

ABSTRACT

SLEEP QUALITY, SLEEP DURATION, AND WEIGHT GAIN IN SYMPTOMATIC MENOPAUSAL WOMEN

By Dawn M. Martin

Relationships between hormonal changes, short sleep duration, and weight gain have been demonstrated, yet few studies have examined these variables together in menopausal women. The purpose of this study was to explore the possible relationships between weight gain, sleep duration, and sleep quality in symptomatic menopausal women; and to determine if there was a difference in weight gain between good and poor quality sleepers.

Meleis' Theory of Transitions was utilized as the theoretical framework. A retrospective descriptive design using a convenience sample of 59 women from three multi-specialty clinics in Northeastern Wisconsin was employed. Subjects were identified by International Classification of Disease (ICD)-9 code 627.2, symptomatic menopause, and were mailed a survey packet, including a demographic questionnaire, with self-report of height and weight, and the Pittsburgh Sleep Quality Index (PSQI) questionnaire.

Pearson's r correlation was used to explore relationships between weight gain, sleep duration and sleep quality. The independent t -test was used to compare differences in weight gain over the previous 6 and 12 months between good and poor quality sleepers. Within the sample, the mean global PSQI score was 7.8 (SD = 4.1) indicating poor sleep quality. The average BMI classification was overweight ($M = 27.7$, $SD = 6.7$). Greater than one-third of women reported sleeping 6 hours or less per night. No significant differences in weight gain or BMI were found between the groups. No significant relationships between weight gain and sleep quality or sleep duration were found. Study replication with an adequately powered sample is warranted.

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IN SYMPTOMATIC MENOPAUSAL WOMEN

by

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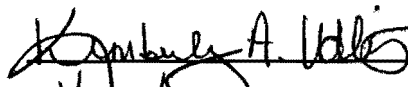
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This clinical paper is dedicated to family. To my husband, Andy, who kept the boat afloat while I pursued my dream. To my parents, who encouraged me to become a nurse from the very beginning. To the loving memory of my sister, Lynn, whom I wish could have been here to help guide me and keep me grounded. To my Aunt Phyllis, who prayed for me and sent me angels for support. To Mike, Megan, and Madge – thank you for believing in me and for constantly reassuring me that I could do this. I could not have accomplished this without all of you.

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CHAPTER 1

INTRODUCTION

The amount of sleep required for optimal health is unclear, yet anyone who has experienced a sleepless night understands that there is a general sense of diminished well-being the next day. Two parallel trends are becoming more common in the United States over the past decade, increasing body mass index (BMI) and a decline in the average sleep time (Gangwisch, Malaspina, Boden-Albala, & Heymsfield, 2005). The estimated prevalence of obese (BMI greater than or equal to 30) adults (age 20 and older) reached 32.9% by 2006 (American Heart Association, 2010). Obesity contributed to more than 300,000 premature deaths and \$147 billion in healthcare costs in 2008, representing 10% of total U.S. health expenditures for that year (AHA, 2010). The sequelae of obesity are a major healthcare concern. Overweight and obese individuals are at increased risk for cardiovascular disease (Grundy, 2004), dyslipidemia, metabolic syndrome (Alberti et al., 2009), diabetes, various cancers (Field et al., 2001), hypertension (HTN), stroke, osteoarthritis, sleep apnea, asthma, depression, and social discrimination (Stein & Colditz, 2004); all of which are associated with increased mortality (Alberti et al., 2009; Field et al., 2001; Grundy, 2004; National Heart Lung and Blood Institute [NHLBI], 1998; Stein & Colditz, 2004).

Obesity affects women more than men (Milewicz & Jedrzejuk, 2007). The prevalence of obesity in women increases with age and is associated with transition through menopause (Milewicz & Jedrzejuk, 2007). Thurston et.al (2009) reported that body fat gains were associated with increased hot flashes during the menopausal transition. Sternfeld et al. (2004) explored the premise that women in their menopausal

transition experience gains in weight, fat mass, and central fat deposition. Their study of midlife women showed significant increases in mean weight and waist circumference with decreased activity levels over 3 years (Sternfeld et al., 2004). Sternfeld, Bhat, Wang, Sharp, and Quesenberry (2005) reported an inverse association of lean mass with menopausal status but no association with age, suggesting that menopausal status, rather than age, is the more important influence on fat mass and changes in body weight.

Evidence of a link between sleep duration and obesity, measured by an increased BMI, has been demonstrated in the literature (Kohatsu et al., 2006, Taheri, Lin, Austin, Young, & Mignot, 2004; Vorona et al., 2005). Several researchers have associated short sleep duration with obesity and/or increased risk factors for obesity (Buscemi, Kumar, Nugent & Nugent, 2007; Gangwisch et al., 2005; Hasler et al., 2004; Kawada, 2002; Singh, Drake, Roehrs, Hudgel, & Roth, 2005; Stamatakis & Brownson, 2007). Furthermore, short sleep duration has been shown to decrease serum leptin and increase serum ghrelin, which compromises insulin sensitivity and increases BMI, possibly explaining the biological mechanism linking short sleep duration and obesity (Taheri et al., 2004).

Women are of particular interest in the relationships between obesity, weight gain, sleep duration, and sleep quality because of the normal female hormonal transition to menopause that occurs in all women (Schuiling & Likis, 2006). Sleep problems occur in 40% to 50% of women going through the menopausal transition (Soares, 2005). These sleep problems may be directly associated with hot flashes, which occur in up to 70% of perimenopausal or early post menopausal women (Soares, 2005). Although hot flashes vary widely in intensity and frequency, nocturnal hot flashes can cause repeated

nocturnal awakenings (Ohayon, 2006), and as a result, symptomatic menopausal women have reported reduced sleep duration and poor sleep quality (Ohayon, 2006; Soares, 2005). Additionally, women are reported to be at an increased risk of obesity if they sleep 5 hours or less per night, or if they sleep 9 hours or more regardless of pre-existing illnesses, such as coronary artery disease (CAD), cancer, HTN, diabetes, obesity, or stroke (Buscemi et al., 2007; Gangwisch et al., 2005; Singh et al., 2005; Taheri et al., 2004).

The phenomenon of shorter sleep duration and poorer sleep quality among women during their menopausal transition is further supported by the Study of Women's Health Across the Nation (SWAN). The SWAN study began in 1994 and was designed to examine the biological, physiological, psychological, and social health of women during their middle years (National Institute on Aging [NIA], 2009). As a result, multiple ancillary studies from the SWAN cohort are now being published. Kravitz et al. (2005) confirmed that women who enter their menopausal transition report trouble sleeping and this was associated with hormone level fluctuations. In 2008, Pien, Samuel, Freeman, Lin, and DeBlasis concluded that hormone levels were predictive of sleep quality. This supported the theory that women who experienced perimenopausal symptoms are also likely to have sleep problems during their menopausal transition due to hormone fluctuations.

Kravitz et al. (2008) demonstrated that self-reported sleep disturbance was associated with progression through the menopausal transition. This was correlated with bleeding status categories, vasomotor symptoms, and changing follicle stimulating hormone (FSH) levels. Sowers et al. (2008) concluded that a faster and greater rate of change in FSH levels was associated with poorer self-reported sleep quality. A cross-

sectional study of menopausal women from the Wisconsin Sleep Cohort Study (Young, Finn, Austin & Peterson, 2003) showed that menopause increases the risk, in a linear manner, throughout the menopausal transition for sleep disordered breathing, a condition of repeated breathing pauses during sleep. The evidence from these studies clearly suggests a strong association between sleep disturbance, poorer sleep quality, and shorter sleep duration among women during their menopausal transition.

Gaps in the Literature

There is a dearth of information within the literature exploring the possible relationships between sleep quality, sleep duration, and weight gain in symptomatic menopausal women. Multiple studies have demonstrated that women tend to gain weight during the menopausal transition (Milewicz & Jedrzejuk, 2007; Sowers et al., 2007; Sternfeld et al., 2004; Sternfeld et al., 2005; Thurston et al., 2009), that sleep disturbances (hormone fluctuations and poor sleep quality) occur during the menopausal transition (Kravitz et al., 2005; Kravitz et al., 2008; Ohayon, 2006; Pien et al., 2008; Sowers et al., 2007; Sowers et al., 2008; Thurston et al., 2009; Young, Finn et al., 2003; Young, Rabago, Zgierska, Austin, & Finn, 2003), and that short sleep duration is related to increases in weight (Buscemi et al., 2007; Gangwisch et al., 2005; Hasler et al., 2004; Kohatsu et al., 2006; Singh et al., 2005; Taheri et al., 2004; Vorona et al., 2005). Yet there is a lack of studies that examined sleep quality, sleep duration, and weight gain together in menopausal women. Additionally, no interventional studies were identified exploring the possible causative role sleep disturbances may have in the common menopause associated weight gains in women. Thus, further exploration is warranted to expand our knowledge in this area of women's health.

Significance for Advanced Nursing Practice

Menopause is a normal life transition process that occurs in all women at some point of life (O`Bryant, Palav, & McCaffery, 2003; Schuiling & Likis, 2006). Recent studies suggest that short sleep duration is associated with weight gain and higher BMI (Buscemi et al., 2007; Gangwisch et al., 2005; Kohatsu et al., 2006; Milewicz & Jedrzejuk, 2007; Singh et al., 2005; Taheri et al., 2004; Vorona, et al., 2005). Also short sleep duration and weight gain have become increasing common trends among menopausal women (Milewicz & Jedrzejuk, 2007; Shin et al., 2005; Soares, 2005). Additional literature indicates that menopausal women commonly report weight gain (Hatcher et al., 2007) and sleep disturbances (Avis, Brockwell, & Colvin, 2005; O`Bryant et al., 2003; Ohayon, 2006) as being problematic during their normal female hormonal transition. Traditionally, decreased physical activity, increased daily caloric intake, hormonal changes, and hot flashes have been viewed as the influential factors for these menopausal problems (Schuiling & Likis, 2006). However, a recent growing body of evidence suggests that short sleep duration is associated with weight gain and higher BMI (Buscemi et al, 2007; Gangwisch et al., 2005; Kohatsu et al., 2006; Milewicz & Jedrzejuk, 2007; Singh et al., 2005; Taheri et al., 2004; Vorona, et al., 2005). The latest literature indicates that weights are not being converted to BMI consistently, which may be why healthcare providers are missing the connection between sleep symptoms and weight gain (Kirk et al., 2009).

Short sleep duration has been associated with an increased risk of HTN, diabetes, stroke, and an increase in BMI in children and adults (Park et al., 2009). Obesity and increased BMI have been linked to an increased risk for cardiovascular

disease, diabetes, HTN, arthritis, and cancer (Hasler et al., 2004). Given the limited effectiveness of treatment for weight problems, the identification of potential modifiable risk factors (i.e., sleep duration and sleep quality) for increased body weight may offer healthcare providers intervention options to combat weight gain and obesity in menopausal women (Hasler et al., 2004).

Statement of Problem

Menopausal women commonly report weight gain (Hatcher et.al, 2007) and sleep disturbances (Avis, Brockwell, & Colvin, 2005; O'Bryant et al., 2003; Ohayon, 2006) as being problematic during their normal female hormonal transition. Traditionally, decreased physical activity, increased daily caloric intake, hormonal fluctuations, and hot flashes have been viewed as causative factors for these menopausal problems (Schuiling & Likis, 2006). However, a recent growing body of evidence suggests that short sleep duration is associated with weight gain and higher BMI (Buscemi et al., 2007; Gangwisch et al., 2005; Kohatsu et al., 2006; Milewicz & Jedrzejuk, 2007; Singh et al., 2005; Taheri et.al., 2004; Vorona et.al., 2005). Since menopause has been linked with poor sleep and increased weight, it is prudent to explore the possible relationship between sleep duration, sleep quality, and weight gain in symptomatic menopausal women.

Purpose of the Study

The purpose of this study was to determine if there was a difference in the amount of weight gain between symptomatic menopausal women who are poor quality sleepers and those who are good quality sleepers, and to explore the possible relationship between weight gain, sleep duration, and sleep quality in symptomatic menopausal women.

Research Questions

1. What is the difference in weight gain and BMI between symptomatic menopausal women who have poor sleep quality and those who have good sleep quality?
2. What is the relationship between weight gain and sleep duration in symptomatic menopausal women?
3. What is the relationship between weight gain and sleep quality in symptomatic menopausal women?

Definition of Terms

Conceptual Definitions

Weight gain: Increase in body weight over existing weight (MEDLINE, 2009).

Body mass index (BMI): The BMI describes weight for height and correlates with body fat content. The BMI is used to assess overweight and obesity and to monitor changes in weight. The BMI is calculated as weight in kilograms divided by height in meters squared or estimated using pounds and inches: [weight (pounds) divided by height (inches) squared] x 703 (National Heart Lung and Blood Institute, 1998).

Symptomatic menopause: The normal cessation of female menstruation occurring in late middle life that includes symptoms such as flushing, sleeplessness, headache, and lack of concentration associated with the menopause (U.S. Department of Health and Human Services, 2010).

Sleep duration: Self reported total sleep time (TST) (Buscemi et al., 2007; Kohatsu et al., 2006; Singh et al., 2005; Taher et al., 2004; Vorona et al., 2005).

