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# Type 2 Diabetes And Insomnia: Impact On Metabolic Control

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**TYPE 2 DIABETES AND INSOMNIA: IMPACT ON METABOLIC CONTROL**

by

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## DEDICATION

To all my friends and family

and especially

to my parents who I know
are cheering for me from heaven.

to my children, Kirstin, Christopher, and Troy,
who have been lovingly supportive during this long process.

to my grandchildren, Jonah and Emmett,
who are the light of my life.

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# CHAPTER 1

# INTRODUCTION

## Background

### Diabetes

Diabetes is one of the most serious health challenges is the United States. In 2007, the prevalence of diagnosed and undiagnosed diabetes of all ages in the United States was reported to be 23.5 million people or 10.7% of the population. The prevalence of those diagnosed was reported to be 19.7 million people. For those age 60 years or older, 12.2 million, or 23.1% of the population have been diagnosed with diabetes. Based on 2006 death certificate reporting, diabetes was reported as the seventh leading cause of death. Overall, the risk of death among people with diabetes is reported to be twice that of those without diabetes (National Institute of Diabetes and Digestive and Kidney Diseases, 2008).

The prevalence of diabetes in Michigan is estimated to be 8.5% of the female population age 18 plus years. The prevalence, reported for both men and women, increases with age (ages 55-64 a prevalence of 16.9% and ages 65-74 a prevalence of 22%). In 2007 the combined direct and indirect costs for diabetes in Michigan were estimated to be $6.5 billion (Michigan Diabetes Action Plan, 2009).

Type 2 diabetes is a chronic disease that can result in serious, even life threatening, long and short-term complications (American Diabetes Association, 2009). Therefore, people with this disease require on-going medical care and diabetes self-management education (DSME) to prevent these complications and to improve their quality of life. The overall management goal is to attain and maintain glycemic control. Nurse Certified Diabetes Educators are trained to provide individualized DSME. Self-

management behavior change is the goal of DSME. Two key components of DSME are nutrition management and exercise. Carbohydrate intake is the focus of nutrition management as carbohydrates increase blood sugar levels. Exercise (150 minutes/week of aerobic physical activity) is recommended as it has been shown to improve blood glucose control, reduce cardiovascular risk factors, contribute to weight loss and improve well-being.

Glycemic control measures how well diabetes is being managed (ADA, 2009). The two primary techniques for assessing blood glucose are self-monitoring of blood glucose (SMBG) and A1C measurement. SMBG provides measurement of blood glucose for a specific point in time. The A1C test best reflects overall glycemic control and is widely used as a guide to treat diabetes. The A1C test represents the proportion of hemoglobin molecules that are glycosolated over a two to three month period. Research has demonstrated that small variations in glycemic control can reduce the risk of developing diabetes complications. The United Kingdom Prospective Study (UKPDS) was a landmark clinical trial, demonstrating each 1% reduction in A1C was associated with a decreased risk of 21% for death related to diabetes, myocardial infarction, or microvascular complications (Stratton et al., 2000). Selvin and colleagues (2004) found that a 1% increase in A1C was associated with an 18% increased risk of heart disease and stroke.

**Insomnia**

Sleep is a multifaceted behavioral state that occupies approximately one-third of the human life-span. Although perceived as a passive state, sleep is a highly active and dynamic state. An adequate amount of quality sleep is necessary to lead a healthy and productive life. Although chronic sleep loss is common in western societies, many people

are unaware of the potential adverse health effects of sleep restriction (Punjabi & Polotsky, 2005).

Although changes in sleep architecture occur as people age, slow wave sleep remains relatively constant from age 60 to the mid 90s. There is no evidence that the need for sleep decreases with age. Older individuals are reported to commonly complain of disrupted sleep resulting in decreased sleep efficiency. Aging *per se* does not cause these disruptions. Other factors such as chronic diseases, medications, primary sleep disorders and changes in the circadian rhythm system are responsible for this decrease in sleep (Sleep Research Society, 2005).

Insomnia has been found to be present in 30% of people over 65 years of age (Perlis, Jungquist, Smith & Posner, 2006). Older women are more likely to report sleep maintenance problems than men. Insomnia includes three sleep behaviors: (a) difficulty getting to sleep, (b) difficulty staying asleep, or (c) waking up too early. Insomnia in the aged is primarily that of waking during the night and unable to get back to sleep, resulting in fragmented nonrestorative sleep. Older adults with insomnia are reported to be more likely to have medical illnesses, physical disability, and elevated levels of anxiety or symptoms of depression than those without insomnia complaints. Comorbid insomnia treatment has traditionally focused on treating the medical condition with the expectation that the insomnia will also resolve. Although this approach may resolve symptoms of the comorbid disorder, the insomnia often does not improve (Roth, 2009). Research has found that treating both the insomnia and the comorbid condition concurrently often improves both the insomnia and the comorbid condition. Although insomnia is likely to be treated by hypnotics, medications for chronic insomnia have been

found to be less effective and produce negative side effects. Side effects include daytime sleepiness, tolerance and rebound insomnia (Perlis, Jungquist, Smith and Posner, 2006).

Chronic insomnia is not a normal, or necessary, part of aging (Kamel and Gammack, 2006). Disrupted sleep is reported, at times, to result in excessive daytime sleepiness. Adverse outcomes of daytime drowsiness include increased risk of falls, difficulty with concentration and memory, and overall decreased quality of life. Kamel and Gammack (2006) also report that insomnia in the elderly is typically undertreated and health care professionals underuse nonpharmacologic interventions.

In summary, chronic insomnia, particularly as identified as fragmented sleep, is prevalent in aging females. People with type 2 diabetes have been reported to have more fragmented sleep than the general population (Trento et al., 2008). The American Academy of Sleep Medicine recommends that psychological and behavioral interventions are effective and recommended in the treatment of chronic primary and comorbid insomnia (Morgenthaler et al., 2006).

Although the metabolic relationship between insomnia and diabetes has not been reported in the literature, the metabolic consequences of sleep deprivation and sleep disruption on healthy individuals has been reported. Short-term sleep deprivation (four hours/night for five nights) of healthy young males resulted in a 30% increase in insulin resistance, in addition to an increased appetite for sweet and fatty foods (Spiegel, Leproult and VanCauter, 1999). Sleep fragmentation across all stages of sleep has been found to decrease insulin sensitivity and glucose effectiveness (Stamatakis & Punjabi, 2009).

The sleep and metabolism relationship has also been studied in persons with type 2 diabetes. Both poor quality of sleep and short sleep duration have been found to be

associated with significantly worse glycemic control (Vigg, Vigg, and Vigg, 2003; Knutson, Ryden, Mander, & VanCauter, 2006). The metabolic association among obstructive sleep apnea (OSA) and fasting hyperglycemia, insulin resistance and type 2 diabetes has been studied with increasing frequency. Treatment with Continuous Positive Airway Pressure (CPAP) was reported to result in a clinically significant decrease in A1C. Although a relationship between interrupted sleep and increased insulin resistance has been reported, no studies on the impact of insomnia treatment on type 2 diabetes control were found in the literature (Hassaballa, Tulaimat, Herdegen & Mokhlesi, 2005).

In addition to the research on the metabolic impact of sleep, research on appetite and exercise demonstrate a relationship between sleep and the diabetes self-care activities of nutrition and exercise. Spiegel, Tasali, Penev and VanCarter (2004) conducted an experimental sleep debt study on 12 healthy young men. Results indicated participants in the sleep debt group experienced increased hunger, especially for carbohydrates and fats. The researchers found that approximately 70% of the variance in increased hunger could be accounted for by the grelin-to-leptin ratio. Chasens, Sereika, Weaver and Umlauf (2007) studied the association among sleepiness, exercise, and physical function in older adults. Daytime sleepiness of older community dwelling adults age 55-84 was found to be associated with physical functional impairments and decreased exercise.

Safe and effective cognitive behavior therapy for insomnia (CBTI) is recommended as the primary treatment for insomnia (Kryger, Roth & Dement, 2005;Morgenthaler, 2006). This treatment is a combination of psychological and behavioral methods. Sleep restriction therapy and stimulus control procedures are combined with a cognitive component designed to alter faulty beliefs and attitudes about sleep. An educational component is focused on sleep hygiene principles and effects of

diet, exercise, caffeine, alcohol and environmental factors. Usually conducted over a 4-8 week period of time, this intervention may be provided individually or in a group. Face to face meetings are a critical component of the therapy. Research has reported continued improvement in sleep behavior following the completion of the program (Kryger, Roth, & Dement, 2005).

In summary, 7.87 % of the Michigan population has type 2 diabetes. Aging women have a higher reported incidence of type 2 diabetes. Both the prevalence of type 2 diabetes and the prevalence of insomnia increase with age. The form of insomnia most prevalent in aging is fragmented sleep. The goal of diabetes management is to attain and maintain an A1C close to normal to prevent diabetes complications. Recent research findings demonstrated that both poor sleep quality and short sleep duration were associated with worsening glycemic control. CBTI has been recommended as the preferred treatment for insomnia. No published studies were found that examined the effect of cognitive-behavioral therapy on fragmented sleep and the relationship among perceived sleep quality, type 2 diabetes control and self-care behaviors.

## Study Purpose and Hypotheses

The purpose of this study was to examine the effects of participation in cognitive-behavioral therapy for insomnia on the sleep quality, quantity and severity of insomnia in post-menopausal women with type 2 diabetes. A secondary purpose was to determine the relationship among changes in sleep quality and quantity, metabolic control and diabetes self-management behaviors. The hypotheses for this study are to:

$H_1$: Participation in cognitive-behavioral therapy for insomnia will improve perceived sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI) among post-menopausal females with type 2 diabetes.

$H_2$: Participation in cognitive-behavioral therapy for insomnia will improve perceived insomnia severity as measured by the Insomnia Severity Index.

$H_3$: Participation in cognitive-behavioral therapy for insomnia will improve sleep quantity as measured by the Actiwatch 2.

$H_4$: A relationship exists between change in perceived sleep quality as measured by the PSQI and diabetes metabolic control as measured by A1C among post-menopausal females with type 2 diabetes.

$H_5$: A relationship exists between change in perceived sleep quality as measured by the PSQI and activity as measured by the Physical Activity Scale among post-menopausal females with type 2 diabetes.

$H_6$: A relationship exists between change in perceived sleep quality as measured by the PSQI and appetite as measured by the Visual Analog Scale among post-menopausal females with type 2 diabetes

**Study Significance for Society, Health Care, and Nursing**

Diabetes is a devastating disease that has developed into a worldwide epidemic. Whereas the prevalence of type 1 diabetes has remained stable, the incidence of type 2 diabetes is increasing by one million individuals annually. Women are diagnosed with type 2 diabetes more often than men. In the United States, more women die each year from diabetes than breast cancer. The Diabetes Prevention Program reported prevention, or at minimum, a delay of type 2 diabetes occurred when activity was increased and weight was decreased in people with pre-diabetes (Childs, Cypress & Spollett, 2005).

An association between sleep duration and the prevalence of type 2 diabetes has been reported in the literature. Metabolic control in individuals with type 2 diabetes has been reported to be worse when poor quality of sleep was reported. Research of improved

sleep behaviors in those with obstructive sleep apnea has been associated with improved metabolic control in individuals with type 2 diabetes. Metabolic control has been determined to prevent long and short-term complications of diabetes. These complications impair quality of life and often lead to death.

Insomnia, affecting 30% of the general aging population, is no longer perceived as a necessary part of aging. This sleep disorder has the potential for increasing insulin resistance, increasing appetite and impeding physical activity, resulting in impaired metabolic control in women with type 2 diabetes. Research on interventions to improve sleep behaviors in those experiencing insomnia and type 2 diabetes has yet to be studied. The potential for decreased appetite, increased activity and improved metabolic control needs to be investigated.

Cognitive Behavioral Therapy for Insomnia (CBTI) has been found to be more effective than the use of medications in improving sleeping behaviors in those with chronic insomnia. Although traditionally those psychologists trained in sleep medicine have conducted Cognitive Behavioral Therapy for Insomnia, the need for clinicians from other disciplines to be trained in this therapy has been reported because more clinicians are needed. A limited number of studies have found nurses effective at conducting CBTI (Epsie et al., 2007; Epsie et al., 2008). The addition of other disciplines to conduct CBTI will enable additional people with insomnia to obtain this health care intervention. Nurses certified as diabetes educators and also trained in CBTI are prepared to both conduct CBTI and also assist with diabetes management for those experiencing both health issues.

Bulechek and McCloskey (1992) identified sleep promotion as a nursing intervention. Nurses treat people with diabetes, regardless of the area of their practice.

Nurses certified as diabetes educators have a unique responsibility both to advocate for and educate their diabetic patients. Behavior change is the focus of diabetes education.

Nurses certified as diabetes educators and trained in CBTI have the background to assist patients with both insomnia and type 2 diabetes to improve sleep behaviors. The potential exists for an expanded role for nurse certified diabetes educators. Results of this study do support this concept. This study was designed also to expand knowledge about post-menopausal women with type 2 diabetes and insomnia, specifically the impact of CBTI on A1C, appetite and activity.

Improved diabetic metabolic control is clinically significant. Results of this study may support the inclusion of sleep assessment, education and management in diabetes care throughout the health care system. Nursing science is both interdisciplinary and collaborative it its art and its science. The body of knowledge that comprises nursing science is accumulated, refined and extended as a result of research. The results of this study will benefit nursing science by providing data to support evidence-based practice as it relates to sleep and diabetes.

# CHAPTER 2

# REVIEW OF LITERATURE

## Introduction

Chapter 2 presents a review of the pertinent literature. The initial section of the literature review provides a current overview of diabetes. The second section focuses on insomnia. The relationship between sleep and diabetes is presented next. The fourth section provides a literature review of cognitive behavioral therapy for improving sleep among aging women with type 2 diabetes and insomnia. The chapter concludes with a review of the Health Belief Model and how this model directed this research.

## The Health Problem of Diabetes

Diabetes is a major health problem in the United States. In 2007, the prevalence of diagnosed and undiagnosed diabetes of all ages in the United States was reported to be 23.5 million people or 10.7% of the population. The prevalence of those diagnosed is reported to be 19.7 million people. For those age 60 years or older, 12.2 million, or 23.1% of the elderly population have been diagnosed with diabetes. Based on 2006 death certificate reporting, diabetes was reported as the seventh leading cause of death. Overall, the risk of death among people with diabetes is reported to be twice that of those without diabetes (National Institute of Diabetes and Digestive and Kidney Diseases, 2008).

Complications of diabetes include heart disease, stroke, blindness, kidney disease, nervous system disease, amputations, dental disease, and complications of pregnancy. In 2004, heart disease was noted on 68% of diabetes-related death certificates. For the same time period, stroke was reported on 16% of diabetes-related death certificates. Diabetes is the leading cause of new cases of blindness among adults 20 to 74 years of age. The leading cause of kidney failure also is diabetes. About 60 to 70% of those with diabetes

experience mild to severe forms of nervous system damage. More than 60% of the nontraumatic lower limb amputations occur in people with diabetes. Periodontal disease is more common in people with diabetes. Poorly controlled diabetes at differing stages of pregnancy can result in birth defects or severe illness to mother and baby (National Institute of Diabetes and Digestive and Kidney Diseases, 2008)

It is estimated that during 2005-2007, 648,100 persons aged 18 years or older (8.5%) living in Michigan had been diagnosed with diabetes. The prevalence increased with age to 21.1% of the population aged 65-74 years. Michigan's diabetes prevalence ranks 15$^{th}$ highest among all the states in the nation. As a result of their diabetes not being managed well, many people are at increased risk for complications. Even though improvements in diabetes care have led to decreased rates for diabetes-related complications and mortality, the costs of diabetes care are increasing. (The Michigan Diabetes Prevention and control Program [MDPCP], Michigan's Diabetes Burden and Diabetes Program – Overview 2008, 2009). In 2007, the estimated total cost for diabetes in the United States was $174 billion. The direct medical costs were estimated to be $116 billion and the indirect costs were reported to be $58 billion (National Institute of Diabetes and Digestive and Kidney Diseases, 2008).

**Sleep and Insomnia**

Sleep is a multifaceted behavioral state that occupies approximately one-third of the human life-span. Although perceived as a passive state, sleep is a highly active and dynamic state. An adequate amount of sleep is necessary to lead a healthy and productive life. Although chronic sleep loss is common in western societies, many people are unaware of the potential adverse health effects of sleep restriction (Punjabi & Polotsky, 2005).

Increased morbidity and mortality have been reported to occur with reduced sleep duration and sleep disturbances (Ayes et al., 2003; Kojima et al., 2000; Kripke, Garfinkel, Wingard, Klauber, Marler, 2002; Mallon, Broman, Hetta, 2002; Nilsson, Nilsson, Hedblad, Berglund, 2001). Ayes et al. (2003) reported that the risk of developing coronary heart disease was increased by approximately 45% in subjects with an average daily sleep duration of 5 hours or less.

Insomnia is the most common sleep complaint of adulthood. Occurring at all stages of adulthood, this condition is often chronic and comorbid with other disorders, particularly depression. Insomnia is defined as complaints of disturbed sleep in the presence of both adequate occasion and circumstance for sleep. Insomnia is identified by three features: (a) difficulty initiating sleep; (b) difficulty maintaining sleep; and (c) waking up too early. One or more of these features indicates insomnia. Acute insomnia may occur in anyone and is limited to one month duration. Chronic insomnia is defined as 30 or more days of the previously stated symptoms. The term, secondary insomnia, has been used when this condition is associated with another chronic condition, such as depression. Although initially thought that management of the comorbid condition could cure the insomnia, research has reported this not to be true (National Institutes of Health State-of-the-Science Conference Statement, 2005).

Although fatigue generally is present with primary insomnia, daytime sleepiness is not. Those experiencing insomnia often are not able to nap during the day, but rather remain in a state of hyperarousal or hypervigilance. Mood disturbances, such as irritability, are usually present. Research suggests that persistent untreated insomnia may be a risk factor for major depression. Sleep loss associated with chronic insomnia may lead to chronic sleep deprivation (Morin & Espie, 2004).

The intensity of insomnia has no formal definition. Generally, clinical researchers consider 30 or more minutes to fall asleep and/or 30 or more minutes of wakefulness after sleep onset as abnormal sleep. Sleep duration is not decreased in all persons with insomnia. Some extend their sleep opportunity to compensate for difficulty falling asleep or maintaining sleep (Perlis, Jungquist, Smith, & Posner, 2005).

**Insomnia in the Aging**

Insomnia has been found to be present in 30% of people over 65 years of age (Kyrger, Roth & Dement, 2005). Older women are more likely to report sleep maintenance problems than men. Insomnia in this population also includes three sleep behaviors: (a) difficulty getting to sleep, (b) difficulty staying asleep, or (c) waking up too early. Insomnia in aging is primarily that of waking during the night and being unable to get back to sleep, resulting in fragmented nonrestorative sleep. Older adults with insomnia are reported to more likely have medical illnesses, physical disabilities, and elevated levels of anxiety or symptoms of depression than those without insomnia complaints. Although likely to be treated by medications, safe and effective cognitive behavior therapies are available. These treatments are a combination of psychological and behavioral methods (Kryger, Roth, & Dement, 2005).

Kamel and Gammack (2006) report that insomnia, is not a normal, or necessary part of aging. Adverse outcomes of daytime drowsiness or fatigue are particularly dangerous for the aging, include increased risk of falls, difficulty with concentration and memory, and overall decreased quality of life. Kamel and Gammack (2006) also reported that insomnia in the elderly is typically undertreated. In addition, the use of nonpharmacologic interventions is underused by health care professionals. Disrupted sleep in the elderly is often associated with chronic disease, including depression.

Hidalgo and colleagues (2006) reported that in their sample of 424 noninstitutionalized elderly insomnia participants, diabetes was the only chronic disease reported with significant frequency.

## Relationship between Sleep and Diabetes

Research on the relationship between sleep and diabetes has focused on sleep duration, sleep disorders, and sleep quality (Gangwisch et al., 2007; Ayas et al., 2003; Spiefel, Leproult and VanCauter, 1999). Sleep duration studies have been conducted to determine metabolic changes that occur with shortened sleep. The sleep disorders reported to be more common in type 2 diabetics are sleep apnea, restless legs syndrome, and insomnia. Often, people experience more than one sleep disorder. Studies on sleep quality focused on the relationship among sleep quality and the incidence of type 2 diabetes and diabetes metabolic control (Vigg, Vigg & Vigg, 2003; Cappuccio, D'Elia, Strzzullo & Miller, 2010). In summary, regardless of the specific sleep focus, research has reported a relationship of type 2 diabetes and sleep.

### Sleep Duration

Epidemiologic studies have explored the relationship between sleep quantity and quality and the incidence of type 2 diabetes. Cappuccio, D'Elia, Strazzullo and Miller (2010) conducted the first systematic review and meta-analysis of 10 such studies (13 independent cohort samples, 107,756 adult male and female participants). Of the 10 studies, four were from Europe, four were from the United States and two were from Japan. The inclusion criteria for this study were original article, prospective design and assessment of sleep disturbances both at baseline and at least three years follow-up. The sleep disturbances included short sleep duration (nine cohorts), long sleep duration (seven cohorts), and difficulty initiating (six cohorts) and maintaining sleep (six cohorts). Short

sleep was defined as equal to or less than 5 hours (3 studies), less than 6 hours (2 studies) and less than 7 hours per night. Long sleep was defined as greater than 8 hours in two studies and equal to or greater than 9 hours per night in four studies. The quality of each study included in this meta-analysis was evaluated using the Downs and Black Quality Index score system. The pooled risk and 95% CI for the quantity of sleep and disturbance of sleep were estimated separately.

Cappuccio and colleagues (2010) concluded that sleep duration and sleep disturbance consistently and significantly predict the risk of developing type 2 diabetes. Short sleep duration was associated with a greater risk of developing type 2 diabetes. Men (RR 2.07 [95% CI 1.16-3.72]) tended to have a greater effect than women (1.07 [0.90-1.28], heterogeneity test $P = 0.04$). Long sleep duration was also associated with a greater risk of type 2 diabetes, > 9 h ($n = 5$; RR 1.38 [95% CI 1.15-1.65], $P = 0.0006$. Difficulty in initiating sleep was associated with a greater risk of type 2 diabetes ($n = 4$; RR 1.58 [95% CI 1.13-2.21] $P = 0.0082$. Difficulty in maintaining sleep was associated with a greater risk of type 2 diabetes ($n = 4$; RR 1.67 [95% CI 1.30-2.14] $P < 0.0001$). In summary, the risk varied from 28% in people who regularly sleep less than 5-6 hours per night to 84% in those with difficulties maintaining sleep.

Although sleep deprivation in rodents has been known to result in death (Everson, Bergmann, & Rechtschaffen, 1998), it was thought that sleep loss in humans resulted only in increased sleepiness and decreased cognitive performance. Both the prevalence of chronic sleep deprivation and sleep-disordered breathing (a secondary cause of sleep deprivation) have increased in recent times. Research has identified negative metabolic and endocrine alterations in both chronic sleep deprivation and obstructive sleep apnea.

The effect of sleep debt on metabolic and endocrine functions was studied by Spiegel, Leproult and VanCauter in 1999. Eleven healthy young men (18 to 27 years of age) were studied for 16 consecutive nights. The first three nights (eight hours of sleep each night) were used to collect baseline data. The following six nights of sleep were limited to four hours each night. Twelve hours of sleep each night during the last seven nights provided sleep-recovery. Carbohydrate metabolism and hormonal profiles were assessed at the end of the sleep-debt and sleep recovery conditions. Carbohydrate metabolism, thyrotropic function, activity of the hypothalamic-pituitary-adrenal axis, and sympathovagal balance were studied. Glucose effectiveness was 30% lower in the sleep-debt condition than after sleep recovery. A decrease in the acute insulin response to glucose is an early indicator of type 2 diabetes. The peak glucose concentrations in response to breakfast in the sleep-debt condition of the young males were similar to that seen in older adults whose insulin response to glucose is delayed. As a result, the blood glucose rises before the insulin is secreted by the pancreas.

Spiegel, Tasali, Penev, and VanCauter (2004) conducted an experimental sleep debt study on 12 healthy young men who did not smoke or take any medications. The men participated in two studies, spaced at least six weeks apart. The two studies were conducted in a randomized order. The first six participants had restricted time in bed (4 hours) and the second six performed the study with extended time in bed (10 hours). Average weight did not change during the time separating the two studies. After the second night, caloric intake was kept constant by infusing intravenous glucose. Validated visual analogue scales for hunger and appetite for various foods were administered. Results of this study reported stable leptin levels across the daytime period under both conditions. The calories were provided by the constant intravenous infusion of glucose.

The average sleep time for the men who spent 4 hours in bed was 3 hours and 53 minutes. The average sleep time for participants who spent 10 hours in bed was 9 hours and 8 minutes. The mean ghrelin levels of those in the sleep restricted group were 28% higher than those who spent 10 hours in bed. Results indicated participants in the sleep debt group experienced increased hunger. The researchers found that approximately 70% of the variance in increased hunger could be accounted for by the increase in the ghrelin-to-leptin ratio. Further research is needed to identify the relationship of food intake and weight gain during sleep restricted periods.

**Sleep Quality and Metabolic Control**

Research studies have reported on the relationship between glycemic control in type 2 diabetics and duration and quality of sleep. Vigg, Vigg, and Vigg (2003) studied 220 adult subjects with type 2 diabetes. A questionnaire about history and management of diabetes was administered and the Pittsburgh Sleep Quality Index (PSQI) was used to assess self-rated sleep quality. A1C data was collected to report glycemic control. A significant number of participants had reduced sleep duration. Both poor quality of sleep and short sleep duration were associated with significantly worse glycemic control. The authors recommended that sleep hygiene should be a part of routine diabetes care.

African Americans with type 2 diabetes (n = 161) were studied to determine if sleep quality and duration impacted glycemic control. Sleep quality and duration were measured by the Pittsburgh Sleep Quality Index (PSQI) and glycemic control was assessed by A1C. Both restricted sleep duration and poor sleep quality were found to be significant predictors of increased A1C levels. The increase in A1C for a perceived sleep debt of three hours per night was 1.1% above the median. With a 5-point increase in

PSQI score, the A1C level was 1.9% above the median (Knutson, Ryden, Mander, & VanCauter, 2006).

