

**SEX DIFFERENCES IN THE SYMPTOM PRESENTATION AND PERCEPTIONS OF
IMPAIRED SLEEP**

by

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Introduction: It is unclear from previous research if women physically experience or only perceive and report different symptoms of impaired sleep that result from serious sleep disorders such as Obstructive Sleep Apnea (OSA). To prevent a missed diagnosis, it is imperative that we clarify and expand upon the different symptomology and perceptions of impaired sleep reported by both women and men.

Objective: To gain insight into sex and gender differences in the perceptions and symptom presentations of impaired sleep and its next-day outcomes.

Methods: Three aims were proposed that would advance insight into the different possible perceptions and symptom presentations that men and women with type 2 diabetes have when coping with impaired sleep. Aim 1, a qualitative analysis, used semi-structured interviews to explore differing patterns of perceptions and symptom presentations of impaired sleep between men and women. Aim 2, examined the codes and categories from the qualitative interviews and compared them to commonly used instruments in sleep research. Aim 3, a quantitative analysis of secondary data examined the physiological measurement of OSA severity, and its influence on sleep quality, mood, excessive daytime sleepiness, and daytime function and moderation by sex.

Results: Aim 1. While both men and women were tired during the day, women provided rich descriptions of an omnipresent fatigue or sleepiness that affected their motivation and energy to get things done and men provided examples of fatigue or sleepiness at specific times of the day

that they were determined to not let affect them. Aim 2. When the sleep instruments were compared to the codes and categories in aim 1, it was found that they did not capture the differing coping styles of men and women who are fatigued or sleepy during the day. Aim 3. In adjusted models, OSA severity was not predictive of the subjective sleep outcomes and no effect by sex.

Conclusion: We concluded that there were differences by sex in the perceptions and symptom presentations of impaired sleep and its next-day outcomes likely due to the influence of gender roles and which sleep instruments are not sensitive to. AHI does not explain subjective sleep outcomes in men or women.

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Preface

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1.0 PROPOSAL INTRODUCTION

Obstructive Sleep Apnea (OSA) is a common cause for impaired sleep with serious health implications but is under-diagnosed and therefore under-treated in women (Franklin & Lindberg, 2015; Lee, Nagubadi, Kryger, & Mokhlesi, 2008; Lin, Davidson, & Ancoli-Israel, 2008; Punjabi, 2008; Ye, Pien, & Weaver, 2009). OSA has gone undiagnosed in women, possibly because the disease has been defined based on symptoms of OSA which are most common among men and include snoring, excessive daytime sleepiness and waking up during the night snorting or gasping for air (Cao & Kushida, 2011). A growing body of evidence suggests that women may have different OSA symptomology, thus contributing to their under-diagnosis (Franklin, Sahlin, Stenlund, & Lindberg, 2013; Lin, Davidson, & Ancoli-Israel, 2008; Mallampalli & Carter, 2014; Miller et al., 2017; Ye et al., 2009). If the symptomology of OSA is different in women compared to men, this would suggest a biologically determined cause and therefore exploring potential biological mechanisms should be undertaken. However, it is unclear from previous research if women experience or only perceive and report different symptoms of OSA than men. Gendered roles, expectations and characteristics may influence the perceptions of impaired sleep while masking or exposing differences in the manifestations or expressions of symptoms. Therefore, it is imperative that we clarify and expand upon the different symptomology and perceptions of impaired sleep reported by both men and women. Using qualitative and quantitative methodologies, this project will examine and compare reports of poor sleep quality and its daytime symptoms in men and women with type 2 diabetes mellitus (T2DM) who are at elevated risk for

OSA. It is estimated that up to 83% of people with type 2 diabetes have undiagnosed OSA making this an ideal group for this study (Pamidi & Tasali, 2012).

We proposed to address this problem by listening to the “voices” of women and men with T2DM at high risk for OSA who have self-reported symptoms that are suggestive of impaired sleep or OSA. The qualitative interviews were reviewed for themes that emerge from the data both as a full group and by sex. A possible reason that women’s OSA symptomology remains unclear is that the research instruments used to measure the symptoms of sleep and OSA do not reflect all the possible symptoms that women perceive or report. Therefore, the themes that emerge were compared with the concepts that are evaluated in common sleep measures to determine if the perceptions of impaired sleep in both sexes are represented. Finally, a secondary analysis of baseline data from an ongoing clinical trial was used to test whether sex moderates the association between objectively and subjectively measured sleep and next-day outcomes that were measured in the parent study.

The proposed study was feasible because 1) it recruited participants for the qualitative aim from the study Effect of Treatment of OSA on Diabetes Self-Management and Glycemic Control: The Diabetes Sleep Treatment Trial (DSTT) (R01DK096028, PI: E. Chasens), and 2) used the baseline data from that trial for the secondary analysis for the quantitative aim. This sample was appropriate for the proposed study because men and women with T2DM share a similar phenotype of increased central obesity that places them both at risk for OSA (Drager, Togeiro, Polotsky, & Lorenzi-Filho, 2013; Huang et al., 2015). However, women experiencing chronic diseases such T2DM, are especially vulnerable to a missed OSA diagnosis. The Symptom Management Model (SMM) placed the perception of symptoms within a framework of overall symptom management and guided this study (Dodd et al., 2001). Sandra Bem’s “Lenses of Gender” provided the

theoretical foundation that guided the interpretation of any differences found between women and men (Bem, 1993).

1.1 Specific aims

Aim 1. Characterize in depth both men's and women's perspectives of and approaches to describing impaired sleep and its impact on daytime function and mood.

Aim 2. Examine the symptom descriptions that emerge in Aim 1 to determine the extent to which they reflect and are concordant with the concepts embedded in standard instruments commonly used to assess sleep quality and its impact on daily functioning.

Aim 3. Utilize baseline data from the DSTT to explore if sex moderates the associations between the objectively assessed presence, severity, and clinical presentation of OSA (apnea + hypopnea index [AHI]; ratio of apneas to hypopneas; % sleep time with oxygen desaturation < 90%; snore index [# snores/flow evaluation period]); and subjective measures of 1) sleep quality, 2) daytime functioning, 3) daytime sleepiness, and 4) mood in men and women with T2DM.

This study directly addressed the National Institute of Nursing Research's focus on improving symptom management by ensuring that symptoms of impaired sleep specific to women are appropriately recognized. This fresh look at the symptoms and perceptions of impaired sleep provided the groundwork for a program of research potentially leading to interventions addressing sleep impairment in both men and women.

1.2 Significance, background, innovation

1.2.1 Background

OSA is a common cause for impaired sleep with serious health implications, but is under-diagnosed and therefore under-treated in women (Franklin & Lindberg, 2015; Lee et al., 2008; Lin et al., 2008; Punjabi, 2008; Ye et al., 2009). It is defined by decreased airflow (hypopneas), or due to repetitive complete apneas or partial obstruction of the upper airway when a person is asleep (Lee et al., 2008). Among clinic populations the ratio of men to women with OSA ranges from 8:1 to 10:1; however, the actual ratio of men to women is estimated to be closer to 2:1 (Lee et al., 2008) or 3:1 (Lin et al., 2008; Ye et al., 2009). Furthermore, depending on age, estimates of prevalence of OSA varies from 10% to 17% in men, and 3 and 9% in women (Peppard et al., 2013). Studies that have examined this prevalence of men to women have not always included balanced samples, and some researchers have suggested that women's risk for OSA approaches that of men after menopause (Lin et al., 2008; Ye et al., 2009). The repercussions of untreated OSA are staggering. It is associated with increased risk for diabetes, high blood pressure, heart disease, metabolic syndrome, stroke, atrial fibrillation, and mortality (BaHammam et al., 2015). Its prevalence has likely increased in the last twenty years possibly due to the increase in obesity in western populations (Peppard et al., 2013).

Awareness among healthcare providers of women's vulnerability to OSA has been low. For instance, a recent weight loss study conducted at the University of Pittsburgh, discovered that 50% of the female participants in its study had undiagnosed OSA (Chasens, Imes, Kline, Strollo, & Burke, 2015). One reason may be that OSA has been defined based on men's presenting symptoms that include snoring, excessive daytime sleepiness and waking up during the night

snorting or gasping for air (Health, 2012). However, research of women's OSA symptoms is conflicting and will be discussed in detail in the following sections.

1.2.1.1 Biological Sex Differences

There is abundant evidence of sex differences in sleep and the pathophysiology of OSA to suggest the manifestation of symptoms in men and women are different. Sex differences are found in the effects of sex hormones on sleep mechanisms, in circadian clock genes, respiratory function, stress responses, and even in sleep duration (Mong et al., 2011). Physiological sex differences also exist within OSA. Women with OSA are likely to be more obese at the same levels of OSA than men, be protected from OSA by estrogen/progesterone prior to menopause, and have different but often more protective upper airway structures than men (Lin et al., 2008). Women with OSA present with fewer complaints of excessive daytime sleepiness and more commonly describe different symptoms such as restless legs and insomnia (Sheperdycky, Banno, & Kryger, 2005; Valipour et al., 2007; Ye et al., 2014). Additionally, the Society for Women's Health Research suggests that women with OSA may be more likely to also report depressed mood and fatigue than men with OSA (Miller et al., 2017). Many of OSA's classic symptoms, breathing pauses when asleep, choking or gasping for air when asleep, morning headaches, daytime sleepiness, (Lee et al., 2008) may mimic symptoms of other disorders (Ejaz, Khawaja, Bhatia, & Hurwitz, 2011).

1.2.1.2 Depression

For instance, depressed mood is associated with both OSA and insomnia in both men and women (Buysse et al., 2008; Ejaz et al., 2011; Franzen & Buysse, 2008). Insomnia, difficulty in either initiating sleep, maintaining sleep, and/or returning to sleep after an early morning awakening, has an increased prevalence in women (Miller et al., 2017) and is sometimes comorbid

with OSA (Luyster, Buysse, & Strollo, 2010). Given variation in instruments used to measure depression, which often include an item about sleep problems, the reported occurrence of depressed mood in women and men with OSA can vary. Data from a secondary analysis (N=212) from the ongoing Diabetes Sleep Treatment Trial (R01 5R01DK096028-02) suggests that insomnia, but not OSA severity is related to depressed mood in women and men with T2DM (Morris et. al., 2018). Chart review studies that examined the relations between OSA and depressive symptomology compared women directly to men and found women more likely to be taking antidepressant medications suggesting a greater likelihood of depression in the presence of OSA (Greenberg-Dotan, Reuveni, Simon-Tuval, Oksenberg, & Tarasiuk, 2007; Peppard, Szklo-Coxe, Hla, & Young, 2006; Shepertycky et al., 2005). However, it is possible healthcare providers had diagnosed depression in these women because they did not see its association with a medical disorder such as OSA. Psychologists have suggested that a depression diagnosis in women may be further confounded by various biases, 1) clinicians may assume women are depressed when they are in fact suffering from a medical disorder, 2) arguments are made that men and women manifest symptoms of depression differently, 3) men are less likely to endorse symptoms of depression because they are associated with femininity (Helgeson, 2011).

Other factors play a role in the assumption women with OSA have greater rates of depression than men with OSA. In the general population, women are more likely to report symptoms of depression than men (Pratt & Brody, 2014). It may be that women's higher rates of depressive symptomology than men in the presence of OSA only reflects the same rates of depression of women in the general population. Depression was not consistently measured using the same instruments across these studies. One study found that depression questionnaires that include questions with greater symptom overlap between chronic disease such as OSA and

depression were more likely to find a relationship between them (Nanthakumar, Bucks, & Skinner, 2016). Recently researchers have questioned the relationship of AHI, a measure of OSA presentation and severity, and depressive symptomology finding them only indirectly related (Björnsdóttir et al., 2015; Lee, Lee, Chung, & Kim, 2015; Sforza, Saint Martin, Barthélémy, & Roche, 2016). Researchers are also investigating symptom clusters in obstructive sleep apnea, (Joosten et al., 2012; Lacedonia et al., 2016; Saaresranta et al., 2016), a promising method to assist in the characterization of OSA symptomology. While some of these studies examine depression as a potential symptom of OSA, they have not yet closely examined the influence of biological sex or gender.

1.2.1.3 **Perceptual differences in symptoms**

Alternatively, it may be that men and women do in fact experience the same symptoms of OSA, but women may be less likely to recognize them. Gendered roles, expectations, and characteristics may influence the perceptions of impaired sleep while masking or exposing differences in the expressions of symptoms. As one study coordinator noted “everyone expects women to be tired.”

Women may often feel the expectation to not only work outside the home, but also to maintain primary responsibility for tasks inside the home which in turn may increase stress and prevent adequate rest. The expectation of fatigue in women may therefore mask the symptoms of a medical disorder.

Other perceived symptoms may also be influenced by factors attributed to gender. Possibly due to social stigma, women are less likely than men to report their symptoms of snoring to a healthcare provider (Chan, Wong, Tang, & Ng, 2012). A factor analysis of the Pittsburgh Sleep Quality Index suggested that women may associate poor sleep quality with sleep disturbances and

their daytime effects such as sleepiness or poor concentration, all overlapping symptoms of depressed mood. Men may be more likely to associate sleep quality with sleep duration and sleep efficiency (Morris, Rohay, & Chasens, 2018). A research study specifically examining impaired sleep outcomes between men and women suggested that when men experience poor sleep quality, their moods are affected negatively, whereas it's daytime sleepiness that affects women's activity, productivity, and vigilance (Chasens et al., 2016).

Consequently, while researchers have described sex differences in the symptomology of OSA through objective measures as described, these differences may not be translated accurately into the clinical setting because men and women may either experience different symptoms or may recognize and prioritize different symptoms. It is therefore likely that many factors confound sex difference research into OSA symptomology, which suggests that much of the research into sex differences in OSA symptomology remains unclear.

Heart disease provides precedent of this problem in women's health research whereas women have presented with different clinical symptoms and risk factors than men (Legato, Johnson M. J., Manson P. A., 2016). Women may also experience different risk factors for heart disease than men. For instance, women with depression experience more severe heart disease than men (Lichtman et al., 2014) and early menopause increases women's risk for heart disease (Ouyang et al., 2016).

1.2.2 **Innovation**

Consideration of the intersection of biological sex differences and gender are what make this study unique. While the National Institute for Health has implemented rules that all human subjects research must be balanced and analyzed by sex, they do not require analysis of gender

roles and socialization. However, gender likely plays a key, but usually invisible role in the findings of many human subject's research studies. While it is necessary to examine biological sex differences, without the analysis of the role of gender in healthcare research, most research is probably incomplete. It is likely that the use of the terms sex or gender contribute to biased interpretations of research findings as the dichotomy of sex and gender also presupposes their cause. This study will not assume that symptoms of OSA in women or men are as a result of environment (gender) or of biology. In other words, the use of the word "gender" assumes results will have socio-cultural causes and is usually used in social sciences research, whereas the use of the word "sex" indicates biological outcomes and is used in the natural sciences. In general, when the word gender is not being used as a euphemism for sex, it is used to presuppose a sociocultural cause of an outcome and it directs research questions and research design away from biological causes. Similarly, biological research assumes a biological cause for sex differences. A goal of this research will be to not assume apriori that sex or gender is the cause of the health disparities in OSA diagnosis between men and women.

1.2.2.1 Feminist theory in research

Briefly, Sandra Bem wrote that gender is perceived and interpreted through three lenses (Bem, 1993). The first lens, androcentrism, looks to men as normal and women as abnormal. The second lens, gender polarization, applies gender difference to all aspects of life; in other words, every decision, preference, and behavior is colored by one's gender. Gender characteristics associated with men usually have a positive connotation; characteristics associated with women usually have a negative connotation. Finally, biological essentialism is the lens that posits that not only do biological traits make men and women different, but also biology produces the gendered

characteristics associated with women and men. This lens is used to explain androcentric perspectives as well as explain why gender differences are so pervasive in culture. It is helpful to use these lenses to determine not only how researchers interpret their findings, but how these lenses may be embedded in the research questions and designs either directly or indirectly through the simple omission of the analysis of women altogether.

Because women have been underdiagnosed with OSA, this project inherently includes a gender polarized perspective to determine if there are characteristics in women that are contributing to a missed diagnosis. Therefore, it may be fruitful to examine the influence of sex and gender in the interpretation of any findings through Bem's three lenses of gender (figure 1). In the figure below, we see that all the lenses overlap in a Venn diagram. In this example, each circle represents a perspective based in either sex or gender that might inform the interpretations of the final outcomes of a research study examining depressive symptomology as a symptom of OSA, more commonly found in women. The model below provides an example of a method to examine the limits of utilizing just gender or sex in research design and interpretation. The theoretical foundation found below will inform the interpretations of this study's findings.

