Effect of Lavender Aromatherapy via Inhalation and Sleep Hygiene on Sleep in College Students with Self-reported Sleep Issues

A DISSERTATION SUBMITTED TO THE FACULTY OF THE UNIVERSITY OF MINNESOTA BY

Angela Smith Lillehei

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

Linda Halcón PhD, Adviser

May 2014

Acknowledgements

I would like to thank Linda Halcón, my academic advisor, for her encouragement to pursue my PhD and for her unwavering support throughout my doctoral studies. I would also like to thank my committee members, Ruth Lindquist, Cynthia Gross, and Mary Jo Kreitzer, for sharing their time and incredible expertise with me on this journey. Linda and Mary Jo have been personal mentors in my pursuit of integrative healing knowledge and wisdom.

I would also like to acknowledge other individuals who facilitated this research. Dave Golden, Director of Public Health and Communications, Boynton Health Service, supported the research taking place at Boynton Health Service with college students and provided assistance with recruitment, personal tracker funding, and a space for the informed consent and assessment processes. Katy Lust, Director of Research, Boynton Health Service was instrumental in getting approval for my research at Boynton Health Service and shared her research expertise. Julie Sanem, Health Advocate Advisor, Boynton Health Service, facilitated the on campus housing recruitment. And Robin Block at Wyndmere Naturals, Inc. supported the research through the provision of the essential oil and the patches and Mark Theno, Bioesse Technologies, Inc. made the blinding possible. And for sharing their statistical analysis expertise, I want to thank Kay Savik, School of Nursing Statistical Consultant, and her Research Assistant, Reilly Hourigan, both of whose assistance was invaluable. And of course I am grateful for all the students who agreed to participate in my study.

I want to extend a sincere note of gratitude to my children Ali, Jens, and Haley for their ongoing encouragement, support, editing skills, and for providing the diversion of normal life. I also want to thank my group of running friends, Leslie Bush, Beth Dooley, Patty Hoolihan, Randy Lebedoff, and Mary Reyelts who provided weekly encouragement. And I want to thank

Kris Torgrimson, who helped keep my energy positive and focused through her life coaching, and all my other amazing friends and family who supported me along the way.

I am also appreciative of the generous support I have received throughout my doctoral studies: Block Grant Fellowship, School of Nursing, University of Minnesota; A. Marilyn Sime Scholarship, Center for Spirituality and Healing, University of Minnesota; Wladimir and Paulina Zenkovich Nursing Fellowship and the Sophia Fund Award, School of Nursing Foundation, University of Minnesota; and Sigma Theta Tau, Zeta Chapter. And I am thankful for the support of my research by Wyndmere Naturals Inc. and Boynton Health Service.

Whatever you can do or dream you can, begin it.
Boldness has genius, power and magic in it.
Begin it now.
W. H. Murray

Abstract

Background: Sleep issues are prevalent and associated with physical, mental, and emotional health, accidents, and human errors and the related health care and work place costs. Both ineffective treatment and lack of treatment contribute to the prevalence of sleep issues and the development of chronic sleep problems. Two thirds of college students report having sleep issues. Better sleep for college students results in better moods, grades, and overall health, with benefits extending into adulthood. Providing safe and effective interventions for this age group has the potential to prevent ongoing sleep issues. Both sleep hygiene and inhaled lavender essential oil (*Lavandula angustifolia*) have been found to have a positive impact on sleep issues, but both treatments are under researched in this population.

Objective: To compare the effectiveness of lavender and sleep hygiene versus sleep hygiene alone on sleep quantity, sleep quality, and well-being and to determine if any effect is sustained at 2-week follow-up.

Method: This double-blind RCT included a convenience sample of college students with self-reported sleep issues. Standard sleep surveys, Fitbit® trackers, and a well-being survey were utilized to study the impact of five nights of inhaled lavender via patch and sleep hygiene compared to sleep hygiene and a blank patch at pre-treatment, post treatment, and 2-week follow-up.

Results: The sample size was large enough to give the study sufficient power to detect statistically significant differences. The lavender and sleep hygiene group demonstrated better sleep quality at post treatment and follow-up. The sleep hygiene only group also demonstrated better sleep quality but to a lesser extent. Additionally a clinical effect on sleep quality was found for the lavender and sleep hygiene group at post treatment, along with a significant finding for

waking feeling refreshed. There was a positive trend in well-being over time for the lavender and sleep hygiene group.

Conclusion: This double blind RCT found sleep hygiene and lavender together, and sleep hygiene alone to a lesser degree, to be effective and safe interventions for college students with self-reported sleep issues, with an effect remaining at follow-up. A clinical effect was demonstrated for the group receiving lavender.

Table of Contents

List of Tables

List of Figures

Abbreviations and Glossary of Terms

Aromatherapy	Use of essential oils for therapy or healing, usually via inhalation or skin absorption
Awakenings	Number of times awakened during sleep, TA
Control group	Sleep hygiene only group
DSD	Daily Sleep Diary, daily self-reported sleep quality and quantity information
Essential oils	Mixtures of volatile, organic compounds originating from a single botanical source and steam-distilled or extracted through cold pressing from the flowers, fruits, stems, leaves, wood, gum, roots or bark of the plant.
GC/MS	Gas chromatography/mass spectrometry, a test to identify chemical constituency of essential oils and other substances
Fitbit® One™ Device	Tracks steps, sleep, calories, etc., including five sleep variables: number of minutes asleep, number of minutes in bed, sleep efficiency, times awakened, and time to fall asleep
Hypnotic	Substance that induces sleep, soporific
IHH	Integrative health and healing
Inhaled essential oils	Breathing the chemical constituents of essential oils in through the nose
Insomnia	Self-reported sleep problem of difficulty falling or staying asleep and may include non-restorative sleep
Insomnia clinical classification systems	Both ICSD-2 and DSM-5 have unique coding for diagnostic criteria of insomnia
Lavandula angustifolia	Latin botanical name for a specific lavender species with unique chemical constituency and healing properties
L. angustifolia	Abbreviation for *Lavandula angustifolia*
Lavender	Common name for a variety of lavender species from the plant family Lamiaceae, when referred to as part of the study it denotes *Lavandula angustifolia.*

PROMIS®	Patient Reported Outcome Measurement Information System, instruments that are funded by the NIH to measure patient-reported outcomes
Assessment Center	Research management tool that provides easy access to the PROMIS instruments
PROMIS sleep disturbance SF8b 8-item	The short form of the PROMIS sleep disturbance instrument that measures sleep disturbance and sleep quality
PSQI Pittsburgh Sleep Quality Index	A standard tool to measure sleep quality, sleep latency (time to fall asleep), sleep duration, habitual sleep frequency, sleep disturbance, use of sleep medications, and daytime function.
Qualtrics®	Online survey tool that meets stringent security requirements of University of Minnesota
SAC	Self-Assessment of Change tool developed to assess the whole person effect complementary therapies or the multi-dimensional shifts in well-being
Sedative	Substance that induces sedation by decreasing irritability and excitement
Sleep efficiency	Number of minutes sleep/number of minutes in bed x 100
Sleep hygiene	General practices and environmental practices that are consistent with good sleep
SHS	Sleep Hygiene Survey, a tool to assess routine sleep hygiene practice based on number of times per week the recommendations are not practiced
Sleep issues/problem	Difficulty with initiating or maintaining sleep
Sleep onset latency	Time it takes to fall asleep
TA	Times awakened, awakenings
Treatment group	Lavender and sleep hygiene group
TST	Total sleep time
TTB	Total time in bed
TTS	Time to fall asleep, sleep latency

List of Appendices

Chapter 1: Introduction

Background

Sleep issues are a prevalent problem in our 24 hours a day, 7 days a week, non-stop society. In the most recent sleep poll exploring prevalence of sleep issues in the US, 40 to 64% of adults reported frequent problems with sleep (National Sleep Foundation, 2009). Additionally, the American Insomnia Survey found that 24% of a representative sample of US health plan subscribers met the more specific clinical diagnostic criteria (DSM IV) for insomnia (Roth et al., 2011). The National Institutes of Health (NIH) Sleep Disorders Research Plan estimates that 25-30% of all children, adolescents, and adults have sleep issues that contribute to disability, morbidity, and mortality (National Institutes of Health [NIH], 2011).

The effects of sleep problems are far ranging, including health, safety, mood stability, and performance. Health effects of sleep problems are both immediate and long term. Immediate effects relate to well-being, performance, daytime sleepiness, and fatigue. Long-term health effects include premature mortality, cardiovascular disease, hypertension, inflammation, obesity, diabetes, and impaired glucose tolerance (Ferrie, Kulmari & Salo, 2011). For example, anxiety and depressive symptoms, among other disorders, are present in 40 to 60% of insomnia cases (Ohayon & Roth, 2003) and have been found to have a bidirectional relationship to insomnia (Ohayon & Roth, 2003; Johnson, 2006; Jansson-Fröjmark, 2008). Additionally, a strong relationship has been found to exist between sleep issues and social problems and substance abuse (Bootzin & Epstein, 2011). Other non-health issues associated with lack of sleep are reduced quality of life, absenteeism, and accidents (Léger & Bayon, 2010; Thase 2005). Due to this widespread prevalence of sleep problems and the increasing awareness of

sleep problems and their association with physical, mental, and emotional health and with accidents and human errors, the epidemiology of sleep is a growing field.

Research focusing on the economic implications of sleep disorders is limited due to small sample sizes, inconsistencies in classification and definitions of insomnia, comorbidities, and methodological issues (Skaer & Sclar, 2010); however both direct and indirect costs have been found to contribute to the economic impact of sleep issues. Direct costs include: doctors, hospitals, sleep clinics, and the price of prescriptions and over the counter medications. Indirect costs include: loss of productivity, absenteeism, accidents (Léger & Bayon, 2010; Thase, 2005), and the costs of the long term health effects associated with sleep issues. In a recent US study using claims data for health service costs from 1999 to 2003, costs combined over a 6 month period were estimated to be $1143 more for patients with insomnia compared to those without insomnia (Ozminski, Wang & Walsh, 2007). In another recent study linking 2004 to 2005 health claims with survey data, mean total health care costs were 75% greater in the group with moderate and severe insomnia than those without insomnia. In addition, mean lost productivity costs were 72% larger in the moderate to severe insomnia group compared to the no insomnia group (Sarsour, Kalsekar, Swindle, Foley &Walsh, 2011). The America Insomnia Survey found projected workplace costs to be $63.2 billion annually for insomnia related absenteeism and presenteeism (Kessler et al., 2011) and the costs of insomnia related workplace errors and accidents to be over $31 billion (Shahly et al., 2012). Despite the difficulty of determining a precise estimate of the costs associated with insomnia and the limitations of cross sectional studies to determine causality, it is clear from the literature that sleep issues are associated with a significant economic burden. Treatment and prevention of insomnia will reduce healthcare costs related to insomnia and its comorbid disorders, while providing additional benefit from

improved daytime functioning and increased productivity (Rosekind & Gregory, 2010; Komada, Nomara, Kusumi, Nakashima, Okajima, Sasia & Inoue, 2012).

Sleep issues, sleep disorders, sleep problems, and insomnia are all terms that refer to self-reported problems of difficulty falling or staying asleep, which may include non-restorative sleep (Buysse, 2013), In addition, there are two prominent clinical diagnostic classifications systems for insomnia (International Classification of Sleep Disorders (ICSD-2) and Diagnostic and Statistical Manual of Mental Disorders (DSM-5)) which are more specific than the general insomnia definition but lack uniformity between them (Kraus & Rabin 2011). Sleep issues occur when the normal two-step process of disengaging from wakefulness and engaging in sleep does not happen. A variety of genetic, environmental, and physiological factors, along with sleep practices, can precipitate problems in the body's sleep-wake mechanisms that normally default to a good sleep. These main sleep-wake mechanisms or processes are: homeostatic, de-arousal, and circadian and they work to balance the system of sleep-wake on an ongoing basis (Espie, 2002). If the sleep-wake process gets disrupted and a pattern of sleep issues continue over time, the factors can build on themselves and create a vicious cycle that can be difficult to shift, leading to chronic insomnia (Bootzin & Epstein, 2011).

Mild insomnia is frequently self-treated using over-the-counter medications, herbs, or behavioral or cognitive techniques that modify the precipitating and contributory factors related to insomnia. Cognitive techniques include , sleep hygiene (following good sleep practices), cognitive behavioral therapy (changing maladaptive thinking for a change in affect and behavior) and sleep restriction therapy (controlling time in bed in order to restore the balance of sleep) (Léger & Bayon, 2010). More severe insomnia is treated with hypnotic drugs that are considered "safe" for short-term use but are often prescribed long-term and have many side effects (including insomnia, the very issue they are trying to correct). This further adds to the

cost and morbidity of health care (Kraus & Rabin, 2012)). The 2009 Sleep Foundation Survey reported sleep medication use at 8%, a statistically significant increase since 2005, with most respondents taking them over three times per week (National Sleep Foundation, 2009). In the National Health and Nutrition Examination Survey 2005-2010 (NHANES), 4% of adults aged 20 and older reported having used prescription sleep aids in the past month (Chong, Fryar & Gu, 2013).

Despite the use of a variety of treatments, short- term insomnia frequently becomes chronic insomnia (Bootzin, 2011). In addition, many people do not treat their insomnia. Of the 64% of respondents who reported experiencing a sleep problem at least a few nights a week within the past month in the 2009 National Sleep poll, only one third reported using a sleep aid/treatment. Sleep aids or treatments included relaxation techniques, sleep medication, alcohol, over the counter drugs, alternative therapy, or herbal supplements (National Sleep Foundation, 2009). Both ineffective treatment and lack of treatment contribute to the development of chronic insomnia and the prevalence of sleep disorders.

Only a small percent of those with sleep issues have been found to use integrative therapies to promote better sleep. An analysis of data from the 2007 National Health Interview Survey (NHIS) found that only 4.5% of those with insomnia have used some form of complementary and alternative medicine (CAM) to treat their condition. The CAM approaches reported included herbs (e.g. aromatherapy), melatonin and related supplements, and other approaches including acupuncture, music, and various relaxation techniques (National Center for Complementary and Alternative Medicine [NCCAM], 2009). Some complementary and alternative healing approaches demonstrate the potential to address the prevalent problem of sleep issues and the use of unsatisfactory treatments and/or the lack of treatment utilization (Gross et al. 2011; NCCAM, 2009). A variety of complementary and alternative healing

approaches have been explored with sleep issues but there are a limited number of rigorous studies. There is a gap between the large number of people with sleep issues, the smaller number who are doing something to aid sleep, and the even smaller proportion utilizing CAM or IHH (integrative health and healing) for insomnia. Additional research in IHH therapies for insomnia will assist in closing this gap.

The use of essential oils, or aromatherapy, is a promising IHH therapy for sleep. The mechanism of action for the therapeutic properties of essential oils is not totally understood but it is believed to be multi-faceted, affecting the physical from a biochemical perspective as well as working at a psychological and energetic level (Battaglia, 2005). Few published studies explore essential oils and sleep. In a systematic review of the literature on inhaled essential oil and sleep completed by the author only 15 studies were identified (Lillehei & Halcón, in press). Eleven were randomized controlled trials (RCTs), most of which were hampered by methodological issues. Lavender was the most frequently studied essential oil for sleep and results trended towards a positive effect (Arzi et al., 2009; Badia, Wesensten, Lammers, Culpepper & Harsh, 1989; Cannard, 1996; Chien, Cheng & Liu, 2012 ; Diego et al., 1998; Goel, Kim & Lao, 2005; Goel & Lao, 2006; Goes, Antunes, Alves & Teixeira-Silva, 2012; Hardy & Kirk-Smith 1995; Hirokawa, Nishimoto & Taniguchi, 2011; Hudson, 1996; Lewith, Godfrey & Prescott, 2005; Moeini, Khadibi, Bekhradi, Mahmoudian & Nazari, 2010; Raudenbush, Koon, Smith & Zoladz, 2003; Stringer & Donald, 2011). Gaps identified through the systematic review of research on inhaled essential oils and sleep included the small number of studies, an even smaller number of RCTs, and lack of documented analysis of the essential oil constituents by gas chromatography/mass spectrometry (GC/MS), report of adverse effects, and follow-up assessments to evaluate effect over time.

Additional research on treatments for sleep issues is needed based on the prevalence of sleep issues and the high associated costs, with both ineffective treatment and lack of treatment contributing to the problem. Interventions that are cost effective, easy to use, accessible, and safe could aid in addressing sleep issues. Essential oils are a promising intervention for sleep. This study adds to the literature on the effects of essential oils on sleep issues. Lavender essential oil was selected for intervention based on the results of the review of the literature, with lavender the most studied and with positive findings for sleep. The specific species of lavender essential oil used was *Lavandula angustifolia* (*L. angustifolia*) because of its specific sedative and hypnotic properties (Battaglia, 2005; Bowles, 2003; Price & Price, 2012). This study addressed the gaps identified above by adding a randomized controlled trial study to the small number of studies on sleep and essential oils and by the addition of an analysis of the components of the essential oil GC/MS, a report of minor adverse effects, and follow-up measures. In addition, the methodology included assessment of multi-dimensional shifts in well-being that has not been addressed in the studies on sleep and essential oils to date. College students were selected as the population of the study because early intervention in young adults can offer prevention for chronic insomnia as they become older adults. Sleep hygiene, as an educational intervention, was included as usual care for a non-medical setting.

This study provided information for young adults on a safe, accessible, cost-effective treatment for sleep issues and an alternative to sleep medications that can become long term and habitual. Lavender and sleep hygiene are sleep interventions that can be used short term, on an as needed basis, for sleep issues throughout the life span and may assist in the prevention of chronic sleep problems.

Research purpose

The purpose of the study was to investigate the effect of inhaled lavender (*L. angustifolia)* aromatherapy and sleep hygiene on sleep quality and quantity compared to sleep hygiene alone in college students with self-reported sleep issues. For the purpose of the study, lavender and *L angustifolia* were used interchangeably, with *L. angustifolia* being the species of lavender oil used for the intervention. Additionally, effects of *L. angustifolia* and sleep hygiene, beyond sleep, were explored to assess the multi-dimensional effects on well-being (including the physical, emotional, cognitive, social, and spiritual domains) for these therapies.

Study Aims

The specific aims of this study were to:

1. Compare the effectiveness of *L. angustifolia* inhalation and sleep hygiene versus sleep hygiene alone on sleep quantity as measured by number of minutes in bed, number of minutes asleep, sleep efficiency, time to fall asleep, and awakenings.
2. Compare the effectiveness of *L. angustifolia* inhalation and sleep hygiene versus sleep hygiene alone on subjective sleep quality as measured by overall quality, satisfaction, waking feeling refreshed, and daytime sleepiness and dysfunction.
3. Determine if any effect is sustained at 2-week follow-up
4. Investigate the effect of *L. angustifolia* inhalation and sleep hygiene compared to sleep hygiene alone on the self-assessment of change for multi-dimensional shifts in well-being including physical, emotional, cognitive, social, and spiritual domains.

Hypotheses

Null hypothesis 1: There will be no change in sleep over time.

Alternative hypothesis 1: There will be a change in sleep over time.

Null hypothesis 2: There will be no difference in sleep between groups.

Alternative hypothesis 2: There will be a difference in sleep between groups.

Implications for Nursing

Both sleep hygiene education and aromatherapy are independent nursing interventions to address sleep issues in college students, as well as self-care interventions that can be taught to clients. The nurse can promote good sleep using sleep hygiene and lavender as tools to assist the client in modifying the precipitating and contributory factors disrupting the sleep cycle and assist with re-balance. Nurses in college health centers could use these practices to assist college students with sleep issues. Additionally, this research lays the ground work for further nursing research in the use of sleep hygiene and aromatherapy and sleep in other settings and populations.

Chapter Two: Review of the Literature

This review of the literature includes the following topics relevant to this study: sleep issues and disruption, college students and sleep, sleep interventions, essential oils and effect on sleep, and lavender and sleep hygiene as interventions for sleep issues.

Sleep Issues and Disruption

For the purpose of this study, a person having sleep issues will be defined as one who self-reports consistently having one or more of the following: time to fall asleep is greater than 30 minutes, awakenings are greater than several times a night and include trouble falling back to sleep, awakening occurs too early in the morning and includes the inability to fall back asleep, and/or frequent sleepiness during the day, frequent naps, or falling asleep at inappropriate times during the day (NIH, National Heart, Lung, & Blood Institute, 2011). Sleep issues or insomnia occurs when the body's automated sleep activation and maintenance mechanism fails (Espie, 2002). Insomnia includes a variety of sleep disturbances: not enough sleep, trouble falling or staying asleep, light or un-refreshed sleep, or inability to sleep when their work schedule allows (Spielman, Nunes & Glovinsky, 1996).

Spielman et al. outlined a conceptual model of sleep disturbance that includes three factors that influence sleep: predisposing, precipitating, and perpetuating factors. Predisposing factors are relatively constant and include predisposition to being a night owl or a worrier, or a having a higher arousal level in sleep and wake. The precipitating factors trigger the initial sleep imbalance (e.g., worry about a test), and then the perpetuating factors keep the sleep imbalances occurring (e.g., worry about difficulty sleeping as night approaches, sleeping late, napping, or use of caffeine), creating a vicious cycle or negative feedback loop. Sleep imbalance can occur with disruptions in one or all of these factors, which in turn disrupts one or more of the

mechanisms of sleep: de-arousal, circadian rhythms, and homeostatic regulation (Pigeon & Perlis, 2006).

The main measures of a good night's sleep versus sleep disturbance are sleep efficiency (SE) (ratio of time spent asleep and time spent in bed) and sleep quality related to the restorative and undisturbed quality of the sleep. Refreshing sleep requires sufficient total sleep time (TST) and synchrony with sleep-wake rhythms and it impacts the ability to function the next day (Rosekind & Gregory, 2010). Strong interrelationships exist between sleep disturbance, daytime sleepiness, cognitive functioning, emotion regulation, social problems, and substance abuse (Bootzin & Epstein, 2011). In addition sleep is important to memory consolidation through encoding and consolidation, which facilitates generalization of knowledge (Ahrberg, 2012). There is much about the complex system of sleep and the effects of sleep disruption that are not known, but the importance of sleep to health and well-being is becoming more and more evident.

College Age Students and Sleep

College is a time of both intellectual and self-growth. In contrast, the sleep behaviors of college students have been found to include sleep deprivation, poor sleep quality, and excessive daytime sleepiness (Lund, Reider, Whiting & Prichard, 2010). Approximately two thirds of college students have reported having sleep problems and poor sleep quality (Hicks & Pellgrini, 1992; Lund et al., 2010). In a 2012 College Student Health Survey of Minnesota, 53% of student respondents reported getting inadequate sleep four or more days per week. For students who reported receiving zero to one day per week of adequate sleep only 55% reported the ability to manage their stress. In contrast, 90% of students who reported six to seven days per week of adequate sleep reported the ability to manage their stress (Boynton Health Service, 2012). In a study on sleep patterns of college students at a Midwestern public university, more

than 30% of the students took longer than 30 minutes to fall asleep, 43%woke more than once nightly, and 33% reported being tired the next day. No differences were found for freshmen, sophomores, juniors, seniors, and graduate students for time to fall asleep (Forquer, Camden, Gabriau & Johnson, 2008).

Similarly over 60% of students assessed for disturbed sleep in another large sample of college students were categorized to be poor sleepers using the Pittsburgh Sleep Quality Index (PSQI) and the poor sleepers reported more problems with both physical and psychological health. Sleep and wake time were also found to be delayed during the weekends and students reported frequently taking prescription, over-the-counter, and recreational psychoactive drugs to alter their sleep/wake state. Stress accounted for 24% of the variance in the PSQI score. Exercise, alcohol, and caffeine use were not found to be predictors of sleep quality (Lund et al., 2010).

In another study of healthy college students and sleep issues, poor sleep quality was initially associated with depression and anxiety. However, after controlling for factors related to depression and anxiety, the study found that sleep duration was associated with diminished attention and sleep quality and sleep medication use were the factors associated with diminished executive function. Similar results were seen with college students' cognitive performance. Despite the high prevalence of sleep issues, students were found to be unaware of the negative effect of sleep deprivation (Pilcher & Walters, 1997). Another study of college age students found that family life stress and the combination of academic stress and family life stress were associated with the highest level of insomnia (Bernert, Merrill, Braithwaite, Van Orden & Joiner, 2007). These findings support the need for ongoing education, assessment, and intervention with college students and sleep.

It is likely that environmental as well as other demands during the college years contribute to or precipitate sleep difficulties. Stress and demands may interfere with good sleep

habits, and these sleep problems, in turn, lead to further problems and thus create more sleep difficulties. This pattern may become a self-perpetuating and vicious cycle or negative feedback loop that students are unaware of and therefore may be unable to alter (Buboltz, Brown & Soper, 2001). Measures of health and well-being in college students were found to be more strongly correlated with sleep quality than sleep quantity (Pilcher, Ginter & Sadwosky, 1997; Pilcher & Ott, 1998) and sleep behaviors have been found to predict physical and psychological health and academic functioning in college students (Wong, Lau, Wan, Cheung, Hui & MOK, 2013).

With the high prevalence of sleep issues in college students and its resulting impact on health and academic performance, providing safe, accessible, and cost-effective self-care treatment option in this age group has the potential to prevent ongoing sleep issues that can become chronic later. Such treatments could reduce economic costs and improve quality of life for young adults, with benefits extending into older adulthood, as well as promote intellectual functioning and self-growth. There is a gap in the literature regarding best practices to address sleep issues in college students.

Interventions for Sleep

Usual treatments for insomnia include: pharmacological therapies, stimulus control therapy (focusing on using the bed and bedroom for sleep only), sleep restriction therapy, sleep hygiene education, cognitive therapy (cognitive restructuring), arousal reduction using relaxation or meditation, and self-help methods. Most of the treatments address the predisposing, precipitating, and perpetuating factors to some degree, but the mechanism of action is poorly understood. When medical help for insomnia is sought, physicians often prescribe a sleeping medication rather than take the time to sort through the predisposing, precipitating, and perpetuating factors or make a referral to someone with that expertise (Spielman et al., 1996). However there are adverse effects related to sleep medications,

including the newer class of nonbenzodiazepines. These adverse effects include daytime drowsiness, increased emergency room visits and hospitalizations, increased rate of accidents, effect on cognition, tolerance, and rebound insomnia (Brandt & Piechocki, 2013; Ford & McCutcheon, 2012; Hair, McCormick & Curran, 2008; Kleykamp, Griffiths, McCann, Smith & Mintzer, 2012; Swainston Harrison & Keating, 2005; Zosel, Osterberg & Mycyk, 2011). Research on sleep interventions has been increasing, however there is still a need for research on mechanisms of action, the effectiveness of a single intervention or when used in combination with other interventions, and prevention of chronic sleep issues. This is especially true in regards to college students, where early sleep issue intervention may prevent chronic sleep problems.

Hypnotic Effect of Inhaled Essential Oils

Essential oils are mixtures of volatile, organic compounds originating from a single botanical source and steam-distilled or extracted through cold pressing from the flowers, fruits, stems, leaves, wood, gum, roots or bark of the plant. They can be ingested, inhaled or absorbed through the skin. In the US, inhalation and skin absorption are considered safe applications. The essential oils are absorbed through the lungs or the skin into the blood stream. Additionally, when inhaled, a neurochemical pathway is activated (Bowles, 2003). The therapeutic effect of essential oils occurs via specific circulatory and neurochemical pathways.

Essential oils have been used to for their therapeutic properties throughout history, including the use of certain essential oils to promote sleep. Evidence on the use of essential oils and sleep is more recent. In a systematic review of the literature completed by the author (Lillehei & Halcón, in press), 15 studies on sleep and the hypnotic effect of inhaled essential oils were identified that were quantitative research studies with a sleep outcome (Arzi et al., 2009; Badia et al., 1989; Cannard, 1996; Chien et al., 2012; Diego et al., 1998; Goel et al., 2005; Goel & Lao, 2006; Goes et al., 2012; Hardy & Kirk-Smith, 1995; Hirokawa et al., 2011;

Hudson, 1996; Lewith et al., 2005; Moeini et al., 2010 ; Raudenbush et al., 2003; Stringer & Donald, 2011). The essential oils used in the studies varied. Ten studies reported using a lavender essential oil, either alone or along with other essential oils. The other essential oils studied included *Citrus sinensis*, vetiver, peppermint, jasmine, rosemary, and blends of essential oils. However only four studies reported the Latin botanical name, which identifies the plant species, and only one reported the chemical composition. Without this information the exact chemical composition of the materials used in the interventions for a majority of these studies is unclear. Essential oil chemical composition varies by species, geographic location, and climate. In addition, oils can also be adulterated with other chemical components. Chemical composition determines the treatment effect, thus making the use of the botanical species name and analysis of the chemical constituency of an essential oil a critical part of the study methodology. Another limitation of a majority of the studies was the lack of adverse effect reporting.

