SLEEP AND FOOD PREFERENCES

BY

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Abstract

Short sleep duration is correlated with an increased BMI, but the mechanisms behind this relationship are not fully known. The purpose of this study was to examine the effect of sleep deprivation on dietary intake. Medical residents in good health served as subjects in this cross-over study. Twenty adults aged 25 to 48 years completed two testing visits: one sleep deprived (≤4 hours of sleep) and one normal (≥6 hours of sleep). Food and beverage intake was collected on the days before and after testing by direct observation of breakfast and completion of 24-hour dietary recalls. Sleep deprivation did not significantly affect total energy intake the day after sleep manipulation. Mean energy intake under the sleep deprived condition was 2164.49± 946 calories and 2365.98± 844 calories under the normal sleep condition (p=0.57).

No differences were seen in macronutrient distribution between the two conditions. There were also no differences in caffeine, fiber, sodium, or sugar intake between the two conditions. In contrast to our expectation, sleep deprivation had no effect on total energy intake or macronutrient distribution. Further research in this area should continue to be conducted as similar studies have found mixed results, and no conclusive statements can be made at this time.
Acknowledgments

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# Table of Contents

List of Tables ........................................................................................................vii
List of Figures .........................................................................................................viii

Chapter

1. Introduction ........................................................................................................1
2. Review of Literature .........................................................................................3
   Obesity ................................................................................................................3
   Sleep ....................................................................................................................3
   Sleep and BMI ....................................................................................................4
   Sleep and Food Selections ...............................................................................6
   Hormones- Ghrelin and Leptin ......................................................................9
3. Methods ............................................................................................................13
   Sample ..............................................................................................................13
   Setting ..............................................................................................................13
   Ethics ................................................................................................................14
   Testing Visits .................................................................................................14
   Cognitive and Stress Measures ..................................................................15
   Dietary Measures ..........................................................................................16
   Materials .........................................................................................................17
   Analysis of Data ............................................................................................17
4. Results .............................................................................................................18
   Demographics .................................................................................................18
List of Tables

Table 4.1: Subject Demographics .................................................................19
Table 4.1: Total Energy and Macronutrient Comparison at Breakfast .......................20
Table 4.3: Caffeine, Sugar, Fiber, and Sodium Comparison at Breakfast ....................20
Table 4.4: Total Energy and Macronutrient Comparison for the Day .........................21
Table 4.5: Caffeine, Sugar, Fiber, and Sodium Comparison for the Day .....................21
List of Figures

Figure 4.1: Meal Locations..................................................................................22
Chapter 1

Introduction

Overweight is defined as having a Body Mass Index (BMI) of 25-29.9 kg/m², while obesity is defined as a BMI of 30 kg/m² or greater. A person that is overweight is at an increased risk of developing other health conditions, including heart disease, type 2 diabetes, certain types of cancers, and osteoarthritis. Being overweight can also contribute to decreased quality of life due to poor self-image, decreased mobility, and the inability to participate in certain activities.

The most recent statistics from the Center for Disease Control and Prevention (CDC) reported that 68% of U.S. adults age 20 or older are classified as either overweight or obese, half of these being obese (1). Some key factors related to the cause of obesity are poor diet, lack of exercise, psychological issues, and genetics. Despite these factors obesity is often preventable and reversible.

Lifestyle factors including sleep time and sleep quality may potentially play a role in a person’s body weight. Recent research results show decreased sleep time is linked to an increased BMI (2). Most of the research done in this area has confirmed this relationship, but little research has been done to gain a better understanding of why sleep time is associated with an increased BMI. There are many factors that potentially affect this relationship and there is not a clear causation between the two variables. One aspect of this correlation is the hypothesis that decreased sleep time affects a person’s food cravings and selections, therefore affecting their BMI. Another hypothesized mechanism is that decreased sleep time could affect the way the body is able to metabolize and utilize nutrients. Sleep time may also affect appetite-regulating hormones, leptin and ghrelin. In the United States there is an estimated 50 to 70 million people
who do not receive adequate amounts of sleep (3). Adequate sleep is typically defined as obtaining at least 7 to 8 hours of sleep per night (3). One of the simplest possible mechanisms is that when one sleeps less, he/she has more awake time, which translates to more opportunities for increased caloric consumption.

The purpose of this study was to examine if there is a correlation between the amounts of sleep an adult receives and the food selections he/she makes. Specifically, the study examined whether more or less sleep is associated with a more healthful, nutrient rich diet. The goal was to gain better understanding of the relationship between decreased sleep time and increased BMI, and to examine if sleep time affects the food choices that individuals make. The basic premise of the study was to compare diet selections made by well-rested versus sleep-deprived persons. The primary research question addressed in this study was:

“Is the amount of sleep an adult obtains related to the food selections he/she makes at breakfast?”

The focus was to look primarily at total energy intake, percent fat, percent carbohydrate, and percent protein intake. Secondary questions proposed include:

1. Is there an association between sleep time and the number of meals/snacks consumed throughout the day?
2. Is obtaining inadequate amounts of sleep associated with eating later in the day?
3. Is there an association between sleep time and intake of caffeine, sugar, sodium, and fiber?
Chapter 2

Review of Literature

Obesity

The current prevalence of 68% of Americans being overweight or obese is significantly high and alarming. “No state has met the nation’s Healthy People 2010 goal to lower obesity prevalence to 15% (1).” In 2008, medical costs associated with obesity were estimated at $147 billion dollars (1). Some factors that have been commonly blamed for the rise of obesity are increased availability of unhealthy fast foods, increased participation in sedentary activities and jobs, as well as a rise in the consumption of calorically dense drinks such as soft drinks (1).

Common strategies for combating obesity include weight loss classes and support groups, exercise programs, medications, and surgeries such as gastric bypass. Genetics do appear to play a role with a higher rate of obesity among African Americans and Hispanics compared to Caucasians and Asians (1). The prevalence of obesity in America has been rising despite efforts of the government and various agencies to combat it. Another factor that appears to play a role in the development of obesity is the amount of sleep an individual obtains. Obtaining insufficient amounts of sleep is associated with having a higher BMI (2).

