664.9
Light-intensity (min/d)	510.6 ± 90.9	277.1 – 693.5
Moderate-intensity (min/d)	133.7 ± 67.7	21.1 – 304.2
Eating behavior		
Eating Variation	1.7 ± 0.5	1 – 3.2
Cognitive Restraint	1.9 ± 0.7	1 – 4.1
Uncontrolled Eating	1.5 ± 0.5	1 – 3.3
Emotional Eating	1.3 ± 0.5	0.5 – 3.7

 TABLE XI

 SUMMARY OF WEEKLY AVERAGES OF SLEEP AND SELF-CARE

H. <u>Research Hypotheses</u>

Our central hypothesis is "sleep disturbance is related to impaired self-care behaviors in older adults with T2DM. Findings for each specific hypothesis are presented in this section.

1. <u>Hypothesis 1</u>

The first hypothesis is: Sleep disturbance is related to impaired overall self-care, after controlling for potential covariates (e.g., gender, age, BMI, diabetes duration, self-efficacy, diabetes distress, fatigue, and daytime sleepiness). Baseline

data from the 64 participants were used to test this hypothesis.

Table XII presents bivariate correlations between self-care and continuous variables. Subjective sleep quality, self-efficacy, diabetes distress, fatigue, and daytime

sleepiness were significantly related to overall self-care measured by the DSMQ-R (r = -

0.53-0.33, p < 0.01). Table XIII shows comparisons of self-care between men and

women. Men and women did not differ in self-care behaviors.

 TABLE XII

 BIVARIATE CORRELATIONS BETWEEN SELF-CARE AND OTHER VARIABLES^a

	Self-	Weekly	Cognitive	Uncontrolled	Emotional	Medication
	care	MET	Restraint	Eating	Eating	adherence
Age	0.20 [†]	-0.12	-0.35**	0.06	-0.02	0.14
BMI	-0.16	-0.17 [†]	0.17^{+}	-0.18 [†]	0.04	-0.003
Diabetes duration	0.22 [†]	-0.10	0.16 [†]	-0.09	0.09	0.09
Sleep quality	-0.36**	0.15	0.02	0.08	0.19 [†]	-0.15
Self-efficacy	0.33**	-0.06	0.15	-0.26*	-0.31*	0.25^{\dagger}
Diabetes distress	-0.53***	-0.16 [†]	0.15	0.15	0.45***	-0.53***
Fatigue	-0.39**	0.10	0.09	0.14	0.48***	-0.34**
Daytime sleepiness	-0.35**	-0.02	-0.08	0.24*	0.10	-0.34**

^a Only correlations of interest are presented.

^b Spearman correlation analysis was used.

 $^{\circ}$ n = 59 (5 participants not taking medication for diabetes).

[†]p < 0.20, *p < 0.05, **p < 0.01, ***p < 0.001.

TABLE XIII
COMPARISONS OF SELF-CARE BY GENDER

	$\overline{x} \pm SD$					
	Self-		Cognitive	Uncontrolled	Emotional	Medication
	care		Restraint	Eating	Eating	adherence ^{a,b}
Male	7.0±1.4	1767.1±1719.5	46.6±23.2	35.6±20.1	29.6±22.8	6.7±1.6
Female	6.7±1.6	1163.3±1060.3	47.5±28.0	34.2±17.7	38.2±27.3	5.9±2.1
t/z	0.6	0.84	-0.1	0.3	-1.4	1.31
р	0.54	0.40	0.89	0.77	0.17	0.19

^aWilcoxon-Mann-Whitney test was used.

^b n = 59 (5 participants not taking medication for diabetes).

The regression model for predictors of overall self-care measured by the DSMQ-R is presented in Table XIV. Initially, seven variables significantly related to overall selfcare at p < 0.2 were included in the model: age, diabetes duration, sleep quality, selfefficacy, diabetes distress, fatigue, and daytime sleepiness. Preliminary diagnostic analysis indicated one participant was an influential case, and thus was excluded from the analysis. The final, more parsimonious model was used. Collectively, the six variables explained 51% of the variation in overall self-care. Sleep quality (coefficient = -0.10, p = 0.012), diabetes distress (coefficient = -0.59, p = 0.001), and daytime sleepiness (coefficient = -0.07, p = 0.041) were significant predictors. Regression diagnostics revealed no violation of the assumptions.

 TABLE XIV

 REGRESSION ANALYSIS FOR PREDICTORS OF SELF-CARE^a

Predictor	Coefficient	β	t	р
Sleep quality	-0.10	-0.26	-2.57	0.012
Diabetes duration	0.03	0.16	1.66	0.102
Self-efficacy	0.21	0.11	0.99	0.326
Diabetes distress	-0.59	-0.39	-3.65	0.001
Fatigue	-0.12	-0.10	-0.89	0.379
Daytime sleepiness	-0.07	-0.21	-2.09	0.041

^a Model statistics: F (6, 56) = 9.75, p < 0.001, R^2 = 0.51, adjusted R^2 = 0.46.

2. <u>Hypothesis 2</u>

The second hypothesis is: Sleep disturbance is related to lower levels of physical activity, after controlling for potential covariates (e.g., gender, age, BMI, diabetes duration, self-efficacy, distress, fatigue, and daytime sleepiness). Both baseline and longitudinal 7-day data were used to test this hypothesis.

a. Multiple linear regression model

Bivariate correlation analyses using baseline weekly MET indicated that BMI (r = -0.17) and diabetes distress (r = -0.16) were significantly related to weekly MET at p < 0.02 (Table XII). Men and women did not differ in weekly MET (Table XIII). In the final regression model predicting weekly MET, four variables were included: age, BMI, sleep quality, and diabetes distress. Regression diagnostics revealed no violation of the assumptions, except non-normal residuals. Therefore, median regression analysis was run to get a more robust estimation (Table XV). The four variables collectively explained 12% of the variation in physical activity. Nevertheless, none of the predictors were significant.

 TABLE XV

 MEDIAN REGRESSION ANALYSIS OF PREDICTORS OF PHYSICAL ACTIVITY^a

Predictor	Coefficient	SE	t	р
Age	-6.5	36.3	-0.18	0.859
BMI	-10.0	27.7	-0.36	0.718
Sleep quality	137.6	66.2	1.96	0.050
Diabetes distress	-362.2	253.9	-1.43	0.159

^a Model statistics: n = 64, $R^2 = 0.12$.

Bivariate correlation analyses using weekly averages of sleep and actigraphy physical activity were conducted to further test the second hypothesis. Physical activity variables include sedentary behavior, light-intensity physical activity, and moderateintensity physical activity. Sedentary behavior was related to subjective TST (r = -0.32, p < 0.05) and objective WASO (r = -0.30, p < 0.05). Light-intensity physical activity was related to objective TST (r = -0.34, p < 0.01). Significant relationships are shown in Table XVI.

	Sedentary	Light-intensity	Eating	Uncontrolled	Emotional
	behavior	activity	Variation	Eating	Eating
Diary					
TST	-0.32*				
SE			-0.26*		
SOL			0.28*		
WASO					
Morning fatigue			0.32*	0.35**	0.36**
Actigraphy					
TST		-0.34**			
SE				-0.28*	
WASO	-0.30*			0.32*	
Number of				0.40**	0.28*
awakenings					

 TABLE XVI

 BIVARIATE CORRELATIONS USING WEEKLY AVERAGES

*p < 0.05; **p < 0.01.

b. Mixed-effect model

Multilevel mixed-effect models were used to further predict physical activity from sleep. Participant baseline characteristics, as well as day and ActiGraph wear time were adjusted. Only significant findings are presented here.

Based on Table XVII, subjective TST was not a significant predictor of time spent in sedentary behavior. Interestingly, the interaction term of morning fatigue and TST was significant, suggesting that the effect of subjective TST on sedentary behavior was different at different morning fatigue levels. The effect was smaller for those with higher morning fatigue. Additionally, compared to men, women spent about 65 more minutes in sedentary behavior (p = 0.046).

TABLE XVIIMULTILEVEL MODEL PREDICTING SEDENTARY BEHAVIOR FROM SUBJECTIVETST^a

Effect (intercent, clence)	Estimate Standard		t/z p		95%CI	
	LStinate	Error	VΖ	ρ	Lower	Upper
Fixed						
Intercept	-399.34	255.19	-1.56	0.120	-904.46	105.78
Gender (female)	64.96	31.71	2.05	0.046	1.27	128.65
Morning fatigue	13.87	7.65	1.81	0.071	-1.19	28.93
TST	0.12	0.08	1.40	0.16	-0.05	0.29
TST * morning fatigue	-0.04	0.02	-2.21	0.028	-0.08	-0.004
Random						
Level 1 (within-person)						
Residual	9373.10	925.78	10.13	< 0.001	7723.44	11375.13
Autocorrelation	0.22	0.08	2.89	0.004	0.07	0.37
Level 2 (between-person)						
Intercept	10048.73	2487.13	4.04	< 0.001	6186.34	16322.61

^a Controlling for age, body mass index, diabetes duration, self-efficacy, diabetes distress, daytime sleepiness, day, and ActiGraph wear time.

Based on Table XVIII, both subjective and objective TST significantly predicted time spent in light-intensity physical activity. For a particular individual, a 1-minute decrease in subjective and objective TST was related to 0.26 and 0.43 minutes increase in light-intensity physical activity, respectively (p < 0.05). Similarly, those with 1 minute less subjective and objective TST spent 0.26 and 0.43 minutes more in light-intensity physical activity, respectively.

TABLE XVIII

MULTILEVEL MODEL PREDICTING LIGHT-INTENSITY PHYSICAL ACTIVITY FROM ${\rm TST}^{\rm a}$

Effect (intercent, clence)	Estimato	Standard		5	95%CI	
Ellect (Intercept, slopes)	Estimate	Error	VΖ	þ	Lower	Upper
<i>Diary</i> Eixed						
Intercent	324 47	211 19	1 54	0 127	-93 80	742 74
Morning fatigue	1 42	2 31	0.62	0.127	-3 12	5 96
TST	-0.26	0.09	-5.13	< 0.000	-0.36	-0.16
Random	0.20	0.00	0.10	< 0.001	0.00	0.10
Level 1 (within-person)						
Residual	6349.27	566.15	11.22	< 0.001	5331.19	7561.78
Autocorrelation	0.13	0.07	1.81	0.07	-0.01	0.26
Level 2 (between-person)						
Intercept	7287.29	1747.72	4.17	< 0.001	4553.07	11663.48
Actigraphy						
Fixed						
Intercept	308.69	210.19	1.47	0.145	-107.49	724.87
Morning fatigue	1.86	2.14	0.87	0.386	-2.36	6.07
TST	-0.43	0.05	-8.61	< 0.001	-0.53	-0.33
Random						
Level 1 (within-person)						
Residual	5609.94	508.14	11.04	< 0.001	4697.41	6699.74
Autocorrelation	0.13	0.07	1.76	0.079	-0.02	0.27
Level 2 (between-person)						
Intercept	6967.52	1672.5	4.17	< 0.001	4352.64	11153.30

^a Controlled for age, gender, body mass index, diabetes duration, self-efficacy, diabetes distress, daytime sleepiness, day, and ActiGraph wear time.

Based on Table XIX, subjective WASO alone was not a significant predictor of time spent in moderate-intensity physical activity. However, the interaction term of morning fatigue and subjective WASO was significant, suggesting that the effect of subjective WASO on moderate-intensity physical activity was different at different morning fatigue levels. The effect was larger for those with higher morning fatigue.

TABLE XIXMULTILEVEL MODEL PREDICTING MODERATE-INTENSITY PHYSICAL ACTIVITYFROM SUBJECTIVE WASO^a

Effect (intercent, clenes)	Estimate Standard		t/z n		95%CI	
Ellect (intercept, slopes)	Estimate Error	ρ	Lower	Upper		
Fixed						
Intercept	206.13	142.06	1.45	0.150	-76.16	488.42
Morning fatigue	-0.89	1.46	-0.60	0.551	-3.82	2.04
WASO	-0.19	0.15	-1.27	0.205	-0.49	0.10
WASO* morning fatigue	0.11	0.04	2.78	0.006	0.03	0.19
Random						
Level 1 (within-person)						
Residual	2149.59	194.59	11.05	< 0.001	1800.12	1566.91
autocorrelation	0.12	0.07	1.66	0.097	-0.02	0.26
Level 2 (between-person)						
Intercept	4107.52	933.40	4.40	< 0.001	2631.19	6412.21

^a Controlled for age, gender, body mass index, diabetes duration, self-efficacy, diabetes distress, daytime sleepiness, day, and ActiGraph wear time.