1.2.2.2 Theoretical Framework: Interpretation of sex differences

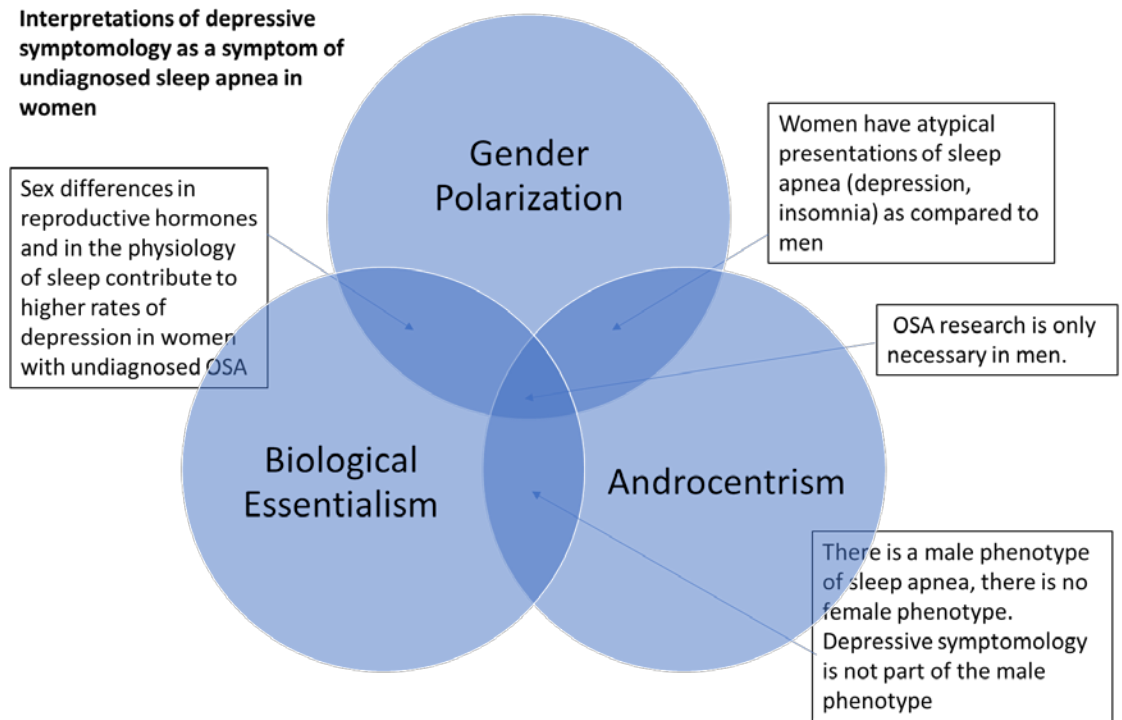


Figure 1 Model of Bem’s Lenses of Gender in sleep and depression research

Gender

Additionally, nursing and healthcare researchers continue to be unclear in the measurements and definitions of sex or gender. Rarely do healthcare researchers, looking at differences between men and women in nursing research, indicate the reasons for the term (sex or gender) they choose to use. Vicki Helgeson, author of *The Psychology of Gender*, defines gender “the social categories of male and female. These categories are distinguished from one another by a set of psychological features and role attributions that society has assigned to the biological category of sex” (Helgeson, 2011, pg 3). The American Psychological Association definition closely mirrors Helgeson and states, “gender is cultural and is the term to use when referring to women and men as social groups. Sex is biological; use it when the biological distinction is

predominant (VandenBos, 2010). Sex and gender have also been used by Wood and Eagly to conceptualize gender identity: 1) gender identity is summation of the traits or characteristics one has that are traditionally associated with a biological sex. 2) gender identity is one's self assigned gender (Wood & Eagly, 2015). As some researchers still use gender interchangeably with the word sex, it is easy to see how problematic the word gender has become. Is it 1) one's gender identification 2) the set of gendered characteristics or roles a person exhibits 3) the biological sex category perceived by others or 4) another word for sex? It is especially unclear how to measure gender, and if checking a box clearly captures any of these categories. For this study, because the definition of the word gender is in flux, the term sex will be used with the understanding that one's biological sex does not necessarily encompass a set gender identity or certain gendered characteristics.

While some theorists currently posit that biological sex categories are also socially constructed, the theory put forth by Art Arnold in "A General Theory of Sexual Differentiation" will guide the understanding of sex differences in this study (Arnold, 2017). While his theory provides detailed direction for biological sex difference researchers in their work, the theory also has implications for this study. He makes the claim that biological sex differences are not monolithic throughout the lifespan. Sex differences may arise and retreat at different points in growth and aging, during times of stress and disease, and are entrenched in the environment and culture; it is almost impossible to tease them apart. Because of this, this author will take the view that both biological sex differences and gender may inform the results.

Methodologically, qualitatively examining perceptions of impaired sleep in men and women who have T2DM and are at high risk for OSA may show areas where women's perceptions of their sleep and its daytime effects are not reflected in sleep instruments. It may be that using

predominantly quantitative methodologies and instruments predetermines the results that have been found thus far in the examination of women's OSA symptomology. Participants can only endorse the possible answers given to them. This can prevent new insights into impaired sleep and impede an accurate understanding of impaired sleep in women. This innovative proposal may inspire new understanding into the symptomology of impaired sleep, thus providing new directions for research.

1.2.3 Significance

By examining the perspectives of the symptoms of impaired sleep in both women and men independently in a balanced sample, this proposal addresses the 2014 National Institutes of Health directive that all researchers examine sex differences from basic research through advanced human interventions research (Clayton & Collins, 2014). This means not only that research projects should be designed to sample women and men equally, but that the study design and analysis must account for the influence of sex. It is not adequate to do a post hoc analysis. In fact, the NIH clearly states that "failure to account for sex as a biological variable may undermine the rigor, transparency, and generalizability, of research findings" (Clayton & Collins, 2014).

However, it is difficult to find systematic reviews in any area of OSA research that account for sex differences in their findings (Araghi et al., 2013; Moon, Punjabi, & Aurora, 2015; Myers, Mrkobrada, & Simel, 2013). Several often-cited literature reviews of the relation between depressive symptomology and OSA do not address the effect of sex or gender (Ejaz et al., 2011; Povitz et al., 2014). A recent systematic review that examined the health outcomes of untreated OSA had only enough evidence to make conclusions about its deleterious effects on men. The authors did not find sufficient samples of women in prior research to make conclusions about the

effect of untreated OSA on their health outcomes (Kendzerska et al., 2014). In individual studies that have attempted to look at sex differences in OSA risk or outcomes, many have significantly under sampled women making the findings unpersuasive (Basta et al., 2008; M. Lee et al., 2014; Simpson et al., 2010; Subramanian, Jayaraman, Majid, Aguilar, & Surani, 2012). This problem makes it difficult to draw accurate conclusions about OSA symptomology in women.

Women may also suffer worse outcomes of untreated OSA than men. One study that was powered to examine sex differences in cardiovascular disease and OSA suggested that women face complications different than men. They found severe OSA to be significantly associated with increased risk of heart failure or death in women only (HR 1.26 [1.05 – 1.50]) (Roca et al., 2015). Additionally, in women but not men, OSA severity is also an independent indicator of risk for cardiovascular disease (HR 1.33 [1.03 – 1.74]) (Roca et al., 2015).

Research and clinical instruments may not be equally sensitive to both sexes. Two studies have found a common sleep instrument, the Epworth Sleepiness Scale (ESS), to be more sensitive to men (Chervin & Aldrich, 1999; Zou et al., 2013). Therefore, results indicating that women are less sleepy than men in the presence of OSA may be incorrect. Additionally, women may identify more with the term “fatigue” and men with “sleepiness” (Eliasson, Kashani, Howard, Vernalis, & Modlin, 2015) which could potentially lead men to more highly endorse questions of sleepiness and women to more highly endorse questions with the word fatigue. A sociological study also suggested that men and women have different attitudes towards their sleep quality, with men in this study being less likely to consider sleep quality a health problem (Venn, Meadows, & Arber, 2013).

1.2.3.1 Theoretical Framework: Symptomology

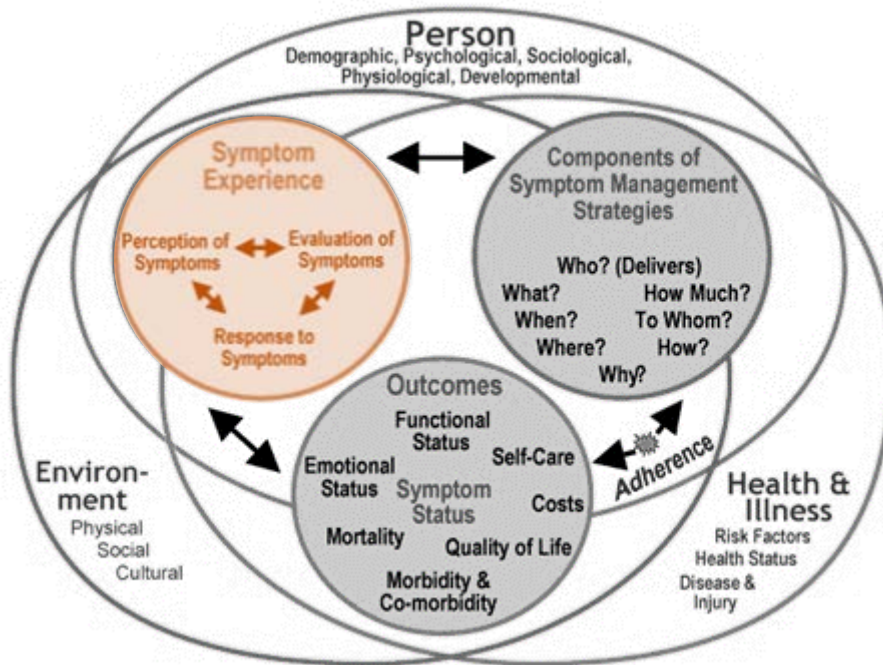


Figure 2: The Symptom Management Model

The Symptom Management Model (SMM) was used as an additional theoretical guide for this study's investigation (Dodd et al., 2001). The SMM holistically centers a person within three domains: Person,

Environment, and Health & Illness. The Person domain considers demographic, psychological, sociological, physiological, and developmental characteristics of the person. The Health & Illness domain includes current health status, risk factors, disease state, and disability. The Environment domain includes the physical, social, and cultural environment. Connected with the three domains are the three essential concepts of symptom experience (perception, evaluation, and response to symptoms), components of symptom management (who, what, when, where, why, how much, to whom, and how), and outcomes/symptom status (functional status, emotional status, self-care, costs, mortality, quality of life, and morbidity and co-morbidity). Guided by the SMM, this study examined the symptom perceptions of men and women with impaired sleep. A person's perceptions of their symptoms may affect their daytime function and how they choose to manage

those symptoms. In particular, for the focus of this study, the Symptom Experience concept (the orange circle), theorizes how the evaluation and perception of symptoms may determine a person's response to them. For example, if a person does not perceive their experience with sleep to affect their daytime mood or function, their overall response will be different than those who do think their sleep does affect their daytime function and mood. A person who does not think his or her sleep quality has an effect in the daytime may be less likely to seek outside care from a healthcare provider potentially leading to a missed OSA diagnosis. This study sought to closely examine both men's and women's perspectives of their sleep and how those perspectives interact with their evaluations and responses to their symptoms.

1.3 Research design and methodology

The dissertation used qualitative descriptions to examine and gain insight into the reported symptoms and perceptions of both women and men, who prior to learning if they have OSA or not, report sleeping poorly. The themes acquired from an analysis of interviews of men and women with impaired sleep were compared to and contrasted with the concept categories from four questionnaires commonly used to examine poor sleep quality and its effects on daytime function and mood in the Diabetes Sleep Treatment Trial (R01 DK096028: E. Chasens, PI).

Aim 1 qualitatively captured the symptom experience as presented in the SMM. Aim 2 determined if the perceptions of the participants are reflected in commonly measured concepts of self-reported sleep instruments. Aim 3 examined the relations between the physiological measurements of OSA severity and the self-reports of the symptoms of impaired sleep. Additionally, it also examined whether sex moderated these relations. Taken together, findings

from this dissertation addressed the central overarching research question of how the role of gender and sex influences the perceptions of impaired sleep both in terms of the participant experience and its physiological manifestations. For Aim 1, recruitment for the qualitative interviews came from the baseline screening sample of the DSTT. For Aim 2, the data came from the findings of Aim 1 and for Aim 3, a secondary analysis of the baseline data from the DSTT was conducted.

1.3.1 Aim 1 - Methodology

Aim 1 was to “characterize in depth both men’s and women’s perspectives of and approaches to describing impaired sleep and its impact on daytime function and mood.”

1.3.1.1 Design

For this aim, one-time individual interviews were conducted. These interviews took a descriptive approach to characterize differences in how men and women perceive sleep and its effects on daytime function and mood. Qualitative description, “as a rich, straight description,” providing “broad insight” has been touted as particularly well suited for instrument development studies (Neergaard, Olesen, Andersen, & Sondergaard, 2009). Following the Symptom Management Model in the symptom experience domain, this method was used to provide a rich understanding of the perceptions of the symptoms of impaired sleep. It provided insight into how those perceptions affect evaluation and responses to symptoms. (For instance, would participants report their symptoms to a healthcare provider? Do participants think short sleep duration affects their mood?)

Sample

Maximum heterogeneity was achieved through purposive sampling, a method of trustworthiness in qualitative research (Neergaard et al., 2009). Using an iterative analyses technique, recruitment and interviews of participants and qualitative data analysis continued until no new themes were revealed and saturation occurred (Taylor, Bogdan, & DeVault, 2015). Anticipated enrollment was 32 (16 men, 16 women) participants who were representative of the demographics of the DSTT. Based on the characteristics of the parent study, we assumed the sample would approach 50% African American. If saturation had been reached prior to this goal, enrollment would be discontinued; otherwise if it was not reached, enrollment was to continue.

Recruitment and setting

Recruitment was from current participants undergoing the baseline assessment of the DSTT. Potential participants were invited to contact the study if they had self-reported T2DM and poor sleep quality. Eligibility criteria for the baseline assessment, determined at the phone screening, included age 18 years or older, self-reported diagnosis of type 2 diabetes, able to read and write English, and being ambulatory and ≥ 0.4 on the Multivariable Apnea Prediction (Sorge et al.) Index (uses the frequency of snoring, breath holding, and snorting, age, sex, and self-reported height and weight to determine the likelihood of OSA). Potential participants were excluded from the DSTT if they had previous or current CPAP use, an acute illness requiring hospitalization in last 3 months, unable to ambulate, a near-miss or automobile accident due to sleepiness, employed in a safety sensitive occupation, or are unwilling to be randomized to sham CPAP. Participants found currently eligible for the baseline assessment of the DSTT at telephone screening were asked if they would be willing to stay for the additional interview. The interview took place in a quiet room within the School of Nursing's Clinical Research Suite or at the Clinical Translational Research Center, if it was more convenient to the participant. Every effort was made

to conduct the interviews at the time of the baseline assessment to ensure they took place before treatment with CPAP and to reduce participant burden. If the DSTT had not provide enough participants, recruitment would have been explored outside the DSTT.

Interviews

Informed consent for the interview was completed prior to any data collection with the participant given adequate time to ask questions. The one-on-one semi-structured interviews were designed to last approximately an hour. The interviews were conducted in a private environment. In order to ensure limited bias during the interviews, a reflexive journal was used to document decisions, processes, and reflections, over the course of the study (Ortlipp, 2008). Bracketing was acknowledged from the beginning of study development through dissemination to separate individual biases or opinion from that which is actually observed (Fischer, 2009). The interviews consisted of about 6-8 open-ended questions. Potential questions are listed in Table 1 below. Sex or gender differences were not made salient to the participants, meaning that the questions were neutrally framed to avoid introducing a gender oriented response bias (Helgeson, 2011). The questions were designed to be broad in order to elicit the participant's own opinions and feelings about their experiences and perspectives of their sleep quality and its effects in their lives. Committee member, Dr. Jennifer Lingler, provided consultation during all stages of these procedures. An interview protocol was developed in consultation with Drs. Lingler, Chasens and Helgeson, and all interviews were audio-recorded and then transcribed verbatim. In case of audio-recording malfunction, detailed notes were taken. All transcribed data was transferred from a word processing program to Atlas.ti ©, a computer program used to organize and manage qualitative data. The program was chosen because it is freely available and relatively easy for first-time users.

Table 1 Potential interview questions

Tell me about your sleep.
What does it mean to you to get a good night's sleep?
Why don't you think that you sleep well?
What constitutes poor sleep for you?
What are some reasons you don't sleep well?
How important to you is it to you to get a good night's sleep?
What bothers you the most about a bad night's sleep?
Does your sleep affect you during the day? If so, how?

1.3.1.2 Analysis

Coding

Coding, using Atlas.ti, was an ongoing process from the very first interview. It continued until categories and themes were established and nothing new was learned (Creswell, 2013). The interviews of men and women were grouped and analyzed separately to ensure that the codes and themes did not get conflated between the sexes. We began with open coding using Atlas.ti to establish and tentatively label categories, creating a list of codes to be used in subsequent steps (Creswell, 2013). Analysis then progressed to axial coding, using Atlas.ti's code manager function by re-reading the text so as to look for relations between the categories in order to generate overall themes (Creswell, 2013). A table of the themes with Atlas.ti's capability was created and verbal examples were included of each one. Atlas.ti's network capability enabled us to visualize all results easily. Dr. Jennifer Lingler, committee member of this grant proposal, I, and Teresa Hagan PhD,

consultant to the committee, did the coding. Discussions among the research team that relate coding, interpreting, and conceptualizing were audiotaped for purposes of documentation. Finally, Bem's Lenses of Gender furnished a conceptual model for interpretation of the results.

1.3.2 **Aim 2 - Methodology**

Aim 2 was to “examine the symptom descriptions that emerge in Aim 1 to determine the extent to which they reflect and are concordant with the concepts embedded in standard instruments commonly used to assess sleep quality and its impact on daily functioning.”

1.3.3 **Design**

For this aim, qualitative data were compared by sex to the concepts examined in seven quantitative self-report sleep measures. While this is not a true mixed-methods study, its methodology was borrowed for this aim. Mixed-method designs often use conceptual categories in order to compare qualitative and quantitative data (Clark & Vicki, 2011). While we did not develop an instrument, qualitative findings were used to compare individual perceptions of sleep symptoms to concepts found in commonly used quantitatively measured instruments in order to determine if men's and women's perspectives are captured by such. In order to associate the themes found in Aim 1 with the concepts evaluated in the sleep instruments, it was essential to “translate” the concepts in a way that they can easily be compared to the themes derived from the interviews. While the instruments have the intended purpose to measure outcomes important to clinicians and researchers, most lay people do not think about their sleep in the clinical terms of “sleep quality” or “functional outcomes.” Therefore, these clinical concepts were translated into

conceptual categories that describe impaired sleep outside a clinical or research setting. The goal was to integrate findings that are participant-centered and use the terms and themes that reflect their perceptions. For example: The FOSQ measures “daytime function” which is not a common term most people use of their sleep. It might be translated it into several dimensions, for instance: “energy,” “friends,” “outside activities,” “work,” etc. to best capture the words our participants might use.

1.3.3.1 Measures

Seven validated instruments for sleep were compared with the qualitative data on symptoms of impaired sleep and mood in men and women. We examined whether there were words, codes, or themes that either men or women used to describe the symptoms or daytime impact of impaired sleep that are not conceptually measured in the instruments.