Sleep

As obesity rates have been rising the amount of sleep that the average American receives has declined. According to the National Sleep Foundation, in 2002, 39% of Americans received less than seven hours of sleep each weeknight (4). Sleep deprivation can affect interpersonal relationships, job performance, and safety (4). Sleep needs change throughout the life cycle but
during adulthood sleep needs are estimated at 7 to 9 hours per night (3). Obtaining an insufficient amount of sleep can be by choice or is often experienced due to physiological reasons making it difficult for someone to fall asleep. Approximately 50% of Americans suffer from insomnia which is defined as difficulty falling asleep, frequent awakenings, waking too early and having trouble getting back to sleep, and waking unrefreshed (4). Other common sleep related disorders include: narcolepsy, sleep apnea, sleep walking, sleep terrors, and restless legs syndrome (4).

**Sleep and BMI**

Research statistics have shown a relationship exists between sleep time and BMI (2). A systematic review that looked at thirty-six studies provided support for the theory that decreased sleep time is linked to increased BMI (2). Several other studies have found results that represent a U-shaped curve where those who receive 7-8 hours of sleep have the lowest BMI, while BMI rises as sleep time decreases (<7 hours) and BMI increases with greater than 8 hours of sleep (2). One study that reported the U-shaped result was the Quebec Family Study (5). This study is a 6-year longitudinal study that was originally developed to observe the role of genetics in the etiology of obesity and related cardiovascular risks. As part of the study, researchers examined the association between sleep and body weight. Sleep duration was obtained by self report by asking participants, “On average, how many hours do you sleep a day?” (5) The participants were classified based on their response into either short sleeper (5-6hr), average sleeper (7-8hr), or long sleeper (9-10hr). The average sleepers had the lowest average BMI (25kg/m²), followed by long sleepers (26.1 kg/m²), and then short sleepers (27.8 kg/m²). Body fat percentage also was measured and average sleepers had the lowest percent body fat while the short sleepers had
the highest percent body fat. After adjusting for covariates the amount of weight gained over six years by short sleepers was 88% more than average sleepers. The risk for developing obesity over the six year period was elevated by 27% for the short sleepers compared to the average sleepers, and a 21% increase in the long duration sleepers (5).

Another study by Patel et al. (2), examined the association between sleep time and BMI in older adults. This ancillary study is different from many other studies because they did not rely on self report to determine sleep duration but rather used wrist actigraphy. With this tool, participants are still able to sleep at home while the researchers can obtain a precise measurement of how much sleep they are obtaining. The findings of 3,055 men and 3,052 women were included in the analysis. This study categorized the amount of sleep into <5hr, 5 to <7hr, 7 to <8hr, and ≥8hr. BMI was found to be 2.48 kg/m² higher in men sleeping less than 5 hours compared to those getting 7-8 hours of sleep. The average BMI was 1.75 kg/m² higher in women in the comparison of these two groups. Waist circumference, hip circumference, and body fat were all higher in the group obtaining <5 hours compared to those obtaining 7-8 hours of sleep. The results from this study also resembled a U-shaped curve; those who received more than eight hours of sleep had higher BMI’s compared to those in the 7-8 hour group (6).

A study recently published in 2011 revealed that this same correlation is present among children. The Family, Lifestyle, Activity, Movement, and Eating (FLAME) study (7) is a longitudinal cohort study that observed children from age 3 to 7 years of age. Sleep and physical activity were only assessed at ages 3, 4, and 5 years. Heights, weights, bioimpedance measures, and DXA scan were conducted at multiple times throughout the study. Sleep time was determined by accelerometers and parent report. Dietary information was collected through a
short questionnaire that recalled the previous day’s food intake. The authors found that for each additional hour of sleep, BMI was reduced by 0.39 kg/m². When they compared data obtained from the bioimpedance and DXA, results revealed that each additional hour of sleep reduced the adjusted fat mass index by 0.43 at age 7 and by 0.48 for the change from age 3 to 7 years of age.

**Sleep and Food Selections**

Research examining sleep duration and food cravings and selections is limited. A small study that observed adolescents found that those who received less sleep had increased food cravings and decreased satiety (8). Researchers collected nutrient intake from each participant by using standardized format interviews, and they assessed cravings using the Food Craving Inventory. The study revealed that those who received less sleep had greater cravings for high fat foods, sweets, and fast foods. The study did not report actual values to quantify the cravings or nutrient intake between the groups.

A study conducted in 2002, examined sleep times and fat consumption in Chinese men and women (9). Self-reported sleep was categorized into less than 7 hours, 7-9 hours, or greater than 9 hours. Dietary intake was determined through food records and food weighing. The results of 2,828 participants were included (mean age=47). Those who reported sleeping the recommended amount of time (7-9 hours) received 31.2% of their calories from fat, compared with those reporting less than 7 hours who received 33.8% of their calories from fat. The long-sleep group reported a lower percentage of fat intake compared to both groups; their mean percent of fat intake was 28.8% of total calories (p<0.001) (9).

Although fat intake was highest in the short sleep group, total energy intake did not follow the same pattern. The group that consumed the fewest calories was the short sleep group,
followed by average sleepers, and then long sleepers. Carbohydrate intake was 52.2% of total calories of the short sleep group, 55.3% for the average sleepers, and 58.1% for the long-sleepers (p<0.001). These results show that there is a significant correlation between sleep time and carbohydrate and fat intake (p<0.001). There was no significant difference between groups when comparing protein intake. It is important to note that the group consuming the least amount of fat was the average sleepers, and the group consuming the least amount of carbohydrates was the short sleepers. Also, there was no significant difference in BMI’s between the groups despite the differences in food intake. The researchers hypothesized that the lack of significant differences in BMI was due to the decreased range of BMI in the Asian cohort compared to previous studies composed of Western cohorts (9).

Studies that have examined energy intake and sleep time have found varied results (9, 10, and 12). Some have shown that decreased sleep time is associated with increased energy intake (10) while others have found an association with decreased energy intake (12). Brondel et al. (10) conducted a crossover study with 12 healthy men and found that sleep restriction was associated with increased energy intake. Subjects were assigned to either 4 or 8 hours of sleep. When subjects only received 4 hours of sleep they consumed 22% more calories compared to 8 hour sleepers. They assessed hunger through a self-reported questionnaire and found that subjects from the sleep deprived group had greater hunger levels before the breakfast and dinner meals.