3. <u>Hypothesis 3</u>

The third hypothesis is: Sleep disturbance is related to impaired eating behavior, after controlling for potential covariates (e.g., gender, age, BMI, diabetes duration, self-efficacy, distress, fatigue, and daytime sleepiness). Both baseline and longitudinal 7-day data were used to test this hypothesis.

a. Multiple linear regression model

Bivariate correlation analyses using baseline data indicated that age, self-efficacy, diabetes distress, fatigue, and daytime sleepiness were related to eating behavior (r = -0.35-0.48, p < 0.05). However, sleep quality was not related to eating behavior (Table XII). Based on Table XIII, men and women did not differ in eating behavior.

Final regression models predicting the three eating behavior are shown in Table
XX. Sleep quality, age, BMI, and diabetes duration explained 23% of the variation in
Cognitive Restraint, but sleep quality was not a significant predictor. Only age
(coefficient = -1.60, $p = 0.001$) and diabetes duration (coefficient = 0.91, $p = 0.012$) were
significant predictors. In the model predicting Uncontrolled Eating, BMI (coefficient = -
0.58, $p = 0.031$) and daytime sleepiness (coefficient = -1.08, $p = 0.041$) were significant
predictors. Sleep quality, self-efficacy, fatigue, and diabetes distress collectively
explained 31% of the variation in Emotional Eating. Surprisingly, fatigue (coefficient =
6.22, $p = 0.025$) and diabetes distress (coefficient = 7.13, $p = 0.32$) were significant
predictors, but not sleep quality. Regression diagnostics revealed no violation of the
assumptions for all three models.

Predictor	Coefficient	β	t	р
Cognitive Restraint ^a				
Age	-1.60	-0.43	-3.49	0.001
BMI	0.47	0.16	1.39	0.170
Diabetes duration	0.91	0.31	2.58	0.012
Sleep quality	-0.18	-0.03	-0.23	0.818
Uncontrolled Eating ^b				
BMI	-0.58	-0.27	-2.21	0.031
Sleep quality	0.04	0.008	0.07	0.946
Self-efficacy	-5.92	-2.37	-1.96	0.055
Daytime sleepiness	1.08	0.26	2.09	0.041
Emotional Eating ^c				
Sleep quality	0.27	0.04	0.34	0.736
Self-efficacy	-3.59	-0.11	-0.89	0.379
Diabetes distress	7.13	0.27	2.20	0.032
Fatigue	6.22	0.30	2.29	0.025

TABLE XX REGRESSION ANALYSIS OF PREDICTORS OF EATING BEHAVIOR

^a Model statistics: F (4, 59) = 4.35, p = 0.004, R² = 0.23, adjusted R² = 0.18. ^b Model statistics: F (4, 59) = 3.15, p = 0.021, R² = 0.17, adjusted R² = 0.12. ^c Model statistics: F (4, 58) = 6.52, p < 0.01, R² = 0.31, adjusted R² = 0.26.

Bivariate correlation analyses using weekly averages of sleep and eating behavior were conducted to further test the third hypothesis. Eating behavior included Eating Variation, Cognitive Restraint, Uncontrolled Eating, and Emotional Eating. Significant relationships are shown in TABLE XVI. Eating Variation was related to subjective SE (r = -0.26, p = 0.05), SOL (r = 0.28, p = 0.036), and morning fatigue (r = 0.32, p = 0.02). Cognitive Restraint was not associated with any sleep variables, only with diabetes duration (r = 0.30, p = 0.02) and BMI (r = 0.28, p = 0.04). Uncontrolled Eating was associated with daytime sleepiness (r = 0.27, p = 0.04) and morning fatigue (r = 0.35, p = 0.008), objective SE (r = -0.28, p = 0.23), WASO (r = 0.32, p = 0.01), and number of awakenings (r = 0.40, p = 0.002). Emotional Eating was related to morning fatigue (r = 0.36, p < 0.01) and number of awakenings (r = 0.28, p < 0.05).

b. Mixed-effect model

Multilevel mixed-effect models were used to further predict eating behavior from sleep. Participant baseline characteristics and day were adjusted. Only significant findings are presented here.

Mixed-effect models predicting Eating Variation from subjective sleep are presented in Table XXI. For the model predicting Eating Variation from subjective SE, when the interaction term of SE and morning fatigue was not included, SE was not a significant predictor. However, when the interaction term was included, SE was a significant predictor. Therefore, only the interaction term was interpreted. The effect of SE on Eating Variation was higher in those with a higher level of morning fatigue. Similarly, for the model predicting Eating Variation from subjective SOL and WASO, only interaction terms were interpreted. The effect of SOL and WASO on Eating

Variation was larger in those with a lower level of morning fatigue.

TABLE XXI MULTILEVEL MODEL PREDICTING EATING VARIATION FROM SUBJECTIVE SLEEP^a

Effect (intercent clance)	Fatimata	Standard	+/	5	95%CI		
Effect (intercept, slopes)	Estimate	Error	VΖ	þ	Lower	Upper	
Fixed							
Intercept	1.80	0.92	1.96	0.055	-0.04	3.65	
Morning fatigue	-0.16	0.07	-2.31	0.021	-0.29	-0.02	
SE	-0.01	0.004	-3.01	0.003	-0.02	-0.004	
SE*morning fatigue	0.002	0.0008	2.53	0.012	0.0005	0.004	
Random							
Level 1 (within-person)							
Residual	0.43	0.04	10.82	< 0.001	0.36	0.51	
autocorrelation	0.14	0.08	1.76	0.079	-0.02	0.29	
Level 2 (between-person)							
Intercept	0.17	0.05	3.07	0.002	0.09	0.32	
Fixed							
Intercept	0.45	0.90	0.50	0.618	-1.35	2.25	
Morning fatigue	0.03	0.02	1.64	0.101	-0.007	0.07	
SOL	0.004	0.002	2.23	0.027	0.0005	0.008	
SOL* morning fatigue	-0.001	0.0004	-2.09	0.037	-0.002	-0.00006	
Random							
Level 1 (within-person)							
Residual	0.44	0.04	10.58	< 0.001	0.36	0.52	
autocorrelation	0.16	0.08	2.04	0.045	0.0008	0.31	
Level 2 (between-person)							
Intercept	0.16	0.05	2.96	0.003	0.09	0.32	
Fixed							
Intercept	0.86	0.94	0.91	0.366	-1.03	2.74	
Morning fatigue	0.03	0.02	1.75	0.080	-0.004	0.07	
WASO	0.005	0.002	2.34	0.020	0.0008	0.009	
WASO* morning fatigue	-0.001	0.0005	-2.58	0.010	-0.003	-0.0003	
Random							
Level 1 (within-person)							
Residual	0.43	0.04	10.43	< 0.001	0.36	0.52	
autocorrelation	0.17	0.08	2.11	0.035	0.009	0.32	
Level 2 (between-person)							
Intercept	0.19	0.06	3.08	0.002	0.10	0.35	

Mixed-effect models predicting Eating Variation from objective sleep are presented in Table XXII. Similar to when subjective sleep was used, significant interactions between sleep and morning fatigue were observed. The effect of objective WASO and number of awakenings on eating variation was larger in those with a lower level of morning fatigue.

TABLE XXII

MULTILEVEL MODEL PREDICTING EATING VARIATION FROM OBJECTIVE SLEEP^a

Effect (intercent clones)	Estimate Standard		t/z n		95%CI	
Ellect (intercept, slopes)	Estimate	Error	VΖ	þ	Lower	Upper
Fixed						
Intercept	1.01	0.95	1.07	0.290	-0.89	2.91
Morning fatigue	0.06	0.03	2.18	0.030	0.006	0.12
WASO	0.0009	0.001	0.79	0.432	-0.001	0.003
WASO* morning fatigue	-0.0006	0.0002	-2.20	0.029	-0.001	-0.00006
Random						
Level 1 (within-person)						
Residual	0.44	0.04	9,87	< 0.001	0.36	0.54
autocorrelation	0.22	0.08	2.63	0.009	0.05	0.37
Level 2 (between-person)						
Intercept	0.19	0.06	2.95	0.003	0.10	0.36
Fixed						
Intercept	0.84	0.98	0.85	0.397	-1.13	2.82
Morning fatigue	0.11	0.03	3.25	0.001	0.04	0.18
Number of awakenings	0.009	0.006	1.30	0.196	-0.005	0.02
Number of awakenings*	-0.005	0.001	-3.45	0.001	-0.008	-0.002
morning fatigue						
Random						
Level 1 (within-person)						
Residual	0.43	0.04	9.94	< 0.001	0.35	0.52
autocorrelation	0.21	0.08	2.57	0.010	0.04	0.36
Level 2 (between-person)						
Intercept	0.21	0.06	3.12	0.002	0.11	0.39

^a Controlled for age, gender, body mass index, diabetes duration, self-efficacy, diabetes distress, daytime sleepiness, and day.

Mixed-effect models predicting Cognitive Restraint from sleep are presented in

Table XXIII. Subjective WASO significantly predicted Cognitive Restraint. One minute

increase in WASO was associated with 0.003 unit decrease in Cognitive Restraint in eating behavior (on a 5-point scale). Although objective number of awakenings alone was not a significant predictor, its interaction with morning fatigue significantly predicted Cognitive Restraint. The effect of number of awakenings on Cognitive Restraint was larger in those with a higher level of morning fatigue.

Effect (intercent clance)	Estimato	-stimate Standard		<u> </u>	95%CI	
Ellect (Intercept, slopes)	Estimate	Error	VΖ	þ	Lower	Upper
Diary						
Fixed						
Intercept	1.42	1.26	1.13	0.264	-1.11	3.95
BMI	0.04	0.01	3.13	0.003	0.01	0.06
Morning fatigue	-0.006	0.02	-0.29	0.776	-0.04	0.03
WASO	-0.003	0.001	-2.11	0.036	-0.006	-0.002
Random						
Level 1 (within-person)						
Residual	0.40	0.03	11.25	< 0.001	0.34	0.48
autocorrelation	0.10	0.07	1.40	0.162	-0.04	0.23
Level 2 (between-person)						
Intercept	0.43	0.10	4.08	< 0.001	0.27	0.70
Actigraphy						
Fixed						
Intercept	1.39	1.25	1.11	0.271	-1.12	3.90
BMI	0.03	0.01	2.93	0.005	0.01	0.06
Morning fatigue	-0.05	0.03	-1.53	0.128	-0.12	0.01
No. of awakening	-0.01	0.007	-1.87	0.062	-0.03	0.0007
Number of awakenings*	0.004	0.001	2.32	0.021	0.0006	0.007
morning fatigue						
Random						
Level 1 (within-person)						
Residual	0.41	0.03	11.35	< 0.001	0.34	0.48
autocorrelation	0.10	0.07	1.32	0.186	-0.04	0.23
Level 2 (between-person)						
Intercept	0.42	0.10	4.06	< 0.001	0.26	0.68

 TABLE XXIII

 MULTILEVEL MODEL PREDICTING COGNITIVE RESTRAINT FROM SLEEP^a

Mixed-effect models predicting Uncontrolled Eating from subjective sleep are presented in Table XXIV. Subjective TST did not significantly predict uncontrolled eating. However, there was a significant interaction between morning fatigue and subjective TST. The effect of TST on Uncontrolled Eating was larger in those with a higher level of morning fatigue. Similarly, the effect of SE on Uncontrolled Eating was larger in those with a higher level of morning fatigue.

 TABLE XXIV

 MULTILEVEL MODEL PREDICTING UNCONTROLLED EATING FROM SUBJECTIVE

 SLEEP^a

Effect (intercent, clence)	Estimate Standard		t/z n		95%CI	
Ellect (intercept, slopes)	Estimate	Error	U/Z	ρ	Lower	Upper
Fixed						
Intercept	1.88	0.92	2/04	0.046	0.03	3.73
Morning fatigue	-0.08	0.04	-1.90	0.058	-0.17	0.003
TST	-0.0008	0.0005	-1.76	0.079	-0.002	0.0001
TST* morning fatigue	0.0002	0.0001	2.26	0.024	0.00003	0.0004
Random						
Level 1 (within-person)						
Residual	0.30	0.03	10.48	< 0.001	0.25	0.36
autocorrelation	0.19	0.07	2.55	0.011	0.04	0.33
Level 2 (between-person)						
Intercept	0.19	0.05	3.53	< 0.001	0.11	0.33
Fixed						
Intercept	2.14	0.92	2.33	0.024	0.30	3.98
Morning fatigue	-0.13	0.05	-2.23	0.027	-0.24	-0.01
SE	-0.01	0.003	-2.91	0.004	-0.01	-0.003
SE* morning fatigue	0.002	0.0007	2.43	0.015	0.0003	0.003
Random						
Level 1 (within-person)						
Residual	0.27	0.02	10.83	< 0.001	0.23	0.33
autocorrelation	0.14	0.07	1.88	0.060	-0.008	0.287
Level 2 (between-person)						
Intercept	0.21	0.05	3.74	< 0.001	0.12	0.35

Mixed-effect models predicting Emotional Eating from sleep are presented in

Table XXV. Neither subjective nor objective TST alone significantly predicted Emotional

Eating. However, there was a significant interaction between morning fatigue and TST.

