Effects of Physical Activity on Sleep in Sedentary Adults with Sleep Problems

by

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ABSTRACT

Physical activity is critical for optimal health and has emerged as a viable option to improve sleep. Moderate- and vigorous-intensity physical activity comparisons to improve sleep in non-exercising adults with sleep problems is limited. The purpose was to determine the effects of moderate- or vigorous-intensity exercise on sleep outcomes and peripheral skin temperature compared to a no-exercise control. The exercise intensity preference also was determined.

Eleven women (46.9±7.0 years) not participating in regular exercise and self-reporting insomnia completed a graded maximal exercise test followed by a crossover trial of three randomly assigned conditions separated by a 1-week washout. Participants performed moderate-intensity [MIC, 30 minutes, 65-70% maximum heart rate (HR_{max})] or high-intensity (HIT, 20 minutes, 1-minute bouts at 90-95% HR_{max} alternating with 1-minute active recovery) treadmill walking or a no-exercise control (NEC) on two consecutive weekdays 4-6 hours prior to typical bed time. A dual-function wrist-worn accelerometer/temperature monitor recorded movement and skin temperature from which sleep-onset latency (SOL), sleep maintenance, sleep efficiency, total sleep time (TST), and peripheral skin temperature changes were calculated. Participants self-reported sleep outcomes weekly, enjoyment of exercise the morning after HIT and MIC, and exercise intensity preference upon completing all conditions. Mixed models analysis of variance examined differences between and within conditions controlling for demographic characteristics and habitual physical activity.

HIT resulted in up to a 90-minute TST increase on night four (448 minutes, 95% CI 422.4-474.2) compared to nights one-three. MIC nights three (43.5 minutes, 95% CI 30.4-56.6) and four (42.1 minutes 95% CI 29.0-55.2) showed nearly a 30-minute SOL worsening compared to nights one-two. No other actigraphy-measured sleep parameters differenced within or between conditions. Self-reported sleep outcomes, peripheral skin temperature change, and exercise enjoyment between conditions were similar ($p>0.05$). More participants preferred lower (n=3) to higher (n=1) intensity activities.

Early evening high-intensity and moderate-intensity exercise had no effect on sleep outcomes compared to a control in non-exercising adults reporting sleep complaints. Sleep benefits from HIT may require exercise on successive days. Participants indicated partiality for lower intensity exercise. More information on timing and mode of physical activity to improve sleep in this population is warranted.

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DEDICATION

I dedicate this dissertation to my wife, Liana, for her unending patience throughout the past 5 years. Also, I dedicate this to my son. These two strong influences provided powerful inspiration to complete this project. Finally, to my parents, who have always encouraged me by saying that whatever I put my mind to, I can accomplish.

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CHAPTER 1

INTRODUCTION

Physical activity elicits benefits on the human condition, including improvements on cardiovascular, metabolic, muscular, and bone outcomes[1]. While physical activity is regarded an important behavior for optimal health, nearly 80% of the U.S. adult and child populations fail to engage in the evidence-based recommendations for physical activity into their daily routine[2]. This is of concern since physical activity engagement decreases throughout the lifespan, with sharper declines found among middle-aged and older adults[3].

In addition to not meeting physical activity recommendations, more than one-quarter of the U.S. population reports occasionally not getting enough sleep. Nearly 50-70 million Americans report sleep complaints annually[4,5]. A poll conducted by the National Sleep Foundation reported that approximately 60% of respondents did not get a good night's sleep at least once in the previous week and almost half of those reporting at least one poor night's sleep stated that poor sleep was a nightly occurrence[6]. Sleep problems are important determinants of both physical and mental health and are associated with premature mortality[7,8].

Parallel to declines in physical activity with age, problems with sleep also increase with age[9]. Despite spending more time in bed, older adults report poorer sleep quality and quantity compared to their younger counterparts because the ability to sleep diminishes with age, often due to insomnia[10]. Insomnia is characterized by difficulty

falling asleep, difficulty staying asleep, early morning awakenings, and reduced sleep efficiency (ratio of time spent asleep to time spent in bed)[11].

The prevalence of sleep complaints in the adult population is relatively high. Nearly one third of adults surveyed report sleep complaints, of which 10% report having insomnia. As well, 30% of employed adults report suboptimal sleep duration[12,13]. Insomnia and suboptimal sleep duration are each associated with overall poor health, cardiovascular (CVD) disease and CVD biomarkers, metabolic dysfunction, stroke, mental well-being status and medical illness, and mortality[10]. If untreated, sleep disturbances may result in poor physical performance in motor skills, increased risk of falls, chronic fatigue, and increased risk for the aforementioned poor health outcomes[14]. Accordingly, researchers have become increasingly interested in understanding ways to improve sleep quality and quantity in adults with poor sleep[15].

Physical activity has emerged as an attractive treatment for poor sleep because of the positive effects it has on virtually all bodily systems that are negatively affected by poor sleep[16]. Physical activity also lacks the deleterious side effects that are common with hypnotics and other sleep aids[17]. Epidemiological studies have shown that leisure-time physical activity and structured exercise are positively associated with sleep improvements in people with a wide range of demographic characteristics[18]. A mechanism for this improvement may be alterations in circadian rhythms that become normalized with exercise in poor sleepers, thereby improving symptoms of insomnia[19,20]. Regular exercise also is positively associated with health outcomes that are predictive of sleep disturbances such as depression, anxiety, high blood pressure, body temperature

regulation, and hormonal circadian rhythms[21,22,23,24,25]. Exercise also causes thermoregulatory adaptive reactions and improves cutaneous circulation in the extremities which may improve the body's ability to fall into and stay asleep[26].

Not all studies report a positive effect of physical activity on sleep[27,28], possibly due to considerable differences in study designs and the dose of physical activity prescribed. The dose of physical activity can vary based on the number of occasions an activity is performed over a specified time (frequency), the amount of time one is engaged in an activity during each session (duration), the exertion level required by the activity (intensity), and the time of day an activity is performed. The type of physical activity performed (mode) generally is determined by a purpose for engaging in an activity. An activity may be performed with the intention of improving health outcomes (e.g., structured exercise routine), as part of competition (e.g., sports), or incorporated into one's daily routine (e.g., during leisure, occupation, or transportation).

Most studies on the effects of physical activity and sleep have used continuous exercise sessions as the activity duration[29]. Few studies have used short bouts of high-intensity exercise coupled with short bouts of rest or light intensity activity on sleep outcomes[30]. While the high-intensity exercise paradigm has been effective in improving cardiovascular disease biomarkers and metabolic dysfunction in adults[31,32], few studies have evaluated the effects of high-intensity exercise on sleep quality. For example, Passos et al.[30] showed moderate-intensity activity and high-intensity activity positively affected sleep onset latency, sleep maintenance, and sleep efficiency in 36-52 year old females with insomnia.

While moderate-intensity activity is commonly prescribed as the dose for physical activity in sleep studies, in comparison, high-intensity activity often takes substantially less time (e.g. 30 minutes vs 50 minutes) and is prescribed at a lower volume of exercise[31,32]. High-intensity activity also elicits greater increases in core body temperature during exercise followed by a core body temperature down-regulation through cutaneous vasodilation and increase in skin temperature[33,34]. This is important since an increased core body temperature is a potential mechanism for poor sleep.

In 1983, Horne and Staff[33] published the earliest results showing the positive relationship between activity intensity and sleep. However, there is a misconception that high-intensity activity, particularly when performed in the evening, disrupts sleep. How one perceives the intensity of a physical activity depends on their age, body weight, and physical fitness level. Those with lower levels of physical fitness, older age, and higher body weight will experience higher levels of exertion at lower levels of absolute physical activity than their more physically fit, younger, and leaner counterparts. Thus, the association of high-intensity activity to sleep disruptions may be highly individual[35]. While some high-intensity activity protocols are considered impractical and intolerable to adults and persons with lower fitness levels[31], Little et al.[36] found that a protocol of 10 x 1-minute high-intensity activity bouts evenly disbursed with 1-minute light-intensity activity bouts were enjoyable in adults with type 2 diabetes. Heart failure patients also tolerated this protocol successfully.

When administered separately, moderate-intensity activity and high-intensity activity appear to be effective in improving sleep acutely[37,38]. However, no study has

compared the prolonged effects of moderate-intensity activity and high-intensity activity on sleep outcomes. It is speculated that a two consecutive days of an high-intensity activity interval protocol of 10 x 1-minute bouts of high intensity treadmill walking followed by 10 x 1-minute bouts light-intensity treadmill walking, will improve sleep at similar levels as two consecutive days of moderate-intensity activity. Thus, this study will use a crossover design to study the effects of two consecutive days of a high-intensity activity protocol and two consecutive days of continuous moderate-intensity activity with a no-exercise control period on measures of sleep quality in adults with self-reported poor sleep quality.

Statement of the Problem

People without obstructive sleep apnea that have sleep disturbances, such as difficulty falling and staying asleep and feeling dissatisfied or worried about their sleep are commonly prescribed hypnotics or hormone therapy, while proper sleep hygiene is recommended[39,40]. Some treatments can be expensive and the beneficial effects on sleep quality may dissipate quickly. Plus, they do not aid in treating comorbid conditions that are related to poor sleep, such as diabetes and heart disease. Exercise is gaining attention as a low cost and efficacious treatment to improve sleep[41]. The benefits of participating in regular physical activity on health outcomes are well understood[42]. However, little research is available about the efficacy of physical activity on sleep quality[41]. Regular physical activity, specifically structured exercise, is effective in improving sleep due to increases in energy expenditure and improved body temperature regulation prior to and during sleep[33,43]. Thus, exercise routines may be an effective treatment modality for adults who are poor sleepers and do not engage in regular exercise routines[3,44]. To date,

little evidence exists of the benefits of bouts of moderate- and vigorous-exercise on sleep quality over consecutive days. In addition, no published studies have compared the effects of moderate- and vigorous-intensity exercise on sleep quality over consecutive days. Given the popularity of intermittent high intensity exercise on health outcomes[31,32], the question remains whether two consecutive days of a low-volume, high intensity exercise has a differential effect than continuous, moderate-intensity exercise or a no-exercise on sleep quality in inactive adults with sleep complaints.

Research Study Aims

The primary purpose of this research is to compare the effects of two consecutive days of moderate-intensity continuous exercise and intermittent bouts of high-intensity exercise with a no-exercise control group on sleep quality in inactive adults with self-reported sleep problems. The secondary purpose of this research is to examine changes in thermoregulation following moderate- and high-intensity exercise sessions as a mechanism between engagement in exercise of different intensities and symptoms of insomnia. The tertiary purpose of this research is to examine the participant's subjective preference of an exercise intensity in improving sleep quality. To test these study hypotheses, the following specific aims will be addressed using a crossover trial that includes a no-exercise control.