A similar study found conflicting results; decreased sleep time was not associated with increased or decreased caloric intake (11). This study was also a cross-over design and consisted of 15 men, which is a very similar study group compared to the previous study (10). This study
differed in that it consisted of two consecutive nights of 4-hour sleep and two consecutive nights of 8-hour sleep, while the previous study only had one night of each. All meals were offered buffet style within a controlled environment. Their results revealed that there was no significant difference in energy intake between the 4-hour sleep and the 8-hour sleep conditions. The researchers reported that there was a statistically significant difference in calories from fat between the 4 hour and 8 hour sleep conditions (35.7% versus 34% respectively; p=0.05) (11). These findings of decreased sleep time associated with increased fat intake are consistent with the findings from the Chinese study presented earlier (9).

Most studies conducted in this area of research have observed the effect of acute sleep deprivation but few studies have examined the effect chronic sleep deprivation. Zadeh et al. (12) compared nutrient intake of subjects who have chronic insomnia to the intake of subjects with normal sleep habits. Insomnia was determined by use of a questionnaire and self-reported dietary intake, which was tracked for 3 days. The researchers found that the normal sleepers consumed significantly more calories than the participants suffering from insomnia. Unlike other studies previously discussed, this study also compared various vitamins and minerals. They found that the normal sleepers consumed significantly more thiamine, folate, B12, and iron (12). Blood levels of these nutrients were not measured, but it might be possible that insomnia could be related to nutrient deficiencies. No significant differences were noted with regard to fat consumption.

Weiss et al. (13) conducted a large study with 240 adolescents examining the relationship between sleep and dietary intake. Short sleep was significantly associated with increased percent of calories from fat (p=0.004) and decreased percent of calories from carbohydrate (p=0.001).
When analyzed by gender, the relationship was significant among girls (p=0.01) but not among boys (p=0.22).

**Hormones - Ghrelin and Leptin**

Although it is not yet fully understood why sleep time may have an effect on dietary intake, it has been hypothesized by multiple researchers that hormones could play a significant role. Two key hormones thought to potentially have an effect are leptin and ghrelin (14). Leptin is a hormone that suppresses the appetite, while ghrelin stimulates the appetite (9).

Researchers of the Wisconsin Sleep Study (14), an ongoing longitudinal study of sleep habits and disorders examined how the hormones leptin and ghrelin were altered based upon sleep time. To obtain total sleep time, the investigators used a combination of methods, including written sleep surveys, overnight stays, and a sleep diary. During the overnight stays a polysomnographic system was used to assess sleep states. Hormone levels were determined from blood drawn the morning after the overnight stay at the lab.

The results from the study revealed that short sleep time was associated with decreased leptin and increased ghrelin levels (14). This directional change in hormones is associated with an increased appetite. Subjects who slept six hours per night had an average leptin level of 15 mg/ml compared to those that slept nine hours (19.4 mg/ml). Ghrelin levels among the shortest sleepers were an average of 1001mg/ml and 807mg/ml among the longest sleepers. These hormones could be a major factor in the relationship between sleep time and food intake. The Wisconsin Sleep Study (14) also assessed the BMI of their participants and found a U-shaped distribution consistent with other studies. Those individuals obtaining 7.5 hours of sleep per night were located at the bottom of the U shaped distribution with BMI increases on either side.
Ghrelin is a 28-amino acid peptide that stimulates appetite (15). It is primarily synthesized and secreted by the stomach. A study done at the Institute of Biomedical Research in Belgrade (15) injected rats with ghrelin to observe the effects of the hormone on the rats’ appetite and weight. The experimental rats were divided into two groups. One group served as the control and the other group received a daily dose of rat ghrelin. Immediately after the dose was administered the rats were observed to see how many times they approached their food dish. The weight of the rats and their food and water intake were recorded daily. The rats received the injections for 5 consecutive days, and were euthanized after the 5th injection. Blood samples were immediately taken after the rats were euthanized.

Results of this study (15) indicate that there was a significant (p<0.05) increase in the number of times the ghrelin treated rats approached their food dish compared to the control group within 2 hours post injection. The pattern held constant for all of the days the rats were observed. Number of approaches in the first 30 minutes was 33% higher in the ghrelin group and 50% higher in the second 30 minute interval. Food intake was measured in grams. The ghrelin group consistently took in more grams of food compared to the control. Water intake was also higher in the ghrelin group.

Body weight of the rats was measured daily. There was a significant increase (p<0.05) in body weight in the ghrelin rats after day 2 and their weight remained high for the remaining days. The results of this study show that increasing ghrelin levels in rats increased their appetite and body weight significantly compared to the control group (15).

Another recent study observed short sleepers versus long sleepers in a laboratory environment and observed their dietary intake as well as their ghrelin and leptin levels (16).
Eleven subjects were observed in the controlled setting for two different 14 day periods. The subjects were assigned in random order to either 5.5 hours or 8.5 hours of sleep time. All meals were eaten on site, and a snack bar was available in each participant’s room. Meals and snacks were weighed before and after consumption to determine total intake. Dietary analysis was conducted using Nutritionist IV to determine the macronutrient breakdown of the food selections. Sleep time was recorded using and EEG Acquisition System.

No significant difference was present among total energy intake at meals between the groups receiving 5.5 hours and 8.5 hours (2536 kilocalories versus 2611 kilocalories respectively). Macronutrient distribution was also similar at meal times. However, there was a significant increase in energy intake from snacks among the short sleep group (P=0.026). The snacks were higher in carbohydrate in the short sleepers versus long sleepers (65% versus 61%, respectively; p=0.04) (16). The researchers of this study also measured leptin and ghrelin levels. There was not a significant difference in ghrelin and leptin levels while the subjects were monitored. With lack of statistical differences between ghrelin and leptin the researchers hypothesized that the increased energy intake in short sleepers could be due to sleep-loss related changes in reward seeking and motivation. They also hypothesized that the effect of sleep on food selection could be linked to newly investigated orexin-containing neurons in the hypothalamus that are linked to the regulation of feeding behaviors as well as walking. These neurons respond to sleep loss, so short sleep time could trigger greater food intake. One limiting aspect of this study was the small number of subjects included in the study (n=11) (16).