Pittsburgh Sleep Quality Index (PSQI)

This questionnaire has seven components (sleep duration, efficiency, quality, latency, disturbances, medication use, and daytime dysfunction). The higher the score, the worse the global sleep quality; scores > 5 indicate poor sleep quality (Buysse et al., 1989). The PSQI has reported good overall reliability (Cronbach’s $\alpha = 0.83$) and validity (sensitivity 89.6% and specificity 86.5%) (Buysse et. al., 1989). There had been no published factor analysis of the PSQI by sex, (Mollayeva et al., 2016) however, it has been found reliable and valid in both older men and in a cohort of Black and White older women (Beaudreau et al., 2012; Spira et al., 2012). A recent factor analysis of the Pittsburgh Sleep Quality Index suggested that women may associate poor sleep quality with sleep disturbances and their daytime effects such as sleepiness or poor concentration,

all overlapping symptoms of depressed mood. Men may be more likely to associate sleep quality with sleep duration and sleep efficiency (Morris, Rohay, & Chasens, 2017).

Epworth Sleepiness Scale

The ESS measures subjective daytime sleepiness in 8 familiar and common situations. Scores range from 0 to 24; a score ≥ 10 indicates a participant is excessively sleepy during waking hours. The single factor ESS has a high reported internal consistency (Cronbach's $\alpha = .88$) (Johns, 1991). The ESS has been found to be differently sensitive to men and women (Chervin & Aldrich, 1999; Zou et al., 2013). In a study comparing the multiple sleep latency test (MSLT), an objectively measured lab test of sleepiness, to the ESS, Chervin & Aldrich found that in adjusted models, the men differed from women in that they appeared significantly less sleepy than the women despite having a higher AHI (t-test, $p < 0.01$ for each variable). In the objective measure of sleepiness (MSLT), women were not found to be sleepier than men. This suggests that gender may be a confounding factor in the ESS. Additionally, Zou et al. established different cut-points of sleepiness in the ESS by sex, with nine being the cut point for males and six for females.

Functional Outcomes of Sleep Quality (FOSQ)

The FOSQ is used to assess the effect of sleepiness on daytime function (Weaver, 1997). The FOSQ consists of 30 questions, grouped into five subscales (i.e., General Productivity, Social Outcomes, Activity Level, Vigilance, and Intimate Relationships and Sexual Activity) through factor analysis. Each question on the FOSQ has a range of responses from 1 (extreme difficulty due to sleepiness) to 4 (no difficulty) that includes an alternative response (could be other reasons). The FOSQ total score ranges from 5 to 20, with higher scores indicating less difficulty in performing activities due to sleepiness. It has good internal consistency (Cronbach's α for the total

score = 0.95; sub-scale scores range from 0.86 to 0.91). The FOSQ is sensitive to correctly identifying normal subjects (total FOSQ ≥ 18) from those with sleep difficulties ($p < 0.001$) (Weaver et al., 1997). Instrument development studies utilized samples of approximately two-thirds men (Weaver et al., 1997) and no known analysis of reliability or validity by sex was found, to date.

Profile of Mood States (POMS)

Mood was measured by the POMS measure. The POMS uses 65 adjectives (e.g., tense, discouraged, and listless) on a Likert scale (i.e., from 0 = not at all to 4 = extremely) to assess feelings during the past week. Six factors of mood are examined in the POMS (i.e., Tension-Anxiety, Depression-Dejection, Anger-Hostility, Vigor-Activity, Fatigue-Inertia, and Confusion-Bewilderment). These factors are summed (with Vigor-Activity reversed) to obtain the summary Total Mood Disturbance (TMD) score. The POMS has been shown to be sensitive to detecting impaired mood in studies examining sleep, and the six POMS factors are internally consistent with the TMD score (Cronbach's $\alpha = .84$.) (McNair, Lorr, & Druppleman, 1971). Norming data for "gender" in the POMS of four samples all showed small but significant differences by gender. The developers decided the differences did not justify separate standards for men and women (McNair & Heuchert, 2008).

PROMIS Sleep Disturbance & PROMIS Sleep Related Impairment Scales.

The sleep disturbance scale broadly measures perceptions of sleep quality, including time to fall asleep, restlessness, and worry over sleep for previous week. The Sleep Related Impairment scale measures daytime function as a result of poor sleep (Buysse et al., 2010). There are 27 & 16 questions respectively; the internal consistency for both was Cronbach $\alpha = 0.9$. Five item Likert

scales assess sleep variables, with higher scores indicating worse sleep disturbance and impairment. In testing, samples were balanced by sex, but sex differences were not evaluated.

Insomnia Severity Index (ISI).

This is a short 7 item scale measuring insomnia (Bastien, 2001). For this Likert scale, the scores range from 0 = no difficulty to 4 = very difficult. It is highly reliable with a Cronbach $\alpha = 0.90$, and Scores of ≥ 10 have a sensitivity of 86.1% and specificity of 87.7%. Testing was conducted in a balanced sample of men and women but was not evaluated by sex.

1.3.3.2 Analysis & interpretation

Using a categorical and thematic display table, with columns for men and women listed separately for easy visualization, the list of conceptual categories from the instruments and the themes from aim 1 that correspond to them were compared for similarities and differences. In order to ensure validity, quotes were utilized that best illustrated the themes and were matched to the conceptual categories as appropriate. It is possible there were themes that did not correspond to the conceptual categories. In that case, a new row included them. Atlas.ti's capabilities were used to create images of these associations.

1.3.4 Aim 3 - Methodology

Aim 3 methodology was to “utilize baseline data from the DSTT to explore if sex moderates the associations between the objectively assessed presence, severity, and clinical presentation of OSA (apnea + hypopnea index [AHI]; ratio of apneas to hypopneas; % sleep time

with oxygen desaturation < 90%; snore index [# snores/flow evaluation period]); and subjective measures of, 1) sleep quality, 2) daytime functioning, 3) daytime sleepiness and 4) mood in men and women with T2DM”.

1.3.4.1 **Sample**

The purpose of the on-going parent study the Diabetes Sleep Treatment Trial (DSTT) is to examine the relation between diabetes self-management and OSA using a CPAP or sham CPAP to determine its effects on glycemic control. Eligibility criteria for the baseline assessment, determined at the phone screening, includes age 18 years or older, self-reported diagnosis of T2DM, able to read and write English, and being ambulatory and ≥ 4 on the Multivariable Apnea Prediction (Sorge et al.) Index (uses the frequency of snoring, breath holding, and snorting, age, sex, and self-reported height and weight to determine the likelihood of OSA). Potential participants are excluded if they had previous CPAP use, an acute illness requiring hospitalization in last 3 months, unable to ambulate, a near-miss or automobile accident due to sleepiness, employed in a safety sensitive occupation, or are unwilling to be randomized to sham CPAP.

1.3.4.2 **Setting**

The baseline assessments are completed at four sites in clinical research laboratories.

1.3.4.3 **Measures**

Primary Measurements: The primary measures will be those of the PSQI, ESS, FOSQ and POMS and the ApneaLink Pro®.

ApneaLink Pro®

A portable sleep testing device is used to assess for OSA severity and presentation as measured by the Apnea/Hypopnea Index (AHI). Participants take the equipment home to use the night following their baseline assessment. The ApneaLink Pro® is an FDA approved level III device that can be used in private homes and does not involve an overnight stay in a sleep lab. The ApneaLink Pro® is automatically scored according to the American Association of Sleep Medicine scoring rules and reviewed by a registered polysomnography technician. Four hours of recording was required for determination that a study was valid; however, two hours of recording with an $AHI \geq 10$ was considered diagnostic for OSA in this study and OSA severity was presented as a continuous variable. Additional analyses conducted also assessed AHI as a categorical variable: mild AHI (5 to 14), moderate AHI (15-30), and severe AHI (>30).

Secondary Measures: These measures were used to describe the sample and as potential co-variables in the analysis.

Demographic Questionnaire

Participants answered questions regarding their age, sex, marital status, race, employment, and income.

Health history

Basic health history including previous surgeries and treatments for chronic disease. Includes specific questions on female (i.e. menopause status, pain with intercourse, hormone replacement) and male (i.e. difficulty in voiding, impotence) sexual function.

Glycemic control

Hemoglobin A1C offered a reliable indication of average glycemic control over the past 2 to 3 months.

Anthropomorphic measures

Measured height and weight was used to calculate body mass index (BMI, kg/m²).

1.3.5 Analysis

This secondary analysis used a cross-sectional observational design. Descriptive statistics included means, standard deviations, frequencies, and percentages. A preliminary examination of the data included univariate and bivariate sample distributions of all the measures and demographic data to determine if the data are distributed normally. Alternative strategies were to be developed in the case of uneven distributions. Student's t-test will be used to examine differences in demographic and clinical variables with continuous data (age, AHI, snore index, BMI, A1C, daytime sleepiness, sleep quality, mood, functional outcomes and insomnia) between males and females. Chi-square tests were used to determine if there was a difference in the proportion of categorical variables of race, educational level, and marital status between male and female participants. Statistical significance was set at $p < .05$ for two-sided hypothesis testing.

We explored possible relations between the measures OSA severity and the primary measures, ESS, POMS, PSQI and FOSQ. Bivariate relations between continuous variables of OSA (snore index & % sleep time with oxygen desaturation < 90%) and questionnaires were examined with Pearson correlations for the entire sample. Multiple linear regression modeling using interaction effects were conducted to determine if sex moderates the relationships using adjusted and unadjusted models. Data analysis and background literature determined possible covariates.

Anticipated Challenges

1. A literature search for methodology in examining sex-differences in qualitative research yielded few results and limited examples of where the methods account for sex or gender bias. This study will take the perspective that there is always inherent sex bias, but steps as described above will be taken to limit it.

2. There are limited examples of qualitative work examining the perspectives of people with sleep disorders about their sleep and its daytime effects.

3. Because purposeful sampling is being used, recruitment was subject to the recruiting limitations of the DSTT. In the event the current DSTT recruitment did not provide adequate participants, other methods of recruitment will be explored.

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1.4 Human subject's involvement and characteristics

This dissertation study was reviewed and approved by the University of Pittsburgh Institutional Review Board (PRO17050421) (Appendix B). Aim 1 will recruit from persons who consented to participate in the DSTT as well as potentially from prior participants in the community. Sampling for Aim 1 will continue until saturation is achieved; it is estimated that up to 32 participants (16 women, 16 men) from the DSTT will be recruited for the interview. Purposive sampling of participants with poor sleep quality will reflect the basic demographics of the DSTT. It is expected that the study will recruit equal numbers of men and women, and approximately one half the sample will mostly likely be African American. The interview will take one hour of their time. Aim 2 does not involve recruitment of any human subjects, as it is a comparison of data from Aim 1 to conceptual concepts embedded in sleep instruments. Aim 3 was a secondary analysis of baseline data from the Diabetes Sleep Treatment Trial (DSTT), (R01DK096028-E. Chasens). Data from 322 persons who consented for this study prior to June, 2018 was analyzed for sex difference and moderation by sex of relations between physiological measures of obstructive sleep apnea and self-report measures of impaired sleep.

1.4.1.1 Inclusion criteria

All participants in the parent study have given informed consent (IRB Protocol 12100605). To be included in baseline assessment in the DSTT, they had an approved telephone screening where they reported T2DM, age 18 years or older, CPAP naïve, without an automobile accident because of sleepiness in the last 12 months, and were willing to be randomized to either CPAP or sham-CPAP.

1.4.1.2 Exclusion criteria

For this study, participants must be willing to participate in an in-depth interview about their nighttime sleep quality and its effects on their daytime function. Participants must be willing to have this interview taped recorded.

1.4.1.3 Sources of Materials

There are two sources of materials, secondary data from DSTT for Aim 3 as well as tape-recorded and then transcribed interviews for Aim 1. All data gathered in Aim 1 in the form of transcribed interviews will be used for this study only. Data will be identified only by participant's assigned unique number and will be stored in locked filing cabinets accessible only to the primary investigator and the transcriber.

1.4.1.4 Potential Risks

There is a potential risk to privacy if there would be a data breach. Participants may get tired or bored when being interviewed for this study. They might be feel uncomfortable talking about their personal lives with the researcher. These risks will be explained ahead of time.

Protection against risk

There are few potential risks in this study. Aim 3 utilizes secondary data that has already been collected and which has existing safeguards for protection of data security. Multiple levels of password protection (i.e., record, file, directory, server, and computer levels) ensure data security. No identifiers other than the participant's assigned unique study identifier will be contained in any of the data files or in any of the subject files that are stored in locked filing cabinets. Interview data for Aim 1 will use the same patient study identifier as that in the parent

study. Transcribed interview and interview tapes will be maintained without other identifiers in secure password protected computer files. Interview participants will be given breaks and refreshments to minimize fatigue or boredom. Participants will be allowed to discontinue the interview at any time during the process. They will be free to decline any specific question.

1.4.1.5 Recruitment and Informed Consent for Aim 1

Participants will be recruited from the current DSTT. Participants scheduled for Assessment 1 will be invited for further participation in this study during the telephone screening for the DSTT; the study staff will briefly explain that there is opportunity to stay for an additional hour after the baseline assessment of the DSTT. Prior to any data collection, this study's PI (J. Morris) will provide written and oral explanations of the study's purpose, protocol, risks, and benefits. The potential participants will have an opportunity to ask questions and then will be asked to sign the form consenting to participate in the study. One signed copy of the consent will be retained in the investigator's study records.

1.4.1.6 IRB review and investigator certification

IRB approval has been obtained to conduct the secondary analysis in Aim 3 and to begin recruiting in Aim 1 (PRO17050421). All study personnel will maintain current certification in Research Practice Fundamentals, as mandated by the IRB. A copy of the Informed Consent is included in Appendix X.

1.4.1.7 Potential Benefits of the Proposed Research to Human Subjects and Others

There is minimal benefit to the research participant to participate in the interview. It is possible that a participant may gain some insight into their thoughts and perceptions on sleep as they respond to questions.

1.4.1.8 Importance of the Knowledge to be Gained

Understanding the differences between men's and women's perception of sleep quality and its effects on next-day function will provide foundational knowledge which will lead to interventions for impaired sleep that could be tailored specific to men and women. The benefits of this study, a greater understanding of the role gender and sex plays in sleep research, far outweigh the minimal risk of this study.

1.4.1.9 Data and Safety Monitoring Plan

Data and safety monitoring was an ongoing activity that reviewed during weekly meetings with the Sponsor and/or Co-Sponsor during which data quality, management and any adverse events arising from the study will be reviewed. A summary of these reviews will be provided to the IRB at the time of the yearly renewal. Any unanticipated adverse events will be reported immediately to the IRB.

1.4.2 Inclusion of Children

Aim 1: As participants in Aim 1 were recruited from the DSTT only, no children will be included. Moreover, because the goal of Aim 1 is to examine how impaired sleep subjectively affects the life and roles of men and women, the inclusion of children was not appropriate.

Aim 2: Data from Aim 1 are compared to conceptual concepts embedded in sleep instruments and does not involve recruitment of any human subjects.

Aim 3: Children < 18 years of age are not included in Aim 1 of this study as it is a secondary analysis and they were not appropriate for the parent study (DSTT). In the DSTT study, children < 18 years were not included because neither the intervention nor the outcome measures are appropriate for younger children. Given the significant differences in sleep in the younger pediatric age group (under 18 years) and sleep of adults, the inclusion of younger children in this clinical trial was not appropriate. Further, there are issues of study design that preclude the involvement of younger children in that trial. First, the pediatric age group is not of legal age to provide informed consent. In addition, many of the instruments used to measure outcomes in the parent study (SenseWear Pro Armband®, ESS, POMS) were not applicable to young children or have not been validated in this less than 18 years age group. Finally, for the current study, which involved the evaluation of patterns of responses between men and women, it was not appropriate to include children.

1.4.3 Inclusion of Women

Aim 1: Because this study is examining sex/gender differences, we purposely sampled equal numbers of men and women thus ensuring that women will be included in equal numbers to men.

Aim 3: As the sample for this aim is a secondary analysis taken from the parent study (DSTT), the sample for Aim 3 will be those persons recruited and consented for DSTT. In the DSTT study, no one was excluded based on race, sex/gender, HIV status or ethnicity. The goal of the DSTT is to recruit 50% women and the current baseline sample meets this goal (58% women).

1.4.4 Inclusion of Minorities

The goal of the DSTT was to have at least 40% minority sample. To date, the sample includes 55% minority participants. To ensure adequate validity in a mixed methods research design, both arms of the study (qualitative and quantitative) should have equal % of minority participants. Therefore, aim 1 of this study reflected through purposeful sampling the same % of minority participants as the DSTT thus ensuring their adequate representation.

2.0 Summary statement

This dissertation project consists of three complementary studies to address the gaps in the understanding sex and gender differences in impaired sleep and overall sleep quality. Funding Support included: NIH F31 NR017336-01(PI: Morris) and the Margaret E. Wilkes Scholarship Fund Award, University of Pittsburgh School of Nursing.

Findings are documented in each of the following three manuscripts:

Manuscript 1. The qualitative analysis used semi-structured interviews to gain insight and explore differing patterns of perceptions and symptom presentations of impaired sleep between men and women.

Manuscript 2: This exploratory report then displayed the codes and categories from the interviews of men and women with impaired sleep and compared them to commonly used instruments in sleep research.

Manuscript 3. This quantitative analysis examined the physiological measurement of OSA severity as measured by AHI and its influence on sleep quality, mood, excessive daytime sleepiness, and daytime function and if sex moderates these relationships.

While each of these aims had a distinct purpose, collectively they advance insight into the different perceptions and symptom manifestations that men and women with type 2 diabetes have when coping with impaired sleep. In the dissertation proposal, Sandra Bem's Lenses of Gender (Bem, 1993) was introduced as the conceptual framework to understand gender bias in previous sex differences research, and to mitigate any presumptions of gender in the design and interpretations of the dissertation's findings. Below is reviewed key dissertation findings embedded within this framework.

Biological determinism: Much of previous sleep research either has not included balanced samples of men and women or conducted a sub-analysis by sex. When women have been examined, it has been in terms of reproductive life stage (pregnancy, menstruation, menopause, or post-menopause) with the implication that women's physiology is primarily responsible for differences in symptomology. Only factors that confirm a biological association are usually considered important enough to be reported.