Sleep disturbances in type 2 diabetes associated with glycemic control were studied by Trento and colleagues (2008). An intervention sample of 47 patients and control sample of 23 patients were studied. The intervention group (mean age of 61years) was diagnosed with type 2 diabetes and treated with oral agents. The control group (mean age of 58 years) was reported to be healthy individuals. Sleep was assessed using both wrist-actigraphy for three consecutive days and self-reported questionnaires on sleep behaviors. Sleep parameters derived from the actigraphy recordings were time in bed, actual sleep time, sleep maintenance, sleep efficiency, sleep latency, fragmentation index, total nocturnal activity and percentage of moving time. The fragmentation index and moving time were significantly higher in patients with diabetes. The study reported that patients with type 2 diabetes were found to move more in bed and have more fragmented, less efficient sleep than healthy control subjects. The type 2 patients in this study had not previously been diagnosed with insomnia. It was recommended that people with type 2 diabetes be assessed for obstructive sleep apnea, restless legs syndrome and insomnia. Trento et al. (2008) concluded that patients with diabetes could experience improved health and quality of life if they participated in treatment for their sleep disorders and were provided education about healthy sleep behaviors.

**Sleep and Diabetes Self-Care Management Behaviors**

Most diabetes management occurs in the daily lives of individuals living with the disease (McCormack et al., 2008). Therefore, over the past 30 years, people living with diabetes have been encouraged to actively manage their disease. The goal of self management programs has been to provide the knowledge and skills needed to

successfully manage their metabolic control. The ultimate goal of self-management is to prevent diabetes complications from occurring, resulting in improved quality of life and increased longevity. Two fundamental self care behaviors are nutritional management and exercise. Research has reported a relationship between sleep and both appetite and exercise.

Nutritional management for diabetes focuses on maintaining healthy eating habits. Since carbohydrates increase blood sugar levels, the intake of these foods is limited. As obesity often is associated with type 2 diabetes, weight loss is advised. Sleep deprivation has been found to be associated with increased appetite, particularly for carbohydrates (Spiegel, Tasali, Penev & VanCauter, 2004). Spiegel and colleagues (2004) conducted an experimental sleep debt study on 12 healthy young men. Results indicated that participants in the sleep debt group experienced increased hunger, especially for carbohydrates.

Exercise is another recommended self-management behavior for people with diabetes. When exercising, insulin sensitivity is increased and calories are burned, resulting in improved metabolic control. Aerobic exercise has been reported to improve cardiovascular status. Research has shown that sleepiness is a barrier to physical exercise (Chasens, Sereika, Weaver, & Umlauf, 2007). Chasens and colleagues (2007) studied the association among sleepiness, exercise, and physical function in older adults. Daytime sleepiness of older community-dwelling adults (age 55-84 years) was found to be associated with physical functional impairments and decreased exercise. Increasing age was not associated with decreases in exercise.

Sleep deprivation is common, not only in the United States but, also worldwide. Research has reported an association between sleep deprivation and increased incidence

of type 2 diabetes, increased insulin resistance, increased appetite, and decreased exercise. Diabetes has also been reported to be associated with increased sleep fragmentation. Insomnia, common in the aging population, results in sleep fragmentation and sleep deprivation. In summary, an overview of the research on the relationship between sleep and diabetes supports the need for sleep intervention studies designed to improve sleep duration and quality in aging women with type 2 diabetes and insomnia.

## Cognitive Behavioral Therapy for Insomnia

Psychological and behavioral interventions have been found to be effective in improving the sleep duration and sleep quality for those experiencing chronic primary insomnia, without the negative side effects of pharmacological treatment. The most common individual therapies for chronic insomnia are sleep restriction, stimulus control, cognitive therapy (CBTI), relaxation training and sleep hygiene. Although certain individual therapies have been reported to improve sleep behaviors, programs that incorporate various interventions have been found to be more effective in helping people with insomnia. Integration of these therapies is known as cognitive behavioral therapy for insomnia. No negative outcomes from this type of therapy have been reported in published research (Perlis, Jungquist, Smith, & Posner, 2005). The individual therapies that are incorporated into CBTI are discussed in detail below.

### Sleep Restriction

Sleep restriction therapy is recommended for those experiencing both sleep initiation and maintenance problems. This technique is designed to limit the time in bed to the amount equal to the person's average total sleep time. To accomplish this, a fixed wake time is negotiated with the participant and the usual sleep time is determined. The

recommendation is that the initial restriction be no less than 4.5 hours (time in bed) (Perlis, Jungquist, Smith, & Posner, 2005).

Once the target amount of time in bed is determined, the bedtime is delayed to later in the evening, or night, so that the time in bed equals the usual total sleep time. Although initially, partial sleep deprivation occurs, the results are a more consolidated sleep. As sleep efficiency increases, patients then increase the amount of time in bed. This is accomplished by lengthening the time in bed by 15-minute increments on a weekly basis when the sleep efficiency is 85 to 90%. Sleep efficiency is determined by sleep diary data. Adjusting the time to bed rather than the wake time is essential to prevent early morning awakenings and to prevent undermining the sleep behavior of associating sleep with the bedroom/bed. Adjusting bedtime, rather than wake up time, also takes advantage of the "curative" effects of delaying the sleep phase (Perlis, Jungquist, Smith, & Posner, 2005).

The effectiveness of sleep restriction is thought to occur for two reasons. Sleep restriction prevents patients from coping with insomnia by extending sleep opportunity. Extending sleep opportunity results in sleep that is shallow and fragmented. In addition, the initial sleep loss that is experienced with sleep restriction is thought to increase the homeostatic pressure for sleep. As a result, shorter sleep latencies and higher sleep efficiency occur (Perlis et al., 2005).

**Stimulus Control**

The American Academy of Sleep Medicine identified stimulus control therapy (SCT) as the first-line behavioral treatment for chronic insomnia. This intervention has been assessed extensively as a monotherapy and has been reported to be effective. Stimulus control focuses on limiting the time and activities in the bed/bedroom. By so

doing, the association of bed and sleep onset is strengthened. Typically four instructions are provided to the person with insomnia: (a) lie down to go to sleep only when sleepy, (b) avoid any bed or bedroom activity other than sleep or sexual activity, (c) if unable to go to sleep in 15 minutes, leave the bedroom, (d) when sleepy, return to the bedroom. Repeat instructions c and d as needed. A fixed wake time, regardless of the amount of sleep, is to be maintained. This conditioning behavior is most effective when only one stimulus is paired with one response. Therefore, the bed, or bedroom, is associated with sleep. Stimulus control is reported to promote sleep and reinforce circadian entrainment. While SCT is generally well tolerated, it is not recommended for individuals with mania, epilepsy, or those prone to falls (Perlis, Jungquist, Smith, Posner, 2005).

**Cognitive Therapy**

Cognitive therapy is designed to change those unhealthy sleep expectations, perceived causes and consequences of insomnia. This form of therapy is founded on the assumption that negative emotions, maladaptive behaviors, and psychological disorders are, for the most part, a result of dysfunctional cognitions. The goal of this form of therapy is to assist individuals to view insomnia and its consequences from a more realistic perspective. In addition, since insomnia patients commonly perceive themselves as victims of this disorder, another goal of this therapy is to improve coping skills and increase a sense of control (Morin & Colin, 2004).

**Relaxation Training**

Relaxation training is most suited for those who report an inability to relax or for people with multiple somatic complaints. Four forms of relaxation therapy target different physiological systems. Progressive muscle relaxation is effective in reducing skeletal muscle tension. Diaphragmatic breathing is designed to induce breathing that is

mechanically driven from the abdomen rather than from the thorax. This results in respiration that is slower and deeper, resembling respiration that naturally occurs at sleep onset. By having participants imagine, in a systematic way, that each of their extremities feel warm, autogenic training focuses on increasing peripheral blood flow. Imagery training focuses on selecting a relaxing image or memory. Guided imagery provides direction for the participant in this form of relaxation therapy. Practice with these interventions during the daytime improves the effectiveness at bedtime (Perlis, Jungquist, Smith, & Posner, 2005).

**Sleep Hygiene Education**

Dr. Peter Hauri is identified as the first to use the term sleep hygiene, approximately 20 years ago. The term is used in reference to those behaviors that promote sleep (Morin & Espie, 2004). Typically, in a Cognitive Behavioral Therapy for Insomnia intervention a handout of sleep hygiene recommendations is provided for participants. These recommendations are thought to include a variety of behaviors that may influence either sleep quality and/or quantity. Individualization of the suggested behaviors is recommended. The typical sleep hygiene measures include the following: (a) Get up at the same time each day, seven days a week; (b) Exercise regularly; (c) Make sure your bedroom is comfortable and free from light and noise; (d) Make sure that your bedroom is at a comfortable temperature during the night; (e) Eat regular meals and do not go to bed hungry; (f) Avoid excessive liquids in the evening; (g) Reduce caffeine intake; (h) Avoid alcohol, particularly in the evening; (i) Smoking may disturb sleep; (j) Don't take your problems to bed; (k) Do not *try* to fall asleep; (l) Put the clock under the bed or turn it so that you cannot see it; (m) Avoid naps; (n) Sleep only as much as you need to feel refreshed during the following day; (o) Establish a bedtime routine; (p) The

bedroom should only be used for sleep and sex (Bulechek & McCloskey, 1992; Perlis et al., 2005)

**Appropriate Participants for Cognitive Behavioral Therapy for Insomnia**

Perlis et al. (2005) recommended that individuals with specific characteristics are appropriate for Cognitive Behavioral Therapy for Insomnia. These people are presented in Table 1.

Table 1

*Type of People Who Are Appropriate for Cognitive Behavioral Therapy for Insomnia*

People who have or report:

- Difficulty falling or staying asleep
- One or more of the following
  - regularly extend their sleep opportunity to compensate for sleep loss and/or
  - stay in bed for protracted periods of time while awake and/or
  - engage in behaviors other than sleep and sex in the bedroom
- Evidence of conditional arousal, e.g. the report of suddenly awake when getting into bed and/or sleeping better when away from home (optional)
- Evidence of poor sleep hygiene [the engagement of behaviors that reduce sleep propensity, e.g., use of alcohol as a hypnotic, stimulant use at night (optional)

Note: Perlis et al., 2005, p. 22

**Cognitive Behavioral Therapy Participant Early Withdrawal**

Ong, Kue, and Manger (2008) conducted a study (n=528) aimed at identifying those participant characteristics that were related to withdrawal from a seven-session Cognitive Behavioral Therapy for Insomnia intervention. Their study findings indicated that short sleep duration and elevated symptoms of depression at baseline was associated with an increased risk of early termination.

**Providers of Cognitive Behavioral Therapy for Insomnia**

Traditionally, Cognitive Behavioral Therapy for Insomnia (CBTI) has been developed and conducted by psychologists. Usually these providers have training and/or degrees in sleep medicine. As the field of sleep has matured providers from related disciplines have been trained to provide CBTI. Epsie et al. (2007) conducted a randomized clinical trial of CBTI with nurses as the therapy providers in a primary care setting. The aim of the study was to evaluate the effectiveness of CBTI in primary care. The two main questions were:

1. Is CBTI superior to treatment as usual in reducing chronic sleep disturbance?
2. Are there predictors of good outcome, or contradictions to the application of Cognitive Behavior Therapy, for insomnia in general practice?

A sample of 201 adults (mean age 54 years) was recruited from 19 general practices in Glasgow, West Lothian, and Edinburgh. Potential participants were screened by telephone interview. A more detailed history was obtained face-to-face and participants completed the Pittsburgh Sleep Quality Index (PSQI), the Hospital Anxiety and Depression Scale (HADS) and the Epworth Sleepiness Scale (ESS). Participants were randomly assigned to receive Cognitive Behavior Therapy (n=107, 72 women) or treatment as usual (n=94, 65 women). Sleep diaries were completed for 2 weeks at baseline, posttreatment and the six month follow-up. Objective sleep data were obtained via actigraphy 14 nights before and after treatment.

The CBTI program consisted of 5 weekly, one hour treatment sessions. The group size was 4 to 6 participants. The intervention included stimulus control, sleep restriction and cognitive therapy strategies.

Seven health visitors were trained to provide the CBTI. In the United Kingdom, health visitors are community nurses with postqualification training and certification. Usually they are based in primary care. The nurse therapists were provided a 12 hour, 2-day course on sleep disorders, working with groups, Cognitive Behavior Therapy principles and instruction on the CBTI program. The nurse therapists were provided a mentor/consultant who was a psychologist with training in behavioral sleep medicine. The consultant worked with the nurse therapists but did not work directly with the study participants.

Study results reported that those who received CBTI experienced improvements in self-reported sleep latency, wakefulness after sleep onset and sleep efficiency. The improvements were partly sustained at follow-up. Participants who received treatment as usual did not improve. Actigraphically estimated sleep improved modestly after CBTI, although no improvement was found in the treatment as usual group. The study concluded that nurses trained in CBTI and supervised by sleep specialists can provide CBTI effectively in the primary care setting (Espie, 2007).

Nurses were the Cognitive Behavior therapists in a second study published by Espie and coworkers in 2008. Cancer nurses, with no prior experience or expertise in sleep medicine were trained to provide this therapy. This randomized control study provided CBTI for breast cancer survivors vs. treatment as usual. Four experienced oncology nurses were trained by attending a short CBTI course, apprenticeship learning opportunities, ongoing mentoring by an experienced clinical psychologist and evaluation of randomly selected session audiotapes. Five groups, of 4-6 participants each, were conducted for five consecutive weeks. Cognitive Behavior Therapy for Insomnia was associated with mean reductions of 55 minutes of wakefulness per night. No change was

found in the treatment as usual group. Epsie and colleagues recommended that health care professionals without prior expertise in sleep can be trained to provide CBTI.

**Cognitive Behavioral Therapy Efficacy Studies**

The first review paper summarizing the evidence regarding the efficacy of psychological and behavioral insomnia treatments was published in 1999. In 2006, Morin and colleagues published an update of the current research (1998-2004). Both reviews were conducted by task forces commissioned by the American Academy of Sleep Medicine. The purpose of the 2006 paper was to update the practice parameters of psychological and behavioral therapies for insomnia. The criteria for studies included in this paper identified four necessary study requirements:

> (a) the main sleep diagnosis was insomnia (primary or comorbid, (b) at least one treatment condition was psychological or behavioral in content, (c) the study design was a randomized controlled trial, a nonrandomized group design, a clinical case series or a single subject experimental design with a minimum of 10 subjects, (d) the dependent measure included 1 or more of the of the following variables (as measured by daily sleep diaries, polysomnography (PSG), or actigraphy): Sleep onset latency (SOL), number of awakenings (NA), time awake after sleep onset (WASO), total sleep time (TST), sleep efficiency (SE), or sleep quality (SQ). (p. 1399)

Thirty-seven studies (n=2,246) met the criteria. The findings of the task force reinforce earlier studies that Cognitive Behavioral Therapy for Insomnia is effective and the results are sustained over time. Although neglected in the first paper, nearly 25% of the current studies included older adults. Findings showed that older persons responded as well as young or middle aged adults to CBTI. Research focused on implementation into primary care and broadening the scope of outcome measures was recommended.

## Theoretical Model

The Health Belief Model was developed in the 1950s in response to the failure of individuals to accept preventive or early screening methods for tuberculosis. Although

these health interventions were provided free of charge or for very low cost, people chose not to participate. Subsequently a research project was conducted to study health patterns and health maintenance associated with this problem (Beck, 1974). As the research group progressed with their activities, specific characteristics became evident. The earliest components of the model indicated that for people to take action to prevent a disease, they must believe that (a) they are personally susceptible to the disease, (b) they could develop the disease, which could impact some component of their lives with at least moderate severity, and (c) they should take certain actions that could be beneficial in either preventing the disease or reducing its severity. For the individuals to take action, they had to perceive that they could obtain greater benefits and encounter fewer barriers. Therefore, the original four correlates of the model were labeled: (a) perceived susceptibility, (b) perceived severity, (c) benefits of action and (d) barriers (Becker, 1974).

Perceived susceptibility was defined as the subjective perceptions regarding risks of contracting a condition. These risks were reported to vary from denial to being in real danger of contracting the disease. This dimension has also been explained as a belief in the diagnosis or susceptibility to illness in general (Becker, 1974, Becker & Janz, 1985)

Perceived severity was defined as perceptions concerning either the seriousness of developing an illness or those of not treating it. Although severity can be perceived in terms of the medical or clinical consequence, it can also be perceived from broader implications, including the effects of on the job, family, and social life. Rosenstock (1985) added that both perceived susceptibility and severity were at least partially dependent on knowledge.

Perceived benefits were reported as those beliefs regarding the effectiveness of actions available to reduce the disease threat. The particular course of behavior in response to the vulnerability of the disease is dependent on this perception. Thus, unless the health action is perceived as feasible and efficacious, a "sufficiently threatened" individual could not be expected to accept the recommended health action (Becker & Janz, 1985).

The fourth of the core dimensions of the Health Belief Model was that of perceived barriers, which are negative aspects of health action that serve as barriers to positive action. Potential barriers include inconvenience, expense, pain, and stress. Susceptibility combined with severity provides the force to take action. Perceptions of benefits, minus the barriers, provide the preferred path of action. The energy or force to act, also called "cue to action" may be internal or external. Internal cues could be symptoms or beliefs. Examples of external cues include media communication or interpersonal interactions (Janz & Becker, 1984).

Prior to 1974, "perceived susceptibility" was the most powerful dimension of the Health Belief Model. In post-1974 research, barriers were found to yield the highest significance ratios. Because the Health Belief Model is based psychologically on beliefs and attitudes, additional variables can influence health actions. One variable that fits conceptually is self-efficacy. Bandura (as cited in Janz & Becker, 1984) initially began the work on this concept. He defined self-efficacy as the belief that one is able to execute the behavior needed to produce the required outcome. Stretcher, DeVellis, Becker and Rosenstock (1986) report that self-efficacy can be enhanced, resulting in subsequent health behavior change. Originally designed to explain why individuals decided to take

preventive care actions, the Health Belief Model later was used to predict the use of self-care behaviors (Becker & Janz, 1985).

The Health Belief Model has several limitations. Most research based on the Health Belief Model incorporates components of the model, rather than the model itself. The original model did not incorporate several other factors, such as environment or economics, in addition to the impact of social norms and peer influences. Lastly, although the Health Belief Model is based on beliefs, beliefs often are the result of behavior change (Dennison, 1996).

**Theory Application to Research**

The Health Belief Model has been used extensively as the theoretical foundation for both qualitative and quantitative diabetes studies. For the present study, the model is presented for explaining the relationship between diabetes and sleep (Figure 1). The relationship of sleep and diabetes is reciprocal. Hypoglycemia, nocturia (as a result of hyperglycemia) and peripheral neuropathy have been known to disrupt sleep and also decrease sleep duration. Sleep has been reported to both directly and indirectly impact diabetes metabolic control. Sleep deprivation has been found to cause glucose intolerance in healthy males, decrease activity levels, and increased appetite. Persons with type 2 diabetes who have poor quality sleep have been reported to have higher A1C levels, indicating worse diabetes control. Untreated obstructive sleep apnea has also been associated with poor metabolic control. Based on the above, therefore, sleep impacts diabetes and diabetes impacts sleep.

Managing both sleep problems and diabetes involves the use of self-care behaviors. The relationship between the two health conditions is reported in the literature to be bi-directional. Benefits and barriers are present for both insomnia and diabetes,

impacting the management of both. For this reason, data on both diabetes self-care behaviors and sleep behaviors will be obtained and reported. Diabetes self-care behaviors will include appetite, exercise, and blood glucose monitoring. Insomnia behaviors will include self-reported sleep onset latency, number and duration of awakenings, total sleep time, sleep efficiency and sleep quality. Sleep behaviors will also be documented with the use of actigraphy.

A diagram of the Health Belief Model as it is associated with sleep and diabetes is provided in Figure 2. Sociodemographic, situational, and environmental variables influence perceptions of health, an awareness of the sleep/diabetes relationships, the perceived importance of sleep and diabetes self-care management and the perceived benefits and barriers to sleep and diabetes self-management. Perceptions of health, awareness of the sleep/diabetes relationships, and cues about sleep and good metabolic control impact the perceived importance of sleep and diabetes self-care management. Perceived benefits and barriers to sleep and diabetes self-management, along with the perceived importance of sleep and diabetes self-management are hypothesized to increase sleep and improve metabolic control.

Figure 3 presents the theoretical framework for this study based on the Health Belief Model. At the construct level, insomnia management entrains disordered 24 hour circadian rhythm that regulates the 24 hour sleep-wake pattern. This sleep-wake pattern is hypothesized to have a relationship with metabolism, activity, and nutrition. At the conceptual level, the behavior change phase advances the daily circadian rest-activity acrophase, resulting in a hypothesized improved perceived sleep quality. This change in perceived sleep quality is hypothesized to be associated with the changes in blood sugar control, physical movement, and appetite. On an empirical level, CBTI, the independent

variable, is defined as the method of behavior change (conceptual level). The PSQI and the ISI are the self-report index for sleep quality (conceptual level) and actigraphy and sleep diary are the objective measure for sleep quality. A1C, the Physical Activity Scale, and the Analog Appetite Scale are empirical measures that evaluate concepts of blood glucose control, physical movement, and appetite.

The Health Belief Model operationalized for the Cognitive Behavioral Therapy intervention for insomnia is presented in Figure 4. The six domains of the model are defined. Intervention activities associated with each of these domains are then listed.

In summary, type 2 diabetes is a serious and prevalent chronic disease. The goal of diabetes management is to prevent short and long-term complications. As a result, the quality of life and longevity of those living with the disease is improved. Research has found a relationship among sleep duration, sleep quality and diabetes metabolic control. Insomnia results in decreased sleep time and poor quality of sleep. Cognitive behavioral therapy is a safe and effective method for treating insomnia. The Health Belief Model was used for this study as it has a long history of use in diabetes studies and is also congruent with the principals of CBTI. The literature has reported the need for intervention studies to evaluate the relationship of improved sleep behaviors and diabetes metabolic control.

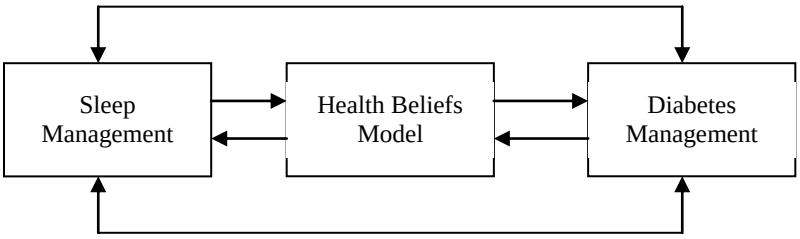



*Figure 1*: Reciprocal Model of Sleep and Diabetes Management with Health Beliefs

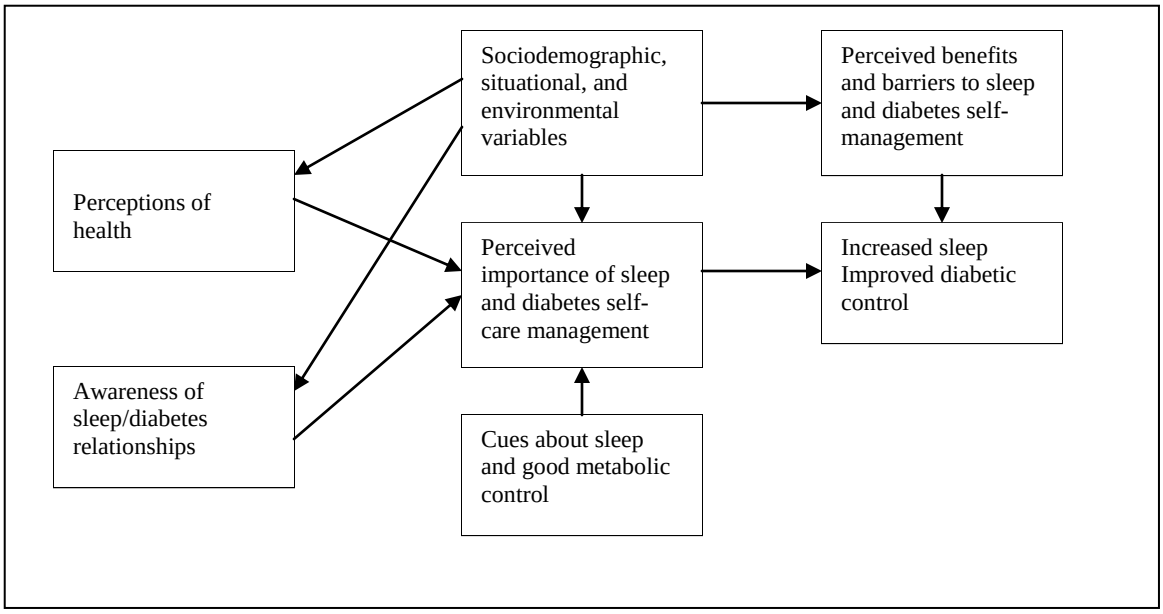



*Figure 2*: Health Belief Model for Sleep and Diabetes Self-Management

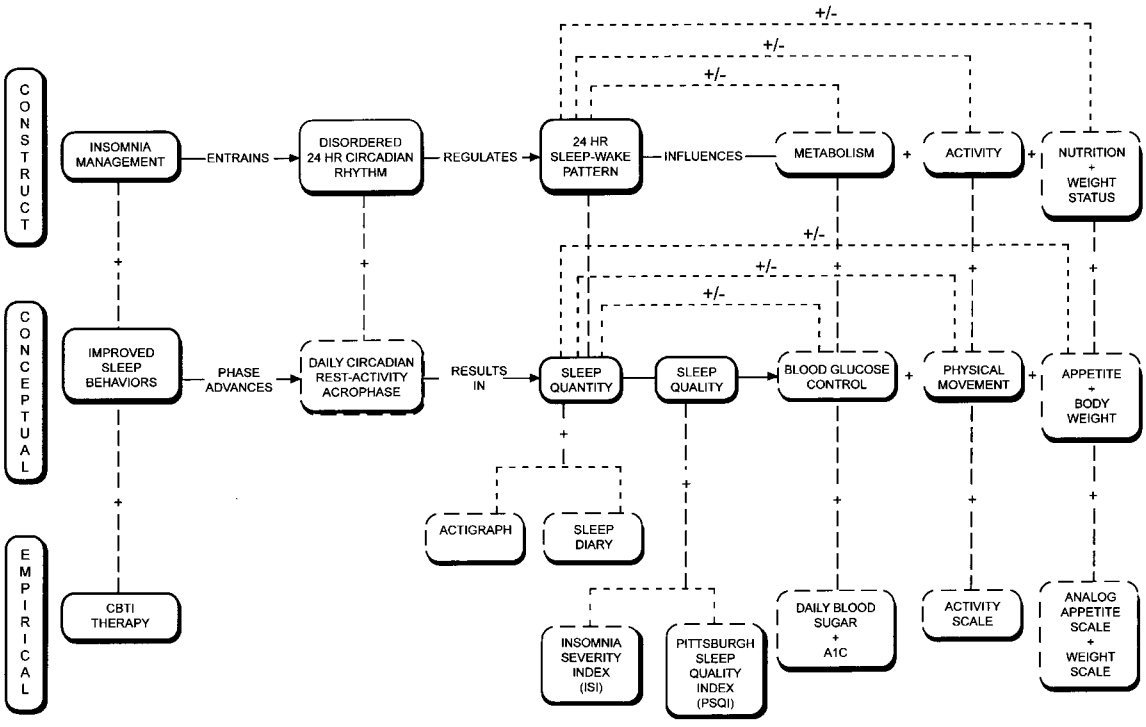



*Figure 3*: Theoretical framework for the Study Intervention

| Concept | Conceptualization Definition | Operational Definition |
|---|---|---|
| Perceived Susceptibility | One's opinion of chances of getting a condition. | 1. Sleep History Assessment: How does your night's sleep affect your day? |
| Perceived Severity | One's opinion of how serious a condition and its consequences are | 1. Insomnia Severity Index.<br>2. The Sleep Behavior Self-Rating Scale.<br>3. Sleep History Assessment: How do you feel about the quality of your sleep? |
| Perceived Benefits | One's belief in the efficacy of the advised action to reduce risk or seriousness of impact. | 1. Motivation for Change Index: If there were a treatment that would, as of tomorrow, fix your insomnia, how would your life be better? |
| Perceived Barriers | One's opinion of the tangible and psychological costs of the advised action. | 1. Sleep History Assessment: What are some things that prevent you from getting a good night's sleep?<br>2. Dysfunctional Beliefs and Attitudes about Sleep Scale.<br>3. Sleep Environment Checklist. |
| Cues to Action | Strategies to activate "readiness". | 1. Decision to participate in study.<br>2. Motivation for Change Index. |
| Self-Efficacy | Confidence in one's ability to take action. | 1. Sleep History Assessment: Are you the kind of person who usually copes well?<br>2. Weekly behavior change activities negotiated based on the participant's confidence to complete the task.<br>3. Cognitive Behavioral Therapy Intervention intended to improve self-efficacy regarding healthy sleep behaviors. |

*Figure 4:* Health Belief Model and Cognitive Behavioral Therapy for Insomnia

# CHAPTER 3

# METHODOLOGY

## Introduction

Beginning with the research design, Chapter 3 presents the study methodology. A description of the study sample is followed by an explanation of the study variables as they relate to the theoretical framework designed specifically for this study. Data collection and analysis are next presented. The chapter concludes with the study assumptions, limitations and statistical hypotheses.