Specific Aims and Hypotheses

Aim 1A

Purpose

The purpose of Aim 1A was to examine the effects of high intensity interval exercise (HIT) and moderate-intensity continuous exercise (MIC) versus a no-exercise control (NEC) on actigraphy-measured sleep outcomes.

Null Hypothesis

There will be no difference between HIT, MIC, and NEC on actigraphy-measured sleep-onset latency (SOL), sleep maintenance (WASO), and sleep efficiency (SE).

Alternate Hypothesis

HIT and MIC will result in superior sleep outcomes of actigraphy-measured sleep onset latency (SOL), sleep maintenance (WASO), and sleep efficiency (SE), compared to a NEC.

Aim 1B

Purpose

The purpose of Aim 1B was to examine the effects of HIT and MIC versus a NEC on self-reported sleep outcomes.

Null Hypothesis

There will be no difference between HIT, MIC, and NEC on self-reported SOL, WASO, and SE.

Alternate Hypothesis

HIT and MIC will result in superior self-reported sleep outcomes of SOL, WASO, and SE compared to a NEC.

Aim 2

Purpose

The purpose of Aim 2 was to examine the effects of HIT and MIC versus a NEC on peripheral distal body temperature changes as a predictor of sleep-onset latency.

Null Hypothesis

There will be no difference between HIT, MIC, and NEC on peripheral body temperature to predict sleep-onset latency.

Alternate Hypothesis

HIT and MIC will result in a greater change in peripheral distal body temperature predicting improved sleep-onset latency compared to a NEC.

Aim 3

Purpose

The purpose of Aim 3 was to determine the subjective assessment of exercise intensity preference as a method of improving sleep.

Null Hypothesis

There will be no difference between HIT and MIC as a method of improving sleep.

Alternate Hypothesis

Participants will prefer HIT over MIC as a method of improving sleep.

Significance of the Research

Physical activity and exercise recommendations have called for older adults to engage in moderate-intensity exercise, such as brisk walking to improve health[42]. Sleep hygiene recommendations suggest exercise can promote good sleep and that vigorous-intensity exercise should be performed in the morning or late afternoon[6]. This latter recommendation is based on the study by Driver et al.[35] showing vigorous-intensity exercise prior to bedtime disrupted sleep. However, this finding is inconsistent as Passos et al.[30] showed vigorous-intensity, interval training led to improved sleep quality. Additional studies are needed to examine the optimal frequency, intensity, volume, and time-of-day of exercise needed to improve sleep quality in adults with self-reported sleep problems.

Epidemiological studies have shown that sedentary lifestyle is positively associated with sleep disturbances[45,46]. Conversely, those who self-report being physically active also report better sleep quality and/or fewer sleep disturbances than age-matched inactive adults[47]. In particular, moderate-intensity exercise is related to sleep improvements[48].

Recent evidence from studies using high intensity exercise suggests short bouts of near-maximal exercise during the evening confers multiple health benefits, including improved sleep complaints[49]. Thus, if high-intensity exercise is interval in design, including rest intervals between the high-intensity bouts, the exercise mode may be as

tolerable and as preferable as continuous moderate-intensity protocols in improving sleep quality. This question has relevance since the prevalence of high intensity-classified exercise decreases and the incidence of sleep disturbances increases with age[3,50].

The proposed research will identify whether differences exist in the intensity of exercise that relates to sleep improvement among a sample of 35-60 year-old adults with self-reported sleep disturbances. Specifically, the research will study differences between intermittent high-intensity exercise and continuous moderate-intensity exercise performed in the late-afternoon and early-evening periods of two consecutive days as compared to no exercise-control on sleep quality in sedentary adults with self-reported sleep disturbances.

Definition of Key Terms

Physical Activity: Any bodily movement produced by skeletal muscles that results in energy expenditure[51].

Exercise: Physical activity that is planned, structured, repetitive, and purposive in the sense that improvement or maintenance of one or more components of physical fitness is an objective[51].

Moderate-intensity Exercise: Exercise at an intensity of 70-80% of maximal heart rate[52].

Vigorous-intensity Exercise: Exercise at an intensity of 80-90% of maximal heart rate[52].

High-intensity Interval Exercise: Exercise that is characterized by relatively short bursts of vigorous activity, interspersed by periods of rest or low intensity exercise for recovery[31].

Sleep-onset Latency: How many minutes it takes to fall asleep, starting from the moment of intention to fall asleep[53].

Wake After Sleep Onset: Total amount of time awake during the night, excluding sleep-onset latency, and the time between the final awakening and the time of getting out of bed[53].

Sleep Efficiency (percentage): Percent of time in bed spent asleep[53].

Sleep Quality: Subjective sleep quality, typically defined by responses on an ordinal or visual analog scale[53].

Insomnia: Generic term with criteria of sleep-onset latency or wakefulness after sleep onset of more than 30 minutes, frequency of at least 3 times a week, and duration of at least 6 months[54].

CHAPTER 2

REVIEW OF LITERATURE

Introduction

Physical activity benefits to human health include improvements in cardiovascular, metabolic, muscular, and bone function. Ever since scientific associations between physical activity and health were described in the mid-20th century, various types and doses of physical activity have been examined on health outcomes[55,56]. Health professionals recognize physical inactivity and insufficient sleep as important health concerns due to their negative relationships and effects on health[1,55,57–59]. Sleep is of particular interest because of the possible bidirectional relationship with physical activity[41]. While enhanced sleep is likely to result in increased levels of physical activity the following day, a lack of physical activity may result in poorer sleep outcomes. This review of literature will explain a brief review of physical activity and health research, the history of and importance of sleep on health, and the relationship between movement patterns (physical activity) and sleep outcomes.

Physical Activity and Health: A Brief Overview of History and Recommendations

Since the 1950's, physical activity has been regarded as a health-enhancing behavior. However, it took nearly 40 years of epidemiological studies of physical activity and chronic disease outcomes to accumulate the evidence needed to make evidence-based recommendations for levels of physical activity needed for good health. One of the first sources of evidence was Morris'[60] 1953 seminal study of London transit workers where they examined cardiovascular mortality and overweight status between 31,000 London

bus drivers and London bus conductors (ticket takers) (age range = 35-64). Conductors spent their shifts running up and down stairs while drivers spent their shifts in a sedentary behavior and experience the stress of driving in London traffic. Conductors had lower rates of cardiovascular disease mortality (30%) and were less likely to be overweight than the drivers. The investigators concluded the lower rates of mortality and overweight among the conductors were due to the differing physical activity levels between the occupations. Morris[61] replicated the findings in a study comparing postal carriers who walked to deliver mail with postal workers who sat and answered telephones or stood and sorted the mail (sample size not reported, age range = 35-59). Results showed that higher levels of physical activity during work was associated with lower levels of cardiovascular disease mortality (50%). These studies opened the discussion that physical activity is related to health outcomes.

In 1978, Paffenbarger et al.[62] directly addressed the question of whether physical activity is related to health outcomes and published a seminal study examining the association between leisure-time physical activity and risk for a first heart. In a prospective cohort study of 16,936 male alumni (age range = 35-74) from Harvard University, Paffenbarger et al. showed that higher levels of energy expended in climbing stairs, walking city blocks, or participating in strenuous sports was inversely associated with risk for a first heart attack. Those who expended more than 2,000 kcal/week reduced their risk for heart attack by 64%; thus, higher levels of physical activity lowered risk for a first heart attack.

With the evidence accumulating about the protective effects of regular physical activity on health outcomes, in 1987 Powell et al.[63] published a review showing the epidemiological criteria for a causal association between regular, moderate-intensity physical activity and a reduction of morbidity and mortality from CVD. Accordingly, the American Heart Association identified a lack of physical activity as a risk factor for coronary heart disease[64]. Other organizations have since established physical activity recommendations or guidelines on the dose of PA needed to reduce the risk for chronic diseases and premature mortality. In 1995, the Centers for Disease Control and Prevention and the American College of Sports Medicine provided a joint statement on physical activity and health stating that every U.S. adult should accumulate 30 minutes or more of moderate to vigorous intensity physical activity on most, preferably all days of the week[65]. In 1996 the Surgeon General released a report titled, *Physical Activity and Health* that emphasized the importance of expending 150 kcal/day or 1,000 kcal/week through moderate, at minimum, intensity activity (e.g., 30 minutes of brisk walking or 15 minutes of running on most if not all days of the week). Nearly a decade later in 2008, the U.S. Department of Health and Human Services released the Physical Activity Guidelines for Americans (PAG)[1]. This was the first comprehensive guidelines on physical activity issued by the federal government. These guidelines further described physical activity as a behavior that reduces the risk of a variety of adverse health outcomes and that additional benefits occur as the amount of physical activity increases through higher intensity, greater frequency, or longer duration. The PAG recommend adults engage in at least 150 minutes a week of moderate intensity or 75 minutes a week of vigorous intensity health-enhancing physical activity to receive most health benefits.

Also, they should perform strength training at least twice per week. Ironically, none of the physical activity recommendations or the PAG address sedentary behaviors aside from advising adults to avoid sedentary behaviors. Because evidence is lacking, there is no reference to the time of day that performing physical activity may be most beneficial for improving organ systems, sleep, or bodily functions.

Measurement of Physical Activity and Sedentary Behaviors

Terminology

In 1985, Caspersen et al.[51] defined the terms physical activity, exercise, and physical fitness to clarify the use of these terms in epidemiological research. Physical activity is defined as "any bodily movement produced by skeletal muscles that results in energy expenditure". Exercise is defined as "planned, structured, and repetitive physical activity with the purpose of improving physical fitness components." If performed with sufficient frequency, intensity, and duration, physical activity and exercise result in increased levels of physical fitness, defined as a set of attributes that people have or achieve that are often inversely related to energy expenditure. Whereas physical activity is necessary to sustain life, the amount of and purpose for which physical activity is performed is dependent on the individual. Physical activity can occur in different domains and at different intensities that can affect health outcomes. For example, the domain of occupational physical activity is activity performed as a requirement of a job. Recreational or leisure-time physical activity is activity performed during one's leisure time. Transportation physical activity is activity performed during travel from one place to another. Other physical activity domains include household, lawn and garden, and

childcare activities. The effects of physical activity and exercise on physical fitness differs due to the energy costs of movement. Higher levels of the energy cost of movement result in higher levels of physical fitness. The opposite is true. Lower levels of movement, termed sedentary behaviors, will cause reduced levels of physical fitness. Sedentary behaviors include activities that involve sitting or lying down and can occur in similar domains as physical activity, such as a recreation or leisure-time activity (e.g. watching TV), during transportation (e.g. sitting in a vehicle), or as part of one's occupation (e.g. sitting at a desk).

To assess the energy costs of movement, it is important to know how to identify and how to measure physical activity and sedentary behaviors. This next section describes methods used to measure physical activity and sedentary behaviors directly with physiological monitors, motion detectors and observation systems and indirectly with questionnaires, diaries and logs.