Sleep quality: A complex phenomenon that includes sleep duration, number of arousals, and restfulness of sleep, which is objective and may vary between individuals (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989).

Operational Definitions

Weight gain: For the purpose of this study, weight gain represented the total increase of pounds in body weight obtained by self-report of weight in pounds currently, at 6 months previous, and at 12 months previous from each study subject on their demographics questionnaire.

Body mass index (BMI): BMI was calculated using the equation: [weight (pounds) divided by height (inches) squared] x 703.

Sleep duration: Sleep duration refers to the total number of actual sleep hours as documented by each study subject on their Pittsburgh Quality Sleep Index (PSQI) questionnaire.

Sleep quality: Sleep quality refers to self-rated overall sleep quality reported on the PSQI questionnaire for each study subject. Poor quality sleep was determined by a global score of greater than five on the PQSI (Buysse et al., 1989); while good quality sleep was determined by a global score of five or less.

Symptomatic menopause: Any woman with an international classification of disease (ICD -9 code) of symptomatic menopause (627.2) documented in the medical record and seen by their healthcare provider within the previous 6 to 12 months.

Assumptions

1. Obesity is a concern for menopausal women.
2. Menopause is a normal life transition for all women.
3. Sleep deprivation is a problem for menopausal women.
4. Every individual has a perception of health and makes lifestyle decisions based on their perceptions.
5. Weight loss and sleep disturbances are troublesome for menopausal women.
6. Sleep disturbance symptoms are likely to bring women to their healthcare provider.
7. Menopausal women will experience weight gain.
8. Twelve months is an adequate length of time to evaluate weight change during menopause.
9. Twelve months is an adequate length of time to evaluate sleep disturbances during menopause.
10. Transitions are often multiple, complex, and simultaneous.
11. Transitions have profound health related effects on patients.
12. Transitions are of interest to Advances Practice Nurses (APN) because of their health consequences.
13. Describing transitions may develop knowledge about the transition.

14. Nursing interventions are aimed at creating conditions conducive to a health transition.
15. Transitions may have implications for nursing practice by identifying vulnerable and critical points during transitions for preventive work.

Chapter Summary

Menopause is a normal transition process that occurs in all women at some point of life (Schuiling & Likis, 2006). Recent studies report evidence suggesting that short sleep duration is associated with weight gain and higher BMI (Buscemi et al., 2007; Gangswisch et al., 2005; Kohatsu et al., 2006; Milewicz & Jedrzejuk, 2007; Singh et al., 2005; Taheri et al., 2004; Vorona et al., 2005). Poor sleep quality and weight gain are two increasing common trends among menopausal women (Milewicz & Jedrzejuk, 2007; Shin et al., 2005; Soares, 2005).

Short sleep duration has been associated with an increased risk of HTN, diabetes, stroke, and an increase in BMI in children and adults (Park et al., 2009). Short sleep duration has also been shown to decrease serum leptin and increase serum ghrelin, which compromises insulin sensitivity and increases BMI (Taheri et al., 2004), which may be a biological mechanism linking short sleep duration and obesity. Obesity has been linked to an increased risk for cardiovascular disease, diabetes, HTN, arthritis, and cancer (Hasler et al., 2004). Given the limited effectiveness of treatment for weight problems, the identification of potential modifiable risk factors, such as sleep duration and sleep quality, could lead to successful approaches to combat obesity (Hasler et al., 2004).

This study was designed to explore the possible differences in weight gain between symptomatic menopausal women who have poor sleep quality and those who do not; and to explore possible relationships between sleep duration, sleep quality, and weight gain. In this chapter, the background of the study, the significance to nursing, the problem statement, purpose of the study, the research question, conceptual definitions, operational definitions, and assumptions were presented.

CHAPTER II

THEORETICAL FRAMEWORK AND LITERATURE REVIEW

Introduction

Chapter II discusses the theoretical framework guiding this research. An image of the theoretical model is included to illustrate the main theoretical concepts. A case study follows the theoretical framework discussion to describe how the theoretical model may be applied in practice for the APN. Finally, a thorough review of the literature regarding menopause, obesity, sleep quality, and sleep duration is provided.

Theoretical Framework

Throughout the human lifespan, one can expect that change will occur. Changes in health status, relationships, environment, and aging of the body create a process of transition. Transition exposes vulnerability within individuals to risks that may affect health and well-being. Illustration of the transition process aids identification of these risks and enhances understanding of the transition process (Meleis, Sawyer, Im, Messias, & Schumacher, 2000).

The Theory of Transitions

A middle-range theory (Meleis et al., 2000) uses transition as a central concept in nursing to illustrate and contemplate the multiple components of any transition (Figure 1). The four main concepts of the framework include: (a) nature of transitions, (b) transition conditions (facilitators and inhibitors), (c) patterns of response, and (d) nursing therapeutics. Each concept is comprised of components that facilitate explanation of the concept as it relates to the transition being described.

Nature of Transitions

The nature of transitions concept describes the types and patterns of transitions that APN encounter when working with patients and families (Meleis et al., 2000). The authors described four types of transition: developmental, situational, health/illness, and organizational. Six potential patterns that may be found in any transition are: single, multiple, sequential, simultaneous, related, and unrelated (Figure 1). The theory implies that transitions are often multiple, complex, and simultaneous, which highlights the importance of assessment by the APN to be aware of and acknowledge all transitions in an individual's or family's life (Meleis et al., 2000). Application of this to the proposed study implies that menopause is a multiple and simultaneous transition. The APN must view menopause as a developmental transition, because it is part of the life cycle transition brought about through aging and a health/illness transition due to the experiences of sleep deprivation and weight gain, which have implications for health risks both now and later in life. Additionally, this would suggest that the menopausal woman who has concern about weight gain and sleep deprivation is undergoing another simultaneous patterned transition.

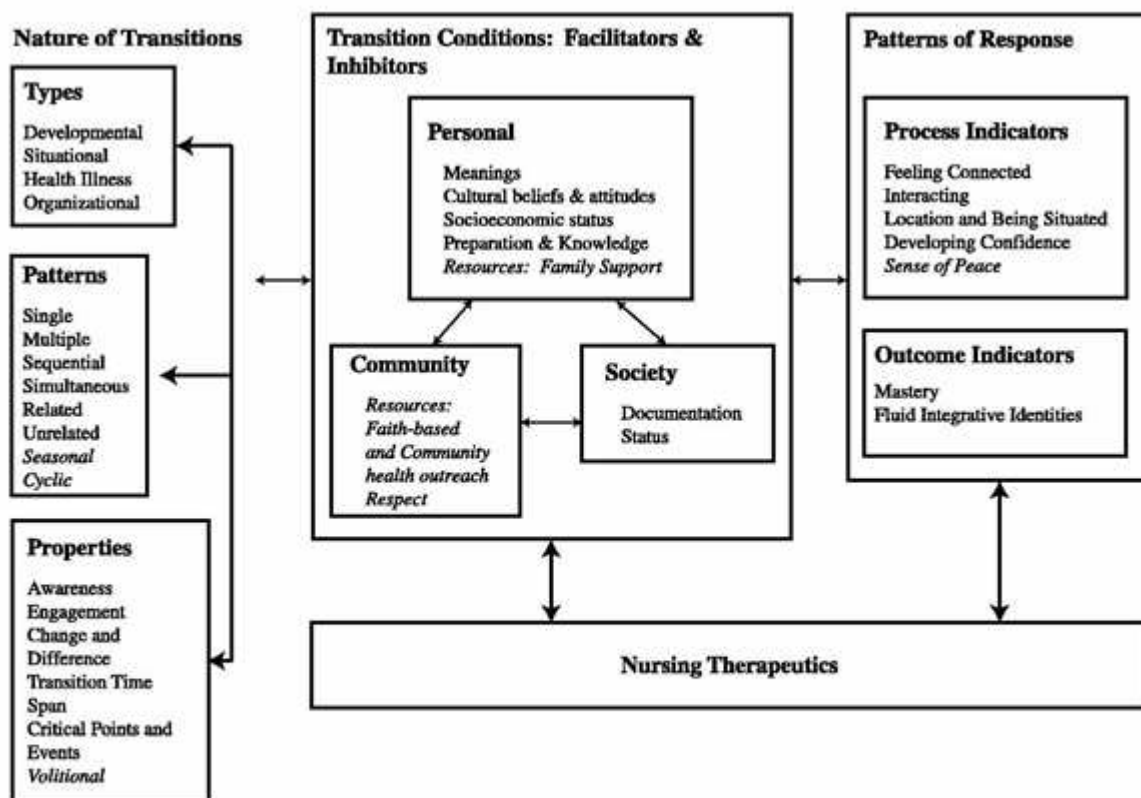


Figure 1. Transitions: A middle-range theory (Meleis et al., 2000).

Universal properties of transition include awareness, engagement, change and difference, transition time span, and critical points and events (Meleis et al., 2000). Awareness describes the idea that an individual suspects that a transition is taking place; engagement describes the individual's involvement in the transition process; change and difference describes the effect and meaning of the transition; time span characterizes the transition flow and movement over time; and critical points and events describes that when reflecting on the transition, there is often an identifiable marker associated with the critical point or event in the transition, and that this is the time when symptoms related to the transition may occur (Meleis et al.). Application of this to the proposed study suggests that women who are not aware that they are menopausal may not identify the status of their transition and are vulnerable to health risks, both now and in their future, which may affect their quality of life. Thus, it is only when the individual experiences the symptoms of weight gain, or the effect of sleep deprivation or other symptoms that are associated with the menopausal transition, that they seek medical advice and guidance from the APN. This critical point is the period of heightened vulnerability.

Transition Conditions: Facilitators and Inhibitors

The concept of transition conditions, facilitators and inhibitors, demonstrates that the components of personal, community, and societal conditions influence achievement of a healthy transition (Meleis et al., 2000). Personal conditions include meanings, cultural beliefs and attitudes, socioeconomic status, and preparation and knowledge. Meanings of transition are dependent on whether the individual experiences a concern during the transition and the impact of the concern related to the transition. Cultural beliefs and attitudes stigmatize the transition, socioeconomic status has an impact on

psychological symptoms, and preparation and knowledge about the transition facilitate management of the transition, where as lack of knowledge inhibits transition progress and increases vulnerability. The components of community and societal conditions expand on the personal component to include resources and trends of stereotyping, respectively. Available resources for advice and support during the transition support a healthy transition; where as negative stereotyping, negative or insufficient advice, and viewing the menopausal transition without the essence of feminization is not adequate (Meleis et al., 2000). Application of this to the proposed study suggests that menopausal women who are knowledgeable about the process and events of menopause may have more or less concerns during this time of transition based on ethnicity, socioeconomic status, and how each individual manages her symptoms in relationship to her other activities of daily life. Additionally, the access she has to an APN for information, her socialization network, and the demands of her position of caretaker within the family matrix will also facilitate and/or inhibit her menopausal transition and have an impact on experience of symptoms, such as weight gain and sleep deprivation.

Patterns of Response

Patterns of response process indicators that characterize healthy transitions include feeling connected, interacting, being situated, and developing confidence and coping. Meleis et al. (2000) indicated that because transitions occur over time, accurate identification of process indicators that facilitate healthy transition or enhance vulnerability and risk promotes early assessment and nursing intervention for healthy outcomes. Meleis et al. have also indicated that feeling connected involves continuing to nurture relationships old and new; interacting brings focus to the transition response

behaviors and gives meaning to the transition itself; location and being situated allows individuals to compare where they are in the transition, in terms of time and space; and developing confidence and coping is evident by the individual's level of understanding of the diagnosis, use of resources, and management strategy of the transition. Application of this to the proposed study places emphasis on the importance of females discussing menopausal experiences with other females and getting the facts from their healthcare providers about what to expect from menopause, so they can develop a management plan together that includes adequate sleep, sleep hygiene, and weight management.

Patterns of response outcome indicators include mastery and fluid integrative identities (Meleis et al., 2000). Mastery is demonstrated by the knowledge, skills, and behaviors developed by the individual during the transition to successfully manage their situation or environment; and mastery marks the healthy completion of the transition (Meleis et al., 2000). The outcome indicator of fluid integrative identities conceptualizes the reformulation of self as a flowing or fluid integrated individual who has completed the transition into a new environment. This individual is involved, makes decisions, and is able to navigate successfully within their new surroundings. Application of the patterns of response outcome indicators to the proposed study illustrates the woman who is successfully flowing with the menopausal transition by using her knowledge and skills to adopt healthy behaviors.

Nursing Therapeutics

The component nursing therapeutics is a means to pull the three main categories (nature of transitions, transition conditions: facilitators and inhibitors, and patterns of response) together for application of health promotion and health prevention through nursing intervention (Meleis et al., 2000). Application of nursing therapeutics to the

proposed study illustrates the woman who is within the menopausal transition following a plan developed collaboratively with her APN for adequate sleep and weight control to synergistically manage her world and optimize health and general well-being.

Case Study

The following case study illustrates the complexity and multidimensionality of the Transitions Middle-Range theory (Meleis et al., 2000) as the patient takes an active role in the collaborative development of a plan for healthy management of the menopause transition.