The effect of TST on Emotional Eating was larger in those with a higher level of morning fatigue.

Effect (intercent, clence)	Estimate Standard		+/	~	95%CI	
Effect (intercept, slopes)	Enect (Intercept, slopes) Estimate Error	VΖ	þ	Lower	Upper	
<i>Diary</i> Fixed						
Intercept	1.32	0.93	1.41	0.165	-0.56	3.19
Morning fatigue	-0.06	0.04	-1.40	0.161	-0.14	0.02
TST	-0.0005	0.0005	-1.09	0.227	-0.001	0.0004
TST * morning fatigue	0.0002	0.0001	1.98	0.049	0.00001	0.0004
Random						
Level 1 (within-person)						
Residual	0.27	0.03	10.33	< 0.001	0.23	0.33
autocorrelation	0.22	0.07	2.97	0.003	0.07	0.35
Level 2 (between-person)						
Intercept	0.21	0.06	3.61	< 0.001	0.12	0.35
Actigraphy						
Fixed						
Intercept	1.44	0.94	1.52	0.134	-0.45	3.33
Morning fatigue	-0.08	0.04	-1.69	0.092	-0.17	0.01
TST	-0.0007	0.0005	-1.39	0.165	-0.002	0.0003
TST * morning fatigue	0.0002	0.0001	2.123	0.035	0.00002	0.0004
Random						
Level 1 (within-person)						
Residual	0.27	0.03	10.10	< 0.001	0.23	0.33
autocorrelation	0.24	0.07	3.20	0.001	0.09	0.37
Level 2 (between-person)						
Intercept	0.21	0.06	3.59	< 0.001	0.12	0.36

TABLE XXV MULTILEVEL MODEL PREDICTING EMOTIONAL EATING FROM TST^a

4. <u>Hypothesis 4</u>

The fourth hypothesis is: Sleep disturbance is related to impaired medication adherence, after controlling for potential covariates (e.g., gender, age, body mass index, diabetes duration, self-efficacy, distress, fatigue, and daytime sleepiness). Both baseline and longitudinal 7-day data were used to test this hypothesis.

a. Multiple linear regression model

Bivariate correlation analyses using baseline data indicated that diabetes distress (r = -0.53, p < 0.001), fatigue (r = -0.34, p = 0.008), and daytime sleepiness (r = -0.34, p = 0.009) were significantly related to medication adherence. Sleep quality was not significantly associated with medication adherence (r = -0.15, p = 0.24). Based Table XIII, men and women did not differ in medication adherence.

In the initial linear regression model predicting medication adherence, five variables were included: sleep quality, self-efficacy, diabetes distress, fatigue, and daytime sleepiness. Preliminary analysis suggested one participant was an outlier and thus were excluded from the analysis. In the final model (Table XXVI), five variables collectively explained 33% of the variation in medication adherence. Sleep quality was not a significant predictor, only diabetes distress (coefficient = -0.99, p = 0.001) significantly predicted medication adherence. Regression diagnostics revealed no violation of the assumptions.

TABLE XXVI REGRESSION ANALYSIS OF PREDICTORS OF MEDICATION ADHERENCE^a

Predictor	Coefficient	β	t	р
Sleep quality	-0.03	-0.07	-0.55	0.587
Self-efficacy	0.004	0.001	0.01	0.992
Diabetes distress	-0.99	-0.44	-3.53	0.001
Fatigue	-0.29	-0.18	-1.38	0.174
Daytime sleepiness	-0.04	-0.11	-0.90	0.371

^a Model statistics: F (5, 52) = 5.21, p < 0.001, R^2 = 0.33, adjusted R^2 = 0.27.

b. Mixed-effect model

Daily medication adherence was measured by two dichotomous variables: take the medication/insulin at the right time and take the right dose of medication/insulin. Weekly averages cannot be obtained. Therefore, only mixed-effect models were run to further predict the medication adherence from sleep. Only subjective SOL significantly predicted the following day take the right dose of medication/insulin. Those with higher subjective SOL were more likely not taking the correct dose of medication/insulin (Table XXVII).

 TABLE XXVII

 GENERALIZED MODEL PREDICTING MEDICATION ADHERENCE FROM SLEEP^a

	Coefficient	Standard Error	X ²	р
Threshold	7.79	4.67	2.78	0.095
Subjective SOL	0.016	0.005	10.15	0.001

V. DISCUSSION

The aim of this study was to examine the relationships between sleep and selfcare in older adults with T2DM. This study is among the first to investigate the relationships by using an ecological momentary assessment method over an 8-day period in the real-world setting. In this study, we found that sleep was related to different aspects of self-care. These findings will have significant implications for future clinical practice and research. In this chapter, study findings, limitations, implications, and conclusions are discussed.

A. <u>Main Findings</u>

1. <u>Subjective sleep and overall self-care</u>

We found that subjective sleep quality was related to diabetes self-care. Bivariate correlations suggested that sleep quality was significantly related to diabetes overall self-care (r = -0.36). This finding is in line with previous studies. In a sample of community-dwelling adults with T2DM and excessive daytime sleepiness (ESS > 10), sleep quality was associated with self-care measured by the Self-Care Adherence subscale of Diabetes Care Profile (r = -0.214).³⁴ In another study¹¹ consisting of 361 T2DM adults, Nefs and colleagues found that those with poor sleep quality (PSQI > 5) had suboptimal self-care, compared to those with good sleep quality. However, potential confounders were not controlled in both studies, which may result in biased results.²²³ Our study went a step further by controlling for covariates, such as diabetes distress and daytime sleepiness. Our regression analysis revealed that sleep quality, second to diabetes distress, was a strong predictor of diabetes self-care. The effect of sleep quality on diabetes self-care was even larger than that of the commonly reported daytime sleepiness.^{34, 120} Empirical research on the impact of sleep on self-care is limited, Riegel and Weaver²²⁴ proposed a conceptual framework suggesting that sleep may affect daytime self-care behaviors through its effect on cognition. Similarly, a review of the current literature by Redeker²²⁵ indicated that sleep disturbance might impair self-care behaviors through its impact on mood, cognitive function, and functional performance. Although these frameworks were developed for patients with heart failure, the underlying mechanism may apply to diabetes patients. Our findings provided supportive evidence on the potential effect of sleep on self-care capacities.

2. <u>Sleep and physical activity</u>

Sleep can be measured by subjective instruments and objective methods. In this study, we measured an individual's overall sleep quality using the PSQI. We also obtained specific objective and subjective sleep parameters (i.e., SOL, SE, WASO, number of awakenings, and TST). Whether measured objectively or subjectively, we found only limited evidence for a relationship between sleep and physical activity, and that relationship was only significant when fatigue was taken into account.

We found no significant relationships between self-reported sleep quality and physical activity. Baseline sleep quality measured by PSQI was not related to weekly MET expenditure in this population. Our finding is consistent with a previous study conducted in T2DM adults. Nefs et al.¹¹ found that weekly MET expenditure did not differ between those with good and poor sleep quality measured by PSQI. Nonetheless,

better sleep quality predicted higher self-reported moderate-to-vigorous physical activity in healthy, sedentary older adults.²²⁶ A systematic review²²⁷ revealed that the correlations between physical activity measured by IPAQ-SF and objective methods were low. IPAQ-SF also overestimated physical activity. Therefore, it was suggested that IPAQ-SF might have limited use in evaluating absolute and relative physical activity. In this study, the correlation between MET expenditures derived from both the IPAQ-SF and ActiGraph was poor, suggesting the poor validity of the IPAQ-SF, which may have contributed to the negative finding. It is also plausible that some participants were so habitually inactive that changes in sleep would not have a strong effect on their physical activity. That may mask the significant association. Nonetheless, significant findings have been reported in other studies. A longitudinal study²²⁸ found that better baseline sleep quality predicted higher levels of physical activity two years later. That study was conducted in 426 community-dwelling older adults (61-100 years). Sleep quality and physical activity were measured using a 5-item and 1-item survey, respectively. Instead of measuring actual physical activity levels, the 1-item instrument asked the participants how active they were on a scale from 1 to 7 during the past few months. It seemed that the instrument measured a different perspective of physical activity from both the IPAQ-SF and ActiGraph. Additionally, although covariates such as age, gender, and chronic conditions were controlled, other symptoms such as fatigue and distress might also need to be controlled to get robust findings. In another study⁸² conducted in 22 older adults, sleep quality measured by PSQI was significantly related to physical activity. However, findings need to be interpreted with caution as potential confounders were not controlled in the bivariate analyses, and study findings may need to be replicated in a
larger sample. It was also reported that better subjective sleep quality (on a 10-point scale) predicted a higher level of physical activity during the second half of the day in patients with pain and insomnia.²²⁹ Patients with pain and insomnia typically have worse sleep quality that may exert a strong influence on physical activity. In this study, patients with self-reported insomnia and uncontrolled pain were excluded. It is possible that the effect of sleep on physical activity was not strong enough to be observed in our participants. Sleep, when examined using a summary score, was not related to physical activity. When specific sleep parameters (e.g., total sleep time and sleep efficiency) were used, we did not find substantial evidence supporting the relationship between subjective/objective sleep and physical activity, either.

In this study, both subjective and objective SOL did not predict physical activity the following day. This finding is in line with previous studies conducted in older adults,^{79,} ²²⁶ patients with multiple sclerosis²³⁰ and insomnia.²³¹ In contrast, significant relationships between SOL and physical activity (e.g., light-intensity physical activity, step counts, or energy expenditure) were reported in patients with lung cancer²³² and females with chronic fatigue syndromes.²³³ However, findings from those two studies need to be interpreted with caution as potential confounders were not controlled in the bivariate analyses. In our study, participant subjective and objective SOL was 7.3 minutes (SD 3.0) and 24.5 minutes (SD 20.7), respectively. These were comparable to the SOL reported in previous studies, where SOL ranged from 10.1 minutes (SD 11.0) in healthy older adults²²⁶ to 23.9 minutes (SD 13.3) in people with multiple sclerosis.²³⁰ Although there was a discrepancy in subjective and objective SOL, our data suggested that the SOL in this population was within the normal range, which may not result in significant impairment in daytime functioning. It is possible that only abnormal, prolonged SOL, which is a characteristic of insomnia symptoms, might result in significant, detrimental consequences. Indeed, in Chen and colleagues study,²³² participants average SOL was 30.9 minutes (SD 36.1), evident of insomnia symptom. A significant association was observed between SOL and light-intensity physical activity. More research is needed to further investigate the relationship between SOL and physical activity.