In this project, we addressed biological determinism by including many sociocultural and demographic factors as covariates when examining the influence of AHI on subjective reports of sleep outcomes. Sociocultural factors and other health factors besides sex, such as race, financial ability, and physical function were found to be more highly influential on the subjective sleep reports than OSA severity. The findings suggest that studies of symptomology or health behaviors that would try to isolate biological sex from sociodemographic factors might be only reporting only a partial picture.

Androcentrism: We addressed androcentrism in by including balanced samples of men and women and by conducting sub-analyses by sex in every manuscript. We also interpreted the findings using approaches that highlighted women's voices. For instance, in the background research for this project, many manuscripts that discussed sex differences in OSA symptomology contained comments that women's descriptions of fatigue or sleepiness were vague compared to men's who were specific (Lin et al., 2008; Ye, Pien, Ratcliffe, & Weaver, 2009). In this context, it is implied that vague descriptions are atypical or abnormal and specific descriptions are normal. The interpretations of women's descriptions as vague fits within historic medical and scientific models which were developed within an androcentric framework characterized by presentation of male symptoms and male subjects within clinical trials. The voice of the women, when allowed to

fully describe their experiences in this study, did not provide “vague descriptions”, but instead gave a rich and complex story of how being tired affected their lives. The women described how low motivation and energy was contextualized within their days and how it affected their caregiving and home responsibilities. In these terms, their descriptions are not atypical or abnormal but fit perfectly with the lives that these women lead. An androcentric medical model is not well equipped to respond to these multifaceted descriptions.

Lastly, gender polarization is idea that men and women are always different which is reflected in the large of amount of research surrounding women, sleep, pregnancy, menstruation, and menopause. However, it is important to note that men and women do not always manifest different physical symptomology despite having different reproductive hormones or other physiological differences. In this study, both men and women reported sleepiness and fatigue during the day in the interviews and on the scale for excessive daytime sleepiness. It wasn't that the physical symptoms were different between men and women, but in the interviews, we learned that the coping styles and the context of descriptions were different between men and women. This suggests gender, or other sociocultural factors play a large role in the interpretations of difference between men and women. It is possible that there may be few or no significant biological sex differences that contribute to the symptomology of impaired sleep, but instead perceived differences may be the result of the influence of the characteristics and roles associated with gender.

By using Bem's Lenses of Gender as a framework for this dissertation, the questions, design and interpretation were reconceptualized to make women visible, not as atypical or abnormal, but as an integral part in understanding sleep. The lenses also promote an interdisciplinary view of sex differences and sleep research that interrogates the boundaries

between the biomedical sciences and humanistic knowledge. Nursing scholarship, rooted in a holistic vision of the person as not only a physical being, but as part of a family, larger communities, and the environment is well positioned to lead the way in integrating these very different epistemological systems of knowledge.

These findings are pertinent to both nursing research and clinical practice. Nursing by its nature is interdisciplinary. The Symptom Management Model that guided this dissertation (Dodd et al., 2001), provided a framework to understand the differing symptom perceptions of men and women within the holistic “person” domain that recognizes the many disciplines integrated into the demographic, sociological, physiological and developmental outcomes that affect a person’s symptom presentations. By examining the influence of gender within this domain, nurse researchers have the opportunity to explore innovative approaches to understanding symptom presentations within many various medical and psychological disorders.

In clinical hospital nursing or advanced practice, nurses must assess not only patient’s objective lab values, but they also must make judgements regarding the causes or importance of a patient’s self-reported symptoms. Nurses are subject to the same biases as the world at large. Understanding that men and women may have different patterns when describing their symptoms can help the nurse recognize for example, that a man might be minimizing his feelings of tiredness or that a woman might be describing symptoms of a sleep disorder instead of depression.

In conclusion, this dissertation accomplished two primary goals 1) it provided additional insight into sex differences in the symptomology of impaired sleep and 2) it challenges the existing framework of sex difference research by incorporating interdisciplinary concepts from psychology, sociology, and feminist theory.

Knowledge obtained from this dissertation work suggests future research studies are needed.

In particular:

- 1) Close examination of sleep instruments for measurement bias between men and women.
- 2) Examining the mechanisms of how gender and other sociocultural factors influence sleep quality and its daytime outcomes.
- 3) Determine if an instrument specific for women would better reflect their perceptions of daytime fatigue and sleepiness than the current standard instruments.
- 4) Examine AHI not as a continuous variable in the parent study, but in categories of OSA severity, comparing them to OSA comorbid with insomnia, those with insomnia, and those without insomnia to see if there are sex differences that arise.
- 5) Investigate possibilities to translate awareness of the different ways that men and women discuss fatigue and daytime sleepiness to healthcare providers.

3.0 Manuscript 1- The Influence of Gender in the Perceptions of Sleep Quality: A Qualitative Analysis

3.1 Abstract

Research suggests that men and women may have differing perceptions of sleep quality. The purpose of this qualitative study was to investigate the perspectives men and women have of their experiences with poor sleep quality including both nighttime sleep and next-day fatigue or sleepiness. We recruited participants from an ongoing randomized clinical trial (R01 DK096028: E. Chasens, PI) in Pittsburgh Pennsylvania, USA; inclusion criteria included type 2 diabetes and self-reported impaired sleep. Semi-structured interviews with participants used open-ended, gender neutral questions. Three independent reviewers analyzed data using a qualitative description approach of men and women separately before comparing both groups. Findings were described using axial codes and representative quotations. The men and women (14 each, mean age=54yrs) characterized their struggles with poor sleep quality within their primary daytime tasks, whether it was within paid employment or in the home. Men aimed to complete their tasks even when tired, describing themselves as “always being on my game.” For women, being tired was a constant barrier to motivation and getting things done. Men described being tired at specific times of the day, whereas women were tired ‘all day.’ Men found naps a pragmatic use of their time; women found naps “unproductive.” Men were more likely to describe early waking as a sleep problem, and women were more likely to report trouble falling asleep. Men and women described daytime sleepiness and fatigue as a result of impaired sleep differently which may reflect an influence of gender role expectations and characteristics. Future research will quantitatively

explore these findings including their impact on the clinical identification and treatment of sleep problems in women.

3.2 Introduction

Most of what is written about sleep in the news, on popular websites and in research is discussed from the perspective of the physiological variables (i.e., sleep duration, time to bed, efficiency, arousals, time spent in REM, etc.) or a medical model of sleep disorders (i.e., obstructive sleep apnea, insomnia). While popular websites inform the public on the recommended duration of sleep, many people perceive their sleep in terms of was it a ‘good night’ or a ‘bad night’ rather than in an objective assessment. Therefore, sleep quality can be considered a personal assessment of one’s sleep and it may not match the objective evaluation of sleep within medical practice. In sleep research, sleep quality is often measured using the Pittsburgh Sleep Quality Index (PSQI) (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989), a questionnaire which assesses seven components of sleep such as sleep duration, medications, disturbances, and how one feels the next day. In a recent factor analysis of the PSQI by sex, the question, “During the past month, how would you rate your sleep quality overall?” accounted for the most variance in all the participants. However, in women overall sleep quality factor loaded with sleep disturbances and daytime dysfunction while overall sleep quality in men factor loaded with sleep duration and sleep efficiency (Morris, Rohay, & Chasens, 2017). These findings suggest that there may be differences in how men and women perceive sleep quality.

In 2014 the National Institutes of Health issued a directive that all researchers examine sex as a biological variable to determine if there are differences between men and women from basic

research through advanced human interventions research (Clayton & Collins, 2014). However, the influence of gender as a social influence is often neglected in research designs. For instance, in discussions of daytime fatigue and sleepiness, biological predictors are prioritized, and social influences are adjusted in regression models to minimize their influence in the findings. Yet women's societal gender roles incorporate not only responsibilities of paid employment, but women of all classes and cultures continue to be expected to have primary responsibility in the home and for children (Treas & Tai, 2016). These responsibilities are often thought to result in a lack of sleep and resultant daytime fatigue or sleepiness. It is likely that the expectations of adherence to gender roles may influence perceptions of sleep quality.

There are two sleep disorders in which either men or women are more likely to be diagnosed. Obstructive sleep apnea (OSA) is recurrent breath holding (apneas) or decreased airflow with oxygen desaturation (hypopnea) during sleep (Cao & Kushida, 2011). Many people with OSA experience poor sleep quality, but not all (Ye et al., 2014). While men are estimated to have twice the risk of OSA compared to women related to their upper body weight gain pattern (Wimms, Woehrle, Ketheeswaran, Ramanan, & Armitstead, 2016), women remain significantly underdiagnosed for this disorder compared to men (Miller et al., 2017). Previous researchers have suggested that women may describe or prioritize their symptoms differently than men (Miller et al., 2017; Ye, Pien, & Weaver, 2009) but this has not yet been qualitatively explored. Insomnia, difficulty in either initiating sleep, maintaining sleep, and/or returning to sleep after an early morning awakening, has an increased prevalence in women (Hall, Kline, & Nowakowski, 2015) and is sometimes comorbid with OSA (Luyster, Buysse, & Strollo 2010). Both sleep disorders, not only effect a person's sleep, but in many cases have profound effects on their ability to function the next day.

The assumption that any differences found between men and women in sleep are strictly biological does not capture the richness and importance of the influence of gender behind the biological realities. Because women have been underdiagnosed with OSA but are more likely to report insomnia compared to men, a fresh look at descriptions of sleep quality in those at risk for these disorders might shed light on the presentations behind these differences. It is possible that women 1) experience different symptoms from men or 2) have the same symptoms as men but recognize and prioritize them differently. Because gender roles, characteristics, and expectations have been little studied in sleep research, it is unclear if they influence the ways men and women perceive, cope with, and manage their symptoms of impaired sleep. To understand how gender impacts the perceptions of impaired sleep, and its potential role in diagnosis of sleep disorders, it is essential to understand the perceptions of those who suffer from such symptoms. The purpose of this study was to qualitatively compare the descriptions of poor sleep quality in men and women within a gender-role framework so as to make visible the differences between men and women that might impact their diagnosis of sleep disorders or other health problems.

3.3 Methods

3.3.1 Design

We conducted semi-structured interviews to qualitatively describe the perspectives of men and women experiencing poor sleep quality. This study was approved by the Institutional Review Board at the University of Pittsburgh.

3.3.1.1 Sample and Recruitment

All participants were recruited from the ongoing Diabetes Sleep Treatment Trial (DSTT: R01 DK096028 PI: Chasens, Clinical Trials NCT01901055). For the parent study, participants with type 2 diabetes were recruited with advertisements asking if they had “poor sleep” or “snored.” Those persons with an A1C > 6.5% and meeting criteria for OSA (an AHI > 10 on a home sleep study) were later randomized to either CPAP or sham CPAP to examine the effect of OSA treatment on glycemic control.

Participants were recruited to the current study during the telephone screening prior to the baseline assessment of the parent study. An a priori decision was made to obtain a sample balanced by sex until data saturation was reached (e.g., no new ideas emerged from the qualitative interviews). Exclusion/inclusion criteria was the same as for the baseline assessment of the parent study. Study staff asked participants if they would be willing to stay after the parent study’s baseline visit to be interviewed. If they agreed, the PI contacted the participants to introduce herself, generally explain the purpose of the study, describe the procedures, and answer any questions. At the time of the interview, participants had expressed a sleep complaint but did not know whether they met criteria for an OSA or other sleep disorder diagnosis.

3.3.1.2 Data Collection

Informed consent for the interview was obtained prior to any data collection. Semi-structured interviews for the current study were conducted by the PI at the University of Pittsburgh School of Nursing and typically lasted about one hour. The questions were designed to be open ended and broad in order to elicit the participant’s perceptions and feelings about their sleep quality and its effects in their lives (see Table 1). All interviews were audio recorded and transcribed verbatim. Transcribed data were transferred from a word processing program to Atlas.ti ©, a

computer program used to organize and manage qualitative data. Questions that invoked stereotyped assumptions about either men's or women's lives were avoided so that participants were not primed to provide answers based on their identified gender roles (Helgeson, 2011). Therefore, the participants were initially blinded to the true purpose of the study (i.e. to examine potential sex differences in perceptions of impaired sleep) and were unblinded at the end of the interview.

Table 2

Interview questions

Tell me about your sleep.

What does it mean to you to get a good night's sleep?

Why don't you think that you sleep well?

What constitutes poor sleep for you?

What are some reasons you don't sleep well?

How important to you is it to you to get a good night's sleep?

What bothers you the most about a bad night's sleep?

Does your sleep affect you during the day? If so, how?

If not discussed by the end:

What interventions have you tried?

3.3.1.3 Coding and Analysis

The PI used a reflexive journal to document decisions, processes, and reflections over the course of the study (Ortlipp, 2008). Bracketing was performed to separate individual biases or opinion from that which is actually observed (Fischer, 2009). Coding was an ongoing, iterative

process that began after the first interview and continued through data saturation. The interviews of men and women were coded separately, each in the following manner. The team, consisting of two experts in qualitative methodology and the PI, inductively established open codes to label categories that emerged throughout the first ten transcripts. Axial codes, which summarize and link codes together, were developed from the open codes using the constant comparison method (Maykut, 1994). The three coders independently applied this coding schema across transcripts until data saturation was achieved. If disagreement about the codes arose, they were discussed until there was agreement. Axial codes were then compared between the interviews of men and women and organized so that similarities and differences were easily visualized within organizing categories. The codes and categories were corroborated by the team and an expert in sleep and next-day function. Focus was given to codes that represent an influence of gender and gender roles towards sleep and next-day function, rather than of the discussion of OSA or type 2 diabetes.

3.4 Results

3.4.1 Characterizing the Sample

Interviews were conducted with a balanced and racially diverse sample of men and women. Table 3 provides an overview of the characteristics of the sample.

Table 3

Characteristics of the Sample

Characteristics	Male	Female (n=14)
	(n=14)	
	means(SD)/ or n/ %	means(SD)/ or n/ %
Age (years)	54.23 (11)	54.43 (12)
African American	4 (29%)	6 (43%)
Married	8 (62%)	6 (43%)
Financial difficulty	3 (23%)	7(50%)
More than 2-year post high school degree	11 (85%)	8 (57%)
BMI (kg/m ²)	35.1 (9.6)	36.3 (6.7)
A1C %	7.7 (1.8)	8.1 (2.3)
Employed/self-employed	6 (43%)	11 (79%)
Retired/ disabled	8 (58%)	3 (21%)

3.4.2 Qualitative findings

Both men and women described struggling during the day with fatigue, sleepiness, or both, as a result of poor sleep the night prior. All participants characterized their struggles with poor sleep quality within their primary daytime tasks, whether it was with paid employment or in the home. Table 4 provides an overview of the findings.

Table 4

Summary of findings: differences and similarities in women’s and men’s reports of coping with impaired sleep.

Organizing categories	Women – Axial codes	Men – Axial codes
Experience of being tired during the day	*Uses the word “tired” to describe daytime fatigue or sleepiness	
	“Tired all day”	Sleepiness affects him at specific times of the day
	Low energy most often described	
	Affects mood good or bad	Reports mood not affected
	Little discussion of ability to think clearly	Frequent discussion of inability to think clearly
Motivation and productivity	Too tired to get things done	Tired but “always on my game”
	Being tired affects motivation	
	Conflict between being tired and getting things done	Determination despite being tired
Attitudes towards naps	Naps are helpful; but they are reluctant to nap because of too much to do	Naps are a pragmatic use of time
	Feels guilty over naps	Does not feel guilty over naps
	*Naps make it hard to sleep at night	
Symptoms of Impaired sleep	Falling asleep is difficult	Waking up too early is a problem
	Frequent waking	Frequent waking
	Hard to fall back to sleep	Hard to fall back to sleep
Factors that prevent good sleep	26 factors described including stress/pain/nocturia	3 factors discussed including nocturia and aging
Interventions for sleep and daytime tiredness	*Use of activity to stay awake	
	*Declines sleep medications	
	15 different methods mentioned	3 methods mentioned
Sleep as a factor in caring for one’s health	Sleep is important to being able to care for others	Multiple references to wives caring for his health and sleep
	Good sleep is caring for self	

*Indicates similarities found between men and women

3.4.2.1 Experience of being tired during the day

Women

Women rarely described their symptoms as affecting only one specific time of day, but they mostly described their symptoms as omnipresent in their day. One woman simply reported she was “tired, tired all day” or another woman reported, “there’s rarely ever a night where I sleep all night long, and in return I am so tired throughout the day.” When women did talk about mornings, it was in terms of being tired, “it’s mainly me just being tired when I’m waking up.” This feeling of being tired in women was typically associated with having low energy and was frequently described in terms of their ability to accomplish tasks. As one woman says, “Oh, I think getting a good night’s sleep I would have a lot more energy and the ability to do and accomplish much more than I do.”

When women spoke about their daytime symptoms resulting from poor sleep, they did so often using complex descriptions. These were best exemplified by a young woman, who had recently completed a master’s degree in Social Work specializing in adolescents. No longer able to work, she described struggling just to get through her day because of constant fatigue. In response to a question about finding the energy to care for herself, she said “I just don’t have the energy or motivation to cook a proper meal or put together a proper meal. So it’s kind of like survival. Like I don’t have the energy and I’m so tired that I’m doing dumb shit—I’m sorry, dumb stuff, like going in the oven without an oven mitt because I’m so tired.” She went on to describe feelings of frustration arising out of not being able to sleep, “I just don’t have the energy, or the patience ‘cause I’m tired, and the biggest annoyance of it is that I’m tired, but I can’t sleep. It’s just it’s a battle with itself, like ‘I’m tired, I’m tired, but who do I blame’.” Because she was tired

but couldn't sleep, she metaphorically described being tired to being in a losing battle between having energy and patience and getting quality sleep.

The women were also much more likely than men to describe how their sleep, whether good or bad, affected their mood. For instance, one woman described how short sleep duration affects her mood the next day, "if I don't get enough sleep I am grouchy." Conversely, another woman when talking about her best night's sleep reported, "When I get those days and it's such a beautiful sleep, you know. It's the quality of life. If I don't get that good night's sleep, I'm like here goes another day, and I go on with my day. When I have a good night's sleep, I just get out of bed like "hello world!" It's nice to feel that way and that really is, that's up there in the high, God, family, children, and sleep."