Mrs. Lopez is a 48-year-old Hispanic female who presented to the Women's Health Clinic 6 months ago for her annual physical with complaints of intermittent hot flashes, unexplained weight gain, no menses for the last 8 months, and mild fatigue for the previous 5 months. She is married with four daughters, ages 25, 23, 20, and 18. She is not college educated and works second shift as a line supervisor for a local food packaging business. Her past medical history is negative for illness and surgery. Her family history is significant for HTN, hypercholesterolemia, and diabetes in both parents and her older brother. She has an older sister and three younger siblings who are healthy. She has no known allergies and is not taking any medications or herbal supplements. She does not smoke and does walk for exercise 30 minutes, 3 days per week in addition to her job requirements. Her weight is 186 pounds, height is 64 inches, and BMI is 32. She was diagnosed as having symptomatic menopause.

Upon work-up, Mrs. Lopez had normal thyroid function and normal glucose; her total cholesterol was 208, triglycerides 145, low density lipoprotein (LDL) 130, and high density lipoprotein (HDL) 42. She was not anemic, as her hemoglobin (Hgb) was 13,

hematocrit (Hct) was 42%, but the complete blood count (CBC) showed her lymphocytes were 19.5% and neutrophils were 73%, representing mild abnormalities. Her Papanicolaou smear was negative for dysplasia. At a return visit, approximately 10 days later to discuss her test results, Mrs. Lopez was referred to the dietician for cholesterol management education, and the dietician's evaluation reflected that she was motivated to learn and understand hypercholesterolemia and the lifestyle changes necessary to prevent complications. In addition, her APN had requested that she complete a 1-week sleep diary, which revealed that she was not getting adequate sleep, averaging 5.5 to 6 hours nightly. Mrs. Lopez confirmed that she had talked with several of her girlfriends and her older sister, who had experienced menopause. Mrs. Lopez's APN discussed that recent studies indicate a relationship between weight gain and sleep deprivation and explained that increased BMI (obesity), cholesterol, and neutrophil levels are positively correlated with decreased sleep time. A handout with sleep hygiene tips was reviewed, and they discussed how her hot flashes contribute to her sleep deprivation. After discussion of the benefits and risks of hormone replacement therapy (HRT) for menopausal symptoms, Mrs. Lopez decided that she would like to try low dose continuous estrogen-progesterone therapy and was given 4 weeks of samples with a prescription for 5 months.

In the 6 months since Mrs. Lopez's diagnosis, she had changed her eating habits and had lost 18 pounds. She exercises for 30 - 40 minutes every day and, as a result of these changes, her cholesterol has lowered to 170, triglycerides 100, LDL 85, and HDL 60, and her lymphocytes and neutrophils are 35% and 60%, respectively. She does not have any caffeinated beverages after 3:00 p.m., her last food intake is no later than

7:00 p.m., and she does not read in bed. Her average sleep time is 7.5 – 8 hours nightly, and her hot flashes have subsided with the HRT.

As illustrated in the Transitions Theory Model (Meleis et al., 2000), the concepts that led toward a healthy transition include the nature of transitions, transition conditions: facilitators and inhibitors, and patterns of response.

The first concept, the nature of transitions, explains that Mrs. Lopez is experiencing a developmental transition related to aging with weight gain and mild fatigue as underlying transitional patterns of sleep deprivation. Additionally, she has the simultaneous situational symptoms of hot flashes as a result of her menopause transition. Initially, she is not aware of her menopausal status or of her sleep deprivation. A critical point of her transition involved seeking the guidance and advice of her APN at her annual physical.

The second concept, transition conditions: facilitators and inhibitors, highlights that Mrs. Lopez's lack of knowledge about her menopause transition was inhibiting her transition. The dietary education and discussions related to her hot flashes and sleep deprivation gave meaning to her transition and facilitated her to make decisions to modify her diet, improve her sleep hygiene, and increase her activity, as well as implement HRT.

The third concept, patterns of response, describes how and why Mrs. Lopez discussed her symptoms with her girlfriend and her older sister. It is through the process indicators of feeling connected and interacting with her peers that she developed a sense of normalcy to the transition that was taking place in her body and the symptoms that accompanied this transition. Using her new skills in sleep hygiene, and her knowledge about menopause, weight gain and sleep deprivation, she was able to bring

balance to her body and understand the implications that this transition had for her future quality of life.

The fourth concept, nursing therapeutics, is demonstrated in this case study by the APN who performed a tailored and accurate assessment of Mrs. Lopez's concerns and provided quality healthcare interventions. Thus, Mrs. Lopez could effectively self-manage her weight and sleep duration to prevent future health risk and promote a healthy menopause transition.

Literature Review

Menopause

There are approximately 45 million women in the U.S. going through menopause at any given time (NIA, 2003). Menopause is a natural process that begins at birth and proceeds as a continuum (Soules et al., 2001). The female reproductive hypothalamic-pituitary-ovarian axis ages to a nonfunctional state, known as menopause, before other organ systems, and usually at a time when a woman is otherwise viewed as healthy. Menopause occurs when the storage of the finite number of oocytes, determined at birth, in the ovary becomes depleted (Soules et al., 2001). The wide age range for menopause (42 - 58 years) has proven to be a poor indicator of reproductive aging. Addressing reproductive aging as a process, using a staging system, clearly identifies what point a woman has reached in the process (Soules et al., 2001).

The Stages of Reproductive Aging Workshop (STRAW) was prompted by medical professionals voicing the need to clarify the confusing terminology used in practice to describe reproductive aging and the menopausal transition (Soules et al., 2001). Workshop success was demonstrated by development of the STRAW staging

system (Appendix A) and nomenclature, which was also adopted by The American College of Gynecology (Soules et al.). Five stages occur before the final menstrual period (FMP), and two stages occur after the FMP. The age range and duration for each stage varies among individual women (Soules et al., 2001). After menarche, a female enters stage -5 where it will take several years to establish regular menstrual cycles. Once menstrual cycles are regular, fertility will peak at stage -4 and then gradually decrease over many years (stage -2 through +2). In stage -3, a subtle elevation of follicle stimulating hormone (FSH) is the first sign of reproductive aging. Stage 0 is the FMP, and stage +1 is declared only after 12 months of amenorrhea. Thus, the actual FMP is not declared until 12 months after it occurs (Soules et al., 2001). Revisions in the nomenclature are reflected from the STRAW staging system as follows (Soules et al., 2001).

- Menopause, stage 0, is the anchor point defined as the 12 months of menorrhoea following the FMP.
- The menopausal transition, stages -2 and -1, is defined by variation in menstrual cycle length with subtle FSH elevation and ends with the FMP, which is not recognized until 12 months of amenorrhoea.
- Post menopause includes stages +1 and +2 and encompasses further decline of ovarian hormone function to a permanent level, as well as accelerated bone loss.
- Stage +1 is defined as 4 years since the FMP.
- Stage +2 is defined as 5 years since the FMP to demise.

Schuiling and Likis (2006) implied that the topic of menopause is forefront in the literature because of the high numbers of female 'baby boomers' reaching middle-age, and they estimated that women would live one-third of their life after menopause. Hatcher (2007) emphasized that evaluation of sleep is important when counseling women about healthy aging. Hot flashes appear to correlate with the rapid decline of estrogen (Hatcher, 2007). Estrogen trough levels are associated with poor sleep, increased anxiety, and depression (Hatcher, 2007). Hallmark gonadotropin changes of the menopause transition include an increased FSH level, decreased estrogen, and decreased inhibition B (Hatcher, 2007). Health risks associated with aging and menopause due to these changing gonadotropin levels are osteoporosis, heart disease, breast cancer, and colon cancer (Hatcher, 2007).

The NIA has implemented The Study of Women's Health Across the Nation (SWAN), a multi-site longitudinal epidemiologic study designed to research the physical, biological, psychological, and social changes of women during the menopausal transition (NIA, 2003). The goal of SWAN's research is to help scientists, healthcare providers, and women learn how mid-life experiences affect health and quality of life during aging (NIA, 2003). The study began in 1996 with a total of 3,302 eligible women who were enrolled and completed the baseline study. Annual visit number 12 is currently being fielded.

Obesity and BMI

In 2006, an estimated 144,100,000 U.S adults (age 20 and older) were overweight or obese, representing 66.3% of the adult population (American Heart Association, 2010). Overweight is defined as a BMI of greater than or equal to 25 (NHLBI, 1998). Obesity is defined as a BMI greater than 30 (NHLBI, 1998). The obesity

epidemic is thought to result from the imbalance of energy intake and energy expenditure (Stein & Colditz, 2004). Health risks related to being overweight or obese include heart disease, HTN, diabetes (Grundy, 2004), cancer, cardiovascular disease (Grundy, 2004), gallstones, and osteoarthritis (NHLBI, 1998; Stein & Colditz, 2004), sleep apnea, respiratory problems, and endometrial, breast, prostate, and colon cancers (NHLBI, 1998).

Kirk et al. (2009) indicated that the BMI ought to be considered a vital sign and that oversight of this vital sign has had enormous implications on diagnosis, management, and healthcare delivery for obese patients. Most healthcare providers agree that multilevel interventions need to be implemented at the public health level through use of guidelines, screening, intensive counseling, and behavioral interventions for prevention of the growing negative consequences of overweight and obesity (Grundy, 2004; Stein & Colditz, 2004).

Field et al. (2001) conducted a 10-year longitudinal study of middle aged women and men to assess the health risks associated with being overweight. Conclusions revealed the incidence of diabetes, gallstones, HTN, and heart disease in both men and women, and of colon cancer (women only) and stroke (men only) increased with BMI. Adults who were overweight, but not obese, were more likely to develop one or more of the above listed diseases than their leaner peers. Results supported the premise that adults with BMI greater than 30.0 are at increased risk of death (Field et al., 2001).

Kawada (2002) studied associations between BMI, blood pressure, and serum lipid levels among rural Japanese subjects ages 40 -- 59. In Asian populations, BMIs, which are considered normal in non-Asian populations, are pre-disposing factors to hypertension and type 2 diabetes mellitus (Kawada, 2002). Findings revealed that the

prevalence of HTN increased with age and BMI and the mean values of serum cholesterol also increased with age and BMI (Kawada, 2002).

Sleep Quality and Sleep Duration

There is no known substitute for adequate sleep (American Academy of Sleep Medicine [AASM], 2008). Experts indicate that sleep has a direct affect on health and recognize that most women need approximately 7 to 8 hours of sleep every night (AASM, 2007). The top six factors that affect a woman's sleep include major life changing events, depression, illness, hormonal changes, bad sleep habits, and medication use (AASM, 2007). Sleep quality is a complex phenomenon that includes sleep duration, number of arousals during sleep, and restfulness of sleep, which is objective and varies between individuals (Buysse et al., 1989). Sleep duration is simply defined as the total sleep time recorded in hours and minutes by self-report (Buscemi, et al., 2007; Kohatsu et al., 2006; Singh et al, 2005; Taheri et al., 2004, Vorona et al., 2005).

Van Dongen, Maislin, Mullington, and Dinges (2003) explored if human sleep could be chronically reduced without consequences. Nocturnal sleep periods were restricted to 8 hours, 6 hours, or 4 hours per day for 14 consecutive days, or to 0 hours for three days. Sleep restriction to less than 6 hours per night reduced cognitive performance equivalent up to two nights of total sleep deprivation. Individual subjective sleep ratings showed subjects to be unaware of the cognitive deficits, which may explain why the impact of chronic sleep restriction on waking cognitive functioning is assumed to be benign (Van Dongen et al., 2003). Physiological sleep responses to chronic restriction did not mirror waking neurobehavioral responses, but cumulative wakefulness greater than 15 hours predicted performance lapses in all experimental conditions.

Therefore, sleep debt results in additional wakefulness that has a neurobiological cost, which has cumulative consequences over time (Van Dongen et al., 2003).

Three studies explored the effect of sleep duration on health. Ayas et al. (2003) studied female health professionals to determine whether decreased sleep duration was associated with increased coronary events. Patel et al. (2004) examined the association between sleep duration and mortality in women. Sleeping 5 hours or less per night was associated with a 39% increase in risk of coronary heart disease (CHD) (Ayas et al., 2003). Those who slept less than 5 hours or more than 9 hours were associated with an increased prevalence of diabetes, HTN, and hypercholesterolemia; and women in these categories were noted to be both older and 'heavier' (Ayas et al., 2003; Patel et al., 2004). Women who slept 9 hours or longer per night also had an increased risk of CHD, but it could not be explained why these individuals slept as much as they did (Ayas et al., 2003). Mortality risk was lowest among women who sleep 6 to 7 hours nightly, and sleeping less than 6 hours or more than 7 hours nightly was associated with increased risk of death (Patel et al., 2004).

Kerkhofs et al. (2007) explored the possibility that sleep restriction may activate inflammatory processes and affect blood parameters known to be associated with cardiovascular events, which seem to occur during and immediately after menopause. Blood samples were compared from 10 healthy postmenopausal women ages 55 to 65 years of age. These blood samples were taken before and after sleep restricted to 4 hours per night for 3 consecutive nights. A significant increase in white blood cells, total cholesterol, and LDL cholesterol was observed after the third night of sleep restriction, making it the first study to describe an increase in total cholesterol and LDL in humans

after sleep restriction. The exact mechanism underlying these serum changes was not determined (Kerkhofs et al., 2007).