## Research Design

This study was designed to be a feasibility study. A quasi-experimental repeated measures, control by constancy, research design using a pretest, intervention, posttest, and follow-up were employed in the study. Although the independent variable was manipulated, a control group was not included. Each participant served as her own control. The precision of a control by constancy repeated measures design was determined by variation within the same subject. Limited funding did not support the use of a large sample size and/or a control group. Participants were recruited by self-selection. This quasi-experimental design included a seven-week cognitive behavioral insomnia intervention. The diagram for this research design is presented in Figure 5.

| | | | |
|---|---|---|---|
| $O_1$ | X | $O_2$ | $O_3$ |

*Figure 5*: Pretest/Posttest Intervention with Follow-up

The Os in the figure indicate data collection periods and the X indicates the intervention. Within two weeks prior to beginning the intervention (X), the participants

completed the instruments for baseline data. Following the seven-week intervention (X), the participants completed the same set of instruments a second time. Three weeks following the completion of the intervention, the women were asked to complete the instruments a third time. The researcher counterbalanced the instruments to help minimize problems associated with remembering both questions and previous responses when completing the instruments three times in an 11-week period.

**Sample**

The goal was to recruit 24 postmenopausal community dwelling women, aged 50 to 75 years of age, from the Metropolitan Detroit area. These women were to have been diagnosed with type 2 diabetes for a minimum of one year and report fragmented sleep occurring for a minimum of six months prior to entering the study.

Prior to recruiting study participants, the study was approved by the Human Investigation Committee (HIC) of Wayne State University and Henry Ford Health System. The study PI began recruitment of the appropriate study participants. To initiate the recruitment process, the PI met with appropriate individuals at Metro Detroit area diabetes educational programs, support groups, endocrinology practices, and senior centers. Permission and support to recruit clients at each site was obtained from these programs. Based on agreed times and dates, the investigator met with the appropriate individual groups (educational programs and support groups) to explain the study and recruit post-menopausal females with type 2 diabetes who met the study guidelines. Fliers about the project were provided for possible participants who are not present at the designated meetings.

**Inclusion Criteria**

Potential study participants were female gender, 50 to 75 years of age, and required to have self-report evidence of fragmented sleep for a minimum of six months prior to entering the study in addition to being diagnosed with type 2 diabetes for a minimum of one year.

**Exclusion Criteria**

Potential participants not meeting the criteria of fragmented sleep or being menopausal, receiving pharmacological treatment for insomnia, being treated for any psychiatric disorders, admitting to suicidal thoughts, a medically diagnosed sleep disorder, or cognitively impaired were excluded. Those being treated with steroids were also excluded from the study as these medications negatively affect both sleep and type 2 diabetes. When a potential participant was found to have an A1C greater than 9% on the pretest session, the individual was asked to delay participation in the study until her A1C is 9% or less. No diabetic medication dosage increases were to be made during the intervention as this would interfere with the study results. Subjects were excluded if diabetic medication dosages were increased.

**Power Analysis**

The required sample size was calculated using the Gpower computer software (Version 3.1; Faul, Erdfelder, Lang, & Buchner, 2007). It is assumed that the correlation coefficient of 0.50 between the variables would be considered evidence of agreement. Based on this assumption, approximately 24 subjects are required to reject the null hypothesis of zero correlation at the 5% level of significance with 80% power.

## Study Variables

The independent variable (CBTI) and the dependent variables (perceived severity of insomnia, perceived quality of sleep, glycemic control, sleep quantity, physical activity and appetite) are presented. Next, demographic, screening and confounding variables are provided.

### Independent Variable

*Cognitive Behavioral Therapy for Insomnia* (CBTI), was defined as a seven week intervention designed to improve chronic fragmented sleep. (Lichstein & Morin, 2000). This seven week CBTI intervention was designed specifically for this study. The three treatment modalities of stimulus control, sleep restriction and sleep hygiene were incorporated into the intervention that was provided on an individual basis.

### Dependent Variables and Measurement

The major dependent variables in this study were perceived severity of insomnia, sleep quality, sleep quantity, glycemic control, exercise and appetite. The definition of each major study variable and the measures are presented below.

For purposes of this study, sleep quality is defined as the person's perceived overall sleep experience and perceived severity of insomnia. The perceived overall sleep experience was measured using the PSQI and reported as the global PSQI score. The perceived severity of insomnia was measured using the ISI.

The Pittsburgh Sleep Quality Index (PSQI; Buysee, Reynolds, Monk, Berman, & Kupfer, 1989) was designed to meet four goals: (a) provide a standardized measure of sleep quality; (b) differentiate between good and poor sleepers; (c) provide a tool that was both easy for individuals, as well as health providers and researchers to use; and (d) develop a useful assessment for a variety of sleep disturbances. This 19-item

questionnaire consists of seven subscales: (a) subjective sleep quality, (b) sleep latency, (c) sleep duration, (d) habitual sleep efficiency; (e) use of sleep medications, (f) day time dysfunction and (g) sleep disturbance. Each subscale is rated from 0 to 3 with the higher scores reflecting more severe sleep complaints. Analysis of the person's overall sleep experience is obtained by summing all subscale scores to obtain an overall score. The lower the overall score, the better the person sleeps.

Buysee et al. (1989) reported on the reliability of the instrument. The Cronbach alpha for the overall score on the PSQI was 0.83, which was indicative of adequate internal consistency. The stability of the instrument was assessed using paired t-tests for dependent samples on the seven component scores and the global score. Using a sample of 91 patients who completed the PSQI twice at a two-week interval, no statistically significant differences were obtained between time 1 and time 2. Statistically significant product moment correlations were obtained between time 1 and time 2, indicating the PSQI was considered stable over a two-week time period.

The PSQI was validated using different subject populations. Group differences resulted in individual component and global scores. These differences were identified using statistical testing and then validated using polysomnography

Although the PSQI provides an evaluation of overall sleep quality with adequate reliability and validity, it is not specific to insomnia. The Insomnia Severity Index (ISI) is a self-report instrument that measures the individual's perception of his/her insomnia. This seven item tool evaluates the perceived severity of sleep onset and sleep maintenance difficulties, satisfaction with current sleep behavior, interference with daily functioning, noticeability of impairment attributed to the sleep problem, and the degree of distress or concern caused by the sleep problem. A scale of 0-4 is used for each item. The

total score ranges from 0 to 28, with a higher score suggesting a more severe insomnia. This tool has been used to both screen for insomnia and detect changes related to insomnia treatment (Bastien, Vallieres & Morin, 2001).

Using two study samples of insomnia patients, Bastien, Vallieres, and Morin (2001) clinically validated the internal consistency, concurrent validity and factor structure of this self-report tool. ISI data from the first study sample (145 community dwelling residents evaluated for insomnia at a sleep disorder clinic) was compared to the sleep diary data of the same sample. Means and standard deviations for each of the seven items, plus the total, were reported. The total ISI score was selected to compare with the sleep efficiency variable of the sleep diary as the sleep efficiency is probably the best composite measure of overall sleep disturbances. The average total score was 19.7 (SD=4.1). As computed from the sleep diary, the average sleep efficiency was 67.7% (SD=14.55). A Cronbach alpha coefficient and item to total correlations were used to estimate the internal consistency. Internal consistency of the ISI was 0.74. The item to total correlations varied from a low of 0.36 to a high of 0.67. The concurrent validity was estimated by correlating the severity rating for the subtypes of insomnia obtained from the ISI with the corresponding quantitative estimates obtained from the sleep diaries and the total ISI score with the sleep efficiency variable of the sleep diary. All correlation coefficients were significant at the 0.01 probability level.

Data from the second study sample was obtained from a larger study comparing the efficiency of cognitive behavior therapy and pharmacotherapy for late life insomnia. The data ISI results were compared to both the sleep diary and polysomnography results. Internal consistency of the ISI was estimated using Cronbach's coefficient alpha and item to total correlations at the pre, post, and follow-up evaluations. The item to total

correlations ranged from 0.32 to 0.71, with a mean of 0.56 at pretreatment; 0.58-0.79, with a mean of 0.69 at post-treatment; and 0.46-0.90, with a mean of 0.72 at follow-up. The internal reliability coefficients were quite stable from 0.76 at baseline to 0.78 at follow-up. Correlations between the change scores from the ISI with those of the sleep diaries and polysomnography studies resulted in small but significant scores indicating the tool is significantly sensitive to changes in insomnia. In summary, the ISI was found to be an adequately reliable tool for assessing patient perceptions of insomnia both for screening and intervention study purposes.

For purposes of this study, sleep quantity was defined as the duration, timing and fragmentation of sleep and was measured by the sleep diary designed specifically for this study and by actigraphy.

Integral to CBTI is the completion of daily sleep diaries. Sleep diaries provide detailed self reported data needed to determine individual baseline sleeping behaviors and needed information to conduct sleep restriction therapy. Researchers have reported that sleep diaries provide relatively reliable information on sleep latency, wakefulness, sleep time, and sleep efficiency (Morin & Espie, 2003). A sleep diary (See Appendix A), specifically designed for this study, was used for self-report of sleep behaviors for baseline data and sleep restriction therapy. Behaviors that hinder or support sleep were documented in the diary and discussed at the weekly sessions. The assumption was made that the study participants provide accurate data.

Although sleep diaries are traditionally used for CBTI, research has identified variation in self-reported data on sleep diaries vs. sleep behavior data obtained via actigraphy (Dautovich, McCrae & Rowe, 2008). Actigraphy involves the use of portable devices that record movement over extended periods of time. These devices have been

used extensively in the study of sleep and circadian rhythms (Morgenthaler, et al., 2007). Although polysomnography is considered the most accurate measurement of sleep behaviors, actigraphy is both less costly and more convenient for sleep assessment over an extended period of time. The use of sleep diaries and wrist actigraphy provides data on sleep behaviors as well as the subjective experience of sleep. Actigraphs are small noninvasive instruments that record limb movement by means of an accelerometer-microprocessor link (Epsie, et al., 2006). The Actiwatch 2, by Respironics Minimmitter, was used for this study. The Actiwatch is 43mm x 23mm x 10mm in size. With the band, the weight is 16 grams. The recording can be measured at 15 second, 30 second, or one minute intervals. For this study the one minute interval was used. The battery life is dependent upon the recording frequency. The charge time for the battery is 6 hours from empty to full. This actigraph is resistant to dust, water, heat, perspiratation and cold. The appropriate software was used to analyze the data.

For purpose of this study, gylcemic control was defined as blood sugar regulation and was measured by the A1C and daily blood glucose self monitoring.

The A1C test best reflects overall glycemic control and is widely used as a guide to treat diabetes. The A1C test represents the portion of hemoglobin molecules that are glycosolated over a two to three month period. Small variations in this blood test represent significant differences in developing diabetic complications (Stratton et al., 2000). The Wayne State University (WSU) College of Nursing laboratory was responsible for analysis of this blood test.

Blood glucose self-monitoring was conducted using the Presto blood glucose meter, by WaveSense, for a minimum of two times each day, before breakfast and before bedtime. The Presto blood glucose meter is reported to be within a 15% range of the

laboratory standard, 96% of the time. Most blood glucose meters are in the 20% range of the laboratory standard. The participants maintained weekly records of their blood sugar results. Blood glucose meter memory checks were also used.

For purposes of this study, exercise was defined as self-reported physical activity lasting a minimum of 5 minutes as measured by the Physical Activity Scale.

The Physical Activity Scale, developed by Aadahl and Jorgensen (2003), was used to assess self-reported physical activity in 24 hours of sports, work, and leisure time on an average weekday. This one page tool describes nine forms of activity. The duration of time for each category was reported for an average weekday. The total amount of time should add up to 24 hours. Validity of this instrument was determined by comparing two self-report measures; the Physical Activity Scale and a physical activity diary. The "Compendium of Physical Activities" approach used for this tool is based on the concept that the intensity of each specific activity can be expressed in metabolic equivalents (METs). This allows for estimation of energy expenditure of specific physical activities. The time engaged in an activity multiplied by the MET value of the activity and by body weight results in estimated energy expenditure.

Face validity of the questionnaire was determined by interviews with 10 volunteers. Concurrent validity was explored through comparison of the activity scale against measurement of physical activity by activity diaries and by CSA accelerometry. The correlation between the MET-time calculated from the physical activity scale and the average MET-time estimated from the activity diary was high ($r$ = 0.74, $P$ = 0.000). Correlation between physical activity scale MET-time and average 24 hour total activity count by accelerometry was nonsignificant (r = 0.20; See Appendix A).

For purposes of this study, appetite was defined as the desire to eat food, or a specific food, as reported by a study participant using a visual analog scale.

The appetite Visual Analog Scale (VAS) was used to assess hunger, satiety, fullness, prospective food consumption, desire to eat something fatty, salty, sweet or savory. The VAS is 100 mm in length with words anchored at each end identifying the most positive and the most negative ratings for each of the above appetite characteristics. Flint, Raben, Blundell and Astrup (2000) found that this widely used tool was reproducible when used to assess appetite at a single data collection point. Validity was difficult to determine, as an objective measure of appetite does not exist. Within-subjects comparisons were found to be more sensitive and accurate than between-subject comparisons. For this study, the within-subject comparison of three data collection times demonstrated the change in the dependent variable (See Appendix A).

**Demographic Variables**

Demographic variables for this study included the personal characteristics of age, education, marital status, employment, insurance and the number of people living in the home. Data on demographic variables was collected using the investigator developed Demographic Survey (See Appendix A).

**Screening Variables**

Actual sleep behaviors were verified by the use of an individual Sleep History Guide and the Insomnia Severity Index. The Sleep History Guide (Morin & Epsie, 2004) provided both an overview of the potential participants' sleep background and details regarding the current sleep problem (See Appendix A). This outline, including appropriate prompt questions, directed the sleep behavior assessment. The Medical History was used to guide the medical assessment (See Appendix A).

Potential cognitive impairment was evaluated using the Mini Mental State Examination (See Appendix A). A score of 20 or less was used to identify cognitive impairment. The Mini-Mental State (MMS) includes eleven questions on cognitive aspects of mental health function and required 5-10 minutes to administer (Folstein, Folstein & McHugh, 1975). The reliability and validity testing was conducted on 206 patients with dementia syndromes, affective disorder, affective disorder with cognitive impairment, mania, schizophrenia, personality disorders, and in 63 normal subjects. Concurrent validity was determined by correlating the MMS scores with the Wechsler Adult Intelligence Scale. For Mini-Mental Status vs. Verbal IQ, Pearson $r$ was 0.776 ($p <$ 0.0001). For MMS vs. Performance IQ, Pearson $r$ was 0.660 ($p < 0.001$). The MMS was found to have adequate reliability on 24 hour or 28 day retest by both single and multiple examiners. When tested 24 hours apart by the same tester, the correlation by a Pearson coefficient was 0.887. When two different examiners were used the Pearson coefficient remained high at 0.827. When the MMS was given an average of 28 days apart, there was no significant difference in the scores, the product moment correlation for test 1 vs. test 2 was 0.98.

**Confounding Variables**

Confounding variables for this study included presence of depression, medications and daily blood glucose levels. Although the study exclusion criteria include sleep medications, psychotropic drugs, and steroids, the list of medications that can affect sleep is extensive (Pagel, 2005).

Although glycemic control was identified as a dependent variable, hypoglycemia and hyperglycemia were recognized as potentially interfering with sleep quality (Childs, Cypress & Spollett, 2005). Participants were asked to monitor daily blood sugar levels in

the morning (fasting state) and before bedtime. Additional blood sugar testing was conducted at the discretion of the participants. To ensure consistency of meter results, WaveSense Presto self-monitoring supplies (blood glucose meters and strips) and individual instruction were provided for each participant. The blood sugar readings were recorded daily on a blood glucose report form created for this study.

## Data Collection Procedure

The study was designed in four phases:

Phase 1: Pretest (recruitment, screening procedures, informed consent and baseline data collection),

Phase 2: Seven week intervention,

Phase 3: Post-test data collection and

Phase 4: Three week follow-up.

### Phase 1

Potential participants demonstrating interest in the study and meeting the initial inclusionary requirements were contacted by telephone or in person to set an appointment to meet with the PI. Screening for possible inclusion in the study occured over the phone or in person using the investigator developed screening tool (See Appendix A)specifically designed for this study. At the agreed upon time for orientation to the study, the PI met with the participant and reviewed the informed consent form. After obtaining written consent from the participant the PI then verified the A1C level. If the potential participant met the inclusion criteria the PI began the data collection. A weekly meeting time and location for the intervention was mutually determined.

The Demographic Questionnaire (See Appendix A) the Medical History (See Appendix A), Sleep History (See Appendix A) and the Mini Mental State Examination

(See Appendix A) directed the interview. Completion of the Medical History was used to screen for pharmacological treatment for insomnia, treatment for psychiatric disorders and suicidal thoughts. Assessment of steroid use and medical stability was also identified by use of the Medical History. Participants were asked to notify the PI of any medication changes. The Sleep History provided additional information on the sleep behaviors of the potential study participant. The Sleep History was used to screen for potential confounding sleep disorders. The Mini Mental State Examination was used to screen for cognitive impairment.

Having met the inclusion criteria and following additional assessment for possible exclusion variables, all qualified participants completed the PSQI, ISI and Physical Activity Scale. The participant was instructed to complete the Visual Analog Scale the following three mornings before breakfast and to return the forms at the next visit. The mean scores of the VAS collected on three days was used for analysis at each data collection point. An A1C test was obtained. Venous blood samples were drawn using usual laboratory technique and stored in a vertical stopper-up position. The samples did not remain at room temperature for more than eight hours. When the assay was not completed in eight hours, the sample was stored at +2 degrees C to +8 degrees C (Synchron System Chemistry Information Sheet, 2007). Assays were completed at the WSU College of Nursing laboratory. Instruction on the use of the sleep diary, actiwatch 2 and blood glucose meter designated for this study were provided during the study orientation. The study participant was advised to complete the daily diaries and use the blood glucose meter during the week prior to the intervention. The participant also received instruction on the use of the wrist actigraph. Participants were advised to wear

the wrist actigraph on the nondominant wrist during the same seven days of data collection.

**Phase 2**

Seven weekly CBTI sessions were held for each of the participants (Study Manual, p 39). In addition to attendance at each of the sessions, participants completed daily sleep diaries, wore wrist actigraphs and self-monitored their blood glucose, using the WaveSense Presto meter a minimum of twice daily (fasting and at bedtime). Individualized instructions for sleep behaviors was negotiated with each participant on a weekly basis.

The seven-session fragmented sleep intervention was conducted individually in a prearranged private room by the PI. Each of the seven sessions lasted from one to one and a half hours in length. The session topics were be:

1. Introduction to treatment program, review of sleep diaries, blood glucose self-monitoring and introduce sleep restriction;
2. Stimulus control therapy and sleep restriction;
3. Introduction to cognitive therapy;
4. Cognitive therapy and introduction to other therapies;
5. Relaxation Therapy;
6. Sleep hygiene
7. Sleep maintenance and relapse prevention; completion of the posttest measures (Perlis, Jungquist, Smith, & Posner, 2005).

At each session the sleep diary from the previous week was reviewed to determine the sleep goal for the coming week. The blood glucose report form was reviewed. The actigraphs were downloaded. The questionnaire appropriate to each

session was completed during the downloading process. The topic for each week was presented and discussed. Additional detail for each class of the intervention is provided in the Class Outline and Teaching Materials presented in the study manual.

**Retention of participants**.

As this intervention is quite demanding, potential participants were informed about the requirements of the study prior to enrollment. Each participant was asked about her ability to commit to the study demands. This topic was again addressed during the first session in the Motivation for Change Index. Potential participants were expected to attend each of the sessions. When a necessary absence occurs, a meeting was rescheduled with the participant. When a participant was unable to complete the intervention, their data was excluded.

**Phase 3**

During class seven of the intervention the posttest data was obtained. Study participants completed the PSQI, the ISI, the Visual Analog Scales and the Activity Scale. Since the A1C test reports change each 8 to 10 weeks, this data was collected only during the pretest and at the follow-up session. The A1C is heavily weighted to the 2 to 4 weeks prior to collection.

**Phase 4**

Three weeks following the completion of the intervention the follow-up session occurred. At this session, study participants completed the PSQI, the ISI, and the Physical Activity Scale. A blood sample for A1C analysis was obtained and analyzed by the Wayne State College of Nursing Laboratory. Each of the participants was asked to complete the appetite VAS for three days before breakfast and self-monitor her blood

sugar before breakfast and at bedtime each day prior to the follow up session. A time for questions and discussion was provided at this meeting.

## Data Analysis

SPSS – Windows, version 20.0 was used to analyze the data obtained from the self-report tools and biomedical markers. The PI collected, coded and input the data into a computer file, both prior to and at the conclusion of the intervention. Follow up data was collected three weeks following the intervention. The A1C was collected prior to the intervention and at the 3-week follow-up.

Frequency distributions and descriptive statistics were used to analyze the demographic data to obtain a profile of the participants. The nominal and ordinal data was analyzed using frequency distributions, while the continuous data will be analyzed using measures of central tendency and dispersion. Data from the dependent variables of A1C, appetite and exercise was collected as interval level data.

To address Hypotheses H1 and H2, in determining the intervention effect of cognitive-behavioral therapy for insomnia, multivariate repeated-measures analysis of variance and covariance was used to test the improvement in sleep quantity and quality within and between participants. For Hypotheses H3 through H6, Pearson correlation coefficients were utilized to determine the relationship between variables measured on ratio or interval scales.

## Assumptions

The following assumptions were made for this study:

Cognitive behavior therapy for insomnia (CBTI) has been shown to be an effective tool in changing sleep behavior and reduces insomnia.

Participants in the study responded to surveys and maintain sleep diaries honestly.

Participants has the capability to improve their insomnia.

## Limitations

Limitations to this study included a small sample size and no comparison group. Each subject was her own control. The study was limited to women who are between 50 and 75 years of age. As a result, the findings are generalizable to men or to men and women who are younger or older than the targeted population. As a result of the short study duration, long term clinical significance was not be assessed. The study was conducted with outpatients in southeast Michigan. While results of the study may be of interest to nursing personnel who are providing treatment for diabetes in other locations or with people of different ages, the findings are not generalizable to their patients.

## Statistical Hypotheses

$H_1$: Participation in cognitive-behavioral therapy for insomnia will improve perceived sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI) among post-menopausal females with type 2 diabetes.

$H_2$: Participation in cognitive-behavioral therapy for insomnia will improve perceived insomnia severity as measured by the Insomnia Severity Index.

$H_{3:}$ Participation in cognitive-behavioral therapy for insomnia will improve sleep quantity as measured by the Actiwatch 2.

$H_4$: A relationship exists between change in perceived sleep quality as measured by the PSQI and diabetes metabolic control as measured by A1C among post-menopausal females with type 2 diabetes.

$H_5$: A relationship exists between change in perceived sleep quality as measured by the PSQI and activity as measured by the Physical Activity Scale among post-menopausal females with type 2 diabetes.

$H_6$: A relationship exists between change in perceived sleep quality as measured by the PSQI and appetite as measured by the Visual Analog Scale among post-menopausal females with type 2 diabetes

# CHAPTER 4

# RESULTS

## Introduction

Chapter 4 presents the study results. The purpose of the study and the research design are first presented. The sample description and demographics are then reported. Following, the study results are presented according to each individual hypothesis. The chapter concludes with additional study findings.