In addition to the variety of sleep outcomes measured, other secondary outcomes were examined in these studies: hedonicity (the like/dislike of the oil/control), expectancy effect (participant expectancy can be positive or negative and has the potential to significantly affect the results), the intensity rating of the aroma, and gender. Of the secondary outcomes studied, only intensity rating and gender were found to have an effect on sleep measures. In addition no adverse effects, or the lack there of, were reported.

In summary, for the 15 studies on the effect of inhalation of essential oils on sleep that were reviewed, lavender was the most studied and findings support a positive short term effect on sleep quality, or a trend in that direction as measured by a variety of sleep outcome measures. No adverse effects were reported. Based on these studies, use of lavender could be a safe, cost-effective therapy or adjunct therapy for sleep issues.

Lavender Essential Oil

Lavender (*L. angustifolia*) essential oil, which is steam distilled from the flower of the lavender plant, was selected for use in this study based on its chemical properties and the author's review of the literature on the effect of inhaled essential oils on sleep. The majority of the 15 studies identified in the review studied the effect of lavender on sleep. Most of these findings were statistically significant in a positive direction, or trending in that direction, for the effect of lavender on sleep (Arzi et al., 2009; Cannard, 1996; Chien et al., 2012; Goel et al., 2005; Hardy & Kirk-Smith 1995; Hirokawa et al., 2011; Hudson, 1996; Lewith et al., 2005; Moeini et al., 2010; Stringer & Donald, 2011). Only one study did not find a positive effect for lavender (Raudenbush et al., 2003). Two more recent studies also found lavender to have a positive effect on sleep (Cho, Min, Hur, & Lee, 2013; Lytle, Mwatha & Davis, 2014). Only four of these 17 studies reported the exact species of lavender. Of those four studies, two noted that *L. angustifolia* was used (Hudson, 1996; Lewith et al., 2005) and the other two used a blend containing *L. angustifolia* (Cannard, 1996; Cho et al., 2013). Additionally, a small to moderate benefit of lavender on sleep was found in a systematic review of the literature specific to lavender and sleep (Fismer & Pilkington, 2012).

Lavender is considered non-toxic, non-irritating and non-sensitizing (Battaglia, 2003). According to an international expert on essential oil safety, there are no known or suspected drug interactions and no contraindications for the use of *L. angustifolia* (Tisserand & Young, 2014, pp. 326-328). Lavender is listed on the US Food and Drug Administration (FDA) Generally Regarded as Safe (GRAS) list. *L. angustifolia* contains many different chemicals providing a wide spectrum of effects including its sedative and/or hypnotic effects (Battaglia, 2005; Bowles, 2003; Price & Price, 2012). The main constituents are linalyl acetate (an ester) 40%, (-) linalool (alcohol/monoterpenol) 31.5%, with additional smaller percentages of other constituents. Linalyl acetate has anti-spasmodic and sedative properties and is thought to subtly

regulate and re-equilibrate the sympathetic nervous system and neuroendocrine system. Linalool has sedative properties and is believed to work at the level of the central nervous system by subtly modifying the response of neurons to L-[H3]-glutamate (Bowles, 2003).

Hedonicity is a term used to describe whether a person likes the aroma of an essential oil or finds it pleasant smelling. The 2013 International Bedroom Poll included questions about whether respondents thought lavender was relaxing or if they liked lavender. A majority of the respondents from six countries who reported: 1) usually waking up when they need to and/or, 2) agreeing they sleep better when they feel relaxed and/or, 3) feeling more relaxed if their bedroom has a fresh, pleasant scent, agreed that lavender is a relaxing scent or that they liked lavender (National Sleep Foundation, 2013). This finding supports the use of lavender for sleep in regards to hedonicity.

Essential oils used in aromatherapy are traditionally administered via inhalation or massage. Inhalation is an easier self-care administration and can be done passively while sleeping. Little research has been done on the most effective dose of lavender for inhalation on sleep. The recommended dose of inhaled lavender for a sleep-inducing effect is one to two drops (Price & Price, 2012). *L. angustifolia* essential oil is considered to have a hypnotic quality based on its chemical composition and a small group of studies, but more rigorous research is needed.

Sleep Hygiene

Sleep hygiene refers to the general practices and environmental factors that are consistent with good sleep, including guidelines for health practices (e.g., diet, exercise, substance use), environmental factors (e.g. light, temperature, noise), and sleep-related behavioral practices (e.g., regular sleep schedule, pre-sleep activities, efforts to try to sleep). Sleep hygiene varies from publication to publication but the core factors include: bed/wake time, use of alcohol and drugs (e.g., caffeine and nicotine), sleeping environment, and exercise.

Most of the research on sleep hygiene has been done on "normal" sleepers with few studies showing a positive effect for those with insomnia (Stepanski & Wyatt, 2003). In practice, sleep hygiene education is widely used for sleep disturbances and is often included with other sleep therapies.

Eight studies were found that examined sleep hygiene and sleep in college age students (Brown, Walter, Buboltz & Soper 2002; Brown, Walter, Buboltz & Soper, 2006; Orzech, Salafsky & Hamilton, 2011; Rothenberger Institute, 2012; Suen, Hon & Tam, 2008; Tsai & Li, 2004). Three of these studies were sleep hygiene course evaluations (Brown et al., 2006; Rothenberger Institute, 2012; Tsai & Li, 2004). All of the eight studies found some positive effects of sleep hygiene on sleep quality. In addition, several studies that explored one component of sleep hygiene in college age students were found. For example, naps were found to have a positive impact on reaction time and mood (Taub, 1976), exercise was not found to impact sleep negatively (Flausino, Da Silva Prado, De Queiroz, Tufik & De Mello, 2012), and alcohol consumption was found to predict sleep duration and differences between week day and weekend hours of sleep and bedtime (Singleton & Wolfson, 2009).

Research in the college student population requires addressing the unique characteristics of this population (Malone, 2011). It is important to use sleep hygiene factors that have had positive correlation to sleep quality such as those used in the previously listed studies. Studies on sleep hygiene as a stand-alone treatment have had mixed results but, as noted above, some positive findings have been reported with college-age students. For the purpose of this study, sleep hygiene, a frequent first line non-medical treatment for insomnia, was considered usual care.

Summary: Literature Review

Sleep is a complex process that is normally self-correcting and includes the components of arousal, homeostasis, and circadian rhythms. Sleep issues occur when these components are

disrupted. The prevalence, incidence and costs of sleep issues are high in our society. Lavender and sleep hygiene have been found independently to have a positive impact on sleep quality. The mechanism of action is unknown but both of these interventions may act on the predisposing, precipitating, or perpetuating factors of sleep disturbance. In addition, lavender may support the natural self-correcting process of sleep with its sedative, hypnotic and balancing effects. For those cases that persist for more than a few weeks but for less than a few months, there is an opportunity for preventing the conditioning factors and alterations in sleep schedule from becoming established patterns. Conducting research on tools that could provide college students a life long way to address sleep issues as they arise could be beneficial in the short and long term. Lavender and sleep hygiene are low cost, self-care options that could provide a safe, cost-effective therapy or adjunct therapy for sleep issues and their impact on physical, mental, social health and economic costs. In addition, these treatments could decrease overuse of prescription sleep aids for college-age students and others. For these reasons lavender (*L. angustifolia)* and sleep hygiene were the focus of this research, with both groups receiving sleep hygiene information (basic good sleep practices information) and the treatment group receiving lavender in addition to the sleep hygiene information.

Conceptual Framework

Sleep is the state of natural unconsciousness. The functions of sleep have not been fully delineated; however it is known that one of the main organs of the body that benefits from sleep is the brain. A key function of sleep is the maintenance of the neuronal and synaptic integrity (a dynamic stabilization process). Mechanisms of sleep include: homeostasis, de-arousal, and circadian rhythms. Falling asleep is an active two-step process that involves 1) leaving the state of wakefulness and 2) going into the state of sleep. Once asleep, an active dynamic oscillatory process occurs that affects multiple body systems (Pidgeon & Perlis, 2006). As a complex system, sleep has been found to impact the immune system, cognition, moods, alertness, energy,

health, and safety. Sleep is a normal process for which predisposing, precipitating, and perpetuating factors can lead to disruption and a vicious cycle or negative feedback. Environmental changes can input into the system and require more energy to adapt. Ineffective response to stimuli leads to disruption of integrity (vicious cycles or negative feedback loops). A conceptual framework for sleep fits into complex systems theory with sleep as a balancing feedback loop.

This study uses the framework of complex system theory incorporating the above sleep framework and Roy's nursing theory on adaptation, which is built on complex system theory (Tomey & Alligood, 1998). Sleep is a balancing loop for energy, homeostasis, knowledge, and movement integration within a complex system that is interacting with other complex systems. A complex system usually has numerous balancing feedback loops it can bring into play, so it can self-correct under different conditions and impacts (e.g., homeostasis, arousal, and circadian rhythms). Usually a balancing loop is resilient and elastic, a dynamic feedback loop. But it may become stuck or unbalanced. A goal would be to restore balance without creating other negative feedback loops or negative imbalances (Meadows, 2008). Most balancing feedback loops have their goals to assist in maintaining balance. In our twenty-four hours a day, seven days a week, non-stop culture, humans frequently ignore their need for rest, which can result in ignored sleep goals and sleep disruption.

In Roy's Adaptation Theory, the term adaptation refers to the interaction of person (systems) and environment (systems). The role of the nurse is to promote the person's ability to affect health positively by enhancing the interaction(s) of the systems (Tomey & Alligood, 1998). A nurse uses research, practice, and teaching to promote the ability of a person to enhance the person-environment system interactions. As noted by Linda Halcón, in her chapter on aromatherapy, essential oils are used by nurses to promote healing or affect health positively

(Snyder & Lindquist, 2009, Chapter 26) and can be used to restore balance or a state of equilibrium for sleep including the person-environment interactions.

Incorporating complex systems theory with Roy's Adaptation Theory as a framework for this research involves the nurse as healer, promoting sleep hygiene and the use of lavender to affect the leverage points in the complex system of sleep in a positive direction impacting sleep homeostasis, arousal, and/or circadian rhythms (the interaction of person and environment). The balancing system of sleep is integrated into the other complex systems that make up the whole body system and assessment of the well-being of the whole person is helpful in measuring effect of interventions on sleep (Figure 1).

Sleep-wake cycle

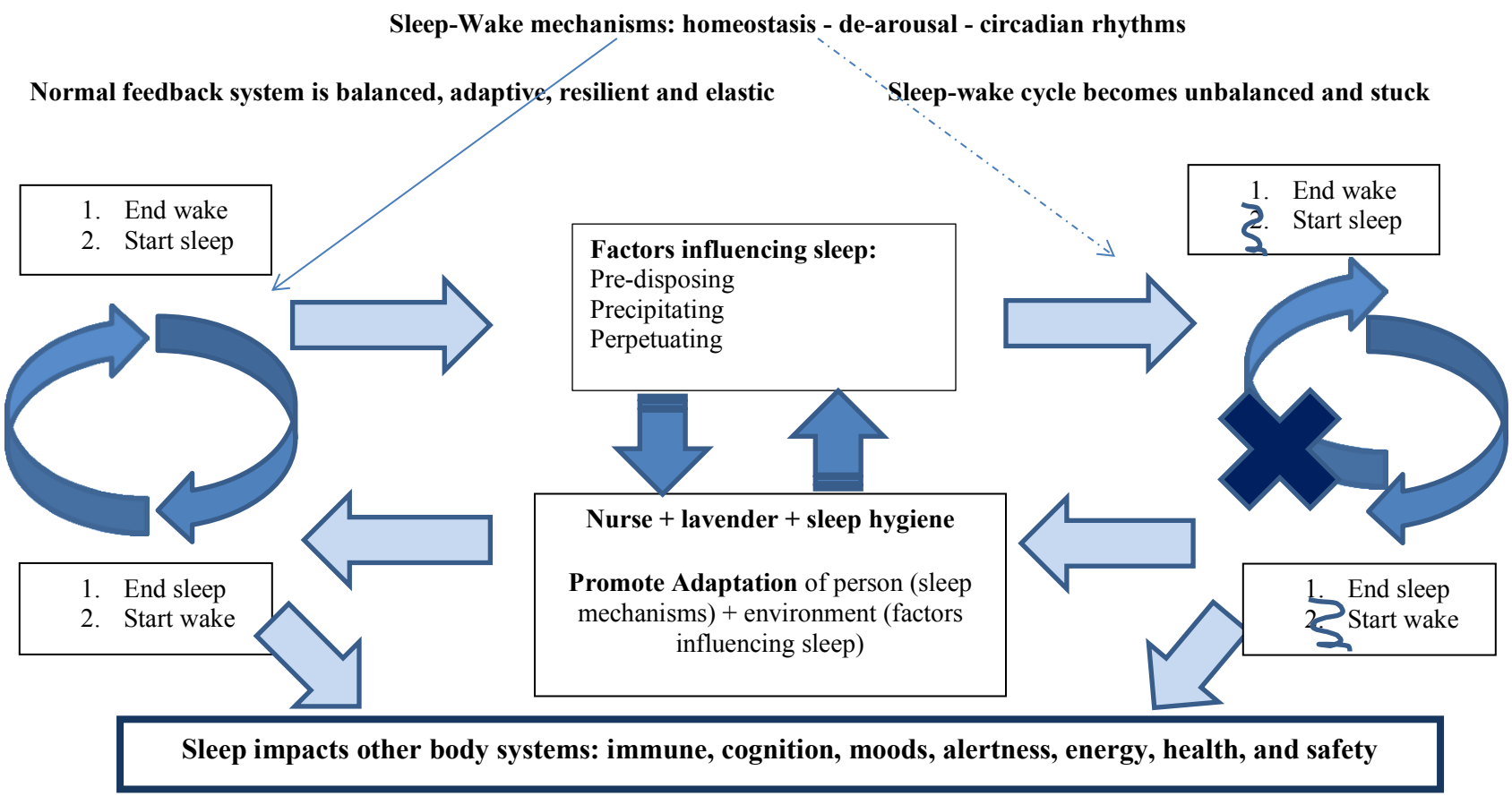


Figure 1. Conceptual Model for Study

Chapter Three: Research Methods

Design

The study was a double-blinded, two-armed, parallel-design, randomized controlled trial (RCT). The participants and investigator were blinded. There were two treatment arms, both receiving sleep hygiene instruction. The difference between the two arms was the use of a lavender patch for one arm and the use of a blank patch or placebo for the other (Table 1).

Table 1

Research Design

Group	**Baseline Assessment**	**Treatment/Daily assessment x 5 nights**	**Post treatment assessment Day 5**	**Follow-up assessment Day 14**
Lavender + sleep hygiene (random assignment)	O1: Pittsburgh Sleep Quality Index (PSQI), PROMIS™ sleep disturbance short form, Sleep Hygiene Survey (SHS)	TX: Lavender patch + sleep hygiene O2: Fitbit® One™ & daily sleep diary (DSD)	O3: PSQI, PROMIS, SHS, SAC	O4: PSQI, PROMIS, SHS, SAC
Sleep hygiene + blank patch (random assignment)	O1: PSQI, PROMIS, SHS	TX: Blank patch + sleep hygiene O2: Fitbit One & DSD	O3: PSQI, PROMIS, SHS, SAC	O4 : PSQI, PROMIS, SHS, SAC

Participants were randomized into one of two parallel groups, as they enrolled in the study, using equal randomization. Blinding is challenging with the aroma of essential oils. To incorporate investigator and participant blinding into this study, patches were prepared, packaged and coded so that neither the participants nor the investigator knew which patches contained lavender and which were blank. The packaging was exactly the same, blank with a stamped code of 1100 or 0011 stamped on it. Participants were told that the difference between

the two groups was the amount of essential oil on the patch and they were not informed as to what essential was being used for the intervention. Therefore participants with the treatment patch could smell an aroma but those in the control group may have believed they had a smaller amount on the patch. The investigator did not review results until the study was completed and data were exported. The random assignment to groups and the blinding minimized bias and balanced both known and unknown factors in the assignment of interventions, increasing strength and internal validity. This two-arm RCT design allowed for between-group comparisons and within-group and within-person changes in the independent variables over time.

Sample

Sample and setting. The sample for this study was a convenience sample of college students with self-reported sleep issues at a large Midwestern university. Inclusion and exclusion criteria were applied (Table 2). The setting for the study was the participant's normal sleep setting.

Table 2

Inclusion and Exclusion Criteria

Inclusion criteria	**Exclusion criteria**
College student =/> 18 years old	Taking prescription sleep medications
English speaking	No period in prior month and had unprotected sex in that time period
Self-reported sleep issue based on sleep issues definition (NIH, National Heart, Lung, Blood Institute, 2011)	Pregnant
Able to get to student health center for the 2 time frames required for initial assessment and post treatment	Working night shifts

Sample size. Sample size determination was based on an Analysis of Covariance for the main outcome, Pittsburgh Sleep Quality Index (PSQI), with a 2-tailed alpha of .05 and a power of 80 %. For the PSQI, clinically significant effect size was set at 3. The calculation for

sample size for the PSQI using standard deviation of 4.57 (Buysse, Reynolds, Monk, Berman & Kupfer, 1988) indicated that 25 participants per group would be needed to detect this effect size. To account for possible attrition, 80 students were recruited.

Recruitment and retention. In order to obtain a wide cross section of students, several recruitment methods were used. Recruitment approaches included: 1) posting flyers (Appendix A) containing a Quick Response Code (QR Code) and a contact email around campus; and 2) presenting the study to health advocates in the on-campus living facilities. Approximately 50 recruitment flyers were posted at a variety of on campus sites including: the student health service, the student union, the recreation center, a library, academic health center career services, classroom buildings, student lounges for health sciences students, and other designated posting areas. A short presentation was made to the health advocates, and flyers were made available to post in their respective on-campus living facilities. Ads in the student newspaper were considered but were not utilized due to cost and the success of the other two recruitment methods identified above. Each participant received a $20 gift card after completion of the post treatment assessment and return of the Fitbit One device and an additional $20 gift card upon completion of the follow-up assessment. Additionally there was a chance to win a drawing for a Fitbit One device for those who completed the study.

Measures taken to protect human subjects. The investigator completed the Human Subjects Protection training and the research proposal was approved for human subjects research by University of Minnesota Institutional Review Board as a Health and Medical/Biological Expedited Review application (Appendix B). Students who expressed interest by contacting a study email address listed on the recruitment flyers were screened for inclusion and exclusion criteria via email. If criteria were met, a thirty minute meeting with the researcher was scheduled for a verbal overview of the study and completion of informed consent if willing to participate. The information contained in the written consent included the

study purpose, risks, and potential benefits of taking part in the study (Appendix C). These were reviewed with each respondent along with the Health Insurance Portability and Accountability Act (HIPAA) form (Appendix D). Randomization and the study sleep practice expectations were explained in detail. The following script was read to each respondent to inform them about the study:

This is a sleep study examining the effect of aromatherapy via patch and good sleep practices on sleep quality and quantity. If you choose to voluntarily participate in this study, you will be randomly assigned to one of two groups. The difference in the treatment between the two groups is the amount of essential oil on the patch. If you take part in this study you will complete questionnaires before, after and at 2 week follow-up after the study is completed. The questionnaires will take about 20 minutes to complete. The intervention will be to practice good sleep habits as outlined in the information you will be provided and to wear an aromatherapy patch on your chest and a personal tracker on your wrist for the designated five consecutive nights (five week day nights) while sleeping in your own bed. You will also be asked to complete an online sleep diary survey for five mornings after wearing the patch and practicing good sleep habits. This sleep diary survey will take about 1 minute to complete. In addition you will need to return to the Boynton Health Service at the end of five nights to return and any unused patches, complete the post treatment surveys and receive your $20 gift card. The follow-up questionnaires can be taken online and when completed an additional $20 gift card will be provided and a chance to win a Fitbit tracker in a drawing once the study is completed. You can discontinue your participation in this study at any time. Identifier information will be stored in a locked file in a locked room in the School of Nursing. No personal information will be collected with the Fitbit tracker or the study questionnaires.

Students were asked to verbalize their understanding of the study and what they were consenting to and encouraged to ask any additional questions. If the student agreed to participate, the participant and the researcher both signed the consent form and the participant signed the HIPAA form. Copies of the two signed forms were provided to the participant. As noted in the script above, participants were informed that they should report any unexpected events to the researcher, that they could leave the study at any time and that all information would be kept confidential, de-identified and password-protected. Consent forms and the list with participants' identifier information linked to the study code of person will be stored in locked files in the School of Nursing for as long as is needed.

Risks and benefits. The risks of adverse effects were minimal as there are no documented risks for lavender aromatherapy via inhalation, sleep hygiene, or the patch. As noted previously, there are no known contraindications for *L. angustifolia* (Tisserand & Young, 2014, pp.326-328). In addition lavender is widely available as a food and cosmetic additive and is listed on the FDA Generally Regarded as Safe (GRAS) list. Pregnant students and female students who had not had their period in the last month and who had engaged in unprotected sex during that time were excluded from this study. There is no evidence of contraindications for lavender aromatherapy via inhalation with pregnancy, and it would be a safer therapy than prescription sleep medications, but avoiding the use of any biological with possible pregnancy is wise. Biocompatibility studies have been completed on the adhesive material used on the patch. It was found to be non-cytotoxic, non-irritating, and non-sensitizing. Furthermore no adverse effects have been documented with the use of sleep hygiene. Participants were instructed to stop study participation if they had any adverse effect from the treatment (e.g., skin irritation) and to remove the patch, wash the area, report the adverse effect on the next day's sleep diary, and return the remaining unused patches to the investigator. Risks were minimal for the participants in this study and participants were instructed how to handle any adverse effects they might experience.

Benefits of the study could be a positive effect on sleep as noted in the studies that examined the effect of inhalation of lavender and sleep hygiene on sleep. Good sleep for college students can lead to better health, mood, and cognition. Other than a potential positive effect on sleep, there was no other direct benefit to the participants who participated in this study.

Measures taken to address potential ethical issues. The potential ethical issues in this study, which have not already been addressed by the informed consent process, included not offering the same intervention to all participants who self-reported sleep issues, the potential carryover effect of aroma to roommates who were not participants in the study and use of a

sham/placebo using misleading information. The study was designed to address these ethical issues. The two-arm study design in which both arms receive sleep hygiene education allowed both groups with sleep issues to have an intervention. This also minimized the ethical implications of using a placebo since both sides received usual care. To address the carryover effect, a patch was selected as the route of essential oil administration. The patch provided essential oil aroma throughout the night while keeping the source close to the study participant and minimizing carry-over aroma to others in same room environment. The ethical issue of using misleading language, where information to participants was implied but not explicit for the placebo or sham condition, was ameliorated to some degree with both groups receiving treatment. No de-briefing was planned at the end of the study and contact with the participants was ended once the study was completed.

Data Collection Instruments

The study variables measured were sleep quantity, sleep quality, sleep hygiene, and several dimensions of well-being including domains of physical, emotional, cognitive, social, and spiritual domains (Table 3). Instruments were selected based on their use in other studies in similar settings, demonstrated reliability and validity, and to capture effects of lavender aromatherapy as an integrative health and healing practice on well-being.

Table 3

Instruments Used to Measure Study Variables

Variable	Measurement
Sleep quantity: time in bed , time asleep, awakenings, sleep efficiency, time to fall asleep	Fitbit One, Pittsburgh Sleep Quality Index (PSQI), Daily Sleep Diary (DSD)
Sleep quality: satisfaction, feel refreshed	PROMIS SF 8b total score, PSQI global score, DSD (item 6) refreshed, PROMIS (item 2) satisfaction
Sleep quality: daytime function	PSQI (items 8 & 9)
Sleep hygiene practices	Sleep Hygiene Survey (SHS)
Dimensions of well-being: physical, emotional, cognitive, social, spiritual	Self-Assessment of Change survey (SAC)

Fitbit® One™ wireless activity tracker. The Fitbit One is a personal tracking device that measures and/or tracks activity, calories, and sleep. Sleep tracking includes five quantitative sleep variables: total time in bed (TTB), total sleep time (TST), sleep efficiency (SE) (# minutes asleep/# minutes in bed), times awakened by tracking movement, and time to fall asleep (TTS). When put in sleep mode, the tracker collects sleep information based on movement. Once it is synched to a computer that has an account set up for Fitbit, it creates readout displays of the four variables listed above (Appendix E). The technical information available for this device includes information related to: a) accelerometer epoch length that is set to a default of 1-min, b) collected information that is downloadable to the user website via a USB port, c) use of a motion sensing technology that is similar to that used in Nintendo Wii, and d) use of a Nordic semiconductor chip (nRF24AP1 GHz). No information was found on the clinical protocol for the parameters to track movement and identify sleep (algorithms and threshold measurements).

In an evaluation of the reliability and validity of this device, the Fitbit was shown to have intra-device reliability of 96.5 – 99.1 comparable to both polysomnography and standard actigraphy. It was found to be similar to the actigraphy in that both devices consistently misidentify wake as sleep, which leads to overestimating sleep time and sleep efficiency compared to polysomnography. A quantitative measurement for sleep is recommended for sleep studies and the Fitbit One device was a feasible one for a large in home study. The default epic length of one minute for the Fitbit One is considered adequate (Montgomery-Downs & Insana, 2012). The baseline, "lights out", is initiated by the user clicking on the device. It can store up to seven day/nights of data, and the battery lasts for five to seven days/nights. Self-report such as a sleep diary has been recommended as a supplement (Buysse, Ancoli-Isreal, Edinger, Lichstein & Morin, 2006).

Daily sleep diary. The daily sleep diary (DSD) was used to supplement the Fitbit One for sleep quantity information and for a daily perspective on sleep quality. It was administered as an on-line survey with a text/email alert to the participant in the mornings. A number of published sleep diaries are available but none are recommended as the preferred format (Buysse et al., 2006). The sleep diary for this study was based on the National Sleep Foundation Sleep Diary (National Sleep Foundation, 2013) and inquired about the same sleep quantity variables as the Fitbit device (number of minutes in asleep, number of minutes in bed, times awakened, and time to fall asleep). It also included questions on sleep quality, events affecting previous night's sleep, adverse effects from the patch, the Fitbit One tracker or sleep hygiene, and adherence to use of tracker and the patch. Sleep diaries are a standard means to collect quantitative sleep data and have been found to be more reliable than actigraphy (Levenson et al., 2013). The sleep diary questionnaire was completed daily in the morning following each of the five nights of lavender and/or sleep hygiene intervention (Appendix F).

Pittsburgh Sleep Quality Index survey. The 19-item scale on the Pittsburgh Sleep Quality Index (PSQI) generates seven component scores: sleep quality, sleep latency (time it takes to fall asleep), sleep duration, habitual sleep efficiency, sleep disturbance, use of sleeping medications, and daytime functioning (Appendix G). The sum of these components (based on all questions except the one about a sleep partner) yields a global score with a total of 21, a higher score indicating poorer sleep quality (Buysse et al., 1988) (Appendix G). Additionally a PSQI score greater than five indicates poor quality sleep and a change in three points indicates a clinical effect. For the purpose of this study these first nine questions (all questions other than the one about the sleep partner) and the global score were used. This instrument has been found to have a high test-retest reliability and good validity for use with good and poor sleepers (Buysse et al., 1988). Originally developed as a clinical assessment tool for insomnia, this instrument assesses sleep quality and disturbances for a prior one month period. However, it has frequently been used in research to assess sleep disturbance over a seven-day interval and was found to have higher test-re-test reliability for shorter intervals than the one month interval (Backhaus et al., 2002). It is one of the recommended measures for treatment effectiveness studies for global sleep and sleep quality (Buysse et al., 2006). Two versions of the PSQI were utilized. The version used at pre-treatment and follow-up referenced the past two weeks. A version that referenced the past one week was used at post treatment to focus on the week of intervention.