Numerous articles can be found that discuss the correlation between sleep time and body weight, but few studies have observed the potential correlation between sleep time and food
selection. Studies that have been completed in this area have been small and further research needs to be conducted.
Chapter 3

Methods

Sample

The purpose of this study was to examine the effects of sleep deprivation, as a result of nights on call in medical residents, on dietary intake and cognitive performance. Residents from the University of Kansas Medical Center Anesthesiology Department between the ages 25-48 years old who were in good health were recruited to participate in the study. Participants were interviewed to determine if they met all inclusion criteria. All subjects had to be currently conducting their residency and be able to come in on two scheduled mornings. Participants were excluded if they had any known sleep disorder, were taking any medication that affects their sleep, were pregnant, and/or had any dietary restrictions. A total of 30 residents completed the consenting process. Out of the thirty, twenty-seven subjects met all inclusion criteria. A total of twenty subjects completed both test days in their entirety.

The study proposed minimal risk to participants. Individual data were only seen by the primary investigator and study coordinator. As compensation for their participation, subjects received free breakfast on both mornings of the study and $20.00 (one $10.00 Target gift card per visit).

Setting

The study was conducted in the General Clinic Research Center at the University of Kansas Medical Center in Kansas City, Kansas. A private room was set up for cognitive testing and breakfast consumption. Dietary recalls took place in person as well as over the phone. The study took place in May 2011 through August 2011.
**Ethics**

The study was approved by the Human Subjects Committee at the University of Kansas Medical Center (protocol #12409). Potential subjects met with the study coordinator in a private room and were allowed ample time for discussion to insure comprehension before signing the consent form to participate (Appendix A). All information was kept confidential. Only the principal investigator and study coordinator had direct access to the data. Research staff was trained to not reveal the name or any identifying information about any of the participants.

**Testing Visits**

Participants were to be available for a 30 to 45 minute session sometime between the hours of 7am and 10am. For this cross-over study, participants were asked to come in one morning after they had been on call and one morning after not being on call. The night of being on call represented a lack of sleep opportunity and was characterized as sleep deprived if the individual obtained ≤4 hours of sleep. If a participant received more than 4 hours of sleep during her/his on-call night she/he was asked to reschedule the morning assessment. The night of not being on call represented an opportunity to obtain adequate sleep and was characterized as normal sleep if the individual obtained ≥6 hours of sleep. If a participant slept fewer hours than the amount specified, then she/he was asked to reschedule.

To assess the amount of sleep received the participants were asked, “How many hours did you sleep in the last twenty-four hours? Please include naps as well.” There were also three additional questions; one that assessed how sleepy they felt at that time; another question that asked the participant to rate his/her sleep quality; and another question that asked the participant to rate the stress level of the previous 24 hours. Participants were asked to rate their level of stress on a 4 point scale, from not at all to extremely stressful, using the following question,
“During the last 24 hours, how stressful did you find your work?” (See Appendix C). To determine physical activity levels, all participants were asked to wear an accelerometer beginning when they woke up the day before the testing assessment through 8:00pm the day of testing. The study staff arranged to meet with the participant approximately 48 hours prior to the testing period to share the device and provided instructions on how to wear it properly. An accelerometer is a small device, which is worn on the waist or hip that senses movement and can accurately assess physical activity.

**Cognitive and Stress Measures**

The primary purpose of this study was to observe dietary intake at breakfast. To help prevent subjects from eating differently due to being observed they were told that the primary purpose of the study was to observe their cognition. Two brief cognitive tests were administered: the “Stop-It” test (17) and the Mittenecker Pointing Test (18). Both computerized tests were brief and thus, minimized response time burden for participants.

The Stop-It test (17) is a computerized test to measure response inhibition. Response inhibition is part of executive functioning and involves suppression of actions that are inappropriate in a given context and that interfere with goal-driven behavior. In the test, a picture of a square or circle is presented on the computer screen and the participant is asked to press one of two keys depending on which image is shown. During a series of trials, an auditory signal will sound close in time to the image of the circle or square, and the participant should refrain from making any response when the auditory signal is presented. The program varies time between the auditory and visual signals. Individuals experiencing reduced inhibitory capacity will have longer inter-stimulus delays.
The Mittenecker Pointing Test (18) assesses random behavior. This test is useful to detect clinically relevant impairments of executive functions. Participants are required to produce sequences of key presses of nine keys on a typical keyboard. They are instructed to press the keys in random order, and to suppress any tendency to repeat sequences or develop routines in their sequences. The computer monitors the sequences and an analysis program calculates a series of variables that reflect randomness. Those experiencing less inhibitory control will show lower randomness scores.

**Dietary Measures**

Participants were instructed to refrain from eating at least four hours before the testing visit. During the testing visit, participants were offered a buffet style breakfast after the cognitive tests. To ensure that participants did not alter their eating habits, they were not told that their food selections were being recorded. Food selections on the buffet varied widely in energy, sugar, fat, and sodium content. Available foods included various cold cereals, bananas, regular and light yogurt, pancakes, bacon, sausage, cinnamon rolls, scrambled eggs, biscuits and gravy, hash browns and toast. Available beverages included apple juice, orange juice, water, coffee, milk, and regular and diet soda. A variety of condiments were available as well. Participants were allowed as much time as they wanted to consume their meal. Foods consumed from the breakfast buffet during the mornings of the testing were recorded by research staff based upon direct observation and weighing of all items before and after breakfast. Participants were also interviewed to determine their dietary intake on the previous day by a standardized, multiple-pass 24-hour recall. All interviews were conducted by a trained and certified research staff member. Participants were called by a staff member the following day to obtain a 24-hour diet
recall in order to determine dietary intake for the remainder of their day. A maximum of three attempts to reach each participant by phone was made to complete their recalls. If they could not be reached, their recall was considered incomplete and not used for analysis. When conducting 24-hour recalls in-person, visual aids (ex: measuring cups) and the multiple pass method were used to help ensure accuracy of reporting. The diet recalls were analyzed using nutrition analysis software (Nutrition Data System for Research, version 2009). Average intake of energy, carbohydrate, protein, fat, sugar, caffeine, fiber and sodium were compared from the day of being on call versus the day not on call.

Materials

Materials for this study included: consent forms, sleep and stress questionnaires, 24-hour recall forms, surveys to collect age, gender and race/ethnicity, accelerometers for each participant, and a computer with a key board to conduct the two cognitive tests. For the breakfast buffet all foods listed above were needed for each participant as well as cooking pans and utensils for preparation as well as serving utensils. A food scale was used to measure the amount of food consumed.