Direct Measurement of Physical Activity and Sedentary Behaviors

Direct measures of physical activity and sedentary behaviors include the use of observation, accelerometers, pedometers, and physiological recording devices. The types of movement recordings and the determination of the energy cost of movement vary with each measurement device. The benefits of using direct measures are that they are less prone to recall and social acceptability bias. However, with the exception of direct observation, direct measures of physical activity and sedentary behaviors are not capable of detecting the domain in which physical activity or sedentary behaviors are performed; instead, they are focused on indicating movement or the lack of movement. Specific to

physical activity behaviors, direct measures also may not reflect the true physical activity intensity relative to the individual, as most accelerometers employ a universal cut-point to translate acceleration signals into intensity levels. This is an important consideration for the use of accelerometers and other direct methods to measure movement as the data processing may lead to different interpretations of physical activity behaviors of individuals or a population.

A brief description of direct measurement of physical activity and sedentary behaviors follows and includes direct observation, accelerometers, pedometers, and physiological recordings.

Direct Observation

Direct observation allows the researcher to observe an individual performing an activity while recording the type, duration, intensity, and possibly the context of the activity (e.g., leisure, occupation, transportation, and household) using video, electronic, or paper data capture tools. Because direct observation often occurs in free-living environments, the observer can record a range of activities performed, the context in which the activity is occurring, and the varying amounts of intensity at random. An example of direct observation used to assess physical activity and sedentary behaviors within a context is the System for Observing Play and Leisure Activity in Youth (SOPLAY). SOPLAY was designed to measure the number of children participating in leisure physical activity in a target area, classifying them into sedentary (lying down or sitting), walking, or very active categories. McKenzie et al.[66] used SOPLAY to assess the physical activity and sedentary behaviors of children in the school environment. In a

sample of 1,081 students across 24 schools in grades 6-8, SOPLAY accurately identified the percentage of boys and girls participating in sedentary activities or moderate-to-vigorous intensity physical activity throughout the school day. An example of the use of direct observation in a school setting is the System for Observing Fitness Instruction (SOFIT). SOFIT was designed as a system for schools to provide a measure of student activity levels during class time. The use of SOFIT to estimate physical activity and sedentary behaviors of children during school was presented by Honas et al.[67]. Thirty-eight students in classrooms for grades 2 through 5 were categorized on a 5-point Likert scale from lying down to very active. SOFIT provided an accurate estimation of classroom based physical activity. Direct observation also is appropriate for use in public health settings. Adams et al.[68] videotaped 15,574 people to determine the effects of a research model on a persons' use of stairs or escalators in an airport.

In summary, direct observation has several advantages over other forms of direct measurement of physical activity. Direct observation is not dependent on laboratory-derived algorithms used to identify movement duration, frequency, and intensity and can provide the context for the performance of physical activity and sedentary behaviors. In addition, direct observation allows the investigator to record the types of movements performed using electronic data capture systems or with video recordings.

Accelerometers

Accelerometers record acceleration of human movement in two-to-three planes resulting in the frequency, intensity, and duration of movement. After adjusting for gravity and filtering out non-human movement (e.g., acceleration of body from riding in

vehicles), accelerometers can provide an accurate measure of physical activity and sedentary behaviors. Within the past 20 years, accelerometers have gained popularity with researchers since they provide objective physical activity and sedentary behavior information in both laboratory and free-living settings[69,70]. Accelerometers are worn on the hip, wrist, thigh, or around the chest to reflect participant movement. Movement accelerations are captured at a pre-determined sampling rate, typically 40-100 times per second (hertz) and are interpreted as counts to reflect intensity and duration of movements. Various types of accelerometers exist and include brands such as the ActiGraph, GENEactiv, ActivPal and other less popular models[71].

The most widely used research grade accelerometer is produced by ActiGraph (ActiGraph LLC, Pensacola, FL) which has been consistently shown to provide an accurate assessment of physical activity frequency, duration, and intensity using threshold and algorithm methods[72]. The ActiGraph software guides the researcher through various types of data processing and has several of the established movement count threshold criteria embedded in the program. Researchers process the data using count thresholds to determine frequency, intensity, and duration of movement in meaningful ways to reflect patterns of physical activity and sedentary behaviors. Count thresholds vary depending on the physical activity component of interest and the population studied. Freedson et al.[73] were the first to establish ActiGraph accelerometer count thresholds. In a laboratory setting, 50 adults performed treadmill exercises at three different speeds while wearing a waist-worn accelerometer. Physical activity intensity thresholds were determined by comparing counts to measured energy expenditure values. Evenson et al.[74] also established count thresholds in children 5-8 years of age. Thirty-

three children wore two different accelerometers at the waist and, similar to Freedson et al., they compared counts to energy expenditure to establish count thresholds for physical activity intensity. The ActiGraph is used in research and in surveillance settings. The National Health and Nutrition Examination Survey uses the ActiGraph accelerometer to monitor population trends in physical activity and sedentary behaviors. In 2008, Troiano et al.[3] first reported accelerometer-measured physical activity in 6,830 individuals, a representative sample of U.S. adults ages 18-49 years. They showed that less than 5% of adults were active at levels sufficient to meet national physical activity recommendations. These data represented the initial estimates of prevalence of adherence to physical activity recommendations from objectively-monitored physical activity. Accelerometers also are used to measure movement in research studies. In the Trial of Activity in Adolescent Girls, Pate et al.[75] used accelerometer-measured physical activity counts to examine the age-related changes in physical activity over two years. Adolescent girls (n=2,331) wore an accelerometer for six days per year to assess the frequency, intensity, and duration of physical activity performed. Despite the intervention efforts, moderate-to-vigorous intensity physical activity declined at a rate of 4% per year.

In the previous examples of the ActiGraph accelerometer uses, investigators used count thresholds to rate the duration and intensity of movement. Despite the wide use of count thresholds, debate remains about the validity of existing cut-points when classifying physical activity intensity in free-living settings. Thus, efforts have led to the examination of machine-learning algorithms and individually developed algorithms to assess the duration and intensity of movement[70]. The GENEactiv (Activinsights Ltd, Cambridgeshire, UK) is a research grade accelerometer that benefits from the use of

machine-learning algorithms and individually developed algorithms. The wrist-worn GENEactiv collects movement accelerations and outputs data without initial data processing. This provides the researcher with the capacity to process the acceleration data using established thresholds or with individually developed algorithms. An advantage of the GENEactiv is that it is worn on the wrist for 24-hour monitoring of movement, including sleep. While the GENEactiv is a relatively new research-grade accelerometer, studies have shown the feasibility and utility of the monitor as compared with other accelerometers. Huberty et al.[76] compared the feasibility of three accelerometers during three weeks of 24-hour monitoring in 21 women, 30 to 64 years old. They deemed GENEactiv as acceptable with 100% of the eligible person-days of GENEactiv data captured for data analysis as compared with lesser amounts of data captured with the other monitors.

A third example of an accelerometer is the ActivPAL (PAL Technologies Ltd, Glasgow, Scotland). The ActivPAL assesses postures and movement during physical activity and sedentary behaviors. The ActivPAL is worn on the thigh and collects acceleration and the angle at which the thigh is positioned with an inbuilt uni-axial accelerometer and inclinometer, respectively. Researchers can determine how much time a person spent in sedentary activities such as sitting or lying down, and in non-sedentary activities such as standing or walking. While the ActivPAL is capable of recording step number for walking cadence, the strengths of the device are in the identification of physical activity and sedentary activity changes and in the assessment of time spent in different postures and sedentary behaviors[77,78]. In a validation study, Edwardson et al.[79] examined the accuracy of time spent in different postures and sedentary behaviors

between thigh- and waist-worn accelerometers, including the ActivPAL, in 34 males and females ages 21-33 years. Results showed the ActivPAL correctly identified 91% of sitting, 100% of lying, and 99% of upright postures.

Pedometers

Pedometers count steps taken by an individual as they go through their daily routines. Early mechanical pendulum pedometers counted steps based on a heel-strike during walking activities. In recent years, pedometers use piezoelectric technology that incorporates steps taken in a unit of time allowing researchers to determine the frequency and duration of physical activity. Earlier pedometer models were designed to be worn at the hip and are excellent in measuring steps at walking speeds > 2 mph[80]. Models that are more recent also are worn at the level of the wrist, chest, ankle, and in pockets. The most accurate readings of steps taken involve wearing pedometers at the ankle. Investigators have compared different brands of pedometers for accuracy. In 2004, Schneider et al.[81] examined the validity of 13 electronic pedometers for measuring steps in 10 subjects with age ranging from 21-45 years while walking at various speeds. Compared to direct observation of steps, several pedometers were within ±1% of the actual steps taken. The most accurate brands included Kenz, Yamax. New-Lifestyles, and Sportline. Advances in technology allow pedometers to store data for weeks and to display the results easily. For example, most electronic pedometers use Bluetooth applications to show results of step data using computer websites and smartphone applications.

The primary advantage of the pedometer is the output metric of steps which makes physical activity easily translatable to both consumers and researchers. For

example, Tudor-Locke and Bassett[82] identified step cut-points to reflect varying levels of physical activity behaviors ranging from sedentary-to-highly active. In a 2004 review, they described sedentary lifestyles as < 5,000 steps per day, low active lifestyles including typical daily activities without sports and exercise as 5,000-7,499 steps per day, somewhat active lifestyles including exercise or elevated occupational activity demands as 7,500-9,999 steps per day, and active lifestyles as ≥ 10,000 steps per day. Another advantage of the pedometer is the output metric of steps per minute can be used to estimate physical activity intensity when walking. Pillay et al.[83] studied 58 men and women, ages 24-38 years, and identified a cadence of 60-120 steps per minute as a moderate-intensity movement. Thus, pedometers provide a practical and inexpensive way to estimate the duration and intensity of physical activity behaviors.

Physiological Recordings

Recordings of one's heart rate and galvanic skin responses are types of physiological recordings that determine the frequency, duration, and intensity of physical activity and sedentary behaviors in laboratory and free-living settings. These associations are possible through the linear relationship between physical activity intensity and physiologic responses to movement or lack of movement[84]. Physiological responses to increased physical activity vary by an individual's fitness level. Thus, it is possible to individualize the assessment of physical activity using monitors that measure physiological responses to movement behaviors. An example of a physiological recording device is the SenseWear armband (BodyMedia, Inc., Pittsburgh, PA). The SenseWear armband is worn over the triceps muscle and collects movement acceleration and records skin temperature and galvanic skin responses using electrical conductivity of

the skin. These input signals have a direct linear relationship with physical activity that allows an estimation of the frequency and duration of physical activity. One strength of the SenseWear armband is the ability to measure various modes of physical activity accurately. In 2004, Jakicic et al.[85] evaluated the SenseWear armband against indirect calorimetry in a sample of 40 adults, 19-27 years old. The SenseWear armband provided accurate measures of physical activity accrued from walking, cycling, stepping, and arm ergometry. Another strength of the SenseWear armband is the accurate measurement of light-to-moderate physical activity intensity. Alternatively, a limitation of the SenseWear armband is the lack of accuracy in assessing sedentary or standing activities or vigorous-intensity activity levels. In 2014, Van Hoye et al.[86] examined the accuracy of the SenseWear armband to assess light-to-moderate and vigorous physical activity intensities against indirect calorimetry in sample of 44 adults, 20-23 years old. The SenseWear armband accurately assessed light-moderate intensity walking but underestimated vigorous-intensity jogging exercise.