Patient-Reported Outcomes Measurement Information System (PROMIS™) Sleep Disturbance survey. The PROMIS sleep disturbance short form (SF8b, PROMIS v.1.0, www.nihpromis.org) served as an additional sleep quality instrument. The data collected in PROMIS instruments, such as the sleep disturbance SF8b, provides researchers with important patient (participant)–reported information about the effect of therapy that cannot be found in traditional clinical quantitative measures. This eight-item short form (SF8b) has been found to

correlate strongly with the PROMIS sleep disturbance long form and found to have greater measurement precision than the Pittsburgh Sleep Quality Index for sleep disturbance, however it does not collect information on quantitative time-based information, which the PSQI collects retrospectively. It was developed for samples with or without sleep disorders and measures sleep quality and disturbance over a previous one week interval. This instrument has been validated in regard to sleep wake function but not on responsiveness to change. The score range is 0-40 with a possible five points for each item and a higher score indicating more disturbed sleep (Buysse et al. 2010 ; Yu et al., 2011) (Appendix H).

The PROMIS instruments, which are provided at no cost by the NIH, are accessible for online administration through the Assessment Center, a research management tool. The Assessment Center was utilized for this study to create a secure, study specific web site where all the study instruments could be administered online to participants, data could be managed and exported to an analysis program. The Assessment Center scores PROMIS based on calibration weights developed using item response theory. It then normalizes the score using a T-score, which rescales the score into a standardized score with a mean of 50 and a standard deviation (SD) of 10. Most PROMIS instruments were calibrated against a large sample of the US population; however, the sleep disturbance questionnaires were calibrated against a sicker population than the general US population, in contrast to the healthy college student sample in this study. Because of this, raw scores were used in analysis. No minimum change that reflects a clinically meaningful difference has been determined for the sleep disturbance instrument (www.nihpromis.org, 2013).

Sleep Hygiene Survey (SHS). A sleep hygiene questionnaire was administered to assess routine sleep hygiene practices at pre-treatment, post treatment, and at follow-up. The sleep hygiene practices assessed were: 1) going to bed and waking on a regular schedule, 2) avoiding caffeine and nicotine late in the day, 3) creating a good sleeping environment (e.g.

wearing ear plugs and a sleep mask and avoiding screens and texting), 4) creating a relaxing bedtime routine (try to leave problems for wake time), 5) avoiding alcohol, large meals and beverages before bed, 6) keeping up with school work, and 7) exercising regularly. This is similar to the NIH list of sleep hygiene practices (NIH 2009), with the exception of not including naps and exercise at bedtime which have been found to not impact sleep for adolescents and/or college students. In addition keeping up with school work and exercising regularly was added to the sleep hygiene list for this study population. This 16 item questionnaire was based on the sleep practices section of the Sleep Hygiene Awareness and Practices Scale (SHAPS) (Lack, 1986) but modified to be specific to the sleep practices as listed above (Appendix I). Responses were for number of days or nights in an average week (or the week of the sleep study for post treatment questionnaire). The score range is from 0-112 with a higher score indicating less healthy sleep hygiene practices. The sleep hygiene practice section of SHAPS has been found to have acceptable test retest reliability. The internal reliability was found to be poor, however, which could reflect that the practices change over time (Brown et al., 2006).

Self-Assessment of Change (SAC) tool. The Self-Assessment of Change tool was developed to measure the multi-dimensional shifts in well-being following integrative health and healing therapies. It measures the extent of perceived changes following participation in a therapeutic intervention using a retrospective pre-test format. The retrospective pre-test format has been found to reduce response shift bias, minimizing the overestimation and underestimation of change. The tool was developed through an iterative process from the participant experience with a focus on convergent content validity that is generalizable to CAM participants. Some divergent content, substantive, and structural validity have been tested and further validity and reliability testing in the CAM population is in process (Thompson et al.,

2011). The paper version of the survey is an 18-item scale of word pairs in visual analog scale format. Participants designate on the scale where they were before (B) the intervention and where they are now (N). For each word pair, participants indicate (B) and (N) on the 100 mm blank line. The positions of the "before" and "after" are measured in millimeters from the left edge of the line, the range for each question is 0 to 100 (Ritenbaugh et al., 2011). Examples of the word pairs include "Not sleeping well/Sleeping well", "Exhausted/Energized", "Stuck//Letting Go", "Hopeless/Hopeful"…" (Appendix J). For the purpose of analysis the word pairs are categorized into six domains of health and well-being (physical, emotional/affective, cognitive, social, spiritual, and overall whole person) (Table 4).

An electronic survey was developed for this tool in Qualtrics®, an online survey tool with tight security features conducive to research. This electronic version is a 16-item scale of word pairs. It does not include the second question related to energy (No Energy/Full of Energy) and the question related to spiritual path (Not on a Spiritual Path/ On a Spiritual Path). This e-survey version of the SAC instrument was included in the post intervention and the two week follow-up assessment to assess the multi-dimensional changes in health and well-being.

The visual analog survey format of the SAC could not be replicated in the Assessment Center, so a hyperlink to the survey was produced in Qualtrics and embedded in the Assessment Center online site along with the other instruments. Participants were instructed to click on this additional link and complete this survey as the last step in the post treatment and follow-up assessment processes.

Table 4

Well-being Dimensions of the Self-Assessment of Change Tool

Whole person (word pairs)		**Physical (word pairs)**		**Cognitive (word pairs)**		**Affective (word pairs)**		**Social (word pairs)**		**Spiritual (word pairs)**	
Exhausted	Energized	Not sleeping well	Sleeping well	Scattered	Focused	Hopeless	Hopeful	Closed-hearted	Open-hearted	Hopeless	Hopeful
Overwhelmed	Empowered	Exhausted	Energized	Blaming	Forgiving	Depressed	Joyful	Isolated	Connected	Blaming	Forgiving
Broken	Whole	Dull senses	Vibrant senses	Defined by my problems	Not defined by my problems	Anxious	Calm			Closed-hearted	Open-hearted
		My body does not recover quickly	My body recovers quickly							Isolated	Connected
										Broken	Whole

Note. Adapted from Ritenbaugh et al. (2011). Developing a patient-centered outcome measure for complementary and alternative medicine therapies I: Defining content and format. *BMC Complementary & Alternative Medicine, 11*, 135.

Open-ended exit question. To collect any additional information or feedback about the experience of participating in this study, an open-ended question was asked at follow-up. Participants were asked: "Please provide any additional feedback about your experience in participating in this study regarding the aromatherapy patch, the Fitbit One tracker, the sleep hygiene practices or any of the questionnaires." Responses to the question were grouped according to subject.

Materials

The materials used for this study consisted of a patch for administration of the oil and the placebo, the *L. angustifolia* oil, and the Fitbit One tracking device.

Patch. A patch was used to administer the *L. angustifolia* aromatherapy via inhalation and provide the placebo or sham procedure via a blank patch. The 3 cm square patch contained a 1 cm disc of absorbent material that holds up to 110 microliters of essential oil. It is designed as a time-release product to slow down the rate of evaporation and extend the normal release times allowing it to evaporate during the night. The patch has a skin barrier adhesive back, so that essential oils are inhaled but not absorbed. This standardized the route of administration. The gel adhesive backing was tested and found to be non-sensitizing, non-irritating and non-cytotoxic (Biosesse Technologies, Inc.). Wyndmere Naturals, Inc. provided both the blank and the *L. angustifolia* patches for the study. The blank patches had nothing applied to them. Both patches were packaged in exactly the same way, with a stamped code to identify the group. Participants were instructed to wear the patch on the middle of the upper chest (Figure 2).

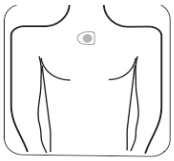


Figure 2. *Patch on chest*

***L. angustifolia* essential oil**. A gas chromatography/mass spectrometry (GC/MS) report for the batch of the lavender essential oil utilized for the study was provided to the researcher (Appendix K). The GC/MS file was compared to the standard for *L. angustifolia* set out by the International Organization for Standardization (ISO) (ISO International Standards, 2002) and to list of key constituents identified by Tisserand (Tisserand & Young, 2014, p.326) (Table 5).

Table 5

Comparison of Chemical Constituencies: L. angustifolia

Key Constituents	**Wyndmere batch for study (%)**	**ISO[1] (% range)**	**Tisserand & Young[2] (% range)**
Linalool	24.5	25–38	30-45
Linalyl acetate	46	25-45	33-46
β-Caryophyllene	4.1		1.8
Terpenin-4-ol	0.6	2-6	<1.5
Borneol	2		1.0
α-Terpineol	0.9	-- -1	<1.5
(Z)-β-Ocimene	1.5	4-10	<2.5
3-Octonone	0.8	trace-2.0	1-2.5
(E)-β-Ocimene	0.9	1.5-6	<2
Lavandulol	0.9	0.3 - --	
Lavandyl acetate	2	2.0- --	
1,8-Cineole	2.2	-- -1	
Camphor	0.7	trace-0.5	
Other	13.7		

[1]International Organization for Standardization
[2]Tisserand & Young, 2014 (p. 326)

The GC/MS analysis for the batch of *L.angustifolia* used for the study patches generally fits the ranges identified by the ISO and Tisserand & Young for the two main ingredients, with linalool being on the lower end of the ranges and linalyl acetate being on the higher end of the ranges. As noted previously both linalool and linalyl acetate have sedative properties (Bowles, 2003). The study batch had a slightly higher percentage of β Caryophyllene, Borneol, 1, 8-Cineole and Camphor and a slightly lower percentage of Terpenin-4-ol and (E)-β-Ocimene. It is unclear to what extent, if any, these small percentage differences had on the sedative and hypnotic properties of the *L. angustifolia* oil used in this study. The patch contained 55 microliters (ul) or one drop of *L. angustifolia* oil applied consistently by a metered pump to the round disc of absorbent material on the patch. The dose was determined based on the literature, the properties of the patch, and to minimize the intensity of the aroma. In addition, an informal survey of 11 family and friends was completed to assess use of one drop (one patch, n=6) or two drops (2 patches, n=5) for hypnotic effect over five consecutive nights. No difference was noted.

Fitbit One personal tracker. The Fitbit One tracks sleep in addition to steps, distance, calories burned, and stairs climbed (Figure 3). The trackers were set up to wirelessly synch to the investigator's laptop by setting up separate email accounts for each device. This allowed the investigator to have access to the information upon synching once the devices were returned. The participants did not have the account information or the synch mechanism so they were unable to view their tracking information, preventing the possible confounding factor of tracking sleep and promoting the return of the trackers for other waves of the study. The small device (4.5 x 2 cm.) was put into a sleep wrist band on the wrist of the participant's non-dominant hand to track sleep. The sleep band had a Velcro closure so it could be adjusted for each participant. The Fitbit One devices were wiped down and the sleep bands were washed between participants.

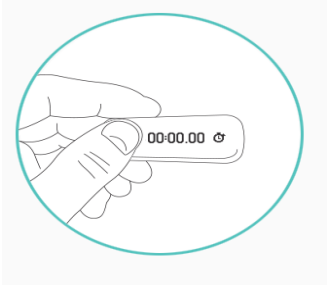


Figure 3. Fitbit One device

Study time line

The study set up and intervention took about seven months to complete (Figure 4). Changes to the original time line included: 1) moving up completion of all instruments and fliers to align with the IRB process, 2) extending the end date for instrument set up in the Assessment Center due to an underestimation of the length of time required to complete this activity, and 3) adding a fourth wave of participants due to the number of Fitbit trackers funded. This extended the study two additional weeks from the original planned schedule. For the most part the projected time line was followed.

Activity	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7
Obtain IRB approval	X						
Complete Human Subject Protection training	X						
Obtain funding for Fitbit™ and incentives	X	X					
Develop tool for demographics	X						
Complete small pilot study for dose & sleep diary	X						
Develop on-line sleep diary	X						
Develop sleep hygiene flier	X						
Develop recruitment materials	X						
Code data/Set up data		X					
Add assessment tools in PROMIS Assessment site/Test site		X	X	X			
Recruit			X	X	X		
Initiate/post treatment/ follow-up x 4 waves				X	X	X	X
Data							
Analysis/ Report							X →

Figure 4. *Study time line*

Study Procedure

The study was completed in 4 waves of 13 to 21 participants (based on number of Fitbit devices and schedule availability for respondents). The principal investigator conducted all intake and all assessments. Once respondents were screened, they were scheduled for initial and post treatment sessions. One to three participants were scheduled during a 30 minute time slot on designated Fridays in a room in the student health center. Roommates who were screened and met inclusion/exclusion criteria were scheduled for different waves of the study to maintain blinding to the degree possible. At the initial meeting the first steps were to explain the study by

reading the study script (refer to Chapter 3, Measures Taken to Protect Human Rights) and complete the consent process for those interested. Once informed consent was obtained, a hyperlink was provided for logging into the PROMIS Assessment Center. Respondents were asked to bring a laptop or notebook to both sessions. Additionally one computer was available for use if needed. New participants received automatically assigned login/passwords, which were generated by the Assessment Center. Participants were asked to write them down for use at post treatment and follow-up. Participant registration in the Assessment Center included collection of demographic data: 1) age, 2) gender, 3) race, 4) ethnicity, and 5) health conditions. An additional question regarding medications did not upload into the Assessment Center correctly; therefore no data were collected about participant medication use. No identifier information was entered into the Assessment Center. A study code was automatically assigned and made available to the investigator. At this time participants also completed the PQSI, the PROMIS SD SF8b, and the sleep hygiene questionnaire.

Once they completed their pre-treatment questionnaires, participants were randomized as they came into the study, using a simple randomization procedure (randomization list), to one of two groups. Envelopes numbered 1-80 were prepared with slips of paper inside identifying group assignment by a non-investigator, keeping the investigator blind. The packaging for the patches was blank except for being stamped #0011 and #1100. Instructions were added to each package via a sticker. A non-investigator validated which number designated treatment and which designated placebo and kept that information until the end of the study so the investigator, who set up the interventions and assessed the outcomes, was unaware of the designation. The envelope number and the patch designation were documented for each participant and left in the envelope. All the envelopes from a wave were sealed until the end of the study. Tracking information collected by the investigator included identifier information: name, email, and password/login information (for participant password retrieval), and study ID

number. In addition emails, Fitbit ID numbers, wave numbers, number of patches returned, and cell numbers for those willing to provide it for text reminders were obtained. Only three participants did not provide cell phone numbers for reminder texts. Reminder emails were sent in place of the texts for these participants.

Participants were given six patches (five nights + one extra), the Fitbit One tracker, detailed instructions for how to use the patch and the tracker (Appendix L), and the list of sleep hygiene practices (Appendix M). The written instructions and sleep hygiene practices were given verbally as well. After the first wave (n=21), participants were given a reminder placard for the intervention (Appendix N) and were asked to demonstrate the use of the Fitbit tracker back to the investigator in order to increase Fitbit data output for the next waves.

Participants were instructed to begin the intervention on Sunday evening and end it Friday morning. Additionally they were told they would receive email and text reminders (if willing to provide their cell number to the investigator) in the evenings to use the patch and Fitbit One and again in the mornings to complete the Daily Sleep Survey. At the end of five nights, the participants were instructed to return the Fitbit device (and any remaining patches if applicable) to their second scheduled session. The second session was scheduled for one week after the pre-treatment session for completion of the post treatment testing (PROMIS SF8B, PSQI, and the SAC instruments).

A link for the follow-up surveys was emailed to each participant fourteen days after treatment completion, with a reminder text message sent if the surveys were not completed within a day and a half. The initial intake and assessment took approximately 30 minutes, the post treatment and follow-up assessments took approximately 20 minutes each, and the daily sleep diary took about five minutes to complete. Instrument questions were set up to encourage a response by having a dialog box displayed if no answer was provided to a question. The dialog box asked them to click OK if they wanted to skip or CANCEL if they wanted to

continue and answer the question. An auto advance feature displayed the next question automatically once an answer was provided, in order to facilitate moving through the assessment process efficiently.

Protocol: Blank patch and sleep hygiene arm. All participants completed pre – intervention questionnaires. The participants assigned to this arm received a flyer for sleep hygiene practice that highlighted sleep benefits and 6 blank patches. The sleep hygiene practices listed in the flyer for this study included: 1) go to bed and wake on a regular schedule, 2) avoid caffeine and nicotine late in the day, 3) create a good sleeping environment (try ear plugs and a sleep mask and avoid screens and texting), 4) create a relaxing bedtime routine (try to leave problems for wake time), 5) avoid alcohol, large meals and beverages before bed, 6) keep up with school work, and 7) exercise regularly (Appendix M). Benefits of better sleep were included on the flyer (e.g. better grades, less sickness, better mood, less stress) (Orzech et al., 2011).

It was suggested to the participants that the flyer be placed where it would be visible during the day and before sleep. The participants received six unlabeled blank patches (five nights + one extra if needed) and written instructions (including pictures on how to open and place patch on the chest). The participants were instructed to place the patch on the upper chest at bedtime and remove the patch on awakening. The patches were labeled for the day of the week they were intended to be used (Sunday through Thursday). In addition all participants received a Fitbit One device with an identification letter on it for data collection purposes and for follow-up on return of device. The login for the Fitbit Device remained with the researcher, as discussed previously, so that participants did not track sleep themselves. Written instructions were provided in regards to: turning the device on at "lights out" and turning it off on awakening for the day/getting out of bed, and wearing it on the non-dominant wrist. Practice with turning on and off was completed by participants upon receiving the device. Questions

were encouraged. Text/email reminders were sent in the evening to remind participants to use the patch and Fitbit One tracker for each of the five nights of intervention. An email was sent each morning after the intervention with the link to Daily Sleep Diary survey, along with an email and text message reminder. At the end of the five nights of intervention the participants received a text/email reminding them to return the Fitbit device and any leftover patches.

Protocol: Lavender and sleep hygiene arm. The treatment protocol for the sleep hygiene + *L angustifolia* patch group was exactly the same as the sleep hygiene + blank patch group except that the patch contained one drop of *L. angustifolia* essential oil. Investigator and participants were blinded to group assignment; therefore, both groups were treated the same.

Treatment integrity measures. Several treatment integrity measures were put in place. These measures included: a) validation of patch group assignment code by a non-investigator, b) participant report of nightly patch and Fitbit use on the sleep diary, c) return of unused patches upon completion of intervention, d) collection of sleep hygiene compliance information with the Sleep Hygiene Survey, e) collection of quantitative sleep information with both the Fitbit tracker information and daily sleep diary, and f) GC/MS analysis of the *L. angustifolia* essential oil to ensure product integrity. The group assignment code, which was blinded to the investigator, was validated by a non-investigator through a smell test of several patches in each group. The only study integrity measure that identified an issue was the validation of patch group assignment. Patch group assignment by the supplier was found to be incorrect with the lavender patches identified as the blank patches and vice versa. The non-investigator made a correction in the documentation of the group assignment, validated that the patches were batched consistently even though assignment was reversed, and kept this blinded from the investigator.

Data Analysis

Data collected in the Assessment Center and Qualtrics were exported to Excel for data analysis. Results from the Fitbit One data were manually entered onto an Excel spreadsheet by the investigator. All results were reviewed and set up for data analysis. Analysis was performed in SAS version 9.2, SPSS 21and R version 2.15.1. Initially an exploratory analysis was completed to assess the normalcy of distribution and to identify any issues with the data.

For the formal analysis, linear regression was utilized when there were single observations on an individual for the specified model and data were approximately normal. Generalized estimating equation (GEE), which accounts for the correlation that occurs on the repeated measures of an individual, was utilized for multiple observations over time. Poisson distribution, logistic regression, and cumulative logistic regression were used with GEE when the outcome variable represented count, binary, or categorical data. Prior to running the models, a correlation matrix was completed for all variables initially included in the models to explore possible autocorrelation between covariates. The most appropriate covariance structure was selected based on the nature of the repeated measurement data and the limitations of the software (SAS only allows independent matrices for multinomial outcomes).

A series of models were created using a two-step process. The first step was fitting a full model using all parameters. Step two involved reducing the parameters based on their statistical significance and their relevance to the outcome. Examples of parameters that remained in the reduced models were age, gender, sleep hygiene, treatment, patch worn all night, and time if it was a longitudinal model. Other parameters remained in or were excluded depending on their statistical significance in the full model. On linear regression-type analysis, the Aikake's information criteria (AIC) were used to compare models for best fit. The AIC

identified little difference between the full and reduced model. Results were considered significant at $p < .05$.

Missing data were handled according to the conventions for each statistical test. For summary statistics the missing data were ignored and for data in long format (GEE and regression) estimates were generated for every variable based on the data present. Limited data were collected from the Fibit One personal tracker and were graphed with variable results. Therefore the Fitbit data were not used for further analysis and were not considered in the results. Missing data for the sleep diary responses were addressed through the use of composite scores for the post treatment assessment period. The daily scores on the sleep diary were added together into a composite score (percentage or weighted sum) for each outcome variable to compile responses from the treatment period (the 5 days of receiving lavender or not) and to account for any missing data.

Aims 1-3 analysis. Determine the effects of five nights of *L. angustifolia* aromatherapy inhalation plus sleep hygiene as compared to the blank patch plus sleep hygiene on sleep quality and quantity immediately post treatment and at two week follow-up.

Null hypothesis 1: No change in sleep over time (2 - tailed)

Null hypothesis 2: No difference in sleep between groups (2-tailed)

Two main equations represent the analyses. For models that did not include time, the following equation was used: $Y_i = \beta_0 + \beta_{\text{lavender}}(\text{lavender}_i) + \beta_{\text{sleep hygiene}}(\text{sleep hygiene}_i) +$ additional covariate. For models that included time, the following equation was used: $Y_i = \beta_0 + \beta_{\text{lavender}}(\text{lavender}_i) + \beta_{\text{sleep hygiene}}(\text{sleep hygiene}_i) + \beta_{\text{time}}(\text{time}_i) +$ additional covariates. In both of these models, Y is sleep as represented by sleep quantity and sleep quality, measured by the PSQI, PROMIS Sleep Disturbance SF 8b, Daily Sleep Diary, and the Self-Assessment of Change survey. Variables in the model included lavender, sleep hygiene, and time for models that included time, plus any additional covariates. For binomial, multinomial and Poisson

outcomes this model was exponentiated for prediction of Y. Models were differentiated based on the distribution, the response variable, and the covariance structure (Table 6). Relative risk was reported when a Poisson model was used and an odds ratio was reported when categorical responses were modeled.

Table 6

Statistical Models used for Analysis: Aims 1-3

	Statistical Model						
	Linear regression	**GEE[1]**	**GEE[2]**	**GEE[3]**	**GEE[4]**	**GEE[5]**	**GEE[6]**
Sleep Quantity Variable	Sleep efficiency score post treatment*	Total Sleep Time Total Time in Bed	Times awakened Time to sleep	Fell asleep easily			Sleep efficiency score post treatment
Sleep Quality Variable	Pittsburgh Sleep Quality Index global score post treatment* PROMIS Sleep Disturbance total score post treatment* Sleep satisfaction post treatment** Daytime sleepiness post treatment** Daytime dysfunction post treatment**				Sleep satisfaction post treatment and follow-up (FU) Refreshed post treatment Daytime sleepiness post treatment and FU	Daytime dysfunction post treatment and FU	Pittsburgh Sleep Quality Index global score post treatment and FU PROMIS Sleep Disturbance total score post treatment and FU

* Normal linear regression
** Multinomial linear regression
[1] General estimating equation (GEE), Gaussian family, identity link, autoregressive-1 (ar-1) covariance structure
[2] General estimating equation (GEE), Poisson family, log link, ar-1 covariance structure
[3] General estimating equation (GEE), binomial family, logit link, ar-1 covariance structure
[4] General estimating equation (GEE), multinomial, cumulative logit, ind covariance structure
[5] General estimating equation (GEE), logistic regression, ar-1 covariance structure
[6] General estimating equation (GEE), Gaussian family, identity link, exchange-able covariance structure

Aim 4 analysis. Determine the effects of five nights of *L. angustifolia* aromatherapy inhalation and sleep hygiene compared to blank patch and sleep hygiene on sleeping well and dimensions of well-being immediately post treatment and follow-up.

Null hypothesis 1: No change in sleep and other dimensions of well-being scores over time (2-tailed)

Null hypothesis 2: No difference in sleep and dimensions of well-being scores between groups (2-tailed)

The analyses are represented by two main equations, depending on the presence of time in the model. For the model that did not include time, the following equation was used: $Y_{i} = \beta_0 + \beta_{lavender}$ (lavender$_i$) + $\beta_{s\ sleep\ hygiene}$ (sleep hygiene$_i$) + additional covariates. For the model that included time, the following equation was used: $Y_{i} = \beta_0 + \beta_{lavender}$ (lavender$_i$) + $\beta_{s\ sleep\ hygiene}$ (sleep hygiene$_i$) + β_{time} (time$_i$) + additional covariates. In models, Y is the self-reported change in sleep (Now – Before). Variables in the model include lavender, sleep hygiene, and time when time is included in the model, plus any additional covariates.

Only the main domain of sleep was modeled using data from the Self-Assessment of Change tool (Table 7). An exploratory analysis of between groups for the 16 word pair questions on the Self-Assessment of Change tool was also completed for post treatment and follow-up. Sleep and other dimensions of well-being were explored for trends between groups over time.

Table 7

Statistical Model used for Analysis: Aim 4

	Statistical Model	
	Linear regression	**GEE[1]**
Sleep Quality Variable	Change in Sleep Quality (Now – Before) Post treatment	Change in Sleep Quality (Now – Before) Post treatment & follow-up

[1] General estimating equation (GEE), Gaussian family, identity link, exchangeable covariance structure

For all four aims, change over time was evaluated in the models by including actual time as a covariate and also by including a treatment group by time interaction. Analysis included exploration of models with several within person error covariance structures that were compatible with the correlation patterns between all-time points of sleep quality, sleep quantity, and self-assessment of change. The null hypotheses were assessed in the initial model to determine if further analysis was warranted: 1) no change across occasions indicated by the model with just an intercept leaving no unexplained variance, and 2) no variation between groups. Rejecting these hypotheses warranted further analysis.

Chapter 4: Results

Sample

Recruitment was completed ahead of schedule. The last wave, which began on November 1, 2013, was filled on October 13, 2013. All 79 of the participants recruited for this convenience sample of college students with self- reported sleep issues completed the pre-assessment. The five nights of intervention and post treatment assessments were completed by 76 (96%) participants, and 72 (91%) completed the two week post intervention follow-up assessment. Figure 5 displays the participant flow for the study. Not all participants who completed the post treatment and follow-up assessments completed the SAC survey. Completing the SAC survey, which was not part of the pre-treatment assessment due to its retrospective pre-test format, required the participant to open an additional link to access the survey in Qualtrics. A participant could X out of the Assessment Center after completing the other surveys without an additional dialog box to remind them to click the additional link due to the limitations of the Assessment Center. Thus the number of participants in each group who completed the SAC survey at post treatment and follow-up was 36 (92%) and 32 (82%) for the lavender and sleep hygiene group and 37 (92.5%) and 31 (77.5%) for the sleep hygiene only group. Additionally the sleep diary was completed for 376 out of a possible 395 participant-nights (95%). The number of participants determined to be required for a well powered study was 25 for each group, therefore the study was adequately powered for each assessment period.