## Purpose of the Study

The purpose of this study was twofold. First the study examined the effects of participation in in cognitive behavioral therapy for insomnia on the sleep quality, sleep quantity and insomnia severity in post-menopausal women with type 2 diabetes. A secondary purpose was to determine the relationship among changes in sleep quantity and sleep quality, metabolic control and diabetes self- management behaviors.

## Research Design

The research design for this 11-week feasibility study was quasi-experimental using a pretest, intervention, posttest, and a follow-up. Following an orientation session, the study participants completed a seven week intervention followed by a three week follow-up. Data was collected at baseline, week seven of the intervention and at the three week follow-up. Figure 3, as previously presented in Chapter 2, provides the theoretical framework for the study intervention.

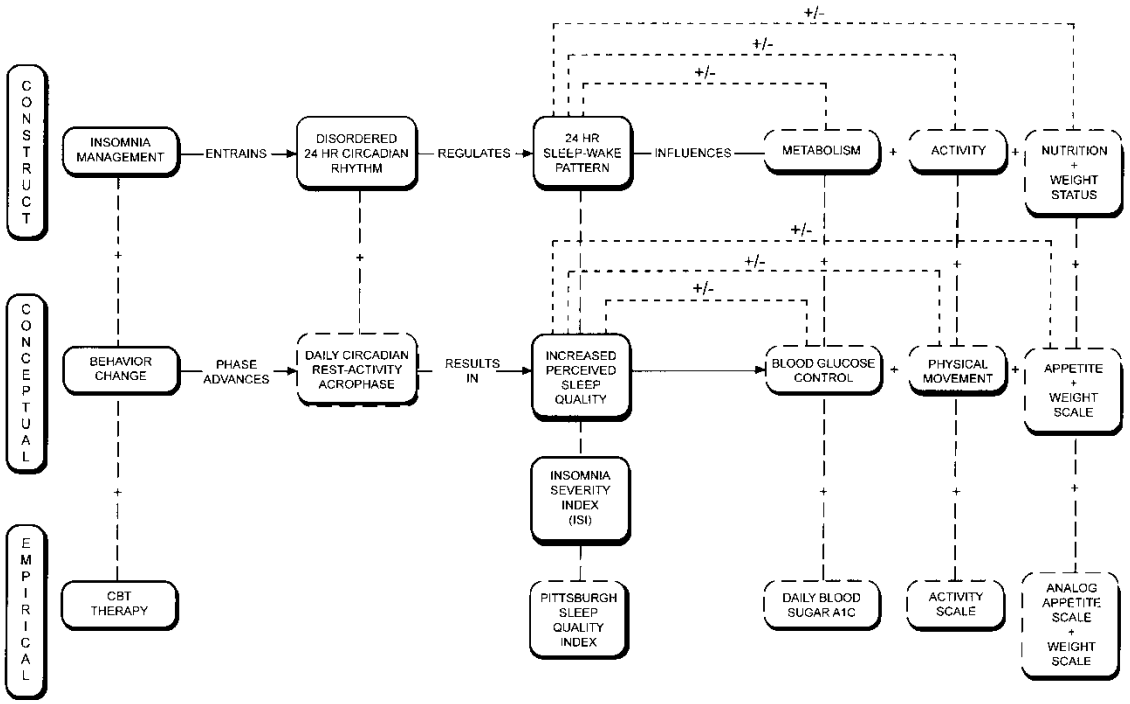



*Figure 3:* Theoretical framework for the Study Intervention (as previously presented)

## Sample Description

The sample criteria for this study were participants aged 50 to 75 years of age who had type 2 diabetes for a minimum of one year and insomnia for a minimum of six months. The hemoglobin A1C level needed to be below 9% to be enrolled in the study. Eighteen participants were consented and 16 were enrolled in the study. Seven of the 16 enrolled participants did not complete the study and were not included in the final analysis. Two participants had elevated A1C levels above 9% and, therefore, could not be enrolled in the study. They were unable to lower their A1C levels adequately for study enrollment prior to the end of the study. During the study, one enrolled participant was found to have obstructive sleep apnea and, therefore, did not meet the participant criteria. One participant became medically unstable and also no longer met the participant criteria. Three participants decided to drop out of the study as they reported that they needed to focus on family issues that developed during the intervention. One participant had

difficulty wearing the actiwatch and decided that it was not a good time for her to participate in the study. In addition, one lady was removed from the study as she did not follow the study protocol. A total of nine participants completed the intervention and the follow-up. Frequency distributions were used to summarize the demographic data for the participants and are presented in Table 2.

Table 2

*Demographic Data (N = 9)*

| Demographic Data | Frequency | Percent* |
|---|---|---|
| Age | | |
| 56 to 60 | 4 | 44.0 |
| 61 to 65 | 2 | 22.0 |
| 66 to 70 | 3 | 33.0 |
| Educational Level | | |
| High school graduate | 2 | 22.0 |
| Some college | 3 | 33.0 |
| College graduate | 1 | 11.0 |
| Master's degree | 3 | 33.0 |
| Marital Status | | |
| Single | 2 | 22.0 |
| Divorced | 1 | 11.0 |
| Married | 4 | 44.0 |
| Widowed | 1 | 11.0 |
| Separated | 1 | 11.0 |
| Insurance | | |
| Medicare + Private | 4 | 44.0 |
| Private | 5 | 56.0 |
| Employment | | |
| Full-time | 1 | 11.0 |
| Part-time | 2 | 22.0 |
| Retired | 5 | 56.0 |
| Disabled | 1 | 11.0 |

*Percentages may not add up to 100% due to rounding

The age inclusion criteria for the study were women aged 50 to 75 years of age. No participants under 56 years of age or over 69 years of age completed the study. Of

those participants who finished the intervention and follow-up, 4 (44%) were 56 to 60 years of age; 2 (22%) were 61 to 65 years of age and 3 (33%) were 66 to 70 years of age.

Educational level as reported by participants: 2 (22%) were high school graduates; 3 (33%) had some college; 1 (11%) was a college graduate and 3 (33%) had Master's Degrees. Regarding marital status, 2 (22%) were single; 1 (11%) divorced; 4 (44%) married; 1 (11%) widowed and 1 (11%) separated. Four (44%) of the study participants reported having Medicare plus a supplemental insurance and 5 (56%) had private insurance. Regarding employment, 1 (11%) was working full time; 2 (22%) were working part time; 5 (56%) were retired and 1 (11%) had obtained a disability status.

**Sample Characteristics**

The participant's A1C levels were tested at pretest and again at 3-week follow-up. Their individual scores are presented in Table 3.

Table 3

*Change in A1C Levels from Pretest to 3-Week Follow-up*

| Participant | A1C #1 | A1C #2 | Change |
|---|---|---|---|
| Participant A | 6.9 | 6.5 | -.4 |
| Participant B | 5.8 | 5.6 | -.2 |
| Participant C | 7.3 | 6.5 | -.8 |
| Participant D | 6.7 | 6.6 | -.1 |
| Participant E | 7.9 | 7.8 | -.1 |
| Participant F | 7.2 | 7.0 | -.2 |
| Participant G | 8.3 | 7.7 | -.6 |
| Participant H | 6.1 | 6.2 | +.1 |
| Participant I | 7.0 | 6.9 | -.1 |

The A1C scores at pretest ranged from 5.8 to 8.3%, with scores at the 3-week follow-up ranging from 5.6 to 7.8%. Eight of the nine participants in the study experienced decreases in their A1C levels. These decreases ranged from .1 to .8%. One woman had a 0.1% increase in her A1C score from pretest to the 3-week follow-up.

Weight was recorded at the three time periods, pretest, posttest, and 3-week follow-up. The change in weight was tested using a repeated measures analysis of variance (ANOVA). See Table 4.

Table 4

*Weight at the Three Time Periods*

| Participant # | Weight #1 | Weight #2 | Weight #3 | Overall Change | F Ratio | Sig |
|---|---|---|---|---|---|---|
| Participant A | 165 | 167 | 165 | 0 | .68 | .536 |
| Participant B | 143 | 145 | 146 | +3 | | |
| Participant C | 213 | 215 | 212 | -1 | | |
| Participant D | 150 | 148 | 145 | -5 | | |
| Participant E | 232 | 230 | 230 | -2 | | |
| Participant F | 226 | 230 | 230 | +4 | | |
| Participant G | 336 | 329 | 315 | -21 | | |
| Participant H | 256 | 251 | 255 | -1 | | |
| Participant I | 213 | 210 | 209 | -4 | | |

The weight at pretest ranged from 143 to 336 pounds, with the weights at posttest ranging from 145 to 329 pounds. The weight at the 3-week follow-up ranged from 145 to 315 pounds. Weight changes from pretest to the 3-week follow-up ranged from a loss of 21 pounds to a gain of 4 pounds. Two participants gained weight, while seven participants lost weight. The results of the repeated measures ANOVA , $F(2, 7) = 0.68$, p

= 0.536 indicates that although the participant's weight varied across the three time periods, the changes were not statistically significant.

The participants were asked to record their physical activity at pretest, posttest, and at 3-week follow-up. Their self-reports were summarized using descriptive statistics for inclusion in Table 5.

Table 5

*Self-report of Physical Activity at Pretest, Posttest, and 3-week Follow-up*

| | Pretest | | Posttest | | 3-Week Follow-up | |
|---|---|---|---|---|---|---|
| Physical Activity | Mean | SD | Mean | SD | Mean | SD |
| Sleep, Rest | 350.00 | 82.16 | 391.67 | 86.96 | 368.33 | 59.58 |
| Sitting, Watching TV | 220.00 | 134.16 | 268.33 | 126.05 | 286.67 | 122.65 |
| Working at desk | 186.67 | 94.31 | 235.00 | 141.11 | 233.33 | 144.48 |
| Cooking, Standing | 171.67 | 82.54 | 151.89 | 90.96 | 145.00 | 100.34 |
| Light cleaning | 148.33 | 114.35 | 181.67 | 112.86 | 155.00 | 77.22 |
| Bicycling | 13.33 | 20.46 | 56.67 | 55.51 | 38.33 | 42.50 |
| Gardening | 55.00 | 44.37 | 45.00 | 48.61 | 35.00 | 36.74 |
| Aerobics | 46.67 | 37.83 | 40.00 | 49.18 | 53.33 | 95.49 |
| Running, Racing | 6.67 | 15.21 | 30.00 | 68.33 | 41.67 | 60.83 |

The mean scores for six of the activities increased from pretest to posttest. At the 3-week follow-up, the mean scores for three of the activities (sitting, watching TV; aerobics; and running, racing) increased from posttest to the 3-week follow-up. The time spent in the remaining physical activities showed decreases from the posttest to the 3-week follow-up.

Descriptive statistics were obtained on the participant's self-report on the eight measures on appetite scale. Table 6 presents results of this analysis.

Table 6

*Self-Report of Appetite at Pretest, Posttest, and 3-week Follow-up*

| | Pretest | | Posttest | | 3-week Follow-up | |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD |
| Hungry | 37.19 | 22.45 | 35.63 | 18.74 | 24.22 | 13.13 |
| Satisfied | 37.67 | 20.12 | 34.74 | 18.65 | 39.19 | 20.07 |
| Full | 37.26 | 28.48 | 27.70 | 19.94 | 37.85 | 26.60 |
| Eat | 46.96 | 15.30 | 44.37 | 11.96 | 42.07 | 13.52 |
| Sweet | 70.11 | 19.13 | 71.19 | 18.54 | 71.96 | 17.60 |
| Salty | 76.33 | 18.83 | 79.26 | 20.19 | 79.26 | 20.19 |
| Savory | 82.89 | 19.83 | 86.07 | 18.91 | 81.37 | 20.68 |
| Fatty | 78.59 | 17.50 | 80.07 | 20.45 | 79.37 | 23.78 |

Note: Anchor points for each of the scale items are included in Appendix A.

The mean scores on the self-reported measures on appetite changed in the appropriate direction. For example, the participants had higher scores for the hungry item at pretest than at posttest and the scores further decreased at the 3-week follow-up. This finding indicated that participants tended to feel less hungry over the course of the study. The item, how full do you feel, the participants' self-reports decreased from the pretest to the posttest and then increased at the 3-week follow-up, indicating that the participants were less full at posttest and felt fuller at the 3-week follow-up.

## Research Hypotheses

The study contained six research hypotheses. They are presented as follows:

$H_1$: Participation in cognitive-behavioral therapy for insomnia will improve perceived sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI) among post-menopausal females with type 2 diabetes.

$H_2$: Participation in cognitive-behavioral therapy for insomnia will improve perceived insomnia severity as measured by the Insomnia Severity Index.

$H_3$: Participation in cognitive-behavioral therapy will improve sleep quantity as measured by the Actiwatch 2.

$H_4$: A relationship exists between change in perceived sleep quality as measured by the PSQI and diabetes metabolic control as measured by A1C among post-menopausal females with type 2 diabetes.

$H_5$: A relationship exists between change is sleep quality as measured by the PSQI and activity as measured by the Physical Activity Scale among post-menopausal females with type 2 diabetes.

$H_6$: A relationship exists between change in perceived sleep quality as measured by the PSQI and appetite as measured by the Visual Analog Scale among post-menopausal females with type 2 diabetes.

**Analysis of Data**

The analysis of data is presented according to each research hypothesis:

$H_1$: Participants in cognitive-behavioral therapy for insomnia will improve perceived sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI) among post-menopausal females with type 2 diabetes.

The following components of the PSQI were individually scored to determine the global score:

- Subjective sleep quality
- Sleep latency
- Sleep duration
- Habitual sleep efficiency
- Sleep disturbances
- Use of sleeping medications
- Daytime dysfunction

The global scores for the PSQI at the three data points were used in a repeated measures ANOVA. Global scores > 5 represents poor sleepers and < 5 represents good sleepers. The results of this analysis are presented in Table 7.

Table 7

*PSQI at Pretest, Posttest, and 3-week Follow-up*

| Time | N | Mean | SD | DF | F Ratio | Sig |
|---|---|---|---|---|---|---|
| Pretest | 9 | 2.89 | 1.27 | 2, 16 | 3.21 | .067 |
| Posttest | 9 | 2.33 | 1.12 | | | |
| 3-Week Follow-up | 9 | 2.00 | 1.00 | | | |

The comparison of the three times for the global PSQI scores was not statistically significant, F (2, 16) = 3.21, p = 0.067. However, when the three time periods were compared, the scores decreased from pretest (m = 2.89, sd = 1.27) to posttest (m = 2.33, sd = 1.12), and continued to decrease to the 3-week follow-up (m = 2.00, p = 1.00). A graph of the change in sleep quality across the three time periods is presented in Figure 6.

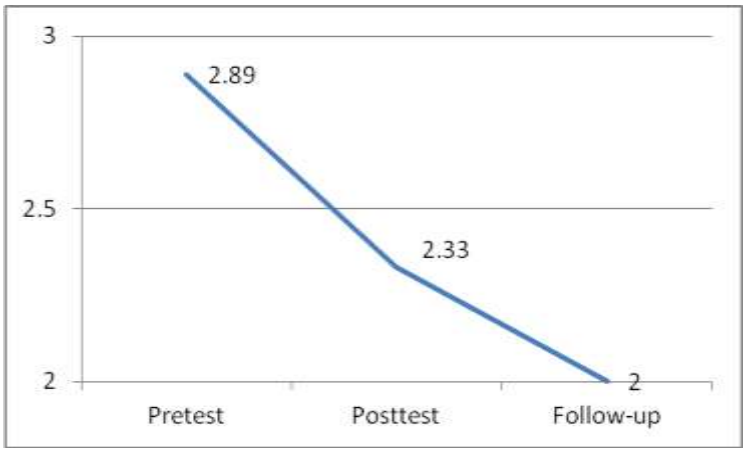



*Figure 6* - Change in sleep quality over three time periods

$H_{2:}$ Participation in cognitive-behavioral therapy for insomnia will improve perceived insomnia severity as measured by the Insomnia Severity Index.

A repeated measures analysis of variance (ANOVA) was used to determine the extent to which changes in insomnia occurred as a result of participating in the study. The participants completed the Insomnia Severity Index (ISI) three times, at pretest, posttest, and 3-week follow-up. The total scores for the ISI were a composite score of the components that were measured:

- Difficulty falling asleep
- Difficulty staying asleep
- Problem waking up too early
- Satisfied/dissatisfied with sleep pattern
- Interfere with daily functioning
- Quality of life impairment
- Worried/distressed about current sleep.

The total scores on the ISI could range from 0 to 28, with higher scores indicating greater severity of insomnia. The guidelines for determining the severity of insomnia are:

- 0-7 = No clinical significant insomnia
- 8-14 = Subthreshold insomnia
- 15-21 = Clinical insomnia (moderate severity)
- 22-28 = Clinical insomnia (severe).

Table 8 presents results of the repeated measures ANOVA.

Table 8

*Insomnia Severity – Pre, Post, and 3 Week Follow-up* (N = 9)

| Time | Mean | SD | DF | F Ratio | Sig |
|---|---|---|---|---|---|
| Pretest | 18.44 | 4.50 | 2, 16 | 15.69 | .003 |
| Posttest | 9.78 | 4.63 | | | |
| 3-Week Follow-up | 6.89 | 4.22 | | | |

The results of the comparison of the mean scores for these three measures of insomnia severity were statistically significant, F (2, 7) = 15.69, p = 0.003. The large effect size provided support that in addition to statistical significance, the change in insomnia severity over the three time periods also had practical significance. The mean scores for insomnia severity was 18.44 (sd = 4.50) at pretest with a decrease to 9.78 (sd = 4.63) at posttest. At the three week follow-up, the mean score had decreased further to 6.89 (sd = 4.23). Figure 7 presents a graphic representation of the change in insomnia severity scores over the three time periods.

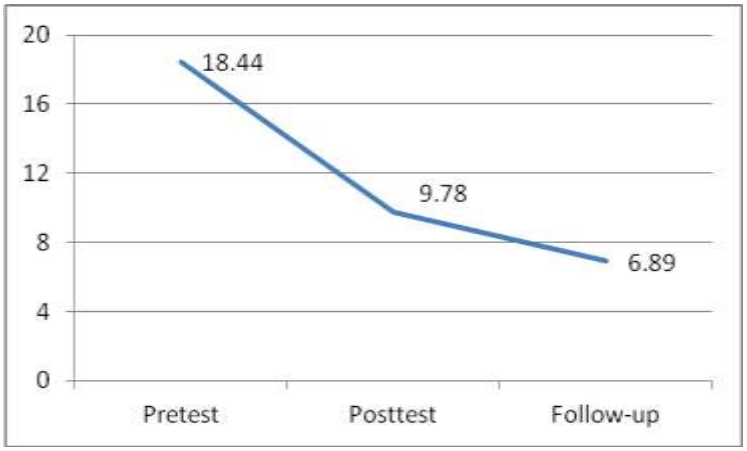



*Figure 7* – Comparison of Insomnia Severity over Three Time Periods

$H_3$: Participation in cognitive-behavioral therapy for insomnia will improve sleep quantity as measured by the Actiwatch 2.

Data from the Actiwatch 2 measuring sleep quantity (in minutes) were obtained for each week of the study and again at the 3-week follow-up. To determine the change in sleep quantity over the time of the study was tested using a repeated measures analysis of variance. Table 9 presents results of this analysis.

Table 9

*Total Sleep Time (In Minutes) Over Duration of Study*

| Week | Number | Mean | SD | DF | F Ratio | Sig |
|---|---|---|---|---|---|---|
| Week 1 | 9 | 355.60 | 88.40 | 7, 56 | 2.24 | .044 |
| Week 2 | 9 | 336.80 | 60.75 | | | |
| Week 3 | 9 | 325.07 | 59.72 | | | |
| Week 4 | 9 | 334.47 | 63.01 | | | |
| Week 5 | 9 | 320.40 | 50.18 | | | |
| Week 6 | 9 | 313.93 | 66.48 | | | |
| Week 7 | 9 | 316.47 | 56.44 | | | |
| 3-Week Follow-up | 9 | 330.13 | 51.47 | | | |

The comparison of the total sleep time for the seven weeks of the study and 3-week follow-up was statistically significant, F (7, 56) = 2.24, p = 0.044. This result indicated that the number of minutes trended downward across the time of the study. At week 1, the mean number of minutes of sleep was 355.60 (sd = 88.40). At week 7, the mean number of minutes of sleep had decreased to 316.47 (sd = 56.44). At the three-week follow-up, the mean number of minutes of sleep had increased to 330.13 (sd = 51.47). Figure 8 illustrates the change in the number of minutes of sleep over the 11 weeks of the study.

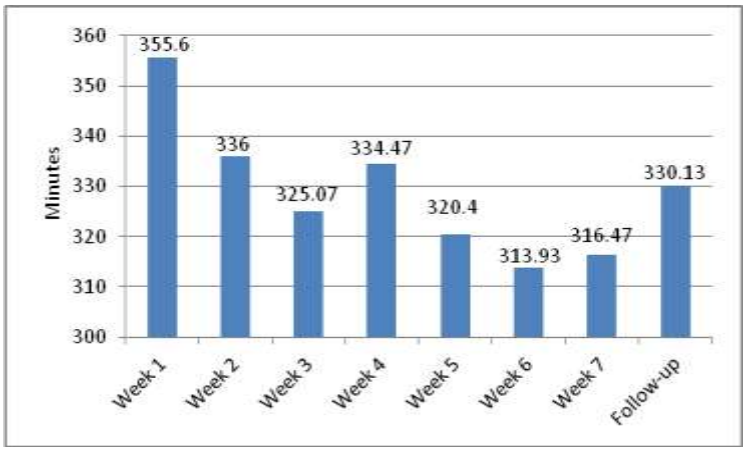



*Figure 8* - Change in quantity of sleep over term of study

$H_4$: A relationship exists between change in perceived sleep quality as measured by the PSQI and diabetes metabolic control as measured by A1C among post-menopausal females with type 2 diabetes.

Pearson product moment correlations were used to determine the strength and direction of the relationship between the change in perceived sleep quality from pretest to the three-week follow-up and diabetes metabolic control as measured by A1C from pretest to posttest. The results of this analysis produced an r-value of -0.29 ($p = 0.446$), which was not statistically significant. The negative correlation suggested that higher change scores for sleep quality were associated with lower levels of A1C.

$H_5$: A relationship exists between change in perceived sleep quality as measured by the PSQI and activity as measured by the Physical Activity Scale among post-menopausal females with type 2 diabetes.

Pearson product moment correlations were used to examine the strength and direction of the relationships between the changes in perceived sleep quality and the measures of physical activity at pretest, posttest, and 3-week follow-up. Table 10 presents results of this analysis.

Table 10

*Change in Sleep Quality and Physical Activity at Pretest, Posttest, and 3-Week Follow-up*

| | Sleep Quality Index | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Pretest | | | Posttest | | | 3-week Follow-up | | |
| Physical Activity Scale | n | r | p | n | r | p | n | r | p |
| Sleep, Rest | 9 | .44 | .235 | 9 | -.08 | .842 | 9 | -.38 | .309 |
| Sitting, Watching TV | 9 | .00 | 1.000 | 9 | -.29 | .444 | 9 | -.29 | .450 |
| Working at desk | 9 | -.07 | .854 | 9 | .22 | .565 | 9 | .52 | .148 |
| Cooking, Standing | 9 | .24 | .535 | 9 | -.26 | .502 | 9 | .07 | .866 |
| Light cleaning | 9 | .02 | .958 | 9 | -.17 | .663 | 9 | .15 | .702 |
| Bicycling | 9 | -.58 | .105 | 9 | -.07 | .849 | 9 | -.46 | .216 |
| Gardening | 9 | -.14 | .720 | 9 | -.06 | .889 | 9 | -.46 | .216 |
| Aerobics | 9 | -.45 | .227 | 9 | .45 | .225 | 9 | -.69 | .040 |
| Running, Racing | 9 | -.59 | .094 | 9 | .50 | .166 | 9 | .17 | .672 |

One statistically significant correlation was obtained between change in sleep quality and participation in aerobics at 3-week follow-up ($r = -0.69$, $p = 0.040$). This result indicated that as time spent in aerobics exercise increased, the change in sleep quality (lower scores indicate improved sleep quality) showed improvement. The remaining correlations were not statistically significant, although some suggested moderate to strong relationships. Correlations between .40 and .60 are considered to be moderate to strong.

$H_6$: A relationship exists between change in perceived sleep quality as measured by the PSQI and the appetite as measured by the Visual Analog Scale among post-menopausal females with type 2 diabetes.

The data on the Visual Analog Scale were analyzed for each item on the scale. Data were collected for three days at each data collection point (pretest, posttest, and 3-

week follow-up). The mean scores for the three collection days at each data point were used to analyze the relationship of appetite and sleep quality (PSQI) global score using Pearson product moment correlations. Table 11 presents results of this analysis.

Table 11

*Change in Sleep Quality and Appetite at Pretest, Posttest, and 3-week Follow-up*

| | Sleep Quality Index | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Pretest | | | Posttest | | | 3-week Follow-up | | |
| Appetite Scale | n | r | p | n | r | p | n | r | p |
| Hungry | 9 | .21 | .592 | 9 | .52 | .148 | 9 | -.30 | .435 |
| Satisfied | 9 | -.23 | .554 | 9 | .02 | .951 | 9 | .51 | .158 |
| Full | 9 | -.21 | .589 | 9 | -.38 | .324 | 9 | .01 | .991 |
| Eat | 9 | .14 | .720 | 9 | -.23 | .555 | 9 | -.11 | .782 |
| Sweet | 9 | -.34 | .376 | 9 | -.83 | .005 | 9 | -.29 | .445 |
| Salty | 9 | .10 | .794 | 9 | -.07 | .862 | 9 | -.06 | .879 |
| Savory | 9 | .07 | .863 | 9 | -.22 | .563 | 9 | -.20 | .603 |
| Fatty | 9 | -.30 | .433 | 9 | -.14 | .713 | 9 | -.23 | .545 |

Note: Anchor points for each of the scale items are included in Appendix A.

One statistically significant correlation in a negative direction between appetite for sweet food and sleep quality (global PSQI score) was obtained at posttest ($r = -0.83$, $p = 0.005$). A negative relationship was reported as a lower quality of sleep score indicated better sleep quality and a higher score for appetite for sweets indicated a lesser appetite for sweets. The remainder of the correlations were not statistically significant.