Men

Men usually described their symptoms specifically in terms of the time of day they experience them. For instance, they spontaneously described mornings regardless if they woke up refreshed or groggy. Some men were tired, "I'm usually tired when I get up," but many men woke up feeling refreshed, "Generally, I get up and don't any have problems getting out of bed or getting started during the day. I make a pot of coffee and I work at home so I start my work anywhere between 7:30 and 8:30 depending on when I got up." Those men who didn't have the option of naps sometimes reported dozing off at work particularly at specific times, "Typically, afternoons are my worst. About 3 or 4 o'clock I have been known to fall asleep for a few seconds at my desk." Yet, evenings also presented a challenge for sleep deprived men. In fact, this man described this symptom as his only problem with his sleep, "Um, usually I fall asleep in the chair while watching tv around 7 o'clock and then I get back up at 8." Six men also expressed concern about their ability to think clearly when tired during the day, and two women reported this symptom. Again

describing the time of day he experienced these symptoms, this man reported, “I am better in the morning like once I do wake up. I am better in the morning versus in the afternoon, forget it. I have to have meetings sometimes, but that must be that either my blood sugar goes down, I don’t know what. That is when I am not my clearest.”

3.4.2.2 **Impact of impaired sleep on motivation and productivity.**

Women

In the interviews of women who reported feeling tired and as though they haven’t gotten enough sleep, the daytime hours represent a struggle to “get things done.” They frequently described feeling exhausted and characterized it as affecting all aspects of their day and life. The pervasiveness of this phenomenon took on a particular significance when women described their responsibilities to others, including family, children, parents, and significant others. For instance, when talking about housekeeping chores, one woman stated, “I might only be able to check off one, maybe two, of those items in a day, whereas when I was younger I could go through that entire list in a day, but it seems like I just get so bogged down and tired that I don’t want to move.”

Additionally, women often described being tired during the day in terms of a lack of motivation: “I want to just sit in the chair, and vegetate,” or from a different woman, “It takes me a while to get motivated to do anything.” A retired woman who organized her husband’s medications said, “sometimes I’m just so tired that I just don’t want to.” These reports were often contextualized as failures of their character, “When I didn’t have a good night’s sleep I get ‘lazy’.” They characterized their daytime sleepiness or fatigue, not objectively, but in the pejorative self-

descriptions of someone who didn't have the fortitude or resilience to overcome being tired. The description of laziness then reinforces their narrative that they are flawed.

Other women reported realizing that they are not going to complete all of their tasks and trying to change their own expectations of fulfilling all of their caregiving and home when discussing her housecleaning routine (abbreviated here), "I am getting a new attitude and stuff like that. If it ain't done, it ain't done.... Now I am learning that no, not everything is going to be spick and span...I did still get some things accomplished still. But I felt this one day, I felt very tired. I didn't feel like doing it. I said you know what, it will be there when I feel a little better and I just rested it. I just didn't let myself do what I wanted to do." On one level, she understands that she could loosen her standards about a clean house; but on a different level this participant is describing a conflict between her feminine expectation of a clean house and the physical need to care for herself and rest when needed.

Men

Like women, men also admitted to feeling very tired after a poor night's sleep, but by contrast men consistently reported feeling that they could fight their tiredness so as to not let it stop them. This attitude was best exemplified by the following quote, "I am on my game regardless if I had any sleep or not." Additionally, men explicitly stated that they don't allow sleepiness to hinder their ability to meet their goals, "The one thing that helps me is that I have a pretty good attitude. I'm going to do what I need to do, and I'm pretty easy going by nature, so I kind of push myself, even though at any time I could sit down and relax because I'm tired." For many male participants, their sleepiness or fatigue did not seem to affect their reported motivation to "get things done."

Similarly, when men did describe perceiving the need for daytime sleep, their descriptions included talk of determination as compared to women's descriptions which were framed around a lack of motivation, "I just wanted to pull the covers up over my head. I got up and did what I needed to do, quasi decent, but if I have to be someplace I will." Another man equated working when tired, to feeling physically ill, but not giving in to it, "when I am sick, I get up, I work until you have to run to the bathroom and throw up. That is what you do." Even if being tired presented a barrier to accomplishing their goals, they described pushing through it and completing all their tasks.

3.4.2.3 Attitudes towards taking naps if sleepy or tired.

Women

Women often described reluctance to take a nap because of other home or caregiving responsibilities. The following quote is from a woman on disability who still didn't feel that she could nap, "There are times where I would be able to do that, but I almost feel too guilty. I just have so much to get done. Not only am I a caretaker, but I'm a [wife], and a parent. There's always a lot going on." It was not simply that women didn't feel they have the time to nap, they reported disapproval of naps. One woman commented "I just think it's unproductive." Additionally, a woman in reference to her elderly mother said, "She takes numerous naps throughout the day, but she's allowed. She's earned it." The implication is that one shouldn't take naps unless one has made worthy of the right to do so. Those who do take naps, often regret or possibly feel guilty for them, "My naps are like 3 hours. That's not good for me because then that's the whole day and you don't get nothing done."

Men

Many of the men in this study worked from home or worked in jobs where they had flexible schedules. For these men, naps were a pragmatic intervention that help them to get their jobs accomplished, “Because I’m self-employed, maybe I have some paperwork to do at that time. Say it’s 3 o’clock or something, I can sleep from 3 to 5. I can get back up and do the paperwork. So, it’s not a big deal for me to sleep during the day.” In fact, some men, like this professional driver, stated that he really liked to take naps, “I usually have a lot of energy when I wake up, but during the day I do get sleepy, naps [in a parking lot] are awesome.” No such positive comments about napping were noted in the women’s interviews.

3.4.2.4 Symptoms and Perceptions of Impaired Sleep.

Similarities in symptom presentation

Several aspects of disturbed sleep were consistently reported by both men and women. Interrupted sleep or waking up frequently during the night was endorsed by ten women and eight men. Additionally, seven women and five men reported difficulties in “falling back to sleep.” However, some participants who reported falling back to sleep easily didn’t see their frequent waking as a problem as exemplified by this woman with severe OSA, “I sleep pretty well... I was telling someone upstairs that I have to get up 4 to 5 times to urinate, but luckily, I go back to sleep. It’s not like I’m up gazing at the ceiling. So it’s okay...” Six women and four men also reported getting too little sleep at night.

Differences in symptom presentation of impaired sleep

Women. Trouble falling asleep at night was often the first thing many women reported during the interview when they described their sleep, but only one man did. Additionally, seven

women described a lack of sound, deep sleep and no men did this. One woman clearly described the feeling, “I just feel like I don’t go into a deep, sound sleep,” while another woman referenced this idea indirectly when talking about her dog “He sleeps like a log. I wish I could sleep like him.”

Men. Different than women, waking up too early was described by nine men as a considerable sleep disturbance, “Usually if I have a good night’s sleep I don’t get up until seven or eight o’ clock” (instead of waking at five o’clock when he didn’t want to get up).

3.4.2.5 Factors identified that prevent good sleep

Women

Ruminating over daytime stresses kept nine women from being able to sleep. Stress from caregiving responsibilities was the most consistently described disruption to sleep in women. Stress often came from family responsibilities or troubles, “And it tends to be if I am very stressed and I am a single mom, so if things get very stressful for me, it becomes a little bit more restless. I can’t turn everything off. I can’t turn my thoughts off. Because I can’t do that, my sleep is disrupted.”

Pain also interfered with the sleep of many of the women, but managing that pain was difficult due to competing caregiving priorities, “In my knees, my hips, and in my shoulder... I did get this knee replaced, and I need this knee replaced, but I don’t have the time to get this knee replaced because then I’m tied up, and who’s going to take care of my spouse.” Her caregiving responsibilities did not allow her to get her pain treated which might improve her sleep.

Men

Conversely, men did not report daytime stresses as preventing good sleep but did report the effects of aging, daytime napping, and nocturia as contributing to their frequent waking, and early rising.

3.4.2.6 **Interventions described for better sleep and daytime energy**

Activity

Both men and women who reported daytime sleepiness reported using activity or physical movement to keep up their energy and get things done. One man who worked two jobs reported, “when I’m going, and going, I’m good. If there’s a lag where I work at [evenings], and I sit down, I say, “ok, I gotta go do something because I’m gonna fall asleep [if continued to sit].” A woman described her time at home, “I stay away from the living room because I know if I sit down in our reclining sofa, I’ll put my feet up, and if I put my feet up, I’m going to be out. So, I putter around the computer room, the dining room, the kitchen, the laundry—trying to stay awake.”

Medications

The participants did not volunteer any comments about the use of assistive sleeping medications or supplements. Because they are a commonly prescribed intervention for impaired sleep, we asked a question about them near the end of the interview. Both men and women in this study avoided sleeping medications in general but for slightly different reasons.

Many more women than men reported having tried sleeping medications, and while some women agreed with men that the use pills for sleep indicated weakness, they also described them as ineffective, costly, or with intolerable side effects the next day. For instance, one woman spoke

about the next-day effects of diphenhydramine, “If I have something to do, it’s not good to take because I’m groggy the next day.” The most important thing in this women’s decision to not use sleeping medications was not so much that she will sleep well, but how it will affect her next day.

Men described perceptions that taking pills would indicate weakness. Only one man in our study reported ever trying sleeping medications but stated, “I don’t believe in taking stuff to make you sleep. I think it becomes addicting.” A couple of men stated that they don’t like to take pills and will try other interventions first such as exercise, “No, I hate sleeping pills. I hate taking pills period, although I have to take them because of my diabetes. If I know I have to have a lot of sleep, I’ll do something. I will do some pushups or sit-ups. I am a member of Planet Fitness and I will go there and do something and tire myself out.” One older man thought not being able to sleep was unavoidable, so a pill wouldn’t help, “What I’m afraid of is that maybe there isn’t enough knowledge on it, and maybe there’s not a whole lot you can do. Maybe you get old and you can’t sleep well, and you don’t feel rested.”

Other interventions

Women spontaneously reported having tried over fifteen different interventions including prayer, pillows, exercise, sleeping separate from spouse, repositioning, and creating a set schedule or ideal atmosphere for sleep (temperature, relaxing music, lavender baths). Men did not volunteer any interventions that they had tried to improve their sleep, but a few reported throughout their interviews that exercise or refraining from daytime naps were helpful in improving nighttime sleep.

3.4.2.7 Sleep as a factor in caring for one's health

While the role of caring behaviors may not seem to have direct relevance to sleep and its outcomes, participants spontaneously and consistently used it to frame their discussion. Five men and eleven women reported motivation to care for their own health, but only men reported their partner's role in caring for their health.

Men

Men spontaneously spoke about their wives over thirty times in the interviews usually in the context of their being the recipient of their wives' caregiving behaviors of their sleep and resultant health. One man exemplified this when asked about how important sleep is to him, "Not as important as it is to my wife." This man reported that his wife had seen the flyers for the parent study, and strongly encouraged him to sign up. He had previously been diagnosed with OSA but didn't follow through with treatment, and his wife was frustrated with his snoring. She had placed a pillow over his head a few times to muffle the sound, and sometimes slept in a separate bedroom.

Other men also pointed out that it was their wives who encouraged them to sign up for the parent study, because otherwise they probably wouldn't have signed up. One man reports his wife noticed his trouble sleeping; otherwise he would not have signed up for the parent study, "Probably not. I didn't know until she said, I think you stop breathing every once in a while." One wife seemed to be more in tune to her husband's blood glucose levels than he was. He reported his wife is sensitive to his bad moods and blood glucose, "When my wife says, 'your sugar is high', I say, I haven't tested it yet, but I bet you it probably is." She noticed his bad mood, and assumed he had a problem with his blood glucose before he did.

Women

Women reported caring for their health as important when describing the effects of poor sleep, “I feel like you aren’t taking care of your body if you don’t get a good night’s sleep. I want it to work for me, so I want to do what I can to take care of it.” Gaining an understanding of their sleep problems is a step they have taken to improve their health. One woman reported that she was having increased troubles controlling her blood glucose levels. She described her thought process in terms of caring for her own self and life, “so maybe it is my sleep apnea...so, being open to that and going back and finding out how sleep and how this and just different aspects and finding out where my overall goal will be because I definitely don’t want to go to insulin if I don’t have to, but I definitely want a quality and active life because I have things that I would love to do that have planned that I have not been able to do because the fact of me living and being a single mom, so just being able to do those types of things and being open to that.”

For other women, motivation to care for one’s self was even more strongly expressed in terms of their caregiving responsibilities, “I’m wondering if it has anything to do with me not breathing right during the night. I don’t know... I’m a full-time caregiver to my spouse who is disabled, and so I do have a lot of stress for being a caretaker and making sure everything is right.” In our sample, there were no women who reported that their husbands had caregiving responsibilities towards their sleep, or worried over other aspects of their health. One newly married woman did report that her husband will be concerned if she is awake at night, but her comments were primarily in terms of her concern about his disturbed sleep “but he’s aware enough if I’m up, then he wakes to ask me if I’m okay. If I’m not sleeping well, then he’s not really sleeping well either.” She was concerned about her sleep because of its effects on her husband.

3.4.3 Discussion and Conclusions

The goal of this study was to explore patterns in the similarities and differences in the perceptions of poor sleep quality and its next-day outcomes between men and women. Pervasive in all interviews from this study, descriptions of sleep quality are embedded within descriptions of the roles the men and women participate in within their day to day lives whether it be paid employment or in the home. Both men and women express concern about getting things done in terms of these roles and the challenges that poor sleep quality and daytime sleepiness or fatigue presents to them. Men described sleep as a pragmatic activity or tool that helps them get more done as evidenced by their willingness to nap. Additionally, while men also portrayed daytime fatigue or sleepiness as a hindrance, they did not refer to it as an insurmountable barrier. They described forcing or pushing themselves to be productive. Women most often described sleep and daytime sleepiness or fatigue as a significant barrier to getting things done.

Early sociologists of sleep (Aubert & White, 1959) observed that sleep is not just a biophysical activity. These scholars asserted that sleep is a social event, “The normal state of sleep means to occupy a culturally determined role which includes the behavior in the transitional periods before and after physiological sleep. The right to enter the state with full privileges furthermore is assumed to depend upon achievements in the state of wakefulness” (Aubert & White, 1959, pg 47). Social rank, therefore, plays a large role in how sleep has been conceptualized. Sleep is conceived as spatially and temporally privileged in that those of the highest rank get to choose where and how long they will sleep. Those of the lowest ranks sleep in noisy or unsafe environments and it is limited by work schedules, family responsibilities and other social expectations. If that is the case, social roles and expectations are also reflected in sleep practices and their next day effects. Gender which represents a hierarchy in which men have higher

status, provides a mechanism to understand the differences in how men and women describe their sleep and next-day symptoms.

For example, Jenny Hislop wrote of the normalization of disrupted sleep in mothers, “Women agree that to have children is to accept an on-going degree of disruption to their sleep” (Hislop & Arber, 2003, pg 835). Men see sleep as a tool useful for certain circumstances such as staying productive in their jobs. “For men, the amount of sleep deemed necessary for functioning appeared to be based on circumstances and expectations” (Meadows et al., 2008, pg 706). Like the descriptions of motherhood and sleep as described by Heslop, the women in this study prioritized their caregiving and household responsibilities over rest and naps.

The struggle these women described, is one of conflicted gender roles or gender role strain (Helgeson, 2011). Self-role discrepancy theory holds that when a man or woman doesn’t live up to the socially constructed roles attributed to their sex, he or she will experience strain or distress. Women are socially expected to exhibit and prioritize communal and caregiving qualities, so when they can’t accomplish the tasks associated with those qualities because they are sleepy or fatigued, it can have negative repercussions, not only to those who they care for, but also through the negative evaluations others place on them or that they place on themselves (laziness). For instance, the women who prioritized her rest instead of a clean house described a role conflict. A clean home was considered by this participant as a reflection that a woman has fulfilled her gender role as a housekeeper, and so she needed to explain in detail and at length why she was prioritizing her rest instead of a clean home. Additionally, women often described prioritizing their caregiving roles, such as the woman who was postponing needed surgery to care for her husband, thus perpetuating the sidelining of their own sleep and health.

Men who described push and determination to fulfill their daytime tasks may be reflecting an adherence to masculinity. They may themselves be less likely to prioritize their health, seeing it as the domain of women (Cameron & Bernardes, 1998). Therefore, they push through significant experiences of fatigue or sleepiness possibly minimizing their effects.

Additionally, these findings suggest that there is temporal difference in the ways in which men and women described their daytime symptoms, whereas women reported the effects of poor sleep quality as an omnipresent effect that permeates all aspects of their day, men described symptoms that affect them at specific times of the day. Clinically, this finding could indicate repercussions for women who report feeling tired as a symptom during their visits with healthcare providers. What if a woman in conversation with her PCP said, “I am just so tired all the time and don’t have the motivation to get anything done?” vs. a man in conversation with his PCP who said, “every day around two o’clock, I just feel like I have to take a nap?” Recently, authors have drawn attention to the ways in which women’s symptoms are dismissed in healthcare settings (Dusenbery, 2018; Norman, 2018). This study provides one possible partial explanation of this problem in that the participant’s descriptions of their daytime symptoms suggest that men’s specific or basic and time of day-oriented descriptions may fit more clearly into healthcare settings that prioritize the biological or physical aspects of illness. Women’s descriptions, being more complex and omnipresent throughout the day do not as clearly fit the specific descriptions needed for an accurate diagnosis.

Intersectional theories and methodologies remind us that that no person identifies as just a woman or a man (Choo & Ferree, 2010; Crenshaw, 1991). We recognize people embrace many identities including their age, religion, health status, education, and race, and these identities may intersect with their gender identity. Therefore, while we found influences of gender, it is likely that

other social roles affected the responses. One particular strength of the study is racial diversity; this study included six African American women and four African American men comprising over one-third of the participants. We found little difference in descriptions of sleep and daytime dysfunction within each sex as a group despite the racial differences. Quotes and descriptions cited are inclusive and representative of both races. Other factors that might have intersected with gender in this study were age, as the participants were primarily at mid-life, or health status as all participants were also coping with a T2DM.