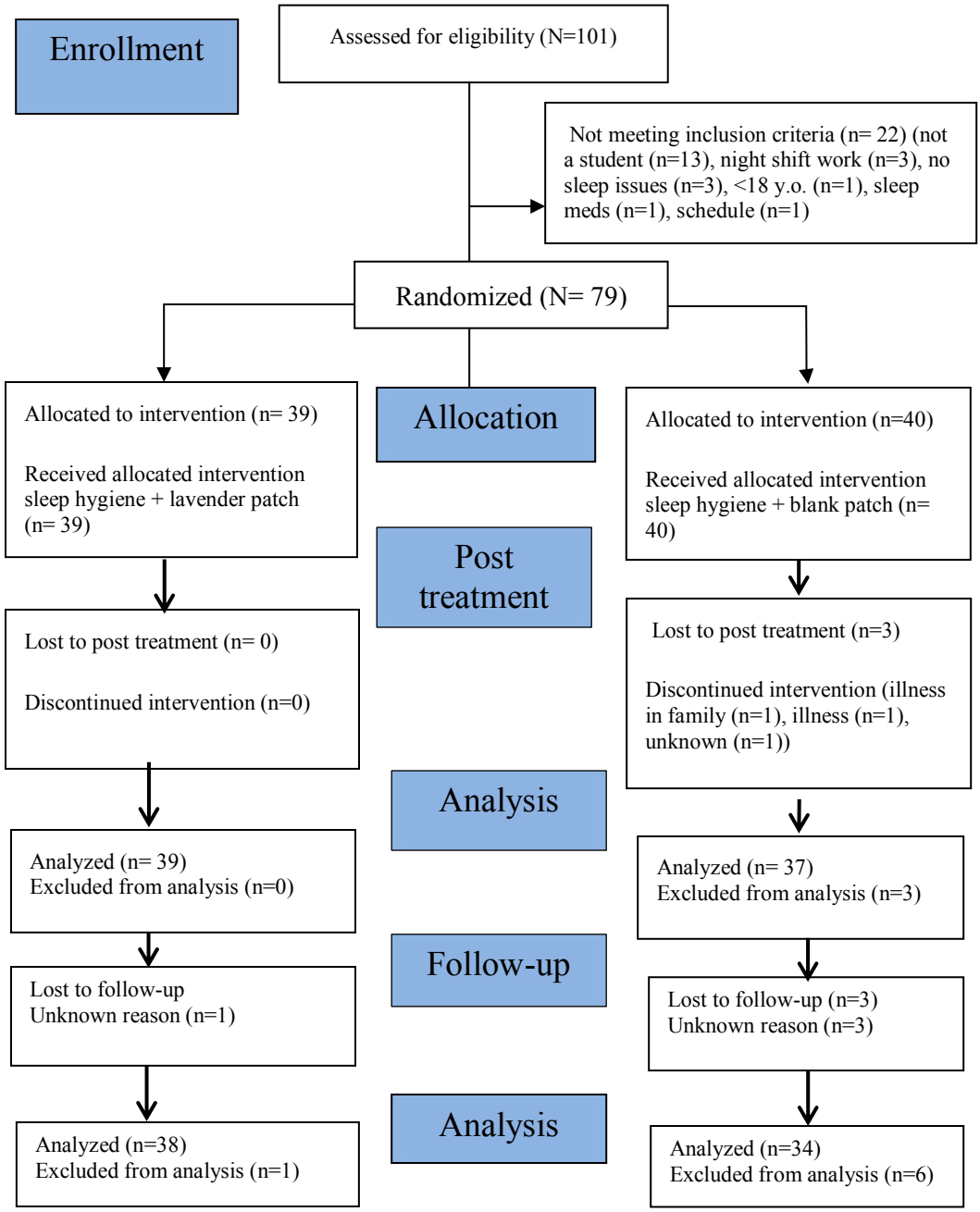


Figure 5.*Sleep Study Flow Diagram*

Note. From The Consort Group. (2010). Flow diagram. Retrieved 2/18, 2014, from http://www.consort-statement.org/consort-statement/flow-diagram0/

Demographics. The overall sample was about two thirds female and one third male, the mean age was 21.6, and the majority of participants were White and not Hispanic or Latino (Table 8). Most participants did not report a health condition. The mean age for the lavender and sleep hygiene group was 20.9 (range of 18 to 28 years) and for the sleep hygiene only group the mean age was 22.1 (ranges of 18 to 36 years) (t-test p-value =.09). The two groups were similar, with the treatment group being slightly younger and having a slightly higher percentage of males, of Asians and not Hispanic or Latinos and reporting fewer health issues. Race was the only demographic factor for which there was a statistically significant difference between groups.

Table 8

Demographics of the Sample by Group

Characteristic	**Lavender + sleep hygiene (n=39)** **n** **%**	**Sleep hygiene only (n=40)** **n** **%**	**Total (n=79)** **n** **%**	**p-Value**
Gender: *Male*	14 36%	10 25%	24 30%	0.46[+]
Female	25 64%	29 73%	54 69%	
NA	0 0%	1 2%	1 1%	
Race: *White*	24 62%	29 73%	53 67%	0.02[++]
Black or African American	0 0%	2 5%	2 3%	
Asian	13 33%	4 10%	17 22%	
American Indian or Alaskan Native	0 0%	1 2%	1 1%	
Other	0 0%	1 2%	1 1%	
NA	2 5%	3 8%	5 6%	
Ethnicity: *Not Hispanic or Latino*	36 92%	31 78%	67 85%	0.34[++]
Hispanic or Latino	1 3%	3 7%	4 5%	
No response	2 5%	6 15%	8 10%	
***Health Conditions:** *No*	34 87%	29 73%	63 80%	0.18[+]
Yes	5 13%	11 27%	16 20%	

*Health conditions reported: depression (4), allergies (n=3), asthma (n=3), anxiety (n=2), ADHD (n=2), overweight (n=1), hypertension (n=1), epilepsy (n=1), cyclothymia (n=1), and vitamin D deficiency (n=1). Some participants reported more than one condition.

[+] Chi square

[++] Fisher's exact test

Fitbit, Patch, and Sleep Hygiene Compliance

Participants reported use of the patch and the Fitbit each morning following the intervention on the Daily Sleep Diary (Table 9). Although subjects reported wearing the Fitbit 365 cumulative person-nights (93%), Fitbit data were recoverable for only 57 person-nights (14%). This was despite assistance from Fitbit Support and additional instruction to the participants for each wave of the study. Participants were asked to return unused patches upon completion of the intervention and the number of unused patches returned was compared to the

reported use for each participant. The number of returned patches matched the use of the patch reported on the sleep diary except in two cases where no unused patches were returned and reported use of the patch was 3 of the 5 nights for one case and 4 of the 5 nights for the other case. Overall the number of unused patches returned at the end of the intervention validated the self-report. The quantitative sleep variables collected on the Fitbit tracker were also collected via self-report on the Daily Sleep Diary as a secondary measure.

Table 9

Patch and Fitbit Reported Use by Night (n=395 person-nights)

	Yes		**Yes, patch fell off**		**No**		**Missing**	
	Number of nights	%	Number of nights	%	Number of nights	**%**	Number of nights	%
Patch treatment (n=195)	120	61%	62	32%	3	2%	10	5%
Patch control (n=200)	103	51.5%	84	42%	1	5%	12	6%
Patch total (n=395)	223	56%	146	37%	4	1%	22	6%
Fitbit treatment (n=195)	182	93%			4	2%	9	5%
Fitbit control (n=200)	183	92%			5	2%	12	6%
Fitbit total (n=395)	365	93%			9	2%	21	5%

Sleep hygiene practices were assessed at pre-treatment, post treatment and at follow up with the Sleep Hygiene Survey. Exploration of the frequency distributions, the means, and the ranges for the Sleep Hygiene Survey questions on specific sleep hygiene practices highlighted a couple of trends. For the individual Sleep Hygiene Survey questions, the frequency distributions

displayed a trend towards better sleep hygiene for both groups from pre-treatment to post treatment and then a shift back towards the pre-treatment level at follow-up, but still improved over pre-treatment scores (Appendix O). The sleep hygiene total score illustrated this general trend, with the mean score for both groups at pre-treatment, post treatment and follow-up, 42.7 (range of 20 to 76), 23.2 (range of 0 to 54), 31.5 (range of 3 to 58) respectively, indicating better sleep hygiene during the intervention (Table 10). The scores between groups were tested for statistically significant differences at pre-treatment, post treatment and follow-up. No statistically significant difference between groups was found (p=0.64, 0.51, and 0.79 respectively).

Table 10

Sleep Hygiene Survey Total Score Frequencies and Means

Group	**Time**	**Mean**	**Std. Deviation**	**Minimum**	**Maximum**	**N**
Lavender + sleep hygiene	Pre	42.72	11.54	20	76	39
	Post	23.16	11.88	4	45	38
	follow-up	31.47	11.07	7	57	36
Sleep hygiene	Pre	41.53	10.79	22	66	40
	Post	21.39	11.34	0	54	38
	follow-up	32.23	12.53	3	58	35
Total	Pre	42.11	11.12	20	76	79
	Post	22.28	11.57	0	54	76
	follow-up	31.85	11.73	3	58	71

Use of sleep aids

Information on the use of sleep aides was obtained from the PSQI. The term sleep aid was not defined in the question the participants answered. One of the exclusion criteria for the study was use of prescription sleep medication and it is not known whether reported use of sleep aids includes prescription sleep medication. However twelve participants (lavender and sleep hygiene group (n= 2), sleep hygiene only group (n=10)) reported using sleep aides at pre-

treatment, post treatment, and follow-up (Table 11). The number of nights of reported sleep aid use was higher at pre-treatment (n=11) than post treatment (n=5) and follow-up (n=7).

Table 11

Use of Sleep Aids (not specified as to type in response)

	Pre-treatment	**Post treatment**	**Follow-up**	**Total**
Lavender and sleep hygiene group: # nights used sleep aid				
1	1	0	1	2
2	0	0	0	0
3	1	0	0	1
Sub-total	2	0	1	3
Sleep hygiene only group: # nights used sleep aid				
1	4	0	1	5
2	2	2	2	6
3	3	3	3	9
Sub-total	9	5	6	20
Total	11	5	7	23

Adverse Effects

Participants were asked to report any adverse effect they experienced with use of the patch, the Fitbit, or sleep hygiene practices each morning following the intervention on the sleep diary. Only a few minor adverse effects were reported including irritation, rash, or tingling/warmth at patch site (n=4), stuffiness in nose (n=1), and itchiness in throat (n=1). All adverse effects were reported for one night only. Four participants reported the scent as annoying, although one of these participants was in the sleep hygiene only group.

Results in Relation to Study Aims

Data collected on all instruments were analyzed to identify significant predictors on the various outcomes, holding all else constant. The lavender and sleep hygiene group and the sleep hygiene group were the primary variables of interest, with gender and age as secondary variables of interest. Daily Sleep Diary variable scores were collected only during the five

mornings following the interventions; therefore no follow-up scores were available. The Daily Sleep Diary variables were added to the models as either weighted sums or percentages to obtain one composite score for the five nights of intervention. The outcomes related to sleep quantity or sleep quality are outlined below. Post treatment occurs immediately at the end of the five nights of intervention, and follow-up is 19 days later (5 nights of intervention plus the two week follow-up). Descriptive statistics including frequencies, means, ranges and distributions were completed for each outcome variable and models for analysis were selected based on distribution, characteristics of the data, and number of assessment points, as identified in the data analysis section (Table 6 and Table 7).

Results for aim 1. To compare the effectiveness of *L. angustifolia* inhalation and sleep hygiene versus sleep hygiene alone on sleep quantity as measured by number of minutes in bed, number of minutes asleep, sleep efficiency, time to fall asleep, and awakenings. Initially the Daily Sleep Diary responses for these variables were graphed for 10 participants who had at least one night of data from the Fitbit with mixed results (Appendix P). As previously noted, the Fitbit data were too limited to be used for analysis.

Total Time in Bed (TTB). No difference in total time in bed was identified between groups (p=0.37). There was a statistically significant association between age, with younger students reporting greater TTB (p=0.009). The pre-treatment Sleep Hygiene Score was close to being significant, for every unit decrease in SHS score at pre-treatment (better sleep practices at baseline), holding all else constant, there was an increase in TTB (p=0.05) or those with better sleep hygiene practices at pre-treatment had more TTB (Table 12). Being female was also close to being significant (p=.05), with being female associated with longer TTB. Age was the only significant finding for Total Time in Bed, with being younger associated with longer TTB.

Table 12

Total Time in Bed (TTB) Post Treatment Model

Variable	Estimate	St Error	P-Value
Lavender + sleep hygiene group	-11.07	12.28	0.37
Time (Days)	3.90	2.33	0.10
Gender (Female)	24.08	12.46	0.05
Age (years)	-3.74	1.43	0.009
Patch worn all night	-15.95	8.61	0.06
Pre Sleep hygiene score	-1.25	0.64	0.05
Post Sleep hygiene score	-0.49	0.56	0.38

Total Sleep Time (TST). Similar results were found for TST, with no differences in the TST between groups (p=0.37). And there was a significant association between age and TST, with younger students reporting longer TST. The pre-treatment Sleep Hygiene Score was close to being significant, for every unit decrease in SHS score at pre-treatment (better sleep practices at baseline), holding all else constant, there was an increase in TST (p=0.05) or those with better sleep hygiene practices at pre-treatment had more TST (Table 12). Being female was also close to being significant (p=.05), with being female associated with longer TST. In addition to age, the other statistically significant predictor of TST was the number of minutes to fall asleep, with shorter time to fall asleep associated with increased TST (p<0.001) (Table 13).

Table 13

Total Sleep Time (TST) Post Treatment Model

Variable	Estimate	St Error	P-Value
Lavender + sleep hygiene group	-11.02	12.19	0.37
Time (Days)	4.01	2.37	0.09
Gender (Female)	23.75	12.30	0.05
Age	-3.71	1.44	0.01
Patch worn all night	-15.79	8.57	0.07
Pre Sleep hygiene score	-1.24	0.64	0.05
Post Sleep hygiene score	-0.50	0.55	0.37
Minutes to fall asleep	-0.94	0.23	<0.001

Sleep Efficiency (SE). Sleep efficiency (number of minutes asleep/number of minutes in bed) was explored using the Daily Sleep Diary responses. There was little variability with a majority of the results near 100%, as might be expected given the similarity between TTB and TST for the sample. Additionally SE was explored using PSQI scores. Models of SE based on PSQI scores at post treatment and at follow-up also did not show any significant findings, confirming the SE results found on the Daily Sleep Diary.

Times Awakened (TA). No difference in TA was identified between the treatment groups (p=0.22) (Table 14). Time was associated with TA (RR of .92, p=0.02). Both groups were associated with fewer awakenings over time. There was also statistically significant findings for treatment*time interaction (RR=.87, p=.02). Both groups were associated with fewer awakenings over time with the lavender and sleep hygiene group associated with fewer awakenings compared to the sleep hygiene only group over time. Additionally the RR of having more awakenings for those who fell asleep easily was 0.65 that of someone who did not fall asleep easily. Those who fell asleep easily were less likely to have awakenings (RR=0.65, p<0.001).

Table 14

Times Awakened Post Treatment Model

Variable	Relative Risk	95%Lower CI	95% Upper CI	P-Value
Lavender + sleep hygiene group	1.29	0.86	1.93	0.22
Time (Days)	0.92	0.86	0.99	0.02
Gender (Female)	1.07	0.74	1.57	0.71
Age	0.99	0.94	1.04	0.73
Patch worn all night	0.90	0.74	1.10	0.30
Pre-Sleep hygiene score	1.00	0.98	1.01	0.74
Post Sleep hygiene score	1.00	0.99	1.02	0.68
Falls Asleep Easily	0.65	0.55	0.75	<0.001
Treatment-Time Interaction	0.87	0.78	0.98	0.02

Time To Sleep (TTS)/Falls asleep easily. The number of minutes to fall asleep (TTS) did not vary by treatment group (RR=1.10, p=0.45)**.** Time was not a significant factor (RR=1.00, p=0.880). And age and gender were not associated. The only variable that had a significant finding was falls asleep easily (RR=0.41, p<0.001). Those who fell asleep easily fell asleep in fewer minutes. The number of minutes it takes to fall asleep may be a difficult variable to collect on self-report, as it can be difficult to track minutes in the wake to sleep transition. The variable falls asleep easily was explored as a potentially more valid way to self-report difficulty falling asleep. Adjusting for other variables, time was found to be significant, with an odds ratio of 1.37 (p=0.01), meaning it is likely for both groups to fall asleep more easily over time (Table 15).

Table 15

Falls Asleep Easily Post Treatment Model

Variable	Odds Ratio	95% Lower CI	95 Upper CI	P-Value
Lavender + sleep hygiene group	1.03	0.61	1.73	0.92
Time (Days)	1.37	1.16	1.62	0.001
Gender (Female)	0.88	0.49	1.59	0.67
Age (years)	0.99	0.94	1.04	0.76
Patch worn all night	1.28	0.79	2.07	0.32
Pre-Sleep hygiene score	1.01	0.99	1.04	0.34
Post Sleep hygiene score	0.99	0.97	1.02	0.53

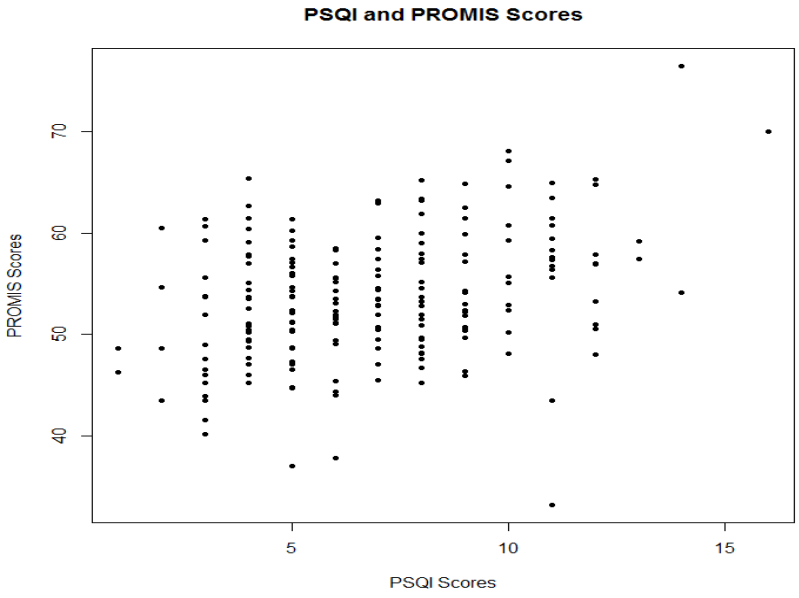
Summary of findings for aim 1. Sleep quantity scores were analyzed only at post treatment as the outcome data were collected following the five nights of intervention. Treatment over time was found to be a predictor of awakenings, with both groups having fewer awakenings over time, but with the sleep hygiene only group to a lesser extent as compared to the lavender and sleep hygiene group. Time was significant for falls asleep easily; both groups had significant findings for falling asleep easier over time. Difference between treatment groups was not found to be significant predictor for total sleep time, total time in bed, sleep efficiency, number of times awakened, or falling asleep easily. Age was found to be a significant predictor for total time in bed and total sleep time in a negative direction.

Results for aims 2 and 3. To compare the effectiveness of sleep hygiene versus sleep hygiene and *L. angustifolia* on subjective sleep quality at post treatment and follow-up as measured by satisfaction, waking feeling refreshed and daytime sleepiness and dysfunction.

Sleep Quality. Overall sleep quality was measured both by the global PSQI scores and the total PROMIS Sleep disturbance SF8b scores as well as questions about sleep quality related to satisfaction, feeling refreshed upon awakening and daytime sleepiness and dysfunction. Although both PSQI global score and the PROMIS SD SF8b total score both measure sleep quality, there are some different measures included in the global or total scores. The PSQI

global score, in addition to sleep quality, also includes measures of sleep latency (time to fall asleep), sleep duration, habitual sleep efficiency, sleep disturbance, use of sleep medications, and daytime functioning. The PROMIS total score includes measures sleep disturbance in addition to quality.

The global scores for the PSQI and the total scores for the PROMIS SD SF8b were compared visually by scatter plot and a correlation coefficient was calculated for strength and direction of relationship, only a slight positive correlation was found (correlation coefficient=0.33) (Figure 6). Even though both instruments measure sleep quality, there was little apparent correlation found due to the different variables included in the global and total scores.



Correlation coefficient: 0.33

Figure 6. *PROMIS Sleep Disturbance SF 8b vs. PSQI correlation scatter plot.*

PSQI global score. The lavender and sleep hygiene group was found to have better sleep quality than the sleep hygiene only group at both post treatment and follow-up, with being in the lavender and sleep hygiene group corresponding to a 1.24 and a 1.65 decrease in the

PSQI score (better sleep quality) for post treatment and follow-up, respectively. SHS scores were also a significant predictor of sleep quality in these two models. For pre-treatment SHS scores at both post treatment and follow-up, a one unit increase in SHS pre-treatment scores corresponded to a .06 decrease in PSQI global score ($p=0.02$ and <0.001), where those with poorer pre-treatment sleep hygiene practices were associated with a slightly better quality of sleep at post treatment and follow-up. For SHS post treatment scores, a one unit increase in SHS scores corresponded to 0.05 ($p=0.02$) increase in PSQI global score at post treatment, where higher SHS (worse scores) post treatment scores were found be significant predictors for slightly worse sleep and conversely better sleep practices was associated with better sleep quality (Tables 16 and 17). Time was not significant however there was a significant treatment-time interaction associated with poorer sleep quality at follow-up ($p=0.02$). There was a slight increase in PSQI scores (worse sleep quality) for the lavender and sleep hygiene from post treatment to follow-up, which could be explained by the fact that this group decreased (improved) their scores to a greater degree at post treatment compared to the sleep hygiene only group and then had a greater increase to return to the follow-up PSQI scores. The difference between mean PSQI scores for the two groups was less at follow-up than at post treatment (Table 16).

Falls asleep easily was associated with sleep quality at post treatment, where a one unit increase in falls asleep easily resulted in a 3.26 decrease in PSQI scores ($p<0.001$). No daytime sleepiness was also found to be significant predictors of sleep quality at follow-up. Those with no daytime sleepiness had lower or better PSQI global sleep scores at follow-up ($p=0.04$).

The mean global score at baseline for the both groups was 8.45, for the lavender and sleep hygiene group it was 8.16 and for the sleep hygiene only group it was 8.73 (Appendix Q). The difference between groups was not statistically significant ($p=0.8$).

In the administration of the PSQI post treatment, eight participants (lavender and sleep hygiene group (n=2), sleep hygiene group (n=6)) inadvertently received the two week version of the PSQI. Questions asked for responses over the past two weeks, rather than over the past one (intervention) week, however, all participants were verbally instructed that the post treatment assessment was related to the intervention week so the actual effect on response may have been minimal.

Table 16

PSQI Global Score Post Treatment Model

Variable	**Estimate**	**Std. Error**	**P-Value**
Lavender + sleep hygiene group	-1.24	0.43	0.01
Gender (Female)	-0.29	0.50	0.57
Age (years)	0.02	0.05	0.77
Pre PSQI score	0.61	0.10	0.00
Pre Sleep hygiene score	-0.06	0.02	0.02
Post Sleep hygiene score	0.05	0.02	0.02
Falls asleep easily	-3.26	0.86	0.00
Patch worn all night	2.20	2.59	0.40
Patch fell off	1.87	2.71	0.49

Table 17

PSQI Global Score for Post Treatment and Follow-up Model

Variable	Estimate	Std. Error	P-Value
Lavender + sleep hygiene group	-1.65	0.49	<0.001
Time	-0.002	0.03	0.94
Gender (Female)	-0.25	0.43	0.55
Age (years)	-0.04	0.05	0.39
Pre PSQI score	0.58	0.08	<0.001
Pre Sleep hygiene score	-0.06	0.02	0.002
Post & FU Sleep hygiene score	0.03	0.02	0.06
Falls asleep easily	-3.12	0.76	<0.001
No daytime sleepiness	-1.98	0.69	0.004
Patch worn all night	1.76	1.86	0.34
Patch fell off	2.24	1.86	0.23
Treatment*Time Interaction	0.07	0.03	0.02

PROMIS Total Score. The PROMIS Sleep Disturbance was modeled in the same way as the PSQI scores with (Tables 18 and 19). Lavender and sleep hygiene group was again found to be a significant predictor of sleep quality. Being in the lavender and sleep hygiene group compared to the sleep hygiene only group corresponded to a 1.78 (p=0.04) and 1.47 (p=0.007) decrease in PROMIS scores (better scores) for post treatment and follow-up respectively, holding all else constant. Sleep hygiene scores were also found to be significant predictors of sleep quality. The sleep hygiene pre-treatment scores were inversely related to follow-up PROMIS scores with a unit increase in sleep hygiene scores corresponding to a 0.08 (p=0.008) decrease in PROMIS score. For the SHS post treatment and follow-up scores, for every 1 unit increase in the sleep hygiene score, there was a corresponding 0 .09 (p=0.03) and 0.08(p=0.03) increase in PROMIS score, and conversely better SHS scores corresponded to better sleep quality at post treatment and follow-up.

At pre-treatment, falling asleep easily was associated with a lower PROMIS score ($p<0.001$) and times awakened was associated with a higher PROMIS score ($p=0.005$). At follow-up additional variables were found to be significant predictors of sleep quality. Falling asleep easily, being refreshed upon awakening, and not having daytime sleepiness were negatively associated with sleep quality ($p=0.03$, $p=0.04$, $p=0.04$). Falling asleep easily, feeling refreshed on awakening, and lack of daytime sleepiness, were associated with lower (better) PROMIS scores. Time to sleep and number of times awakened were positively associated with sleep quality ($p=0.04$, $p<0.001$), with longer time to fall asleep and more awakenings associated with higher (worse) PROMIS scores.

Table 18

PROMIS Total Score for Post Treatment Model

Variable	**Estimate**	**Std. Error**	**P-Value**
Lavender + sleep hygiene group	-1.78	0.83	0.04
Gender (Female)	0.22	0.96	0.82
Age (years)	-0.12	0.10	0.24
Pre PROMIS Score	0.40	0.10	<0.001
Pre-Sleep hygiene score	-0.04	0.05	0.37
Post-Sleep hygiene score	0.09	0.04	0.03
Falls asleep easily	-7.01	1.77	<0.001
Times Awakened	0.17	0.06	0.005
Patch worn all night	0.61	4.97	0.90
Patch fell off	-0.05	5.24	0.99

Table 19

PROMIS Total Score for Post Treatment and Follow-up Model

Variable	Estimate	Std. Error	P-Value
Lavender + sleep hygiene group	-1.47	0.54	0.007
Time	0.01	0.05	0.90
Gender (Female)	0.66	0.69	0.34
Age (years)	-0.14	0.09	0.12
Pre PROMIS Score	0.32	0.07	<0.001
Pre Sleep hygiene score	-0.08	0.03	0.008
Post & FU Sleep hygiene score	0.08	0.04	0.03
Time To Sleep	0.01	0.01	0.04
Falls asleep easily	-4.08	1.82	0.03
Times Awakened	0.17	0.04	<0.001
Refreshed upon awakening	-4.02	1.94	0.04
Slightly refreshed upon awakening	-2.75	1.54	0.08
No daytime sleepiness	-3.28	1.60	0.04
Patch worn all night	3.40	3.34	0.31
Patch fell off	4.14	3.47	0.23

Lavender and sleep hygiene and sleep hygiene alone were significant predictors of sleep quality for both the PSQI global score and the PROMIS total score at both post treatment and follow-up. Lavender and sleep hygiene was a stronger predictor of sleep quality than sleep hygiene alone.

Satisfied, Refreshed, Daytime Sleepiness and Dysfunction. Several specific questions were used to estimate the association between the variables of interest and the outcomes of satisfied with sleep, refreshed upon awaking, daytime sleepiness and dysfunction on sleep. Being satisfied with sleep was measured using responses to PROMIS question 2 (In the past 7 days I was satisfied with my sleep: Not at all, a little bit, somewhat, quite a bit, very much.). Waking feeling refreshed was measured by Daily Sleep Diary question 6 (When I woke up for the day I felt: refreshed, somewhat refreshed, fatigued.) Daytime sleepiness and daytime function were measured by PSQI question 8 (During the past 2 weeks/1 week, how often have

you had trouble staying wake while driving, eating and engaging in social activity?: not at all, less than once a week, once or twice a week, three or more times a week) and question 9 (During the past 2 weeks, how much of a problem has it been for you to keep up enough enthusiasm to get things done?: not at all, less than once a week, once or twice a week, three or more times per week) respectively. Each of these will be reported separately.

The model for satisfaction at post treatment could not be used for analysis because the distribution of the responses did not allow for appropriate estimation. At follow-up, the lavender and sleep hygiene group and sleep hygiene only group were not found to be significant predictors for satisfied with sleep (Table 20). Feeling somewhat refreshed had a very high odds ratio at follow-up, indicating that those who feel somewhat refreshed upon wakening were more satisfied with their sleep (OR=8.03, p=0.04). Fewer times awakened was also associated with higher odds of being satisfied with sleep (OR=.95, p=0.03). And pre-treatment sleep hygiene scores were associated with slightly higher odds of sleep satisfaction at follow-up (OR=1.05, p=0.03).