Analysis of Data

As this was a pilot study, there were no previous studies using these tests in order to conduct a power analysis. Studies using similar neuro-psychological tests had small sample sizes. Descriptive statistics were used to characterize the mean results for dietary intake (breakfast and 24-hour intake) on the two testing days. Analysis of paired data was carried out using t-tests with Excel. A p-value of ≤0.05 was considered statistically significant. Diet recalls were analyzed using nutrition analysis software (Nutrition Data System for Research, version 2009).
Chapter 4

Results

The purpose of this study was to investigate the effect of sleep deprivation on food preference and selection, specifically looking at total energy intake and macronutrient distribution.

Demographics

Thirty individuals underwent the consenting process. Three of these individuals were excluded from participation. Reasons for exclusion included: pregnancy, following a vegetarian diet, and an egg allergy. Out of the 27 who enrolled, there were twenty males (74%) and seven females (26%). After the participants were randomized for their first visit, seven had to withdraw from the study. Five of them had schedule conflicts, one graduated, and one was not compliant (See Consort Diagram, Appendix A). The remaining twenty participants consisted of fifteen males (75%) and five females (25%). Study demographics for all enrolled participants and those who have completed the study can be found in Table 4.1.
Table 4.1 Subject Demographics

<table>
<thead>
<tr>
<th></th>
<th>Total enrolled n=27</th>
<th>Completers n=20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>32±5.15*</td>
<td>32±5.58*</td>
</tr>
<tr>
<td>Gender</td>
<td>M=74%(n=20), F=26%(n=7)</td>
<td>M=75%(n=15), F=25%(n=5)</td>
</tr>
<tr>
<td>Weight (lbs)</td>
<td>171.2±32.0*</td>
<td>168.4±33.8*</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>24.5±3.2*</td>
<td>24.1±3.1*</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>96%(n=26)</td>
<td>100%(n=20)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>4%(n=1)</td>
<td>0%(n=0)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian/White</td>
<td>89%(n=24)</td>
<td>85%(n=17)</td>
</tr>
<tr>
<td>African American</td>
<td>4%(n=1)</td>
<td>5%(n=1)</td>
</tr>
<tr>
<td>Asian</td>
<td>7%(n=2)</td>
<td>10%(n=2)</td>
</tr>
</tbody>
</table>

*Data are presented as the mean ± standard deviation.

Breakfast

All participants were offered a breakfast buffet the morning after obtaining normal sleep and after their night of sleep deprivation. No significant difference was seen between total energy intake or macronutrient distribution between the two conditions (See Table 4.2). There was no significant difference in fiber, sugar, or sodium intake between conditions. Participants consumed a mean intake of 38.7±45.9 mg of caffeine after normal sleep and 14.8±31.2 mg after sleep deprivation, however this difference did not reach significance (p=0.06) (See Table 4.3).
Table 4.2 Total Energy and Macronutrient Comparison at Breakfast

<table>
<thead>
<tr>
<th></th>
<th>Total Energy kcal</th>
<th>Carbohydrate % of energy</th>
<th>Protein % of energy</th>
<th>Fat % of energy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Sleep (≥6 hrs.)</td>
<td>791.8 ±672.8</td>
<td>37.6±17.4</td>
<td>16.9±6.1</td>
<td>45.4±14.1</td>
</tr>
<tr>
<td>Sleep Deprived (≤4 hrs.)</td>
<td>737.5 ±470.5</td>
<td>42.8±20.1</td>
<td>16.5±4.9</td>
<td>40.6±17.8</td>
</tr>
<tr>
<td>p-value</td>
<td>0.53</td>
<td>0.27</td>
<td>0.71</td>
<td>0.24</td>
</tr>
</tbody>
</table>

n=20. All values are presented as mean± standard deviation.

Table 4.3 Caffeine, Sugar, Fiber, and Sodium Comparison at Breakfast

<table>
<thead>
<tr>
<th></th>
<th>Caffeine milligrams</th>
<th>Sugar grams</th>
<th>Fiber grams</th>
<th>Sodium milligrams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Sleep (≥6 hrs.)</td>
<td>38.7±45.9</td>
<td>32.9±38.9</td>
<td>3.2±3.4</td>
<td>1519.1±1302.6</td>
</tr>
<tr>
<td>Sleep Deprived (≤4 hrs.)</td>
<td>14.8±31.2</td>
<td>37.2±35.1</td>
<td>2.9±2.5</td>
<td>1354.7±1055.7</td>
</tr>
<tr>
<td>p-value</td>
<td>0.06</td>
<td>0.32</td>
<td>0.50</td>
<td>0.27</td>
</tr>
</tbody>
</table>

n=20. All values are presented as mean± standard deviation.

24-Hour Recall

To track food intake, 24-hour dietary recalls were collected for all participants on the day after obtaining normal sleep and the day after being sleep deprived. The recall included all foods and drinks consumed starting at 12:00am through 11:59 pm. Fourteen out of the twenty subjects completed both testing days and all of the 24-hour recalls. The mean energy intake for all participants was 2264 calories. The mean energy intake after sleep deprivation was 2164 calories, and 2366 calories after normal sleep; however, the difference was not significant (p=0.57). No significant differences in macronutrient distribution occurred between the two
conditions (See Table 4.4). No significant differences were noted in caffeine, sugar, fiber, or sodium intake for the day (See Table 4.5).

Table 4.4 Total Energy and Macronutrient Distribution for the Day

<table>
<thead>
<tr>
<th></th>
<th>Total Energy</th>
<th>Carbohydrate</th>
<th>Protein</th>
<th>Fat</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>kcal</td>
<td>% of energy</td>
<td>% of energy</td>
<td>% of energy</td>
</tr>
<tr>
<td>Normal Sleep</td>
<td>2366.0±843.7</td>
<td>45.3±10.2</td>
<td>16.1±3.7</td>
<td>34.7±8.0</td>
</tr>
<tr>
<td>(≥6hrs.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep Deprived</td>
<td>2164.5±946.0</td>
<td>45.8±10.5</td>
<td>15.3±3.5</td>
<td>36.9±8.3</td>
</tr>
<tr>
<td>(≤4 hrs.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p-value</td>
<td>0.57</td>
<td>0.92</td>
<td>0.58</td>
<td>0.57</td>
</tr>
</tbody>
</table>

n=14. All values are presented as mean ± standard deviation.