Another example of a physiological monitor used to measure physical activity and sedentary behaviors is the Zephyr BioHarness (Zephyr Technology, Annapolis, MD). The Zephyr BioHarness (referred to as the BioHarness) combines accelerometry, heart rate measurement and respiration measures through a chest-worn strap providing the researcher with movement accelerations, beats per minute, and breaths per minute to estimate physical activity and sedentary behaviors. The BioHarness has been evaluated for accuracy against previously validated physiological systems. In 2013, Kim et al.[87] demonstrated the BioHarness accurately assessed heart rate and breathing rate during graded treadmill exercise as compared to a 12-lead electrocardiogram and open-circuit

spirometer, respectively, in 12 health men ranging in age from 21-29 years. Also in 2013, Jovanov et al.[88] showed the BioHarness was accurate in showing postural changes when compared to direct observation in seven healthy subjects performing a sequence of sitting and standing movements. The BioHarness system is useful in-practice and in sports performance settings as it is easy to use, has training system software, has device integration with performance clothing, and it provides Bluetooth integration for real-time feedback.

Overall, all direct measures of physical activity and sedentary behavior offer an accurate assessment of the frequency and duration of those behaviors and the intensity of physical activity. While some measures incorporate physiological recordings to aid in measurement of movement, all methods, including direct observation, aim to evaluate the movement of the individual. As the strengths and limitations of each measurement device vary, researchers should consider the types of physical activity or sedentary behavior they wish to measure before using a particular type or brand of objective monitor.

Indirect Measures of Physical Activity

Indirect measures of physical activity and sedentary behaviors include the use of questionnaires, records, and logs. All indirect measures benefit from the ability to capture the purpose, self-reported frequency and duration of physical activity and sedentary behaviors, and the intensity of varying types of physical activity[89]. In addition, each indirect measure has a unique benefit when estimating physical activity and sedentary behaviors. From these self-reported metrics, researchers can compute the estimated energy cost of movement. However, because of the reliance on the individual self-

reporting of physical activity or sedentary behaviors, subjective measures have a reporting bias. Common sources of bias include the inability of some population groups to complete questionnaires, logs, or records because of a lack of understanding of the construct of physical activity or sedentary behaviors queried or poor literacy. Further, limited memory, problems telescoping one's behavior beyond the recall time period, and social desirability to be more active than one's actual activity levels can result in an over- or under-reporting of physical activity and of sedentary behaviors[90]. The indirect measures described here include questionnaires, records, and logs.

Questionnaires

Questionnaires are presented in various forms and require respondents to estimate their own physical activity and/or sedentary behavior levels. The level of detail in a questionnaire varies. Most questionnaires ask participants to recall the duration and intensity of physical activity or sedentary behaviors they did over a defined time period such as a week or month[55]. Three types of questionnaires are used in research and/or surveillance settings. Global questionnaires categorize a participant as active or inactive based on their physical activity level derived from a few brief questions. For example, the United States Behavioral Risk Factor Surveillance System uses a single question to classify individuals as engaging in physical activities during the past month[91]. Recall questionnaires are more detailed than global questionnaires and ask the participant to provide information about the frequency, duration, and intensity of different types of physical activity or sedentary behaviors performed over a specified period such as the previous week or month. Recall questionnaires also may ask respondents to provide domain-specific activities, such as daily duration of computer use at work (e.g.,

occupational sedentary behavior), or weekly frequency of walking to a bus stop (e.g., transportation physical activity). An example of a recall questionnaire is the short form of the International Physical Activity Questionnaire (IPAQ). The IPAQ has respondents answer how many days and how much time they spent in the past week doing vigorous activities, moderate activities, walking, and time spent sitting during a usual day. Quantitative history questionnaires may have as many as 70 items and are more comprehensive than recall questionnaires. They require respondents to recall the frequency, intensity, and duration of physical activities over a period in the past (e.g., past month, year, or lifetime). A strength of quantitative history questionnaires is the inclusion of various types of categories, such as occupational, household, different types of sport and leisure, transportation, family care, and home and yard activities, which is impossible to know unless one directly observes the behaviors. An example of a quantitative questionnaire is the Minnesota Leisure Time Physical Activity Questionnaire. It lists 18 major activity groups and 62 individual activities and asks respondents to indicate the number of occasions per month they performed each activity and average duration of the activity[92].

In general, questionnaires are limited in their utility due to biases in their internal and external validity. Internal validity is reduced if respondents are unable to understand the questionnaire to complete the items accurately. External validity often is limited depending on the population measured. Older adults, children, and those with poorer education are underrepresented when designing questionnaires and when performing validation studies. Thus, questionnaires may not be relevant to such populations and the external validity of the questionnaire may be unknown for such populations.

Records

When using physical activity or sedentary behavior records (records), individuals list physical activity and sedentary behaviors during the day as they occur. To complete the record, individuals identify each behavior and record a new entry into a paper or electronic form when the behavior changes, such as changing from sitting watching TV to standing and doing the dishes. By recording information as behaviors change, researchers obtain a better understanding of the social context of physical activity and sedentary behaviors, such as attitude toward an activity or support for the activity. Dunton et al.[93] provided an example of record use in a study that matched accelerometer-measured physical activity in 121 children to self-completed electronic records. Children recorded the activity, location of activity, if any friends were present during the activity, mood during the activity, and enjoyment of the activity. The record information allowed researchers to determine empirically that physical activity was most enjoyable when they performed it outdoors and was least enjoyable when performed alone. Records may include various information depending on the study objectives. For example, to obtain information about time spent in differing postures, a researcher may have respondents record the duration of an activity while sitting, lying down, standing, or walking. A researcher also can obtain information about the purpose of the activity (e.g. child care, household, transportation) and a respondent's perceived effort of the activity (light, moderate, or vigorous)[94].

Logs

Logs require individuals to record specific activities or sedentary behaviors into a simplified record as they participate in the activities throughout the day. A logbook often

requires the respondent to identify movement information within discreet periods (e.g. 15- or 30 minute intervals) throughout the day or at the end of the day. Logs provides a simple way to collect information about types or intensities of physical activity and sedentary behaviors performed during each day. Several types of logs exist for use in research and in practice settings. A popular log is the Bouchard Activity Log[95]. This 3-day log has respondents identify specific activities performed every 15-minutes according to their intensity level on a scale from 1 to 9. Examples of activities and respective intensities range from sleeping (n=1) to high-intensity sports activities (n=9). The main benefit of recording specific activities, in addition to identifying the activity intensity, is the accurate reflection of the individual's physical activity intensity fluctuations over a period of time or throughout the day.

In summary, various types of methods are available to assess physical activity and sedentary behaviors. Direct measures of acceleration, posture, and physiological responses have the greatest accuracy to assess the frequency, duration, and intensity of movement. While dependent on self-report, indirect measures are best to identify the types of movement or sedentary behaviors performed. Combining direct and indirect measures provide the most complete measure of physical activity and sedentary behaviors.

Measurement of Sleep Behaviors

Terminology

Sleep behaviors are identified using quantitative or qualitative sleep parameters that employ a classification system to allow consistency in the definition of terms[96].

Quantitative sleep parameters identify the time one spends in bed attempting to sleep and the time one spends asleep each night. These parameters include the measurement of sleep duration (time spent asleep), sleep onset latency (time spent in bed attempting to fall asleep initially), sleep maintenance (time spent awake and number of awakenings during the night after falling asleep initially), and sleep efficiency (the ratio of time spent asleep to time spent in bed). Alternatively, qualitative sleep parameters reflect the overall quality of one's sleep. Sleep quality can be rated from poor-to-excellent as measured with self-report ratings of poor sleep quality overall, self-reported bad dreams resulting in trouble sleeping, self-reported or physician-reported taking of medication to help with sleep due to trouble sleeping, self-reported feeling of restlessness during sleep, or self-reported difficulty concentrating and irritability during the day due to trouble sleeping. Sleep quality also can be determined by detecting brain wave patterns and comparing time spent asleep in light sleep stages that are less restorative to time spent asleep in deep sleep (slow wave sleep) that are more restorative.

Sleep researchers use both direct and indirect methods to measure quantitative and qualitative sleep parameters. Direct methods used to measure quantitative and qualitative sleep parameters include polysomnography and the Zmachine. These methods record brain wave activity during sleep. Indirect methods that measure quantitative and qualitative sleep parameters include the measurement of bodily movements during the night and the use of self-report questionnaires and diaries about one's sleep. This section describes the direct and indirect methods of measuring sleep parameters.

Direct Measurement of Sleep

Polysomnography

Polysomnography is a comprehensive recording of the bio-physiological changes that occur during sleep. Polysomnography records and analyzes brain wave activity, eye movements, respiration, skeletal muscle activation, and heart rhythm during sleep by placing electrodes and sensors on the head, face, and body. From these measurements, clinicians and researchers can distinguish the body states of wake, sleep, and sleep stages (light, deep, and REM) to examine quantitative and qualitative sleep parameters. The quantitative sleep parameters include sleep duration, sleep onset latency, sleep maintenance, and sleep efficiency. The qualitative sleep parameters include time spent in light sleep stages, time spent in slow wave sleep, and time spent in REM sleep.

Polysomnography is considered the gold-standard in sleep measurement due to its precision in distinguishing wake versus sleep states and in identifying time spent in light sleep, slow wave sleep, and REM sleep stages. These measures allow the accurate quantification of disturbances in quantitative and qualitative sleep parameters. Thus polysomnography is the preferred method of screening for disorders such as sleep apnea, restless-leg syndrome, and narcolepsy which are characterized by disturbances in sleep parameters[97].

While polysomnography is considered the gold-standard for assessing sleep stages, it has limitations that make it difficult to capture the variability in sleep parameters over longer periods of time to determine typical sleeping patterns[97]. In 1966, Agnew et al.[98] described the phenomena of the "first-night effect" of polysomnography in

a sample of 43 adults, age ranging 16-31 years. Participants experienced polysomnography for four consecutive nights. The first-night effect was described as having poorer sleep on the first night of polysomnography testing compared to the three succeeding nights of testing. Results showed the first night effect resulted in more time spent in light sleep stages, delayed slow-wave sleep, and more changes between light and slow-wave sleep. These changes were small and non-significant between the second and fourth nights indicating the presence of a first-night effect. The first-night effect was likely due to the unfamiliar sleeping environment and monitoring equipment.