Stamatakis and Brownson (2007) examined associations between sleep duration, physical activity, and nutrition. Obesity related behaviors were defined as not meeting physical activity requirements, low fruit and vegetable consumption, frequently eating fast food, and having an overall high fat diet. Shorter sleep duration was associated with younger age, and obesity related behaviors were common among both short and long sleepers. Age adjusted associations for obesity related behaviors were stronger for short sleep durations when restricted to non-obese subjects, particularly related to high fat diets. Eating fast food was strongly associated with short sleep duration in the obese individuals. Stamatakis and Brownson concluded that habitual short sleep duration is associated with behaviors that impact energy balance and eventually lead to weight gain.

Poor sleep quality has been associated with diabetes (Behan et al., 2007; Knutson, Ryden, Mander, & Van Cauter, 2006), poor health, having a sleep disorder, psychological distress (Baker, Wolfson, & Lee, 2009), and cardio-metabolic risk factors (Haseli-Mashhadi et al., 2009). Knutson et al., (2006) studied 161 subjects diagnosed with diabetes type 2, while Behan et al., (2007) studied 180 subjects diagnosed with type 1 or type 2 diabetes. Sleep quality was assessed using self- report PSQI, and glycemic control was assessed using hemoglobinA1c (HbA1c) levels. Body mass index and fasting plasma glucose (FPG) were recorded only in the study by Behan et al. In patients without diabetic complications, glycemic control was associated with perceived sleep debt but not PSQI score (Knutson et al., 2006). In contrast, in patients with at least one complication, HbA1c level was associated with PSQI score but not perceived

sleep debt (Knutson et al., 2006). In type 1 diabetics there was a positive correlation between PSQI score and HbA1c (Behan et al., 2007). In type 2 diabetics there was no correlation between PSQI score and HbA1c, FPG or BMI (Behan et al., 2007).

Baker et al. (2009) studied 959 women (18 to 64 years of age) surveyed by telephone in the National Sleep Foundation's 2007 Sleep in America Poll. Poor sleep quality was reported by 27% of respondents, and daytime sleepiness was reported by 21% of all subjects surveyed. Poor sleep quality and daytime sleepiness were both independently associated with poor health, having a sleep disorder, and psychological distress (Baker et al., 2009). Addressing sleep related complaints in women was found to be important to daytime functioning and quality of life (Baker et al., 2009).

Haseli-Mashhadi et al. (2009) studied sleep quality and its' association with cardio-metabolic risk factors in 1,458 Chinese men and 1,831 women (ranging in age from 50 to 70 years). A questionnaire was used to assess sleep quality, socio-demographical factors, health factors, and fasting blood samples obtained. One half of the study sample reported good sleep quality (Haseli-Mashhadi et al., 2009). Good physical and mental health and no depression were associated with a report of good sleep quality; however self-reported short sleep duration was associated with poorer quality sleep (Haseli-Mashhadi et al., 2009). A significant positive association of sleep quality and concentration of plasma insulin, total and LDL cholesterol, and index of insulin resistance were evident in data analysis (Haseli-Mashhadi et al., 2009). Overall, good sleep quality in this Chinese population was low (Haseli-Mashhadi et al., 2009).

Menopause and Obesity

Obesity is a common problem in gynecology practice and is related to insulin resistance and the metabolic syndrome (Milewicz & Jedrzejuk, 2007). Perimenopausal

women are the most vulnerable to these conditions because of visceral obesity which increases with age (Milewicz & Jedrzejuk). Understanding the association of menopause and body weight is important, because excess weight increases risk for cardiovascular disease, stroke, and all cause mortality in middle age (Sowers et al., 2007). In the literature, thermoregulatory models argue that body fat is associated with increased frequency of hot flashes (Thurston et al., 2009); and, there is controversy regarding the extent to which menopause status, age, lifestyle changes, and hot flashes (caused by fluctuating hormone levels) accounts for increased weight experienced by mid-life women (Sowers et al., 2007 Sternfeld et al., 2004; Sternfeld et al., 2005; Thurston et al., 2009).

Sternfeld et al. (2005) and Thurston et al. (2009) examined body composition and fat distribution in menopausal women. Sternfeld et al. found that for Chinese women, late perimenopause and postmenopause was independently associated with an increase in percent body fat compared to premenopausal women. Among White women, no relation with percent body fat was observed with either menopausal status or age. Total activity was not related to lean mass in either Chinese or Whites and total increased physical activity was related to a decreased waist circumference in Whites only. Waist circumference was not associated with age in either group (Sternfeld et al., 2005). They concluded that rapid hormone changes and menopausal status, rather than age, may be the more significant influence on lean mass in women moving through the menopausal transition. The question of whether increased level of body fat is related to the menopausal transition remains undetermined (Sternfeld et al., 2005).

Thurston et al. (2009) studied whether gains in body fat were related to vasomotor symptoms in women during the menopausal transition and reported that hot

flashes increased with fat gains over time, and those women who gained body fat during midlife have an increased likelihood of reporting hot flashes. They noted that since associations were observed for fat gains, rather than overall body fat level, it is the acquisition of the body fat that is important. Explanation for this was that hot flashes are heat dissipation events and body fat is an insulator, so more events may be required to dissipate a given amount of heat (Thurston et al., 2009). Behavioral interventions to manage hot flashes are few and have questionable efficacy. Whether dietary, physical activity, or other methods to prevent these gains during the menopausal transition would help prevent or manage hot flashes was not determined (Thurston et al., 2009).

Sowers et al. (2007) examined FSH levels in middle aged women to determine if their change in FSH correlated with fat mass change. A sample of 543 women was evaluated over 6 years by measurement of serial FSH levels, waist circumference, and skeletal and fat mass. Data analysis revealed a cumulative 3.4 kg increase in fat mass, 0.23 kg decrease in skeletal mass, and 5.7 cm increase in waist circumference (Sowers et al., 2007). FSH level change was positively correlated with fat mass change (Sowers et al., 2007). Results reveal that significant changes in body composition occur during menopause, and these changes have important implications for healthy or unhealthy aging (Sowers et al., 2007).

Sternfeld et al. (2004) examined the contributions of aging, change in menopausal status, and physical activity to weight and waist circumference changes in racially and ethnically diverse women, over 3 years. As weight increased, waist circumference increased independently with age and time. Menopausal status was found not to be related to waist circumference, but tended to be higher in women as they became menopausal (Sternfeld et al., 2004). As daily physical activity (or exercise)

increased, weight and waist circumference decreased (Sternfeld et al., 2004). Thus, midlife women were found to experience an increase in weight and waist circumference over time, but findings suggested that maintaining or participating in physical activity contributes to prevention or attenuation of weight gains. Whether or not a menopause-related increase in waist circumference, independent of age, exists was not determined (Sternfeld et al., 2004).

Menopause and Sleep

Menopause is considered to be a risk factor for sleep disordered breathing (SDB) according to the Wisconsin Sleep Cohort Study, and evaluation for SDB should be a priority for menopausal women with complaints of snoring, daytime sleepiness, or unsatisfactory sleep (Young, Finn et al., 2003). To determine if menopause is an independent risk factor for SDB, Young, Finn et al. (2003) conducted a study using in laboratory polysomnography (PSG) and collected detailed data on stage of menopause, duration of postmenopause, HRT use, history of hysterectomy and oophorectomy, vasomotor symptoms, and serum FSH from a sample of 589 midlife women. Results demonstrated that at every age between 32 and 52, and at every BMI level, SDB is higher for perimenopausal and postmenopausal women compared to premenopausal women after controlling for age, body habitus, and lifestyle factors. Young, Finn et al. concluded that the perimenopausal transition is associated with SDB and indicated that because sleep complaints in perimenopausal women are associated with natural symptoms of this aging transition, underlying SDB may be overlooked.

Pien et al. (2008) examined how sleep quality is affected by reproductive hormone levels, menopausal status, and menopausal symptoms. Subjects reported that sleep quality was strongly affected by hot flashes and depressive symptoms associated

with menopause, and perimenopausal women generally reported worse sleep quality than premenopausal women. However, self-reported sleep quality did not decline during the menopausal transition. Higher FSH levels and low inhibin B levels, a hormone produced by ovarian cells, and its decrease precedes the menopausal decline of estradiol, were associated with subject reports of poorer sleep quality. Pien et al. concluded that menopausal status may be less important to sleep quality than the degree of vasomotor and other symptoms experienced during the menopause transition which seem to be affected by hormone levels.

Kravitz et al. (2005), Ohayon (2006), and Sowers et al. (2008) have conducted studies to determine whether reproductive hormone levels are associated with trouble sleeping in women during their menopausal transition. Kravitz et al. analyzed urinary hormone levels and sleep assessments from 630 women, aged 43 to 53 years, in the Daily Hormone Study component of the SWAN study during a single menstrual cycle to examine relationships between hormone patterns and sleep. Seventy-four percent of study subjects reported trouble sleeping on at least one night, and 19.2% reported trouble sleeping almost three nights per week. Women in the beginning of the menopausal transition reported a higher percentage of sleep difficulty at the cycle beginning and end. FSH and pregnanediol glucuronide (PdG), a progesterone metabolite, were associated with reduced sleep quality, but varied according to menopausal stage. The association between increased PdG and trouble sleeping contrasts other data, suggesting that progesterone facilitates sleep (Kravitz et al., 2005). Because progesterone is a central nervous system depressant, the expectation would be to see PdG increases with better sleep. Kravitz et al. also confirmed that vasomotor

and mood symptoms were strongly associated with trouble sleeping in premenopausal and perimenopausal women.

Ohayon (2006) assessed the prevalence and severity of hot flashes in menopausal women aged 35 to 65 years to determine whether hot flashes are associated with insomnia. The mean age of natural menopause among study participants was 50.3, and a total of 32.8% of the 982 women reported having hot flashes. Of these women, 50.9% experienced night sweats in addition to daytime hot flashes, and 15.5% experienced severe hot flashes. Of the women who reported hot flashes, 81.3% had symptoms of chronic insomnia. Although association between the severity of hot flashes and insomnia was identified, it was not determined that hot flashes cause insomnia (Ohayon, 2006).

Sowers et al. (2008) used data from the SWAN Sleep Study to determine if a more rapid rate of change in FSH levels was associated with poorer sleep. The mean value of FSH increased over the 7 year study period and discovered that the rate of change had doubled by the 7th year. A higher rate of subjective sleep complaints measured by the self-report PSQI questionnaire was associated with a greater rate of FSH level change and longer total sleep time but poor sleep quality. HRT users were excluded from this study because of potential for confounding results. Sowers et al. concluded that women who transition rapidly should be considered for therapeutic and lifestyle interventions that address menopausal symptomatology, rather than targeting only sleep characteristics.

Young, Rabago, Zgierska, Austin, and Finn (2003) objectively measured sleep quality in 589 menopausal women by full in-laboratory polysomnography (PSG) and also by self-report of sleep problems. Menopause was found not to be associated with

diminished sleep quality when measured by PSG; however, their results did indicate that perimenopausal and postmenopausal women are twice as likely to be dissatisfied with their sleep when compared to premenopausal women. Additionally, objective sleep quality did not differ by those who reported hot flashes or flushes. Young, Rabago, et al. warned that although primary care guidelines and literature indicate that sleep disruption associated with hot flashes and vaginal atrophy experienced during the menopausal transition are hallmarks of menopause and can often be simply treated with HRT, signs and symptoms that would normally indicate a full sleep evaluation in premenopausal women ought to be taken as seriously in menopausal women, because underlying sleep disorders may be otherwise missed.

Kravitz et al. (2008) conducted a 7 year longitudinal analysis to determine whether difficulty sleeping increased with progression through the menopausal transition. Subjects were aged 42 to 52 years, in premenopause or early perimenopause, and were participating in the SWAN study. Difficulty falling asleep and staying asleep increased throughout the menopausal transition, but early morning awakening decreased with late perimenopause and postmenopause. Vasomotor symptoms were associated with those reporting any sleep difficulty. Decreased estrogen levels were associated with trouble falling asleep and trouble staying asleep, and increased FSH levels were associated with increases in only trouble staying asleep. Kravitz et al. concluded that sleep changes in menopause transitioning women are attributable, at least in part, to sex hormone fluctuation, although precise relationships could not be defined.

Obesity and Sleep

Several studies have been conducted to determine whether sleep duration is associated with obesity, as defined by BMI. Subjects were recruited in many different manners. Buscemi et al. (2007) surveyed 200 subjects attending internal medicine clinics via an independent surveyor who also reviewed medical records. Gangwisch et al. (2005) analyzed data recorded from subjects who participated in the National Health and Nutrition Examination Survey in 1984, 1987, and 1992. Hasler et al. (2004) utilized trained health professionals to interview and follow 496 subjects at ages 27, 29, 34, and 40 for psychiatric, medical conditions, and health habits. Kohatsu et al. (2009) conducted a cross analysis on data from 990 participants using data collected in the Keokuk County Rural Health Cohort Study in Iowa from 2004. Singh et al. (2005) paid \$25 to 3,158 subjects in Michigan, contacted randomly, to participate in one, 20 minute telephone interview. Vorona et al. (2009) utilized a nurse or study coordinator to administer questionnaires and measured weight and height, at the time of the interview, for 924 subjects from four primary care practices.