We did not find significant relationships between subjective/objective SE and physical activity from the temporal analyses. Findings regarding this aspect have been inconsistent. Similar to our finding, SE was not a significant predictor of physical activity the following day in middle-aged women aged around 55 years,^{78, 234} adults,²³⁵ patients with pain and concurrent insomnia,²²⁹ multiple sclerosis,²³⁰ lung cancer,²³² chronic fatigue syndrome,²³³ and insomnia.²³¹ In contrast, in older women aged 73.3 years (SD 1.7), higher SE was associated with more time of moderate-to-vigorous physical activity.⁷⁹ Differences in sample characteristics might account for the inconsistency. Compared to Lambiase et al. study,⁷⁹ our participants were younger (60.4 years) and almost half of them were still working. Work and family responsibilities may have a larger impact on their sleep-wake schedules. For instance, even if an individual had low SE during the night, she/he may still need to engage in daily routines due to family and work obligations, which may obscure the association between sleep and daytime physical activity. Additionally, the sample was more homogenous in gender and ethnicity (e.g., all were women, and 91.7% were White) in Lambiase et al. study,⁷⁹ which may explain discrepancies between our findings. People with higher SE may feel

more refreshed and energized upon awakening to engage in daytime activities. In our study, participant SE was approximately 80% (51.8%-97.3%), slightly lower than the one reported in Lambiase et al. study (85.5%). In older adults²³⁶, physical activity, quantified as MET, was related to SE. Participants with a higher SE reported higher MET than those with a lower SE. Participants in that study had similar characteristics (age, gender, and sleep) to our participants. Operationalization of physical activity may have contributed to different findings. Importantly, averages of sleep and physical activity across multiple days were used in Wilckens et al. study.²³⁶ Using aggregated data may inflate type 1 errors.²²²

Subjective WASO alone was not a significant predictor of physical activity. Few studies have examined the relationship between WASO and physical activity. Our finding is in line with a previous study conducted in patients with insomnia.²³¹ In contrast, a significant relationship between WASO and physical activity was reported. In Dzierzewski et al. study²²⁶ conducted in older adults aged 63.4 years (SD 8.7); those who experienced more WASO reported participating in less moderate-to-vigorous physical activities. Participant self-reported WASO was 18.2 minutes in that study, which was similar to ours (19.7 minutes). Differences in participant characteristics and physical activity measurements might explain the inconsistent findings. In Dzierzewski et al. study,²²⁶ 83.5% of the participants were women, as compared to 51.6% in this study. Gender differences in both sleep^{237, 238} and physical activity²³⁹ have been reported, which may contribute to the variations in the degree of association between sleep and physical activity. Additionally, in Dzierzewski et al. study,²²⁶ physical activity was measured by self-reported questionnaire, which carries recall bias and may be

subject to subjective misperception. Thus, findings may not be comparable. In another study²³⁰ conducted in patients with multiple sclerosis, aggregated WASO was related to PA at different intensity levels, controlling for age, fatigue, and disease severity. Participant characteristics may explain the inconsistent findings. In Aburub et al. study,²³⁰ participants experienced constant fatigue, which was also significantly related to physical activity. People with a high level of perceived fatigue may feel less motived or energized to be physically active. It is plausible that fatigue, instead of WASO, influenced physical activity during the day. Although our study was not designed to examine the interaction between sleep and fatigue, we found that the interaction term of morning fatigue and subjective WASO was a significant predictor of physical activity. Similarly, there seemed to be an interaction between morning fatigue and TST in predicting sedentary behaviors. These findings suggest that the effect of sleep on physical activity depends on fatigue levels. Much work in cancer patients has indicated a close relationship between sleep disturbance and fatigue.²⁴⁰ A recent study in people with T2DM also supports the significant relationship.²⁴¹ Sleep and fatigue share the same pathophysiological pathway involving inflammatory markers such as Interleukin-6.²⁴² Sleep disturbance may result in increased fatigue and tiredness, which likely impacts engaging in physical activity. Whether it is fatigue, sleep, or the interaction between sleep and fatigue that affects physical activity remains unclear. Future studies are needed to shed more lights on how sleep and fatigue interact with each other in affecting daytime functioning, including physical activity.

Objective number of awakenings was not related to physical activity in this population. Frequent nocturnal awakenings or fragmented sleep are characteristics of

poor sleep quality. Fragmented sleep is less restorative than consolidated sleep, and may lead to sleepiness-related daytime impairment.²⁴³ The evidence is limited on the relationship between nocturnal awakenings and physical activity. In an experimental study²⁴⁴ conducted in 15 healthy young men, fragmented sleep resulted in lower physical activity counts. Lambiase and colleagues⁷⁹ found that less sleep fragmentation was associated with greater daily activity counts and more moderate-to-vigorous physical activity. Their study was conducted in a homogenous sample of 143 older women aged 73.3 years (SD 1.7). In another study²³³ conducted in female adults with chronic fatigue syndrome, nocturnal awakenings were negatively related to energy expenditure and step counts. There may be gender differences in the relationship between sleep and physical activity that were not captured in the previous three studies. Findings from the experimental study²⁴⁴ may not be extrapolated to real life due to the acute sleep manipulation in the laboratory environment. Omitting some key covariates in the Aerenhouts et al. study²³³ may have overestimated the relationship. Nonetheless, it is also possible that our study was not powered enough to detect a significant relationship. More studies are needed to advance our knowledge in this area.

We did not find much evidence supporting the significant relationship between TST and physical activity. Similar findings were reported in previous studies conducted in adults,^{235, 236, 245} older women,^{78, 79} patients with multiple sclerosis,²³⁰ lung cancer,²³² chronic fatigue syndrome,²³³ and insomnia.²³¹ Nevertheless, In the previously mentioned experimental study,⁷⁷ a 4-hour sleep restriction resulted in a higher proportion of light-intensity physical activity and a lower proportion of high-intensity physical activity.

Differences in the reduction of physical activity data may explain the inconsistency. In Schmid et al. study,⁷⁷ the physical activity level was classified based on activity count during specific hours (8 am to 8 pm). In comparison, we used the recommended algorithm to obtain physical activity at different intensities. We used physical activity data during all waking hours. These two reduction processes could have produced dramatically different data. In addition, an acute reduction in TST from a normal duration to four hours could result in fatigue, excessive daytime sleepiness, and even interfere with cognitive function and motivation to engage in daily activities. These changes may cause reduced physical activity. Our participant average subjective and objective TST was 402.8 minutes (SD 77.1) and 394.6 minutes (SD 70.4), respectively. These were similar to the ones reported in other populations.^{78, 79, 234, 235} Participants in this study maintained relatively normal sleep duration based on the recommendation of at least 7 hours of sleep per night.²⁴⁶ They did not experience a dramatic decrease in TST. It is possible that only when TST was reduced to a certain amount did the detrimental effects begin to be observed. Interestingly, we observed a negative association between TST and light-intensity physical activity. One minute decrease in subjective and objective TST was related to 0.26 and 0.43 minutes increase in light-intensity physical activity, respectively. Similar findings were reported in a large-scale national study.⁸⁰ Compared to optimal sleep (7-9 hours), short sleep (< 7 hours) was associated with an average of 11.9 minutes (SE 1.2) additional light-intensity physical activities. In Kishida and Elavsky study,²³⁴ longer TST was associated with less moderate-to-vigorous physical activity. Conceptually, within a 24-hour period, less time sleeping would result in more waking time the following day. During waking hours, an individual can choose to

be either active or inactive. In this study, with the TST decreasing, participants chose to spend more time in light-intensity physical activity during the waking hours, but no change in sedentary behavior or moderate-intensity physical activity.

Both sleep and physical activity are complex constructs that can be operationalized using different methods. Based on the evidence mentioned above, variations in the measurement of those two constructs may explain the inconsistent findings across studies. For the measurement of physical activity, there is no consensus on the threshold for physical activity at various intensity levels. The thresholds used in the reduction of accelerometer data can produce dramatically different results and may obscure important group differences.²⁴⁷ In this sample, we used the commonly used threshold for sedentary behavior (< 100 counts/minute), light-intensity physical activity (100-1951 count/minute), and moderate-intensity physical activity (1952-5724 count/minute). Different thresholds have been used in other studies. For instance, 2020^{79, 234} or 760^{78, 81} counts/minute have been used as the threshold for moderateintensity physical activity. ActiGraph placement might affect the degree of the relationship between physical activity and variables of interest. Although physical activity assessed by waist- and wrist-worn accelerometers were moderately correlated,¹⁶⁷ the waist-worn accelerometer performed better than the wrist-worn one in identifying activity intensity threshold.^{168, 171} In this study, participants were instructed to wear the ActiGraph on the non-dominant wrist instead of waist to ensure adherence. During waking hours, participant spent an average of 315.9 minutes (SD 114.4), 510.6 minutes (SD 90.9), and 133.7 minutes (SD 67.7) in sedentary behavior, light-intensity, and moderate-intensity physical activity, respectively. Compared to previous studies

that used the same or lower threshold, participants in this study spent more time in moderate-intensity physical activity.^{78-80, 82, 230, 248} Similarly, sedentary time estimated here was lower compared to the ones reported in those studies. Overestimation of moderate-intensity physical activity and underestimation of sedentary behavior by wristworn accelerometer has been reported in a previous study.²⁴⁹ Waist-worn accelerometer captures whole body movement, whereas wrist-worn accelerometer also captures wrist or upper-body specific movements, resulting in higher absolute physical activity values. Nonetheless, waist- and wrist-worn accelerometer had a similar activity accrual pattern over the course of the day, suggesting that each location is capable of estimating total physical activity.²⁵⁰ A recent study²⁵¹ indicated that the accuracy of an accelerometer in evaluating step counts also depends upon gait speed in healthy young adults, which may have important implications in explaining the inconsistent findings. Our study consisted of older adults aged between 50 and 78 years old. There were wide variabilities in their physical functioning, such as gait speed. Other study participants may have various levels of gait speed, resulting in incomparable findings. Future research is needed to shed more light on how methodological differences in the measurement of physical activity may affect the relationships between physical activity and constructs of interest.

Methodological differences in the measurement of sleep may also explain the inconsistent findings across studies. In this study, sleep was assessed by objective ActiGraph and subjective sleep diary, ActiGraph,^{78, 234} Actiwatch,^{79, 231, 232, 252} SenseWear,^{233, 236} PSG,²³⁵ sleep dairy,^{80, 226} or self-reported instrument^{81, 82} have been used by others. Although both ActiGraph and Actiwatch produced similar results for

various sleep parameters,^{152, 153} discrepancies have been reported.²⁵³ More importantly, there is a lack of agreement between objective and subjective sleep measures,^{157, 254, 255} which could result in inconsistency in the relationship between sleep and physical activity. Particularly, when sleep quality was evaluated by an instrument, one's perception of the quality of his/her sleep instead of specific parameters (e.g., SOL, TST) was evaluated. Compared to individual sleep parameters, subjective perception may have a stronger influence on one's motivation to engage in daily activities, such as physical activity. Additionally, the scoring algorithm for sleep could result in discrepancies. In this study, the default sensitivity setting was used (cut-off of 20 activity count combined with 10 minutes of immobile/mobile for sleep onset and sleep offset). Different settings have been used in other studies.^{79, 252} Nonetheless, even when sleep was measured using the gold standard of PSG, no significant relationship was found between sleep and physical activity.²³⁵

3. <u>Sleep and eating behavior</u>

Analyses using cross-sectional data did not reveal significant relationships between sleep and eating behavior (e.g., Cognitive Restraint, Uncontrolled Eating, and Emotional Eating). In contrast, a previous study⁹³ conducted in 53 young adults at risk for diabetes found that sleep quality assessed by PSQI was negatively related to eating behavior. Those with poorer sleep had worse eating behavior. Differences in participant characteristics might explain the inconsistent findings. In that study, participants were younger (average age 37 years). Both sleep and eating behavior may be different for people at different age groups. Indeed, participants in the previous study all had good sleep quality (mean PSQI 2.0); whereas 54.7% of participants had poor sleep quality in our study (mean PSQI 7.0). Additionally, our participants all had T2DM as compared to the healthy adults who are at risk for T2DM.⁹³ Healthy eating is one of the major components of diabetes management. Therefore, our participants may have different eating behaviors that were not comparable to those reported in the previous study. Those differences might contribute to the different magnitudes of association between sleep and eating behavior. Another study²⁵⁶ also reported that poorer sleep quality was associated with increased emotional eating. However, study findings may not be generalizable to other populations as only young women (aged 18.7 years) were included. Previous evidence indicates women had more sleep disturbance²⁵⁷ and unhealthy eating behavior²⁵⁸, compared to men. Therefore, gender might play a role in the relationship between sleep and eating behavior. It is worth mentioning that our study may be underpowered for detecting the significance as the sample size was determined based on our first hypothesis.

When aggregated data were used, eating behavior was related to various sleep parameters. Mixed-effect models provided further support for the significant temporal relationships. We found that the interaction between morning fatigue and subjective sleep quality (i.e., SE, SOL, and WASO) significantly predicted Eating Variation. The effect of SE on Eating Variation was higher in those with a higher level of morning fatigue. The effect of SOL and WASO on Eating Variation was larger in those with a lower level of morning fatigue. Similarly, objective WASO and number of awakenings interacted with morning fatigue in predicting Eating Variation the following day. Only a handful of studies have examined how sleep might affect eating variation. Similar to our study, a previous study²⁵⁹ investigated Eating Variation by asking the overall amount of

food and snack eaten in young adults. Eating Variation was measured on the same scale as ours. Nonetheless, stress was the primary variable of interest rather than sleep. They found that the majority of participants reported an effect of stress on the overall amount eaten. Sleep disturbance, particular sleep restriction, has been shown related to elevated stress.²⁶⁰ Therefore, sleep disturbance may present a risk factor for psychosocial consequences associated with increased stress, such as eating behavior.