Table 20

Sleep Satisfaction Post Treatment and Follow-up Model

Variable	**Odds Ratio**	**95% Lower CI**	**95% Upper CI**	**P-value**
Time	0.98	0.93	1.03	0.40
Lavender + sleep hygiene group	1.71	0.77	3.82	0.19
Pre-Satisfied w/sleep (a little bit)	2.31	0.84	6.36	0.10
Pre-Satisfied w/sleep (somewhat)	7.09	2.02	24.90	0.002
Gender (Female)	0.48	0.19	1.20	0.12
Age	1.04	0.93	1.16	0.50
Patch worn all night	0.90	0.03	31.66	0.95
Patch fell off	0.99	0.02	51.92	0.99
Pre-Sleep hygiene score	1.05	1.00	1.09	0.03
Post & FU-Sleep hygiene score	0.97	0.93	1.01	0.12
Somewhat refreshed	8.03	1.13	57.39	0.04
Total Sleep Time	0.99	0.98	1.00	0.01
Times Awakened	0.95	0.91	0.99	0.03

In the analysis of feeling refreshed upon awakening, the lavender and sleep hygiene group was found to have a statistically significant association with waking feeling refreshed. At post treatment the lavender and sleep hygiene group was found to more likely wake feeling refreshed compared to the sleep hygiene group. Those in the lavender and sleep hygiene group had 1.87 greater odds indicating feeling refreshed than those in the sleep hygiene only group ($p=0.01$) (Table 21). Time was also significant (OR=1.18, $p=.03$), with both groups having slight odds of waking feeling refreshed. Sleep hygiene scores were not associated with feeling refreshed upon wakening. Being refreshed was also found to be associated with time to sleep (OR= .99, $p<0.001$) and daytime sleepiness (OR=.45, $p=0.003$) in a negative direction, where those with longer times to fall asleep and more daytime sleepiness were less likely to feel refreshed.

Table 21

Waking Refreshed Post Treatment Model

Variable	**Odds Ratio**	**95% Lower CI**	**95% Upper CI**	**P-value**
Lavender + sleep hygiene group	1.87	1.15	3.03	0.01
Time	1.18	1.02	1.37	0.03
Age	1.01	0.97	1.05	0.56
Gender (Female)	1.32	0.71	2.47	0.38
Wore Patch All Night	1.00	0.63	1.59	0.99
Pre-Sleep hygiene score	1.01	0.98	1.04	0.50
Post-Sleep hygiene score	0.99	0.97	1.01	0.32
Total Sleep Time	1.80	1.51	2.15	<.0001
Time to Fall Asleep	0.99	0.97	1.00	0.004
Daytime sleepiness	0.45	0.27	0.77	0.003

No relationship was found between daytime sleepiness and treatment group (p=0.45) (Tables 22 and 23). Sleep hygiene scores were significant with pre-treatment hygiene scores having an odds ratio of 0.91 (p=0.003) and .94 (p=0.001) at post treatment and follow-up respectively and post treatment and follow-up sleep hygiene scores having in odds ratio of 1.07 (p=0.03) and 1.05 (p-0.03) at post treatment and follow-up. Those with higher pre-treatment hygiene scores have slightly higher odds of daytime sleepiness and those with higher sleep hygiene scores for post treatment and follow-up have slightly lower odds for daytime sleepiness. However the odds ratio for all the sleep hygiene scores were close to 1 indicating there is little effect on odds of daytime sleepiness. Gender and age were found to be significant predictors on daytime sleepiness. Females have a higher odds of daytime sleepiness than males with an odds ratio of 2.8 at follow-up (p=0.04). And older students have an odds ratio of 0.86 (p=.040) for daytime sleepiness, with being older associated with less daytime sleepiness at post treatment, with a similar odds ratio at follow-up (OR=.90, p=0.01). At follow-up feeling refreshed on awakening was statistically significant with an odds ratio of .05 (p=.01) that

indicates those who feel refreshed on awakening have slightly lower odds to feel daytime sleepiness.

Table 22

Daytime Sleepiness Post Treatment Model

Variable	**Odds Ratio**	**95% Lower CI**	**95% Upper CI**	**P-value**
Lavender + sleep hygiene group	0.63	0.19	2.08	0.45
Pre-Trouble w/daytime sleepiness (< 1 x week)	0.86	0.12	6.26	0.88
Pre-Trouble w/daytime sleepiness (1-2 x week)	3.09	0.64	14.96	0.16
Pre-Trouble w/daytime sleepiness (> 3 x week))	93.36	10.11	862.12	<.0001
Gender (Female)	3.22	0.76	13.63	0.11
Age	0.86	0.74	0.99	0.04
% Nights Patch Worn All Night	0.01	0.00	3.28	0.12
% Nights Patch Fell Off	0.01	0.00	7.49	0.18
Pre-Sleep hygiene score	0.91	0.85	0.97	0.003
Post-Sleep hygiene score	1.07	1.01	1.13	0.03
No daytime sleepiness	0.003	0.0001	0.16	0.004
Refreshed	0.04	0.001	2.03	0.11
Somewhat refreshed	0.02	0.001	0.28	0.004

Table 23

Daytime Sleepiness Post Treatment and Follow-up Model

Variable	Odds Ratio	95% Lower CI	95% Upper CI	p-value
Time	1.03	0.98	1.09	0.26
Lavender + sleep hygiene group	0.92	0.45	1.89	0.83
Pre-Trouble w/daytime sleepiness (< 1 x week)	2.89	0.91	9.20	0.07
Pre-Trouble w/daytime sleepiness (1-2 x week)	4.85	1.58	14.91	0.006
Pre-Trouble w/daytime sleepiness (> 3 x week)	59.81	11.25	318.02	<.0001
Gender (Female)	2.80	1.04	7.51	0.04
Age	0.90	0.83	0.98	0.01
Patch worn all night	0.61	0.02	22.43	0.79
Patch fell off	0.36	0.01	19.33	0.62
Pre- Sleep hygiene score	0.94	0.91	0.98	0.001
Post & FU-Sleep hygiene score	1.05	1.00	1.10	0.03
Refreshed	0.05	0.00	0.49	0.01
Somewhat refreshed	0.04	0.01	0.25	0.001

The lavender and sleep hygiene group was less likely to report daytime dysfunction at both post treatment (p=0.02) and follow-up (0.009) (Tables 24 and 25). For the lavender and sleep hygiene group, the odds of indicating daytime dysfunction were 0.18 at post treatment and 0.33 at follow-up, indicating that the lavender and sleep hygiene group was less likely to feel daytime dysfunction, compared to the sleep hygiene only group. At follow-up the treatment-time interaction was significant with the treatment group over time having a slightly higher odds of daytime dysfunction (OR=1.10. p=0.03). There was a slight increase in daytime dysfunction for the lavender and sleep hygiene group at follow-up, which could be explained by the fact that the difference between the two treatment groups was less at follow-up than it was at post treatment. Time was also significant at follow-up (OR=.93, p=0.06), with both groups having slightly lower odds of daytime dysfunction over time. Pre-treatment sleep hygiene scores were

not significant in this model at post treatment or follow-up (p=0.12, p=.23) and the post-treatment and follow-up sleep hygiene scores were also not significant (p=.67, p=.09).

Total sleep time was a significant predictor of daytime dysfunction at both post treatment and follow-up, those with higher total sleep times having slightly lower odds of daytime dysfunction at post treatment (OR=.86, p=0.006) and follow-up (OR=.99, p=0.02). At follow-up lack of daytime sleepiness was significant for daytime dysfunction, with those reporting no daytime sleepiness having lower odds for daytime dysfunction (OR= 0.15, p=0.02).

Table 24

Daytime Dysfunction (Ability to Keep Up Enthusiasm to Get Things Done) Post Treatment Model

Variable	**Odds Ratio**	**95% Lower CI**	**95% Upper CI**	**P-value**
Lavender + sleep hygiene group	0.33	0.13	0.84	0.02
Pre-Keep up enthusiasm (only slight problem)	6.02	0.63	57.41	0.12
Pre-Keep up enthusiasm (somewhat of a problem)	18.68	1.82	192.06	0.01
Pre-Keep up enthusiasm (Very big problem))	206.25	15.17	2803.15	<.0001
Gender (Female)	1.56	0.52	4.72	0.43
Age	0.96	0.85	1.09	0.56
% Nights Patch Worn All Night	0.08	0.0003	27.33	0.40
% Nights Patch Fell Off	0.26	0.001	121.15	0.67
Pre-Sleep hygiene score	0.96	0.91	1.01	0.12
Post-sleep hygiene score	1.01	0.96	1.06	0.67
Total Sleep Time	0.86	0.77	0.96	0.006

Table 25

Daytime Dysfunction (Ability to keep up enthusiasm to get things done) Post Treatment and Follow-up Model

Variable	Odds Ratio	95% Lower CI	95% Upper CI	P-value
Time	0.93	0.86	1.00	0.06
Lavender + sleep hygiene group	0.18	0.05	0.66	0.009
Time*Treatment Interaction	1.10	1.01	1.20	0.03
Pre-Keep up enthusiasm (only slight problem)	12.06	1.09	132.99	0.04
Pre-Keep up enthusiasm (somewhat of a problem)	28.04	2.61	301.33	0.006
Pre-Keep up enthusiasm (Very big problem))	190.7	14.21	2559.33	<.0001
Gender (Female)	0.84	0.38	1.82	0.66
Age	0.98	0.89	1.08	0.75
Patch worn all night	0.35	0.00	49.35	0.68
Patch fell off	1.35	0.01	226.69	0.91
Pre sleep hygiene score	0.97	0.93	1.02	0.23
Post & FU-sleep hygiene score	1.03	1.00	1.07	0.09
No daytime sleepiness	0.15	0.03	0.71	0.02
Total Sleep Time	0.99	0.99	1.00	0.02

***Summary of Findings for Aims 2 and 3*.** The lavender and sleep hygiene group and sleep hygiene scores were found to be significant predictors of overall sleep quality, with lavender and sleep hygiene having a greater effect compared to sleep hygiene only. Additionally, the lavender and sleep hygiene group was more likely to wake feeling more refreshed and have less daytime dysfunction at post treatment and follow-up. Sleep hygiene score was found to be a significant predictor of daytime sleepiness, with lower sleep hygiene scores at post treatment and follow-up associated with less daytime sleepiness. Age and gender were significant predictors of outcome for daytime sleepiness, with being female and younger associated with more daytime sleepiness.

Aim 4. To investigate the effect of *L. angustifolia* inhalation and sleep hygiene on self-assessment of change for the well-being domains of physical, emotional, cognitive, social, spiritual, and the overall whole person using the Self-Assessment of Change survey.

Sleeping Well and Dimensions of Well-being. The Self-Assessment of Change tool with a retrospective pre-test format included data on self-assessment of sleeping well (e.g. How well were you sleeping "Before and Now") at post treatment and again at follow-up. The change scores were modeled for post treatment and follow-up for exploratory purposes. No significant findings were noted for the post treatment model. However the lavender and sleep hygiene group, compared to the sleep hygiene only group, approached significance ($p = 0.059$) in association with better sleep. The lavender and sleep hygiene group was found to be a statistically significant predictor in the follow-up model, with being in the treatment group, compared to the sleep hygiene only group corresponding to a 7.40 increase in unit change score for sleeping well, holding all else constant ($p=0.02$). Falls asleep easily was also found to be significant in a positive direction at follow-up ($p=0.003$) (Table 26).

Table 26

Sleeping well (Self-Assessment of Change) for Post Treatment and Follow-up Model

Variable	Estimate	St. Error	P-Value
Lavender + sleep hygiene	7.40	3.22	0.02
Time	-0.43	0.27	0.12
Gender (Female)	-1.31	3.87	0.73
Age	0.13	0.37	0.73
Pre-Sleep hygiene score	0.20	0.16	0.21
Post & FU-Sleep hygiene score	-0.31	0.17	0.07
Falls asleep easily	18.80	6.35	0.003
Total Sleep Time	-0.04	0.02	0.08
Patch worn all night	-24.89	18.43	0.18
Patch fell off	-18.56	19.95	0.35

An exploratory analysis of each question on the Self-Assessment of Change survey was completed. Statistically significant findings between treatment groups for the questions on sleep (p=0.013), energy (0.027), and vibrancy (0.049) were found at post treatment. These specific traits were all included in the broader well-being domain of "physical" with energy also falling under "whole person". The question on calm was close to being significant between groups at post treatment (p=0.059) (Table 27 and Appendix R).

Mean change cores were graphed by group and assessment period for each question. The lavender and sleep hygiene group trended higher at post treatment than at follow-up for change scores on most domains and trended higher than the sleep hygiene only group for each assessment period (Figure 7). The sleep hygiene only group also trended higher at post treatment than at follow-up.

Table 27

Self-Assessment of Change Item Pairs and Domains with Statistically Significant Beneficial Findings for Lavender and Sleep Hygiene Compared to Sleep Hygiene Only at Post treatment.

Key: Statistically significant ▢ Close to significant ▨

Whole person (word pairs)		**Physical (word pairs)**		**Cognitive (word pairs)**		**Affective (word pairs)**		**Social (word pairs)**		**Spiritual (word pairs)**	
Exhausted	Energized	Not sleeping well	Sleeping well	Scattered	Focused	Hopeless	Hopeful	Closed-hearted	Open-hearted	Hopeless	Hopeful
Overwhelmed	Empowered	Exhausted	Energized	Blaming	Forgiving	Depressed	Joyful	Isolated	Connected	Blaming	Forgiving
Broken	Whole	Dull senses	Vibrant senses	Defined by my problems	Not defined by my problems	**Anxious**	**Calm**			Closed-hearted	Open-hearted
		My body does not recover quickly	My body recovers quickly							Isolated	Connected
										Broken	Whole

Note. Adapted from Ritenbaugh et al. (2011). Developing a patient-centered outcome measure for complementary and alternative medicine therapies I: Defining content and format. *BMC Complementary & Alternative Medicine, 11*, 135.

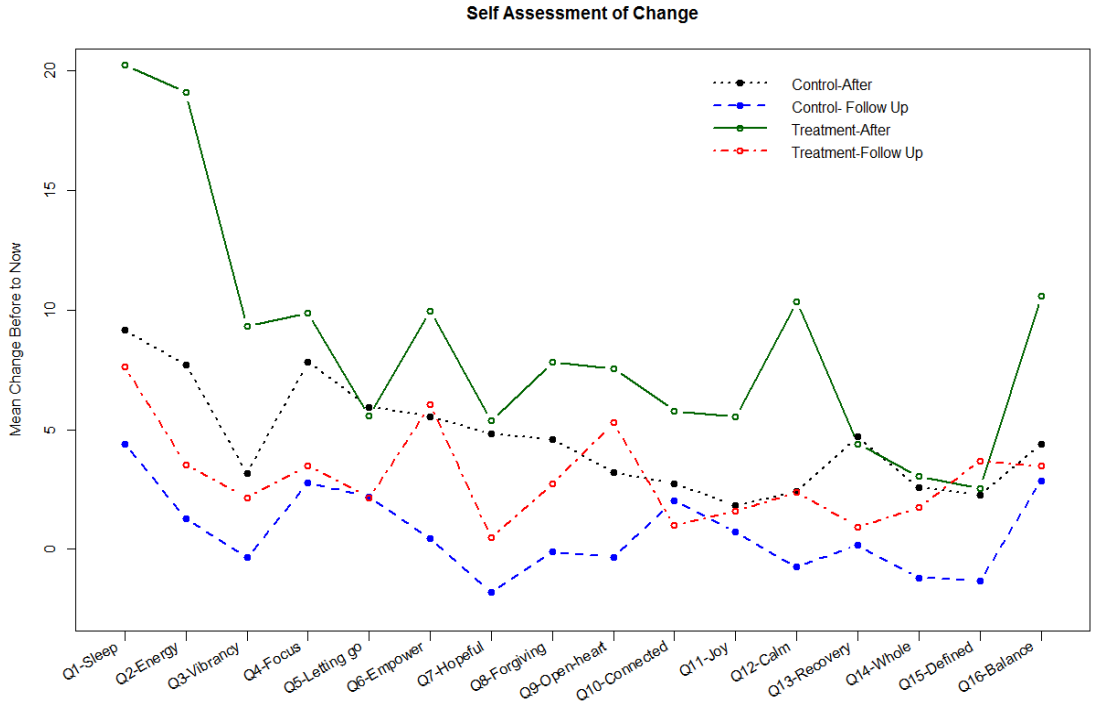


Figure 7. SAC Change Scores by Group and Assessment Period

Overall Summary of Findings for Sleep Quantity and Quality. Lavender and sleep hygiene and sleep hygiene alone were significant predictors for sleep quality outcomes at both post treatment and follow-up, including global/total scores and the outcomes of satisfaction, waking refreshed, daytime sleepiness and daytime dysfunction. The lavender and sleep hygiene group reported a greater effect compared to the sleep hygiene only group for most of the outcomes (better sleep quality, felling refreshed on awakening, and less daytime dysfunction). Sleep hygiene and lavender and sleep hygiene were also found to be significant predictors of sleep quantity as measured by reported times awakened after the intervention period and sleep hygiene alone was associated with falls asleep easily. Both groups reported fewer times awakened. Sleep variables were also found to be significant predictors of other sleep outcomes.

For example, the only sleep variable that was found to be a predictor of daytime sleepiness was waking feeling refreshed. Both total sleep time and daytime sleepiness were found to be significant predictors of daytime dysfunction, with more total sleep time associated with less daytime dysfunction and more daytime sleepiness associated with more daytime dysfunction. The only sleep variable that was found to be associated with better sleep on the Self-Assessment of Change survey was falls asleep easily.

Open-ended questions

In addition to the above analyses, several open-ended questions were asked. Two of the questions were related to sleep disturbances: 1) (Daily Sleep Diary) "My sleep was disturbed by (list any factors that disturbed your sleep)" and 2) (PSQI) "During the past 2(1) week, how often have you had trouble sleeping because you….Other reason(s), please describe". The "other reasons" referred to any reasons other than those already listed in previous questions such as cannot go to sleep in 30 minutes, wake in the middle of the night or early morning, have to use the bathroom , cannot breathe comfortably, cough or snore loudly, feel too cold , feel too hot, had bad dreams , or have pain. At follow-up an additional open-ended question was asked: "Please provide any additional feedback about your participation in this study regarding the aromatherapy patch, the Fitbit One tracker, the sleep hygiene practices or any of the questionnaires."

Sleep Disturbance. The most common factors for sleep disturbance reported on the sleep diary for the 5 nights of intervention were roommates (n=31), noise other than roommates (n= 29), uncomfortable (restless, too hot, too cold etc.) (n=26), stress and worry (n=21), and presence of the patch (lavender and sleep hygiene group (n=14), sleep hygiene only group (n=3)). Interruptive factors reported on the PSQI were collected at pre-treatment, post treatment, and follow-up. There were more responses to the questions that listed specific sleep disturbance factors for checking off than to the open-ended questions, with a range responses from n=29

(cough or snore) to n=188 (wake in the middle of the night or early AM). Additional factors listed on the PSQI were similar to those listed on the sleep diary except that the presence of the patch was only mentioned twice on the PSQI (lavender and sleep hygiene group (n=1), sleep hygiene only group (n=1)). The number of pre-listed sleep disturbance factors checked off was higher at post treatment assessment than pre- treatment and follow-up. For the open-ended questions, responses were similar for the sleep diary and the PSQI.

Open-ended question at follow-up. Thirty six participants responded to the study follow-up assessment/open-ended question: "Please provide any additional feedback about your participation in this study regarding the aromatherapy patch, the Fitbit One tracker, the sleep hygiene practices or any of the questionnaires". Sixteen of the respondents were in the lavender and sleep hygiene group and 20 in the sleep hygiene only group. Responses were grouped into categories of like responses. Response was placed in more than one category if appropriate (Table 28).

Table 28

Responses to Open-ended Questions at Follow-up: "Please provide any additional feedback about your participation in this study regarding the aromatherapy patch, the Fitbit One tracker, the sleep hygiene practices or any of the questionnaires."

Response category	**Sleep hygiene only (n=20)**	**Lavender + sleep hygiene (n=18)**	**Total (n=38)**
Sleep hygiene helpful	2	5	7
Sleep hygiene not helpful	0	0	0
Liked smell of patch	0	2	2
Did not like smell of patch	0	1	1
Patch helpful	1	2	3
Patch not helpful/no difference	1	0	1
Patch fell off	4	4	8
Blinding an issue with aromatherapy	1	1	2
Overall intervention helpful	3	1	4
Overall intervention not helpful /no difference	3	0	3
Issues with intervention (mouth breather, had to change what usually wore to bed, stomach sleeper)	2	1	3
Other (questions not clear, longer study would be better, better Fitbit instructions, would like results)	3	1	4

Summary of Results

The sample for this study was two thirds female, one third male, the majority White, with a mean age of 21.6 years with race being a statistically significant difference between groups. Retention was very good with few dropouts, yielding a study sample with adequate power for analysis. The lavender and sleep hygiene group and the sleep hygiene only group were found to be associated with better sleep quality, with the lavender and sleep hygiene having a greater effect compared to the sleep hygiene only group. This was determined by both the PSQI global score and the PROMIS total score at post treatment and follow-up. The

lavender and sleep hygiene group demonstrated a clinical effect for improved sleep quality based on the PSQI. In addition, the lavender and sleep hygiene group was found to be a significant predictor of fewer awakenings and waking more refreshed at post treatment and less daytime dysfunction at post treatment and follow-up. Both groups were associated with fewer awakenings and falling asleep easily over time. Sleep hygiene scores were associated with less daytime sleepiness at post treatment and follow-up.

The Self-Assessment of Change scores questions were analyzed using exploratory statistics. Sleeping well was modeled and showed a trend toward a significance effect for lavender and sleep hygiene compared to sleep hygiene only at post treatment and significance at follow-up. In addition to better sleep, improvement in energy and vibrancy were found for the lavender and sleep hygiene group at post treatment. Graphing of mean change scores by group and assessment time displayed a trend of the lavender and sleep group to have better change scores compared to the sleep hygiene only group at both post treatment and follow-up and to have better post treatment change scores than follow-up (Figure 7).

Responses to open-ended questions for sleep disturbances and study feedback were summarized. A wide variety of sleep disturbances were reported in response to the open-ended questions and the PSQI questions regarding specified sleep disturbances. Feedback on the study from participants included several comments about the intervention being helpful or not, and several specific comments about the intervention and the assessments. These comments would be helpful in future studies of this type.

Chapter 5: Discussion

The purpose of this study was to determine the value of inhaled lavender for addressing sleep issues among college students. This goal was addressed by a RCT with participant and investigator blinding that examined the effect of inhaled *L. angustifolia* and sleep hygiene compared to sleep hygiene alone on college students with sleep issues. Results were positive for both lavender and sleep hygiene. The group receiving lavender demonstrated improved sleep quality at post treatment and follow-up and the sleep hygiene only group also demonstrated improved sleep quality but to a lesser extent. For sleep quantity, both groups were associated with fewer awakenings and falling asleep more easily over time. Few minor adverse effects were noted and there was a high rate of adherence to the intervention, suggesting lavender and sleep hygiene as a safe, easy and effective intervention for sleep.

Sample

The ability to recruit 79 out of the targeted 80 participants and the flow of the majority of the participants through the study allowed for an adequately powered study. The sample size from pre-treatment to follow-up remained higher than the sample size estimation, allowing for accurate statistical tests that were able to detect effects of a given size in this study.

This sample was comprised of students with self-reported sleep issues based on the inclusion/exclusion criteria. Although the definition of sleep issues or insomnia is based on self–report, the PSQI instrument used in the study allowed some confirmation of the presence of sleep issues. On the PSQI, a global score greater than 5 out of a possible 21 is indicative of sleep issues. The mean PSQI global score for lavender and sleep hygiene group was 8.2 (range is 4-13), for the sleep hygiene only group 8.7 (range is 2-16) and for the total sample 8.5 (range is 2-16). The self-report of sleep issues was validated by the mean PSQI scores for both groups at pre-treatment, although not all participants had PSQI scores less than 5.

Randomization as participants entered the study into two groups created similar treatment and control groups from a demographic perspective. Race was the only demographic variable that was found to be significant for difference between groups.

The total sample was one third male and two thirds female with a mean age of 21.6 years, two thirds of the sample was White and most were not Hispanic or Latino. There were few reported health conditions. Other than gender the sample seemed representative of the Midwest college students (The College Board, 2013). Overrepresentation with females was present in other essential oil and sleep studies where convenience samples were obtained (Diego et al., 1998; Hirokawa et al., 2012). This could be related to women typically reporting more sleep issues and perhaps being more open to using aromatherapy than men.

Treatment Integrity

Three issues affecting treatment integrity were identified and explored during the research process: the patch falling off during the night, the lack of Fitbit data, and participant and investigator blinding. Participants were asked to report the use of patch and whether it stayed on all night on the sleep diary. "Patch fell off" was not found to be a statistically significant predictor on any of the outcomes. This could be due to the fact that the inhalation of lavender might continue, even if the patch fell off the chest, as long as it is still near the sleeping participant. Alternatively the inhalation of lavender at the beginning of the night, before the patch fell off, may have provided enough of a dose response for lavender to be a statistically significant predictor of sleep quality. Originally, the sleep quantity data collected on the daily sleep diary was to be a second indicator of sleep quantity, with the Fitbit collecting sleep quantity data based on movement rather than self-report. Despite most participants reporting wearing the Fitbit One tracker most nights, there were little data available. Multiple attempts were made to resolve the problem with the Fitbit support staff and to increase Fitbit training for participants in each successive wave, however the amount of data collected wave to wave did

not increase. Possible reasons for the lack of Fitbit data were user error and a Fitbit firmware update that appeared, according to the company, to cause problems with data gathering and synchronization. This was identified as an issue after completion of the study. Therefore sleep diary data became the single source of the quantitative sleep data. Although not an objective measure, self-report of sleep quantity on sleep diaries has been found to be more reliable than actigraphy, which measures sleep based on movement similar to the Fitbit tracker (Levenson et al., 2013; Montgomery-Downs et al., 2012). Comparison of these two methods for measuring sleep quantity was not possible with the lack of Fitbit data, but the sleep diary was considered a reliable source of sleep quantity information. Neither the patch falling off nor the lack of Fitbit tracker data appeared to compromise the study.

Blinding was a challenge and whether the participants remained blinded throughout the study is not known. One participant commented at post treatment that he knew he was in the control group because he could not smell the essential oil. He was told that the patches had different amounts of oil because it was not known how much was needed for an effect, the same statement that was read to each interested respondent in describing the study. No other participants commented to the investigator on their group assignment, but two participants commented about the difficulty of blinding in this study on the open-ended question at follow-up. The investigator was able to remain blinded by not looking at the data collected during the study, not keeping a list of the group assignment with the other information being tracked, and not opening any of the stamped patches.

Additionally compliance with sleep hygiene practice was explored with the Sleep Hygiene Survey. The questionnaire collected information on individual sleep practices (e.g. use of caffeine, screen time at bed time, etc.) at pre-treatment, post treatment and follow-up. There was positive trending in all sleep practices from pre-treatment to post treatment and then a trend back to pre-treatment practices at follow-up. This suggests that participants did follow the sleep

hygiene guidelines to a greater extent during the intervention and that these practices tapered off after completion of the intervention. This may have implications for ongoing sleep hygiene education in the population.

Adverse Effects

A few minor adverse effects were reported, all regarding skin irritation at the site of the patch. Of note four participants reported that the scent of the patch was too strong/annoying (Lavender and sleep hygiene group n=3, sleep hygiene group n=1).The report of a participant in the sleep hygiene only group finding the scent annoying may imply that the blinding protocol was effective for some participants.

Aim 1 Discussion

The focus of aim 1 was the effect of lavender and sleep hygiene on sleep quantity measures which included: total time to bed, total sleep time, sleep efficiency, times awakened, and time to sleep. Both groups were found to be associated with fewer times awakened and falling asleep more easily over time. Neither group was associated with total time in bed, total sleep time or sleep efficiency as measured by the PSQI and the sleep diary. Age was found to be a significant predictor for total time in bed and total sleep time in a negative direction. In general little effect on sleep quantity outcomes was demonstrated by lavender and sleep hygiene.

The mechanisms of action of the interventions of lavender and sleep hygiene on sleep are not known. The results of the sleep quantity analysis based on the sleep diary are of interest in regards to which variables were associated and which were not. This could have implications for future research into target of treatment effect and mechanism of action.

Aims 2 and 3 Discussion

Aims 2 and 3 addressed the outcomes of the sleep quality variable. Sleep quality improved in both groups. There was a difference in overall sleep quality between the lavender

and sleep group and the sleep hygiene only group in the PSQI global score and the PROMIS sleep disturbance SF8b total score, with the lavender group having a greater effect compared to the sleep hygiene only group. Both groups demonstrated a within person effect over time in addition to the between group effect with better scores at post treatment compared to pre-treatment and follow-up and better scores at follow-up compared to pre-treatment. Thus, both lavender and sleep hygiene were significant predictors for sleep quality, with the addition of lavender yielding better sleep quality than sleep hygiene alone.