Findings revealed that subjects who slept less than 6 hours per night were more likely to be obese and have a higher BMI (Buscemi et al., 2007; Gangwisch et al., 2005; Hasler et al., 2004; Kohatsu et al., 2006; Singh et al., 2005; Vorona et al., 2005). Remaining awake beyond midnight increases the likelihood of obesity (Vorona et al., 2005), and lower BMI and lower weight gains were found in those with longer sleep durations (Hasler et al., 2004; Kohatsu et al., 2006). Unlike the others, Gangwisch et al. (2005) found that sleep durations over 7 hours were not consistently associated with either an increase or a decrease likelihood of obesity. Vorona et al. found that overall,

women slept more than men. No significant sex predictors of obesity were noted by Hasler et al. (2004), Kohatsu et al. (2006), or Singh et al. (2005).

Conversely, Buscemi et al. (2007) found the association between short sleep duration and obesity occurred only in women. Singh et al. (2005) discovered that lower sleep duration was associated with a higher prevalence of diabetes; however, after adjusting for BMI, sleep duration was no longer a significant predictor in multiple regression analyses. Vorona et al. (2005) determined that a 1.86 hour decrease in sleep duration per week was equal to an increase in BMI that would equate to 2.9 pounds. In subjects ages 18 to 49, sleep apnea, diabetes, HTN, drinking alcohol, and not smoking were associated with obesity in the overall model (Buscemi et al., 2007). These researchers concluded that their data support an association between short sleep duration and higher BMI (Buscemi et al. 2007; Gangwisch et al., 2005; Hasler et al., 2004; Kohatsu et al., 2006; Singh et al., 2005; Vorona et al., 2005). Additionally, because sleep duration is potentially modifiable, their results may have important implications for the prevention and treatment of obesity (Kohatsu et al., 2006; Vorona et al., 2005) and may provide the background for future therapeutic trials in weight loss for patients with or without established medical problems (Buscemi et al., 2007; Gangwisch et al., 2005). Researchers recognized that findings may have been limited by the use of self-reports for sleep duration (Buscemi et al., 2007; Gangwisch et al. 2005; Kohatsu et al., 2006; Singh et al., 2005) and that confounding factors, other than sleep limitation, may contribute to obesity (Buscemi et al., 2007; Singh et al., 2005; Vorona et al., 2005).

Taheri et al. (2004) examined the associations between sleep duration, BMI, and serum leptin and ghrelin in 1,024 volunteers from the Wisconsin Sleep Cohort Study. Leptin is an adipose hormone that suppresses appetite (satiety), and ghrelin is a

stomach peptide that stimulates (hunger) appetite (Taheri et al., 2004). The researchers found that short sleep recorded by polysomnography and on self-reports correlated with reduced leptin and elevated ghrelin, and persons sleeping less than 8 hours nightly had an increased BMI proportional to decreased sleeping time. Taheri et al. concluded that short sleep duration and the differences in leptin and ghrelin levels could account for the increased BMI observed with decreased sleep duration and suggested that sleep deprivation may also increase preference for lipid rich and higher calorie foods as ghrelin levels increase. Thus, in societies where chronic sleep restriction is common and food is widely available, changes in appetite, regulatory hormones with sleep restriction may contribute to obesity (Taheri et al., 2004).

Menopause, Sleep, and Obesity

There is a lack of information within the literature about the differences in weight gain between symptomatic menopausal women who have shorter sleep duration and poorer quality of sleep than those who do not. Huerta, Mena, Malacara, and Diaz de Leon (1995) studied 151 women (age 36 to 70) to determine the association of obesity, attitudes toward sexuality, and diverse hormones to glucose, insulin, cortisol, prolactin, and FSH levels. Sleep alterations (difficulty falling asleep, sleep waking, and early morning awakening) were assessed as contributing factors to depression (Huerta et al., 1995). Findings revealed a negative association between rising FSH levels, depression, and sexual satisfaction (Huerta et al., 1995). Depression, FSH, and cortisol levels were increased in late menopause, and women in late menopause had more problems with sleep alterations, decreased sexual interest, and increased depression (Huerta et al., 1995). Sleep problems, depression, and elevated levels of insulin and cortisol were

associated with being overweight (Huerta et al., 1995). Waist/hip ratio had a positive association with sleep alterations and depression (Huerta et al., 1995).

Multiple studies have demonstrated that women tend to gain weight during the menopausal transition (Milewicz & Jedrzejuk, 2007; Sowers et al., 2007; Sternfeld et al., 2004; Sternfeld et al., 2005; Thurston et al., 2009), that sleep disturbances (hormone fluctuations and poor sleep quality) occur during the menopausal transition (Kravitz et al., 2005; Kravitz et al., 2008; Ohayon, 2006; Pien et al., 2008; Sowers et al., 2007; Sowers et al., 2008; Thurston et al., 2009; Young, Finn et al., 2003; Young, Rabago et al., 2003), and that short sleep duration is related to increases in weight (Buscemi et al., 2007; Gangwisch et al., 2005; Hasler et al., 2004; Kohatsu et al., 2006; Singh et al., 2005; Taheri et al., 2004; Vorona et al., 2005); yet ,there is a lack of studies that examined sleep quality, sleep duration, and weight gain together in menopausal women. Additionally, no interventional studies were identified exploring the possible causative role sleep disturbances may have in the common menopause associated weight gains in women.

Chapter Summary

The Theory of Transitions (Meleis et al., 2000) served as the framework for this study. Researchers have supported the relationships between menopause and weight gain, menopause and sleep disturbances, and short sleep duration and weight gain, yet there is a dearth of studies that examines these factors concurrently in menopausal women. Concerns about weight gain and growing evidence supports that sleep quality and sleep duration are possibly associated with weight gain in symptomatic menopausal women. Therefore, it is plausible that a comprehensive sleep assessment in

symptomatic menopausal women may be paramount to managing these risk factors now and for health in later years.

CHAPTER III METHODOLOGY

Introduction

The purpose of this study was to determine if a difference exists in the amount of weight gain between symptomatic menopausal women who have poor sleep quality and those who do not have poor sleep quality, and to explore the possible relationship between sleep duration, sleep quality, and weight gain in symptomatic menopausal women. Included in this chapter are the design, sample and sampling method, description of instrumentation, data collection procedure, and analysis.

Design of the Study

A retrospective descriptive design was used to evaluate the relationships between sleep duration, sleep quality, and weight gain in symptomatic menopausal women. Data was collected from questionnaires, including a demographic questionnaire that requests a self-report of weight and height measurements and the PSQSI questionnaire (Buysse et al., 1989). The questionnaires were sent anonymously via mail to patients' residences for completion.

There are several potential variables that may affect an individual's BMI, sleep duration, and sleep quality. Potential variables may include diet, caloric intake, physical activity, smoking status, age, ethnicity, and socioeconomic status. Unfortunately, these potential variables could not be statistically controlled for due to the non-experimental design of the study.

Population, Sample and Setting

The target population of interest was symptomatic menopausal women. The convenience sample consisted of 59 women seen by their healthcare provider, at least once in the previous 6 to 12 months, with a diagnosis of symptomatic menopause, ICD-9 code 627.2, from three multi-specialty clinics in northeastern Wisconsin. Inclusion criteria were: (a) diagnosis of symptomatic menopause, ICD-9 code 627.2, documented in the medical record; (b) seen by a healthcare provider at least once in the previous 6 to 12 months; and (c) be able to read and to write English.

Data Collection Instruments

Demographic Questionnaire

The demographic questionnaire (Appendix B) completed by each subject consisted of a self-report of current height (in inches) and weight (in pounds), ethnicity, age, marital status, level of education, employment status, current living arrangements, economic status, exercise status, and smoking status. Participants were also requested to record weight and height measurements currently and recall weight and height measurements at 12 months previous and 6 months previous. Body mass index (BMI) was calculated from the demographic questionnaire self-reports by using the reported weight in pounds divided by the reported height in inches squared, then multiplied by 703.

The Pittsburgh Sleep Quality Index

Buysse et al. (1989) discussed that sleep quality is an important concept, as many adults complain about difficulty falling asleep and/or difficulty maintaining sleep, and poor quality sleep can be an indicator of medical and sleep disorders. The PSQI

(Buysse et al., 1989) questionnaire (Appendix C) was developed specifically to assess sleep quality and sleep disturbances in clinical populations. Smyth (2008) suggested that use of the PSQI may enable APN to identify and improve sleep problems quickly or use the tool for sleep disturbance screening. The PSQI is made up of 19 self-report questions grouped into seven component scores, each weighted equally on a scale of zero to three. The seven components include sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medications, and daytime dysfunction. The seven component scores are added up to yield a global PSQI score, ranging from 0 to 21. Higher scores depict worse sleep quality (Buysse et al., 1989). A cut score of five was used to distinguish between good and poor sleepers. Poor quality sleep was determined by a global score of greater than five on the PSQI, while good quality sleep was determined by a global score of five or less (Buysse et al., 1989).

Buysse et al. (1989) tested instrument validity and reliability of the PSQI properties over an 18-month field trial with good and poor sleepers. The seven component scores of the PSQI demonstrated an overall Cronbach's alpha of 0.83, and stability over time was substantiated by test-retest correlation for global PSQI scores with Cronbach's alpha of 0.85 (Buysse et al.). Instrument validity was demonstrated in the distribution of global PSQI scores using a post hoc cutoff score of five, which correctly identified 88.5% of all patients and controls ($\kappa = 0.75$, $p < 0.001$). Buysse et al. reported that this represented a sensitivity of 89.6% and a specificity of 86.5%, thus confirming that the PSQI could correctly identify poor sleep quality.

Data Collection Procedures

Study approval from the Institutional Review Boards (IRB) of the University of Wisconsin Oshkosh and the northeastern Wisconsin multi-specialty clinic, where eligible subjects were recruited, was obtained and documented according to required procedures. The proposed protocol of this study mandated that an Honest Broker be used to collect and view any patient information necessary to conduct this research. An Honest Broker from the clinic was recruited prior to submission of IRB approval for this study. As an employee of the clinic, the Honest Broker had a full understanding of the health Insurance and Portability and Accountability Act (HIPPA) regulations, completed the mandatory HIPPA training required by the clinic, and completed required Honest Broker training mandated by the clinic. Upon approval, the pre-recruited Honest Broker requested a billing report, coded within the previous 6 to 12 months, of patients diagnosed with the ICD-9 code 627.2 (symptomatic menopause). The billing report generated a list of providers identified as having used the specified diagnosis code and a number of eligible subjects seen by each provider.

To gain access to eligible subjects, the PI obtained a signed provider form letter (Appendix D) from each provider identified by the billing list as having eligible subjects. The provider letter explained how the patient was deemed eligible for the study, acknowledged that the provider was aware of the study, confirmed that the identity of the PI was known to the provider, and indicated the intended purpose of the study. By signing the form letter, the provider granted permission to the PI to access their eligible patient pool for this study. If the provider did not sign the provider form letter, the provider was removed from the list and his/her patients were no longer eligible for participation in the study. A copy of the signed provider form letter was included in the

study packet for each patient to identify the patient-provider relationship, so patients understood how they were identified for participation in the study.

A patient information sheet (Appendix E) was created to introduce the PI and the purpose of the study to the patient, provide participation instruction to the patient, explain participant risk, explain how anonymity is intended to be maintained, provide information about human subject participation rights for the study, and provide contract information for subjects who had questions or concerns about study participation. The patient information sheet also informed subjects that participation was voluntary and explained that withdrawal from the study may be requested at any time without penalty. A copy of the patient information letter was included in each participant study packet.

Labels were generated for mailing by the Honest Broker. Patient address labels were affixed by the Honest Broker after the PI prepared all study packets. The PI did not have access to patient address labels or any patient information. The PI affixed return address labels to the mailing envelope and to the pre-addressed postage paid return envelope. The return address labels affixed to the mailing envelopes directed the study packets back to the Honest Broker in the event that a study packet did not reach the intended recipient. This was used as a measure to minimize potential breach of patient confidentiality. Completed questionnaires were returned to a post office box rented by the PI.

Study packets included the signed provider form letter, the patient information sheet, the demographics questionnaire, the PSQI questionnaire, and a pre-addressed postage paid return envelope. The study packets were prepared and sorted by provider name by the PI. The sorting of the study packets by provider name assured that the Honest Broker could match the patient address labels with their appropriate healthcare

provider. Then, the Honest Broker affixed all patient address labels to the mailing envelopes and mailed all the study packets. Subjects were instructed not to place any identifying marks (including return addresses) on the questionnaires or return envelopes.

Subjects who chose to participate in the study included those who voluntarily completed and returned both questionnaires. All information remained anonymous, and no identifying data was collected by the PI. Returned questionnaires have been kept by the PI in a locked file cabinet. All computer information is password protected. Returned questionnaires and computer files will be kept for a period of 3 years and will be available for IRB review upon request. After 3 years, all paper files will be shredded and all computer files will be deleted.