In conclusion, it is critical that while we posit that women's perceptions and descriptions of impaired sleep and daytime function may be fundamentally different from men's descriptions, these findings likely were influenced or vary by factors such as race, socio-economic status, employment, health status, religion etc. Therefore, sleep should be understood as a process of cultural and gender differences that is negotiated within a biological framework. Future research investigating the gendered experiences of sleep via quantitative methods may be able to further clarify the cultural and gendered processes of sleep.

4.0 Manuscript 2 - Are Women's and Men's Perspectives of Sleep, Daytime Fatigue, and Sleepiness Captured in Sleep Instruments? An Exploratory Investigation

4.1 Abstract

Introduction: Qualitative interviews suggest that there is an influence of gender that is especially visible in the descriptions of next-day impairment in men and women. This exploratory study examined how the gendered perceptions of sleep and next-day function derived from the interviews might be found or be missing in common sleep instruments.

Methods: Six validated instruments used to measure sleep outcomes were compared with the codes that emerged from a qualitative study that investigated possible differences in perspectives of sleep quality between men and women. Using a categorical display table, the list of codes from the interviews for men and women respectively were compared to the instruments.

Results: While the instruments measure many of the codes, they did not query the use of naps or other sleep interventions. Many of the instruments used very broad questions which do not capture the gendered differences in the context important to the participant's descriptions such as paid employment, references to caregiving activities, or the specific temporal descriptions of daytime fatigue and sleepiness.

Conclusion: The results suggest that further investigation is needed to assess if these commonly used sleep instruments are sensitive to both sexes.

4.2 Introduction

Many researchers when discussing sex differences in obstructive sleep apnea (OSA) symptomology have suggested that women report “different”, “atypical” or “vague” descriptions of impaired sleep compared to men (Lin, Davidson, & Ancoli-Israel, 2008; Ye, Pien, & Weaver, 2009; Wimms, Woehrle, Ketheeswaran, Ramanan, & Armitstead, 2016). We conducted a qualitative study with men and women (Morris, in preparation), that supports a pattern in which women described the daytime symptoms of impaired sleep as being tired, an omnipresent lack of motivation or low energy instead of a specific symptom that can be clearly recited in a doctor’s office. Conversely, men often described specific symptoms of sleepiness at certain times of the day that might be easily understood as a possible symptom of OSA. Participants often discussed their napping habits and many of the general discussions were contextualized in terms of caregiving; the men described being cared for, the women described caring for themselves and others. The interviews suggested that there is an influence of gender, (social roles and expected characteristics), that is especially visible in the descriptions of next-day impairment in men and women.

While many commonly used sleep instruments were originally tested in focus groups that included both men and women, none incorporated a sub-analysis by sex as part of their design (Bastien, 2001; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989; Buysse, et al., 2010; Chervin & Aldrich, 1999; Weaver, et al., 1997). Therefore, it is unclear if they adequately capture women’s descriptions of impaired sleep and daytime function and if men and women would attribute the same meanings to the questions. This exploratory study examined how the gendered perceptions of sleep and next-day function derived from our qualitative interviews might be included or be missing in the common sleep instruments.

4.3 Methods

4.3.1 Description of qualitative study

The purpose of the initial study was to qualitatively explore the perspectives men and women with T2DM have of their experiences with poor sleep including both nighttime sleep and next-day fatigue or sleepiness. Participants were recruited from baseline assessments of an ongoing randomized clinical trial (R01 DK096028: E. Chasens, PI); inclusion criteria included T2DM and self-reported impaired sleep. Semi-structured interviews included open-ended and gender-neutral questions. Three reviewers with expertise in qualitative analysis, used a qualitative description approach to code the interviews of men and women separately before comparing both groups. Axial codes and representative quotations were used to describe the sample. The men and women (14 each, mean age=54yrs) described their struggles with poor sleep quality, daytime fatigue, and sleepiness within their primary daytime responsibilities, whether it was with home responsibilities or job responsibilities. Men endeavored to complete their tasks even when tired and described themselves as “always being on my game.” For women, being tired was described as an omnipresent barrier to motivation and completing tasks. Men expressed being tired at specific times of the day (e.g. 2pm, 7pm, evenings etc.) whereas women were tired “all day.” Men perceived naps a pragmatic use of their time; women found naps “unproductive.” Men were more likely to describe early waking as a sleep problem while women were more likely to report trouble falling asleep. We concluded that gender role expectations and characteristics may have played a role in the different descriptions of poor sleep quality.

4.3.2 Method for instrument evaluation

Six validated instruments for sleep were compared with the qualitative data on symptoms of sleep disturbance and daytime function in men and women. Because many researchers use short forms when available to reduce participant burden, they were compared instead of the long forms. While not a true mixed-methods study, procedures for analyses were borrowed from its methodology. Using a categorical display table (Clark, 2011, page 226), with sections for men and women listed separately for easy visualization, the list of codes from the interviews were compared to the instruments by the author (J.L.M.) and then corroborated by two sleep experts (F.S.L, E.R.C). Codes and categories that either men or women used to describe the symptoms of impaired sleep or the daytime impact of impaired sleep were compared to the instruments to investigate whether they were or were not measured. Codes were compared liberally to the questions on the instruments. If there was any possibility that a code from the interviews would ‘fit’ within the context of a question, the instrument was considered to be inclusive of that code.

4.3.2.1 Instruments

Pittsburgh Sleep Quality Index (PSQI).

This questionnaire has seven components (sleep duration, efficiency, quality, latency, disturbances, medication use, and daytime dysfunction). The higher the score, the worse the global sleep quality; scores > 5 indicate poor sleep quality (Buysse et al., 1989). The PSQI has reported good overall reliability (Cronbach’s $\alpha = 0.83$) and validity (sensitivity 89.6% and specificity 86.5%). There had been no published factor analysis of the PSQI by sex (Mollayeva et al., 2016), however, it has been found reliable and valid in both older, mostly White men, and in a cohort of

Black and White older women (Beaudreau et al., 2012; Spira et al., 2012). A recent factor analysis of the PSQI suggested that women may associate the concept of “poor sleep quality” with sleep disturbances and their daytime effects whereas men may be more likely to associate “poor sleep quality” with short sleep duration and poor sleep efficiency (Morris, Rohay, & Chasens, 2017).

Epworth Sleepiness Scale (ESS).

The ESS measures subjective daytime sleepiness in eight daytime settings. Scores range from 0 to 24; a score ≥ 10 is usually used to indicate has excessive daytime sleepiness. The ESS has a high reported internal consistency (Cronbach’s $\alpha = .88$) (Johns, 1991). The ESS was found to be more sensitive to men than women (Chervin & Aldrich, 1999). Additionally, different cut-points of sleepiness in the ESS by sex were suggested in a Chinese sample, with nine being the cut point for males and six for females (Zou et al., 2013).

Functional Outcomes of Sleep Quality (FOSQ).

There are both the original FOSQ (Weaver et al., 1997) and a shortened form of the FOSQ (Chasens, Ratcliffe, & Weaver, 2009). The shortened form was used in this evaluation. The FOSQ instruments are used to assess the effect of sleepiness on daytime function. The FOSQ consists of 30 questions, grouped into five subscales (i.e., General Productivity, Social Outcomes, Activity Level, Vigilance, and Intimate Relationships and Sexual Activity) through factor analysis. The FOSQ-10 includes questions from all of the subscales in a 10-item version with internal reliability, $\alpha = 0.87$. Each question on the FOSQ has a range of responses from 1 (extreme difficulty due to sleepiness) to 4 (no difficulty) that includes an alternative response (could be other reasons). The FOSQ total score ranges from 5 to 20, with higher scores indicating less difficulty in performing activities due to sleepiness. It has good internal consistency (Cronbach’s α for the total score =

0.95; sub-scale scores range from 0.86 to 0.91). The FOSQ is sensitive to correctly identifying normal subjects (total FOSQ ≥ 18) from those with sleep difficulties ($p < 0.00$). Instrument development studies utilized samples of approximately two-thirds men (Weaver et al., 1997) and no known analysis of reliability or validity by sex was found, to date.

PROMIS Sleep Disturbance & PROMIS Sleep-Related Impairment: Short Forms (SF)

The PROMIS Sleep Disturbance scale broadly measures perceptions of sleep quality, including time to fall asleep, restlessness, and worry over sleep during the previous week. The PROMIS Sleep-Related Impairment scale measures daytime function as a result of poor sleep (Buysse et al., 2010). There are 27 & 16 questions in the long questionnaires respectively and 4, 6 and 8 options each in the short forms respectively. This study evaluated the eight-question option questionnaire. The internal consistency for both long forms was Cronbach $\alpha = 0.9$. Five item Likert scales assess sleep variables, with higher scores indicating worse sleep disturbance and impairment. In testing, samples were balanced by sex, but sex differences were not evaluated.

Insomnia Severity Index (ISI).

This is a short 7 item questionnaire that measures insomnia severity (Bastien, 2001). For this Likert scale, the scores range from 0 = no difficulty to 4 = very difficult. It is highly reliable with a Cronbach $\alpha = 0.90$, and scores of ≥ 10 have a sensitivity of 86.1% and specificity of 87.7%. Testing was conducted in a balanced sample of men and women but was not evaluated by sex.

4.4 Results

Table 5 and 6 display the codes and their associations with the instruments. As expected, no one instrument captured all of the participant’s voices, whereas no one participant related to every question on any one questionnaire. However, several codes that consistently described perspectives shared in the interviews were not captured anywhere in the instruments. Because there were many codes, and many questions to compare, it is only possible to make broad observations in this exploratory analysis.

Table 5

Categorical display table comparing women's codes and categories to the concepts and questions found in the listed sleep instruments

Axial codes	Descriptive codes for daytime outcomes of fatigue or sleepiness	PROMIS: Sleep related	PROMIS: Sleep disturbance	Pittsburgh Sleep Quality Index	FOSQ-10	Epworth Sleepiness Scale	Insomnia Severity Index
Impact on motivation and productivity	Frustration/ Hopeless	X					
	Low motivation	X		X			X
	Poor sleep affects energy	X			X		
Attitudes towards taking naps	Limits naps because she had stuff to do						
	Limits naps because it prevents good nighttime sleep						

Being tired during the day	Tired all day/all the time	X					
	Context of being tired: family responsibilities and caregiving	X					
	Effects on clear thinking	X			x		X
	Feels irritable when tired	X					
	Falling asleep when doesn't want to	X		X	X	X	X
	Tired when wakes up	X	X				
	Uses activity to stay awake						
Sleep is part of caring for one's health	Caring for her own sleep and health						
	Avoids medications			X			
	Meds for pain and depression help sleep						
Symptoms of Impaired sleep							
Interventions for poor sleep	Tried various interventions						
Descriptions of poor sleep	Frequent waking at night		X	X			X
	Lack of deep sleep		X	X			
	Restless		X	X			

	Hard to fall asleep		X	X			X
	Too little sleep		X	X			
	Trouble falling back to sleep		X	X			
Causes of poor sleep	Sleep and pain						
	Nocturia		X	X			

Table 6

Categorical display table comparing men’s codes and categories to the concepts and questions found in the listed sleep instruments.

Axial codes	Descriptive codes for daytime outcomes of fatigue or sleepiness	PROMIS: Sleep related impairment	PROMIS: Sleep disturbance	Pittsburgh Sleep Quality Index	FOSO-10	Epworth Sleepiness Scale	Insomnia Severity Index
Impact on motivation and productivity	Works at an outside job: forces self to work “always on my game”	X		X			
Attitudes towards taking naps	When works at home: naps are refreshing						
	Limits naps: prevent good nighttime sleep or not helpful						
Being tired during the day	May feel sleepy or fall asleep during work (usually with various specific times)	X		X	X	X	X
	[Afternoon] sleepiness/fatigue makes it harder to think clearly	X			X	X	X
	Evening sleepiness				X		
	Has energy in the mornings	X					

	No energy in the mornings	X			X	X	X
	Context of being tired: Paid employment						
	Has energy in the mornings	X					
	Stays up late (tv,work etc.)						
Sleep is part of caring for one's health	Wife, roommate, mother, complains or reports his snoring						
	References to caring for his health						
	Avoids medications			X			
Symptoms of Impaired sleep							
Causes of poor sleep	Nocturia		X	X			
	Aging effects sleep						
Descriptions of poor sleep	Frequent wakening		X	X			X
	Restless		X	X			
	Can't fall back to sleep						
	Wakes up too early -good sleep waking up at ideal time		X				X

4.4.1.1 Daytime perspectives

Impact of impaired sleep on motivation and productivity.

In the interviews, men and women described different styles of coping with being tired during the day; women described a lack of motivation, and men spoke of a determination to not let tiredness/sleepiness affect their productivity. Several instruments capture these perceptions by incorporating items that a participant might possibly interpret as querying low motivation including, “During the last month, how much of an effort has it been to get up enough enthusiasm to get things done?” (PSQI, Q9), PROMIS – sleep related impairment (SF), “I had a hard time getting things done because I was sleepy,” or the ISI Q7, “To what extent do you consider your sleep problem to interfere with your daily functioning. Currently?”

Being tired during the day.

The word ‘tired’ was the word primarily used by both men and women to describe their daytime feelings of fatigue or sleepiness. With the exception of the FOSQ-10 in which all questions utilize the words “sleepy or tired,” the instruments vary in their use but most are inclusive of daytime sleepiness. The PROMIS – Sleep related impairment- (SF) includes the question, in the last seven days, “I felt tired,” which could be broadly interpreted by men or women, but it may not capture the temporal perspective, whereas men felt tired at specific times of the day and women felt tired all day. The FOSQ-10 includes two questions that query the timing of sleepiness, “Do you have difficulty being as active as you want in the morning because you are sleepy or tired,” and “Do you have difficulty being as active as you want in the afternoon because you are sleepy or tired.” The original FOSQ includes a third question that asks about difficulty in being active during the evening secondary to being sleepy or tired. Both men and women endorsed daytime

sleepiness and poor concentration and they are items on the PROMIS Sleep-Related Impairment (SF), the FOSQ-10, and ISI. Women reported irritability when tired, and that was captured by the PROMIS short form Sleep-Related Impairment. Question seven on the PSQI states “During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?”

4.4.1.2 Context of being tired.

In every interview, descriptions of daytime function were contextualized within the daytime occupations and tasks of the participants. Women were more likely to contextualize their days in terms of caregiving activities (children, spouses, parents), regardless if they worked at outside employment. The men, who were often self-employed contextualized their daytimes symptom in terms of their jobs. The original FOSQ, not reviewed in the tables, attempts to reflect these ideas through specific questions of hobbies and other activities. However, the other instruments do not ask questions about how daytime fatigue and sleepiness increase the strain in completing caregiving duties or fulfilling the obligations of paid employment.

Attitudes towards taking naps.

Naps are not queried on the instruments, yet they were spontaneously described by many of the participants whether they were reluctant to take them or found them to be a pragmatic tool.

Sleep is part of caring for one's health.

In all the interviews, concepts of being cared for, caring for others or caring for oneself was an integral aspect to the descriptions of either sleep, or part of the contextualized descriptions of next-day function. Men described being cared for when their wives worried about their snoring,

and women described low motivation in terms of their family or caregiving responsibilities. Both men and women described getting good sleep as a form of self-care. These concepts are not part of any sleep instrument.

4.4.1.3 Descriptions of poor sleep

Women were more varied in their descriptions of sleep impairment than men were. The PSQI and the PROMIS Sleep Disturbances- SF capture most of the codes that derived from the men's and women's interviews because they were very broad in nature. For instance, the PROMIS Sleep Disturbances- SF includes the item "I had a problem with my sleep" which could be interpreted very generally. One interesting finding from the interviews was that many participants described waking up frequently at night, but didn't consider it a problem unless they couldn't fall back to sleep. Trouble falling back to sleep at night after waking is not clearly captured in any of the instruments.

4.4.1.4 Causes and interventions for poor sleep.

Women were more likely than men to describe what they thought were the causes of their poor sleep and to describe interventions they'd tried to sleep better. For instance, women discussed over fifteen different interventions, such as switching pillows, separate bedrooms and lavender baths, whereas men discussed limiting naps and exercise. The instruments do not capture the specificity of these ideas yet the women in particular offered many such descriptions.

4.4.1.5 Summary of counts

Table 5 depicts the number of codes each instrument captured that were expressed by women; Table 6 depicts the codes captured that were expressed in men. The PROMIS-Sleep-

Related Impairment -SF captured the most codes from the interviews reflecting nine codes in women and six in the men. The PROMIS– Sleep Disturbance-SF questionnaire captured seven codes in women but only three in men. The PSQI captures women’s codes ten times but only four of men’s. The FOSQ-10 captured three of the women’s codes and four the men’s; the ESS captured one of the women’s codes and three of the men’s codes, and the ISI captured five of each. In terms of specific codes, descriptions of daytime sleepiness and outcomes in both men and women were most closely captured by all the instruments. References to specific times of day that symptoms occurred were mostly closely reflected by the men’s codes.

4.5 Discussion

This was an exploratory exercise in which we compared different patterns in the sleep and next-day function of men and women to examine how well the sleep instruments captured the voices of the men and women in our previously conducted qualitative interviews. The goal was not to argue if a particular code or category should be incorporated in an instrument, but simply to become aware of other patterns and perceptions of sleep that may not be captured therein. We found that many codes and patterns from both the men’s and women’s interviews were not captured in the instruments, in particular, discussions of napping, sleep interventions, the context of the descriptions of daytime function as within paid employment or home and caregiving responsibilities, and the different ways both men and women cope with being tired (low energy and motivation or determination and push). However, we also found that the participants did

describe many of the concepts important within the instruments i.e., daytime sleepiness, daytime difficulty in getting things done, poor concentration, and most descriptions of sleep.

These instruments have the intended purpose to measure outcomes important to clinicians and researchers, but most lay people do not think about their sleep in the clinical terms of “sleep quality,” “sleep efficiency,” or “functional outcomes.” During the interviews, participants talked in terms of what was important to their own lives, and in language that reflected their own perspectives. However, questions that attempt to understand the perceptions of sleep itself such as the PROMIS-Sleep Impairment question “I had a problem with my sleep,” are too broad to provide the specific conditions or perspectives that could lead to personalized interventions. Therefore, it should not be interpreted that these instruments do a better job of capturing women’s perceptions; it may be that women provided more varied descriptions of their sleep and very broad questions captured more codes. Likewise, questionnaires that attempt to measure the outcomes of impaired sleep in the daytime do not comprehensively capture the situational contexts and possible influence of gender in the responses. As the PROMIS-Sleep-Related Impairment -SF contains the question “I felt tired,” it was again possible to include more codes from women without understanding the nature of the problem. In addition, as the questionnaires contain many references to specific times of day, they likely capture more of men’s perspectives of daytime fatigue and sleepiness.