Table 4.5 Caffeine, Sugar, Fiber, and Sodium Comparison for the Day

<table>
<thead>
<tr>
<th></th>
<th>Caffeine</th>
<th>Sugar</th>
<th>Fiber</th>
<th>Sodium</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>milligrams</td>
<td>grams</td>
<td>grams</td>
<td>milligrams</td>
</tr>
<tr>
<td>Normal Sleep</td>
<td>76.8±76.0</td>
<td>98.0±74.6</td>
<td>17.7±6.1</td>
<td>4099.7±1412.3</td>
</tr>
<tr>
<td>(≥6hrs.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep Deprived</td>
<td>92.7±93.1</td>
<td>115.7±74.6</td>
<td>14.6±5.4</td>
<td>3535.3±1915.6</td>
</tr>
<tr>
<td>(≤4 hrs.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p-value</td>
<td>0.57</td>
<td>0.49</td>
<td>0.14</td>
<td>0.44</td>
</tr>
</tbody>
</table>

n=14. All values are presented as mean ± standard deviation.

Food Intake

Subjects ate an average of 4.25 meals/snacks per day. Subjects showed a slight trend to eat more meals/snacks under the sleep deprived condition with an average 4.5 meals, compared to 4.0 under normal sleep conditions. The difference was not statistically significant (p=0.07). Meals consumed after 8:00 p.m. were identified to see if there was a difference between groups. After 8:00 p.m. subjects ate an average of 0.43 meals or snacks after their short-sleep night and
0.57 meals or snacks after their normal-sleep night. The difference did not reach significance at p=0.50. An average of 223 calories was consumed after 8:00 p.m.

There was a significant difference in the amount of time between the last eating occasion and breakfast the morning of the test. Under sleep deprived conditions, there was an average of 9.05 hours between the final meal the day before testing and breakfast on test day. Under normal conditions there was an average of 11.85 hours (p<0.01). Subjects primarily ate their meals either at work or at home (See Figure 4.1).

**Figure 4.1 Meal Locations**
Discussion

The aim of this study was to examine the effect of sleep deprivation on dietary intake. No significant differences were found between conditions in regards to total energy intake and macronutrient distribution, despite our hypothesis that sleep deprivation would result in an increased caloric intake and a greater percentage of calories from fat.

Study Demographics

Twenty subjects completed this study. Other similar studies have had small sample sizes. The study by Brondel et al. (10) included twelve men and Schmid et al. (11) included 15 men. No published studies have been done with a similar design that included a large sample size. All participants in this study were in the process of completing their medical residency in anesthesiology at the University of Kansas Medical Center. Only fourteen of the twenty subjects completed all of the 24-hour recalls in their entirety. The seven that did not complete the recalls could not be reached by telephone in order to complete one or both of the 24-hour recalls after the study days.

The average BMI of all participants in the study was 24.5±3.2 kg/m$^2$. One subject was obese with a BMI of 31.79 kg/m$^2$, and ten of the twenty-seven were overweight. Out of the twenty participants who completed the study, the average BMI was 23.1±3.1 kg/m$^2$, with eight overweight participants. Other studies have restricted their study sample to include only healthy weight participants which could explain some of the discrepancies between studies. Our study was predominantly male (74%) and Caucasian (89%).
Breakfast

In our study we chose to look at dietary intake at breakfast separate from the entire day, since breakfast was provided to participants buffet style in a controlled environment where we could accurately track food intake. There were no significant differences with the breakfast meal. There was a trend for subjects to consume more caffeine after the normal sleep night, but it did not reach statistical significance (p=0.06). This result was likely influenced by the schedules of the subjects. Most were getting ready to begin a work shift after the night of normal sleep, while they had just completed a work shift after the sleep deprivation night. The participants were going home after breakfast to sleep and thus were likely not interested in consuming caffeine. In the Nedeltcheva study (16), participants remained in a sleep laboratory and all foods were provided and were recorded through direct observation. Dietary intake was looked at by day and by meal. They allowed participants only one caffeinated beverage a day, so it is not possible to compare data to assess for a similar trend. When the researchers analyzed breakfast alone, they also did not observe any difference in energy intake between short-sleepers and normal-sleepers. They did find that sleep deprivation was significantly associated with increased intake of calories from snacks.

In the study by Bronel et al. (10), the investigators studied dietary intake by meal. Their study was a crossover study very similar in design to the present study. They found that sleep deprivation was associated with increased energy intake at breakfast as well as increased preprandial hunger at breakfast. The difference in results compared to our study could be due to the foods offered by studies. The present study provided a full-breakfast buffet with a variety of foods, while the Bronel study (10) only offered subjects toast with butter and jam for breakfast.
and allowed them to consume an unrestricted quantity. Increased energy intake was also seen at dinner but not during lunch.

Schmid et al. (11) offered subjects a breakfast buffet similar to the one provided in the present study. At breakfast, no significant differences occurred in energy intake or macronutrient distribution due to sleep deprivation. This study also had a small sample size (n=15). These were the only studies that have examined dietary intake by meals.

24-Hour Recall

More studies have been conducted that compare dietary intake by full-day recalls. In our study, sleep deprivation was not associated with any changes in energy intake or macronutrient distribution. Other studies have found sleep deprivation to be associated with increased energy intake (10) and others have found an association with decreased energy intake (12). There is currently not an explanation as to why there has been such variance between results. Many of the studies have been done with small sample sizes which could explain why some have failed to show any relationship. Also, there is not uniformity in the classifications of sleep time. We chose to classify sleep deprivation as \( \leq 4 \) hours and normal sleep as \( \geq 6 \) hours. Our original aim was to use \( \geq 8 \) hours of sleep to classify normal sleep, but few participants were able to obtain 8 or more hours of sleep. Many studies use different sleep-time categories, making it challenging to compare studies side by side.

The largest study conducted was with 2,828 Chinese men and women. All information on sleep and diet were collected through mailed surveys. The researchers found that short-sleep (<7 hours) was associated with a higher percentage of energy intake from fat. This study had adequate power due to its large sample size and evaluation of normal sleep patterns instead of a
single-night intervention. They found that those who slept less than or equal to 7 hours consumed the least amount of calories compared to those sleeping 7-9 hours and those who slept 9 or more hours.

The study that found sleep deprivation was associated with increased calories from snacks did not find an association with total calories for the day (16). In the study by Schmid et al. (16) there was neither a positive nor negative association with sleep time and caloric intake. The investigators classified short sleep by ≤4 hours and normal sleep as ≥8 hours. More studies need to be done with large sample sizes and consistent classifications of sleep time to gain a better understanding of this relationship.