Data collection procedures, as described, imposed minimal risk to subjects and supported voluntary subject participation. Breach of confidentiality was minimized by use of an Honest Broker to request, collect and view the billing list, affix patient address labels, and mail assembled study packets upon completion. Questionnaires were not pre-coded, and participants were requested not to place any identifying marks on the questionnaires or return envelope. No reminder cards were mailed to patients. The PI was unable to identify who received or who returned questionnaires.

Data Analysis Procedures

The Statistical Package for the Social Sciences (SPSS) version 17.0 (IBM, 2008) was used for data analysis. Descriptive and inferential statistics were used to analyze the data. Descriptive statistics were used to describe the sample, including central tendencies, ranges, and frequencies.

The independent t-test was used to explore the differences in self-reported weights between women who are good sleepers and those who are poor sleepers using the global PSQI score. Pearson's r correlation using the PSQI component scores for sleep duration, sleep quality, and weight gain (in pounds) was used to establish whether a relationship existed between weight gain and sleep. An alpha level of 0.05 was used.

Limitations

The foremost limitation of this study was a limited power for statistical analyses due to sample size. A second limitation could result in sample bias from self-reported data, as well as potential for poor subject response. Third, the non-experimental design does not allow for controlling of extraneous variables, such as physical activity level and dietary caloric intake, and may have hindered comparability between groups. Fourth, the sample from one healthcare institution may lack ethnic heterogeneity of the sample and limit generalizability. Fifth, the lack of experimental design did not allow inference of casual relationships between weight gain and sleep. Finally, self-report from study participants may not reveal weight changes over time for subjects during the period under investigation

Chapter Summary

The purpose of this study was to determine if there was a difference in the amount of weight gain between symptomatic menopausal women who are poor quality sleepers and those who are not, and to explore the possible relationship between sleep duration, sleep quality, and weight gain in symptomatic menopausal women. Subjects were recruited from three multi-specialty clinics of one healthcare institution in

northeastern Wisconsin. A retrospective descriptive design was employed. Fifty-nine subjects participated in the study. Descriptive and inferential statistics were used to analyze the data. Protection of human subjects and limitations of the study were discussed. A study timeline was considered and is included as Appendix F.

CHAPTER IV

RESULTS AND DISCUSSION

Introduction

The purpose of this study was to determine if there was a difference in the amount of weight gain between symptomatic menopausal women who are poor quality sleepers and those who are good quality sleepers' and to explore the possible relationship between weight gains, sleep duration, and sleep quality in symptomatic menopausal women. The independent t-test was used to explore the differences in self-reported weights between women who are good quality sleepers and those who are poor quality sleepers. Pearson's r correlation, using the PSQI component scores for sleep duration and sleep quality, and weight gain (in pounds), was used to establish whether a relationship existed between weight gain and sleep duration, as well as sleep quality.

Results

Demographic Data

A total of 162 study packets were mailed to women who had been seen by their healthcare provider at least once in the previous 6 to 12 months and had been diagnosed with ICD-9 code 627.2, symptomatic menopause. Of the 162 eligible participants, 59 completed and returned both questionnaires, representing a 36.4% return rate. All returned questionnaires met the inclusion criteria, and no subjects were excluded from further data analysis.

The sample consisted of all females with an average age of 55.9 years (SD = 7.1), ranging from 44 to 80 years of age. Self-reports from the majority of the participants identified subjects to be White (96.6%) and married (84.7%). The mean current BMI was 27.7 (SD = 6.7), indicating that, on average, this sample was classified as overweight. Few subjects reported exercising on a daily basis (3.4 %), while 37.3% reported that they exercised one to three days per week, and 28.8% reported never exercising. Sample characteristics are summarized in Table 1. Self-reported weight and BMI characteristics are summarized in Table 2.

Table 1

Sample Characteristics (n = 59)

	Frequency	Percent
Gender		
Female	59	100
Marital Status		
Divorced	4	6.8
Widowed	1	1.7
Married	50	84.7
Single	2	3.4
Never Married	2	3.4
Race		
Asian	1	1.7
White	57	96.6
Black/African American	0	0.0
Native American	0	0.0
Pacific Islander	0	0.0
Other	1	1.7
Education		
High School	23	39.0
Trade/Vocational School	12	20.3
College	16	27.1
Post College	8	13.6

(table continues)

	Frequency	Percent
Employment		
Full time	33	56.0
Part time	9	15.3
Unemployed	2	3.4
Homemaker	2	3.4
Retired	13	22.0
Living Arrangements		
Live alone	7	11.9
Live with spouse only	37	62.7
Live with spouse and children	12	20.3
Live with someone else	3	5.1
Income		
Less than \$20,000	4	6.8
\$21,000-\$35,000	5	8.5
\$36,000-\$50,000	7	11.9
\$51,000-\$65,000	12	20.3
\$65,000 or more	31	25.5
Exercise		
Never	17	28.8
1-3 days a week	22	37.3
3-5 days a week	13	22.0
5-6 days a week	5	8.5
Daily	2	3.4
Smoking		
Never	38	64.4
Quit greater than 12 months ago	14	23.7
Quit less than 12 months ago	1	1.7
Currently smoking	6	10.2

Table 2

Self-reported Mean Weights and BMI (n = 59)

	Current	6 months	12 months
Weight (lbs)	158.5	156.3	155.3
SD	39.7	38.2	38.6
BMI	27.6	27.3	27.1
SD	6.7	6.5	6.5

lbs = pounds, BMI = body mass index, SD = standard deviation

Analysis of PSQI Data

All 59 participants completed the PSQI as a measure of participants' sleep quality and patterns. The PSQI is made up of 18 self-report questions grouped into seven component scores, each weighted equally on a scale of zero to three. The seven components include: sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medications, and daytime dysfunction (Buysse et al., 1989). The seven component scores were then added up to yield a global PSQI score, ranging from 0 to 21 (Buysse et al., 1989). Higher scores depicted worse sleep quality and a cut score of five was used to distinguish between good quality and poor quality sleepers. Poor quality sleep was determined by a global score of greater than five on the PSQI, while good quality sleep was determined by a global score of five or less. A scoring key was used to determine each component score (Buysse et al., 1989).

Component one addressed sleep quality (Question 9) by asking the subject to rate their sleep quality. A response of 0 indicated perception of very good sleep quality, while a response of 3 indicated perception of very bad quality sleep. Component two

addressed sleep latency (Questions 2 and 5) by asking how long (in minutes) it has taken for the subject to fall asleep and also asks the subject to rate how often she cannot get to sleep within 30 minutes. A response to Question 5 of 0 indicated no difficulty, while a score of 3 indicated severe difficulty. Component three assessed sleep duration (Question 4) by asking the subject how many hours she actually sleeps per night. A response of 0 was equivalent to greater than 7 hours, 1 was equivalent to 6 to 7 hours, 2 was equivalent to 5 to 6 hours, and 3 was equivalent to less than 5 hours. Component four assessed habitual sleep efficiency (Questions 1, 3, and 4) by calculating the number of hours spent in bed and determining the number of hours slept. A habitual sleep efficiency percentage was obtained and converted into a total component score, with 0 indicating good efficiency, while 3 indicated very poor efficiency. Component five assessed sleep disturbances (Questions 5b -- 5j) by asking about night and early morning awakening, nocturia, breathing comfortably, coughing or snoring, too cold, too hot, bad dreams, pain, and other reasons for trouble sleeping. Each question was scored individually. Then, the sum of scores was converted into a total component score, with 0 indicating no difficulty, while 3 indicated severe difficulty. Component six assessed use of sleeping medication by simply asking about use of prescription or over the counter (OTC) medication to sleep. A score of 0 indicated no use of medications, while 3 indicated frequent use of medications. Component seven assessed daytime dysfunction (Questions 7 and 8) by asking the subject to rate how often she has had trouble staying awake during activities and how much of a problem it is to her to keep up enthusiasm to get things done. A total component score of 0 indicated no difficulty, while 3 indicated severe difficulty. The global PSQI score was the sum of each component score. A score of 5 or less depicted a good sleeper, while a

score of 6 or more depicted a poor sleeper. The seven component scores of the PSQI had an overall reliability coefficient of (Cronbach's alpha) 0.748, indicating an acceptable degree of internal consistency, meaning that all of the component scores appear to measure a particular aspect of sleep quality.

The average global PSQI score was 7.8 (SD = 4.1), with a range from 1 to 21. Approximately two-thirds of subjects were classified as having poor sleep quality (66%), while one-third of the subjects were classified as having good sleep quality (33.9%). The majority of subjects reported that it took them less than or equal to 15 minutes to fall asleep (59.3%). Approximately one-third of the subjects spent 8 to 8.5 actual hours in bed (33.9%), with 22% reporting 7 hours of actual sleep each night. PSQI characteristics are summarized in Table 3.

Table 3

PSQI Data (n=59)

	Frequency	Percent
<u>Minutes to Sleep</u>		
≤ 15	35	59.3
16-30	17	28.8
31-60	3	5.1
> 60	4	6.8
<u>Actual Hours in Bed</u>		
5.60	1	1.7
6.00	2	3.4
6.20	1	1.7
6.50	2	3.4
7.00	7	11.9
7.25	2	3.4
7.50	6	10.2
7.75	2	3.4
7.80	1	1.7
8.00	11	18.6

(table continues)

	Frequency	Percent
8.20	1	1.7
8.25	2	3.4
8.50	6	10.2
8.75	1	1.7
9.00	4	6.8
9.25	1	1.7
9.50	4	6.8
10.00	3	5.1
11.00	1	1.7
12.00	1	1.7
<u>Actual Hours of Sleep</u>		
4.00	2	3.4
4.50	1	1.7
5.00	6	10.2
6.00	12	20.3
6.50	5	8.5
7.00	13	22.0
7.50	5	8.5
7.75	1	1.7
8.00	12	20.3
8.50	1	1.1
9.25	1	1.7
<u>Global PSQI Scores</u>		
1	1	1.7
2	3	5.1
3	4	6.8
4	5	8.5
5	7	11.9
6	4	6.8
7	4	6.8
8	7	11.9
9	4	6.8
10	7	11.9
11	8	13.6
14	1	1.7
15	1	1.7
18	2	3.4
21	1	1.7

Differences in Weight Gain Between Good Quality Sleepers and Poor Quality Sleepers

Changes in weight scores were calculated by subtracting self-reported weight at 6 months previous and at 12 months previous from current reported weight. Independent t-tests were used to examine differences in weight gain between those who were good sleepers and those who were poor sleepers. At 12 months, poor quality sleepers averaged an increase in weight of 3.47 lbs. (SD = 10.7), and good quality sleepers averaged an increase in weight of 2.7 lbs. (SD = 9.6). However, this difference was not found to be statistically significant, $[t(57) = 0.27, p = 0.79]$. Similarly, at 6 months, poor sleepers averaged an increase in weight of 2.58 lbs (SD = 8.9), and good quality sleepers averaged an increase in weight of 1.47 lbs (SD = 6.21), but this was also found not to be a statistically significant difference $[t(57) = 0.50, p = 0.62]$. This data indicated that symptomatic menopausal women who had poor quality sleep did not significantly differ in weight gain from those who had good quality sleep at 6 months or at 12 months previous.

Differences in BMI Between Good Quality Sleepers and Poor Quality Sleepers

Body mass index was calculated by the PI for each subject's self-reported current weight, weight at previous 6 months and weight at previous 12 months by the equation: $[\text{weight (pounds)} \div \text{height (inches)}^2 \times 703]$. Changes in BMI were calculated by subtracting the 6 month BMI and 12 month BMI from the current BMI. Independent t-tests were used to analyze the differences. Poor quality sleepers averaged an increase in BMI (M = 0.69, SD = 1.94), as did good quality sleepers (M = 0.20, SD = 1.67) at 12 months, but this was not a significant change $[t(57) = 0.96, p = 0.34]$. At 6 months, poor quality sleepers averaged a BMI increase (M = 0.46, SD =

1.61) as did good sleepers ($M = 0.15$, $SD = 0.98$), but again this was not statistically significant [$t(57) = 0.79$, $p = 0.44$]. This data indicated that symptomatic menopausal women who were good quality sleepers did not differ from those symptomatic menopausal women who were poor quality sleepers in changes with their BMI in the previous 6 months and 12 months. Differences in weight gain between good quality sleepers and poor quality sleepers are summarized in Table 4.

Table 4

Differences in Weight and BMI Change from Current to 6 and 12 months Previous (n = 59)

	Six Month Weight Change			Twelve Month Weight Change		
	Good Sleepers	Poor Sleepers	p-value	Good Sleepers	Poor Sleepers	p-value
	<u>M(SD)</u>	<u>M(SD)</u>		<u>M(SD)</u>	<u>M(SD)</u>	
Weight ^a	1.47(6.21)	2.50(8.90)	0.62	2.70(9.60)	3.47(10.70)	0.79
BMI ^b	0.15(0.98)	0.46(1.61)	0.44	0.20(1.67)	0.69(1.94)	0.34

^a = weight in pounds, ^b = body mass index, M = mean, SD = standard deviation

Relationships Between Weight Gain and Sleep Duration

Relationships between weight gain and sleep duration were explored using Pearson's r . Again, changes in weight scores were calculated by subtracting self-reported weight at 6 months previous and at 12 months previous from current reported weight. Sleep duration was determined by the number of actual hours of sleep recorded on the PSQI questionnaire by each subject. At 6 months, no significant relationship was found between average weight gain and self-reported hours of actual sleep ($r = 0.05$, $p = 0.63$). Also, at 12 months, there was no significant relationship between average weight

gain and sleep duration was found ($r = 0.04$ with $p = 0.78$). The data indicated that in this sample, no relationships were found between weight gain and sleep duration.