**Ancillary Findings**

Pearson product moment correlations were used to determine if there was a relationship between the insomnia severity index from pretest to posttest and at the 3-

week follow-up and the A1C levels at pretest and posttest. The results of this analysis are presented in Table 12.

Table 12

*Severity of Insomnia and A1C*

| | Insomnia Severity | | | | | |
|---|---|---|---|---|---|---|
| | Pretest | | | 3-week Follow-up | | |
| A1C | n | r | p | n | r | p |
| Pretest | 9 | -.16 | .678 | | | |
| 3-week Follow-up | | | | 9 | .31 | .412 |

Inverse relationships were found at pretest between the insomnia severity and the AIC (r = -.16, p =.678). The inverse relationship suggested that higher A1C levels were associated with lower scores on the insomnia severity index. In contrast, at the 3-week follow-up, a positive relationship was obtained between A1C and the insomnia severity index (r =.31, p = .412). This moderate relationship indicated that lower scores on the A1C were associated with lower scores on the insomnia severity index. Neither relationship was statistically significant.

## Summary

The results of the data analyses that were used to describe the sample and test the hypotheses that were established for the study have been presented in this chapter. Conclusions and recommendations based on these findings can be found in Chapter 5.

# CHAPTER 5

# DISCUSSION

## Introduction

In this chapter the results of the study are discussed beginning with the sample description. Additional findings, conclusions, limitations of the study, suggested study design changes, and implications for nursing practice are then presented. The chapter concludes with recommendations for future research.

## Summary of Research Findings

The purpose of this feasibility study was first to determine the impact of a seven week cognitive behavioral therapy intervention on the sleep behaviors of women aged 50-75 years of age with type 2 diabetes. The outcomes of this intervention were then analyzed for relationships of change in sleep quality on metabolic control, appetite and physical activity.

Although the target sample size was 24 women aged 50-75 years of age, 18 women consented to be in the study and nine women aged 56-69 years of age completed the intervention and the three-week follow-up. Of the nine women who completed the study, most were married, educated and had insurance. Each of the women reported insomnia for at least six months and type 2 diabetes for a minimum of one year.

Following extensive recruitment efforts (newspaper and radio advertisements and visits with diabetes educators, primary providers, diabetes support groups, and community diabetes programs) over a 14-month period, the decision was made to close the study to new participants.

A variety of reasons could account for the limited number of study participants. The sample criteria limited participants to women aged 50-75 years of age who had

insomnia for a minimum of six months and type 2 diabetes for a minimum of one year. Advertising materials specifically stated that participants needed to be female. Yet, men responded to the newspaper and radio advertisements requesting to be in the study. At recruitment activities, potential participants reported that they weren't interested in committing to a study that lasted 11 weeks. Retired women often compensate for poor sleep by going back to bed in the morning and taking naps. Since they do not need to get up in the morning and stay awake as they would when working, the need to experience a quality 7-8 hours of sleep is not as important to them. In addition, the relationship of poor quality and quantity of sleep to diabetes and general good health is not well established in our society. Doctors often do not assess sleeping behaviors of their patients, and therefore, do not provide recommendations regarding sleeping habits. In addition, fatigue is the symptom of insomnia. Senior citizens often believe that fatigue is associated with aging rather than a symptom of poor quality sleep. Therefore, the need to decrease the severity or eliminate insomnia is often not perceived as a major concern.

The women, as a group, reported improved sleep following the seven week intervention. Although not statistically significant, the Pittsburgh Sleep Quality Index (PSQI) results indicated that the women experienced improved sleep at both the posttest and 3-week follow-up data collection points. The PSQI reports overall quality of sleep as related to good and poor sleepers. Those who report a global score >5 are considered poor sleepers. The Insomnia Severity Index (ISI) results did indicate that the severity of insomnia began at a clinical level of moderate insomnia, decreased to a sub threshold level at the posttest and further decreased to no insomnia at the conclusion of the study. The statistical results were significant with a sample size of 9. Based on the results of this analysis, the null hypothesis of no change in insomnia severity over the three time

periods is rejected. This supports findings in the literature that reports that CBTI is an effective treatment for insomnia (Morin et al., 2006).

The women in the study wore Actiwatch 2 devices to objectively record their sleep time. The amount of sleep in minutes was recorded weekly during the study and at 3-week follow-up. A repeated measures analysis of variance was used to determine if the sleep times varied across the time of the study. The results of this analysis were statistically significant, F (7, 56) = 2.24, p = .044. Figure 9 presents the sleep times across each week of the study.

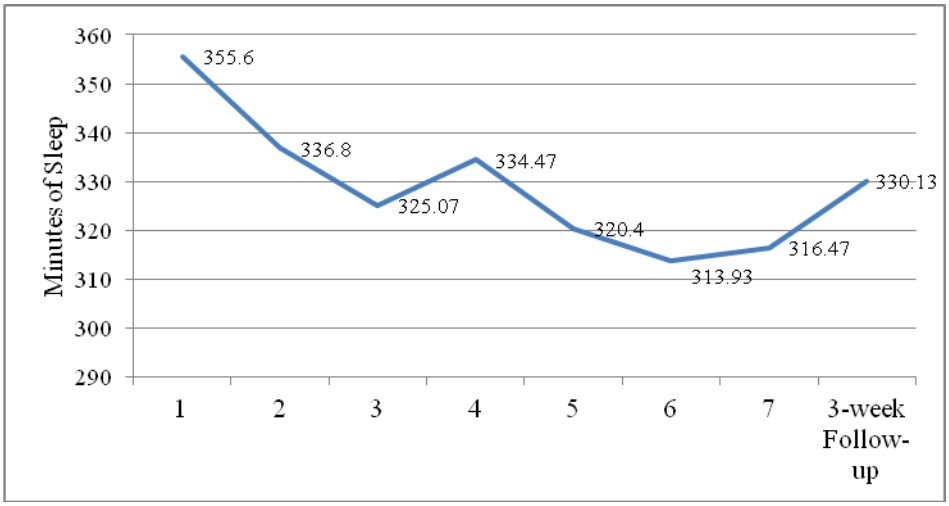



*Figure 9* - Minutes of Sleep across the Study

The mean sleep duration at the first week of the study was 355.60 (sd = 88.40) minutes (5.93 hours). At the end of the 3-week follow-up, the mean sleep duration was 330.13 (sd = 51.47) minutes (5.50 hours). Although the mean number of minutes of sleep duration had decreased from the beginning of the study to the follow-up, the change from the seventh week to the three-week follow-up showed an increase of 14 minutes. While it appears that the sleep duration decreased significantly, sleep restriction may have been

the reason for the decrease in sleep quantity. The use of sleep restriction is designed to improve sleep efficiency by decreasing total time in bed. After baseline data are collected during the first week of the study, the average total sleep time is used to determine the total time in bed. The principle is that the person will be very tired at bedtime and sleep consolidation will occur. Continuation of a regular bedtime and wake time helps the person develop a consistent circadian rhythm. An increase of 15 minutes in total sleep time is recommended when the sleep efficiency is 90% or above. If the sleep efficiency falls below 85%, the recommendation is to decrease the total time in bed by 15 minutes. Although the recommendation to determine the specific time in bed is to start with the time that the person wishes to wake up and get out of bed and then count backwards to determine the bedtime, participants in this study found that they were not able to stay awake till the recommended bedtime. Therefore, the actual recommended bedtime and wake up time were determined by starting with the bedtime and then counting forward. Participants in cognitive-behavioral therapy are advised that their sleep may worsen before it improves as a result of sleep restriction. Establishing a routine bedtime and awakening has been found to take a minimum of three weeks into the intervention (Morin & Espie, 2004). Cognitive behavioral studies typically include a 6 month and one year follow-up as over time the sleep duration has been reported to increase (Morin, et al.,2006). A three week follow-up was included in this study based on expected change in the hemoglobin A1C test which is reported to occur at ten to twelve week intervals.

Pearson product moment correlation was used to determine the strength and direction of the relationship between change scores for perceived sleep quality and diabetes metabolic control as measured by A1C. A correlation of -0.29 ($p = .446$) was obtained indicating that higher A1C levels were associated with lower change scores for

perceived sleep quality. In addition, the A1C levels at pretest ranged from 5.8 to 8.3, with levels at the 3-week follow-up ranging from 5.6 to 7.8. Eight of the nine participants, including the participant that began the study with an A1C level of 5.8, experienced decreases in their A1C levels. Three of the nine participants may have had further lowering of their A1C levels as they had reductions in the dosage of their diabetes medications. From a clinical perspective, this finding is promising.

Pearson product moment correlations were used to test the direction and strength of the relationship between perceived sleep quality and activity as measured by the Physical Activity Scale at pretest, posttest, and 3-week follow-up. One statistically significant correlation was obtained between participation in the category aerobics and perceived sleep quality at the 3-week follow-up, $r = -.69$, $p = .040$. Only the category of running,racing was a more rigorous activity reported on the scale. The mean number of minutes spent in aerobic activity at pretest was 6.67. This increased to 30 minutes at the posttest and then an increase to 41.67 minutes at the three-week follow-up. Although not statistically significant, the mean number of minutes in six of the other seven categories increased from pretest to three-week follow-up. Although Chasens, Sereika, Weaver, & Umlauf (2007) found that sleepiness was associated with decreased exercise, fatigue is the symptom associated with insomnia. Women in the age group studied, tended not to be less physically active than younger adults. No studies relating amount of exercise to severity of insomnia were found in the literature.

The correlations between the PSQI and the eight measures of appetite provided evidence of one statistically significant direct correlation between appetite for sweet food and sleep quality at posttest ($r = .83$, $p = .005$). Since carbohydrate foods increase blood sugar, increased appetite for sweets is of significant concern for people with type 2

diabetes. Other correlations were stronger than expected, but were not statistically significant because of the small sample size. Figure 12 presents the appetite measures at pretest, posttest, and 3-week follow-up.

The first four appetite measures reported participants' hunger, satisfaction, fullness and amount they could eat before breakfast. The first of the eight measures on the appetite visual analog scale was "How hungry do you feel?" Higher scores indicated that the participant was "more hungry." The participants had higher scores for this item at pretest than at posttest. The scores further decreased at the 3-week follow-up. This finding indicated that participants tended to feel less hungry over the course of the study. "How satisfied do you feel?" was the next measure to be evaluated. Higher scores indicated that the participant was more satisfied. Although the posttest scores were lower than the pretest scores, the three-week follow-up scores increased, indicating participants were more satisfied at the conclusion of the study. The third item on the visual analog scale was "How full do you feel?" Higher scores indicated that the participant was closer to being totally full. The scores at pretest were lower than posttest, but then higher at the 3-week follow-up. The indication was that the participants were closer to feeling full at the conclusion of the study. "How much do you think you can eat?" was item number four on the visual analog scale. Lower scores indicated that the participant was able to eat less. The scores lowered from pretest to posttest and then again at the 3-week follow-up. The participants reported feeling that they could eat less at the conclusion of the study than at the beginning. These findings are of clinical value. The quantity of food intake for women with type 2 diabetes is reported to often be greater than the recommended amount, resulting in increased blood sugar levels and weight gain. A decreased appetite is helpful in reducing food intake.

The next four appetite measures relate to appetite for types of food (sweet, salty, savory and fatty). Item five on the visual analog scale was "Would you like to eat something sweet?" Higher scores indicate that the participant did not want to eat something sweet. The participants reported that they were less likely to eat something sweet at the posttest than at the pretest. At the 3-week follow-up the participants were less likely to eat something sweet than at the posttest. "Would you like to eat something salty?" was item number six. The higher scores indicated that the participant was less likely to eat something salty. The results indicated that the participants were less likely to eat something salty at the posttest than at the pretest. Results at the 3-week follow-up were the same as at the posttest showing no change during this 3-week period. Since most people with diabetes also have hypertension, this relationship is important clinically. Item seven on the analog scale was "Would you like to eat something savoury?". The higher scores indicated that the participant was less likely to eat something spicy. The participants reported that they were more likely to eat something savoury at the posttest than at the pretest. At the 3-week follow-up, they were less likely to eat something savoury than at the pretest. "Would you like to eat something fatty?" was item number eight. The higher scores indicated that the participant was less likely to eat something fatty. The scores were higher at the posttest than at the pretest. Lower scores were reported at the 3-week follow-up than at the pretest. The scores indicate that the participants were less likely to eat something fatty at the 3-week follow-up than at the pretest. See Figure 10 for a graphical representation of the three time periods.

Earlier research by Spiegel, Tasali, Penev, & Van Cauter (2004) reported that sleep curtailment in healthy young males was associated with increased hunger, especially for sweets. Although this study looked at sleep quality in relationship to

appetite markers, hunger for sweets was found to have a statistically significant correlation. Further research in this area is recommended as this study found a relationship between sleep quality, rather than sleep quantity, and an appetite for sweets.

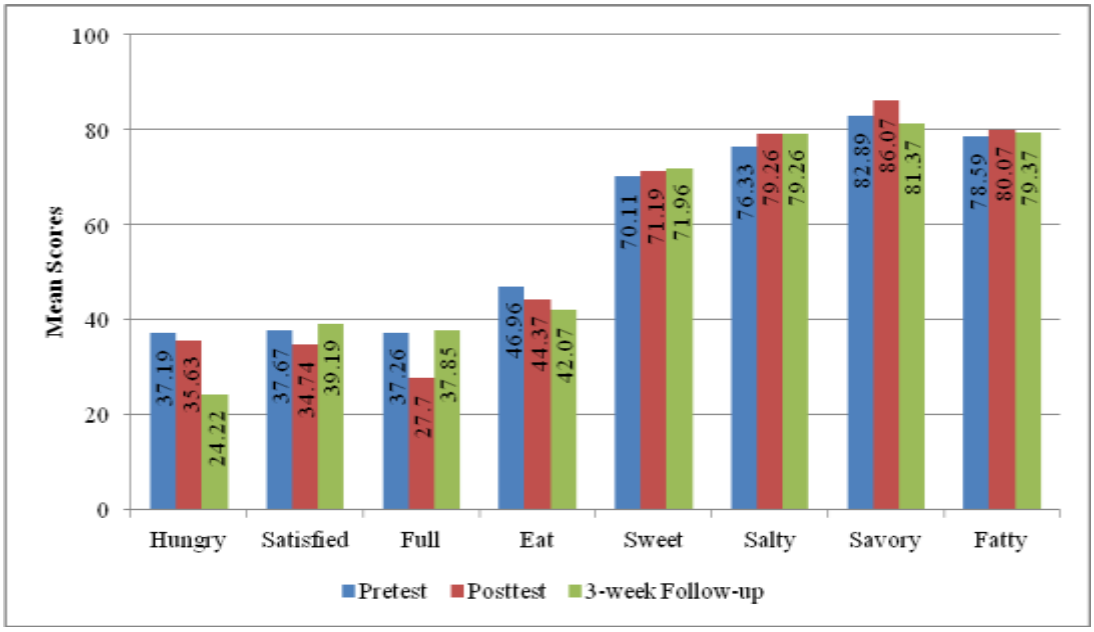



*Figure 10*- Appetite Measures at Pretest, Posttest, and 3-Week Follow-up

**Additional Findings**

The relationship between the A1C levels and insomnia severity was tested at pretest and 3-week follow-up. The relationship at pretest was low ($r = -.16$, $p = .678$), but increased substantially at posttest ($r = .31$, $p = .412$). At pretest, the negative relationship indicated that higher insomnia severity was associated with lower A1C levels. In contrast, at the 3-week follow-up, the relationship became positive, indicating that lower A1C levels were related to lower insomnia severity. As the sample was quite small, reasons for the low negative relationship at pretest were unclear. The desired outcome was that lower insomnia severity would be related to lower A1C levels, providing beginning evidence that improved insomnia severity was associated with improved metabolic control as

evidenced by lower A1C levels. These results support the need for additional research with a larger sample.

## Conclusions

Although not statistically significant, an improvement in self-reported overall sleep quality was found at the completion of the cognitive behavioral therapy intervention. An improvement in overall sleep quality with a small sample suggests that further research with a larger sample size is needed to better understand this finding. The PSQI global scale scores indicate overall sleep quality. Thus, the results of the PSQI are not specific to quality of sleep for those with insomnia. Therefore, perceived insomnia severity was also measured.

Cognitive-behavioral therapy for insomnia was found to improve self-reported insomnia severity. Using ANOVA, the comparison of the mean scores for the three measures of insomnia severity were statistically significant, $F(2,7) = 15.69$, $p = .003$. The insomnia severity at the pretest was reported to be moderate severity clinical insomnia. At the posttest the participants had moved to sub threshold insomnia. At the conclusion of the study, the participants reported, as a group, to have nonclinical insomnia. This supports a large body of research indicating that cognitive behavioral therapy for insomnia is an effective method of treatment for insomnia (Epsie et al., 2008) and is beginning evidence that CBTI has potential for treating insomnia in aging women with type 2 diabetes.

Although sleep quantity, as reported by the Actiwatch 2, did decrease during the study, the total sleep time began to improve by week seven. This was an expected result with the use of sleep restriction. The behavior changes needed to develop healthy sleep habits included learning to sleep without a television playing and not watching television

during the night, going to bed at a regular time, avoiding alcohol and caffeine from dinner to bedtime, and awakening at a regular time are major behavior changes. Some participants had support from family members, and in some situations, family members were barriers to behavior change. Some of the participants had experienced insomnia with poor sleep habits for many years. One of the participants reported frequently not sleeping more than one or two hours per night. As one participant reported. "This is a work in progress". For future studies a longer follow-up period is recommended as sleep duration following CBTI has been reported to increase over time (Epsie et al., 2008).

Each method of collecting sleep data has limitations, therefore, participants also maintained sleep diaries. The Actiwatch 2 devices did not record all changes including evening napping and morning resting in bed. The Actiwatch was more accurate at determining total sleep time from bedtime till arising in the morning as participants had difficulty knowing how long they were awake during the night. Thus, the two methods of recording sleep behaviors complemented each other.

The change in perceived sleep quality as measured by the PSQI and diabetes metabolic control as measured by A1C among aging females with type 2 diabetes was analyzed using Pearson product moment correlations. A negative correlation indicated that higher change scores for sleep quality were associated with lower levels of A1C. Although the results were not statistically significant, eight of the nine participants experienced a decrease in A1C levels. Three of these participants also experienced reductions in their diabetes medication dosages. Since the ISI scale is for measuring insomnia, this tool was also used. A moderate relationship between insomnia severity and A1C levels at the 3-week follow-up were found. Thus, lower A1C levels were associated

with lower scores on the ISI. The small sample size may be responsible for not obtaining statistically significant results.

The physical activity scale was used to gather data pretest, posttest and 3-week follow-up. The category of running/racing on the Physical Activity Scale was found to have a statistically significant correlation between change in sleep quality as reported by the PSQI at the three-week follow-up ($r = -.69$, $p = .040$). The number of minutes in seven of the nine activity categories did increase from pretest to 3-week follow-up. The expectation was that participants would be less active with poor quality of sleep. Beginning evidence suggests that improved quality of sleep may improve physical activity, especially in the running/racing category. Further investigation with both a larger sample and over a longer period of time is recommended.

Appetite was measured using the Visual Analog Scale before breakfast at each of the data collection points to determine if improved sleep quality changed appetite reported for each of the eight appetite measures. Results indicated that participants tended to feel less hungry, more satisfied, closer to feeling full, could eat less, were less likely to eat something sweet, just as likely to eat something salty, less likely to eat something savory and less likely to eat something fatty at the completion of the study. The one measure that reported statistical significance at the three-week follow-up was appetite for something sweet. As metabolic control of diabetes is strongly impacted by food intake, these results provide evidence that further research in this area is needed with a larger sample size. The finding that improved quality of sleep is positively associated with a decreased appetite for sweets is of particular importance clinically as carbohydrates increase blood sugar levels. Thus, this statistically significant relationship is also clinically significant.

Weight scores were also obtained at the three measurement points to provide additional information regarding nutritional status. The participant's weights remained relatively stable over the 11 weeks of the study. Seven participants lost weight during the study and two gained weight. One participant lost 21 pounds during the study unintentionally, while one participant gained four pounds and another gained three pounds. The results of repeated measures ANOVA were not statistically significant, providing additional evidence of the stability of weight across the study.

**Limitations**

Limitations of this study include a small sample size, no control group and a short follow-up time period. Although a target sample size of 24 women 50 to 75 years of age was needed for statistical power, nine participants completed the intervention and all data measurement periods. Hypotheses #1, 2, 5 and 6 used self-reported data. The budget for this study limited the use of additional data collection methods such as a polysomnogram for the measurement of sleep quantity and/or continuous glucose testing to further evaluate changes in blood sugar during each 24 hour day of the study. As the sample size was small, increased sample size may result in improved statistical results. Previous studies, using cognitive behavioral therapy to improve sleep behaviors of those with insomnia, found improved quality and quantity of sleep at the 6 month and 1 year follow-up data collection points. Since women with A1C levels of 9% or less were included in the study, those with higher A1C levels were excluded from the study. Research has reported those with poor sleep tend to have higher A1C levels (Vigg, Vigg, & Vigg, 2003). Lowering an A1C level is easier when the A1C is higher at baseline. Lowering and A1C that is 5.8 at baseline (participant #2) is more difficult. In addition, the sample

was limited to women aged 50 to 75 years of age who had both type 2 diabetes and insomnia. Therefore this study cannot be generalized to the overall population.

**Suggested Changes in the Feasibility Study**

Results of this study indicate that further research with a larger sample is recommended. Changes in recruitment and intervention sessions, in addition to including a six month and a one year follow-up data collection times are suggested. Although extensive recruitment was conducted, a change in the wording (Sleep Study to Insomnia Study) on the study flyer and newspaper advertisements may have been helpful. Including the tool on motivation for change questionnaire to the orientation session rather than the first intervention session may be helpful in decreasing the drop-out rate. Obtaining sleep data using a polysomnogram as part of the orientation would confirm that participants did not have obstructive sleep apnea or another undiagnosed sleep disorder. In terms of the intervention, the session on relaxation may be more beneficial earlier in the intervention as many of the participants reported the need to relax. Inviting participant partners (co-sleepers) to one of the sessions might improve partner support. Clinically the order of sessions can be individualized when providing CBTI individually. This may be a consideration for future research. Participants reported feeling better at the end of the intervention. Including both a depression tool and a fatigue questionnaire may provide insight into this participant response. In addition, including home polysomnography would provide information regarding the impact of sleep states on reported sleep quality. Adding the six month and one year follow-up sessions would provide longer term results. Although there are some reported differences in sleep behaviors between men and women, it is suggested that the sample be expanded to include both sexes that have insomnia and type 2 diabetes. It is also suggested that in

future research the sample be expanded to include women with diabetes at younger ages. Although pre and peri-menopausal women have sleep issues associated with their physical life changes, they often are more stimulated to improve sleep behaviors. In addition, once a person lives with poor sleep for an extended period of time, changing sleep behaviors becomes more difficult.

## Implications for Nursing Practice

Nurses are involved in the care of people with diabetes in many settings. The need to assess both the quality and quantity of sleep of people with diabetes is important regardless of the setting. This study provides additional evidence that perceived sleep quality has a relationship to diabetes metabolic control. Therefore nurses need to be educated to assess sleep behaviors of people with diabetes and refer their clients to sleep specialists as appropriate. Certified nurse diabetes educators have a special role in this area. With training in sleep behaviors, especially cognitive behavioral therapy for insomnia, certified diabetes educators could provide both insomnia and diabetes self-management education for people experiencing both chronic diseases (Roth, 2009).

## Recommendations for Further Research

This study suggests that there is a relationship between perceived improved sleep quality and improved diabetes metabolic control. A study with a larger sample size and also 6-month and 1-year follow-up times is recommended to obtain statistical significance. Additional studies are recommended to include both men and women of differing ages as this study was limited to aging females. Another factor to be studied is the effect of the duration of both diabetes and insomnia on the intervention outcomes. Lastly, research that combines both CBTI and diabetes counseling is recommended as

this combined treatment might be expected to have a greater impact on metabolic control and insomnia (Roth, 2009).

**APPENDIX A**

**Type 2 Diabetes and Insomnia: Impact on Metabolic Control**
**Study Manual**

*TYPE 2 DIABETES AND INSOMNIA:*

*IMPACT ON METABOLIC CONTROL*

*STUDY MANUAL*

Table of Contents

# Sleep Study

Do you have trouble getting to sleep
and staying asleep?

Are you a woman aged 60 to 70 years of age?

Do you have type 2 diabetes?

Consider enrolling in an 11 week study.
*Possible benefits are*:

- You sleep longer
- You sleep through the night.

If you are interested in learning more about the study:

Call: Cheryl Tannas at:
**(313) 530-9895.**

334 Cohn Building
Wayne State University
Detroit, MI 48202

Sleep and Metabolic Control

April 2011

## Initial Screening

Individuals will be evaluated using the screening tool (Study Manual, p 22) either by phone or in person to determine eligibility to attend a study orientation session. For those meeting the initial screening criteria, additional assessment at the orientation session will determine final intervention eligibility.

## Intervention Outline/Dialog

### Orientation

Goals:

Determine if potential study participant meets the criteria of the study.

If so,

Obtain signed consent.

Collect data

Schedule intervention sessions

Presenter: Cheryl Lee Tannas

Time: 15-20 minutes

1. Introduction of the Sleep and Metabolic Control study to potential study participants. Introduction of the study author, explanation of the study, purpose risks, benefits, freedom to decline participation in the study without consequences, experimental groups and activities. Signature of the consent form.

   Dialog:

"My name is Cheryl Tannas. I am a doctoral student in the college of Nursing at Wayne State University. The purpose of this study is to determine if improved sleep behaviors are related to diabetes metabolic control. The study is part of my requirements to complete my doctoral education. I am conducting a study of women, aged 60 to 70 years of age with type 2 diabetes and disrupted sleep to learn better ways to assist women in managing their type 2 diabetes. I am a nurse who is certified as a diabetes educator and was trained in Cognitive Behavioral Therapy for Insomnia at the University of Michigan

"

> *"The known risks to participating in this study are minimal. The possibility of emotional discomfort associated with answering some of the questions does exist. The other possible risk is that of bruising or possibly infection at the site where the small sample of blood will be obtained. There are many potential benefits to participating in the study. The two major potential benefits are improved sleeping and improved diabetes control."*
>
> *"You have the freedom to decline participation in the study without consequences. Your participation is completely voluntary. Your data will be identified only by a study code number and maintained is a secure location. If you choose not to participate, you will not be penalized in any way."*
>
> *"If you want to participate in the study, you need to sign the consent form (Study Manual, p31) before we can go further with the orientation. Please keep in mind that a final decision as to your study participation*

*will be determined at the end of the orientation session. If you chose, we will go over the consent form together."*

If the potential study participant decides to sign the consent form the orientation session will continue. If the individual decides not to sign the consent form she will be thanked for her interested and wished the best of luck in the future.