When using polysomnography to measure sleep status, multiple nights of data collection are preferred to capture normal night-to-night variability in sleep. However, the high cost and time commitment associated with polysomnography makes it difficult to collect data for more than one night[99]. While polysomnography is considered the most accurate method to measure sleep, its limitations may outweigh the benefits for non-clinical uses. Therefore, polysomnography should not be the only tool used to diagnose sleep disorders that are characterized by the persistence of poor sleep parameters such as insomnia[53].

Zmachine

The Zmachine (General Sleep Corporation, Euclid, OH) is a portable single channel electroencephalographic (EEG) system used to measure brain wave activity during sleep. Electrodes placed on the differential mastoid behind each ear measure brain wave activity and output data in 30-second epochs and are classified as wake, light sleep, slow wave sleep, and REM sleep of the sleeper. The Zmachine can accurately detect

wake versus sleep states to determine quantitative sleep parameters and it can accurately score sleep stages to determine sleep quality (light, deep, or REM stages). To measure the accuracy of the Zmachine as a quantitative measure of sleep, Kaplan et al.[100] enrolled 99 normal and sleep-disordered adults, ages 18-60 years. Compared to sleep technologist observations of sleep brain wave patterns, the Zmachine epoch-scoring algorithms accurately identified quantitative sleep parameters of total sleep time, sleep efficiency, sleep onset latency, and sleep maintenance. In the same sample, Wang et al.[101] reported the Zmachine as a valid measure of qualitative sleep parameters. When compared to sleep technologist observations, the Zmachine algorithms calculated correctly the time spent in light sleep stages, time spent in slow wave sleep, and time spent in REM sleep. The Zmachine also is easy to use as a portable device for in-home analyses of sleep. Rosenberger et al.[102] used the Zmachine to validate four wearables to measure the quantitative sleep parameter of sleep duration in 40 subjects, age range 21-76 years in an at-home, 24-hour study. Overall, when compared to polysomnography, the Zmachine is useful in measuring various sleep parameters due to its non-intrusiveness on sleep and its portability for in-home analyses of sleep.

Indirect Measurement of Sleep

Actigraphy

Actigraphy is the process of using motion capture devices, such as the accelerometer worn on the wrist or ankle, or possibly placed under a pillow during sleep to collect data on motor activity during sleep behaviors. Actigraphy objectively identifies quantitative sleep parameters of sleep duration, sleep onset latency, sleep maintenance,

and sleep efficiency through the collection of movement data downloaded to a computer for analysis of activity or inactivity using wake and sleep algorithms.

In 1995, Sadeh et al.[103] published a seminal review summarizing the validity of actigraphy to measure quantitative sleep parameters. They compared the sleep parameters obtained from actigraphy with the gold-standard polysomnography in adults, ages 20-76 years. The summary of empirical data showed no significant differences between actigraphy and polysomnography for quantitative sleep parameters of sleep duration, sleep onset latency, sleep maintenance, and sleep efficiency ($p > 0.05$). They also showed that actigraphy may be helpful in the assessment of insomnia, circadian-rhythm disorders, and restless leg syndrome that are characterized by disturbances in quantitative sleep parameters[103]. Based on these conclusions and other validation studies[104,105], the Board of Directors of the American Sleep Disorders Association recognizes actigraphy as a reliable and valid method for detecting quantitative sleep parameters..

As with all sleep assessment methods, actigraphy has advantages and limitations to its use. Actigraphy is not capable of distinguishing qualitative sleep parameters, such as time spent in sleep stages because it does not collect brain wave activity recorded with direct measures such as polysomnography and the Zmachine. Alternatively, the advantages of using actigraphy over direct measures of sleep include the non-invasive, longitudinal method of examining quantitative sleep parameters in the ambulatory, free-living setting thereby reflecting individuals' night-to-night variability in quantitative sleep parameters[106]. In addition, actigraphy does not result in a first-night effect on sleep[107,108]. These advantages were demonstrated by Rowe et al.[109] who used actigraphy

to examine sleep parameters in 103 adults, aged 60 and older, for 14 consecutive nights. They determined that at least three days of actigraphy measurement was feasible and that having an increased frequency of measurement more accurately reflected one's quantitative sleep parameter patterns. To increase the accuracy of actigraphy in measuring sleep parameters, Rowe et al. recommended that researchers and/or clinicians average the quantitative sleep parameter of sleep-onset latency over a period of at least seven days to reflect the night-to-night variability that naturally exists when in bed attempting to fall asleep initially.

Self-report Measures

Self-report measures of sleep provide useful subjective information of one's quantitative and qualitative sleep parameters in free-living settings. Quantitative sleep parameters measured by self-report measures include sleep duration, sleep onset latency, and sleep maintenance. Qualitative sleep parameters include self-reporting bad dreams resulting in trouble sleeping, taking medication to improve poor sleep, and whether trouble sleeping may be affecting activities (i.e. work, exercise), concentration, or mood the following day. Self-report measures to examine sleep parameters include diaries and questionnaires.

Diaries, also called sleep logs, are records of sleep behaviors that have the participant record daily wake times and nightly bed times. Diaries also may require the participant to record the previous night's sleep onset latency and wake time on the subsequent morning. Diaries are acceptable measures of sleep duration[110]. However, participant burden may be high as subjectively estimating one's wake times, bed times,

and sleep onset latency accurately may be time consuming and difficult for participants, especially for those suffering from disturbances in sleep duration[111]. Age bias has been report in the completion of sleep diaries. In 2012, Short et al.[112] explored discrepancies in sleep duration and sleep maintenance when measured by sleep diaries compared to actigraphy in a sample of 385 adolescents (231 males, 154 females), between 13-18 years old. The study duration was 8 nights. Examination of mean differences in sleep duration and sleep maintenance between the methods found sleep duration measured by actigraphy to be 85 minutes less on average compared to sleep diary-reported sleep duration (Cohen's $d = -1.21$, $p < 0.001$). Similarly, actigraphy-measured sleep maintenance was on average 67 minutes longer than sleep diary-measured sleep maintenance ($d = 1.89$, $p < 0.001$). These results show the utility of using sleep diaries to measure sleep parameters.

Questionnaires assess quantitative and qualitative sleep parameters of sleep duration, sleep onset latency, and sleep maintenance, and assess qualitative sleep parameters, such as difficulty concentrating due to poor sleep quality on the prior night. The main benefit of using questionnaires to assess sleep parameters includes accurately reflecting night-to-night variability in sleep parameters over an extended period while being unobtrusive on sleep. An example of a widely used questionnaire to examine sleep in all populations is the Pittsburgh Sleep Quality Index (PSQI). Developed by Buysse et al.[113] in 1988, the PSQI assesses quantitative sleep parameters of sleep duration, sleep onset latency, sleep efficiency, and sleep maintenance, and qualitative sleep parameters of overall sleep quality, the use of sleep medication, and daytime dysfunction due to trouble sleeping over the previous 1-month interval. The PSQI has 19 items for the

sleeper to rate quantitative and qualitative sleep parameters. The PSQI item responses are categorized to create seven sleep component scores indicating the severity of sleep difficulties. Each component score is rated form 0-3 points (0 = no difficulty; 3 = severe difficulty). The component scores are summed to create a global sleep score with a range of 0-21 (0 = no sleep difficulty; 21 = severe sleep difficulties). In 2002, Backhaus et al.[114] compared the accuracy and test-retest reliability of the PSQI against polysomnography in a sample of 80 patients with insomnia (46.3 ± 15 years) and a control group of 45 healthy adults (43.3 ± 9.5 years). Correlation analyses showed the PSQI global score as valid compared to polysomnography for measuring sleep duration ($r = -0.27$, $p = 0.074$), sleep onset latency ($r = 0.28$, $p = 0.063$), sleep maintenance ($r = 0.12$, $p = 0.427$), and sleep efficiency ($r = -0.32$, $p = 0.034$). The global score also showed high test-retest reliability over 45.6 ±18 days ($r = 0.87$, $p < 0.001$). The investigators concluded that the PSQI has good validity and high test-retest reliability in measuring quantitative and qualitative sleep parameters in a clinical population and that it is an acceptable measure of habitual sleep parameters.

Questionnaires also can replace diaries as an unobtrusive measure of quantitative sleep parameters. In a study to develop a single-administration tool to replace sleep diaries over a 2-week experiment, Monk et al.[115] developed the Sleep Timing Questionnaire (STQ). The questionnaire requires participants to provide information about typical sleep duration, sleep onset latency, and sleep maintenance. To determine the accuracy and test-retest reliability of the STQ, Monk et al. compared the STQ to wrist actigraphy and a 2-week sleep diary. In a sample of 23 adults, ages 20-89 years, correlation analyses demonstrated the STQ was effective in recording bed time (r =

0.592, p = 0.003), wake time (r = 0.769, p < 0.001), sleep onset latency (rho = 0.855, p < 0.001), and sleep maintenance (rho = 0.838, p < 0.001). In the same study, Monk et al.[115] also reported the results of STQ test-retest reliability testing in two samples of adults (n=101 and n=93, ages 20-89 years). Correlation analyses demonstrated high test-retest reliability for bed time (r = 0.705, p < 0.001) and wake time (r = 0.826, p < 0.001) compared to sleep logs completed over two weeks. They concluded that the STQ was valid and reliable and could provide a time-efficient method of estimating quantitative sleep parameters.

Comparison of self-report versus objective measures of sleep.

The benefit of self-report logs and questionnaires as compared with objective measures of sleep, such as the Zmachine or accelerometers, is the ease of use in determining the subjective quality of a person's sleep. However, limitations of using sleep diaries and questionnaires include the improper estimation of good or poor sleep. For example, Carskadon et al.[111] reported that individuals may under-estimate sleep duration or over-estimate sleep onset latency and sleep maintenance in comparison to polysomnography. McCrae et al.[116] examined this possibility in detail, demonstrating that individuals can self-report sleep complaints and have subjectively and objectively defined good or poor sleep parameters. Conversely, individuals can self-report no complaints with sleep but have subjectively and objectively defined poor sleep parameters. In a four-group study (noncomplaining good sleepers, noncomplaining poor sleeper, complaining good sleepers, complaining poor sleepers) of 116 adults 60 years and older (average age not reported), McCrae et al. monitored sleep for 2-weeks using sleep logs and actigraphy. Correlation analyses showed relationships between actigraphy- and sleep log-measured

quantitative sleep parameter of sleep duration for noncomplaining good sleepers ($r = 0.84$, $p < 0.001$) and quantitative sleep parameters of sleep duration and sleep onset latency for noncomplaining poor sleepers ($r = 0.80$ and $r = 0.81$, $p < 0.001$) but none for complaining sleepers. Therefore, individuals can sleep well (measured objectively) and report poor sleep, as well as sleep poorly (measured objectively) and report good sleep.