Relationships Between Weight Gain and Sleep Quality

Sleep quality was determined by global PSQI score. The higher the PSQI score the poorer the sleep quality. Changes in weight scores were calculated by subtracting self-reported weight at 6 months previous and at 12 months previous from current reported weight. No significant relationships were demonstrated between average weight gain and self-reported sleep quality at 12 months ($r = -0.29$, $p = 0.83$). Also, at 6 months, no significant relationship between average weight gain and self-reported sleep quality was demonstrated ($r = -0.145$, $p = 0.27$). The data indicated that in this sample, no relationships were found between weight gain and sleep quality. Table 5 illustrates the relationships between weight gain, sleep quality, and sleep duration.

Table 5

Relationships between Weight Gain, Sleep Quality, and Sleep Duration (n = 59)

Weight Gain	Sleep Duration	Sleep Quality
6 months	$r = -0.145$	$r = 0.050$
	$p = 0.270$	$p = 0.630$
12 months	$r = -0.290$	$r = 0.040$
	$p = 0.830$	$p = 0.780$

Discussions of Findings

Most studies have examined the differences and correlations of obesity and sleep duration between the different classifications of BMI (Buscemi et al., 2007; Gangwisch et al., 2005; Kohatsu et al., 2006; Singh et al., 2005; Taheri et al., 2004; Vorona et al., 2005), menopause and sleep (Kravitz et al., 2005; Kravitz et al., 2008; Ohayon, 2006; Pien et al., 2008; Sowers et al., 2008; Young, Rabago et al., 2003; Young, Finn et al., 2003) or menopause and obesity (Sowers et al., 2007; Sternfeld et al., 2004; Sternfeld et al., 2005; Thurston et al., 2009). However, few studies have examined the possible relationships between sleep quality, sleep duration, and weight gain in symptomatic menopausal women.

Demographics

In the current study, symptomatic menopause was determined by ICD-9 code 627.2 (symptomatic menopause), as determined by their healthcare provider in the previous 6 to 12 months. Previous researchers have used menstrual bleeding criteria (Kravitz et al., 2005; Young, Rabago et al., 2003), FSH level and menstrual bleeding criteria (Kravitz et al., 2008), or FSH level and self report of hot flashes (Ohayon, 2006; Sowers et al., 2008; Young, Finn et al., 2003) to determine menopausal status.

The wide age range for menopause (42 to 58 years) has proven to be a poor indicator of reproductive aging (Soules et al., 2001). However, Sowers et al. (2008) found that 33.3% of women reported hot flashes and 50% experienced night sweats at an average age of 50.3 years. Other researchers have reported menopausal subjects' mean age of menopause as 51.6 (Young, Finn et al., 2003), 53 (Ohayon, 2006), and 47 (Kravitz et al., 2005). The mean age of the current sample was 55.9 (SD = 7.1).

Overweight is defined as a BMI of greater than or equal to 25 (NHLBI, 1998). It is estimated that two-thirds of the U.S. adult population is either overweight or obese (AHA, 2010). The menopausal transition has been linked with increases in body fat (Thurston et al., 2009) and waist circumference (Sowers et al., 2007). Previous research has found that BMI among menopausal women during their transition was approximately 28 (Kravitz et al., 2008; Ohayon, 2006; Sowers et al., 2008; Young, Rabago et al., 2008). In the current study, the mean BMI was 27.7 (SD = 6.7), indicating that on average, this sample of women was overweight. Sternfeld et al. (2004) suggested that maintaining or participating in physical activity contributes to prevention or attenuation of weight gains. Only 3.4% of the current sample of women reported exercising on a daily basis and 29% reported never exercising at all.

The average global PSQI score in the current sample was 7.8 (SD = 4.1), indicating poor sleep quality. Hormonal changes have been cited as one of the top six factors that affect a woman's sleep (AASM, 2007). Approximately two-thirds of the current sample of symptomatic menopausal women was classified as having poor sleep quality. In a national telephone survey, Barker et al. (2009) reported that 27% of women aged 18 to 64 reported poor sleep quality. Kravitz et al. (2005) reported that 74% of women experienced trouble sleeping on at least one night per week, and those women in the beginning of the menopausal transition reported a higher percentage of sleep difficulties. Other researchers have also reported high rates of sleep disturbances and complaints in women during the menopausal transition (Ohayon, 2006; Sowers et al., 2008; Young, Rabago et al., 2003).

Taheri et al. (2004) found that persons sleeping less than 8 hours nightly had an increased BMI proportional to decreased sleeping time. Several other researchers also

supported an association between short sleep duration and higher BMI (Buscemi et al., 2007; Gangwisch et al., 2005; Hasler et al., 2004; Kohatsu et al., 2006; Singh et al., 2005; Vorona et al., 2005). In the current study, the average actual hours of sleep per night was 6.7 hours and 35.7% reported sleeping 6 hours or less every night.

Differences in Weight Gain and BMI

Between Good Quality Sleepers and Poor Quality Sleepers

There is a dearth of studies that examined weight gain, BMI, and sleep quality in symptomatic menopausal women. Huerta et al. (1995) found that sleep alterations were present in 76.9% of early menopausal women and 70.9% of late menopausal women. BMI was 28.8 (SD = 5.0) among early menopausal women and 26.8 (SD = 6.3) among late menopausal women (Huerta et al., 1995). This indicated that early menopausal women had poorer sleep quality and were more overweight than those women in late menopause. In the current study, it appears that poor sleep quality occurs in conjunction with higher weight and increased BMI; however, there was no significant statistical difference in weight gain or BMI between good and poor quality sleepers. Comparison to previous research was difficult, as few researchers examined weight gain or BMI and sleep quality utilizing the PSQI questionnaire or examined differences in weight gain between good and poor quality sleepers..

Relationships Between Weight Gain and Sleep Duration

Several researchers have reported that short sleep duration is related to increases in weight (Buscemi et al., 2007; Gangwisch et al., 2005; Hasler et al., 2004; Kohatsu et al., 2006; Singh et al., 2005; Taheri et al., 2004; Vorona et al., 2005). In the current study, at 6 months, no significant relationship was found between average weight gain and self-reported hours of actual sleep. Also, at 12 months, there was no

significant relationship between weight gain and sleep duration found. Small sample size and lack of statistical power may have limited the findings of this study.

Relationships Between Weight Gain and Sleep Quality

Sleep quality is a complex phenomenon that includes sleep duration, number of arousals during sleep, and restfulness of sleep, which is objective and varies between individuals (Buysse et al., 1989). There are few studies that have examined sleep quality and weight gain (Baker et al., 2009; Behan et al., 2007). Behan et al. (2007) reported that 50% of diabetics surveyed were classified as poor quality sleepers; however there was no significant correlation between PSQI score and BMI found in the group as a whole. Baker et al. reported that over 25% of people with type 2 diabetes within their sample had poor sleep quality. Of the poor quality sleepers, 29.8% reported a BMI of 30 or greater, indicating obesity, and 24.6% reported a BMI of 25.0 to 29.9, indicating overweight. Although the PSQI was not utilized to assess sleep quality, age nor BMI were demonstrated to be risk factors for poor quality sleep (Baker et al., 2009). In the current study, no significant relationships were demonstrated between average weight gain and self-reported sleep quality at 6 months or at 12 months.

Chapter Summary

The purpose of this study was to determine if there is a difference in the amount of weight gain between symptomatic menopausal women who are poor quality sleepers and those who are good quality sleepers, and to explore the possible relationship between weight gains, sleep duration, and sleep quality in symptomatic menopausal women. The sample consisted of 59 women diagnosed with symptomatic menopause, identified by ICD-9 code 627.2, by their healthcare provider at one of three multi-

specialty clinics in two northeastern Wisconsin cities within the previous 6 to 12 months. The participants ranged in age from 44 to 80. The average current BMI was 27.7, indicating overweight classification. Thirty-nine participants (66%) were identified as poor quality sleepers by self-report on the PSQI questionnaire. The mean age of symptomatic menopause subjects was 55.9.

There is a paucity of research that examines the concepts of sleep quality, sleep duration, and weight gain in symptomatic menopausal women simultaneously. Based on the results of this study, it cannot be assumed that relationships exist between sleep duration or sleep quality and weight gain in symptomatic menopausal women or that weight gain is a common phenomenon among symptomatic menopausal women who have poor sleep quality. However, this study does reveal that symptomatic menopausal women report lack of good quality sleep and, on average, report weights consistent with a classification of overweight. Because of the literature supported sequelae of both sleep disturbances and overweight, further study is warranted in this population.

CHAPTER V

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Introduction

Overweight and obese individuals are at increased risk for cardiovascular disease (Grundy, 2004), dyslipidemia, metabolic syndrome (Alberti et al., 2009), diabetes, various cancers (Field et al., 2001), hypertension (HTN), stroke, osteoarthritis, sleep apnea, asthma, depression, and social discrimination (Stein & Colditz, 2004). Several researchers have associated short sleep duration with obesity and/or increased risk factors for obesity (Buscemi et al., 2007; Gangwisch et al., 2005; Hasler et al., 2004; Kawada, 2002; Singh et al., 2005; Stamatakis & Brownson, 2007). And, short sleep duration has been shown to decrease serum leptin and increase serum ghrelin, which compromises insulin sensitivity and increases BMI, which may explain the biological mechanism linking short sleep duration and obesity (Taheri et al., 2004).

Women are of particular interest in the relationships between obesity, weight gain, sleep duration, and sleep quality, because of the normal female hormonal transition to menopause that occurs in all women (Schuiling & Likis, 2006). Sleep problems may be directly associated with hot flashes (Soares, 2005), and nocturnal hot flashes can cause repeated nocturnal awakenings (Ohayon, 2006), resulting in reported reduced sleep duration and poor sleep quality (Ohayon; Soares,). The phenomenon of shorter sleep duration and poorer sleep quality among women during their menopausal transition is further supported by the Study of Women's Health Across the Nation

(SWAN), which was designed to examine the biological, physiological, psychological, and social health of women during their middle years (NIA, 2009).

Menopausal women commonly report weight gain (Hatcher et al., 2007) and sleep disturbances (Avis et al., 2005; O'Bryant et al., 2003; Ohayon, 2006) as being problematic during their normal female hormonal transition. Decreased physical activity, increased daily caloric intake, hormonal fluctuations, and hot flashes have been viewed as causative factors for these menopausal problems (Schuiling & Likis, 2006). Since menopause has been linked with sleep disturbances (Kravitz et al., 2005; Kravitz et al., 2008; Ohayon, 2006; Sowers et al., 2008; Young et al., 2003) and increased weight (Sowers et al., 2009; Sternfeld et al., 2004; Sternfeld et al., 2005; Thurston et al., 2009) it was prudent to explore the possible relationship between sleep duration, sleep quality, and weight gain in symptomatic menopausal women.

Study Summary

The purpose of this study was to determine if there was a difference in the amount of weight gain between symptomatic menopausal women who are poor quality sleepers and those who are good quality sleepers; and to explore the possible relationship between weight gains, sleep duration and sleep quality in symptomatic menopausal women.

A retrospective descriptive design using a convenience sample of 59 symptomatic menopausal women from three multi-specialty clinics in two northeastern Wisconsin cities was employed. Subjects were recruited by ICD-9 billing code 627.2, symptomatic menopause, mailed a participant study packet, and then requested to complete and return two questionnaires. Data collection instruments included a

demographic questionnaire, which included self-report of height and weight, and the Pittsburgh Sleep Quality Index (PSQI) questionnaire. The independent t-test was used to compare the differences of weight gain between symptomatic menopausal women who have good sleep quality and those who do not. Pearson's r correlation was used to establish whether relationships exist between weight gain and sleep quality as well as sleep duration.

Throughout the human lifespan, one can expect that change will occur. Changes in health status, relationships, environment, and aging of the body create a process of transition (Meleis et al., 2000). Transition exposes vulnerability within individuals to risks that may affect health and well-being. Illustration of the transition process aids identification of these risks and enhances understanding of the transition process (Meleis et al., 2000). Although not statistically significant, symptomatic menopausal women in this study did have increases in weight over time and did report a higher percentage of poor sleep quality, which may affect health and overall well-being. Therefore, employing Meleis' Theory of Transitions as a theoretical framework for this study was appropriate.

Results of this study revealed that, in this sample of symptomatic women, there were no significant differences in weight or BMI change over a 6 and 12 month time period between good quality sleepers as compared to poor quality sleepers. Also, there was no significant correlation between sleep quality or sleep duration and changes in weight during the time period under investigation. However, 66% of symptomatic menopausal women in this sample were found to have poor sleep quality, and their average weight was classified as overweight. Additionally, 37.3% of symptomatic menopausal women in this sample were found to exercise less than three days per week

and 28.8% were found to never exercise. These findings illustrate that among symptomatic menopausal women, there is evidence of poorer sleep quality, increased weight, and lack of exercise, which may affect the overall health of these individuals in now and in years to come.