Signed Consent

Time: 5-10 minutes

*"Since you have decided to sign the consent form we will go over it together before you sign. You will be given a copy for your records."*

Review of the consent form will then occur.

Screening

Time: 40 minutes

*"To further determine whether this intervention may be of benefit to you I will ask you questions about your sleeping behaviors and also about your general health. The Medical History Checklist (Study Manual, p. 25) will be completed and a sleep history will be taken using the Sleep History Guide (Study Manual, p.27)."*

Data Collection

Time: 40 minutes

*"There are a couple of survey tools (Pittsburgh Sleep Quality Index and the Insomnia Index, Study Manual pp.38&41) that you need to complete now, at the end of the study and four weeks following the end of the study. Two other forms will be used during the study to evaluate your*

*appetite (Study Manual, p. 42) and exercise activity (Study Manual, p.43). In addition I will draw blood to do an A1C test and obtain your current weight. If your A1C is more than 9, you will need to see your doctor to develop a plan to lower your blood sugar. Once your A1C is 9 or less you are eligible to participate in the study."*

Baseline Data

Time: 30 minutes

*"To prepare for the study you will need to collect some information for three days prior to session 1. This includes completing a daily sleep diary (Study Manual, p.36), checking your blood sugar before each meal and before you go to bed for the evening, wearing a device that measures your sleeping patterns and completing a form about your appetite before each meal and at bedtime. Now we will review the use of the sleep diary.(The Sleep Diary will be explained). Are you comfortable completing this form? If so, I will review the use of the blood glucose meter that you are asked to use for this study. You will also be provided with strips to test your blood sugar. Both demonstration and return demonstration of the blood glucose meter will occur. Next we will review the form to evaluate your appetite. (Each form will be explained). Before you begin our weekly meetings, will you please complete these forms for 3 consecutive days? Do you have any questions at this time? (answer questions) The only issue left is to set dates and times for our seven weekly meetings. (meetings will be scheduled)*

## *Intervention*

### *Session 1*

Presenter: Cheryl Lee Tannas

Time: 90 minutes

1. Session Goals

   Review Class Outline

   Complete Motivation to Change and review with participant.

   Complete Sleep Behavior Self-Rating Scale and review with participant

      Collect data (sleep diary, VAS, blood glucose from the blood glucose meter and actigraph results)

      Assess sleeping behavior

      Develop a sleep schedule for the participant

2. Session Content (dialog):

"*I am so glad to see you. To begin with, did you have any problems completing the sleep diary? (address any concerns) What about using the blood glucose meter or wearing the actigraph? (address any concerns) Also, do you have any questions about the VAS ? (address any concerns).*"

*"Before we begin with the information for tonight, I want to review the seven classes that are part of this study. Provide and discuss the class outline (Study Manual, p 45) designed for this study. An overview of the study content is provided on the class outline. (Stress that some of the activities are more helpful to each person than others are) You may want to refer to it in the future."*

*"While I download your blood glucose meter and your wrist actigraph I'd like you to complete two questionnaires(Motivation for Change and Sleep Behavior Self-*

*Rating Scale – Study Manual pp 48 &49). After you complete the questionnaires we will discuss your choices. (Discuss the completed questionnaires with the study participant)"*

*"Next I'd like to discuss sleep restriction with you. The purpose of restricting your sleep is to reshape your sleep so that it will meet your needs. This may be challenging for you in the beginning, but it has been found to be quite effective for many people. It is important to stabilize your sleep so that you can both increase the amount and quality of sleep that you will experience on a regular basis."*

*"To begin with let's look at the sleep diary that you have been keeping. We can determine how much sleep you are actually getting each night, when you usually go to bed and when you usually get up in the morning. We can also look at any napping that you are doing. (Look at the sleep diary with the participant. Determine what the total sleep time is for this individual). When do you want to wake in the morning? It is important to put this time into practice. To determine the time to retire we will subtract your sleep time from your rising time. For you it is recommended that you go to bed at ___ and wake up at ___. It is important that you follow this schedule seven days each week. Napping is discouraged. Next week we will determine how well this has worked for you and determine what changes to make."*

*"A couple of more issues to consider when you sleep this week are that you only go to bed when you are sleepy and that you observe the 15 minute rule. Although we have determined a time for you to go to sleep, it is important that you are sleepy when you go to bed. If you are not sleepy, then delay when you go to bed. Also, lying in bed is one of the behaviors supports sleeplessness. Therefore, if you are not able to sleep after 15 minutes, please get out of bed and do something that is relaxing. Reading is*

*an example of a relaxing activity. Watching TV and using a computer tend to keep people awake. What do you think will work for you?"*

*"Last but not least is the need to maintain this schedule for seven days each week. Behavior change is accelerated by consistency across the week. Once a good sleep habit is established it will be difficult to break. The longer that you use the techniques that you will learn during out time together, the better you will be at getting a "good night's sleep". Before you leave what questions do you have? If you have questions during the week, you can call me at _____. Next week we will meet on _____ at ____. Sleep Well!"*

*Session 2*

Presenter: Cheryl Lee Tannas

Time: 90 minutes

1. Session Goals

   Complete Sleep Environment Checklist and review results with participant

   Complete Caffeine Knowledge Quiz and review with study participant

   Obtain Data (Sleep Diary, blood sugar results from the glucose meter and actigraph results)

   Assess treatment gains and barriers with study participant

   Make adjustments in the participants sleep schedule

   Discuss Stimulus Control Therapy with participant

   Participant to set one goal associated with Stimulus Control Therapy

   Discuss stimulus control therapy and participant set appropriate goals.

2. Session Content (dialog):

   *"Hello, (participant). So how did this past week go for you? (Answer questions and review the sleep diary. Mutually agree on the new sleep schedule.*

*Praise the participant for progress and assist in problem solving for the barriers that occurred.)"*

*"Tonight/today we will discuss some of the factors that can either promote or disrupt your sleep. To begin with will you please complete the Sleep Environment Checklist and the Caffeine Knowledge Quiz(Study Manual pp51 & 53)? While you do that I will download you blood glucose meter and the actigraph. Then we will discuss the questionnaires."*

*"Now that you have finished these two questionnaires, let's talk about your answers. (Review each of the answers on the Sleep Environment Checklist. Stress that making the connection between sleep and the bed promotes sleep. The bedroom needs to only be used for sleep. Sexual activity is the only exception to this rule. Identify other barriers to sleep reported on the checklist.) Next we can review the Caffeine Quiz. Caffeine is a strong stimulant that can prevent you from sleeping. (Review that Caffeine quiz with the participant. Identify the appropriate amounts of caffeine in the items listed on the quiz.)"*

*"In addition to caffeine, alcohol has been found to disrupt sleep. Do you use a night cap in your bedtime routine? If yes: Alcohol has been found to awaken people during the night if it is ingested too close to bedtime. If you choose to consume some alcohol, dinner time is a good time to do this. Although drinking needs to be in moderation, some people find that a glass of wine with dinner helps them to relax before bedtime."*

*"Other factors that have been found to disrupt sleep are being hungry and being too full. Do you include a bedtime snack in your meal plan? If so, does it seem to be helpful? Low blood sugar can wake you up during the night. Has this*

*happened to you? If you are not able to get back to sleep do you check your blood sugar? Sometimes although you do not have symptoms of low blood sugar, it may be low and therefore preventing you from going back to sleep. Also, how many times did you say that you get up to go to the bathroom? When your blood sugar is high, how often do you need to get up to go to the bathroom?"*

*"Based on what we have discussed during our time together are there any changes in your bedroom and/or bedtime routine that you want to make? What about your caffeine and/or alcohol use? (This is the time for the participant to make a goal or more that is appropriate.)"*

*"What questions do you have for me? (Answer Questions) Do you have enough blood sugar strips for the next week? According to my schedule our meeting for next week is on ___ at _____. Is this correct? I'm looking forward to seeing you next week. If you need to reach me, don't hesitate to call.?"*

*Session 3*

Presenter: Cheryl Lee Tannas

Time: 90 minutes

1. Session Goals

   Complete the Pre-Sleep Arousal Scale and review the results with the participant

   Discuss overview of Cognitive Therapy with the participant

   Collect data (sleep diary, blood sugar results from blood glucose meter and actigraph results)

Assess treatment gains and barriers with participant

Make adjustments in the participants sleep schedule

2. Session Content (dialog)

*"It's good to see you. Now that you have been in the study for a couple of weeks, how are you sleeping? (Discuss) Is this anything like you expected? (Discuss) Let's take a look at your sleep diary to determine the goal for this coming week. (Discuss treatment goals and barriers.) Determine sleep goal"*

*"While I download your blood glucose meter and your actigraph, will you please complete the Pre-Sleep Arousal Scale (Study Manual, p54)? This week and next we will talk about Cognitive Therapy. After you complete the questionnaire we will discuss what this means and how it may be of help to you. (Download blood glucose meter and actigraph. Participant will complete the Pre=Sleep Arousal Scale)*

*"First, let's look at how you completed the Pre-Sleep Arousal Scale. Before we review each of your responses, are there any of the questions that caught your attention? (Discussion) Some of the thoughts that you have may be helping or hindering your sleep. If you have a thought or belief that is harmful, we can think about a thought that may be more helpful. (Discussion) Next week we will review more specific thoughts that may be helpful or harmful. Are you willing to write down any thought that you experience this coming week? Will you please these thoughts with you next week?"*

*"In summary, this coming week you will go to bed at____ and get up at _____. You will record any negative thoughts that come to mind. Do you have any questions about your sleep diary, blood glucose machine or actigraph? According to my calendar you are scheduled to come back on___ at ____. Have a wonderful week."*

Session Four

Presenter: Cheryl Lee Tannas

Time: 90 minutes

1. Session Goals

Complete Dysfunctional Beliefs and Attitudes about Sleep Scale and review.

Discuss dysfunctional beliefs about sleep

Collect data (sleep diary, blood glucose from the blood glucose meter and actigraph results

Assess treatment gains and barriers

Make adjustments in the participants sleep schedule

2. Session Content (dialog):

*"Hello ____. How has your past week been? Did you write down some negative thoughts or beliefs? (Discuss) Tonight while I download your blood glucose meter and your actigraph, will you please complete the Dysfunctional Beliefs and Attitudes about Sleep Scale (Study Manual, p 56)? This is a longer questionnaire than the usual ones. We will review it when you are done. After that we will go over your sleep diary and decide what your sleep schedule for this coming week."*

*"I am done downloading your blood glucose meter and your actigraph. Are you done completing the questionnaire? (If yes) OK. Let's go over how you responded to the questions. (review questionnaire) As we discussed last week, negative thoughts and beliefs can be adjusted to thoughts that will support you getting a good night's sleep. Can you think of an example of this? How about another one? As with last week, will you write down any negative thoughts you*

*experience during the week. This time will you write down how the thought or thoughts influence your sleep?"*

*"Last, but not least, let's take a look at your diary. (Discuss) Based on our discussion, sounds like this week you should go to bed at ____ and get up at ____. Does this sound OK to you? Do you need any supplies? According to my schedule, we will meet on ____ at _____ next week. If you have any questions, please don't hesitate to call."*

*Session 5*

1. Session Goals

Collect data (sleep diary, blood glucose from the blood glucose meter and the actigraph results)

Assess treatment gains and barriers

Make adjustments to the participants sleep schedule

Discuss ways to change negative sleep beliefs and attitudes

Discuss relaxation therapies

Participant to practice relaxation techniques using the relaxation CD or Relaxation Therapy Transcript

Provide relaxation therapy CD and/or relaxation therapy transcript for participant

2. Session Content (dialog):

*"Hello (participant). I'm glad to see you. Will you please tell me how the past week has been for you? Before I download your blood glucose meter and actigraph, let's take a look at your sleep diary.(Assess treatment gains and barriers.) Based on the results of your diary, let us discuss what adjustments to make in your sleep schedule. (Make appropriate changes.) Does this sound like these changes will work for you? While I download your blood glucose meter, will*

*you please share with me how your diabetes management has been this week? Next, while I download your actigraph, is there anything else about your sleep during the past week that you would like to share?"*

*"Before we talk about relaxation, did you record any negative sleep beliefs or attitudes? What did you do to cope with this (these) issue (issues)? (Discuss concerns)"*

*"The topic for tonight is relaxation. Before we talk about different forms of relaxation, it is important to note that relaxation does not mean "going to sleep". Relaxation makes it easier to go to sleep. This distinction is important to keep in mind."*

*"The four forms of relaxation therapy are (1)progressive muscle relaxation (used to reduce skeletal muscle tension; (2)diaphragmatic breathing (used to help you breathe slower, more deeply and driven from your abdomen rather than your thorax) (Demonstrate); (3) Autogenic training is designed to increase your blood flow in your extremities by imaging that your extremities feel warm; and (4)imagery (using a multisensory approach to imagining a relaxing experience). Often more than one approach is used in a single activity. Practice is important to obtain the desired response from these relaxation methods. What method, or methods, have you tried in the past? How did it work? What approach do you want to try this week? When will you practice?"*

*"Before you leave tonight, I'd like you to try a relaxation exercise. Are you will to do this? I will be reading the exercise for you(Study Manual, p62). You will also be given a copy of this exercise and also a relaxation CD for you to use at home this week. I will lower the light as I begin to read the relaxation therapy*

*transcript. (read 12 minute session) How was that for you? Keep in mind that this exercise is more effective the more often that you practice it."*

*"Do you have any questions or concerns before you leave? Please keep in mind that you can contact me anytime. Before you leave, are there any supplies that you need? I look forward to seeing you next week."*

Session 6

1. Session Goals

   Complete Sleep Hygiene Practice Scale and discuss answers

   Obtain data (sleep diary, blood sugar results from blood glucose meter, and actigraph results)

   Assess treatment gains and barriers

   Make adjustments in the participant's sleep schedule

   Participant to set a sleep hygiene goal

2. Session Content (dialog):

*"We are now at session 6 of this program. So far what do you think about the progress that you have made? (discuss thoughts) During this session we will talk about what is called sleep hygiene. To introduce this topic, will you please complete the Sleep Hygiene Practice Scale (Study Manual, p 66)? While you do that I will download you blood glucose meter and your actigraph."*

*"Before we review the Sleep Hygiene Practice Scale, let's look at your sleep diary. Based on what you have recorded, the recommendation is that you go to bed at ____. What do you think about that? Did you try to use a relaxation session? If so, how often and did it help?"*

*"To begin our discussion on sleep hygiene, let's go over how you completed the Sleep Hygiene Practice Scale. (Discuss this tool. Ask what approaches the*

*participant has used) Assist the participant to set at least one sleep hygiene goal. Also review the sleep restriction plan for the coming week. Advise participant to collect VAS for three days prior to next visit. Also request that participant check her blood sugar before each meal and also at bedtime during the same three days. Discuss any concerns about sleep and/or diabetes. According to my calendar you are scheduled to meet on_____ Will this still work for you?"*

*Session 7*

1. Session Goals

Complete the Glasgow Sleep Effort Scale and discuss

Discuss sleep maintenance

Discuss relapse prevention

Collect data (sleep diary, VAS, Physical Activity Scale, blood glucose from blood glucose meter, and actigraph results)

Complete initial data collection tools (PSQI, Insomnia Severity Index)

Obtain and record A1C and weight.

Schedule follow up session

2. Session Content (dialog):

*"Tonight (today) is our last session, except for your follow up session. Before we start with tonight's agenda, do you have anything that you want to discuss? (Discussion) Per our usual routine, will you please complete the Glasgow Sleep Effort Scale (Study Manual, p67) while I download your blood glucose meter and actigraph? (Discuss questionnaire after participant completes the form) Tonight we need to talk about maintaining the progress that you have made. Preventing relapse is an important part of recovering from insomnia. What technique that you have used during this program was the most helpful? (Discuss) Can you see*

*any possible barriers to you continue to making progress? Research has shown that people continue to improve their sleeping behaviors overtime if they continue to use the techniques that have been learned. Before you complete the questionnaires that you filled out before you began the study, is there anything else that you want to discuss? (Discussion) Now, will you please complete the questionnaires? Before you leave I will give you the supplies that you will need before the follow up session."*

*"Before you leave, here are the supplies you will need to collect data before the follow up. Please don't hesitate to call if you have any questions."*

## *Follow Up Session*

1. Session Goals

Collect follow up data (PSQI, Insomnia Severity Index, VAS, Physical Activity Scale, blood sugar from blood glucose meter and actigraph results, A1C and weight)

Answer any questions.

If sleep behaviors have not improved, ask the participant to obtain a polysomnography and share the results.

Thank the participant for participating in the study.

2. Session Content (dialog):

*"I'm so glad to see you! How have you been doing? (Discussion) At this session you need to complete the questionnaires while I will download your blood glucose machine and your actigraph, In addition I will weigh you and draw your blood. Before you leave we can discuss any additional issues that you have. "*

*Provide questionnaires. Download the blood glucose machine and actigraph. Review the questionnaires for completion before drawing the blood and weighing*

*the participant. If the participant has not improved her sleep behaviors, ask her to obtain a sleep study and share the results. "Now that we have collected this information, what else do you want to discuss? (Discussion) Thank you so much for participating in this study. You have my phone number to call for any future questionnaires. When the presentation of this study is scheduled, I will notify you if you want to attend."*

# *Screening Tools*

Screening Tool
ID_____ DATE_____

**Inclusion Criteria**

____ female gender

____ type 2 diabetes for a minimum of one year

____ 60-70 years of age

____ fragmented sleep

____ medically stable

____ able to complete data collection tools

**Exclusion Criteria**

____ Medical conditions: Diagnosed sleeping disorders, major depressive disorder, psychiatric disorders

____ Medications: sleeping medications, steroids

____ Suicidal thoughts

____ Cognitive Impairment - MMS results

## Demographic Questionnaire

ID_____ DATE_____

Sex: Female____

Age: _____years

Educational level

Some high school ____
High School graduate ____
Some College ____
College Graduate ____
Master's degree _____
PhD _____

Marital Status

Single ____
Divorced ____
Married ____
Widowed ____

Insurance

Medicare ____
Private ____
Medicaid ____
None ____

Employment

Full time ____
Part time ____ hours _____
Retired _____

# Medical History Checklist

## Medical History Information Form

Current weight: _____ ID: _____
Current height: _____ Date: _____
Weight 5 years ago: _____ BMI: _____
Blood Pressure _____ A1C: _____

| Medication | Dose | Schedule | Reason taking it |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Put checkmark in the box:

- ❑ Head injury
- ❑ Hemorrhage
- ❑ Meningitis
- ❑ Migraine
- ❑ Multiple Sclerosis
- ❑ Parkinson's
- ❑ Seizures
- ❑ Stroke
- ❑ Shingles
- ❑ Chest pain
- ❑ Irregular Heart Rhythm
- ❑ Congestive Heart Failure
- ❑ Heart Attack
- ❑ Vision problem
- ❑ Blood Clots
- ❑ Asthma
- ❑ Colitis
- ❑ Constipation
- ❑ Gastric Ulcer Disease
- ❑ Pancreatitis
- ❑ Gastric bleeding
- ❑ Heartburn
- ❑ Esophageal Reflux
- ❑ Cystitis
- ❑ Kidney Stones
- ❑ Menopause
- ❑ Ovarian Cysts
- ❑ Pelvic Inflammatory Disease
- ❑ Kidney failure
- ❑ Blood disorders
- ❑ Chronic Pain
- ❑ Hepatitis
- ❑ Pneumonia
- ❑ Tuberculosis
- ❑ Cancer
- ❑ Diabetes
- ❑ Thyroid Problems
- ❑ Obesity
- ❑ Arthritis
- ❑ Fibromyalgia
- ❑ HIV disease
- ❑ Psoriasis
- ❑ Hives or rashes
- ❑ Dental problem
- ❑ Grinding teeth
- ❑ Sleep Apnea
- ❑ Restless Legs
- ❑ Liver Disease

Other: _____

List Surgeries with dates: _____
_____

Question: During the past year, have you had thoughts that you would be better off dead, or hurting yourself in some way?
Not at all ___ Several days___ More than half of days____ Nearly every day____

**ID_____ DATE_____**

**Outline Plan for a Sleep History Assessment Comprising Content Areas and Suggested Interview Questions**

| Content Area | Prompt question | Supplementary questions |
|---|---|---|
| *Presentation of the sleep complaint* | | |
| Pattern | Can you describe the pattern of your sleep on a typical night? | Time to fall asleep?<br>Number and duration of wakenings?<br>Time spent asleep?<br>Nights per week like this? |
| Quality | How do you feel about the quality of your sleep? | Refreshing?<br>Enjoyable?<br>Restless? |
| Daytime effects | How does your night's sleep affect your day? | Tired?<br>Sleepy?<br>Poor concentration?<br>Irritable?<br>Particular times of day? |
| *Development of the sleep complaint* | Do you remember how this spell of poor sleep started? | Events and circumstances?<br>Dates and times?<br>Variation since then?<br>Exacerbating factors?<br>Alleviating factors?<br>Degree of impact/intrusiveness? |
| *Lifetime history of sleep complaints* | Did you used to be a good sleeper? | Sleep in childhood?<br>Sleep in adulthood?<br>Nature of past episodes?<br>Dates and times?<br>Resolution of past episodes? |
| *General health status and medical history* | Have you generally kept in good health? | Illnesses?<br>Chronic problem?<br>Dates and times?<br>Recent changes in health? |
| *Psychopathology and history of psychological functioning* | Are you the kind of person who usually copes well? | Psychological problems?<br>Anxiety or depression?<br>Dates and times?<br>Resourceful person?<br>Personality type? |
| *Issues of differential diagnosis*<br><br>Sleep-related breathing disorder (SBD)<br><br>Periodic limb movements in sleep (PLMS) and restless legs syndrome (RLS)<br><br>Circadian rhythm sleep disorders<br><br>Parasomnias | Are you a heavy snorer?<br><br><br><br>Do your legs sometimes twitch or can't keep still?<br><br><br><br>Do you feel you want to sleep at the wrong time?<br><br>Do you sometimes act a bit strangely during your sleep? | Interrupted breathing in sleep?<br>Excessively sleepy in the day?<br><br>Excessively sleepy in the day?<br>Trouble sitting still without moving the extremities?<br><br>Too early?<br>Too late?<br><br>Behavioral description?<br>Time during night?<br><br>Times and places?<br>Collapses triggered by emotion? |

| Content Area | Prompt question | Supplementary questions |
|---|---|---|
| Narcolepsy | Do you sometimes just fall asleep without warning? | Poor sleep at night? |

ID _____

Date_____

**MINI-MENTAL STATE**

Maximum Score | Score

ORIENTATION

5 ( ) What is the (year) (season) (date) (day) (month)?

5 ( ) Where are we: (state) (country) (town) (hospital) (floor).

REGISTRATION

3 ( ) Name 3 objects: 1 second to say each. Then ask the patient all 3 after you have said them. Give 1 point for each correct answer. Then repeat them until he learns all 3. Count trials and record.

Trials

MINI-MENTAL STATE

ATTENTION AND CALCULATION

5 ( ) Serial 7's 1 point for each correct. Stop after 5 answers. Alternatively spell "world" backwards.

3 ( ) Ask for the 3 objects repeated above. Give 1 point for each correct.

9 ( ) Name a pencil, and watch (2 points)

Repeat the following "No ifs, and or buts." (1 point)

Follow a 3-stage command:

"Take a paper in your right hand, fold it in half, and put it on the floor" (3 points)

Read and obey the following:

CLOSE YOUR EYES (1 point)

Write a sentence (1 point)

Copy design (1 point)

Total score

ASSESS level of consciousness along a continuum

Alert Drowsy Stupor Coma

## *Orientation Tools*

**[Behavioral] Research Informed Consent**

Title of Study: **TYPE 2 DIABETES AND INSOMNIA: IMPACT ON METABOLIC CONTROL**

Principal Investigator (PI): Cheryl Tannas
College of Nursing
313-530-9895

**Purpose**

You are being asked to be in a research study of sleep behaviors because you are a woman aged 60 to 70 years of age with type 2 diabetes and insomnia. This study is being conducted at Wayne State University and Henry Ford Health System. The estimated number of study participants to be enrolled at Wayne State University and Henry Ford Health System is about 24. **Please read this form and ask any questions you may have before agreeing to be in the study.**

In this research study, the amount of time you sleep and how well you sleep both before and after the 7 week program will be studied. These sessions are about how to sleep better. Also, a possible link between your sleep behaviors and your blood sugars, appetite and activity will be studied.

**Study Procedures**

If you agree to take part in this research study, you will be asked to participate in a seven week program to improve your sleep. In addition you will be asked to come for both an orientation and a three week follow up meeting. The questions asked will be about you general health. Specific questions will focus on your sleep and diabetes. If you decide not to answer a question, you will not be asked to leave the study. Your participation in this study will last a total of 11 weeks. The first session (orientation) will last approximately 2 ½ hours. Each following session will last 1 to 1 ½ hours.

TYPE 2 DIABETES AND INSOMNIA: IMPACT ON METABOLIC CONTROL

At visit 1 you will have the following procedures:

- The entire study, including the consent form will be explained to you.
- You will be asked about your medical history as well as your medications and your sleep behaviors.
- You will complete a questionnaire and have your weight and a small sample of blood (1 teaspoon) collected.
- You will be notified if you qualify for the study after all necessary test results are examined.
- Blood glucose meter teaching and dispensing.Instruction on how to perform at home daily blood glucose test at least before breakfast and before bedtime/daily for at least 7 days prior to visit 2.
- Dispensing and review of the sleep diary.
- Instruction on how to complete the sleep diary and instructions to complete the diary for at least 7 days prior to visit 2.
- Dispensing and review of the actigraph. The actigraph is a device that looks like a watch. It is worn on your wrist. By recording motion and light it will provide information about your general activity and sleep schedule.
- Instruction on how to use the actigraph and instructions to wear the actigraph for 7 days prior to visit 2.