We also found that subjective WASO was negatively associated with Cognitive Restraint. The interaction between morning fatigue and the number of awakenings predicted Cognitive Restraint. Similarly, the interaction between morning fatigue and subjective SE predicted Uncontrolled Eating. Low SE, long WASO, and frequent nocturnal awakenings are characteristic of poor sleep quality. Empirical evidence on how sleep quality affect eating behavior has been limited. Current reviews provided possible explanations for the underlying mechanisms. Lundahl and Nelson⁸⁷ provided an integrative review of how sleep disturbance may contribute to unhealthy eating behavior through biological, cognitive, emotional, and behavioral pathways. Volkow et al.²⁶¹ also suggested that higher order controls from the brain are involved in unhealthy eating behavior. Specifically, four neural circuits are essential: reward-saliency, motivation-drive, learning-conditioning, and inhibitory control-emotional regulationexecutive function. During exposure to certain cues, the expected reward (processed by learning circuit) inhibits cognitive control while over-activating the reward and motivation circuits, resulting in impaired ability to constrain the drive to consume food despite attempts to do so. Sleep disturbance might be such a cue. Indeed, Martin et al.⁸⁹ provided empirical evidence by examining brain activities when making impulsive

momentary choices in obese adults with poor versus good sleep quality (measured by PSQI). They found that those with poor sleep quality demonstrated decreased brain activation in multiple regions responsible for cognitive control, which may impair self-control when making immediate decisions. Those with poor sleep quality also showed poor eating behavior.

Total sleep time alone was not a significant predictor of eating behavior. However, there was a significant interaction between morning fatigue and TST in predicting Uncontrolled Eating and Emotional Eating. The effect of TST on those eating behavior was larger in those with a higher level of morning fatigue. Amounting research had invested the effect of sleep duration on eating behavior. Specifically, Kilkus et al.93 reported that actigraphy TST was not related to any eating behavior measured by the TFEQ. In contrast, when the eating behavior was measured by calorie intake, significant findings were reported. An experimental study²⁶² found that insufficient sleep may induce changes in brain activities regulating appetites, which may trigger increased desirability for high-calorie foods. Dashti and colleagues⁹¹ found that short sleep (< 5h/night) was associated with higher energy intake. Likewise, compared to the normal sleep condition (9h/night); participants consumed more calories under the insufficient sleep condition (5h/night). They also consumed 42% more calories from after dinner snacks containing more carbohydrates, under the insufficient sleep condition.²⁶³ Galli and colleagues⁹² also reported an inverse relationship between actigraphy TST and calorie intake. Variations in the measurement of eating behavior could explain the inconsistency between study findings. The TFEQ measures one's perception, which cannot reflect the actual food/calorie intake. Additionally, it seems that only when sleep

duration was restricted to a certain degree did it begin to affect eating behavior. Indeed, in a longitudinal study,²⁶⁴ 276 adults were recruited, and Uncontrolled Eating was measured by the subscale of the TFEQ. In short-duration sleepers (< 6h/night) only, those with a high level of Uncontrolled Eating reported more calorie intake, compared to those with a low level of Uncontrolled Eating. This relationship was not observed in those with normal sleep duration (>6h/night). Furthermore, it has been suggested that insufficient sleep may alter brain mechanisms involved in non-homeostatic eating behavior (e.g., mood).⁸⁶ In this study, we observed a significant interaction between TST and morning fatigue. It seems plausible that symptoms, such as fatigue, might be involved in regulating eating behavior.

Overall, we found that sleep or morning fatigue alone was not a predictor, but their interaction was a significant predictor of eating behavior. In this study, a significant relationship was found between sleep quality and fatigue (r = 0.34, p < 0.01). Previous evidence also supports the significant relationship between sleep and fatigue.^{241, 265, 266} Kaminska and colleagues²⁶⁷ suggested that sleep fragmentation (e.g., frequent nocturnal awakening) could induce or exacerbate fatigue due to excessive central nervous system activation. It is possible that sleep disturbance during the night may result in more fatigue upon awakening. Individuals who experience more fatigue may engage in more unhealthy eating behavior in an attempt to mitigate fatigue. A study by Yoshikawa et al.¹¹⁷ found that fatigue was related to eating behavior in healthy young adults, supporting a possible fatigue-eating coupling mechanism. In this study, the interactions between sleep and fatigue in predicting eating behavior were unexpected findings. Further research, using a larger sample size, is warranted to examine the moderating or mediating effect of fatigue on the relationships between sleep and selfcare behaviors.

4. <u>Sleep and medication adherence</u>

We did not find strong evidence supporting the significant relationship between sleep and medication adherence using baseline data. Our finding is inconsistent with previous findings. Knafl and Riegel⁹⁸ collected objective medication adherence data from a cohort with heart failure. They found that older adults with poor sleep quality (PSQI > 5) had a higher chance of having poor medication adherence (OR = 3.02, 95% CI = 1.45 - 7.07). Babson et al.²⁶⁸ also reported that subjective sleep guality measured by PSQI was related to objectively measured medication adherence in patients with HIV. Measurement variances might explain the inconsistency. We used the self-reported MMAS-8 assessing medication adherence, which subjects to recall bias. Although the MMAS-8 demonstrated adequate internal reliability (Cronbach's α = 0.77) in this population, it may not capture the actual medication-taking behaviors as compared to the objective assessment. Therefore, the association may be attenuated. Additionally, our sample size included in the analysis was 59, which may not be large enough to detect the significance. Nonetheless, it is worth mentioning that daytime sleepiness might confound the relationship between sleep and medication adherence, which were not controlled in Knafl and Riegel study.⁹⁸ Indeed, in another study conducted in patients with heart failure, a significant relationship between sleep daytime sleepiness and medication adherence was reported. In our study, we also found a significant bivariate association between daytime sleepiness and medication adherence (r = -0.34). Thus, it is plausible that daytime sleepiness instead of sleep is the actual

factor related to medication adherence. It is also possible that daytime sleepiness mediates the relationship between sleep and medication adherence. Additionally, we found that fatigue and diabetes distress were related to medication adherence. Previous evidence also suggested that sleep disturbance was related to fatigue²⁴¹ and distress.²⁶⁹ Omitting those variables, when examining the relationship between sleep and medication, may lead to misleading findings. Diabetes distress and fatigue are particularly common in people with diabetes. Future studies with a larger sample size would enable a closer examination of the complex inter-relationships between sleep disturbance and other symptoms in predicting medication adherence.

Our mixed-effect model revealed a significant effect of subjective SOL on medication adherence the following day. To improve participant adherence to the protocol, we measured medication adherence by asking whether participants took their medication/insulin at the correct dose and at the correct time. We found that those with longer SOL were more likely to "not take the medication/insulin at the right time". Prolonged SOL is a characteristic of insomnia. Although we did not include people with diagnosed insomnia, the sleep diary suggested that one-third of our participants had SOL longer than 30 minutes. Therefore, our finding provided evidence for the potential adverse effect of sleep disturbance on medication adherence. Assessing behavior may be an intervention that could induce changes in behaviors of interest.²⁷⁰ It is important to take into consideration participant reactivity when interpreting the findings. In this study, several participants indicated that the self-care diary raised their awareness of medication-taking behaviors. A total of 52 participants completed the post-study survey asking about their experience in participating in this study. Approximately 63.5%

indicated that they did not change their medication-taking behaviors at all by participating. The remaining changed their behaviors to different degrees. Previous studies^{271, 272} did not detect significant reactivity during intensive data collection on pain or drinking behaviors. In this study, participant behaviors were evaluated on a daily basis for eight days. Therefore, reactivity may be minimal and wore off as participants got habituated. Nevertheless, future studies are needed to shed more lights on how participant reactivity might affect relationships under investigation.

B. <u>Study Limitations</u>

This study is among the first to examine the temporal relationships between sleep and self-care in the context of older adults with T2DM. However, study findings need to be interpreted in light of limitations. First, the correlational design precluded us from determining causality. Nonetheless, the use of EMA to collect longitudinal data allowed us to examine the temporal relationships, which provided stronger causal inference than the traditional cross-sectional design. Second, convenience sampling was used, which limited the generalizability of the study. Study findings may only be generalized to older adults with T2DM. Exclusion criteria were chosen to minimize confounding by other medical conditions, such as depression and insomnia. Participant eligibility was assessed using self-reported information from the participants. It is possible that some participants had insomnia or depression without being diagnosed. Furthermore, the sample size was determined by simulations using baseline data from 50 participants. The sample size, while adequate to test the main hypothesis, may not be large enough to test the remaining hypotheses that used the longitudinal data. The study may also be underpowered to test the moderating or mediating effect of fatigue on the relationships between sleep and self-care. Nonetheless, we collected 8-day data from each participant and participant demonstrated good adherence, which may enhance the power. Third, baseline data (e.g., symptoms and diabetes self-care) were collected using self-reported questionnaires, which may bring subjective bias. However, we used common, validated questionnaires, which demonstrated adequate validity and reliability in our sample. The ActiGraph was worn on the wrist to measure both sleep and physical activity. Wearing the device on the wrist, instead of the waist, may have compromised its reliability and validity in the assessing physical activity. However, wrist placement ensured participant adherence and provided a more accurate assessment of sleep than the waist placement. Lastly, eating behavior was measured by self-reported perception rather than actual food or calorie intake. How study findings can be translated into clinically meaningful change remains to be tested. In summary, future studies are warranted to replicate our findings in a larger, more representative sample. Such studies should include more accurate assessment of objective physical activity by placing the accelerometer on the waist. More detailed assessments of eating behavior are also recommended (e.g., subjective and objective measures).

C. Implications

Sleep disturbance in people with diabetes is common and has frequently been ignored in clinical practice. Self-care is the key to diabetes management. Findings from this study demonstrated significant relationships between sleep and self-care behaviors. Our findings can be easily translated into practice. Routine assessment and effective intervention of sleep should be further highlighted by the American Diabetes Association diabetes care guideline as part of the overall diabetes management regimen. That would increase diabetes educators' awareness of the importance of sleep, which would facilitate the incorporation of sleep into diabetes management in clinical practice. For instance, diabetes health providers are recommended to include comprehensive sleep assessment at every clinical visit. Diabetes educators should consider including sleep-related education during patient education seminars. We also found that sleep may be related to eating behavior, which is an essential part of diabetes self-care. In practice, diabetes educators should educate their patients on the adverse effect of sleep disturbance in eating behavior. Sleep and fatigue may interact with each other, affecting daytime self-care including physical activity and eating behavior. A detailed evaluation of diabetes symptoms, such as fatigue, should be considered when developing sleep-related interventions.

This study provided preliminary supporting evidence on the effect of sleep on self-care behaviors. Surprisingly, sleep interacted with fatigue in predicting self-care the following day. These findings have important implications for future research. More studies are needed to further examine the relationships between sleep and self-care by including fatigue as a mediator or moderator. Meanwhile, fatigue should be included in any studies whose focus is sleep in T2DM patients. Omitting fatigue might result in misleading findings or even a failure to capture important relationships of interest. Furthermore, experimental studies are needed to examine how improving sleep would affect self-care, particularly eating behavior.

D. <u>Conclusions</u>

In older adults with T2DM, poor sleep quality is associated with poor self-care. A closer examination of the relationships between sleep and different components of self-care revealed little supportive evidence on the impact of night sleep on daytime accelerometer-derived physical activity and medication adherence. However, sleep likely affects daytime self-care, especially eating behavior, through its interaction with fatigue in the free-living environment.

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APPENDICES

Appendix A

Dada Collection Instruments

- 1. Baseline Questionnaire
- 2. Pittsburgh Sleep Quality Index
- 3. Diabetes Self-Management Questionnaire-Revised
- 4. International Physical Activity Questionnaire-Short
- 5. Three-Factor Eating Questionnaire-R18V2
- 6. Morisky Medication Adherence Scale-8
- 7. Diabetes Empowerment Scale-Short Form
- 8. Diabetes Distress Scale
- 9. Diabetes Symptom Checklist-Revised
- 10. Epworth Sleepiness Scale
- 11. STOP-Bang
- 12. Sleep and Šelf-care Diary
- 13. Post-Study Survey

Baseline Questionnaire

Instructions: the following questions ask you about your basic information and general health. Please read and answer each one carefully.