**Food Intake**

In this study there was a significant difference in the amount of time between the last eating occasion and breakfast the morning of the test. Under sleep deprived conditions, there was an average of 9.05 hours between the final meal of the day before testing and breakfast on test day. Under normal conditions, there was an average of 11.85 hours (p<0.01). Other studies have not reported on this because they either have not studied intake by meal or have fed the subjects in a controlled environment with set meal times. In our study this finding was likely influenced by the residents work schedules. While under the sleep deprived condition, subjects were at an on-call shift, and under normal sleep conditions, they were not at work. Additionally participants were asked to refrain from eating 4 hours prior to their testing times.
Limitations

Several limitations exist in the current study. These include small sample size, lack of power analysis, lack of generalizability, and diet evaluation. The sample used for this study was small with 20 participants being included in this report. The original goal was to enroll 30 subjects. Out of the 20 subjects who completed the study, only 14 fully completed all of the 24-hour diet recalls. Since this was a pilot study, no power analysis was conducted to determine the most appropriate sample size. The small sample size limits the ability to detect significance and the ability to generalize results to the general public. The study sample was comprised of mostly white, men which also limits the ability to generalize results.

A major limitation of this study is that results cannot be generalized to the general public due to the specificity of the subjects. All subjects who participated in the study were currently completing their medical residency in anesthesiology. A night that was used to represent a lack of sleep was a night that they were working an on-call shift. Factors such as: how active they were at work and how stressful their shift was both could impact the dietary selections that they made the subsequent day. Also when subjects completed their on-call shift many were likely planning on going home and going to sleep which likely altered what they ate that day as well as how much time they were awake in order to eat. The day after subjects received normal sleep they went into work. This is likely why there was a difference seen in caffeine intake at breakfast; as the short-sleepers were just getting off work and free to go home, and the normal-sleepers were just getting ready to start a work-shift. Also, as medical professionals the residents might be more conscious of the foods they eat and might not be representative of the general public.
This study was designed to only compare the effect of a single night of sleep deprivation to a single night of normal sleep. Participants were not asked to report their typical sleep patterns, so the study does not report on the effect of chronically under-sleeping.

Finally there is a limitation in obtaining dietary intake by 24-hour recall. Despite using the multiple-pass method and visual aids to help with accuracy, the diet recalls cannot be guaranteed to be entirely accurate. Inadequate results can be due to subject under or over reporting, forgetfulness, and misestimation of portion sizes. Although participants were not told that they were being observed at breakfast, they might have suspected it and ate differently. The breakfast buffet provided foods for the participants that they might not have consumed within their normal living conditions.

**Future Research**

More research still needs to be conducted in this area since there have been inconsistencies between studies. In the future it would be ideal to have a larger sample size that is recruited from the general public to provide better representation. Similar studies have been done that look at the effect of short-term sleep deprivation, but few studies have looked at the effect of chronic sleep deprivation. An idea for a future study would be to examine dietary intake for at least a week of subjects who chronically are sleep deprived (≤4 hours per night, at least 5 days/week). Some previously conducted studies have found that “over-sleeping” may have just as much of an impact on dietary intake as “under-sleeping”. Future studies should break sleep time into specific categories; e.g. 4-5 hours, 5-6 hours, 6-7 hours, etc. It has been hypothesized that sleep deprivation may alter the way that the body metabolizes and utilizes nutrients; future studies should be developed to further investigate this hypothesis.
Conclusion

Many studies have confirmed that sleep deprivation is associated with increased BMI and subsequently health conditions such as heart disease and type 2 diabetes. Some previous studies have found that sleep deprivation was associated with increased energy intake while others have seen an association with decreased energy intake. Sleep deprivation has also been associated with altered macronutrient distribution, typically increased intake from fat. This study did not find any relationship between sleep time and energy intake or macronutrient distribution. This could likely be due to the limitations of this study, specifically having a small sample size. Further research is needed in this area and is warranted since obesity is such a prevalent problem in the United States.
Literature Used

   


3. Centers for Disease Control and Prevention. Are you getting enough sleep?
   

   


6. Sanjay P. The association between sleep duration and obesity in older adults.
   


8. Landis A. Sleep, hunger, satiety, food cravings, and caloric intake in adolescents.
   


Appendix A

Enrollment Process, Consort Diagram
Enrollment Process

30 Underwent consenting process

1 Discontinued pregnancy
1 Discontinued vegetarian diet
1 Discontinued egg allergy

27 Randomized for 1st visit

14 Assigned to on-call first testing visit
1 Discontinued-noncompliance
4 Discontinued-schedule conflicts

13 Assigned to non-call first testing visit
1 Discontinued-graduation
1 Discontinued-schedule conflict

20 Completed Both Testing Visits
Appendix B

24-Hour Dietary Recall Form
<table>
<thead>
<tr>
<th>Time/Place</th>
<th>Meal</th>
<th>Food/Beverage Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Time/Place</td>
<td>Meal</td>
<td>Food/BeVERAGE Description</td>
<td>Amount</td>
</tr>
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<td>----------------------------</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In terms of the amount of food you ate, would you say this was: Close to the amount you usually eat? A lot more than you usually eat? A lot less than you usually eat? Why? (Be Specific).
___________________________________________________________________________________
___________________________________________________________________________________

Was information: Reliable? Unable to recall 1 or more meals? Unreliable for other reasons? Why? (Explain why recall is incomplete/ unusable).
___________________________________________________________________________________
___________________________________________________________________________________

Vitamin/Mineral/Supplement Use/Dosage?
___________________________________________________________________________________
___________________________________________________________________________________
Appendix C

Sleep and Cognition Data Form
Sleep and Cognition Data Form

Name/ID: _________________

Date / Time: ______________

Circle one of the following:    On-Call    Not On-Call

Please check the tests or surveys were completed

  Stop-It Test: Completed: __________

  Mittenecker Pointing Test: Completed: __________

  24-hour Recall from previous day: __________

Survey questions:

  How many hours did you sleep in the last twenty-four hours (including naps)? __________

  How sleepy do you feel at this time? Rate your level between 1 (not sleepy at all) to 5 (very sleepy) by circling below.