In summary, various types of methods are available for assessing sleep behaviors. The most accurate direct measures of quantitative and qualitative sleep parameters are polysomnography and the Zmachine because they can detect brain wave patterns to identify wake from sleep. The most accurate indirect measures are accelerometers as they analyze movements while in bed. Lesser accurate indirect measures of sleep parameters are self-report measures using diaries or questionnaires. To maximize the benefits and mitigate the limitations of each method, a combination of objective monitors (i.e. accelerometers) and subjective tools (i.e. diaries and questionnaires) should be used, thereby providing the most complete measure of sleep behaviors[117].

Descriptive Epidemiology of Sleep

Patterns in habitual sleep parameters evolve throughout the lifespan resulting in age-related changes in sleep even when excluding conditions such as mental disorders, physical illness, drugs/alcohol, sleep apnea, and other sleep disorders[9]. Four consistent age-related changes in quantitative and qualitative sleep parameters include the alteration of sleep duration, increased sleep onset latency, decreased sleep maintenance, and reduced sleep efficiency. In a detailed meta-analysis of quantitative sleep parameters from childhood to old age in health individuals, Ohayon et al.[9] studied changes in sleep

over the lifespan. They used the *Q* statistic, a homogeneity test to indicate whether variation is greater than expected from sampling error to examine normal changes in quantitative and qualitative sleep parameters. Changes in quantitative sleep parameters showed,

- a linear decline in sleep duration of about 10 minutes per decade ($Q = 343.63$, $p < 0.0001$)
- a gradual increase in sleep onset latency until the age of 65 followed by a larger increase ($Q = 92.25$, $p < 0.0001$)
- a worsening of sleep maintenance of 10 minutes per decade with elderly adults reported as much as 60 minutes per night ($Q = 177.07$, $p < 0.0001$)
- a 3% decrease in sleep efficiency with elderly adults reporting sleep efficiency of less than 80% per night ($Q = 372.28$, $p < 0.0001$).

Changes in qualitative sleep parameters showed,

- a decrease in overall sleep quality demonstrated by more time spent in light sleep stages (stage 1: $Q = 179.2$, $p < 0.0001$; stage 2: $Q = 310.53$, $p < 0.0001$),
- less time spent in deep sleep stages ($Q = 406.03$, $p < 0.0001$).

Other studies have reported additional changes in self-reported qualitative sleep parameters, such as an increase in daytime sleepiness, irritability due to trouble sleeping, and an increase of 7% in the use of sleeping aids[118,119].

Altered sleep patterns characterized by poor and highly variable sleep parameters can result in insomnia, a term widely used to characterize the disturbance of sleep. Investigators and clinicians describe insomnia as having poor quantitative or qualitative

sleep parameters either acutely or persisting for longer periods (e.g., ≥ six months). Insomnia sleep parameters include extended time to fall asleep initially (sleep onset latency, > 30 minutes), extended time spent awake after initially falling asleep (sleep maintenance > 30 minutes), or extended time spent awake in bed while attempting to sleep (sleep onset latency + sleep maintenance > 30 minutes). Clinicians confirm the presence of acute and chronic insomnia based on the self-report or the measurement of these sleep parameters. If poor sleep parameters persist for three or more nights per week continuously for six months or longer one is clinically diagnosed with insomnia[54,120].

A 2005 poll conducted by the National Sleep Foundation revealed that 54% of surveyed respondents have experienced at least one symptom of insomnia at least a few nights a week over the past year[6]. Studies are few, but in adult populations (18 years and older) the indicate that insomnia has an annual incidence rate between 31% and 37%, with the latter being the most recent report by Ellis et al. in 2012 (n = 1095, 75% females, 32.7±13.8)[121,122] . In addition to the high reporting of insomnia, insomnia symptoms tend to persist for at least a year. Morphy et al.[123] the persistence of insomnia in a sample of men (n = 1175) and women (n = 1487) 18 years old and older (51.7 ±17.5 years). Self-reported quantitative sleep parameters at baseline and 1-year follow-up indicated that of participants reporting symptoms of insomnia at baseline, 69% (95% CI = 65.0-73.3) continued to report insomnia symptoms. Population-based studies[124,125] and a National Sleep Foundation[6] poll have shown the prevalence of insomnia in all-age adults to range between 10-40% with one in three adults reporting at least one insomnia symptom. Age and gender are the primary demographic differentiators of insomnia prevalence. The prevalence of insomnia is lower between the ages of 15 and 44 years (3%), begins

increasing at 45 years (20%), and reaches its peak prevalence in adults 65 years and older (65%)[126]. Insomnia is more prevalent in women (39-60%) than in men (10-13%)[7,127]. A meta-analysis with 1,265,015 persons (56.8% female, ages 15 to ≥65 years) by Zhang and Wing[128] showed that women were at greater risk for insomnia (RR = 1.41, 95% CI = 1.28-1.55, $p < 0.001$) than were men (reference group). Other studies also have shown that insomnia increases with age in women (≥ 65 years: RR = 1.73, 95% CI = 1.65-1.83, $p < 0.001$; 31-64 years: RR = 1.46, 95% CI = 1.29-1.63, $p < 0.001$; 15-30 years: RR = 1.28, 95% CI = 1.13-1.43, $p < 0.001$) compared to men (referent group). This change often is attributed primarily due to the physiological effects of menopause. Age-related increases in insomnia in men may be related to lifestyle factors such as physical inactivity, obesity, or psychiatric disorders[124,127,128].

Factors other than age are associated with an increased prevalence of insomnia. Insomnia is increased in those with comorbid conditions such as heart disease (44%), cancer (41%), high blood pressure (44%), breathing problems (60%), urinary problems (42%), chronic pain (49%), gastrointestinal problems (55%), and psychiatric disorders (40%) and in those working in occupations requiring abnormal or rotating shifts[129–131]. Socio-demographic and economic factors related to insomnia include marital status (10-15% higher in separated/divorced and widowed females), education level (7-10% higher in those who have not completed high school), and occupational status (10% higher for unemployed)[125,132].

In summary, changes in sleep parameters that result from increased age include decreased sleep duration, increased sleep onset latency, decreased sleep maintenance, and

reduced sleep efficiency. Insomnia is a sleep disorder characterized by the poor sleep parameters of sleep onset latency and sleep maintenance which can occur acutely or persist over long periods of time. Insomnia awareness is increased among national organizations as incidence rates are not marginal and once reported are likely to persist. In addition, insomnia increases in prevalence with age which is associated with increases in other comorbid conditions.

Health Effects of Insomnia

Insomnia is a contributor to premature morbidity and mortality[58,133]. Two important effects of insomnia include cardiovascular disease (CVD) and type 2 diabetes (T2D). Cardiovascular disease is a collective term that includes stroke, coronary heart disease, peripheral vascular disease, and other forms of vascular problems. Type 2 diabetes is a condition in which poor handling of ingested glucose results in hyperglycemia. Studies examining the health effects of insomnia have focused on CVD and T2D. This section reviews six of the notable studies relating insomnia to CVD and T2D.

To examine the relationship between insomnia and cardiovascular events, Hsu et al.[134] compared a sample of 22,040 adults (9,456 males, 47.7 ± 15.7 years) diagnosed with insomnia with 22,040 age-, sex-, and comorbidity-matched controls. Physician-diagnosed insomniacs and the matched control group were followed until they presented with a heart attack, stroke, or the study end date. Those diagnosed with insomnia had more than double the incidence (IR = 2.25 versus 1.08 per 1,000 person-years) of acute myocardial infarction per 1000-person years. Cox proportional hazard regression

analyses revealed an association between insomnia and a higher risk of acute myocardial infarction (HR = 1.68, 95% CI = 1.31-2.16, $p < 0.01$). Thus, insomnia is associated with an increased risk for future cardiovascular events.

The quantitative sleep parameter of sleep duration is an important predictor of cardiovascular disease. In a sample of 30,397 adults (58.9% female) aged 18 years and older (average age not reported) from the National Health and Nutrition Examination Survey, Sabanayagam and Shankar[135] compared sleep duration with CVD, defined as having a physician-diagnosed heart attack, angina, or stroke. Adults were categorized based on self-reported sleep duration into ≤ 5 hours (mean age 48.3 ± 17.0 years, 58.9% female), 6 hours (mean age 46.5 ± 16.5 years, 55.2% female), 7 hours (mean age 46.0 ± 16.6 years, 53.8% female), 8 hours (mean age 48.1 ± 18.3, 56.4% female), and ≥ 9 hours (mean age 53.1 ± 21.6 years, 58.4% female) of sleep per night. Seven hours sleep per night group was the referent category. Multivariate logistic regression showed those sleeping ≤ 5 hours per night (OR = 2.20, 95% CI 1.78-2.71), 6 hours per night (OR = 1.33, 95% CI 1.13-2.57), 8 hours per night (OR = 1.23, 95% CI 1.06-1.41) or ≥ 9 hours/night (OR = 1.57, 95% CI 1.31-1.89) were at increased odds for any cardiovascular disease. This population-based study provides evidence of a positive (U-shaped) relationship between both short and long sleep duration and CVD, indicating that too little or too much sleep relates to poor health.

Poor self-reported sleep quality and the qualitative sleep parameter of short time spent in slow wave sleep increases the risks for cardiovascular disease risk factors. Cooper et al.[136] studied the relationship between flow-mediated dilation, a clinical

indicator of cardiovascular disease, and either PSQI-measured sleep quality or polysomnography-measured sleep stages in a sample of 100 adults, aged 35.7±9.54 years. Regression analysis showed that a lower PSQI global score (β_{SE} = -0.164, 0.07, $p < 0.05$) was related to better flow-mediated dilation. This inverse relationship reflects a direct association between better sleep quality and reduced risks for cardiovascular disease.

To examine the relationship between insomnia and type 2 diabetes, Vgontzas et al.[137] reported sleep laboratory data from 1,741 adults, 20 years and older. Self-reported insomnia for more than one year was significantly associated with a higher risk for type 2 diabetes (OR = 1.84, 95% CI 1.05-3.20, $p < 0.05$). Meta-analyses have been conducted to examine the consistency of relationship between insomnia and diabetes. Anothaisintawee et al.[138] published a meta-analysis describing the association between insomnia sleep parameters (poor sleep onset latency and poor sleep maintenance) and incident diabetes compiling 36 studies. In a pooled sample of 40,649 participants over six studies, poor sleep onset latency (RR = 1.55, 95% CI 1.23-1.95) and poor sleep maintenance (RR = 1.72, 95% CI 1.45-2.05) were associated with increased risks for developing type 2 diabetes.

Specifically, the quantitative sleep parameters of sleep onset latency and sleep maintenance are consistently associated with increased risks for type 2 diabetes. Cappuccio et al.[139] confirmed these results in a meta-analysis of 10 studies. Results showed similar relative risks to the previously reported meta-analysis[138], as poor sleep onset latency (RR = 1.57, 95% CI 1.25-1.97) and poor sleep maintenance (RR = 1.84,

95% CI 1.39-2.43) were significantly associated with increased risk of type 2 diabetes in 107,756 adults (no age range reported).