A: Demographics

- 1. Gender: Female \Box Male \Box
- 2. Age: _____ (years)
- 3. Years of education: _____(years)
- 4. Race
 - □ Caucasian/White
 - □ African-American
 - \Box Asian
 - □ Native American/Pacific Islander American
 - □ Other
- 5. Ethnicity
 - □ Hispanic/Latino
 - □ Not Hispanic/Latino
- 6. Marital status
 - □ Married and not separated
 - □ Separated
 - □ Divorced
 - $\hfill\square$ Living with a partner
 - \Box Widowed
 - □ Single
- 7. Work status
 - □ Not working
 - □ Part-time
 - □ Full-time
 - Please specify your job:______

B: Health Information

1.	Height (cm):	_Weight (kg):
	Waist circumference (cm):	_Neck circumference (cm):
	BP (mmHG):	_A1C (%):
2.	Your smoking status:	
	□ Never smoker	
	$\hfill\square$ Former smoker (quitted smoking	for over 1 year)
	 Current smoker (more than 1 ciga tobacco/month) 	arette/day, or 1 cigar/week, or chew 30grams of
3.	In a typical week, how often do you o	drink any type of alcoholic beverage?
	\Box 2 or more drinks per day	
	1 drink per day	
	□ 4-6 times/week	
	□ 1-3 times/week	
4.	When were you diagnosed with diab	etes?
5.	What is your current treatment regim	ien?
	□ Insulin	
	Oral medication only	
	\Box Insulin and oral medication	
	□ Exercise/diet control	
	□ Other, specify:	

6. Are you currently having the following disease/symptom?

Disease/Symptom	Ye	s/No
High blood pressure	No 🗆	Yes 🗆
Hyperlipidemia (high cholesterol or triglyceride)	No 🗆	Yes 🗆
Neuropathy		
Foot or hand numbness and tingling	No 🗆	Yes 🗆
Neuropathic pain	No 🗆	Yes □
Nephropathy (kidney disease)	No 🗆	Yes 🗆
Retinopathy (eye problems)	No 🗆	Yes 🗆
Heart disease	No 🗆	Yes 🗆
Respiratory disease		
Asthma	No 🗆	Yes 🗆
COPD	No 🗆	Yes 🗆
Other	No 🗆	Yes 🗆
Thyroid disease	No 🗆	Yes 🗆
Cholecystitis/gallstones	No 🗆	Yes 🗆
Snore while sleeping	No 🗆	Yes 🗆
Were you diagnosed with sleep apnea?	No 🗆	Yes 🗆
(If YES) When?		
Are you currently using CPAP therapy?	No 🗆	Yes 🗆

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Subject's Initials		ID#	D	ate	Time	AM PM
	PITTSBURGH SLEEP QUALITY INDEX					
INST The shou Pleas	RUCTIONS: following questions ld indicate the most se answer all questi	relate to your usual s accurate reply for the ons.	leep habits during e <u>majority</u> of days	the past month <u>onl</u> and nights in the pa	<u>v</u> . Your ans ast month.	swers
1.	During the past m	onth, what time have	you usually gone	to bed at night?		
		BED TIM	1E			
2.	During the past me	onth, how long (in mir	nutes) has it usuall	y taken you to fall a	sleep each	night?
		NUMBER OF M				
3.	During the past m	onth, what time have	you usually gotter	n up in the morning	7	
		GETTING UF	P TIME			
4.	During the past m different than the	honth, how many hou number of hours you	ırs of <u>actual sleep</u> spent in bed.)	did you get at nigh	nt? (This m	nay be
		HOURS OF SLEEP	PER NIGHT			
For ea	ach of the remainin	g questions, check t	the one best resp	onse. Please answ	ver <u>all</u> ques	tions.
5.	During the past m	onth, how often have	you had trouble s	leeping because yo	u	
a)	Cannot get to slee	ep within 30 minutes				
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week		
b)	Wake up in the m	iddle of the night or e	arly morning			
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week		
c)	Have to get up to	use the bathroom				
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week	_	

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_

d)	Cannot breathe comfortably			
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
e)	Cough or snore lo	udly		
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
f)	Feel too cold			
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
g)	Feel too hot			
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
h)	Had bad dreams			
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
i)	Have pain			
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
j)	Other reason(s), p	lease describe		
	How often during t	he past month have y	/ou had trouble sle	eping because of this?
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
6.	During the past m	onth, how would you	rate your sleep qua	ality overall?
		Very good		
		Fairly good		
		Fairly bad		
		Very bad		

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7. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

Not during the
past month_____Less than
once a week____Once or twice
a week____Three or more
times a week____

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the	Less than	Once or twice	Three or more
past month	once a week	a week	times a week

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

Only a very slight problem

Somewhat of a problem

A very big problem

10. Do you have a bed partner or room mate?

No problem at all

No bed partner or room mate

Partner/room mate in other room

Partner in same room, but not same bed

Partner in same bed

If you have a room mate or bed partner, ask him/her how often in the past month you have had . . .

a) Loud snoring

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
b)	Long pauses betw	een breaths while asle	eep	
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
c)	Legs twitching or je	erking while you sleep)	
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week

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d)	Episodes of disori	ientation or confusion	during sleep		
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week_	
e)	Other restlessnes	s while you sleep; plea	ase describe		
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week_	

Diabetes Self-Management Questionnaire-Revised (DSMQ-R)

	The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the last 8 weeks , please specify the extent to which each statement applies to you.	applies to me very much	applies to me to a consider- able degree	applies to me to some degree	does not apply to me
1.	I check my blood sugar levels with care and attention.	□3	□2	□1	0
2.	The food I choose to eat makes it easy to achieve optimal blood sugar levels.	□3	2	 1	0
3.	I keep all doctors' appointments (appointments with health professionals) recommended for my diabetes treatment.	□3	2	 1	□0
4.	I take my diabetes medication (e. g. insulin, tablets) as prescribed (very accurately).	□3	2	<u></u> 1	□0
5.	Occasionally I eat lots of sweets or other foods rich in carbohydrates (more or more often than would be good).	□3	2	 1	□0
6.	I record my blood sugar levels (or analyse the value chart with my blood glucose meter/computer).	□3	□2	1	0
7.	I tend to avoid (omit) diabetes-related doctors' appointments (appointments with health professionals).	□3	<u></u> 2	 1	0
8.	I am regularly physically active to improve my diabetes treatment.	□3	2	 1	□0
9.	I follow relevant dietary recommendations for people with diabetes (e. g. by doctors, nurses or dietitians).	□3	2	 1	□0
10.	I do not check my blood sugar levels frequently enough to achieve good blood glucose control.	□3	□2	1	0
11.	I avoid physical activity, although it could improve my diabetes.	□3	2	1	□0
12.	I tend to forget or skip my diabetes medication (e.g. insulin, tablets).	□3	□2	1	0
13.	Sometimes I have real 'food binges' (not triggered by hypoglycaemia).	□3	2	 1	□0

14.	Regarding my diabetes care, I should see my medical practitioner(s) more often.	□3	2	□1	0
15.	I am less physically active than would be optimal for my diabetes.	□3	2	1	□0
		applies to me very much	applies to me to a consider- able degree	applies to me to some degree	does not apply to me
16.	I could improve my diabetes self-care considerably.	□3	2	□1	0
17.	I estimate the carbohydrate content (glycaemic load) of my meals (in order to improve my glycaemic control).	□3	2	 1	0
18.	I eat (choose my food) without regard to diabetes.	□3	2	□1	0
19.	I see my doctor/health professional regularly to check/discuss my diabetes treatment.	□3	2	<u></u> 1	0
20.	My diabetes self-care is poor.	□3	□2	□1	0
	The following statements describe self-care activities related to intensive insulin treatment and should only be answered by people using rapid acting insulin.				
	I do not use insulin. I use long acting insulin only.				
21.	I check my blood sugar levels before each meal.	□3	2	□1	0
22.	I precisely adapt my insulin doses to the carbohydrate content (glycaemic load) of my meals.	□3	2	1	0[]
23.	I adjust the timing of my insulin injections and food intake.	□3	□2	□1	0[]
24.	I adapt my insulin doses to the current blood sugar levels as well as preceding or planned activities.	□3	2	 1	0
25.	I seek to ensure regular meals and snacks over my day.	□3	□2	□1	0
26.	I always carry carbohydrates (glucose) to enable quick treatment of hypoglycaemic (low blood sugar) episodes.	□3	2	1	0
27.	In case of hypoglycaemic episodes, I take <i>appropriate</i> amounts of carbohydrates in order not to cause excessive hyperglycaemia (high blood sugar).	□3	<u></u> 2	<u></u> 1	0

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INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling?

 days per week
 No vigorous physical activities
 Skip to question 3

 How much time did you usually spend doing vigorous physical activities on one of those days?

 hours per day
 minutes per day

Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.



4. How much time did you usually spend doing **moderate** physical activities on one of those days?

 _hours per day	minutes per day
Don't know/Not sure	3

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

	days per week			
	No walking			
6.	How much time did you usually spend walking on one of those days?			
	hours per day minutes per day			
	Don't know/Not sure			
	The last question is about the time you spent sitting on weekdays during the last 7 days . Include time spent at work, at home, while doing coursework and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.			

7. During the last 7 days, how much time did you spend sitting on a weekday?

 hours per day	minutes per day
Don't know/Not sure	

This is the end of the questionnaire, thank you for participating.

SHORT LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised August 2002.

Three-Factor Eating Questionnaire-R18V2



they make me fat

- L Definitely true
- ▲ Mostly true
- □ Mostly false
- \square_4 Definitely false

myself by eating

- L Definitely true
- \square_2 Mostly true
- □ 3 Mostly false
- 4 Definitely false

This section contains statements and questions about eating habits and feelings of hunger. *Read each statement carefully and answer by ticking the alternative that best applies to you.*

11. I consciously hold back at meals to keep from gaining weight

- D Definitely true
- \square_2 Mostly true
- □ Mostly false
- □₄ Definitely false

- 15. When I see something that looks very delicious, I often get so hungry that I have to eat right away
 - D Definitely true
 - \square_2 Mostly true
 - \square_3 Mostly false
 - 4 Definitely false
- 12. When I smell appetizing food or see a delicious dish, I find it very difficult to keep from eating - even if I've just finished a meal
 - D Definitely true
 - \square_2 Mostly true
 - □ Mostly false
 - 4 Definitely false

16. When I feel depressed, I want to eat

- D Definitely true
- \square_2 Mostly true
- \square_3 Mostly false
- \Box_4 Definitely false

- 13. I'm always hungry enough to eat at any time
 - Definitely true
 - \square_2 Mostly true
 - \square_3 Mostly false
 - \square_4 Definitely false

- 17. Do you go on eating binges even though you're not hungry?
 - $\Box_1 \text{ Never} \\ \Box_2 \text{ Rarely}$
 - 3 Sometimes
 - \square_4 At least once a week

14. If I feel nervous, I try to calm down by eating

- D Definitely true
- └ Mostly true
- \square_3 Mostly false
- 4 Definitely false

18. How often do you feel hungry?

- \Box_1 Only at mealtimes
- \square_2 Sometimes between meals
- □3 Often between meals

 \square_4 Almost always

Morisky Medication Adherence Scale-8

Instructions: You indicated you that you are taking medications for your diabetes. Individuals have identified several issues regarding their medication-taking behavior, and we are interested in your experience. there is no right or wrong answer. Please answer each question based on your personal experience with your diabetes. (Please check your response below)

1.	Do you sometimes forget to take your medicine?	No=1, Yes=0		
2.	People sometimes miss taking their medicines for	No=1, Yes=0		
	reasons other than forgetting. Over the past 2 weeks,			
	were there any days when you did not take your			
	medicine?			
3.	Have you ever cut back or stopped taking your	No=1, Yes=0		
	medicine without telling your doctor because you felt			
	worse when you took it?			
4.	When you travel or leave home, do you sometimes	No=1, Yes=0		
	forget to bring your medicine?			
5.	Did you take all your medicine yesterday?	No=1, Yes=0		
6.	When you feel like your symptoms are under control,	No=1, Yes=0		
	do you sometimes stop taking your medicine?			
7.	Taking medicine every day is a real inconvenience for	No=1, Yes=0		
	some people. Do you ever feel hassle about sticking			
	to your treatment plan?			
8.	How often do you have difficulty remembering to take	(A)=4, (B)=3,		
	all your medicine?	(C)=2,		
	(A) Never/rarely (B) Once in a while (C) Sometimes	(D)=1, (E)=0		
	(D) Usually (E) All the time	Divide score by 4		

Diabetes Empowerment Scale-Short Form (DES-SF)

The 8 items below constitute the DES-SF. The scale is scored by averaging the scores of all completed items (Strongly Disagree =1, Strongly Agree = 5)

Check the box that gives the best answer for you.

In general, I believe that I:

1. ...know what part(s) of taking care of my diabetes that I am dissatisfied with.

	\square_2	\square_3	4	5
Strongly	Somewhat	Neutral	Somewhat	Strongly
Disagree	Disagree		Agree	Agree

2. ...am able to turn my diabetes goals into a workable plan.

	\square_2		4	
Strongly	Somewhat	Neutral	Somewhat	Strongly
Disagree	Disagree		Agree	Agree

3. ...can try out different ways of overcoming barriers to my diabetes goals.

	\square_2		4	5
Strongly	Somewhat	Neutral	Somewhat	Strongly
Disagree	Disagree		Agree	Agree

4. ...can find ways to feel better about **having** diabetes.

	\square_2		4	
Strongly	Somewhat	Neutral	Somewhat	Strongly
Disagree	Disagree		Agree	Agree

5. ...know the **positive** ways I cope with diabetes-related stress.

	\square_2			\Box_5
Strongly	Somewhat	Neutral	Somewhat	Strongly
Disagree	Disagree		Agree	Agree

6. ...can ask for support for having/caring for my diabetes when I need it.