The qualitative study suggests that women may respond to questions about daytime fatigue and sleepiness differently. From the interviews, it’s likely that most women would have indicated that being tired significantly interfered with their daily function. Question four of the ISI asks; “To what extent do you consider your sleep problems to interfere with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) currently?” Yet even while some men also described poor sleep quality or feeling sleepy or

tired at certain times of the day, they also often expressed determination to not let it interfere with their daily function. Therefore, men may be more likely to indicate on the questionnaire that their sleepiness does not interfere with their daily function, despite also describing daytime tiredness. It is unknown whether the male respondents minimized their impairment, perhaps reflecting gender expectations. However, this suggests that women's higher rates of sleep impairment such as insomnia may not be so much reflective of their perspectives of their sleep, but reflective of their perspectives of the daytime outcomes that result from poor sleep.

This exploratory report has limitations. In order to know what questions can truly reflect differences between men and women and which ones contain measurement bias, each question would have to be thoroughly tested in men and women taking into cultural and health status'. The interviews consisted of 28 participants (14 men, and 14 women) and therefore can only speak to gendered patterns found within these interviews. Different patterns might be found in a different group of participants. Lastly, we examined only a limited set of questionnaires. Others may contain the missing codes.

4.6 Conclusion

In order for a sleep instrument to be valid it must be sensitive to the presentation of both men and women's symptoms and the outcomes. The result of this study suggests that further investigation is needed to assess if commonly used sleep instruments are sensitive to both sexes. Unfortunately, if the perspectives of impaired sleep are either not included or are misinterpreted, there is a significant possibility of failure to diagnose or misdiagnosis of sleep disorders. For example, the expression of lack of motivation in women with impaired sleep may lead to an

incorrect diagnosis of depression. Conversely, a man's denial of the impact of the sleepiness on functional outcomes may minimize the extent that impaired sleep has on their daily function. It is essential that in studies assessing behavioral or perceptual sleep outcomes, the influence of gender roles and characteristics must be taken into account.

5.0 Manuscript 3 - Sex Differences and its Role as a Possible Moderator of the Association between Obstructive Sleep Apnea with Mood, Sleep Quality, Daytime Sleepiness and Daytime Function in Persons with Type 2 Diabetes

5.1 Abstract

Objective/Background: Based on the literature it is unclear if there are sex differences in obstructive sleep apnea (OSA) pathophysiology that may affect the reports of subjective sleep outcomes. The purpose of this study was to explore sex differences and potential moderation by sex on the relationships of OSA severity and self-reports of mood, sleep quality, daytime sleepiness, and function in participants with type 2 diabetes (T2D) who were recruited into a randomized controlled trial of CPAP for OSA because of “poor sleep,” “snoring” or who consider themselves at risk for OSA.

Participants: This cross-sectional study was a secondary analysis of baseline data from the Diabetes Sleep Treatment Trial (DSTT) and included a racially diverse (58% White, 62% non-White) sample of 322 men (50.9%, n = 164) and women (49.1%, n=158), on average 56.5 years of age (SD=10.5) with type 2 diabetes, a mean 8.0 A1C% (SD=1.8).

Methods: Primary measures were apnea-hypopnea index (AHI) and the self-reported sleep measures of Pittsburgh Sleep Quality Index (PSQI), Epworth Sleepiness Scale (ESS), and Functional Outcomes of Sleep Quality Questionnaire (FOSQ) and mood based on the Profile of Mood States (POMS). Standard group comparative methods were used to assess for sex differences. To explore moderation by sex of AHI severity with self-reports of mood, sleep quality, daytime sleepiness, and function, hierarchical multiple linear regression was used.

Results: Women reported significantly worse sleep quality, excessive daytime sleepiness, and daytime function than men ($p < .05$); however, men had significantly worse AHI than women ($p < .05$). Sex did not moderate the relations of AHI and the sleep outcomes measures. In fully adjusted models for age, sex, BMI, glycemic control (A1C), race, financial ability and marital status, AHI did not show a significant association with sleep outcomes. In unadjusted and covariate-adjusted models, perception of financial difficulty and age had significant associations with all sleep measures but ESS.

Conclusion: In a community sample of people with T2D at high risk for OSA, there was no association of AHI with sleep outcomes or moderation by sex. Women reported worse sleep quality, daytime sleepiness and function than men but there were no sex differences in mood. Age and financial ability had greater associations with subjective reports of sleep and its next day outcomes than OSA severity, suggesting a limited role of AHI in subjective sleep outcomes.

5.2 Introduction

While obstructive sleep apnea (OSA), recurrent breath holding (apneas) or decreased airflow with oxygen desaturation (hypopnea) during sleep is more prevalent in men, the incidence of OSA in women after menopause begins to approach that of men (Ye, Pien, Ratcliffe, & Weaver, 2009). Yet, it is estimated that up to 90% of women with OSA in the United States are unaware that they have this disorder (Miller et al., 2017).

OSA has been under diagnosed in women, possibly because the disease has been defined based on men's symptoms which include snoring, excessive daytime sleepiness and waking up during the night snorting or gasping for air (Cao & Kushida, 2011). It has been suggested that

women have different symptoms of OSA from men including increased likelihood of depressed mood, insomnia and daytime fatigue and sleepiness (Eliasson, Kashani, Howard, Vernalis, & Modlin, 2015; Miller et al., 2017). There is abundant evidence of sex differences in sleep and the pathophysiology of OSA to support this claim. Sex differences are found in the effects of sex hormones on sleep mechanisms, in circadian clock genes, respiratory function, stress responses, and even in sleep duration (Mong et al., 2011). Biological sex differences also exist in the presentation of OSA. Women with OSA are likely to be more obese at the same levels of OSA severity than men, are protected from OSA by estrogen/progesterone prior to menopause, and have different upper airway structures than men (Lin, Davidson, & Ancoli-Israel, 2008; Ye et al., 2009). However, it is unclear if OSA itself is the cause of increased reports of depression, insomnia and excessive daytime sleepiness in women or if other factors may play a role in the manifestations of symptoms.

Furthermore, much of the discussion about OSA has concerned the health consequences of OSA and less has been discussed regarding OSA severity on daytime symptoms and function, and its effects on a person's abilities to manage their chronic disease or day-to-day responsibilities (Ye et al., 2009). Persons with type 2 diabetes (T2D) are at high risk for OSA (Aurora & Punjabi, 2013), and their challenges with day-to-day self-care can be significantly affected by impaired sleep, impacting daytime function, sleepiness and mood. The purpose of this study was to explore sex differences and potential moderation by sex on the relationships between OSA severity and self-reports of mood state, sleep quality and insomnia, daytime sleepiness, daytime function in participants with T2D who were recruited because of "poor sleep," "snoring" or considering themselves at risk for OSA.

5.3 Methods

5.3.1 Design.

This study was a cross-sectional secondary analysis of data collected from the baseline assessments from the ongoing Diabetes Sleep Treatment Trial (DSTT; R01-DK096028). The purpose of the parent study is to examine the effect of treating OSA using continuous positive airway pressure (CPAP) compared to sham CPAP on glucose control and diabetes self-management behavior in persons with T2D.

5.3.2 Sample.

The sample was recruited from three sites: the greater Pittsburgh, Pennsylvania community, the Veterans Administration Pittsburgh Healthcare System (VAPHS), and West Virginia University. Participants were recruited from a research registry, diabetes clinics or doctor's offices, bus advertisements, social media platforms, the VAPHS Sleep Center, and from the electronic health record at West Virginia University. Potential participants were telephone screened to determine their eligibility for the baseline assessment. Informed consent was obtained prior to any research activity at the baseline assessment. Eligibility criteria for the baseline assessment included age 18 years or older, self-reported diagnosis of T2D, no acute illnesses requiring hospitalization in last 3 months, able to read and write English, and being ambulatory. Potential participants were excluded if they had previous CPAP use, a near-miss or automobile accident due to sleepiness, employed in a safety sensitive occupation, or were unwilling to be randomized to sham CPAP.

5.3.3 Measures

5.3.3.1 Dependent Variables.

Pittsburgh Sleep Quality Index (PSQI). This questionnaire which identifies good and poor sleepers, has seven components (sleep duration, efficiency, quality, latency, disturbances, medication use, and daytime dysfunction). The higher the score, the worse the global sleep quality; scores > 5 indicate poor sleep quality (Buysse et al., 1989). The PSQI has reported good overall reliability (Cronbach's $\alpha = 0.83$) and validity (sensitivity 89.6% and specificity 86.5%). It has been found to be reliable and valid in both older men and in a cohort of Black and White older women (Beaudreau et al., 2012; Spira et al., 2012).

Epworth Sleepiness Scale (ESS). The ESS measures subjective daytime sleepiness in 8 familiar and common situations. Scores range from 0 to 24; a score ≥ 10 indicates a participant is excessively sleepy during waking hours. The ESS has a high reported internal consistency (Cronbach's $\alpha = .88$) (Johns, 1991). The ESS has been found have different sensitivity for men and women (Chervin & Aldrich, 1999; Zou et al., 2013).

Functional Outcomes of Sleep Quality (FOSQ). The FOSQ is used to assess the effect of sleepiness on daytime function (Weaver et al., 1997). The FOSQ consists of 30 questions, grouped into five subscales (i.e., General Productivity, Social Outcomes, Activity Level, Vigilance, and Intimate Relationships and Sexual Activity) based on exploratory factor analysis. Each question on the FOSQ has a range of responses from 1 (extreme difficulty due to sleepiness) to 4 (no difficulty) that includes an alternative response (could be other reasons). The FOSQ total score ranges from

5 to 20, with higher scores indicating less difficulty in performing activities due to sleepiness. It has good internal consistency (Cronbach's α for the total score = .95 and ranges from .86 to .91 for the subscale scores). The FOSQ is sensitive to correctly identifying normal subjects (total FOSQ ≥ 18) from those with sleep difficulties ($p < .001$). Instrument development studies utilized samples of approximately two-thirds men (Weaver et al., 1997). To date, no known analysis of reliability or validity by sex has been conducted.

Profile of Mood States (POMS). Mood state was measured by the POMS. The POMS uses 65 adjectives (e.g., tense, discouraged, listless) with 5-point Likert scaling from 0 = not at all to 4 = extremely to assess feelings during the past week. Six factors of mood were identified in the POMS (i.e., Tension-Anxiety, Depression-Dejection, Anger-Hostility, Vigor-Activity, Fatigue-Inertia, and Confusion-Bewilderment). These factors are summed (with Vigor-Activity reversed) to obtain the summary Total Mood Disturbance (TMD) score (McNair & Druppleman, 1971). The POMS has been shown to be sensitive to detecting impaired mood in studies examining sleep, and the six POMS factors are internally consistent with the TMD score (Cronbach's $\alpha = .84$). Norming data for "gender" in the POMS of four samples all showed small but significant differences by gender. The developers decided the differences did not justify separate standards for men and women (McNair & Druppleman, 1971).

5.3.3.2 Independent Variables.

ApneaLink Pro®. The primary independent variable of OSA severity as the Apnea/Hypopnea Index (AHI) was assessed using a portable sleep testing device, the ApneaLink Pro®. It also measures oxygen desaturation (ODI), % sleep time with oxygen desaturation $< 90\%$. Participants take the equipment home to use the night following their baseline assessment. The ApneaLink Pro® is an FDA approved level III device that can be used in private homes and does not involve

an overnight stay in a sleep laboratory. The ApneaLink Pro® is automatically scored according to the American Association of Sleep Medicine scoring rules and reviewed by a registered polysomnography technician.

Demographic questionnaire. In this questionnaire participants self-reported their age, sex, marital/partner status, education, and race. They were included as covariates if there were differences by sex for these characteristic and if correlated with the other primary variables of interest.

Financial difficulty. A question about one's ability to meet their financial needs was included: "how difficult is it for you to meet your basic needs (i.e., food, housing, utilities, and health care)." Possible responses for financial difficulty were "no difficulty," "some difficulty," and "extreme difficulty"; for analysis, responses were dichotomized as "not at all difficult" and "some to extreme difficulty." Previous literature supports a relationship between sleep quality and financial security (Jarrin, McGrath, Silverstein, & Drake, 2013).

Body Mass Index (BMI) [kg/m²]. Measured height and weight were obtained in order to calculate body mass index.

Glycemic control. A1C was obtained via venipuncture during the clinical evaluation. A1C offers a reliable indication of glycemic control over the past 2 to 3 months (American Diabetes Association, 2018).

5.3.4 Analysis

Data analyses were conducted using IBM® SPSS® Statistics v24. Preliminary analysis included univariate and bivariate sample distributions to determine if the data were distributed normally. While participants complete the POMS at the baseline assessment, the PSQI, FOSQ and

ESS are completed at home and sent back. Questionnaires that weren't sent back were considered missing and not included in the analysis. Student's t-test was used to examine differences in continuous demographic and clinical characteristics and the continuous variables (AHI, age, BMI, A1C, daytime sleepiness, sleep quality, mood, and functional outcomes) between males and females. Log transformations were conducted when the continuous variables contained a skewed distribution. Chi-square tests of independence were used to determine if there were differences in the distributions of categorical demographic variables of race, educational level, financial ability, and marital status by sex (male, female). Hierarchical multiple linear regression modeling considering the interaction with sex were conducted to determine if sex moderates the relationships between AHI and the outcomes of mood and self-reported sleep measures in unadjusted and covariate-adjusted regression models. AHI was treated as a continuous type predictor variable in order to increase statistical power to detect relationships between AHI and dependent variables. Statistical significance was set as $p < .05$.

5.4 Results

Table 1 reports descriptive statistics for demographic and clinical characteristics for the total sample and comparisons by sex. Overall, the sample ($N = 322$) was middle aged (median = 57.0), racially diverse (i.e., 40.8% Non-White [African American, $n = 118$ (36%); American Indian, $n = 2$, (0.6%); Asian, $n = 1$ (0.3%); Native Hawaiian or other Pacific Islander, $n = 1$ (0.3%); Biracial, $n = 10$ (3%)]), balanced by sex (49% female), and not currently married or partnered (57%). The majority of participants were overweight or obese (91% with $BMI \geq 25$) and had sub-

optimal glucose control (50% of the sample had a median A1C \geq 7.7%). The majority (53.7%) of participants had some post high school education.

Sex Differences. Men were significantly older, more likely to be married and to have a higher AHI than women, while women were significantly more likely to report poor sleep quality, daytime sleepiness and difficulty in meeting their financial needs than men ($p < .05$). No significant differences by sex were found for education, overall mood, BMI, or A1C levels ($p \geq .05$).

Table 7 Characteristics of the total sample and by sex

Characteristics, n (%) or Mean \pm SD	Total N=322	Sex		<i>p</i> -value
		Women n=158,	Men n=164	
Age (years) (n = 322)	56.4 \pm 10.6	54.7 \pm 10.7	58.1 \pm 10.2	.005
Nonwhite (primarily African American) (n = 322)	132 (40.9)	78 (59.1)	54 (40.9)	.002
Married/Partnered (n = 322)	138 (42.8)	54 (39.1)	84 (60.9)	.002
Associate or college degree or higher (n = 321)	176 (54.6)	87 (49.4)	89 (50.6)	.837
Some/extreme financial difficulty (n = 321)	138 (42.9)	82 (59.4)	56 (40.6)	.001
BMI (kg/m ²) (n = 321)	34.9 \pm 7.0	35.3 \pm 7.3	34.6 \pm 6.8	.315
AHI (apnea/hypopnea index) (n = 282)	15.5 \pm 17.6	11.6 \pm 14.0	19.4 \pm 19.8	.000
A1C (%) (n = 316)	8.0 \pm 1.8	7.9 \pm 2.0	8.0 \pm 1.7	.547
Profile of Mood States (POMS): Total (n = 322)	28.9 \pm 34.1	29.9 \pm 34.1	27.8 \pm 34.1	.580
Pittsburgh Sleep Quality Index (PSQI): Global Sleep Quality (n = 289)	10.1 \pm 4.1	10.6 \pm 4.1	9.6 \pm 4.0	.024
Epworth Sleepiness Scale (ESS): Daytime sleepiness (n = 293)	10.1 \pm 4.7	10.6 \pm 4.9	9.5 \pm 4.6	.049
Functional Outcomes of Sleep Quality (FOSQ): Total (n = 288)	16.1 \pm 3.0	15.7 \pm 3.2	16.6 \pm 2.7	.007

AHI = Apnea/hypopnea Index, higher scores are greater OSA severity; POMS adult normative for Total score: Men = 14.8, Women = 20.3, where higher scores are worse; PSQI > 5 = poor sleep quality; ESS \geq 10 = excessive daytime sleepiness; FOSQ, higher scores = better daytime function.

5.4.1 Regression

All of the covariates (age, race, marital status, financial difficulty) except education were significantly different between men and women. Therefore, they were included in the covariate-adjusted models.

No significant interactions of sex and AHI were found in any of the models and so they are not reported. Table 8 shows the adjusted regression results for OSA severity (AHI) on global sleep quality, daytime sleepiness, functional outcomes sensitive to impaired sleep and depressed mood.

Global sleep quality (PSQI). In unadjusted models, having lower AHI ($R^2 = 0.035$, $b = -1.73$, $SE = 0.54$), being unmarried ($R^2 = 0.028$, $b = -1.47$, $SE = 0.48$), being female ($R^2 = 0.018$, $b = 1.09$, $SE = 0.48$), being nonwhite ($R^2 = 0.016$, $b = 1.06$, $SE = 0.49$), younger age ($R^2 = 0.031$, $b = -0.067$, $SE = 0.22$) and reporting financial difficulty ($R^2 = 0.038$, $b = 1.60$, $SE = 0.48$) were each significantly associated with worse perceived sleep quality ($p < 0.05$). In the covariate-adjusted model, AHI was no longer significantly associated with perceived sleep quality.