Overall, poor quantitative and qualitative sleep parameters are associated with increased morbidity and mortality. Sleep deficiency is observed as poor quantitative and qualitative sleep parameters. This can result in physiological dysfunction which increases risk for developing cardiovascular and metabolic disorders[140].

Endogenous Factors Affecting Sleep Parameters

There are many factors that influence sleep duration, sleep onset latency, sleep maintenance and sleep quality. Physiological factors (also called endogenous factors) that interact to influence sleep quantity and quality include fluctuations of hormones, blood pressure, and core body temperature. Environmental or behavioral factors (also called zeitgebers) interact to influence the sleep circadian rhythm include light and physical activity. This section discusses the endogenous factors and the zeitgebers of physical activity affecting quantitative and qualitative sleep parameters.

Obtaining optimal sleep involves the interaction of several physiological rhythms. Biological processes that cycle over a 24-hour period are termed circadian rhythms. Circadian rhythms are studied in relation to sleep include endogenous factors of hormones, such as melatonin, core body temperature, and blood pressure. These circadian rhythms are symbiotic and fluctuate resulting in optimal sleep times dependent on the interdependent rhythms [141]. This process is depicted in Figure 1 by Lack et al.[142] showing fluctuations in melatonin, core body temperature, and desire to sleep (termed sleep propensity) over a 24-hour day.

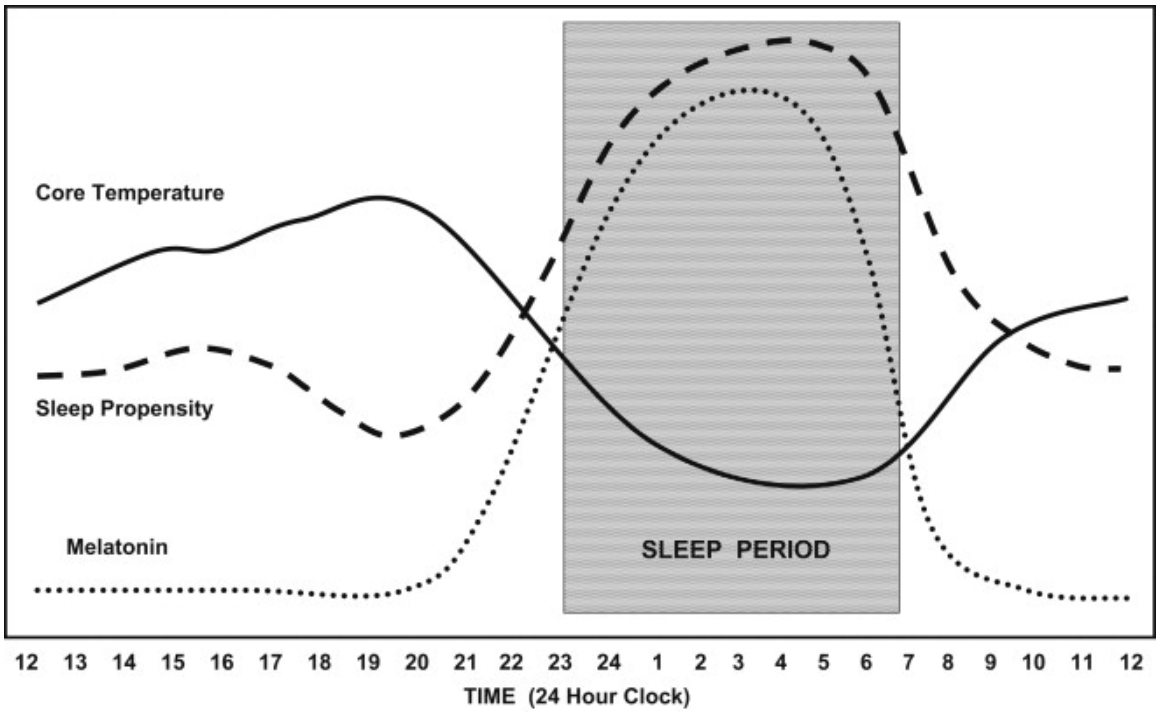

Figure 1. Endogenous Rhythms of Core Body Temperature, Desire to Sleep, and Melatonin Levels Compared to the Sleep Period.

The figure further shows that sleep propensity coincides to a decline in core body temperature and increase in melatonin release approximately two hours prior to sleep. The figure also shows that sleep propensity reaches its peak in the early morning hours (3:00-5:00am), coinciding with peak melatonin release and lowest core body temperature. When altered, these circadian rhythms can improve or worsen quantitative and qualitative sleep parameters. The following section provides a description of and a comparison between the circadian rhythms of melatonin, core body temperature, and blood pressure and their altering effects on the worsening of sleep parameters.

Melatonin Circadian Rhythm

The pineal gland releases melatonin approximately two hours prior to natural sleep. Peaking in the middle of the night, melatonin results in the vasodilation of

peripheral blood vessels resulting in a drop in core body temperature and is responsible for maintenance of a lower core body temperature during sleep. In a study to determine the circadian rhythm of melatonin release in young adults, Sletten et al.[143] examined the timing of melatonin release in men (n=14) and women (n=14) of average age 22.2±2.6 years. Melatonin release was examined after three weeks of maintaining either an early evening (10:30pm-6:30am, 1.85±0.50 hours) or late evening (12:30am-8:30am, 1.98±1.25 hours) sleep schedules. Regression analysis showed that the time of melatonin release was significantly related to habitual bed and wake times ($R = 0.48$, $R = 0.39$, $p < 0.05$). With results indicating melatonin release precedes sleep by about 2 hours, the timing of melatonin release is important for optimal sleep onset latency.

Individuals with poor quantitative sleep parameters may have a disconnect or faltering in the timing of melatonin release in relation to bedtime. This faltering can worsen with increasing age. To examine the timing and magnitude of melatonin release in relation to the quantitative sleep parameter of sleep onset latency, Olbrich and Dittmar[144] compared 11 older women with poor sleep patterns (ages 62-72 years), 9 older women with good sleep patterns (ages 60-82 years), and 10 younger women with good sleep patterns (ages 23-28 years). The objective of the study was to determine if the magnitude and timing of melatonin release differed by age and, if so, if the differences had an effect on PSQI-measured sleep. Analysis of variance tests revealed that older women with poor sleep patterns had the lowest mean increase in melatonin of the three groups (older women with poor sleep = 7.0±9.63 pg/m; older women with good sleep = 15.6±24.1 pg/m; younger women with good sleep were not reported, $p < 0.05$). Melatonin increase also was delayed by approximately 50 minutes in older women with poor sleep

patterns as compared to the women with good sleep patterns (older women = 7:57pm; younger women = 8:10pm). In addition, the PSQI score was significantly higher in older women with poor sleep patterns (9.7±2.2, $F = 45.79$, $p < 0.001$) as compared to older women with good sleep patterns (3.4±1.2) and younger women with good sleep patterns (3.9±1.1). Because older women with good sleep patterns had a similar magnitude of melatonin release as younger women, the delayed and limited melatonin release from the pineal gland in older women with poor sleep patterns may have resulted in their poorer sleep.

Melatonin release prior to sleep has an effect on other biological systems with circadian rhythms. In 2016, Gubin et al.[145] investigated the effects of melatonin administration on the circadian rhythm of blood pressure in 97 elderly men and women enrolled in a crossover study. Throughout the 3-week trial, 63 participants received either 1.5 mg melatonin (79% female, 80.7±6.3 years) or a placebo (n = 34, 61% female, 78.7±6.5 years) once a day at 10:30pm. Systolic blood pressure was measured five times per day. Interpretation of the circadian rhythm of blood pressure was biphasic as expected and it showed peaks (8:00am and 5:00pm) and troughs (11:00am-2:00pm and 3:00am) in all participants. A cosinor analysis to examine rhythm differences revealed a more pronounced biphasic rhythm in both systolic (5.6±0.3 mmHg, $p < 0.05$) and diastolic (4.1±0.3 mmHg, $p < 0.05$) blood pressures during the melatonin treatment. In addition, analysis of variance tests showed that melatonin administration improved systolic ($F = 27.32$, $p < 0.0005$) and diastolic ($F = 33.64$, $p < 0.0005$) blood pressures compared to the control week without melatonin. These analyses demonstrate the hypotensive effect of

melatonin resulting lower blood pressures in the middle of evening sleep, thus enhancing the circadian rhythm of blood pressure and enabling better sleep.

In summary, melatonin release results in vasodilation coinciding with increased skin temperature, decreased core temperature, and reduced blood pressure. Melatonin release ideally occurs two hours prior to bed time and when blunted or delayed, worsens sleep parameters.

Core Temperature Circadian Rhythm

The human body maintains its core temperature within a specific range for the optimal functioning of body cells at a temperature near 37° C or 98.6° F. Temperature regulation is accomplished when heat uptake and production are balanced by heat loss through the skin. Heat loss occurs due to vasodilated arteries that redirect blood flow from the muscles to the cutaneous vascular beds. The augmented skin blood flow facilitates core temperature cooling and is considered the primary site of heat loss[146]. Within 75 minutes of sleep, a reduction in core body temperature is facilitated by an increase in heat loss from the skin. This heat loss is considered a predictor of optimal sleep parameters. In a comprehensive review of sleep regulation, Lack et al.[142] described the relationship between body temperature and insomnia. He concluded that poor sleep onset latency may be related to delayed temperature rhythms and that poor sleep maintenance is likely associated with nocturnally elevated core body temperature.

A seminal study examining changes in core body temperature as a mechanism for improving sleep was conducted by Horne and Staff[33] in 1983. A sample of 8 adults (mean age 25.4±4.4 years, 25% women) performed two vigorous-intensity running sessions of

40 minutes separated by a 30-minute rest, two light-intensity running sessions of 80 minutes separated by 15 minutes, and a control condition consisting of passive body heating by sitting in warm water. Visual inspection of core temperature showed all exercise conditions resulted in a reduction of core temperatures as compared with the control condition. T-tests compared the exercise conditions and passive heating control condition on polysomnography-measured sleep parameters. Compared to baseline, the light-intensity exercise condition increased sleep duration (484.4±20.9 minutes vs. 464.5±20.5 minutes, $p < 0.05$) and the high-intensity exercise condition increased time spent in slow wave sleep (88.9±22.0 minutes vs. 75.6±17.4 minutes, $p < 0.05$). Passive heating also improved time spent in slow wave sleep compared to baseline (93.6±16.0 minutes vs. 75.6±17.4 minutes, $p < 0.01$). The authors concluded that regardless of the source, body heating improved both quantitative and qualitative sleep parameters. This provided an exercise and a non-exercise method to improve poor sleep.