1	2	3	4	5
Strongly	Somewhat	Neutral	Somewhat	Strongly
Disagree	Disagree		Agree	Agree

7. ...know what helps me stay motivated to care for my diabetes.

1			4	5
Strongly	Somewhat	Neutral	Somewhat	Strongly
Disagree	Disagree		Agree	Agree

8. ...know enough about myself as a person to make diabetes care choices that are right for me.

	\square_2	3	4	5
Strongly	Somewhat	Neutral	Somewhat	Strongly
Disagree	Disagree		Agree	Agree

DDS

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

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

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

DDS

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

Diabetes Symptom Checklist (DSC-R)

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Instructions

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People with diabetes can experience various discomforting physical and mental symptoms related to their disease. In order to know how much you are troubled by particular symptoms, we would like you to fill in this questionnaire. Please circle whether you have experienced the symptom or not in the <u>past month</u>, today included. If you circle "yes" then indicate to what extent the symptom listed has caused you discomfort by circling the number that most closely reflects your experience.

If a symptom did NOT occur, please circle "No" in the column "DID SYMPTOM OCCUR"

EXAMPLE

	DID SYMPTOM OCCUR?	THE SYMPTOM DID OCCUR AND WA TROUBLESOME TO ME					
		not at all	a little	moderately	very	extremely	
Sore throat?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5	

This answer means:

In the last month I did have a sore throat and it was a little troublesome to me.

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How much trouble have these symptoms given you over the last month?

	DID SYMPTOM OCCUR?	THE SYMPTOM DID OCCUR AND WAS TROUBLESOME TO ME				
	23	not at all	a little	moderately	very	extremely
1. Little get up and go (energy)?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5
2. Pain in the calves when walking?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5
3. A numb (reduced sensation) feeling in the feet?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5
4. A general feeling of fatigue?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5
5. Shortness of breath at night?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5
6. Feeling sleepy or drowsy?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5
7. Difficulty concentrating?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5
8. Moodiness?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5
9. A numb (reduced sensation) feeling in the hands?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5
10. Constantly blurred vision (even when wearing glasses)?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5

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How much trouble have these symptoms given you over the last month?

	DID SYMPTOM OCCUR?	THE SYMPTOM DID OCCUR AND WAS TROUBLESOME TO ME						
		not at all	a little	moderately	very	extremely		
11. Tingling in the limbs at night?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
12. Being very thirsty?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
13. Heart palpitations or throbbing in the heart region?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
14. Deteriorating eyesight?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
15. Burning pain in the calves at night?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
16. Dry mouth?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
17. Increasing fatigue during the course of the day?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
18. Flashes of light or black spots in the field vision?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
19. Irritability right before mealtimes?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
20. Fatigue when getting up in the morning?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		

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How much trouble have these symptoms given you over the last month?

	DID SYMPTOM OCCUR?	THE SYMPTOM DID OCCUR AND WAS TROUBLESOME TO ME						
		not at all	a little	moderately	very	extremely		
21. Shooting pains in the legs?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
22. Alternating sharp and blurry vision?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
23. Frequent need to urinate?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
24. Pain in the chest or heart region?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
25. Burning pain in the legs during the day?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
26. Tingling or prickling in hands or fingers?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
27. Quickly becoming annoyed or irritated?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
28. Suddenly reduced eyesight?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		
29. A strange feeling in the (lower) legs or feet when they are touched?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5		

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How much trouble have these symptoms given you over the last month?

	DID SYMPTOM OCCUR?	THE SYMPTOM DID OCCUR AND WAS TROUBLESOME TO ME					
	· · · · · · · · · · · · · · · · · · ·	not at all	a little	moderately	very extr	remely	
30. Shortness of breath during physical exertion?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5	
31. An unclear feeling in the head?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5	
32. Drinking a lot (all kinds of liquids)?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5	
33. Difficulty staying attentive?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5	
34. Tingling or prickling in the legs or feet?	No Yes $\rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5	
Any other symptoms:							
35	$Yes \to \to \to \to$	1	2	3	4	5	
36	$Yes \to \to \to \to$	1	2	3	4	5	
37	$Yes \rightarrow \rightarrow \rightarrow \rightarrow$	1	2	3	4	5	

Please check that you have filled out all the questions

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Epworth Sleepiness Scale

ID:_____ Today's date: _____

How likely are you to doze off or fall asleep in the following situations, in contrast to just feeling tired?

This refers to your usual way of life recently.

Even if you haven't done some of these things recently, try to figure out how they would have affected you.

Use the following scale to choose the **most appropriate number** for each situation:

- 0 = **no chance** of dozing
- 1 = slight chance of dozing
- 2 = **moderate chance** of dozing
- 3 = **high chance** of dozing

It is important that you answer each item as best as you can.

Situation	Chance of Dozing (0-3)
Sitting and reading	
Watching TV	
Sitting inactive in a public place (e.g., a theater or a meeting)	
As a passenger in a car for an hour without a break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking to someone	
Sitting quietly after a lunch without alcohol	
In a car or bus, while stopped for a few minutes in traffic	
THANK YOU FOR YOUR COOPERATION © M.W. Johns 1990-97. Used under Licens	Se



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Name		
Height	Weight	
Age	Male / Female	

STOP-BANG Sleep Apnea Questionnaire

Chung F et al Anesthesiology 2008 and BJA 2012

STOP		
Do you S NORE loudly (louder than talking or loud enough to be heard through closed doors)?	Yes	No
Do you often feel TIRED , fatigued, or sleepy during daytime?	Yes	No
Has anyone OBSERVED you stop breathing during your sleep?	Yes	No
Do you have or are you being treated for high blood P RESSURE?	Yes	No

BANG		
B MI more than 35kg/m2?	Yes	No
AGE over 50 years old?	Yes	No
NECK circumference > 16 inches (40cm)?	Yes	No
GENDER: Male?	Yes	No

TOTAL SCORE		
-------------	--	--

High risk of OSA: Yes 5 - 8

Intermediate risk of OSA: Yes 3 - 4

Low risk of OSA: Yes 0 - 2



SLEEP AND SELF-CARE DIARY

Sleep and Self-care in Diabetes	
---------------------------------	--

Date_____

Study ID _____

***** Please Complete **<u>Upon Waking</u>** *****

Date: Time (Nov	w):		-					
1. What time did you get into be	d?							
2. What time did you try to go to	sleep?							
3. How long did it take you to fal	l asleep?							
4. How many times did you wak final awakening?	e up, <u>NO</u>	<u>r</u> coun	ting you	ır				
5. In total, how long did these av	vakening	s last?						
6. What time was your final awa	kening?							
7. What time did you get out of b	ed for the	e day?						
8. Did you wake up earlier than	planned?				□No		if Yes	
					How muc	h earl	ier	
9. In TOTAL , how long did you s	sleep?							
10.Did you take a nap or doze du	uring the o	day?			□No □ if Yes			
					How many times			
					How long <u>in total</u>			
11. How many drinks containing	alcohol di	d you	have?					
12. How would you rate the qualit	y of your	sleep?						
□Very poor □Poor	□Fair		Good	[□Very goo	bd		
13. How rested/refreshed did you feel when you woke-up for □Not at all rested □Slightly rested □Well-rested □Very well-rested					he day? ⊡Somew	hat re	sted	
14.On a scale from 0-10, what is	your curr	ent <u>fat</u>	i <u>gue</u> rat	ing?				
0 1 2 3 Not At All	4	5	6	7	8	9 N	10 /lost Possible	
15.Morning blood sugar level (if t	ested):							

Sleep and Self-care in Diabetes			Date_	Date					Study ID		
			***** Be	efore	Bed *	****					
	As you get into bed tonight, please answer the following										
1.	1. On a scale from 0-10, what is your current fatigue rating?										
	01	23	4	5	6	7	8	9	10		
	Not At All							Мс	ost Pos	sible	
2.	Did you check y	our blood sug	ar level befo	ore bed	1?						
	□No	🗆 Yes	, What's the	e numb	er:		-				
	Wev	want to know	a bit about	t your o	diabete	s self-c	are ac	tivitie	s toda	У	
1.	Did you take the	e <u>correct dose</u>	of your diat	petes p	ills/insu	lin?					
	□Yes	🗆 No		□ N	lot takin	ig meds	/insulin	i i			
~											
2.		e pilis/insuiin a □ N-	t the <u>right ti</u>	<u>me</u> ?			(i				
	⊔Yes	L NO			lot takin	ig meas	/insuiin				
3.	Did vou adiust tl	he insulin dosa	age based o	on aluc	ose valı	ues, foo	d, and	exerci	se?		
	□Yes	🗆 No	0		IA						
	Now, please	indicate the o	legree to w	hich y	ou are	<u>agree</u> v	vith the	e follo	wings	statemen	t
1	Today Lata ma	ro opocko thar		~							
			⊡ Modera	u. Itoly		n.		amoly			
				litely		i y		entery			
2.	Today, I ate mo	re at main me	als than I us	sually d	0.						
	□ Not at all	□ A little	🗆 Modera	tely	🗆 Ve	ry	Extre	emely			
3.	Today, I delibera	ately took sma	II helpings t	o conti	rol my w	eight.					
	🗆 Not at all	□ A little	Modera	tely	□ Ve	ry	Extre	emely			

Diary

Version 1, 10/27/2016

Sle	eep and Self-care in Diabetes		Date		Study ID	
4.	. Today, I consciously held back on how much I ate at meals to keep from gaining weight.					
	🗆 Not at all	□ A little	□ Moderately	□ Very	Extremely	
5.	Sometime during today, when I started eating, I just couldn't seem to stop even though I was not					
	hungry.					
	🗆 Not at all	□ A little	Moderately	□ Very	Extremely	
6.	Today, I was always hungry enough to eat at any time.					
	\Box Not at all	\Box A little	Moderately	□ Very	□ Extremely	
7.	. Today, I wanted to eat when I was emotionally upset, including anxious, sad, tense, nervous, lonely, and depressed.					
	🗆 Not at all	□ A little	Moderately	□ Very	□ Extremely	
8.	 Today, I ate too much because I was emotionally upset, including anxious, sad, tense, nervous, lonely, and depressed. 					
	🗆 Not at all	□ A little	Moderately	□ Very	□ Extremely	

Sleep and Self-care in Diabetes	Date	Study ID
Sleep and Self-Care in Diabetes	Date	

Physical Activity

- Vigorous activities: take hard physical effort and make you breathe much harder than normal.
- Moderate activities: take moderate physical effort and make you breathe <u>somewhat harder</u> than normal.
- <u>Walking</u>: includes at work and at home, walking to travel from place to place, and any other walking solely for recreation, sport, exercise, or leisure.
- Today, did you do <u>vigorous</u> physical activities like heavy lifting, digging, aerobics, or fast bicycling?
 □ No
 □ Yes, how much time:_____
- Today, did you do <u>moderate</u> physical activities like carrying light loads, bicycling at a regular pace? Do NOT include walking.

□ No □ Yes, how much time:

Today, did you <u>walk</u> for at least 10 minutes at a time?
 □ No
 □ Yes, how much time:

Today, <u>how much time</u> did you spend <u>sitting</u>: including time spent at work, at home, during leisure time, time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch TV? Please specify: _____
Post-Study Survey

Please answer the questions from your experience in participating in this study. There is no right or wrong, the information you provided will help us to improve the quality of our future study.

	Wearing the Watch	Not at all	A little	Moderately	Very	Extremely
1.	Wearing the watch was inconvenient	1	2	3	4	5
2.	Wearing the watch interfered with my activities	1	2	3	4	5
3.	How much did wearing the watch make you change your exercise behavior?	1	2	3	4	5
4.	How much did wearing the watch make you change your sleep behavior?	1	2	3	4	5

Appendix A (continued)

Daily Diary	Not at all	A little	Moderately	Very	Extremely
1. I had difficulties understanding the diary questions	1	2	3	4	5
 I had difficulties typing my responses 	1	2	3	4	5
 I had difficulties accessing the internet 	1	2	3	4	5
 I had difficulties opening the link 	1	2	3	4	5
 Completing the diary was inconvenient 	1	2	3	4	5
Completing the daily diary interfered with my activities	1	2	3	4	5
 Overall, filling out the diary was pleasant 	1	2	3	4	5
8. Overall, filling out the diary was challenging	1	2	3	4	5
9. Overall, filling out the diary was stressful	1	2	3	4	5
10. How much did answering the diary make you change your <i>eating</i> behavior?	1	2	3	4	5
11. How much did answering the diary make you change your <i>medication-taking</i> behavior?	1	2	3	4	5
12. How much did answering the diary make you change your exercise behavior?	1	2	3	4	5
13. How much did answering the diary make you change your <i>sleep</i> behavior?	1	2	3	4	5
14.I would be interested to participate in similar studies in the future	1	2	3	4	5
15. I would recommend to others to participate in a similar study	1	2	3	4	5

Appendix B

Institutional Review Board Approval

UNIVERSITY OF ILLINOIS AT CHICAGO

Office for the Protection of Research Subjects (OPRS) Office of the Vice Chancellor for Research (MC 672) 203 Administrative Office Building 1737 West Polk Street Chicago, Illinois 60612-7227

REVISED Approval Notice

Initial Review (Response To Modifications)

February 6, 2017

Bingqian Zhu, RN, MSN Biobehavioral Health Science 845 S. Damen Avenue M/C 802 Chicago, IL 60612 Phone: (312) 513-2253 / Fax: (312) 996-4979

RE: Protocol # 2016-1112

"Relationships between sleep and self-care in type 2 diabetes: An ecological momentary perspective"

Dear Dr. Zhu:

Please note that stamped and approved .pdfs of all recruitment and consent documents will be forwarded as an attachment to a separate email. OPRS/IRB no longer issues paper letters and stamped/approved documents, so it will be necessary to retain the emailed documents for your files for auditing purposes.