Daytime sleepiness (ESS). In unadjusted models, younger age ($R^2 = 0.018$, $b = -0.60$, $SE = 0.26$) and female sex ($R^2 = 0.013$, $b = -1.09$, $SE = 0.55$) were each significantly associated with worse daytime sleepiness ($p < 0.05$); however, AHI was not significantly associated with daytime sleepiness ($p > 0.05$). In the covariate-adjusted model, AHI showed a trend toward being significantly associated with daytime sleepiness ($p = 0.054$).

Functional Outcomes of Sleep: Total. Keeping in mind lower scores indicate worse function on the FOSQ, men ($R^2 = 0.022$, $b = -0.941$, $SE = 0.348$), those without financial difficulty ($R^2 = 0.087$, $b = -1.80$, $SE = 0.339$), and older participants ($R^2 = 0.049$, $b = -0.062$, $SE = 0.016$) each significantly explained better daytime function as a result of sleepiness in unadjusted models (p

<0.05). In the fully adjusted model AHI remained a nonsignificant association with daytime function as a result of sleepiness ($p \geq 0.05$).

Mood state (POMS). Financial difficulty significantly explained worse overall mood in the unadjusted model ($R^2 = 0.040$, $b = 0.013$, $SE = 0.004$) as well as in the adjusted model ($b = 0.87$, $SE = 0.64$). In the fully adjusted models, AHI did not have a significant effect on TMD ($p \geq 0.05$).

Table 8 Multiple hierarchical linear regression model of the association of AHI on the outcomes of excessive daytime sleepiness, daytime function, mood, and sleep quality

Variable	Epworth Sleepiness Scale (n=253)	Functional Outcomes of Sleep – Total (n=248)	Profile of Mood States - Total † (n=263)	Pittsburgh Sleep Quality Index (n=253)
	b (SE)	b (SE)	b (SE)	b (SE)
BMI (kg/m ²)	0.07 (0.05)	<0.01 (0.03)	<0.01 (<0.01)	-0.04 (0.05)
A1C (%)	0.19 (0.17)	0.11 (0.10)	<0.02 (0.07)	0.07 (0.04)
Age (years)	-0.05 (0.03)	0.06 (0.02)*	-0.04 (<0.01)**	-0.06 (0.03)*
Female	0.69 (0.62)	-0.27 (0.36)	-0.32 (0.25)	-0.19 (0.52)
Non-White	-0.97 (0.69)	0.44 (0.40)	-0.69 (0.28)*	-0.07 (0.58)
Financial ability: some-to-extreme difficult	0.87 (0.64)	-1.71 (0.37)*	1.41 (0.27)**	1.25 (0.54)*
Marital status: married/partnered	-1.03 (0.64)	0.55 (0.37)	-0.25 (0.31)	-1.42 (0.54)**
R^2	.061*	.165**	.126**	.079**
AHI	1.44 (0.74)	-0.74 (0.44)	0.33 (0.07)	-0.08 (0.63)
ΔR^2	.014	<.01	<.01	<.01
Sex*AHI	-2.30 (1.36)	1.02 (0.60)	-0.08 (0.55)	-0.13 (1.14)
ΔR^2	.084	.181	.153	.110

* $p < .05$, ** $p < .01$; b (SE) = unstandardized coefficient (standard error), † square root transformed, AHI = Apnea/hypopnea index; Profile of Mood States (POMS), higher scores = worse mood; Epworth Sleepiness Scale (ESS), higher scores = more daytime sleepiness; Pittsburgh Sleep Quality Index (PSQI), higher scores = worse sleep quality; Functional Outcomes of Sleep Questionnaire (FOSQ), higher scores = better daytime function; Financial ability = “no difficulty” or “some-to-extreme difficulty” meeting financial needs

5.5 Discussion

The purpose of this study was to explore sex differences and possible moderation by sex of the relationships between OSA severity and self-reports of overall mood, sleep quality, daytime sleepiness, and daytime function in people with T2D at high risk for OSA who reported trouble sleeping. These sleep outcomes have been suggested to represent sex differences in symptom reports of OSA. While there were many significant sex differences in the measures, we did not find that sex moderated the relations between OSA severity and outcomes of mood, sleep quality, daytime sleepiness, or function. The associations between OSA severity and the self-reported outcomes of mood and sleep were minimal, with a lower AHI score associated with PSQI in unadjusted models but not in adjusted models. Previous research suggests that perceptions of sleep quality are associated with factors other than OSA severity (Kang et al., 2017; Macey, Kumar, Ogren, Woo, & Harper, 2014; Scarlata et al., 2013). Our study corroborates these findings in that the perception of poor financial ability as a social determinant has a stronger association with perceived sleep quality than AHI.

Higher AHI scores trended toward significance on worse excessive daytime sleepiness, which is not unexpected finding as daytime sleepiness is commonly found in people with OSA (Greenberg, Laticova, & Scharf, 2015). Since men had overall worse OSA severity in this sample, it would be expected that men would have reported worse daytime sleepiness; however, women were significantly sleepier. The literature is conflicting regarding excessive daytime sleepiness in women and men with OSA, as some studies have found no difference between the sexes, other studies have found either men or women with OSA to experience more daytime sleepiness (Lee et al., 2014; McCall, Harding, & O'Donovan, 2006; Shepertycky, Banno, & Kryger, 2005; Wahner-Roedler et al., 2007; Ye et al., 2009). Recent studies using cluster analysis methodology suggest

that sex is not associated with symptoms of excessive daytime sleepiness (Ye et al., 2014). Our study suggests that while we did not find moderation by sex in the relations of AHI and sleep outcomes, social determinants jointly did partially explain sleep outcomes.

It has been suggested that women with OSA have greater rates of depressive symptomology and worse mood than men with OSA which leads healthcare providers to diagnose depression instead of a sleep disorder in these women (McCall et al., 2006; Shepertycky et al., 2005). In this study, there were no sex differences in mood state and no direct relationship between OSA severity on total mood state either in the total sample or by sex. A literature review of the relationship between OSA and depressive symptomology found wide ranging rates of depression (5% to 63%) in people with OSA (Ejaz, Khawaja, Bhatia, & Hurwitz, 2011). These studies were heterogenous, not balanced by sex (or it was not analyzed) and used many different measures of depression including questionnaires that query sleep. When depression measures are used that have a sleep question, studies are more likely to find a relationship between AHI and depressed mood (Nanthakumar, Bucks, & Skinner, 2016). A possible reason we did not find an association between AHI and mood disturbance is that the POMS does not contain questions about sleep.

Since we did not find moderation by sex, or little association between OSA severity with sleep outcomes, the larger story in this sample may be the associations with social determinants. The measures used in this study were all subjective reports and would necessarily be influenced not only by individual characteristics, but also by cultural factors such as socio-economic status, race or sex. Younger age and financial difficulty were the most common significant predictors in most of the models and may be associated with racial differences particular to this sample. Non-whites, who were primarily African American, were also significantly more likely to be female, younger age and reported worse financial difficulty than Whites. Older age in this sample may be

protective in that it was associated with being White, male, and having a better perceived ability to pay bills. These findings are corroborated by other studies that have found social determinants partially explain sleep symptoms in midlife women (Hall et al., 2009; Im, Ko, Chee, & Chee, 2015). It is important to recognize that sleep is a subjectively evaluated activity, as such, it is important in statistical models to incorporate, and not simply adjust for the social determinants that might be associated with one's sleep.

Limitations: Although the sample size was moderately large and well distributed by sex and race, a limitation to this study is that recruitment was not designed to evaluate the question being asked in this study nor was the sample size determined a priori for this investigation. Participants were recruited through advertisements asking if they have type 2 diabetes and “trouble sleeping.” Therefore, the participants were oversampled for impaired sleep, but their sleep could potentially have been affected by not only OSA but also by other sleep disorders or inadequate sleep duration. In particular, insomnia, a known risk for women, was not included in the models because its questions may overlap with those of the other measures. However, insomnia may be comorbid with OSA in some participants which may have contributed to more severe reports of impaired sleep outcomes. Finally, OSA severity (AHI) was measured using a home sleep study which may underestimate OSA severity in persons who were not asleep during the recording period.

5.6 Conclusion

Our study suggests that objectively measured OSA severity is not significantly associated with negative subjective symptoms that frequently accompany OSA. Social determinants such as

perception of ability to pay bills, along with age all had more influence on reports of sleep quality, daytime function, and mood than sex or OSA severity. These findings suggest that subjective reports of sleep quality, daytime function and mood are likely influenced by social factors. Researchers should be mindful when doing investigations on subjectively measured sleep outcomes that social determinants play in their participant's perceptions of sleep and daytime outcomes.

Appendix A : SLEEP OUTCOMES QUESTIONNAIRES

Sleep Related Impairment – Calibrated Items

Please respond to each item by marking one box per row.

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep10	I had a hard time getting things done because I was sleepy	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep11	I had a hard time concentrating because I was sleepy	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep119	I felt alert when I woke up	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Sleep120	When I woke up I felt ready to start the day	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Sleep123	I had difficulty waking up	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep124	I still felt sleepy when I woke up	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep18	I felt tired	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep25	I had problems during the day because of poor sleep	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep27	I had a hard time concentrating because of poor sleep	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Sleep Disturbance – Short Form 8a

Please respond to each question or statement by marking one box per row.

		Very poor	Poor	Fair	Good	Very good
Sleep109	My sleep quality was.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
In the past 7 days...						
		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep116	My sleep was refreshing.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Sleep20	I had a problem with my sleep	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep44	I had difficulty falling asleep	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep108	My sleep was restless	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep72	I tried hard to get to sleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep67	I worried about not being able to fall asleep	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep115	I was satisfied with my sleep.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1

Site: _____ ID #: _____
 Technician: _____ Date of Data Entry: _____
 Trial: _____

Name: _____ Date: _____

FUNCTIONAL OUTCOMES OF SLEEP QUESTIONNAIRE (FOSQ)

Some people have difficulty performing everyday activities when they feel tired or sleepy. The purpose of this questionnaire is to find out if you generally have difficulty carrying out certain activities because you are too sleepy or tired. In this questionnaire, when the words “sleepy” or “tired” are used, it means the feeling that you can’t keep your eyes open, your head is droopy, that you want to “nod off”, or that you feel the urge to take a nap. These words do not refer to the tired or fatigued feeling you may have after you have exercised.

DIRECTIONS: Please put a () in the box for your answer to each question. Select only **one** answer for each question. Please try to be as accurate as possible. All information will be kept confidential.

(0) I don't do this activity for other reasons	(4) No difficulty	(3) Yes, a little difficulty	(2) Yes, moderate difficulty	(1) Yes, extreme difficulty
---	-------------------------	---------------------------------------	---------------------------------------	--------------------------------------

- | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. Do you have difficulty concentrating on the things you do because you are sleepy or tired? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Do you generally have difficulty remembering things, because you are sleepy or tired? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Do you have difficulty operating a motor vehicle for <u>short</u> distances (less than 100 miles) because you become sleepy or tired? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Do you have difficulty operating a motor vehicle for <u>long</u> distances (greater than 100 miles) because you become sleepy or tired? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Site: _____ ID #: _____
 Technician: _____ Date of Data Entry: _____
 Trial: _____
 Name: _____ Date: _____

(0) I don't do this activity for other reasons	(4) No difficulty	(3) Yes, a little difficulty	(2) Yes, moderate difficulty	(1) Yes, extreme difficulty
---	-------------------------	---------------------------------------	---------------------------------------	--------------------------------------

5. Do you have difficulty visiting with your family or friends in their home because you become sleepy or tired?

6. Has your relationship with family, friends or work colleagues been affected because you are sleepy or tired?

7. Do you have difficulty watching a movie or videotape because you become sleepy or tired?

8. Do you have difficulty being as active as you want to be in the evening because you are sleepy or tired?

9. Do you have difficulty being as active as you want to be in the morning because you are sleepy or tired?

(0) I don't engage in sexual activity for other reasons	(4) No	(3) Yes, a little	(2) Yes, moderately	(1) Yes, extremel y
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10. Has your desire for intimacy or sex been affected because you are sleepy or tired?

Thank you for completing this questionnaire.

Insomnia Severity Index

The Insomnia Severity Index has seven questions. The seven answers are added up to get a total score. When you have your total score, look at the 'Guidelines for Scoring/Interpretation' below to see where your sleep difficulty fits.

For each question, please CIRCLE the number that best describes your answer.

Please rate the *CURRENT* (i.e. *LAST 2 WEEKS*) *SEVERITY* of your insomnia problem(s).

Insomnia Problem	None	Mild	Moderate	Severe	Very Severe
1. Difficulty falling asleep	0	1	2	3	4
2. Difficulty staying asleep	0	1	2	3	4
3. Problems waking up too early	0	1	2	3	4

4. How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?

Very Satisfied Satisfied Moderately Satisfied Dissatisfied Very Dissatisfied
 0 1 2 3 4

5. How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

Not at all
 Noticeable A Little Somewhat Much Very Much Noticeable
 0 1 2 3 4

6. How WORRIED/DISTRESSED are you about your current sleep problem?

Not at all
 Worried A Little Somewhat Much Very Much Worried
 0 1 2 3 4

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

Not at all
 Interfering A Little Somewhat Much Very Much Interfering
 0 1 2 3 4

Guidelines for Scoring/Interpretation:

Add the scores for all seven items (questions 1 + 2 + 3 + 4 + 5 + 6 + 7) = _____ your total score

Total score categories:

0–7 = No clinically significant insomnia

8–14 = Subthreshold insomnia

15–21 = Clinical insomnia (moderate severity)

22–28 = Clinical insomnia (severe)

Used via courtesy of www.myhealth.va.gov with permission from Charles M. Morin, Ph.D., Université Laval

Epworth Sleepiness Scale

Name: _____ Today's date: _____

Your age (Yrs): _____ Your sex (Male = M, Female = F): _____

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

This refers to your usual way of life in recent times.

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

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

- 0 = would **never** doze
- 1 = **slight chance** of dozing
- 2 = **moderate chance** of dozing
- 3 = **high chance** of dozing

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

Situation

Chance of Dozing (0-3)

Sitting and reading _____

Watching TV _____

Sitting, inactive in a public place (e.g. a theatre or a meeting) _____

As a passenger in a car for an hour without a break _____

Lying down to rest in the afternoon when circumstances permit _____

Sitting and talking to someone _____

Sitting quietly after a lunch without alcohol _____

In a car, while stopped for a few minutes in the traffic _____

THANK YOU FOR YOUR COOPERATION

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Appendix B : IRB APPROVAL



University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
<http://www.irb.pitt.edu>

Memorandum

To: Jonna Morris , RN
From: Margaret Hsieh,MD Vice Chair
Date: 6/26/2017
IRB#: [PRO17050421](#)
Subject: Sex Differences in the Perceptions and Symptom Presentations of Impaired Sleep

The University of Pittsburgh Institutional Review Board reviewed and approved the above referenced study by the expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110. Your research study was approved under:

45 CFR 46.110.(6)
45 CFR 46.110.(7)

This study is supported by the following federal grant application:

F31 NR017336-01 Sex Differences in the Perception and Symptom Presentation of Impaired Sleep

The risk level designation is Minimal Risk.

Approval Date: 6/23/2017
Expiration Date: 6/22/2018

For studies being conducted in UPMC facilities, no clinical activities can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Appendix C INFORMED CONSENT



University of Pittsburgh

Consent to Act as a Participant in a Research Study

Title: The Perceptions of Sleep Quality Study

Principle Investigator:

Jonna L. Morris, PhD(c), RN
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If you have any questions about your rights as a research subject or wish to talk to someone other than the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

Source of Support: (NINR: F31 NR017336-01)

What is the purpose of this study?

This study is being conducted to learn about the experiences and perceptions of impaired sleep in people with Type 2 diabetes and how they feel during the day.

Who is being asked to take part in this study?

You are invited to participate in this study because you have Type 2 diabetes and reported poor sleep quality. We are hoping to enroll up to 40 participants into the study.

What will we do in this study?

For this study, you will be interviewed and asked several questions about your sleep and how it affects you the next day. We are very interested in your thoughts, opinions, and perspectives of how sleep impacts your life. The interview will take less than an hour and take place at the University of Pittsburgh, School of Nursing. We will audio record the interview so that we have an accurate record of our discussion for research analysis. The recordings will be typed by the research team and erased once the transcriptions are checked for accuracy. Neither your name nor any other identifying information will be associated with the transcript. Only the research team or other researchers interested in this research will have access to the deidentified transcripts.

Additionally, we will collect data about you from the Diabetes Sleep Treatment Trial. We will collect your demographic information such as your age and race. We may also collect other information you provide in the questionnaires or your sleep study results.

Voluntary Participation

Your participation in this research study is entirely voluntary. Once started, we can stop the interview at any time. If there are any words you do not understand, feel free to ask me. I or investigators will be available to answer your current and future questions. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh.

Right to Withdraw

You can, at any time withdraw from this research study; you can also withdraw your authorization for us to use your identifiable information for the purposes described above. This means that you will also be withdrawn from further participation in this research study. Any identifiable research or information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw from this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh.

What are the possible risks and discomforts of this research study?

There is a possibility that you may get tired or bored when we are asking you questions and some questions may make you feel uncomfortable. If at any time during the interview, you feel uncomfortable answering a question please let me know; we can skip any question that you do not want to answer.

We will protect your privacy by assigning a code number to the recording of the interview. We will keep your personal information separate from the interview recording on a password protected server. The only people who will have access to the interview will be the investigators of the study. We will use the recording only for the study and it will be kept confidential, but there still remains an infrequent risk of a breach of confidentiality.

University of Pittsburgh policy directs that records must be maintained for at least 7 years following final reporting or publication of a project.

What are the possible benefits of participating in this study?

There will be no direct benefit for your participation this study. It may give us insight into assisting future patients with handling impaired sleep.

What will I be paid if I take part in this research study?

You will be paid \$20.00 for your time and participation in this study.

Consent to participate

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form I agree to participate in this research study. A copy of this consent form will be given to me.

Participant's Name: (Print) _____

Signature _____ Date _____

Investigator Certification

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date

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