A score greater than five signifies poor sleep quality on the PSQI and a change of three is considered to be a clinical effect. The pre-treatment mean PSQI scores for the lavender and sleep hygiene group and the sleep hygiene only group were 8.2 and 8.7, respectively (Appendix Q). Both groups had mean PSQI scores that were greater than five at pre-treatment, indicating poor sleep quality. While both groups had significant findings for better sleep quality at post treatment and follow-up, the lavender and sleep hygiene group at post treatment had a mean PSQI score of 4.9, while the sleep hygiene only group had a mean PSQI score of 6.5, indicating normal sleep on average at post treatment for the lavender group. The mean change from pre- to post treatment for the lavender and sleep hygiene group was 3.2, which indicates a clinical effect for the lavender group. No clinical effect was demonstrated for the sleep hygiene only group. The participants, on average, had sleep issues as defined by the PSQI score at pre-treatment. The lavender and sleep hygiene group fell into the normal range for the PSQI and the sleep hygiene did not and a clinical effect was seen for the lavender and sleep hygiene group based on mean change scores.

In addition to overall sleep quality, sleep quality was explored with survey items on sleep satisfaction, refreshed upon awakening, daytime sleepiness, and the presence of daytime dysfunction. Compared to the sleep hygiene alone group, lavender and sleep hygiene group reported waking feeling more refreshed and less daytime dysfunction, Sleep hygiene scores

were associated with less daytime sleepiness. Age and being male were also associated with more daytime sleepiness. In addition waking feeling refreshed was a significant predictor of less daytime sleepiness as well. Overall, better sleep quality was found to be associated with the lavender and sleep hygiene group compared to the sleep hygiene only group. The sleep hygiene only group also experienced better sleep quality, but to a lesser extent than lavender and sleep hygiene.

Aim 4 Discussion

Aim 4 measured multi-dimensional shifts in overall well-being using the Self-Assessment of Change survey. It was included in the study to identify the extent of perceived changes in order to capture the multi-dimensional shifts in well-being that can occur with integrative therapies. The change in sleep score was significantly higher for the lavender and sleep hygiene group at follow-up, indicating that the treatment group perceived that they had a greater positive change in sleep at follow-up compared to the sleep hygiene only group. The association approached significance at post treatment as well. In analysis of each self-assessment of change variables, higher mean change scores were found in the lavender and sleep hygiene group compared to the sleep hygiene only group at both post treatment and follow-up. This suggests that lavender may have an effect on the dimensions of well-being, in addition to sleep. Statistically significant change in two of these variables, energy and vibrancy, were found in the lavender and sleep hygiene group at post treatment, with the question regarding calm almost statistically significant. The sleep hygiene only group also had positive mean change scores for most questions at post treatment and continued to report change at follow-up, although some of the changes for the sleep hygiene only group at follow-up were changes in a negative direction. All the change scores remained in a positive direction for the treatment group. This exploratory analysis suggests that lavender had a positive effect on sleep and a positive and balancing effect on well-being at post treatment and follow-up, with positive

change being greater at post treatment. A trend towards positive change was also found in the sleep hygiene group at post treatment, but to a lesser extent, and both positive and negative change scores were found at follow-up in that group.

Sleep Disturbance

Fewer sleep disturbances were identified in the open question format than when participants were asked about a specific sleep disturbance on the PSQI. This suggests difficulty in recalling sleep disturbances if not prompted. The sleep disturbances identified included roommates, noise, being uncomfortable, and stress. These findings would be expected for college students, but present a reminder of how many sleep disturbance factors occur for college students. In addition participants reported that the intervention itself, wearing the patch and specifically having it fall off, created sleep disturbances. All of these sleep disturbances likely influenced quality of sleep during the study.

Open-ended Question at Follow-up

The open-ended question at follow-up attempted to capture additional comments that might be helpful in a future study. Overall, more participants responding to this question thought the intervention was helpful than not helpful. Some participants reported liking the smell of the lavender and some reported not liking it, suggesting a study using more than one essential oil for sleep might be appropriate. Comments were made about the patch falling off, which coincided with the report on the daily sleep diary. Comments also were made about the patch and its impact on sleep patterns in regards to clothing worn (n=1), sleep positions (n=1) and mouth breathing (n=1). Sleep patterns like these may have also affected participants' ability to inhale the lavender, as well as disturbing their sleep. The patch provides a standardized way to deliver aromatherapy, however for future studies, better ways of securing it should be explored such as using tape and/or have a stronger adhesive backing. Additionally males with hair on their chest may need to be willing to shave a spot for the patch. Sleep patterns that are

not conducive to wearing an inhalation patch, such as those listed above, could be added to the exclusion criteria and participants screened for them prior enrollment in a study. Other comments included unclear questions on the surveys (n=1), a suggestion for a longer study (n=1), a request for better Fitbit instructions (n=1) and a request for the results (n=1). These comments would be good to consider in future studies. In addition to providing results to participants at the end of the study, it may be beneficial to debrief participants on group assignments and provide information about lavender to control group participants after the study period.

Discussion in relation to the literature

The findings of this study included both within person change and between group change in sleep quantity and quality over time, with the lavender group demonstrating better sleep quality over time. These findings are supported by the small number of studies on lavender and sleep (Arzi et al., 2009; Cannard, 1996; Chien et al., 2012; Cho et al., 2013; Goel et al., 2005; Hardy & Kirk-Smith 1995; Hirokawa et al., 2011; Hudson, 1996; Lewith et al., 2005; Lytle et al. 2014; Moeini et al., 2010; Stringer & Donald, 2011) These findings were summarized by Lillehei and Halcón (in press). The literature on sleep hygiene in college students also supports the findings of this study (Brown et al., 2002; Brown, Walter et al., 2006; Orzech et al., 2011; Rothenberger Institute, 2012; Suen et al., 2008; Tsai & Li, 2004). The ease of recruitment and participant compliance in the study support the literature in regards to the prevalence of sleep issues, specifically in college students.

Additionally, aromatherapy appears to be one IHH intervention that could be used to address sleep issues in a holistic way. Both sleep hygiene and lavender inhalation may have affected sleep by addressing predisposing factors, precipitating factors, and perpetuation factors that can disrupt the usual mechanism of sleep (Léger & Bayon, 2010). This study adds a blinded

RCT to the literature on the effect of inhaled essential oils and sleep hygiene on sleep. Gaps in the literature were also addressed by inclusion of the chemical analysis of the essential oil and inclusion of a follow-up assessment at two weeks post treatment. There is little research on the long term effects for lavender and sleep hygiene interventions. Additionally, no published research has assessed multi-dimensional shifts in well-being on interventions for sleep. This study produced some significantly positive findings for the lavender and sleep hygiene group on sleep quality at follow-up, although scores seemed to drift back towards pre-treatment levels after the intervention was completed. The lavender group trended towards a higher change score than the sleep hygiene only group for well-being dimensions measured, according to the results of the Self-Assessment of Change survey. Additional studies of the effects over time and of multi-dimensional shifts in well-being would help to determine if these findings can be replicated.

The RCTs identified in the review of the use of inhaled essential oils and sleep support the use of objective and subjective measures of sleep. In this study, the objective measure of sleep, data collected by the Fitbit One tracker using movement as a proxy for sleep, were missing and inconsistent and therefore could not be used in the analysis. However, the literature does support the use of the sleep diary for the quantitative sleep measures (Levenson et al., 2013). Additionally sleep quality has been found to have a higher correlation with measures of health and well-being in college students than sleep quantity (Pilcher, Ginter & Sadwosky, 1997; Pilcher & Ott, 1998). Overall the results of this study are supported by the literature and this study addresses gaps in the literature in the areas of follow-up, documentation of essential oil chemical constituency analysis and exploration of multi-dimensional effects of well-being.

General discussion

These results support the value of lavender essential oil and sleep hygiene on sleep quality and the methods improved on those of previous studies. Methodological strengths

included the measures to ensure essential oil treatment integrity, recruitment approaches, study flow, the reporting of adverse effects, participant adherence to the study protocol, and the use of standard sleep measurement tools (PSQI and the sleep diary) along with the newer PROMIS sleep disturbance SF 8b and the Self-Assessment of Change survey. Use of the Fitbit One tracker data would have added to the internal validity of the study; however the Daily Sleep Diary tool has been validated as a sleep quantity measure and it was completed for a majority of participant-nights during the intervention. Adding all instruments to the Assessment Center and scheduling participants for their assessment periods assisted with the study flow.

A positive association for the lavender and sleep hygiene group and the sleep hygiene group on sleep quality were demonstrated by both the PSQI and the PROMIS sleep disturbance tool, results with the lavender and sleep hygiene group having a greater effect than the sleep hygiene only group. The concurrence between the two tools adds to the strength of the findings. The lavender and sleep hygiene group reached a clinical effect at post treatment, and their scores moved from poor quality to good quality sleep based on the PSQI. This did not occur with the sleep hygiene only group. The lavender and sleep hygiene group also reported feeling more refreshed on awakening and less daytime dysfunction. Better sleep hygiene scores were associated with less daytime sleepiness. The Sleep Hygiene Survey pre-treatment score was a statistically significant predictor of several outcomes in different directions. High sleep hygiene scores at pre-treatment were found to be a significant predictor of both poor and good sleep quality and quantity. The finding of poorer sleep hygiene scores at pre-treatment being associated with better sleep quality may be due to having a greater chance to improve sleep when the participant starts out with poor sleep hygiene. The greater change in mean score from pre-treatment to post treatment than from post treatment to follow-up, with follow-up remaining higher than pre-treatment, suggests that participants increased their use of sleep hygiene

practices during the intervention and decreased them after the intervention, but continued to practice more sleep hygiene than they did prior to the intervention.

There were few significant findings in the quantitative sleep outcomes. However both groups had fewer awakenings over time and fell asleep more easily over time. These findings suggest that both the lavender and sleep hygiene group and the sleep hygiene only group experienced a positive effect on sleep quantity and sleep quality outcome measures, although lavender and sleep hygiene was found to be a more effective for improving sleep quality than sleep hygiene alone. The effect on sleep quality was robust, with a more marginal effect on sleep quantity.

The assessment of self-reported change (SAC) demonstrated a positive shift in well-being by both treatment interventions, with a greater effect for the lavender and sleep hygiene group. The findings of the Self-Assessment of Change were supported by the findings from the other sleep measures; lavender has a positive association with sleep quality and feeling refreshed upon awakening.

Of interest was the finding of the association of the two groups with some of the same sleep outcomes and also with some unique ones. For example the variables total sleep time and the lavender and sleep hygiene group compared to the sleep hygiene only group were statistically significant for waking refreshed and daytime dysfunction. Total sleep time was not a significant finding for daytime sleepiness and sleep hygiene score was significant. This suggests that sleep hygiene and lavender work at similar and unique points in the sleep cycle, perhaps affecting different predisposing, precipitating and perpetuating factors and by helping to re-balance or create a shift in the system. The effect for both interventions studied seemed to last to some degree over time. At two week follow-up there was some improvement remaining for both groups on the outcome of sleep quality, with lavender having a greater effect at follow-up as well as at post treatment. Improved sleep quality was sustained after the intervention

period, although to a lesser extent. The lavender and sleep hygiene and the sleep hygiene may have assisted with some re-balancing in the sleep-wake cycle that lasted over time. More research is needed to determine the mechanisms of action of lavender and sleep hygiene on sleep. Sleep is a complex system and much is still unknown, however sleep hygiene and lavender together, and sleep hygiene alone to a lesser degree, appear to be effective and safe interventions for college students with self-reported sleep issues.

Use of a basic sleep education tool along with inhaled lavender essential oil provides an effective, low cost, accessible option for sleep issues. Both sleep hygiene and lavender can be added to the box of tools for addressing sleep issues and moving from stuck to unstuck in the complex system of sleep. Having a variety of self-care options for sleep allows for individual intervention based on personal characteristics and preferences and the environment.

Chapter 6: Limitations

External validity

This convenience sample of students from a large Midwestern University was representative of the overall student population except in gender, with more females than males included in the sample. This difference in proportion of females to males in relationship to the overall student population limits the generalizability of the study to the overall college population. However, females have been found to be more likely than males to identify themselves as having sleep issues in general. This could be explored in future studies in order to better assess generalizability. Having the study setting be that of the participants' normal sleep setting, rather than a sleep laboratory, increased the external validity. The groups were similar from a demographic perspective at baseline except for race which created an imbalance across groups.

Internal validity

Although steps were taken to increase internal validity, several limitations need to be considered. A controlled experimental design, like this RCT study with participant and investigator blinding, promotes internal validity by minimizing experimenter bias, selection bias, and regression toward the mean. However threats to internal validity for this study included possible selection bias, and self-report bias. Selection bias was controlled for with the randomization process and comparison of the demographics between the two groups. However there may have been an unidentified difference between the two groups that interacted with the dependent variable that was not anticipated. The internal validity could also have been compromised due to self-report bias. With the inability to use the Fitbit tracker information for objective data, all data were collected via questionnaires with self-report responses. As noted previously, the Fitbit trackers recorded limited sleep data despite participants reporting a high

rate of use. Action was taken to resolve the issue by additional instruction to participants and working with Fitbit support. However, due to what appeared to have been a Fitbit firmware update issue and potentially some user error, not enough data was collected. Measures were taken to decrease the effect of self-report on the internal validity including use of: standardized tests, concurrent testing with different instruments measuring similar outcomes for comparison of response scores, and retrospective pre-test design. Additionally, the confidentiality of responses was stressed to the participants through the informed consent process and confidentiality was maintained throughout the study.

Although self-report has been identified as a potential limitation of this study, with the use of quantitative measure the gold standard for scientific research, the knowledge of the importance of the patient or participant report in research is gaining along with its acceptance as a valid primary measure. The NIH funding of the Patient Reported Outcome Management Information System (PROMIS) is evidence of this trend.

Internal validity was addressed by the study design and the study protocol but some possible limitations remain. These are addressed below.

Other Limitations

Other limitations include the patch falling off and the blinding procedure. The patch falling off frequently may have compromised internal validity; however, it was not a significant finding for any of the variables measured. The intervention itself, wearing a patch, can be disruptive to the quality of sleep, possibly limiting the effect of the intervention. The smell of the lavender also compromised the blinding of the study, although participants were told that there were different amounts of essential oil on the patch for each group in order to minimize this as a limitation. Additionally, the administration of the two week PSQI survey in place of the one week PSQI to a small number of participants at post treatment was also a limitation, but

correct verbal instructions along with the small number of participants affected minimized the impact. These limitations need to be taken into account along with the internal and external validity limitations.

The limitations of this design were balanced by the strength of the RCT design and the steps taken to decrease the effect of bias, although internal validity issues remained. The patch falling off may have compromised the standardization of dose/duration for the participants in the lavender and sleep hygiene group. An even greater effect may have been observed with an absolutely known and consistent dose of lavender and without the patch falling off and possibly disturbing the sleep of the participants.

Chapter 7: Conclusions and Recommendations

Conclusions

This RCT with participant and investigator blinding examined the effect of inhaled *L. angustifolia* and sleep hygiene on college students with sleep issues and found statistically significant associations for between groups and within person over time. Results were largely positive. The group receiving lavender demonstrated improved sleep quality at post treatment and follow-up and the sleep hygiene only group also demonstrated improved sleep quality but to a lesser extent. Additionally a clinical effect was found for the lavender and sleep hygiene group. The lavender and sleep hygiene group was also associated with waking feeling refreshed. A positive association with sleep quantity was also found for both groups, but it was nominal. Lavender and sleep hygiene, and again to a lesser extent sleep hygiene alone, were also found to be positively associated with dimensions in well-being change scores, suggesting a beneficial effect on well-being.

This participant and investigator blinded RCT study addressed key gaps in the literature. Studies in essential oils and sleep, sleep hygiene, and sleep in college students, and best practices to address sleep issues in college students are small in numbers and this study adds to the literature in these areas. Lavender and sleep hygiene offer safe, accessible and effective self-care interventions for self-reported sleep issues in college students.

Implications and Recommendations for Nursing Practice and Research

The mechanism of action for lavender and sleep hygiene are not known, however this study did find a positive association between these interventions and the complex system of sleep. Conceptually, nursing has long recognized the significance of maintaining a balance between rest and activity for optimal functioning and based on Roy's adaptation theory, the role of the nurse as healer is to promote the ability of persons to affect health positively to enhance adaptation and interaction of person and environment based on a complex systems framework

(Roy, Tomey & Alligood, 1998). Sleep, as a balancing feedback loop, may get stuck leading to sleep issues and resulting co-morbidities. Nurses have a role in addressing the factors that influence the sleep cycle and promote good sleep through direct nursing interventions and through education of self-care interventions. Further research and new nursing practices in the area of sleep promotion and chronic insomnia prevention and treatment are needed. Nurses are uniquely positioned to address sleep issues in a variety of settings including schools and colleges and along the age continuum (Malone, 2011). The nurse functions as healer in the area of sleep issues through a framework of complex systems and the enhancement of adaptation for re-balancing, assisting in the assessment and intervention of the predisposing, precipitating and perpetuating factors related to sleep issues. Nursing's role in the ongoing research and practice in the healing benefits of essential oils, sleep hygiene, and other healing modalities to address sleep issues is critical.

Recommendations for Future Research

This study provides a strong base for a trajectory of sleep research using self-care and integrative therapies in non-clinical settings. Future research should include: using actigraphy or polysomnography as a sleep biomarker measure, using a better patch system or an alternative essential oil application, using different doses of essential oils, using other essential oils, combining essential oils with other integrative therapies, studying other populations and settings, and conducting longer interventions. Additionally, this study examined the effects of interventions on sleep over time by including follow-up assessments and also measured the whole person effect or the multi-dimension effect on well-being of the interventions. Both of these areas warrant further research. The mechanisms of action for lavender and for sleep hygiene are not known. Further exploration of which specific sleep outcomes are associated with each intervention may provide clues to the mechanism of action for sleep interventions. Similar studies should consider better control for blinding and for the use of sleep aids and

stratification by gender. Incorporating a debriefing at the end of the study to clear up any misleading information used for blinding purposes is also recommended. Participants were very interested in the results; therefore allowing participants to obtain results at the end of the study is suggested. There is much research to do in this area to find best practices to assist those with sleep issues to have better sleep and thereby improved physical, emotional and mental health.

Sleep is a remission, a release from the "constant continuity" of all
the threads which one is enmeshed while waking…..It is a form of time that leads us elsewhere than to the things we own or are told we need.

Jonathon Crary, 24/7

References

Ahrberg, K. (2012). The interaction between sleep quality and academic performance. *Journal of Psychiatric Research, 46*(12), 1618-1622. doi:10.1016/j.jpsychires.2012.09.008

Arzi, A., Sela, L., Green, A., Givaty, G., Dagan, Y., & Sobel, N. (2010). The influence of odorants on respiratory patterns in sleep. *Chemical Senses, 35*(1), 31-40.

Backhaus, J. (2002). Test-retest reliability and validity of the Pittsburgh Sleep Quality Index in primary insomnia. *Journal of Psychosomatic Research, 53*(3), 737-40. doi:10.1016/S0022-3999(02)00330-6

Badia, P., Wesensten, N., Lammers, W., Culpepper, J., & Harsh, J. (1990). Responsiveness to olfactory stimuli presented in sleep. *Physiology & Behavior, 48*(1), 87-90.

Battaglia, S. (2003). *The complete guide to aromatherapy* (Second ed.). Brisbane, Australia: The International Centre of Holistic Aromatherapy.

Bernert, R. A., Merrill, K. A., Braithwaite, S. R., Van Orden, K. A., & Joiner, T. E., Jr. (2007). Family life stress and insomnia symptoms in a prospective evaluation of young adults. *Journal of Family Psychology, 21*(1), 58-66.

Bootzin, R., & Epstein, D. (2011). Understanding and treating insomnia. *Annual Review of Clinical Psychology, 7*, 435-458.

Bowles, E. J. (2003). *The chemistry of aromatherapeutic oils* (Third edition ed.). Crowns Nest NSW, Australia: Allen & Unwin.

Boynton Health Service, University of Minnesota. (2012). *2012 college student health survey report: Health and health-related behaviors Minnesota postsecondary students*. Minneapolis: Regents of the University of Minnesota.

Brandt, N. J., & Piechocki, J. M. (2013). Treatment of insomnia in older adults: Re-evaluating the benefits and risks of sedative hypnotic agents. *Journal of Gerontological Nursing, 39*(4), 48-54.

Brown, F. C., Buboltz, W. C., Jr, & Soper, B. (2002). Relationship of sleep hygiene awareness, sleep hygiene practices, and sleep quality in university students. *Behavioral Medicine, 28*(1), 33-38.

Brown, F. C., Buboltz, W. C., Jr, & Soper, B. (2006). Development and evaluation of the sleep treatment and education program for students (STEPS). *Journal of American College Health, 54*(4), 231-237.

Buboltz, W. C., Jr, Brown, F., & Soper, B. (2001). Sleep habits and patterns of college students: A preliminary study. *Journal of American College Health, 50*(3), 131-135.

Buysse, D. (2013). Insomnia. *JAMA: The Journal of the American Medical Association, 309*(7), 706-716. doi:10.1001/jama.2013.193

Buysse, D. J., Ancoli-Israel, S., Edinger, J. D., Lichstein, K. L., & Morin, C. M. (2006). Recommendations for a standard research assessment of insomnia. *Sleep, 29*(9), 1155-1173.

Buysse, D. J., Reynolds, C., Monk, T., & Berman, S. & Kupfer, D. (1988). The Pittsburgh Sleep Quality Index: A new instrument for psychiatric practice and research. *Psychiatry Research, 28*, 192--213.

Buysse, D. J., Yu, L., Moul, D. E., Germain, A., Stover, A., Dodds, N. E., . . . Pilkonis, P. A. (2010). Development and validation of patient-reported outcome measures for sleep disturbance and sleep-related impairments. *Sleep, 33*(6), 781-792.

Cannard, G. (1996). The effect of aromatherapy in promoting relaxation and stress reduction in a general hospital. *Complementary Therapies in Nursing & Midwifery, 2*(2), 38-40.

Chien, L., Cheng, S., & Liu, C. (2012). The effect of lavender aromatherapy on autonomic nervous system in midlife women with insomnia. *Evidence-Based Complementary and Alternative Medicine, 2012*, 740813-740813. doi:10.1155/2012/740813

Cho, M., Min, E., Hur, M., & Lee, M. (2013). Effects of aromatherapy on the anxiety, vital signs, and sleep quality of percutaneous coronary intervention patients in intensive care units. *Evidence-Based Complementary and Alternative Medicine, 2013*, 381381-381381. doi:10.1155/2013/381381

Chong, Y., Fryar, C. & Gu, Q. (August, 2013). Prescription sleep aid use among adults: United States, 2005-2010. Retrieved 2/3/2014, 2014, from http://www.cdc.gov/nchs/data/databriefs/db127.pdf

Diego, M. A., Jones, N. A., Field, T., Hernandez-Reif, M., Schanberg, S., Kuhn, C., . . . Galamaga, M. (1998). Aromatherapy positively affects mood, EEG patterns of alertness and math computations. *International Journal of Neuroscience, 96*(3-4), 217-224.

Espie, C. (2002). Insomnia: Conceptual issues in the development, persistence, and treatment of sleep disorder in adults. *Annual Review of Psychology, 53*(1), 215-243.

Ferrie, J. E., Kumari, M., Salo, P., Singh-Manoux, A., & Kivimaki, M. (2011). Sleep epidemiology--a rapidly growing field. *International Journal of Epidemiology, 40*(6), 1431-1437.

Fismer, M., & Pilkington, K. (2012). Lavender and sleep: A systematic review of the evidence *European Journal of Integrative Medicine, 4*, e436--e447.

Flausino, N. H., Da Silva Prado, J. M., de Queiroz, S. S., Tufik, S., & de Mello, M. T. (2012). Physical exercise performed before bedtime improves the sleep pattern of healthy young good sleepers. *Psychophysiology, 49*(2), 186-192.

Ford, J. A., & McCutcheon, J. (2012). The misuse of Ambien among adolescents: Prevalence and correlates in a national sample. *Addictive Behaviors, 37*(12), 1389-1394.

Forquer, L. M., Camden, A. E., Gabriau, K. M., & Johnson, C. M. (2008). Sleep patterns of college students at a public university. *Journal of American College Health, 56*(5), 563-565.

Goel, N., Kim, H., & Lao, R. P. (2005). An olfactory stimulus modifies nighttime sleep in young men and women. *Chronobiology International, 22*(5), 889-904.

Goel, N., & Lao, R. P. (2006). Sleep changes vary by odor perception in young adults. *Biological Psychology, 71*(3), 341-349.

Goes, T., Antunes, F., Alves, P., & Teixeira-Silva, F. (2012). Effect of sweet orange aroma on experimental anxiety in humans. *Journal of Alternative & Complementary Medicine, 18*(8), 798-804. doi:10.1089/acm.2011.0551

Gross, C. R., Kreitzer, M. J., Reilly-Spong, M., Wall, M., Winbush, N. Y., Patterson, R., . . . Cramer-Bornemann, M. (2011). Mindfulness-based stress reduction versus pharmacotherapy for chronic primary insomnia: A randomized controlled clinical trial. *Explore: The Journal of Science & Healing, 7*(2), 76-87.

Hair, P. I., McCormack, P. L., & Curran, M. P. (2008). Eszopiclone: A review of its use in the treatment of insomnia. *Drugs, 68*(10), 1415-1434.

Hardy, M., Kirk-Smith, M. D., & Stretch, D. D. (1995). Replacement of drug treatment for insomnia by ambient odour. *Lancet, 346*(8976), 701.

Hicks, R. A., Johnson, C., & Pellegrini, R. J. (1992). Changes in the self-reported consistency of normal habitual sleep duration of college students (1978 and 1992). *Perceptual & Motor Skills, 75*(3 Pt 2), 1168-1170.

Hirokawa, K., Nishimoto, T., & Taniguchi, T. (2012). Effects of lavender aroma on sleep quality in healthy Japanese students. *Perceptual and Motor Skills, 114*(1), 111-122.

Hudson, R. (1996). The value of lavender for rest and activity in the elderly patient. *Complementary Therapies in Medicine, 4*, 52-57.

ISO International Standards. (2002). *Oil of lavender (Lavandula angustifolia mill.).* (No. ISO 3515:2002 (E)). Switzerland: International Organization for Standardization.

Jansson-Fröjmark, M., & Lindblom, K. (2008). A bidirectional relationship between anxiety and depression, and insomnia? A prospective study in the general population. *Journal of Psychosomatic Research, 64*(4), 443-449. doi:10.1016/j.jpsychores.2007.10.016

Johnson E.O., Roth, T., & Breslau, N. (2006). The association of insomnia with anxiety disorders and depression: Exploration of the direction of risk. *Journal of Psychiatric Research, 40*(8), 700-708. doi:10.1016/j.jpsychires.2006.07.008

Kessler, R., Berglund, P., Coulouvrat, C., Hajak, G., Roth, T., Shahly, V., . . . Walsh, J. (2011). Insomnia and the performance of US workers: Results from the America Insomnia Survey. *Sleep, 34*(9), 1161-1171. doi:10.5665/SLEEP.1230

Kleykamp, B. A., Griffiths, R. R., McCann, U. D., Smith, M. T., & Mintzer, M. Z. (2012). Acute effects of zolpidem extended-release on cognitive performance and sleep in healthy males after repeated nightly use. *Experimental & Clinical Psychopharmacology, 20*(1), 28-39.

Komada, Y., Nomura, T., Kusumi, M., Nakashima, K., Okajima, I., Sasai, T., & Inoue, Y. (2012). A two-year follow-up study on the symptoms of sleep disturbances/insomnia and their effects on daytime functioning. *Sleep Medicine, 13*(9), 1115-1121. doi:10.1016/j.sleep.2012.05.015

Kraus, S., & Rabin, L. (2012). Sleep America: Managing the crisis of adult chronic insomnia and associated conditions. *Journal of Affective Disorders, 138*(3), 192-212. doi:10.1016/j.jad.2011.05.014

Lack, L. C. (1986). Delayed sleep and sleep loss in university students. *Journal of American College Health, 35*(3), 105-110.