Your Initial Review (Response To Modifications) was reviewed and approved by the Expedited review process on January 19, 2017. You may now begin your research

Please note the following information about your approved research protocol:

Protocol Approval Period:January 19, 2017 - January 19, 2018Approved Subject Enrollment #:95Additional Determinations for Research Involving Minors:These determinations have not

Appendix B (continued)

been made for this study since it has not been approved for enrollment of minors.

Performance Sites:	UIC
Sponsor:	Chancellor's Graduate Research Award, Center for
Research on Health and Aging	
PAF#:	Not applicable
Research Protocol(s):	
) 01 1010 D.1 (V. : 2.01/00/2017

a) Sleep and Self-care in Diabetes; Version 3; 01/09/2017

Recruitment Material(s):

- a) Flyer; Version 1; 10/27/2016
- b) Online Announcement; Version 1; 10/27/2016
- c) Research Match; Version 1; 10/27/2016
- d) Eligibility Checklist; Version 2; 12/05/2016
- e) Telephone Script; Version 3; 01/09/2017
- f) Future Research Contact; Version 3; 01/09/2017 **<u>REVISED</u>**

Informed Consent(s):

- a) Sleep and Self-care in Diabetes; Version 2; 12/05/2016
- b) A waiver of documentation of informed consent has been granted under 45 CFR 46.117 and an alteration of consent has been granted under 45 CFR 46.116(d) for recruitment purposes only ;minimal risk; verbal consent to screening/eligibility questions will be obtained; written consent/ will be obtained at enrollment.

Your research meets the criteria for expedited review as defined in 45 CFR 46.110(b)(1) under the following specific category(ies):

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual., (7) Research on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Appendix B (continued)

Receipt Date	Submission Type	Review Process	Review Date	Review Action
11/03/2016	Initial Review	Expedited	11/30/2016	Modifications
				Required
12/05/2016	Response To	Expedited	12/09/2016	Modifications
	Modifications			Required
01/09/2017	Response To	Expedited	01/19/2017	Approved
	Modifications			

Please note the Review History of this submission:

Please remember to:

 \rightarrow Use your <u>research protocol number</u> (2016-1112) on any documents or correspondence with the IRB concerning your research protocol.

 \rightarrow Review and comply with all requirements on the OPRS website at,

"UIC Investigator Responsibilities, Protection of Human Research Subjects" (http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0924.pdf)

Please note that the UIC IRB has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact OPRS at (312) 996-1711 or me at (312) 355-0816.

Sincerely,

Alison Santiago, MSW, MJ Assistant Director, IRB # 2 Office for the Protection of Research Subjects

Enclosure(s) will be sent as an attachment in a separate email:

- 1. Informed Consent Document(s):
 - a) Sleep and Self-care in Diabetes; Version 2; 12/05/2016
- 2. Recruiting Material(s):
 - a) Flyer; Version 1; 10/27/2016
 - b) Online Announcement; Version 1; 10/27/2016
 - c) Research Match; Version 1; 10/27/2016
 - d) Eligibility Checklist; Version 2; 12/05/2016

Appendix B (continued)

- e) Telephone Script; Version 3; 01/09/2017
- f) Future Research Contact; Version 3; 01/09/2017
- cc: Mariann R. Piano, Biobehavioral Health Science, M/C 802 Cynthia Fritschi (Faculty Advsior), Biobehavioral Health Science, M/C 802

VITA

BINGQIAN ZHU

University of Illinois at Chicago (UIC), College of Nursing 845 S. Damen Ave. Chicago, IL 60612 312-513-2253, bzhu8@uic.edu

EDUCATION

2012	BSN	Nursing	Xi'an Jiaotong University	Xi'an, China
2014	MSN	Nursing	Xi'an Jiaotong University	Xi'an, China
2018	PhD	Nursing	University of Illinois at Chicago	Chicago, IL

TEACHING EXPERIENCE

2015 - 2017	Teaching Assistant Global Health Leadership	Undergraduate Study Abroad Program Office, College of Nursing
2014 - present	Teaching Assistant Biobehavioral Health Scier	NURS534: Advanced Physiology nce, College of Nursing
2011 - present	Thesis Coach College of Online Educatio	Online Nursing Program on, Xi'an Jiaotong University

RESEARCH EXPERIENCE

2016 - present	PI Project: Relationships between sleep and self-care in type 2 diabetes: An ecological momentary perspective Support: UIC Center for Research on Health and Aging (\$3,000) UIC Chancellor's Graduate Research Award (\$5,000) Provost's Award for Graduate Research (\$2,000) College of Nursing PhD Student Research Award (\$1,000) Sigma Theta Tau Research Award (\$1,000)
2016 - present	Research Assistant PI: Cynthia Fritschi Project: The effects of a supervised 12-week walking program on inflammatory markers and fatigue in aging women with type 2 diabetes: A pilot study (Internal Research Support Program)
2016	Research Assistant PI: David Carley Project: Cannabimimetic treatment of obstructive sleep apnea: A

proof of concept trial (5UM1HL112856-02)

2016 Research Assistant PI: Bilgay Izci-Balserak Project: Sleep-related determinants of gestational diabetes (1R00-NR013187)

PUBLICATIONS

- Zhu, B., Ma, C., Chaiard, J., & Shi, C. (2017). Effect of continuous positive airway pressure on glucose metabolism in adults with type 2 diabetes: A systematic review and meta-analysis of randomized controlled trials. Sleep Breath. [Epub ahead of print]. PMID: 28812180.
- **Zhu, B.**, Quinn, L., & Fritschi, C. (2017). Relationship and variation of diabetes-related symptoms, sleep disturbance and sleep-related impairment in adults with type 2 diabetes. J Adv Nurs. 74(3), 689-697.
- <u>Zhu, B.</u>, Vincent, C., Kapella, M., Quinn, L., Collins, E., Ruggiero, L., Park, C., & Fritschi, C. (2017). Sleep disturbance in people with diabetes: A concept analysis. J Clin Nurs, 27(1-2), e50-60.
- **Zhu, B.**, Hershberger, P., Kapella, M., & Fritschi, C. (2017). The relationship between sleep disturbance and glycemic control in adults with type 2 diabetes: An integrative review. J Clin Nurs, 26(23-24), 4053-4064.
- <u>Zhu, B.</u>, Xie, M., Park, C., & Kapella, M. (2017). Adaptation of the Pittsburgh Sleep Quality Index in Chinese adults with type 2 diabetes. J Chin Med Assoc. [Epub ahead of print]. PMID: 29258729.
- Kapella, M., Vispute, S., <u>Zhu, B.</u>, & Herdegen, J. (2017). Actigraphy scoring for sleep outcome measures in chronic obstructive pulmonary disease. Sleep Med, 37, 124-129.
- Shi, C., Qiu, S., Riester, S. M., Das, V., <u>Zhu, B.</u>, Wallace, A. A., ... & Votta-Velis, G. (2017). Animal models for studying the etiology and treatment of low back pain. J Orthop Res. [Epub ahead of print]. PMID: 28921656.
- Zhu, B., Li, X., Wang, D., Yu, X. (2014). Sleep quality and its impact on glycemic control in patients with T2DM. Int J Nurs Sci, 1, 260-265.
- **<u>Zhu, B.</u>**, Sauer, R. Wu, L., Simon, L., Shah, K., Khain, U., Izci-Balserak, B. (2017). Validity of actigraphy in sleep measurements in pregnant women. Sleep Health. [In Revision]

PUBLISHED ABSTRACTS

- Zhu, B., Park, C., Quinn, L., & Fritschi, C. (2017). Predictors of glucose variability in T2DM adults (Abstract). Diabetes, 66 (Suppl 1), A229.
- Fritschi, C., <u>Zhu, B.</u>, & Quinn, L. (2017). Temporal relationships between glucose, sleep, and fatigue in T2DM. Diabetes, 66 (Suppl 1), A207.
- <u>Zhu, B.</u>, Quinn, L., Park, C., Riesche, L., Fritschi, C. (2015). Patient-reported outcomes as predictors of sleep in T2DM adults (Abstract). Diabetes, 64 (Suppl 1), A218.

PRESENTATIONS (*Invited)

- *Zhu, B. (2018, March) Relationships between sleep and self-care in adults with type 2 diabetes: An Ecological Momentary Perspective (*Oral*). UIC College of Nursing Resaerch Day, Chicago, IL.
- <u>Zhu, B.</u>, Fritschi, C., & Quinn, L. (2017, June). Predictors of glucose variability in T2DM adults (*Poster*). American Diabetes Association 77th Scientific Sessions, San Diego, CA.
- Fritschi, C., <u>Zhu, B.</u>, & Quinn, L. (2017, June). Temporal relationships between glucose, sleep, and fatigue in T2DM (*Poster*). American Diabetes Association 77th Scientific Sessions, San Diego, CA.
- Zhu, B., Vincent, C., Kapella, M., Quinn, L., Collins, E., Ruggiero, L., Park, C., & Fritschi, C. (2017, April). Sleep disturbance in people with diabetes: A concept analysis (*Poster*). Midwest Nursing Research Society 2017 Annual Research Conference, Minneapolis, IN.
- **Zhu, B.**, Quinn, L., Park, C., Collins, E., Riesche, L., & Fritschi, C. (2016, March). Realtime predictors of fatigue in adults with T2DM (*Poster*). Midwest Nursing Research Society 2016 Annual Research Conference, Milwaukee, WI.
- <u>Zhu, B.</u>, Quinn, L., Park, C., Riesche, L., & Fritschi, C. (2015, June). Patient-reported outcomes as predictors of sleep in T2DM adults (*Poster*). American Diabetes Association 75th Scientific Sessions, Boston, MA.
- *Zhu, B., Li, X. (2014, June). A correlational study between sleep quality and glycemic control in patients with T2DM (*Oral*). CMB China Nursing Network (CCNN) Graduate Forum 2nd Sessions, Shanghai, China.

HONORS AND AWARDS

2017	UIC Graduate College Student Presenters Award
2017	UIC Graduate Student Council Travel Award
2017	UIC Health Professional Student Council Travel Grant

2016 UIC Virginia M. Ohlson International Student Scholarship UIC Graduate Student Council Travel Award 2015 **MNRS Student Poster Competition Award** 2015 UIC Virginia M. Ohlson International Student Scholarship 2015 2014 UIC Van Doren Scholarship Third prize for graduate thesis at CCNN Graduate Forum, China 2014 "Excellent Graduate Student", Xi'an Jiaotong University 2014 "Excellent Student", Xi'an Jiaotong University 2012 Student Exchange, Nethersole School of Nursing, HongKong 2011 National Motivational Scholarship, China 2010

PROFESSIONAL MEMBERSHIP

2016 - present	American Diabetes Association
2016 - present	American Academy of Sleep Medicine
2015 - present	Sigma Theta Tau International (Alpha Lambda Chapter)
2015 - 2016	Midwest Nursing Research Society

SERVICE

2017 - present	Reviewer, Journal of Advanced Nursing
2017	Student panelist, NURS 566 Lit Review Course
2016 - present	Tutor, Rwanda Human Resources for Health Program
2016	Volunteer staff, 19th Power of Nursing Leadership, Chicago
2016	Volunteer, 2016 Diabetes Conference, Chicago
2016 - present	International Student Rep, Graduate Student Nurses Organization
2016 - 2017	Liaison, MNRS Research Interest Group
2015	Doctoral student panelist, Biobehavioral Health Science
2015	Preceptor, 2015 First Ladies' Health Initiative, Chicago

LICENSURE

2014 - present Registered Nurse Xi'an, China