Limitations

While the literature supports relationships between sleep duration and weight gain, weight gain and hormone fluctuation in menopause, and hormone fluctuations of menopause and sleep disturbance, there is a paucity of research that examines sleep quality, sleep duration, and weight gain in symptomatic menopausal women simultaneously. The results of this study do not provide evidence that sleep duration or sleep quality impact weight gain in symptomatic menopausal women and does not provide evidence that weight gain is a common phenomenon among symptomatic menopausal women who have poor sleep quality.

The small sample size reduced the power for statistical analysis, and there may have been sample bias using self-reports of sleep. Extraneous variables, such as physical activity level and dietary intake, were not controlled in the non-experimental design of this study, thus having an undetermined impact on the findings. The sample lacked ethnic heterogeneity, therefore limiting generalizability, and no causal inference can be inferred between weight gain and sleep.

Conclusions and Implications for Advanced Practice Nursing

The results of this study create several implications for advanced practice nursing. The mean current BMI of participants in this study was 27.7, indicating

overweight, and 66% reported exercising less than three days per week. The association of menopause and body weight is important because excess weight increases risk for cardiovascular disease and stroke and all cause mortality in middle age (Sowers et al., 2007). Advanced practice nurses need to be aware that women in their menopausal transition may be more vulnerable to weight gain due to rapid hormonal changes and should incorporate education about the importance of an active lifestyle advocating for literature supported exercise interventions to promote overall health and general well-being.

The mean global PSQI score was 7.8, and the mean self-reported actual hours of sleep was 6.7 hours per night, indicating that participants were generally poor quality sleepers with short sleep durations. Short sleep duration has been associated with an increased risk of HTN, diabetes, stroke (Park et al., 2009), and an increase in BMI (Buscemi et al., 2007; Gangwisch et al., 2005; Hasler et al., 2004; Kohatsu et al., 2006; Singh et al., 2005; Vorona et al., 2005). Advanced practice nurses must be aware of potential for sleep disturbances in women during their menopausal transition and assess for sleep quality and sleep disturbances that may otherwise be mistaken as unremarkable characteristics of menopause. The PSQI is a reliable tool to use for sleep quality assessment and may be used to introduce discussion about sleep duration and potential sleep disturbances.

Menopause is a normal life transition process that occurs in all women at some point of life (O`Bryant et al., 2003; Schuiling & Likis, 2006). All female patients should be educated about menopausal transition and the affects of overweight and obesity. Advanced practice nurses have a responsibility to keep current in all areas of disease

management in order to provide the highest quality care and avoid complications of obesity and sleep disturbances during the menopausal transition.

Recommendations for Further Research

The literature review and the results of this study demonstrate a need for further research. Research to be considered includes the following:

1. The review of literature revealed a paucity of studies addressing sleep quality, sleep duration, weight gain, and symptomatic menopause simultaneously.

These outcomes must be measured, analyzed, and replicated before a definitive conclusion can be reached about associations. Replication of this study with an adequately powered sample size is warranted.

2. Studies measuring sleep quality sleep duration, and weight gain in symptomatic menopause must be done using a larger sample in a different geographical location with greater cultural diversity size in order to provide data more representative of the population as a whole.
3. A prospective study may yield more accurate data than that available in this retrospective design and may minimize sample bias when subjects are not required to reflect on time greater than one month previous.
4. Variables, such as dietary intake and physical activity as related to sleep and weight gains, need to be considered and controlled for in further research.
5. Studies examining the relationship of a woman's specific knowledge about weight management, sleep hygiene, and menopause are needed.

Chapter Summary

Menopause is a normal process in the female life cycle. Women often experience weight gain and sleep disturbances during this transition. This study revealed that symptomatic menopausal women report a high prevalence of poor sleep quality, with an average sleep duration of 6.7 hours each night. This sample also reported an average current BMI of 27.7, indicating a high prevalence of overweight classification among symptomatic menopausal women. Limitations with this research study included small sample size, lack of control for extraneous variables, homogeneity of the sample, and retrospective design.

Findings from this study support two important implications for APN practice. First, APNs must be aware of the prevalence of sleep related concerns (i.e., short sleep duration and poor quality sleep) and obesity among symptomatic menopausal women. And second, APNs should assess symptomatic menopausal women for sleep related concerns and then implement literature-supported interventions to improve health and promote general well-being.

Further research is needed to determine the role of sleep quality and sleep duration in weight gain during the menopause transition. Recommendations for future research include using a prospective design, inclusion of possible confounding variables, examinations of specific knowledge about menopause, weight management, and sleep hygiene, and replication of the study using a larger more representative sample.

APPENDIX A
The STRAW Staging System

		Final menstrual period (FMP)							
Stages:		-5	-4	-3	-2	-1	0	+1	+2
Terminology:	Reproductive			Menopausal transition			Postmenopause		
	Early	Peak	Late	Early	Late*	Early*		Late	
Duration of stage:				Perimenopause					
	Variable			Variable			(a) 1 yr	(b) 4 yrs	until demise
Menstrual cycles:	Variable to regular	Regular		Variable cycle length (>7 days different from normal)	≥2 skipped cycles and an interval of amenorrhea (≥60 days)	Amen x 12 months	None		
Endocrine:	Normal FSH		↑ FSH	↑ FSH		↑ FSH			

*Stages most likely to be characterized by vasomotor symptoms

Adapted from Soules, M. R. et al. Fertility and Sterility 2001; 76:874

APPENDIX B
Demographic Questionnaire

Demographics Questionnaire

This questionnaire will provide a broad description of those participating in the study. All information will remain anonymous. **Please do not include your name on this paper.**

Please read each question carefully. Place an X on the line next to the selection that is most appropriate for you. Please try to answer every question. If none of the answer selections seem exactly right, chose the one that comes nearest to being right for you.

1. What is your age? _____

2. What is your race or ethnicity?

_____ American Indian/ Native American

_____ Asian

_____ Black/ African American

_____ Hispanic/ Latino

_____ White/ Caucasian

_____ Pacific Islander

_____ Other

3. What is your marital status?

_____ Divorced

_____ Widowed

_____ Married

_____ Single

_____ Never Married

4. What is the highest level of education you completed?

_____ Grade School or less

_____ High School

_____ Trade/Vocational School

_____ College

_____ Post College

5. What is your current employment status?

_____ Employed Fulltime

- Employed Part-time
- Unemployed/ Looking for work
- Student
- Homemaker
- Retired

6. What are your current living arrangements?

- Live alone
- Live with spouse only
- Live with Spouse and children
- Live with someone else

7. What is your annual total household income status?

- Less than \$20,000
- \$21,000 – \$35,000
- \$36,000 - \$50,000
- \$51,000 - \$65,000
- \$65,000 – or more

8. How often do you exercise?

- Never
- 1 - 3 days a week
- 3 - 5 days a week
- 5 - 6 days a week
- Daily

9. What is your smoking status?

- Never
- Quit greater than 12 months ago
- Quit less than 12 months ago
- Currently smoking

10. Please record the following information about your height and weight as accurately as possible:

a.) Current:

_____ Height (feet and inches)

_____ Weight (pounds)

b.) 6 months ago:

_____ Height (feet and inches)

_____ Weight (pounds)

c.) 12 months ago:

_____ Height (feet and inches)

_____ Weight (pounds)

Thank you for completing this questionnaire.

APPENDIX C

The Pittsburgh Sleep Quality Index (PSQI)

The Pittsburgh Sleep Quality Index (PSQI)

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

During the past month,

1. When have you usually gone to bed? _____
2. How long (in minutes) has it taken you to fall asleep each night? _____
3. When have you usually gotten up in the morning? _____
4. How many hours of actual sleep do you get at night? (This may be different than the number of hours you spend in bed) _____

5. During the past month, how often have you had trouble sleeping because you	Not during the past month (0)	Less than once a week (1)	Once or twice a week (2)	Three or more times a week (3)
a. Cannot get to sleep within 30 minutes				
b. Wake up in the middle of the night or early morning				
c. Have to get up to use the bathroom				
d. Cannot breathe comfortably				
e. Cough or snore loudly				
f. Feel too cold				
g. Feel too hot				
h. Have bad dreams				
i. Have pain				
j. Other reason(s), please describe, including how often you have trouble sleeping because of this reason(s):				
6. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?				
7. During the past month, How often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				

8. During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?				
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	Very good (0)	Fairly good (1)	Fairly bad (2)	Very Bad (3)
9. During the past month, how would you rate your sleep quality overall?				

Reprinted from: *Journal of Psychiatric Research*, 28(2), Buysse, D.J., Reynolds III, C.F., Monk, T.H., Berman, S.R., & Kupfer, D.J.

Sleep Quality Index: A New Instrument for Psychiatric Practice and Research, 193-213, Copyright 1989, with permission from Elsevier Science.

APPENDIX D
Provider Letter

Insert Official Company Letterhead and logo

RE: Research Study Participation

Dear Patient,

You are receiving this letter because I am aware of a student research project in which you are eligible to participate. Dawn Martin, an Aurora employee and graduate student from the University of Wisconsin Oshkosh Graduate Nursing Program, is conducting an interesting research study to explore the potential relationships between sleep duration, sleep quality and weight gain in menopausal women. This research is a requirement for her Masters in Science degree in Nursing. I encourage you to consider being in the study because this is an area that we, as professionals, need to better understand.

Your eligibility for this study was determined by Aurora Medical Group clinic staff reviewing a list my patients who have been diagnosed with “symptomatic menopause”. Dawn Martin does not have access to your name or contact information. Clinic staff has mailed this packet with my approval.

Participation in this study is being offered to all patients who were seen at Aurora Medical Group at Oshkosh in the past 6-12 months for symptomatic menopause. This research project has been approved by the University of Wisconsin Oshkosh and the Aurora Health Care Institutional Review Boards for Protection of Human Participants.

As your healthcare provider, I am not a part of this study and will not have access to responses or the results of this study, except through professional publications that Dawn Martin may write. Your participation in this study is completely voluntary and will not interfere with or change your treatment at any time. The information gathered through these surveys is completely **anonymous**. Please be assured that should you choose not to participate, this **will not affect** the relationship we have built or any care that you receive at Aurora Health Care.

Thank you for your time.

Sincerely,

Insert Provider Signature Here

APPENDIX E

Patient Information Sheet of Introduction

Sleep Duration, Sleep Quality and Weight Gain in Menopausal Women: Is there a link?

UW- Oshkosh Graduate Nursing Student Research – Dawn Martin

My name is Dawn Martin. I am an Aurora employee and a student from the University of Wisconsin Oshkosh completing the requirements for a Master of Science degree in nursing to practice as a Family Nurse Practitioner. I am conducting this research study to explore the possible relationships between sleep duration, sleep quality and weight gain in symptomatic menopausal women. All patients who were seen at Aurora Medical Group at Oshkosh in the past 6-12 months with a diagnosis of “symptomatic menopause” are being asked to participate in this study. Your name was included in a list of patients who had this diagnosis that was generated by your healthcare provider’s office.

The information obtained from you for this study will be kept completely anonymous. An employee from Aurora Medical Group generated a list of eligible patients from your healthcare provider’s office and mailed this information packet to you. This person does not have access to your medical records or your responses. As the primary researcher, I have no access to your identity or your medical record. The completed questionnaires will be returned to me, placed in a locked file and only I, as the primary researcher, will have access to the locked file. Upon completion of this study, the list of eligible patients and all questionnaires will be destroyed.

If you chose to participate, please complete the two questionnaires, place them in the postage paid, pre-addressed return envelope and mail the envelope. Do not put a return address on the envelope to help keep your anonymity. Completing the surveys takes approximately 15 minutes. Completion and return of the questionnaires implies that you understand the information provided and agree to participate.

Please do not write your name or any identifying information on the questionnaires.

Any information that you provide cannot be linked to you. Your participation in this study is completely voluntary and anonymous. You may withdraw participation at any time without penalty. Should you decide not to participate, please throw away this survey packet. There will be no penalty to you.

Being in this study presents no risk or cost to you, other than the time it takes to complete the questionnaires. While being in this study does not benefit you directly, the findings may provide important information about sleep duration, sleep quality and potential relationships to weight gain in menopausal women; and may help to improve strategies for patient education and guide health promotion efforts. Results from this research, reported in journals or meetings, will be in group form only. This research study has been approved by the University of Wisconsin Oshkosh and the Aurora Health Care Institutional Review Boards.

If you have questions or complaints about your treatment as a participant in this study, please call or write to:

Institutional Review Board, Chair
For the Protection of Human Participants
C/o Grants Office
University of Wisconsin Oshkosh
Oshkosh, WI 54901
(920) 424-4515

Questions regarding research subjects' rights can be forwarded to:

Aurora Health Care Research Subject Protection Program/IRB Office
945 N. 12th Street
P.O. Box 342 W310
Milwaukee, WI 53201- 0342
(414) 219-7744

The chairperson or research subject protection program manager may ask for your name. However, all complaints are kept confidential.

Thank you for your time. Your participation in this research study is appreciated.

Sincerely,

Dawn Martin RN BSN CCAP

APPENDIX F
Study Timeline

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