Léger, D., & Bayon, V. (2010). Societal costs of insomnia. *Sleep Medicine Reviews, 14*(6), 379-389. doi:10.1016/j.smrv.2010.01.003

Levenson, J., Troxel, W., Begley, A., Hall, M., Germain, A., Monk, T., & Buysse, D. (2013). A quantitative approach to distinguishing older adults with insomnia from good sleeper controls. *Journal of Clinical Sleep Medicine, 9*(2), 125-131. doi:10.5664/jcsm.2404

Lewith, G. T., Godfrey, A. D., & Phillip, P. (2005). A single-blinded, randomized pilot study evaluating the aroma of *Lavandula augustifolia* as a treatment for mild insomnia. *The Journal of Alternative and Complementary Medicine, 11*(4), 631-637.

Lillehei, A., & Halcón, L. (2014). A systematic review of the effect of inhaled essential oils on sleep. *The Journal of Alternative and Complementary Medicine.* doi: 10.1089/acm.2013.0311

Lund, H. G., Reider, B. D., Whiting, A. B., & Prichard, J. R. (2010). Sleep patterns and predictors of disturbed sleep in a large population of college students. *Journal of Adolescent Health, 46*(2), 124-132.

Lytle, J., Mwatha , C., & Davis, K. (2014). Effect of lavender aromatherapy on vital signs and perceived quality of sleep in the intermediate care unit: A pilot study. *American Journal of Critical Care, 23*(1), 24-29. doi:10.4037/ajcc2014958

Malone, S. K. (2011). Early to bed, early to rise?: An exploration of adolescent sleep hygiene practices. *Journal of School Nursing, 27*(5), 348-354.

Meadows, D. & Wright, D. (Ed.). (2008). *Thinking in systems*. USA: Sustainability Institute.

Moeini, M., Khadibi, M., Bekhradi, R., Mahmoudian, S., & Nazari, F. (2010). Effect of aromatherapy on the quality of sleep in ischemic heart disease patients hospitalized in intensive care units of heart hospitals of the Isfahan University of Medical Sciences. *Iranian Journal of Nursing and Midwifery Research, 15*(4), 234-239.

Montgomery-Downs, H. E., Insana, S. P., & Bond, J. A. (2012). Movement toward a novel activity monitoring device. *Sleep & Breathing, 16*(3), 913-917.

National Center for Complementary and Alternative Medicine, NIH. (2009). Sleep disorders and CAM: At a glance. Retrieved 04/12, 2013, from www.nccam.nih.gov/health/sleep/ataglance.htm

National Institutes of Health. (2011). *Sleep disorders research plan.* (No. NIH Publication No. 11-7820), National Institutes of Health.

National Institutes of Health, National Heart, Lung, and Blood Institute. (2009). At-A-glance: Healthy sleep. Retrieved 04/09, 2013, from www.nhlbi.nih.gov/health/public/sleep/healthy_sleep_atglance.pdf

National Institutes of Health, National Heart, Lung, and Blood Institute. (2011). In brief: Your guide to healthy sleep. Retrieved 05/05, 2013, from www.nhlbi.nih.gov/health/public/sleep/healthysleepfs.pdf

National Sleep Foundation. (2009). 2009 sleep in America poll. Retrieved 11/02, 2012, from http://www.sleepfoundation,org/article/sleep-america polls/2009-health-safety

National Sleep Foundation. (2013). 2013 International Bedroom Poll. Retrieved 2/3/2014, 2014, from http://www.sleepfoundation.org/sites/default/files/RPT495a.pdf

National Sleep Foundation. (2013). Sleep diary. Retrieved 2/15, 2014, from http://www.sleepfoundation.org/tools-for-better-sleep/images/SleepDiaryv6.pdf

Ohayon, M. M., & Roth, T. (2003). Place of chronic insomnia in the course of depressive and anxiety disorders. *Journal of Psychiatric Research, 37*(1), 9-15. doi:10.1016/S0022-3956(02)00052-3

Orzech, K. M., Salafsky, D. B., & Hamilton, L. A. (2011). The state of sleep among college students at a large public university. *Journal of American College Health, 59*(7), 612-619.

Ozminkowski, R., Wang, S., & Walsh, J. (2007). The direct and indirect costs of untreated insomnia in adults in the United States. *Sleep, 30*(3), 263-273.

Pigeon, W. R., & Perlis, M. L. (2006). Sleep homeostasis in primary insomnia. *Sleep Medicine Reviews, 10*(4), 247-254.

Pilcher, J. J., Ginter, D. R., & Sadowsky, B. (1997). Sleep quality versus sleep quantity: Relationships between sleep and measures of health, well-being and sleepiness in college students. *Journal of Psychosomatic Research, 42*(6), 583-596.

Pilcher, J. J., & Ott, E. S. (1998). The relationships between sleep and measures of health and well-being in college students: A repeated measures approach. *Behavioral Medicine, 23*(4), 170-178.

Pilcher, J. J., & Walters, A. S. (1997). How sleep deprivation affects psychological variables related to college students' cognitive performance. *Journal of American College Health, 46*(3), 121-126.

Price, S., & Price, L. (Eds.). (2012). *Aromatherapy for health professionals* (Fourth edition ed.). London: Elsevier Churchill Livingstone.

PROMIS Network. (2013). Patient reported outcomes management information systems (PROMIS). Retrieved 2/19, 2014, from www.nihpromis.org

Raudenbush, B., Koon, J., Smith, J., & Zoladz, P. (2003). Effects of odorant administration on objective and subjective measures of sleep quality, post-sleep mood and alertness, and cognitive performance. *North American Journal of Psychology, 5*(2), 181-192.

Ritenbaugh, C., Nichter, M., Nichter, M. A., Kelly, K. L., Sims, C. M., Bell, I. R., . . . Coons, S. J. (2011). Developing a patient-centered outcome measure for complementary and alternative medicine therapies I: Defining content and format. *BMC Complementary & Alternative Medicine, 11*, 135.

Rosekind, M. R., & Gregory, K. B. (2010). Insomnia risks and costs: Health, safety, and quality of life. *American Journal of Managed Care, 16*(8), 617-626.

Roth, T., Coulouvrat, C., Hajak, G., Lakoma, M., Sampson, N., Shahly, V., . . . Kessler, R. (2011). Prevalence and perceived health associated with insomnia based on DSM-IV-TR; international statistical classification of diseases and related health problems, tenth revision; and research diagnostic Criteria/International classification of sleep disorders, second edition criteria: Results from the America Insomnia Survey. *Biological Psychiatry, 69*(6), 592-600. doi:10.1016/j.biopsych.2010.10.023

Rothenberger Institute, University of Minnesota. (2012). *Sleep, eat and exercise (SEE) fact sheet*

Sarsour, K., Kalsekar, A., Swindle, R., Foley, K., & Walsh, J. (2011). The association between insomnia severity and healthcare and productivity costs in a health plan sample. *Sleep, 34*(4), 443-450.

Shahly, V., Berglund, P., Coulouvrat, C., Fitzgerald, T., Hajak, G., Roth, T., . . . Kessler, R. (2012). The associations of insomnia with costly workplace accidents and errors: Results from the America Insomnia Survey. *Archives of General Psychiatry, 69*(10), 1054-1063. doi:10.1001/archgenpsychiatry.2011.2188

Singleton, R. A., Jr, & Wolfson, A. R. (2009). Alcohol consumption, sleep, and academic performance among college students. *Journal of Studies on Alcohol & Drugs, 70*(3), 355-363.

Skaer, T., & Sclar, D. (2010). Economic implications of sleep disorders. *Pharmacoeconomics, 28*(11), 1015-1023.

Snyder, M. & Lindquist, R. (Ed.). (2009). *Complementary & alternative therapies in nursing* (6th ed.). NY: Springer Publishing.

Spielman, A. J., Nunes, J., & Glovinsky, P. B. (1996). Insomnia. *Neurologic Clinics, 14*(3), 513-543.

Stepanski, E. J., & Wyatt, J. K. (2003). Use of sleep hygiene in the treatment of insomnia. *Sleep Medicine Reviews, 7*(3), 215-225.

Stringer, J., & Donald, G. (2011). Aromasticks in cancer care: An innovation not to be sniffed at. *Complementary Therapies in Clinical Practice, 17*, 116-121.

Suen, L. K., Hon, K. L., & Tam, W. W. (2008). Association between sleep behavior and sleep-related factors among university students in Hong Kong. *Chronobiology International, 25*(5), 760-775.

Swainston Harrison, T., & Keating, G. M. (2005). Zolpidem: A review of its use in the management of insomnia. *CNS Drugs, 19*(1), 65-89.

Taub, J. M., Tanguay, P. E., & Clarkson, D. (1976). Effects of daytime naps on performance and mood in a college student population. *Journal of Abnormal Psychology, 85*(2), 210-

217.

Thase, M. (2005). Correlates and consequences of chronic insomnia. *General Hospital Psychiatry, 27*(2), 100-112. doi:10.1016/j.genhosppsych.2004.09.006

The College Board. (2013). University of Minnesota: Twin Cities. Retrieved 3/31, 2014, from https://bigfuture.collegeboard.org/college-university-search/university-of-minnesota-twin-cities?tp=bf&searchType=site_qfs&bf_cat=college

The Consort Group. (2010). Flow diagram. Retrieved 2/18, 2014, from http://www.consort- statement.org/consort-statement/flow-diagram0/

Thompson, J. J., Kelly, K. L., Ritenbaugh, C., Hopkins, A. L., Sims, C. M., & Coons, S. J. (2011). Developing a patient-centered outcome measure for complementary and alternative medicine therapies II: Refining content validity through cognitive interviews. *BMC Complementary & Alternative Medicine, 11*, 136.

Tisserand, R., & Young, R. (2014). *Essential oil safety* (Second ed.). London: Churchill Livingstone Elsevier.

Tomey, A., & Alligood, M. (1998). Sister Callista Roy. *Nursing theorists and their work* (4th ed., pp. 243--266). St. Louis, MO: Mosby-Year Book, Inc.

Tsai, L. L., & Li, S. P. (2004). Sleep patterns in college students: Gender and grade differences. *Journal of Psychosomatic Research, 56*(2), 231-237.

Wong, M., Lau, E., Wan, J., Cheung, S., Hui, C. H., & MOK, D. (2013). The interplay between sleep and mood in predicting academic functioning, physical health and psychological health: A longitudinal study. *Journal of Psychosomatic Research, 74*(4), 271-277. doi:10.1016/j.jpsychores.2012.08.014

Yu, L., Buysse, D. J., Germain, A., Moul, D. E., Stover, A., Dodds, N. E., . . . Pilkonis, P. A. (2011). Development of short forms from the PROMIS™ sleep disturbance and sleep-related impairment item banks. *Behavioral Sleep Medicine, 10*(1), 6-24.

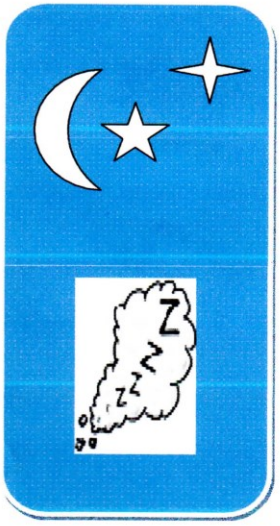
Zosel, A., Osterberg, E. C., & Mycyk, M. B. (2011). Zolpidem misuse with other medications or alcohol frequently results in intensive care unit admission. *American Journal of Therapeutics, 18*(4), 305-308.

Appendix A

Recruitment Flyer

Appendix A: Recruitment Flyer

Sleep Study ...a volunteer research study for U of M students



Looking for students for a research study on the effect of aromatherapy on sleep

Would the study be a good fit for me?
Yes if you:

- Are 18 years of age or older
- Have difficulty falling asleep, awaken frequently during the night, or are sleepy during the day
- Are not pregnant or taking prescribed sleep medication

What would happen if I took part in this study?
You would:

- Complete before and after sleep questionnaires
- Wear an essential oil patch on your chest and a personal tracker on your wrist for 5 nights in your home or dorm & practice good sleep habits
- Complete an online sleep diary for 5 consecutive mornings

Participants completing study will receive $40 and a chance to win a Fitbit® One™ personal tracker.

Possible benefits if you take part in the study are improved sleep quality and/or quantity.

To volunteer for this sleep research study or for more information, contact **Angie Lillehei,** RN, MPH, (PhD candidate) at **lill0111@umn.edu**

School of Nursing, University of Minnesota
Principal Researcher: Angie Lillehei, RN, MPH
IRB approval # 1306M37061

Appendix B

IRB Approval letter

07/30/2013
Angela S Lillehei
School of Nursing1331
Room 5-140 WDH
308 Harvard St S E
Minneapolis, MN 55455
RE: "Lavender Aromatherapy and Sleep Hygiene on Sleep in College Students with Self-reported Sleep issues"
IRB Code Number: **1306M37061**
Dear Dr. Lillehei:
The Institutional Review Board (IRB) received your response to its stipulations. Since this information satisfies the federal criteria for approval at 45CFR46.111 and the requirements set by the IRB, final approval for the project is noted in our files. Upon receipt of this letter, you may begin your research.
IRB approval of this study includes the HIPAA form received June 25, 2013, and the consent form dated August 2011 (received July 29, 2013).
The IRB would like to stress that subjects who go through the consent process are considered enrolled participants and are counted toward the total number of subjects, even if they have no further participation in the study. Please keep this in mind when calculating the number of subjects you request. This study is currently approved for 80 subjects. If you desire an increase in the number of approved subjects, you will need to make a formal request to the IRB.
For your records and for grant certification purposes, the approval date for the referenced project is and the Assurance of Compliance number is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003). Research projects are subject to continuing review and renewal , approval will expire one year from that date. You will receive a report form two months before the expiration date. If you would like us to send certification of approval to a funding agency, please tell us the name and address of your contact person at the agency.
As Principal Investigator of this project, you are required by federal regulations to inform the IRB of any proposed changes in your research that will affect human subjects. Changes should not be initiated until written IRB approval is received. Unanticipated problems or serious unexpected adverse events should be reported to the IRB as they occur.
The IRB wishes you success with this research. If you have questions, please call the IRB office at 612-626-5654.
Sincerely,
Christina Dobrovolny, CIP
Research Compliance Supervisor
CD/ks
CC: Linda Halcon

Appendix C

Consent Form

CONSENT FORM

Effect of Aromatherapy and Sleep Hygiene on Sleep in College Students with Self-reported Sleep Issues

You are invited to participate in a research study of the effect of aromatherapy delivered via a patch placed on the skin and the use of good sleep practices on sleep. You were selected as a possible participant because you identified an interest in the study and you meet the inclusion/exclusion criteria. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Angie Lillehei, RN, MPH, a PhD candidate in the School of Nursing.

Study Procedures

If you agree to participate in this study, we would ask you to do the following:

1) Be randomized to one of two groups.

2) Wear an aromatherapy patch and a Fitbit® One™ personal tracker for 5 consecutive nights and complete an online sleep diary each morning after wearing the patch and personal tracker in your home or dorm while sleeping. The groups will differ as to amount of essential oil on the patch.

3) Follow the sleep practices you will be informed about in the study.

4) Complete the 1 minute online sleep diary survey the 5 mornings after wearing the patch.

5) Complete 3 questionnaires before the study, 4 questionnaires right after the study, and then 5 questionnaires two weeks after completion of the patch and good sleep practices intervention. The surveys will take 15-20 minutes to complete each time.

6) Return the Fitbit One personal tracker and any unused patches to the researcher at the Boynton Health Center at the end of the 5 nights of intervention.

Risks of Study Participation

The study has the following minimal risks: possibility of an allergy or reaction to the patch and risks to confidentiality. Although the patch adhesive was found to be non-irritating and non-sensitizing, there is a slight possibility of an allergy or reaction to the patch. In addition confidentiality will be addressed according to the section below, however confidentiality is not absolute so there are minimal risks to confidentiality.

Benefits of Study Participation

There is no direct benefit to subjects who participate in this study.

Confidentiality

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify you as a subject. Research records will be stored securely and only researchers will have access to the records. Identifying information will be destroyed one year after the study.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota Twin Cities. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Contacts and Questions

The researcher conducting this study is: Angie Lillehei MPH, RN, the Principal Investigator and Linda Halcon, PhD, RN, the Advisor. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact them at the School of Nursing, 5-140 Weaver Densford Hall, 308 Harvard St. SE, Angie Lilliehei at 612-961-7902 or lill0111@umn.edu, or you may contact the advisor Linda Halcon at 612-626-6450 or halco0111@umn.edu.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), **you are encouraged** to contact the Research Subjects' Advocate Line, D528 Mayo, 420 Delaware St., Southeast, Minneapolis, Minnesota 55455 , (612) 625-1650.

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature of Subject_____

Date_____

IRB Code # 1306M37061

Version Date: August 2011

Appendix D

HIPAA Form

HIPAA[1] AUTHORIZATION TO USE AND DISCLOSE

INDIVIDUAL HEALTH INFORMATION FOR RESEARCH PURPOSES

1. Purpose. As a research participant, I authorize Angie Lillehei and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research project entitled Effect of Aromatherapy and Sleep Hygiene on Sleep in College Students wil Self-reported Sleep Issues, [Human Subjects' Code].

2. Individual Health Information to be Used or Disclosed. My individual health information that may be used or disclosed to conduct this research includes: demographic information (age,gender,ethnicity) and self-reported prescription medications and health conditions.

3. Parties Who May Disclose My Individual Health Information.

The researcher and the researcher's staff may obtain my individual health information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals and/or clinics) for the purposes of carrying out this research study. I authorize these parties to disclose my individual health information to the researcher and the researcher's staff for the purposes of carrying out this research study.

4. Parties Who May Receive or Use My Individual Health Information. The individual health information disclosed by parties in item 3 and information disclosed by me during the course of the research may be received and used by Angie Lillehei and the researcher's staff and the PI's advisor. Also, if I receive compensation for participating in this study, identifying information about me may be used or disclosed as necessary to provide compensation.

HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information.

5. Right to Refuse to Sign this Authorization. I do not have to sign this Authorization. If I decide not to sign the Authorization, I may not be allowed to participate in this study or receive any research related treatment that is provided through the study. However, my decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

6. Right to Revoke. I can change my mind and withdraw this authorization at any time by sending a written notice to Angie Lillehei, c/o Linda Halcon, PhD, RN, 5-140 Weaver Densford Hall, 308 Harvard St. SE, Minneapolis, MN 55455 to inform the researcher of my decision. If I withdraw this authorization, the researcher may only use and disclose the protected health information already collected for this research study. No further health information about me will be collected by or disclosed to the researcher for this study.

7. Potential for Re-disclosure. Once my health information is disclosed under this authorization, there is a potential that it will be re-disclosed outside this study and no longer covered by this authorization. However, the research team and the University's Institutional Review Board (the committee that reviews studies to be sure that the rights and safety of study participants are protected) are very careful to protect your privacy and limit the disclosure of identifying information about you.

7A. Also, there are other laws that may require my individual health information to be disclosed for public purposes. Examples include potential disclosures if required for mandated reporting of abuse or neglect, judicial proceedings, health oversight activities and public health measures.

This authorization does not have an expiration date.

I am the research participant or personal representative authorized to act on behalf of the participant.

I have read this information, and I will receive a copy of this authorization form after it is signed.

_____ _____

signature of research participant or research participant's personal representative

date

_____

printed name of research participant or research participant's personal representative

description of personal representative's authority to act on behalf of the research participant

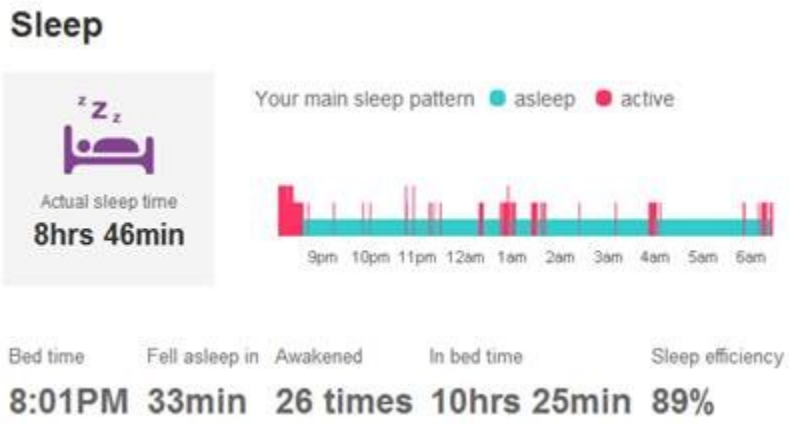
Signature of Person Obtaining Consent_____

Date_____

Appendix E

Fitbit One – Example of Output

Fitbit®One™ display of data



Appendix F

Daily Sleep Diary

Daily Sleep Diary

1. Today's date: _____

2. I went to bed last night at: _____

3. Last night I fell asleep in (number of minutes): _____

4. I was able to fall asleep easily:

____ Yes
____ No

5. I woke up during the night (number of times): _____

6. When I woke up for the day, I felt:

____ Refreshed
____ Somewhat refreshed
____ Fatigued

7. Last night I slept a total of (hours): ____

8. My sleep was disturbed by (list any factors that affected your sleep):

_____

9. Yesterday I felt sleepy or drowsy at least once:

__ Yes

__ No

10. The patch was worn last night:

____ Yes
____ Yes, but fell off
____ No

11. The Fitbit personal tracker was worn last night:

____ Yes
____ No

12. List any adverse effects you noticed with the patch, the Fitbit tracker, or the sleep hygiene practices:

_____
_____

Appendix G

Pittsburgh Sleep Quality Index

Subject's Initials ID# Date Time AM/PM

PITTSBURGH SLEEP QUALITY INDEX

INSTRUCTIONS:

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

Please answer all questions.

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

BED TIME _____

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

NUMBER OF MINUTES _____

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

GETTING UP TIME _____

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

HOURS OF SLEEP PER NIGHT _____

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

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

a) Cannot get to sleep within 30 minutes

Not during the Less than Once or twice Three or more
past month_____ once a week_____ a week_____ times a week_____

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

Not during the Less than Once or twice Three or more
past month_____ once a week_____ a week_____ times a week_____

c) Have to get up to use the bathroom

Not during the Less than Once or twice Three or more
past month_____ once a week_____ a week_____ times a week_____

Page 2 of 4

d) Cannot breathe comfortably

Not during the Less than Once or twice Three or more
past month_____ once a week_____ a week_____ times a week_____

e) Cough or snore loudly

Not during the Less than Once or twice Three or more
past month_____ once a week_____ a week_____ times a week_____

f) Feel too cold

Not during the Less than Once or twice Three or more
past month_____ once a week_____ a week_____ times a week_____

g) Feel too hot

Not during the Less than Once or twice Three or more
past month_____ once a week_____ a week_____ times a week_____
h) Had bad dreams
Not during the Less than Once or twice Three or more
past month_____ once a week_____ a week_____ times a week_____
i) Have pain
Not during the Less than Once or twice Three or more
past month_____ once a week_____ a week_____ times a week_____
j) Other reason(s), please describe_____
_____
____
How often during the past month have you had trouble sleeping because of this?
Not during the Less than Once or twice Three or more
past month_____ once a week_____ a week_____ times a week_____
6. During the past month, how would you rate your sleep quality overall?
Very good _____
Fairly good _____
Fairly bad _____
Very bad _____
Page 3 of 4
7. During the past month, how often have you taken medicine to help you sleep (prescribed or
"over the counter")?
Not during the Less than Once or twice Three or more
past month_____ once a week_____ a week_____ times a week_____
8. During the past month, how often have you had trouble staying awake while driving, eating
meals, or engaging in social activity?
Not during the Less than Once or twice Three or more
past month_____ once a week_____ a week_____ times a week_____
9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?
No problem at all _____
Only a very slight problem _____
Somewhat of a problem _____
A very big problem _____
10. Do you have a bed partner or room mate?
No bed partner or room mate _____
Partner/room mate in other room _____
Partner in same room, but not same bed _____
Partner in same bed _____
If you have a room mate or bed partner, ask him/her how often in the past month you have had . . .
a) Loud snoring
Not during the Less than Once or twice Three or more

past month_____ once a week_____ a week_____ times a week_____
b) Long pauses between breaths while asleep
Not during the Less than Once or twice Three or more
past month_____ once a week_____ a week_____ times a week_____
c) Legs twitching or jerking while you sleep
Not during the Less than Once or twice Three or more
past month_____ once a week_____ a week_____ times a week_____
Page 4 of 4

Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ: Psychiatry Research, 28:193-213, 1989.

Appendix H

PROMIS Sleep Disturbance SF 8b

PROMIS Item Bank v. 1.0 – Sleep Disturbance – Short Form 8b

Sleep Disturbance – Short Form 8b **Please respond to each item by marking one box per row.** In the past 7 days...		**Not at all**	**A little bit**	**Some what**	**Quite a bit**	**Very much**
Sleep108	My sleep was restless …					
Sleep115	I was satisfied with my sleep ...					
Sleep116	My sleep was refreshing.....					
Sleep44	I had difficulty falling asleep …					
In the past 7 days…	**Never**	**Rarely**		**Sometimes**	**Often**	**Always**
Sleep87	I had trouble staying asleep.....					
Sleep90	I had trouble sleeping ...					
Sleep110	I got enough sleep ...					
Sleep109	My sleep quality was ...	**Very Poor**	**Poor**	**Fair**	**Good**	**Very good**

Appendix I

Sleep Hygiene Survey

Sleep Hygiene Practice Questionnaire

For each of the following behaviors state the number of days per week (0-7) that you engage in the activity or have that experience. Base your answer on what you would consider an average week.

NOTE: if you are completing this questionnaire as the set of questionnaires post treatment, please base your answer on the week of the study while wearing the patch.

Indicate the number of days or nights in an average week (or number of days or nights during the week of the sleep study if you are completing this questionnaire post treatment) you:

1. Go to bed hungry ___
2. Go to bed thirsty ___
3. Drink fluids 30 minutes before sleep ___
4. Eat food 3 hours before bedtime ___
5. Ingest/drink caffeine 3 hours before bedtime ___
6. Smoke or drink alcohol 3 hours before going to bed ___
7. Use sleep medication (prescription or over the counter) ___
8. Worry as you prepare for bed about your ability to sleep at night ___
9. Do not wind down and relax 30 minutes before bed ___
10. Exercise strenuously within 3 hours of bedtime ___
11. Have your sleep disturbed by light (overhead lights, TV, phone, computer or ipad screens)___
12. Have your sleep disturbed by noise (texting, other noises in your environment) ___
13. Have your sleep disturbed by your partner or roommate ___
14. Do activities in bed such as homework, texting, internet surfing, etc. ___
15. Sleep less because you needed to catch up on school work ___
16. Sleep more or less than your usual and recommended hours of sleep ___

Modified from Sleep Hygiene Awareness and Practice Survey, Lacks, P. & Rotert, M. (1986) Knowledge and practice of sleep hygiene techniques in insomniacs and good sleepers, *Behav Res Ther,* 24(3), 365-368.

Appendix J

Self-Assessment of Change Tool

Participant ID: _____ 1
Study ID: XXX 2
For staff use only

Self-Assessment of Change

Today's Date X/X/X 3

How long has it been since XXX

- ☐ 1 Less than 3 months
- ☐ 2 3 to 6 months
- ☐ 3 7 to 12 months
- ☐ 4 1-2 years
- ☐ 5 2-3 years
- ☐ 6 3-5 years
- ☐ 7 5-10 years
- ☐ 8 More than 10 years

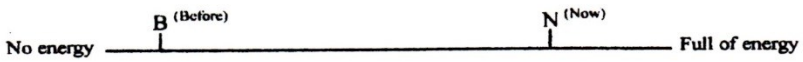
The word pairs that you find below ask you to reflect on life changes that you have experienced since: XXX
Use what you know about yourself ***now***, to respond.

Here's how to fill this out:

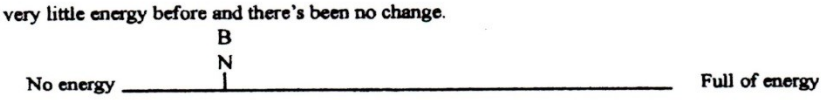
- Mark the line to show where you were before
- Mark the line for where you are now and label it **N**.