  1  2  3  4  5

  How would you describe the quality of your sleep? Rate your sleep quality from 1 (very low quality) to 5 (very high quality) by circling below.

  1  2  3  4  5

  During the last 24 hours, how stressful did you find your work? Rate your stress level from 1 (not stressful at all) to 4 (extremely stressful) by circling below.

  1  2  3  4

Incentive Received/ Initials: Yes____  No____

Follow-up 24 hour recall completed: __________
Appendix D

Informed Consent Form
CONSENT FORM

Sleep and Cognition

Protocol #12409

Sponsor: KU Endowment and the Department of Dietetics and Nutrition

INTRODUCTION

You are being asked to join a research study. You are being asked to take part in this study because you are a resident physician. You do not have to participate in this research study. The main purpose of research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at the University of Kansas Medical Center (KUMC). Participation in this research study is not an educational requirement of residency programs at KUMC. The choice to participate or not to participate will not impact the educational experience of participants at KUMC or their professional development in any way.

This consent explains what you have to do if you are in this study. It also describes the possible risks and benefits. Please read the form carefully and ask as many questions as you need to before deciding about this research.

You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating.

The research study will take place at the University of Kansas Medical Center (KUMC) with Dr. Cheryl Gibson as the researcher. A maximum of 40 people will be in the study at KUMC.

BACKGROUND

Work hour restrictions for residents to only 80 hours per week were instituted by the Accreditation Council for Graduate Medical Education (ACGME) in 2003 due to concern over negative effects of sleep deprivation on resident's well-being and patient safety. Despite the work hour restrictions, long working hours resulting in sleep deprivation remain common for residents. Previous research has documented dose dependent negative impacts on cognitive performance. Negative impacts on cognitive performance such as declines in memory, attention, vigilance as well as increased errors have been reported in residents in the post call condition.

Decreased sleep time has also been associated with obesity. The mechanism for this relationship is unknown but it has been hypothesized that obesity in this population is a result of changes in food preferences and/or hormonal changes.
PURPOSE OF THE STUDY

The purpose of this pilot project is to evaluate the impact of a night on call on sleep time and cognitive performance. As a secondary question, we will evaluate the impact of nights on call on food selections.

PROCEDURES

If you are eligible and decide to participate in this study, your participation will consist of 2 visits over approximately 1 month. Your participation will involve the procedures below. The order of the two sessions will be randomly assigned.

<table>
<thead>
<tr>
<th>Night On Call Assessment</th>
<th>Non-Call Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accelerometer</td>
<td>Stop It Test</td>
</tr>
<tr>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Completed the day of call</td>
<td></td>
</tr>
<tr>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Completed on a day you are not on call</td>
<td></td>
</tr>
</tbody>
</table>

Data collection of age, gender, race/ethnicity and measurements of height and weight will be taken by staff during the testing interview.

Night On Call Assessments

This assessment will be completed between the hours of 7 and 10 a.m. in the General Clinical Research Clinic (GCRC) following the day you are on call and wearing the accelerometer. The Stop-It Test and Mittenecker Pointing Test are completed on a computer in the GCRC along with the Food Recall Interview. The Breakfast Buffet will be provided immediately following your visit in the GCRC and you will be called the following day to discuss your food and beverage intake for the remainder of the day.
Non-Call Assessments

This assessment will be completed between the hours of 7 and 10 a.m. in the General Clinical Research Clinic (GCRC) following the day you are not on call and wearing the accelerometer. All procedures for this assessment are identical to those of the Night On Call Assessment.

RISKS

There are no risks identified with this project. You will be asked to report any food allergies so that you are not served breakfast foods that you will not tolerate.

NEW FINDINGS STATEMENT

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS

Researchers hope that the information from this research study may be useful to benefit resident physicians and others who may get limited sleep.

ALTERNATIVES

Participation in this study is voluntary and will not impact your educational or professional development in any way. Deciding not to participate will have no effect on the care or services you receive at the University of Kansas Medical Center.

COSTS

There is no cost for participation in this study.

PAYMENT TO SUBJECTS

You will receive a breakfast following both assessment periods. You will also be paid $10 upon completion of the Night On Call Assessment and $10 upon completion of the Non-Call Assessment for a total of $20. Payment will be made by Target gift card. If you withdraw before the study is complete, you will be paid for each visit that you completed.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to write checks for your study payments. Study payments are taxable income. A Form 1099 will be sent to you and to the Internal Revenue Service if your payments are $600 or more in a calendar year.

IN THE EVENT OF INJURY

If you have a serious side effect or other problem during this study, you should immediately
contact Cheryl Gibson at 913-588-7207. A member of the research team will decide what type of treatment, if any, is best for you at that time.

If you have a bodily injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party, but you will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form.

**INSTITUTIONAL DISCLAIMER STATEMENT**

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow for payment to persons who are injured in research at KUMC.

**CONFIDENTIALITY AND PRIVACY AUTHORIZATION**

The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Your health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission for KUMC to use and share your health information. If you decide not to sign the form, you cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities. You may be identified by information such as name, address, phone, date of birth, social security number, or other identifiers. Your health information will be used at KU Medical Center by Dr. Gibson and members of the research team, the KUMC Research Institute, the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies. Study records might be reviewed by government officials who oversee research, if a regulatory review takes place.

All study information that is sent outside KU Medical Center will have your name and other identifying characteristics removed, so that your identity will not be known. Because identifiers will be removed, your health information will not be re-disclosed by outside persons or groups and will not lose its federal privacy protection.
Your permission to use and share your health information remains in effect until the study is complete and the results are analyzed. After that time, researchers will remove personal information from study records.

**QUESTIONS**

Before you sign this form, Cheryl Gibson or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

**SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY**

You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC. The entire study may be discontinued for any reason without your consent by the investigator conducting the study. You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write Dr. Cheryl Gibson. The mailing address is Dr. Debra Sullivan, University of Kansas Medical Center, 3901 Rainbow Blvd, MC 4013, Kansas City, KS 66160. The research team will stop collecting any additional information about you. The research team may use and share information that was gathered before they received your cancellation.

**CONSENT**

Dr. Cheryl Gibson or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.

*You will be given a signed copy of the consent form to keep for your records.*
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<th>Signature of Participant</th>
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Print Name of Person Obtaining Consent

| ________________________ |      |
| Signature of Person Obtaining Consent | Date |
| ________________________ |      |