At weekly visits 2-7, you will have the following procedure:

- Blood glucose meter downloaded onto the computer.
- Actigraph downloaded onto the computer.
- Patient education questionnaires completed.
- Education on improving sleep behaviors.
- Set sleep behavior goal for the following week.

At visit 8 you will have the following procedures:

- Blood glucose meter downloaded onto the computer.
- Actigraph downloaded onto the computer and then collected.
- Sleep diary collected and reviewed.
- Patient questionnaires from session 1 will again be completed.
- Your weight will be obtained.
- A review of your sleep behaviors during the sleep sessions will be reviewed.
- Session 9 will be scheduled 3 weeks from this date.

At visit 9 you will have the following procedures:

- Blood glucose meter downloaded onto the computer.
- Sleep diaries collected and reviewed.
- Patient questionnaires form session 1 will again be completed.
- Your weight will be obtained.
- Blood draw.
- Study summary.

Your identity will not be disclosed. Any information collected during this study will be coded and only used for the purposes of this study.



_____
Participant's Initials

TYPE 2 DIABETES AND INSOMNIA: IMPACT ON METABOLIC CONTROL

**Benefits**

The possible benefits to you for taking part in this research study may include improved sleep behaviors and blood glucose control. You may not be helped by participating in this study. However, others may be helped by what is learned from this study.

**Risks**

Although slight, there are two possible risks that have been identified related to this study.

One risk is related to the blood sample. Always, there is a small risk of discomfort when the sample is drawn, bruising at the site, or dizziness. To minimize this risk, the blood sample will be drawn by a trained person.

The second risk is related to the questionnaire. Some participants find that some questions make them uncomfortable. You can choose not to answer a question. You also have the opportunity to talk to the person conducting the study about any subject.

There may also be risks involved from taking part in this study that are not known to researchers at this time.

**Alternatives**

You do not have to participate in this study. Your other choices may include:

- Getting treatment for insomnia without being in the study, such as behavioral therapy for insomnia or medications.
- Taking part in another study.
- Getting no treatment.

**Study Costs**

- Participation in this study will be of no cost to you.

**Compensation**

You will not be paid for taking part in this study. Parking vouchers will be provided if needed.

TYPE 2 DIABETES AND INSOMNIA: IMPACT ON METABOLIC CONTROL

**Research Related Injuries**

In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Care for such will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Wayne State University. If you think that you have suffered a research related injury, contact the PI right away at 313-530-9895.

**Confidentiality**

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Human Investigation Committee (HIC) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity.

**Voluntary Participation/Withdrawal**

Taking part in this study is voluntary. You have the right to choose not to take part in this study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

The PI may stop your participation in this study without your consent. The PI will make the decision and let you know if it is not possible for you to continue. The decision that is made is to protect your health and safety, or because you did not follow the instructions to take part in the study

**Questions**

If you have any questions about this study now or in the future, you may contact Cheryl Tannas at the following phone number 313-530-9895. If you have questions or concerns about your rights as a research participant, the Chair of the Human Investigation Committee can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call (313) 577-1628 to ask questions or voice concerns or complaints.



_____
Participant's Initials

TYPE 2 DIABETES AND INSOMNIA: IMPACT ON METABOLIC CONTROL

**Consent to Participate in a Research Study**

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

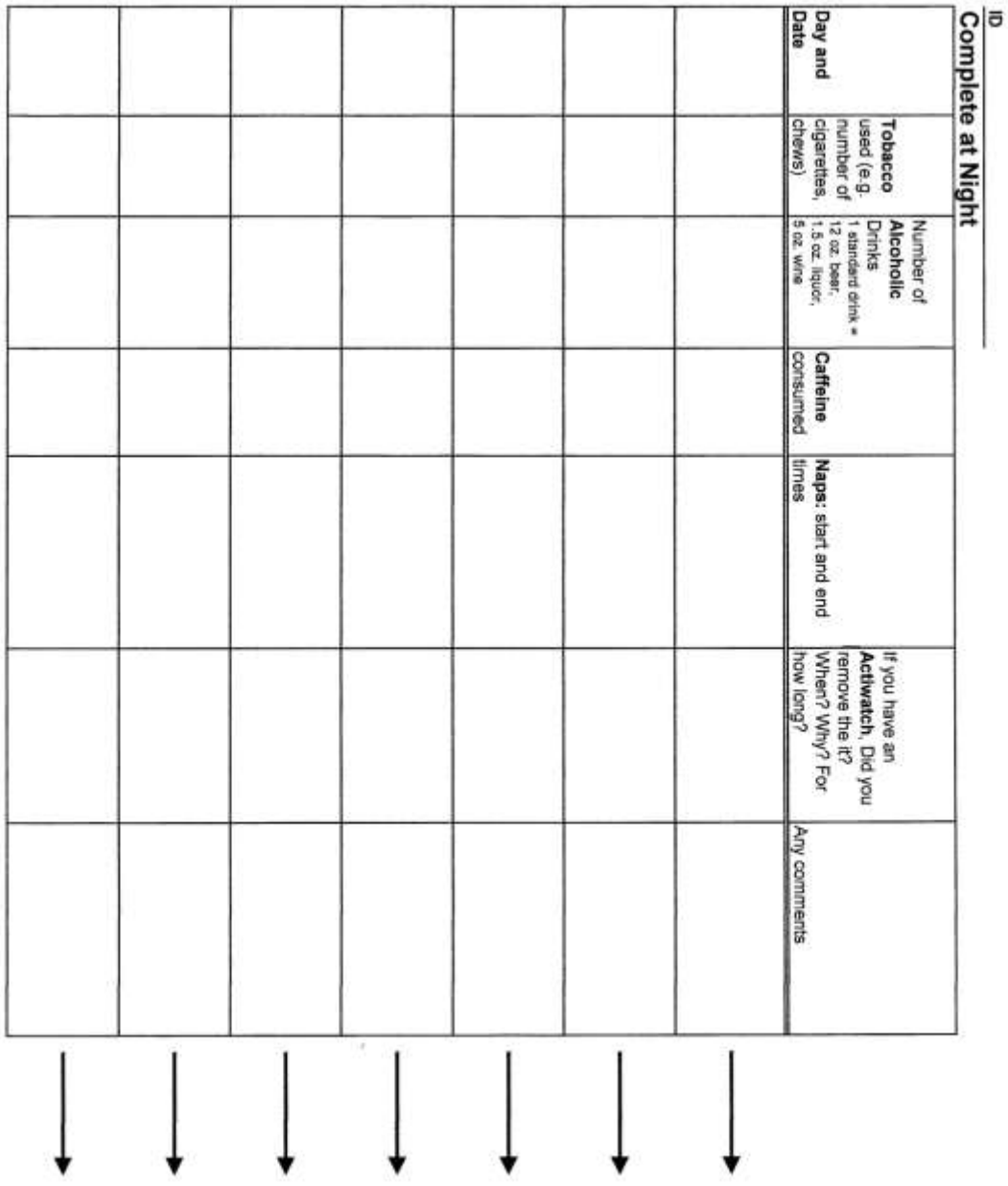
| | |
|---|---|
| Signature of participant | Date |
| Printed name of participant | Time |
| Signature of witness** | Date |
| Printed of witness** | Time |
| Signature of person obtaining consent | Date |
| Printed name of person obtaining consent | Time |

**Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).

APPROVAL PERIOD
JUL 08 '11 JUL 07 '12
WAYNE STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD

| | |
|---|---|
| Signature of translator | Date |
| Printed name of translator | Time |

*Sleep*
*Diary*



**Complete in Morning** in reference to last night

| Last Night, I **went to bed** at: | Last Night, I **turned out the lights** at: | After lights out, I **fell asleep** in: | The **number of times** I woke up during the night was: | Once I fell asleep, I was **awake** for a total of: | This morning, I got **out of bed** at: | Last night, the **quality** of my sleep was: 1 = very poor 2 = poor 3 = fair 4 = good 5 = very good | This morning, I **feel:** 1 = very tired 2 = tired 3 = somewhat rested 4 = rested 5 = very rested |
|---|---|---|---|---|---|---|---|
| am / pm | am / pm | | | | am / pm | | |
| am / pm | am / pm | | | | am / pm | | |
| am / pm | am / pm | | | | am / pm | | |
| am / pm | am / pm | | | | am / pm | | |
| am / pm | am / pm | | | | am / pm | | |
| am / pm | am / pm | | | | am / pm | | |
| | | | | | | | |

# Pittsburgh Sleep Quality Index (PSQI)

ID: _____ Date:_____ Age _____

**Instructions:**

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month.

Please answer all questions.

1. During the past month, when have you usually gone to bed at night?

   USUAL BED TIME _____

2. During the past month, how long (in minutes) has it usually take you to fall asleep each night?

   NUMBER OF MINUTES _____

3. During the past month, when you have you usually gotten up in the morning?

   USUAL GETTING UP TIME _____

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed.)

   HOURS OF SLEEP PER NIGHT_____

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

5. During the past month, how often have you had trouble sleeping because you…

   a) Cannot get to sleep within 30 minutes

   Not during past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

   b) Wake up in the middle of the night or early morning

   Not during 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 past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

d) Cannot breathe comfortably

Not during past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

e) Cough or snore loudly

Not during past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

f) Feel too cold

Not during past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

g) Feel too hot

Not during past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

h) Had bad dream

Not during past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

i) Have pain

Not during past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

j) Other reason(s), please describe

_____

_____

How often during the past month have you had trouble sleeping because of this?

Not during past month____ Less than once a week____ Once or twice a week____ Three or more times a week___

6. During the past month, how would you rate your sleep quality overall?
   - Very good ____
   - Fairly good ____
   - Fairly bad ____
   - Very bad ____

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

Not during past month____ Less than once a week____ Once or twice a week____ Three or more times a week____

# The Insomnia Severity Index

ID: _____ Date:_____

8. Please rate the current (i.e., last 2 weeks) severity of your insomnia problem(s).

| | None | Mild | Moderate | Severe | Very |
|---|---|---|---|---|---|
| a. Difficulty falling asleep: | 0 | 1 | 2 | 3 | 4 |
| b. Difficulty staying asleep: | 0 | 1 | 2 | 3 | 4 |
| c. Problem waking up too early: | 0 | 1 | 2 | 3 | 4 |

9. How satisfied/dissatisfied are you with your current sleep pattern?

| Very satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied |
|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 |

10. To what extent do you consider your sleep problem to interfere with your daily functioning (e.g. daytime fatigue, ability to function at work/daily chores, concentration, memory, mood, etc.).

| Not at all interfering | A little | Somewhat | Much | Very much interfering |
|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 |

11. How noticeable to others do you think your sleeping problem is in terms of impairing the quality of your life?

| Not at all noticeable | A little | Somewhat | Much | Very much noticeable |
|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 |

12. How worried/distressed are you about your current sleep problem?

| Not all all worried | A little | Somewhat | Much | Very much worried |
|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 |

*Guidelines for Scoring/Interpretation*

Add scores for all seven items (1a + 1b + 1c + 2 + 3 + 4 + 5) =
Total score ranges from 0-28; if total score falls between:

0-7 = No clinically significant insomnia
8-14 = Subthreshold insomnia
15-21 = Clinical insomnia (moderate severity)
22-28 = Clinical insomnia (severe)

ID: _____

*Visual Analog Scale*

Questions on appetite and desire for specific food

| | | |
|---|---|---|
| I am not hungry at all | How hungry do you feel? | I have never been more hungry |
| I am completely empty | How satisfied do you feel? | I cannot eat another bite |
| Not at all full | How full do you feel? | Totally full |
| Nothing at all | How much do you think you can eat? | A lot |
| Yes, very much | Would you like to eat something sweet? | No, not at all |
| Yes, very much | Would you like to eat something salty? | No, not at all |
| Yes, very much | Would you like to eat something savoury? | No, not at all |
| Yes, very much | Would you like to eat something fatty? | No, not at all |

## APPENDIX I

### Physical Activity Scale

Describes total amount of physical activity on an average weekday. Translated into English from the Danish version of the physical activity scale.

**Physical activity**

| | | Examples | Minutes | Hours | Time: |
|---|---|---|---|---|---|
| A |  | Sleep, rest | □□□ 15 30 45 | □□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10 | |
| B |  | Sitting quietly, watching television, listening to music or reading | □□□ 15 30 45 | □□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10 | |
| C |  | Working at a computer or desk, sitting in a meeting, eating | □□□ 15 30 45 | □□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10 | |
| D |  | Standing, washing dishes or cooking, driving a car or truck | □□□ 15 30 45 | □□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10 | |
| E |  | Light cleaning, sweeping floors, food shopping with grocery cart, slow dancing or walking downstairs | □□□ 15 30 45 | □□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10 | |
| F |  | Bicycling to work or for pleasure, brisk walking, painting or plastering | □□□ 15 30 45 | □□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10 | |
| G |  | Gardening, carrying, loading or stacking wood, carrying light object upstairs | □□□ 15 30 45 | □□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10 | |
| H |  | Aerobics, health club exercise, chopping wood or shoveling snow | □□□ 15 30 45 | □□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10 | |
| I |  | More effort than level H: Running, racing on bicycle, playing soccer, handball or tennis | □□□ 15 30 45 | □□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10 | |

## *Teaching Tools*

## *Class Outline*

| Session | Content | Participant Activities |
|---|---|---|
| Session 1 | Review CBTI, sleep diaries, blood glucose meter, wrist actigraphy. Introduce sleep restriction. | 1. Review Class Outline<br>2. Complete Motivation for Change and review<br>3. Complete Sleep Behavior Self-Rating Scale and review<br>4. Discuss sleep restriction<br>5. Review Sleep Diary results and set sleep goals<br>6.Download BG meter & actigraph. |
| Session 2 | Sleep Restriction<br>Stimulus Control Therapy | 1. Complete Sleep Environment Checklist and review<br>2. Complete Caffeine Knowledge Quiz and review<br>3. Review Sleep Diary Results and set sleep goals.<br>4. Download BG meter & actigraph |
| Session 3 | Introduce Cognitive Therapy | 1. Complete The Pre-Sleep Arousal Scale and review<br>2. Discuss overview of Cognitive Therapy<br>3. Review Sleep Diary results and set sleep goals<br>4. Download BG meter & actigraph |
| Session 4 | Cognitive Therapy<br>Introduction to other therapies | 1.Complete Dysfunctional Beliefs and Attitudes about Sleep Scale and review.<br>2. Review Sleep Diary results and set sleep goals.<br>3. Download BG meter & actigraph |
| Session 5 | Relaxation Therapies | 1. Discuss ways to change negative sleep beliefs and attitudes.<br>2. Discuss Relaxation Therapies<br>3. Review Sleep Diary results and set sleep goals.<br>4. Provide Relaxation CD & Relaxation Therapy Transcript<br>5. Download BG meter & actigraph |
| Session 6: | Sleep Hygiene | 1. Complete Sleep Hygience Practice Scale and discuss<br>2. Set sleep hygiene goal<br>3. Review Sleep Diary results and set sleep goals. |

| | | |
|---|---|---|
| | | 4. Download BG meter & actigraph<br>5. Provide shower gel and body lotion. |
| Session 7: | Sleep Maintenance and Relapse Prevention<br>Data collection | 1. Complete The Glasgow Sleep Effort Scale and Discuss.<br>2. Review Sleep Diary results and discuss future goals<br>3. Discuss sleep maintenance and Relapse Prevention<br>4. Download BG meter & actigraph<br>5. Complete data collection tools.<br>Pittsburgh Sleep Quality Index<br>Insomnia Severity Index |

# Sleep Restriction Guidelines

In the case of positive clinical gains (Sleep Efficiency (SE) > 90 %) – upwardly titrate total sleep opportunity.

In the case of no or marginal gains (SE between 85 and 90 %), maintain schedule.

In the case of negative gains (SE < 85%), downwardly titrate total sleep opportunity.

# Motivation for Change Index

**MFCI**
**(Motivation For Change Index)**

ID: _____ Date:_____

13. Because of my insomnia I can't (Please list)

_____ _____
_____ _____
_____ _____
_____ _____
_____ _____

14. If there were a treatment we could use that would, as of tomorrow, fix you insomnia—in what way(s) would your life be better?

_____ _____
_____ _____
_____ _____
_____ _____
_____ _____

15. If there were a treatment we could use that would fix your insomnia how many hours per week would you be willing to invest in the process?

____ 1 hour____ 2 hour____ 4 hour____ 8 hour____ 10 hour

16. If there were a treatment we could use that would fix your insomnia BUT it would take time, how long would you be willing to wait?

____ 1 week ____ 2 weeks ____ 4 weeks ____ 8 weeks ____ 10 weeks

17. If there were a treatment we could use that would fix your insomnia BUT to get better it would mean that you'd get worse before you get better, how much worse would you be willing to get?

____ 10% ____ 20% ____ 40% ____ 80% ____ 100%

18. To make a difference in your life, how much improvement would represent a real accomplishment?

____ 10% ____ 20% ____ 40% ____ 80% ____ 100%

# Sleep Behavior Self-Rating Scale

**Instructions for patients** **ID_____ DATE_____**

This rating scale helps us to understand what your behavior patterns around bedtime is like. It is fairly self-explanatory. Please take a few minutes to fill it in as accurately as you can. Please indicate how often you do the following things *in your bed before falling asleep or while in your bedroom.* Complete the form by considering what you would do in an average week.

| Behavior | Never | Rarely | Sometimes | Often | Very Often |
|---|---|---|---|---|---|
| Read a book or magazine | | | | | |
| Watch TV | | | | | |
| Listen to the radio | | | | | |
| Have a conversation with someone | | | | | |
| Speak on the telephone | | | | | |
| Eat or drink | | | | | |
| Smoke | | | | | |
| Please also | answer the | following | questions: | | |
| I take naps during the day or evening | | | | | |
| I fell sleepy when I go to bed | | | | | |
| I switch the light off as soon as I get into bed | | | | | |
| I spend a lot | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| of time lying awake in bed at night | | | | | |
| If I can't get to sleep within approx. 20 minutes I get out of bed and move to another room until I feel sleepy again | | | | | |
| I set myself a regular rising time each morning | | | | | |
| If I have a bad night's sleep I still get up at my usual time | | | | | |

Sleep Environment Checklist ID_____ DATE_____

**SLEEP ENVIRONMENT QUESTIONNAIRE**

1. I use an alarm clock five or more days a week.

   True False Not Applicable

2. I keep the temperature in the bedroom so cold that I have 2 or more blankets on the bed to stay warm at night.

   True False Not Applicable

3. The blinds and curtains in the bedroom are so effective that at sunrise the room is so dark its hard to tell that the sun came up.

   True False Not Applicable

4. I have spent real time and money making sure that my mattress and pillow are perfect for me.

   True False Not Applicable

5. During the night, my bedroom is insulated so well that I rarely if ever hear outside noise from the road, neighbors, etc.

   True False Not Applicable

6. House noise from the radiators, floor boards, etc. is so minimal that I am rarely aware of such sounds.

   True False Not Applicable

7. My home is a safe place. My partner and/or pet and/or the locks and alarm system and/or concern and support of my neighbors provide me a level of comfort such that I rarely if ever worry about being safe at night.

   True False Not Applicable

8. On three or more nights per week, I engage in two or more of the following behaviors in the bedroom: watch TV, read, plan, worry, work, clean, or eat.

   True False Not Applicable

9. My pets rarely, if ever, keep me from falling asleep or wake me up during the night.

   True False Not Applicable

10. My bed partner's sleep schedule or habits while in bed (reading, moving about, stealing the covers, snoring, etc.) rarely, if ever, disturb my sleep.

    True False Not Applicable

11. My child's/children's sleep schedule or habits while in bed or during the night rarely if ever disturb my sleep.

    True False Not Applicable

ID_____ DATE_____

## Caffeine Knowledge Quiz

For each item on the following list, indicate whether you believe it contains caffeine or another stimulant by placing a Y (yes) or an N (no) in the space provided. If you are not sure, make your best guess. If you have never heard of an item please place an X in the space._____

| | | |
|---|---|---|
| ____7-Up soft drink | ____lemonade | ____Mountain Dew |
| ____regular tea | ____root beer | ____cola soft drinks |
| ____Dristan cold remedy | ____chocolate cake | ____Dexatrim diet pills |
| ____aspirin | ____regular coffee | ____Tylenol |
| ____Dr. Pepper soft drink | ____Excedrin | ____Aqua Ban diuretic |
| ____Midol menstrual relief | ____Sudafed decongestant | ____Sprite soft drink |

The Pre-Sleep Arousal Scale ID_____ DATE____

**Instructions to patient**

*This scale is fairly self-explanatory. We are interested to find out about how you are feeling in your mind and in your body before you fall asleep. Please describe how intensely you experience each of the symptoms mentioned below as you attempt to fall asleep, by circling the appropriate number.*

**Further instructions to clinician**

Two separate scores can be obtained for the PSAS. The sub-scale score for cognitive arousal comprises the total of items 1 to 8, and the sub-scale score for somatic arousal comprises the total of items 9 to 16.

| | Not at all | Slightly | Moderately | A lot | Extremely |
|---|---|---|---|---|---|
| 1. Worry about falling asleep | 1 | 2 | 3 | 4 | 5 |
| 2. Review or ponder the events of the day | 1 | 2 | 3 | 4 | 5 |
| 3. Depressing or anxious thoughts | 1 | 2 | 3 | 4 | 5 |
| 4. Worry about problems other than sleep | 1 | 2 | 3 | 4 | 5 |
| 5. Being mentally alert, active | 1 | 2 | 3 | 4 | 5 |
| 6. Can’t shut off your thoughts | 1 | 2 | 3 | 4 | 5 |
| 7. Thoughts keep running through your head | 1 | 2 | 3 | 4 | 5 |
| 12. Being distracted by sounds, noise in the environment | 1 | 2 | 3 | 4 | 5 |

| | Not at all | Slightly | Moderately | A lot | Extremely |
|---|---|---|---|---|---|
| 9. Heart racing, pounding or beating irregularly | 1 | 2 | 3 | 4 | 5 |
| 10. A jittery, nervous feeling in your body | 1 | 2 | 3 | 4 | 5 |
| 13. Shortness of breath or labored breathing | 1 | 2 | 3 | 4 | 5 |
| 14. A tight, tense feeling in your muscles | 1 | 2 | 3 | 4 | 5 |
| 15. Cold feeling in your hands, feet or your body in general | 1 | 2 | 3 | 4 | 5 |
| 16. Have stomach upset (knot or nervous feeling in stomach, heartburn, nausea, gas, etc.) | 1 | 2 | 3 | 4 | 5 |
| 17. Perspiration in palms of your hands or other parts of your body | 1 | 2 | 3 | 4 | 5 |
| 18. Dry feeling in mouth or throat | 1 | 2 | 3 | 4 | 5 |

# Dsyfunctional Beliefs and Attitudes about Sleep Scale

ID: _____ Date:_____

Instructions

Several statements reflecting people's beliefs and attitudes about sleep are listed below. Please indicate to what extent you personally agree or disagree with each statement. There is no right or wrong answer. For each statement, circle the number that corresponds to your own personal belief. Please respond to all items even though some may not apply directly to your own situation.

Strongly disagree ___ Strongly agree

0 1 2 3 4 5 6 7 8 9 10

19. I need 8 hours of sleep to feel refreshed and function well during the day.

Strongly disagree ___ Strongly agree

0 1 2 3 4 5 6 7 8 9 10

20. When I don't get proper amount of sleep on a given night, I need to catch up on the next day by napping or on the next night by sleeping longer.

Strongly disagree ___ Strongly agree

0 1 2 3 4 5 6 7 8 9 10

21. Because I am getting older, I need less sleep.

Strongly disagree ___ Strongly agree

0 1 2 3 4 5 6 7 8 9 10

22. I am worried that if I go for 1 or 2 nights without sleep, I may have a "nervous breakdown."

Strongly disagree ___ Strongly agree

0 1 2 3 4 5 6 7 8 9 10

23. I am concerned that chronic insomnia may have serious consequences on my physical health.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

24. By spending more time in bed, I usually get more sleep and feel better the next day.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

25. When I have trouble falling asleep or getting back to sleep after nighttime awakening, I should stay in bed and try harder.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

26. I am worried that I may lose control over my abilities to sleep.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

27. Because I am getting older, I should go to bed earlier in the evening.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

28. After a poor night's sleep, I know that it will interfere with my daily activities on the next day.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

29. In order to be alert and function well during the day, I believe I would be better off taking a sleeping pill rather than having a poor night's sleep.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

30. When I feel irritable, depressed, or anxious during the day, it is mostly because I did not sleep well the night before.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

31. Because my bed partner falls asleep as soon as his/her head hits the pillow and stays asleep through the night, I should be able to do so too.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

32. I feel that insomnia is basically the result of aging and there isn't much that can be done about this problem.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

33. I am sometimes afraid of dying in my sleep.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

34. When I have a good night's sleep, I know that I will have to pay for it on the following night.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

35. When I sleep poorly on one night, I know it will disturb my sleep schedule for the whole week.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

36. Without an adequate night's sleep, I can hardly function the next day.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

37. I can't ever predict whether I'll have a good or poor night's sleep.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

38. I have little ability to manage the negative consequences of disturbed sleep.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

39. When I feel tired, have no energy, or just seem not to function well during the day, it is generally because I did not sleep well the night before.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

40. I get overwhelmed by my thoughts at night and often feel I have no control over this racing mind.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

41. I feel I can still lead a satisfactory life despite sleep difficulties.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

42. I believe insomnia is essentially the result of a chemical imbalance.

Strongly disagree — Strongly agree

0 1 2 3 4 5 6 7 8 9 10

43. I feel insomnia is running my ability to enjoy life and prevents me from doing what I want.

Strongly disagree ——— Strongly agree

0 1 2 3 4 5 6 7 8 9 10

44. A “nightcap” before bedtime is a good solution to sleep problem.

Strongly disagree ——— Strongly agree

0 1 2 3 4 5 6 7 8 9 10

45. Medication is probably the only solution to sleeplessness.

Strongly disagree ——— Strongly agree

0 1 2 3 4 5 6 7 8 9 10

46. My sleep is getting worse all the time and I don’t believe anyone can help.

Strongly disagree ——— Strongly agree

0 1 2 3 4 5 6 7 8 9 10

47. It usually shows in my physical appearance when I haven’t slept well.

Strongly disagree ——— Strongly agree

0 1 2 3 4 5 6 7 8 9 10

48. I avoid or cancel obligations (social, family) after a poor night’s sleep.

Strongly disagree ——— Strongly agree

0 1 2 3 4 5 6 7 8 9 10

**Scoring and interpretation guidelines**

The total DBAS score is obtained by adding the score of each item (reverse score for item 23) and dividing by the total number of items. There are no norms available for this scale but a higher score indicates that your patient endorses more intense and more frequent dysfunctional beliefs and attitudes about sleep.