Here are 3 examples of how to fill this out:

1. I had almost no energy before and I've got more energy now.



2. I had very little energy before and there's been no change.



3. I've got some energy now, but I had more energy before.

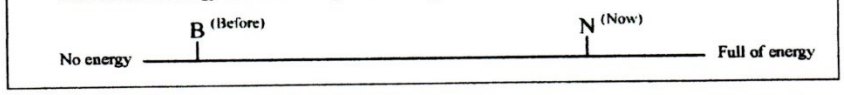
Form C; Version 5.10.10

Participant ID: _____ 1
Study ID: XXX 2
For staff use only

"B" is for where you were ***before*** XXX
"N" is for where you are ***now***.
Place a "B" and an "N" based on how you see things ***now***.

EXAMPLE

I had almost no energy before and I've got more energy now.



Not sleeping well _____ Sleeping well 5

Exhausted _____ Energized 7

Dull Senses _____ Vibrant Senses 9

Scattered _____ Focused 11

Stuck _____ Letting Go 13

Overwhelmed _____ Empowered 15

Hopeless _____ Hopeful 17

Blaming _____ Forgiving 19

Form C; Version 5.10.10

Participant ID: _____

Study ID: XXX

For staff use only

"B" is for where you were ***before*** XXX
"N" is for where you are ***now***.
Place a "B" and an "N" based on how you see things ***now***.

EXAMPLE

I had almost no energy before and I've got more energy now.

No energy — B (Before) — N (Now) — Full of energy

Closed-hearted	Open-hearted	21
Isolated	Connected	23
Depressed	Joyful	25
Anxious	Calm	27
My body does not recover quickly	My body recovers quickly	29
Broken	Whole	31
Defined by my illness or problems	Not Defined by my illness or problems	33
Unbalanced	Balanced	35

Form C; Version 5.10.10

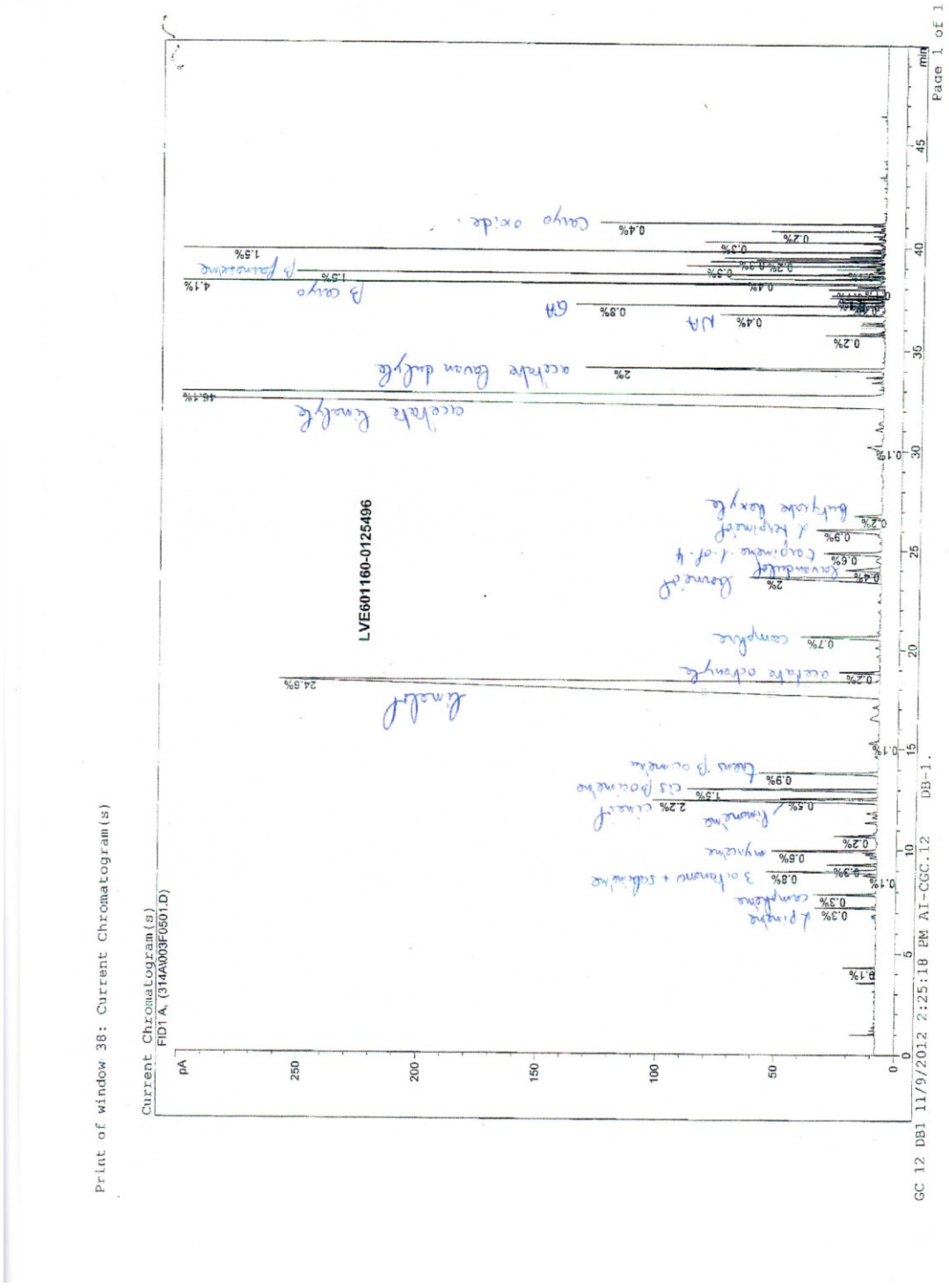
XXX

For staff use only

37

Appendix K

GC/MS for study batch of Lavandula angustifolia



Appendix L

Participant Instructions for Patch and Fitbit One

Sleep study instructions

For the designated **5 consecutive study nights**, please follow these instructions.

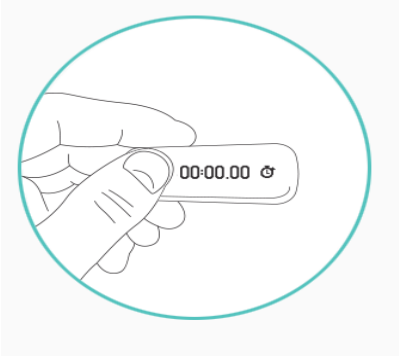
Instructions for applying the patch:

* 1) Apply the patch as you get into bed for the night. (Apply patch #1 the first night, patch #2 the second night and so on. If you forget to apply a patch, save that patch to return with the Fitbit at the end of the 5 nights.)
* 2) Remove all lotions and oils from your upper chest. Open the patch as directed on the back of the package. Peel off both the top layer and the clear liner. The silver, sticky surface is applied to your skin.
* 3) Put the patch on the middle of your upper chest as illustrated on the back of the patch package. Apply it to your bare skin. (A cami or tank top can be used.) Avoid covering patch with clothing.
* 4) If you happen to wake up and the patch has fallen off, you can just re-attach it.
* 5) Remove the patch before you get out of bed in the AM.
* 6) Check your email for the survey link to complete a short questionnaire each morning after wearing the patch.

NOTE: If you have any type of skin reaction or any other reaction, please remove patch from your skin and dispose of it outside the sleeping area. Do not use any more patches and return unused patches to researcher at the end of the 5 night period. Report any reactions on the online sleep diary the next AM.

Fitbit® One™ instructions:

* Press and hold button on tracker until you see the flashing stopwatch as illustrated below.



* 2) Insert into sleep wristband and place on your non-dominant wrist.
* 3) Upon awakening, press and hold the same button to end sleep recording.
* 4) Synching will be done by researcher upon return of the Fitbit at the end of the 5 nights of recording.

If you have any questions, please email me at alillehei@lill0111@umn.edu.

Thank you for your participation.

Angie Lillehei RN, PhD candidate
Researcher

Appendix M

Sleep Hygiene Practice Flyer

Want……

Better grades?

Better creativity?

Better moods?

Better health?

Better endurance?

Less stress?

….Get more sleep!

Practices to help improve amount and quality of sleep:

* Do not drink anything right before bed and avoid food, caffeine, alcohol, and nicotine several hours before bed

* Wake up and go to bed the same time everyday

* Set a time during the day for thinking and planning so can avoid worry at bedtime

* Keep up with school work

* Keep a quiet sleep environment (try ear plugs and/or a sleep mask and keeping clock faced away from your bed)

* Avoid screen time before and at bedtime

* Exercise regularly (may want to avoid strenuous exercise at bedtime).

Appendix N

Reminder Placard

5 Night Sleep Study

START: Sunday PM 11/3 to Monday AM 11/4

Sunday PM* Monday PM* Tuesday PM* Wed PM* Thursday PM

Appendix O

Sleep Hygiene Survey Scores Post treatment and Follow-up

SHS Score_Total

	Time	Mean	Std.Deviation	Minimum	Maximum	N
Treatment	Pre-treatment	42.72	11.544	20	76	39
	Post treatment	23.16	11.879	4	45	38
	Follow-up	31.47	11.065	7	57	36
Control	Pre-treatment	41.53	10.794	22	66	40
	Post	21.39	11.339	0	54	38
	Follow-up	32.23	12.533	3	58	35
Total	Pre-treatment	42.11	11.115	20	76	79
	Post	22.28	11.568	0	54	76
	Follow-up	31.85	11.732	3	58	71

SHS_1 Go to bed hungry

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	0	11	12	3
	1	5	4	9
	2	9	13	2
	3	11	6	17
	4	1	4	5
	5	1	1	2
	7	1	0	1
Post treatment	NA	1	2	3
	0	20	19	39
	1	11	6	17
	2	2	11	13
	3	4	1	5
	4	1	1	2
Follow-up	NA	3	5	8
	0	15	15	30
	1	9	3	12
	2	5	9	14
	3	4	6	10
	4	2	0	2
	5	1	2	3

SHS_2 Go to bed thirsty

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	0	18	18	36
	1	7	10	17
	2	7	6	13
	3	4	2	6
	4	2	4	6
	5	1	0	1
Post treatment	NA	1	2	3
	0	26	24	50
	1	3	8	11
	2	7	4	11
	3	0	1	1
	4	2	0	2
	5	0	1	1
Follow-up	NA	3	5	8
	0	22	20	42
	1	4	5	9
	2	6	5	11
	3	1	3	4
	4	1	1	2
	5	0	1	1
	6	1	0	1
	7	1	0	1

SHS_3Drink fluids 30 minutes before sleep

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	0	3	2	5
	1	1	0	1
	2	3	5	8
	3	5	5	10
	4	2	4	6
	5	7	11	18
	6	3	2	5
	7	15	11	26
Post treatment	NA	1	2	3
	0	8	8	16

	1	3	6	9
	2	5	8	13
	3	6	5	11
	4	4	3	7
	5	6	6	12
	6	2	1	3
	7	4	1	5
Follow-up	NA	3	5	8
	0	6	3	9
	1	2	3	5
	2	6	5	11
	3	4	10	14
	4	2	3	5
	5	4	7	11
	6	4	0	4
	7	8	3	11
	10	0	1	1

SHS_4 Eat food 3 hours before bed

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	0	2	0	2
	1	1	0	1
	2	6	2	8
	3	3	5	8
	4	8	5	13
	5	4	9	13
	6	2	6	8
	7	13	13	26
Post treatment	NA	1	2	3
	0	9	7	16
	1	4	6	10
	2	5	8	13
	3	6	5	11
	4	6	1	7
	5	3	6	9
	6	1	0	1
	7	4	5	9
Follow-up	NA	3	5	8
	0	7	0	7

	1	5	5	10
	2	1	5	6
	3	7	7	14
	4	6	3	9
	5	3	5	8
	6	3	4	7
	7	4	5	9
	14	0	1	1

SHS_5 Ingest drink caffeine

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	0	26	23	49
	1	4	6	10
	2	6	4	10
	3	2	4	6
	5	1	3	4
Post treatment	NA	1	2	3
	0	33	30	63
	1	3	5	8
	2	1	1	2
	3	1	1	2
	4	0	1	1
Follow-up	NA	3	5	8
	0	28	23	51
	1	4	6	10
	2	2	2	4
	3	2	3	5
	5	0	1	1

SHS_6 Smoke or drink alcohol 3 hours before bed

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	0	22	26	48
	1	8	8	16
	2	6	4	10
	3	1	0	1
	4	2	1	3
	5	0	1	1
Post treatment	NA	1	2	3
	0	30	28	58

	1	6	6	12
	2	2	2	4
	3	0	2	2
Follow-up	NA	3	5	8
	0	20	23	43
	1	11	6	17
	2	2	5	7
	3	1	0	1
	4	0	1	1
	5	1	0	1
	6	1	0	1

SHS_7 Use sleep medication (prescription or over the counter)

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	0	37	31	68
	1	1	3	4
	2	1	3	4
	3	0	1	1
	4	0	2	2
Post treatment	NA	1	2	3
	0	38	33	71
	2	0	1	1
	3	0	2	2
	4	0	1	1
	5	0	1	1
Follow-up	NA	3	5	8
	0	35	29	64
	1	1	1	2
	2	0	2	2
	4	0	1	1
	5	0	2	2

SHS_8 Worry as you prepare for bed about ability to sleep

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	0	10	7	17
	1	9	4	13
	2	4	7	11
	3	5	5	10

	4	4	5	9
	5	4	9	13
	7	3	3	6
Post treatment	NA	1	2	3
	0	18	13	31
	1	9	9	18
	2	5	8	13
	3	2	5	7
	4	2	2	4
	5	1	1	2
	7	1	0	1
Follow-up	NA	3	5	8
	0	14	13	27
	1	8	5	13
	2	3	5	8
	3	4	5	9
	4	3	4	7
	5	3	2	5
	7	1	0	1
	8	0	1	1

SHS_9 Do not wind down and relax 30 minutes before bed

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	0	3	8	11
	1	1	3	4
	2	7	4	11
	3	6	7	13
	4	6	6	12
	5	7	8	15
	6	0	2	2
	7	9	2	11
Post treatment	NA	1	2	3
	0	7	8	15
	1	8	7	15
	2	8	11	19
	3	8	7	15
	4	4	2	6
	5	2	2	4

	6	1	0	1
	7	0	1	1
Follow-up	NA	3	5	8
	0	4	5	9
	1	3	0	3
	10	0	1	1
	2	6	6	12
	3	6	7	13
	4	7	7	14
	5	5	5	10
	6	3	2	5
	7	2	2	4

SHS_10 Exercise strenuously within 3 hours of bedtime

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	0	18	21	39
	1	7	7	14
	2	7	7	14
	3	3	2	5
	4	2	1	3
	5	2	1	3
	6	0	1	1
Post treatment	NA	1	2	3
	0	23	28	51
	1	3	6	9
	2	6	3	9
	3	5	1	6
	5	1	0	1
Follow-up	NA	3	5	8
	0	22	27	49
	1	4	4	8
	2	3	2	5
	3	4	2	6
	4	2	0	2
	5	1	0	1

SHS_11 Have your sleep disturbed by light

Time	Days Per Week	Treatment	Control	Total

Pre-treatment	0	11	16	27
	1	6	4	10
	2	4	5	9
	3	4	5	9
	4	5	1	6
	5	4	4	8
	6	1	2	3
	7	4	3	7
Post treatment	NA	1	2	3
	0	17	22	39
	1	6	4	10
	2	9	6	15
	3	2	4	6
	4	0	2	2
	5	3	0	3
	7	1	0	1
Follow-up	NA	3	5	8
	0	10	17	27
	1	6	4	10
	2	11	5	16
	3	4	6	10
	4	2	0	2
	5	2	3	5
	6	1	0	1

SHS_12 Have you been disturbed by noise (texting, other noises in your environment

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	0	7	11	18
	1	8	4	12
	2	6	8	14
	3	4	6	10
	4	9	5	14
	5	0	3	3
	6	0	1	1
	7	5	2	7
Post treatment	NA	1	2	3
	0	17	12	29
	1	9	12	21
	2	3	6	9

	3	3	5	8
	4	2	1	3
	5	2	2	4
	6	1	0	1
	7	1	0	1
Follow-up	NA	3	5	8
	0	11	15	26
	1	4	4	8
	2	10	7	17
	3	4	3	7
	4	3	5	8
	5	3	0	3
	7	0	1	1
	9	1	0	1

SHS_13 Have your sleep disturbed by your partner or roommate

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	0	15	13	28
	1	8	6	14
	2	5	8	13
	3	2	5	7
	4	3	3	6
	5	5	3	8
	6	0	1	1
	7	1	1	2
Post treatment	NA	1	2	3
	0	20	14	34
	1	8	6	14
	2	4	8	12
	3	3	7	10
	4	2	1	3
	5	1	1	2
	7	0	1	1
Follow-up	NA	3	5	8
	0	16	13	29
	1	6	4	10
	2	7	5	12
	3	2	6	8
	4	3	4	7

	5	2	1	3
	7	0	2	2

SHS_14 Do activities in bed such as homework, texting, internet surfing, etc

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	0	5	5	10
	1	1	1	2
	2	8	7	15
	3	1	3	4
	4	1	1	2
	5	4	7	11
	6	6	4	10
	7	13	12	25
Post treatment	NA	1	2	3
	0	11	12	23
	1	10	10	20
	2	5	3	8
	3	1	6	7
	4	2	2	4
	5	6	4	10
	6	2	0	2
	7	1	1	2
Follow-up	NA	3	5	8
	0	7	7	14
	1	3	4	7
	2	7	6	13
	3	4	6	10
	4	3	2	5
	5	6	5	11
	6	4	2	6
	7	2	3	5

SHS_15 sleep less because need to catch up on school work

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	0	2	2	4
	1	1	7	8
	2	5	2	7
	3	6	4	10
	4	5	8	13

	5	10	9	19
	6	3	5	8
	7	7	3	10
Post treatment	NA	1	2	3
	0	7	6	13
	1	9	13	22
	2	10	7	17
	3	1	6	7
	4	2	3	5
	5	8	2	10
	6	1	1	2
Follow-up	NA	3	5	8
	0	3	4	7
	1	2	4	6
	2	9	5	14
	3	5	10	15
	4	6	3	9
	5	4	5	9
	6	1	2	3
	7	6	2	8

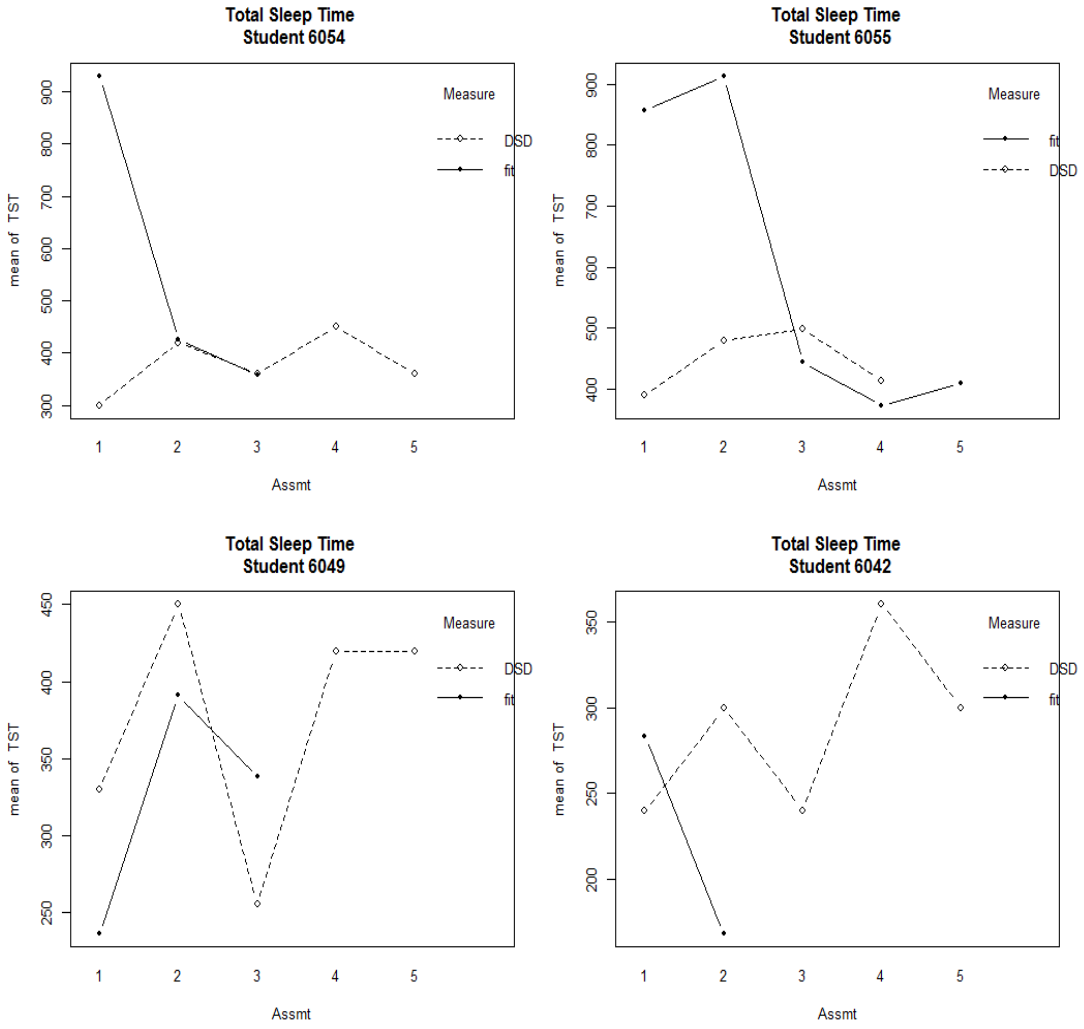
SHS_16 sleep more or less than usual amount

Time	Days Per Week	Treatment	Control	Total
Pre-treatment	1	1	1	2
	2	2	5	7
	3	2	3	5
	4	2	4	6
	5	6	8	14
	6	9	4	13
	7	17	15	32
Post treatment	NA	1	2	3
	0	9	12	21
	1	3	5	8
	2	7	5	12
	3	3	7	10
	4	4	5	9
	5	6	4	10
	6	1	0	1
	7	5	0	5

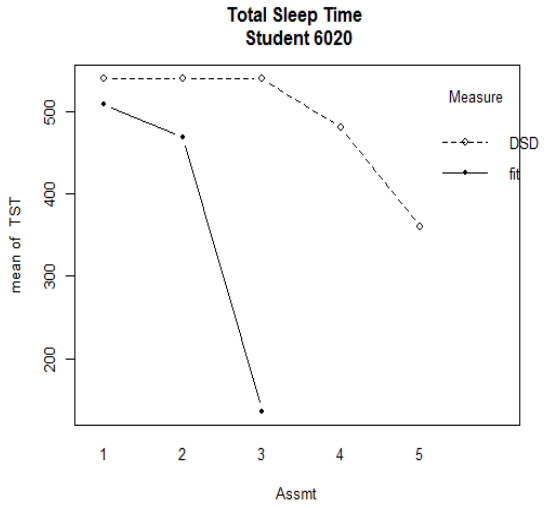
	NA	3	5	8
	0	5	3	8
	1	3	1	4
	2	6	7	13
Follow-up	3	4	5	9
	4	2	4	6
	5	8	5	13
	6	2	2	4
	7	6	7	13
	9	0	1	1

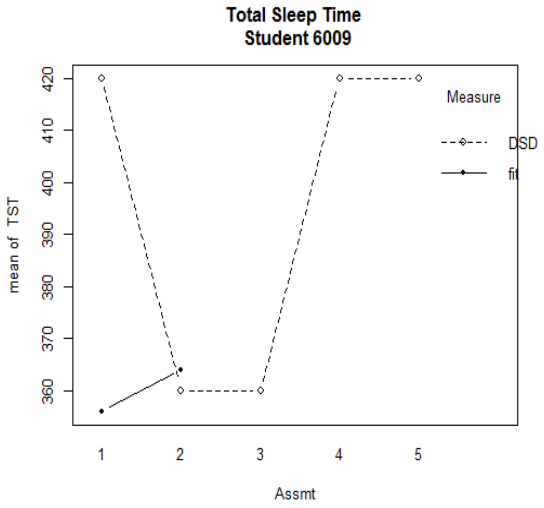
Appendix P

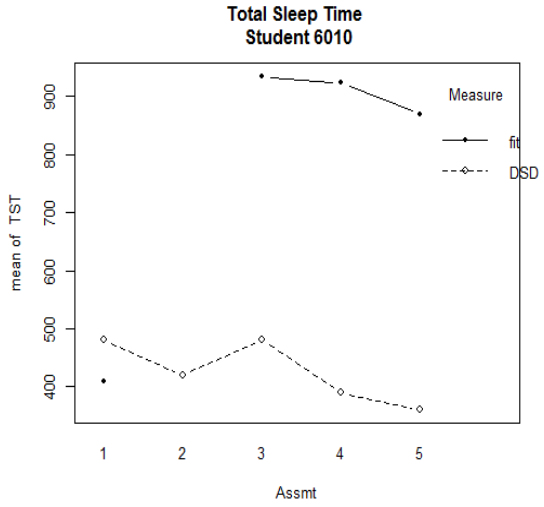
Fitbit and DSD Plots



Fitbit compared to DSD plots (continued)







Appendix Q
PSQI Frequency Distributions and Mean Scores

PSQI global score frequencies and means

Survey period		Mean	Std. Deviation	Min	Max	N
Pre	Treatment	8.16	2.224	4	13	38
	Control	8.73	2.650	2	16	40
	Total	8.45	2.453	2	16	78
Post	Treatment	4.92	2.173	1	11	38
	Control	6.46	2.873	2	14	37
	Total	5.68	2.641	1	14	75
Follow up	Treatment	6.17	2.618	3	11	35
	Control	6.85	3.154	1	13	33
	Total	6.50	2.888	1	13	68

Appendix R

Self-Assessment of Change Mean Scores Post treatment and Follow-Up

Self-Assessment of Change Mean Scores for Post treatment

Post treatment	Treatment Mean (SD)	Control Mean (SD)	P-Value
Q1-Sleep	20.25 (22.75)	9.16 (12.71)	0.01
Q2-Energy	19.08 (25.32)	7.7 (16.6)	0.03
Q3-Vibrancy	9.31 (17.31)	3.16 (5.68)	0.05
Q4-Focus	9.86 (17.4)	7.84 (19.98)	0.65
Q5-Letting go	5.56 (12.45)	5.95 (12.31)	0.89
Q6-Empower	9.94 (15.17)	5.54 (18.18)	0.26
Q7-Hopeful	5.36 (10.54)	4.81 (8.81)	0.81
Q8-Forgiving	7.81 (13.99)	4.59 (10.65)	0.28
Q9-Open-heart	7.56 (18.13)	3.22 (8.11)	0.20
Q10-Connected	5.78 (9.01)	2.73 (7.6)	0.12
Q11-Joy	5.53 (10.34)	1.81 (11.56)	0.15
Q12-Calm	10.36 (19.5)	2.41 (15.64)	0.06
Q13-Recovery	4.39 (6.94)	4.7 (8.33)	0.86
Q14-Whole	3.06 (5.53)	2.59 (6.16)	0.74
Q15-Defined	2.56 (5.87)	2.24 (6.59)	0.83
Q16-Balance	10.58 (18.09)	4.38 (12.99)	0.10

Self-Assessment of Change Mean Scores for Follow-up

Follow-Up	Treatment Mean (SD)	Control Mean (SD)	P-Value
Q1-Sleep	7.62 (21.54)	4.39 (17.07)	0.510
Q2-Energy	3.53 (18.87)	1.29 (16.65)	0.619
Q3-Vibrancy	2.16 (12.21)	-0.35 (9.26)	0.361
Q4-Focus	3.50 (7.31)	2.77 (15.41)	0.813
Q5-Letting go	2.16 (16.69)	2.19 (15.63)	0.993
Q6-Empower	6.06 (17.75)	0.45 (19.99)	0.244
Q7-Hopeful	0.47 (11.35)	-1.81 (12.42)	0.451
Q8-Forgiving	2.75 (10.68)	-0.1 (11.53)	0.314
Q9-Open-heart	5.28 (15.31)	-0.32 (7.05)	0.067
Q10-Connected	1.00 (16.33)	2.03 (18.12)	0.813
Q11-Joy	1.59 (12.48)	0.71 (16.51)	0.812
Q12-Calm	2.38 (10.62)	-0.74 (14.93)	0.345
Q13-Recovery	0.94 (8.56)	0.16 (14.17)	0.794
Q14-Whole	1.75 (8.41)	-1.19 (9.4)	0.196
Q15-Defined	3.69 (6.48)	-1.32 (12.17)	0.048
Q16-Balance	3.47 (9.33)	2.84 (11.72)	0.815