An abbreviated 16-item version is currently under validation.

Relaxation Therapy Session Transcript
Version 1

The exercises on this tape are designed to help you relax. Relaxation is a skill, which you can learn. It is just like any other skill, so don't be surprised if you find it takes practice because this is how we learn skills. So do practice. Practice a couple of times a day, especially as you start to learn. Of course, you will want to use the relaxation when you go to bed, to help you relax and go to sleep, but you will find it most useful if you have already learned what to do.

It is best to practice at a time when you know you won't be disturbed. The tape will last between ten and fifteen minutes so you will need at least that length of time set aside. When you do your relaxation exercises in your bed, you will be able to listen to the tape there too. But after a while you will have learned what to do and you will be able to just follow the exercises in your own mind.

The exercises themselves begin now,

Settle yourself down. Lie down with your hands and arms by your sides; have your eyes closed. That's good.

We will start by just thinking about your breathing. Your breathing can help you relax; the more deep and relaxed it is the better you will feel and the more in control you will feel. So begin by taking some slow regular breaths. Do that now. Breathe in fully, fill up your lungs fully; breathe in, hold your breath for a few seconds now, and let go, breathe out… Do that again, another deep breath, filling in your lungs fully when you breathe in, hold it… and relax, breathe out. Continue that in your own time, noticing that each time you breathe in the muscles in your chest tighten up, and as you breathe out there is a sense of letting go. You can think the word 'relax', each time you breathe out. This will remind you that breathing out helps you to relax. It will also help you to use this word to tell yourself to relax whenever you need to. You will find that your body will begin to respond. Breathing slowly, comfortably, regularly, and deeply; thinking the word 'relax' every time you breathe out; enjoying just lying still and having these moments to relax, concentrating on the exercises.

Now, I'd like you to turn your attention to your arms and hands. At the moment just lie them at your sides. I'd like you to create some tension in your hands and arms by pressing your fingers into the palms of your hands and making fists. Do that with both hands now. Fell the tension in your

hands, feel the tension in your fingers and in your wrists, feel the tension in your forearms. Notice what it is like. Keep it going…and now relax. Let those hands flop. Let then do whatever they want to do; just let them relax. Breathing slowly and deeply, you will find that your fingers will just straighten out and flop, and your hands and arms will feel more relaxed. Allow them to sink into the couch or into the bed, just allow your arms to be heavy. Breathing slowly and deeply, thinking the word 'relax' each time you breathe out, and finding that your hands and arms just relax more and more and more. Your arms and your hands are so heavy and rested. It's almost as if you couldn't be bothered moving them. Just because you have let go of the energy and tension that was in the muscles there. Breathing slowly and deeply, both your hands, both your arms, are heavy and rested. Let go of the energy and tension that was in the muscles there, breathing slowly and deeply. Both your hands, both your arms, are heavy and rested and relaxed.

I'd like you to turn attention now to your neck and shoulders. Again we're going to get your neck an shoulders into a state of relaxation following some tension. We're going to introduce. I'd like you to do that by pulling your shoulders up towards your ears. Now, do that; pull your shoulders up towards your ears. Feel the tension across the back of your neck, across the top of your back and in your shoulders. Feel the tension, keep it going not so much that it's sore, but keep it constant. Feel it, and now let it go…relax; go back to breathing slowly and deeply. Let that tension drain away, let it go. Breathe deeply, and as you do so, notice that the tension, almost like a stream, drains away from your neck, across you shoulders, down the upper part of your arms, down the lower part of your arms and out through you fingertips. Draining out and leaving a sense of warmth and relaxation deep in your muscles. Breathing slowly and deeply and allowing that to take place. Just let the tension go. If it doesn't seen to go don't force it, it will go itself. Be confident about that. Just breathe slowly and deeply and allow yourself to be relaxed; remembering to think the word 'relax', each time you breathe out. Using the word 'relax' to focus on the sense of relaxation that you get, using the word 'relax' to remind you of the success your are having in relaxing your body.

I'd like you to concentrate now on your face, and on your jaw, and on your forehead. I'd like you to create some tension in these parts of your body by doing two things together at the same time. These things are to screw up your eyes really tightly and bite your teeth together. Do these things together now. Bite your teeth together; feel the tension in your jaw. Screw up your eyes; feel the tension all around your eyes, in your forehead, in your cheeks, throughout your face, wherever there is tension. Now keep it going…and relax; breathing in through your nose and out through your mouth, slowly

and deeply. Notice how your forehead smoothes out and then your eyelids and your cheeks. Allow your jaw to hang slightly open. Allow your whole head to feel heavy and to sink into the pillow; breathing slowly and deeply. Allow there to be a spread of relaxation across the surface of your face and into all those muscles in your face. Allow your eyelids to feel heavy and comfortable, your jaw and your whole head; breathing slowly and deeply, enjoying the relaxation which you feel in your whole body. Relax each time you breathe out. Relax just that little bit more each time you breathe out.

Concentrating now on your legs and feet, I want you to create some tension here by doing two things at the same time; and these things are to press the backs of your legs downwards and to pull your toes back towards your head. Do these things together now. Create the tension in your legs, press the backs of your legs downwards and pull your toes back towards your head. Feel the tension in your feet, in your toes, in your ankles, in the muscles in your legs. Feel what it is like. Don't overdo it; just notice what it is like…and relax. Breathing slowly and deeply once more; just allow your feet to flop any old way. Allow the muscles to give up their energy, give up their tension. Let it go, breathing slowly and deeply. Notice how your feet just want to flop to the side. Notice how your legs feel heavy as if you couldn't be bothered moving them. They are heavy and comfortable and rested and relaxed. Just that little bit more relaxed each time you breathe out.

Be thinking about your whole body now; supported by the bed, sinking into it, but supported by it. You've let go the tension throughout your body. Your body feels rested, comfortable. Enjoy each deep breath you take. Just use these few moments now to think about any part of your body that that doesn't feel quite so rested and allow the tension to go. It will go. Breathe slowly and deeply; thinking the word 'relax' each time you breathe out. Just let any remaining tension drain away; from your hands, your arms, your neck and your back. They are heavy and rested, comfortable and relaxed, from your face and your eyes, from your forehead; letting the muscles give up their energy. Like a steam of relaxation flowing over your whole body. Let your legs and feet feel relaxed; sinking into the bed. Breathe slowly and deeply.

In a few moments, this tape will finish; but you can continue to relax. You may wish to repeat some of the exercises yourself and that is fine. You may wish to enjoy just continuing as you are. You may with to think on a visualization scene or build pictures in your mind that will help you to relax further. It's up to you, but continue to relax. End of tape.

# Relaxation CD
# Version 2
# Sleep Hygiene Practice Scale

For each of the following behaviors, state the number of days per week (0-7) that you engage in that activity or have that experience. Base your answers on what you would consider an *average* week for yourself. Indicate the number of days or nights in an average week you:

| | Days per week |
|---|---|
| 1. Take a nap. | |
| 2. Go to bed hungry. | |
| 3. Go to bed thirsty. | |
| 4. Smoke more than one packet of 144igarettes per day. | |
| 5. Use sleeping medications (prescribed or over the counter). | |
| 6. Drink beverages containing caffeine (e.g. coffee, tea, cola) within 4 hours of bedtime. | |
| 7. Drink more than 3 ounces of alcohol (e.g. 3 mixed drinks, 2 beers or 3 glasses of wine within two hours of bedtime. | |
| 8. Take medications/drugs with caffeine within 4 hours of bedtime. | |
| 9. Worry as you prepare for bed about your inability to sleep. | |
| 10. Worry during the day about your inability to sleep at night. | |
| 11. Use alcohol to facilitate sleep. | |
| 12. Exercise strenuously within 2 hours of bedtime. | |
| 13. Have your sleep disturbed by light. | |
| 14. Have your sleep disturbed by noise. | |
| 15. Have your sleep disturbed by your bedpartner (put N/A if no partner). | |
| 16. Sleep approximately the same length each night. | |
| 17. Set aside time to relax before bedtime. | |
| 18. Exercise in the afternoon or early evening. | |
| 19. Have a comfortable night-time temperature in your bed/bedroom. | |

The Glasgow Sleep Effort Scale

The following seven statements relate to your night-time sleep pattern *in the past week.*

Please indicate by circling one response how true each statement if for you.

1. I put too much effort into sleeping at night when it should come naturally

   Very much To some extent Not at all

2. I feel I should be able to control my sleep at night

   Very much To some extent Not at all

3. I put off going to bed at night for fear of not being able to sleep

   Very much To some extent Not at all

4. I worry about not sleeping if I am in bed at night and cannot sleep

   Very much To some extent Not at all

5. I am no good at sleeping at nights

   Very much To some extent Not at all

6. I get anxious about sleeping before I go to bed at night

   Very much To some extent Not at all

7. I worry about the long term consequences of not sleep at night

   Very much To some extent Not at all

Appendix B

Human Investigation Committee Approval

WAYNE STATE UNIVERSITY

IRB Administration Office
87 East Canfield, Second Floor
Detroit, Michigan 48201
Phone: (313) 577-1628
FAX: (313) 993-7122
http://irb.wayne.edu

Full AAHRPP Accreditation

## NOTICE OF EXPEDITED APPROVAL

**To:** Cheryl Tannas
Adult Health/Administration
27485 South River Rd

**From:** Dr. Scott Millis S. Millis, PhD 8.8.
Chairperson, Behavioral Institutional Review Board (B3)

**Date:** July 08, 2011

**RE:** IRB #: 066211B3E
Protocol Title: Type 2 Diabetes and Insomnia: Impact on Metabolic Control
Funding Source: Unit: College of Nursing
Protocol #: 1106009847

**Expiration Date:** July 07, 2012

**Risk Level / Category:** Research not involving greater than minimal risk

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The above-referenced protocol and items listed below (if applicable) were **APPROVED** following *Expedited Review* Category ( #2 #7 )* by the Chairperson/designee *for* the Wayne State University Institutional Review Board (B3) for the period of 07/08/2011 through 07/07/2012. This approval does not replace any departmental or other approvals that may be required.

- Revised Protocol Summary Form (received in the IRB Office 07/05/2011)
- Protocol (received in the IRB Office 06/03/2011)
- Behavioral Research Informed Consent (revision dated 05/31/2011)
- Sleep Study Flyer
- Data Collection Tools: Screening Tool, Demographic Questionnaire, Medical History Checklist, Interview Questions, Mini-Mental State, Motivation for Change Index (MFCI), Sleep Behavior Self-Rating Scale, Sleep Environment Checklist, Caffeine Knowledge Quiz, Pre-Sleep Arousal Scale, Dysfunctional Beliefs and Attitudes About Sleep Scale, Relaxation Therapy Session Transcript, Sleep Hygiene Practice Scale, The Glasgow Sleep Effort Scale, Morning & Night Journal, Pittsburgh Sleep Quality Index (PSQI), Physical Activity Scale, and Visual Analog Scale.

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* Federal regulations require that all research be reviewed at least annually. You *may* receive a *"Continuation Renewal Reminder"* approximately two months prior to the expiration date; however, it is the Principal Investigator's responsibility to obtain review and continued approval ***before*** the expiration date. Data collected during a period of lapsed approval is unapproved research and can never be reported or published as research data.

* All changes or amendments to the above-referenced protocol require review and approval by the IRB **BEFORE** implementation.

* Adverse Reactions/Unexpected Events (AR/UE) must be submitted on the appropriate form within the timeframe specified in the IRB Administration Office Policy (http://www.irb.wayne.edu/policies-human-research.php).

**NOTE:**

1. Upon notification of an impending regulatory site visit, hold notification, and/or external audit the IRB Administration Office must be contacted immediately.
2. Forms should be downloaded from the IRB website at **each** use.

*Based on the Expedited Review List, revised November 1998

# REFERENCES

Aadahl, M. & Jorgensen, T. (2003). Validation of a new self-report instrument for measuring physical activity. *Medicine and Science in Sports and Exercise. 3*5(7) 1196-1202.

American Diabetes Association. Retrieved from: http://www.diabetes.org

Ayes, N.T., White, D.P., Al-Delaimy, W.K., Manson, J.E., Stampfer, M.J., Speizer, F.E., . . . & Hu, F.B. (2003). A prospective study of self-reported sleep duration and incident diabetes in women. *Diabetes Care. 26*(2), 380-384.

Bastien, C.H., Vallieres, A., & Morin, C.M. (2001). Validation of the insomnia severity index as an outcome measure for insomnia research. *Sleep Medicine. 2*(4), 297-307.

Becker, M.H. (ed) (1974). The health belief model and personal health behavior. *Health Education Monograph. 2*, 324-508.

Bulecheck, G.M., & McCloskey, J.C. (1992). *Nursing Interventions: Essential Nursing Treatments(2nd ed.).* W.B. Saunders Company: Philadelphia.

Buysee, D.J., Reynolds, C.F., Monk, T.H., Berman, S.R., & Kupfer D.J. (1989). The Pittsburgh Sleep Quality Index: A new instrument for psychiatric practice and Research. *Psychiatric Research. 28,* 193-213.

Campbell, D.T. & Stanley, J.C. (1963). *Experimental and Quasi-Experimental Designs for Research*. Houghton Mifflin:Boston.

Cappuccio, F.P., D'Elia, L., Strazzullo, P. & Miller, M.A. (2010). Quantity of quality of sleep and incidence of type 2 diabetes: a systematic review and meta-analysis. *Diabetes Care. 33*(2), 414-420.

Chasens, E.R., Sereika, S.M., Weaver, T.E., & Umlauf, M.G. (2007). Daytime sleepiness, exercise, and physical function in older adults. *Journal of Sleep Research. 16*(1). 60-65.

Childs, B.P. Cypress, M., & Spollett, G. (Eds.), (2005). Complete Nurse's Guide to Diabetes Care. American Diabetes Association: Alexandria.

Dautovich, N. D., McCrae, C. S., Rowe, M. (2008). Subjective and objective napping in older adults: Are evening naps "bad" for nighttime sleep? *Journal of the Geriatric Society*. *56*, 1681-1686.

Epsie, C.A., Fleming, L., Cassidy, J., Samuel, L., Taylor, L.M., White, C.A., . . . Paul, J. (2008). Randomized controlled clinical effectiveness trial of cognitive behavior therapy compared with treatment as usual for persistent insomnia in patients with cancer. *Journal of Clinical Oncology*. *26*(28). 451-4658.

Epsie, C., MacMahon, K. M. A., Kelly, H., Broomfield, N.M., Douglas, N.J., Engleman, H.M., . . . Wilson, P. (2007). Randomized clinical effectiveness trial of nurse-administered small-group cognitive behavior therapy for persistent insomnia in general practice. *Sleep*. *30*(5), 574-584.

Everson, C.A., Bergmann, B.M., & Rechtschaffen, A. (1998). Sleep deprivation in the rat: III. Total sleep deprivation. *Sleep. 12*(1), 13-21.

Faul, F., Erdfelder, E., Lang, A.G., & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavioral Research Methods*, *39*, 175-191.

Flint, A., Raben, A., Blundell, J.E., & Astrup, A. (2000). Reproducibility, power and validity of visual analogue scales in assessment of appetite sensations in Single test meal studies. *International Journal of Obesity*. *24*, 38-48.

Folstein, M.F., Folstein, S.E., & McHugh, P.R. (1975). "Mini-mental state": a practical method for grading the cognitive state of patients for the clinician. *Journal of Psychiatric Research*. *12*, 189-198.

Gangwisch, J.E., Heymsfield, S.B., Boden-Alvala, B., Buijs, R.M., Kreier, F., Pickering, T.G., . . . Malaspina, D. (2007). Sleep duration as a risk factor for diabetes incidence in a large U.S. sample. *Sleep. 30*(12), 1667-1673.

Hassaballa, H.A., Tulaimat, A., Herdegen, J.J. & Mokhlesi, B. (2005). The effect of continuous positive airway pressure on glucose control in diabetic patients with severe obstructive sleep apnea. *Sleep and Breathing. 9*(4), 176-180.

Janz, N.K. & Becker, M.H. (1984). The health belief model: a decade later. *Health Education Quarterly. 11*(1), 1-47.

Kamel, N.S. & Gammack, J.K. (2006). Insomnia in the elderly: cause, approach, and treatment. *American Journal of Medicine. 119*(6), 463-469.

Kojima, M., Wakai, K., Kawanmura, T. Tamakoshi, A., Aoki, R., Lin, Y., . . . Ohno, Y. (2000). Sleep patterns and total mortality: a 12 year follow-up study in Japan. *Journal of Epidemiology*. *10*, 87-93.

Kripke, D.F., Garfinkel, L., Wingard, D.L., Klauber, M.R. & Marier, M.R. (2002). Mortality associated with sleep duration and insomnia. *Archive General Psychiatry. 59*(2), 131-136.

Knutson, K.L., Ryden, A.M., Mander, B.A., & VanCauter, E. (2006). Role of sleep Duration and quality in the risk and severity of type 2 diabetes mellitus. *Archives of Internal Medicine. 166*, 1768-1774.

Lichstein, K.L. & Morin, C.M. (Eds). (2000). *Treatment of Late-life Insomnia*. Thousand Oaks: Sage.

Lustberg, L. & Reynolds, C.F. (2000). Depression and insomnia: questions of cause and effect. *Sleep Medicine Review. 4*(3), 253-262.

Mallon, L., Broman, J.E. & Hetter, J. (2002). Sleep complaints predict coronary artery disease mortality in males: a 12-year follow-up study of a middle-aged Swedish population. *Journal of Internal Medicine. 251*(3), 207-216.

Michigan Department of Community Health.(2009). Michigan diabetes action plan. *Diabetes Partners in Action Coalition.*

Morgenthaler, T., Alessi, C., Friedman, L., Owens, J., Kapur, V., Boehlecke, B., . . . Swick, T.J., (2007). Practice parameters for the use of actigraphy in the assessment of sleep and sleep disorders: an update for 2007. *Sleep*. *30*(4), 519-529.

Morgenthaler, T., Kramer, M., Alessi, C., Friedman, L., Boehlecke, B., Brown, . . . American Academy of Sleep Medicine (2006). Practice parameters for the psychological and behavioral treatment of insomnia: an update. An American academy of sleep medicine report. *Sleep*. *29*(11), 1415-1419.

Morin, C.M., Bootzin, R.R., Buysse, D.J., Edinger, J.D., Espie, C.A., Lichstein, K.L. (2006). Psychological and behavioral treatment of insomnia: update of the recent evidence (1998-2004). *Sleep*. *29*(11), 1398-1414.

Morin, C.M. & Epsie, C.A. (2003). *Insomnia: A Clinical Guide to Assessment and Treatment*. Kluwer Academic/Plenum: New York.

National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics fact sheet: general information and national estimates on diabetes in the United States, 2002. Bethesda, MD: Department of Health and Human Services,

National Institutes of Health, 2003. Rev. ed. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health.

Nilsson, P.M., Nilsson, J.A., Hedblad, B., & Berglund, G. (2001). Sleep disturbance in association with elevated pulse rate for prediction of mortality—consequences of mental strain? *Journal of Internal Medicine. 250*(6), 521-529.

Pagel, J.F. (2005). Medications and their effect on sleep. *Primary Care. 32*(2), 491-509.

Perlis, M.L., Jungquist, C., Smith, M.T. (2005). *Cognitive Behavioral Treatment of Insomnia: A Session by Session Guide*. Springer: New York.

Punjabi, N.M. & Polotsky, V.Y. (2005). Disorders of glucose metabolism in sleep apnea. *Journal of Applied Physiology. 99*(5), 1998-2007.

Rosenstock, I.M. (1985). Understanding and enhancing patient compliance with diabetic regimens. *Diabetes Care. 8*(6), 610-616.

Roth, T. (2009). Comorbid insomnia: current directions and future challenges. *American Journal of Managed Care.* Supplement, S6-S13.

Selvin E., Marinopoulos, S., Berkenblit G., Rami, T., Brancati, F.L., Powe, M.R. & Goldin, S.H. (2004). Meta-analysis: glycosylated hemoglobin and cardiovascular disease in diabetes mellitus. *Annals of Internal Medicine. 141*(6), 421-431.

Spiegel, K., Leproult, R. & Van Cauter, E. (1999). Impact of sleep debt on metabolic and endocrine function. *Lancet. 354*,(9188), 1435-1439.

Spiegel, K., Tasali, E., Penev, P & Van Cauter, E. (2004). Brief communication: Sleep curtailment in healthy young men is associated with decreased leptin levels, elevated ghrelin levels, and increased hunger and appetite. *Annals of Internal Medicine. 141*(11), 846-850.

Stamatakis, K.A. & Punjabi, N.M. (2009). Effects of sleep fragmentation on glucose metabolism in normal subjects. *Chest.137*(1), 95-101.

Stratton, I.M., Adler, A.I., Matthews, D.R., Manley, S.E., Cull, C.A., Hadden, D., . . . Holman, R.R. (2000). Association of glycemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): Prospective observational study. *British Medical Journal. 321*(7258), 405-412.

Strecher, V.J., DeVellis, B.M., Becker M.H. & Rosenstock, I.M. (1986). The role of self-efficacy in achieving health behavior change. *Health Education Quarterly. 13*(1), 73-92.

*Synchron Systems Chemistry Information Sheet*. (2007). Fullerton, CA: Beckman Coulter, Inc.

Trento, M., Basile, M., Borgo, E., Grassi, G., Scuntero, P., Trinetta, A., . . . Porta, M. (2008). A randomized controlled clinical trial of nurse, dietician-and pedagogist-led Group Care for the management of Type 2 diabetes. *Journal of Edocrinology Investigation. 31*(11), 1038-1042.

Vigg, A., Vigg, A., & Vigg, A. (2003). Sleep in type 2 diabetes. *Journal Association Physicians India*. *51*, 479-481.

Wolkove, N., Elkholy, O., Baltzan, M., & Palayew, M. (2007). Sleep and aging: 1. Sleep disorders commonly found in older people. *Canadian Medical Association Journal. 176*(9), 1299-1304.

Wu, J.C., Gillin, J.C., Buchsbaum, M.S., Schachat, C., Darnall, D.A., Keator, D.B., . . . Bunney, W.E. (2007). Sleep deprivation PET correlations of hamilton symptom improvement ratings with changes in relative glucose metabolism in patients with depression. *Journal of Affective Disorders. 107*(1-3), 181-186.

## ABSTRACT

**TYPE 2 DIABETES AND INSOMNIA: IMPACT ON METABOLIC CONTROL**

by

**CHERYL LEE TANNAS**

December 2012

**Advisor**: Dr. Jean Davis

**Major**: Nursing

**Degree** Doctor of Philosophy

Diabetes is one of the most serious health challenges in the United States, affecting nearly 21 million Americans. The goal of diabetes management is to maintain the blood glucose close to normal to prevent diabetic complications and therefore extending life expectancy and improving quality of life. Research now indicates a relationship of the quantity and quality of sleep to glycemic control in type 2 diabetics. No research on the impact of insomnia on diabetes prevention and/or management was found in the literature. The purpose of this 11-week intervention study was to examine the effects of participation in Cognitive Behavioral Therapy for Insomnia (CBTI) on the sleep quality, quantity and insomnia severity of aging women (50-74 years) with type 2 diabetes for at least one year and insomnia for a minimum of six months. The secondary purpose was to determine the relationship among changes in sleep quality and quantity, metabolic control and diabetes self-management behaviors. Nine participants aged 56 to 69 completed the orientation, seven week intervention and 3-week follow-up. The global sleep quality scores, measured by the Pittsburgh Sleep Quality Index, demonstrated an improvement in sleep quality. Insomnia severity, as measured by the Insomnia Severity Index, was found to decrease insomnia severity from the moderate level insomnia group

to the sub threshold insomnia group. Although sleep quantity, as measured by the Actiwatch 2, decreased during the intervention as a result of sleep restriction the amount of sleep had begun to increase at posttest. Using the Physical Activity Scale, the mean number of minutes in seven of the eight measures increased from pretest to 3-week follow-up. Using the Analog Scale for Appetite, appetite for sweets was found to significantly decrease as the sleep quality improved. Eight of the nine participants were found to have lower A1C levels at the 3-week follow-up. In summary, CBTI was found to improve self-reported sleep quality. As a result, physical activity increased and appetite decreased, especially for sweet foods. Hemoglobin A1C levels decreased in eight of the nine participants. Improved insomnia may improve metabolic control and improve diabetes self-management behaviors. Additional research is needed.

# AUTOBIOGRAPHICAL STATEMENT

## CHERYL LEE TANNAS

EDUCATION:
PhD: Wayne State University, 2012
MSN: Oakland University, 1996
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Diploma, Henry Ford Hospital School of Nursing, 1967

REGISTRATION:
License to Practice as a Registered Nurse -
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CERTIFICATION:
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WORK EXPERIENCE

2002-2012
Diabetes Self-Management Consultant, Department of Medical Education, University of Michigan Medical School. Responsibilities have been those needed to conduct diabetes care research studies, including recruitment of study participants, implementation of interventions and data collection. Interventions have included a three-year diabetes case study project and an education/group/phone call support study.

1995-2002
Director, Detroit Diabetes Empowerment Project, Detroit Health Department. Responsibilities include the planning, development and implementation of a data-based empowerment program to improve diabetes care given to the underserved and minority population served by the five clinics in the Family Primary Care Network.

ORGANIZATIONS

Member of the American Association of Diabetes Educators.
Member of the Michigan Organization of Diabetes Educators.
Member of the American Diabetes Association (ADA).
Member of Sigma Theta Tau.
Member of the Sleep Research Society.
Member of the Racial and Ethnic Approaches to Community Health Detroit Partnership (REACH) Steering Committee.
Member of the Michigan Diabetes Partners in Action Coalition (DPAC).
Member of the DPAC Data, Research and Evaluation Workgroup.