In 1994, Campbell and Broughton[34] further investigated the relationship between body temperature and sleep. In a sample of six men and four women (average age 69.1, SD or range of age not reported), Campbell and Broughton examined the association of core body temperature, measured with a rectal thermistor, and sleep parameters measured with polysomnography. The steepest rate of decline in core temperature occurred at 75 minutes (SD = 81.6, range 0.3-217 minutes) prior to one's self-selected bedtime. Polynomial regression analysis showed the timing of the maximal rate of core body temperature relative to bed time was positively related to the amount of wakefulness within the first hour after bed time ($r = 0.40$, $p < 0.04$). Therefore, to reduce the sleep

parameter of sleep onset latency, the maximal rate of core body temperature decline should be closest to bedtime.

To examine core body temperature in relation to poor sleep maintenance, Lushington et al.[147] tested nighttime temperatures with quantitative sleep parameters in elderly adults. Core body temperature measured with rectal probes and polysomnography-measured sleep parameters were conducted for four nights in a sample of 16 participants (11 women, 5 men; mean age 65.4±7.4 years) with good sleep patterns and 16 participants (11 women, 5 men; mean age 64.3±7.2 years) classified as insomniacs. Inspection of the rhythm of the core body temperature in the good sleepers and the insomniacs showed no differences in core body temperatures prior to sleep. However, the insomniacs had a blunted reduction in core temperature within 2-4 hours after the initiation of sleep. Independent sample t-tests showed that the good sleepers spent less time awake after initially falling asleep as compared to the insomniacs (40±3 minutes vs. 144±21 minutes, $p < 0.0005$). In addition, the good sleepers experienced a lower mean core temperature from the onset of sleep to 6.5 hours after the onset sleep as compared to the insomniacs (36.51±0.06° C vs. 36.80±0.06° C, $p < 0.005$). Based on the results, the elevation in core body temperature influenced poor sleep maintenance resulting in excessive wake time during the sleep period. This finding supports the hypothesis that an elevated core body temperature as a potential mechanism for insomnia.

In summary, decreases in core body temperature are due to increased skin vasodilation which in turn creates an optimal internal human body temperature resulting in improved sleep parameters. As decreases in core body temperature occur about 75

minutes prior to sleep, sleep parameters worsen when the time between the maximal rate of decline in one's core body temperature and bed time are lengthened and when the core body temperature does not reach an optimal temperature.

Blood Pressure Circadian Rhythm

Blood pressure maintains a circadian rhythm characterized by a 10% reduction from day to night, termed "dipping". Dipping in blood pressure circadian rhythm are induced from external factors, such as posture, and endogenous factors such as melatonin release [148]. A failure to experience a "non-dipping" of nocturnal blood pressure has been linked to risks for cardiovascular disease[149]. Recent research also indicates that non-dipping nocturnal blood pressure also may be associated with poor sleep parameters[150,151]. In 2009, Lanfranchi et al.[151] examined if insomniacs have elevated blood pressure and if a reduction in blood pressure fluctuations from day to night are related to poor sleep. A sample of 9 insomniac women (42.0±7.0 years) were compared to a control group of 13 age- and sex-matched good sleepers. All subjects underwent polysomnographic recordings to examine possible effects of blood pressure fluctuations on qualitative sleep parameters. Interpretation of the 24-hour circadian rhythm of blood pressure revealed insomniacs experienced a blunting of blood pressure dipping during sleep as compared to controls. Paired sample t-tests revealed insomniacs had higher night systolic blood pressure values compared to good sleepers (111±15 mmHg vs. 102±12 mmHg, $p < 0.05$) and the percent change in systolic blood pressure from day to night was significantly smaller in insomniacs compared to the control group with good sleeping patterns (-8±6 mmHg vs. -15±5 mmHg, $p < 0.05$). Comparisons between groups also revealed that insomniacs spent less sleep time in restorative REM sleep as compared to

the control group (20±5% vs. 25±4%). The authors concluded that blunting of nocturnal blood pressure was related to impaired sleep in insomniacs which supports the relationship between insomnia and poor health parameters, such as cardiovascular disease.

In summary, blood pressure values that dip during sleep coincide with optimal sleep maintenance and insomniacs often experience a blunting of blood pressure dipping. Non-dipping blood pressure is predictive of cardiovascular disease. Therefore, the encouragement of blood pressure to dip during sleep could improve sleep parameters in insomniacs.

PA and Movement Effects on Sleep Parameters

Physical activity is a significant zeitgeber that influences endogenous rhythms and improve sleep. Accordingly, physical activity has gained attention as an important treatment for poor sleep parameters and insomnia. This section describes the mechanisms by which physical activity improves sleep parameters, results from meta-analyses or systematic reviews that have summarized the effects of physical activity on sleep parameters, provides comparisons of physical activity dose on sleep parameters, and it presents recent research examining the bidirectional relationship between physical activity and sleep.

Mechanisms

Two main mechanisms through which increasing physical activity can improve sleep are endogenous circadian rhythms and energy expenditure. This section describes

the physical activity mechanisms to alter endogenous rhythms and the elicitation of energy expenditure to alter sleep.

Endogenous Rhythms

Release of melatonin occurs approximately 2 hours prior to sleep. The timing and magnitude of melatonin release has some influence on quantitative sleep parameters of sleep onset latency and sleep maintenance. To examine the effects of physical activity on melatonin release and timing, Buxton et al.[152] employed a crossover design to compare high-intensity exercise sessions in the morning (approximately 11:00am), afternoon (approximately 1:00pm), evening (approximately 8:00pm), and night (approximately 1:00am) to a no-exercise control condition in a sample of 38 men (24.0±3.3 years). A two-way analysis of variance showed that 10-minutes of moderate-intensity exercise sessions resulted in a larger increase in melatonin release compared to the no-exercise control (20.3±12.1 pg/mL vs. 5.7±10.6 pg/mL, $p = 0.02$). A factorial analysis of variance revealed a significant improvement in the timing of melatonin release following the evening exercise (30±15 minutes sooner) compared to the no-exercise control (25±14 minutes later, $p < 0.05$). Therefore, physical activity altered the melatonin circadian rhythm by advancing its release, increasing its magnitude in the evening, and possibly improving sleep parameters. In a more recent study conducted by Cai et al.[153] , melatonin release and PSQI-measured sleep quality were compared between a group performing moderate-intensity step aerobics for 45 minutes, three times per week for 10 weeks (n = 10, 57.6±0.69 years) with a no-exercise control (n = 9, 59.33±1.13 years). Wilcoxon's rank-sum test determined that within-group mean differences in evening melatonin improved in the exercise group from baseline to follow-up (32.34 ng/mL, 95% CI 12.45-

52.23, $p < 0.05$) while the control group showed no change (-6.31 ng/mL, 95% CI -12.87-0.25, $p > 0.05$). Mann-Whitney U-test showed significant between-group differences in melatonin release (38.65 ng/mL, 95% CI 18.23-59.07, $p < 0.05$). The PSQI score, an indicator of poor sleep based on self-reported quantitative and qualitative sleep parameters, was significantly improved from baseline to post-training in the exercise group (-2.00, 95% CI = 0.65-3.35, $p < 0.05$). The authors concluded that regular physical activity may improve sleep parameters by increasing the magnitude of melatonin release.

The circadian rhythm of core body temperature also is influenced by physical activity and sleep. A recent study by Yamanka et al. (2015) thoroughly examined the effects of physical activity on the core body temperature and sleep parameters. A sample of 22 male adults (mean age 22.0±1.8 years) either performed two hours of interval cycling exercise in the morning (two hours after wake time), two hours of interval cycling exercise in the evening (10 hours after wake time), or participated in waking rest on the 6th day of a baseline recording period. Core body temperature was measured by a thermistor probe. Sleep parameters of sleep onset latency, sleep efficiency and total sleep time were measured by polysomnography. Heart rate variability, a measure of parasympathetic nervous system activity required for optimal sleep, was measured using a heart rate monitor during sleep. Core body temperature, expressed as an 8-hour area under the curve (AUC) was analyzed using a one-way repeated-measures ANOVA to compare the baseline period to each of the three conditions. Results showed a significant increase by 9.2±10.7°C throughout the evening exercise condition. The morning exercise condition resulted in a significant increase in sleep quality (10.5±9.7%, $p < 0.05$) and greater improvement in high frequency heart rate variability (300 msec^2, $p < 0.01$), a

marker of parasympathetic nervous system activity required for optimal sleep, between the exercise and baseline measurements. The authors concluded that while the time-of-day needed to be further studied, physical activity had an effect on core body temperature in addition to sleep parameters after following a strict baseline entrainment protocol.

Physical activity also has an effect on the circadian rhythm of blood pressure to improve sleep parameters. In a 2014 cross-sectional study, García-Ortiz et al.[154] examined the relationship between physical activity and the circadian rhythm of blood pressure in a sample of 1,345 adults (mean age 55±14 years, 59.3% women). They used accelerometry to measure physical activity. The ratio of sleep to awake systolic blood pressure values identified dipping or non-dipping blood pressure rhythm phases. Logistic regression analysis indicated that participants obtaining the highest tertile of accelerometer counts per minute (upper third of activity) had increased odds of having a dipping blood pressure as compared to having a non-dipping blood pressure (OR = 1.79, 95% CI 1.35-2.38). The authors concluded that an inverse relationship exists between physical activity and nocturnal blood pressure that may interrelate to influence evening sleep.

Energy Expenditure

The other mechanism by which physical activity improves sleep parameters is by eliciting energy expenditure that results in increased need for restorative sleep. Introduced in 1981, Shapiro et al.[155] described that an increase in energy expenditure triggers a need for the body to recover thereby increasing time in restorative sleep. This concept was tested by Shapiro et al.[155] in a sample of adults (n=6, mean age 21.7 years,

gender not reported). Energy expenditure was created by running a 92-kilometer marathon. Sleep parameters were measured with polysomnography before- and up to four nights after the 92-kilometer marathon. Analysis of variance tests indicated that a higher percentage of sleep was spent in deep, slow wave sleep stages for two nights after the marathon compared to pre-race measurements ($F_{4,20} = 44.0$, $p < 0.001$). The percentage of time in slow wave sleep returned to baseline by the third night. The authors concluded that increasing energy expenditure increased qualitative sleep when the body needs a recovery period due to daily activity. Even though the duration of the exercise treatment was extreme, these results demonstrated that a high dose of physical activity improved sleep.

In 2012, Kline et al.[156] expanded on the Shapiro et al. study by investigating whether different doses of physical activity that elicited different amounts of energy expenditures would improve sleep parameters. A sample of 437 (57.3±6.5 years) post-menopausal women completed a no-exercise control condition and light-intensity physical activity conditions consisting of energy expenditures equal to four kilocalories per kilogram body weight per week (KKW), 8 KKW, and 12 KKW. All conditions lasted six months with the physical activity sessions performed four times per week. Participants self-reported the Medical Outcomes Study Sleep Scale (MOS) to determine typical sleep onset latency, sleep maintenance, and daytime drowsiness at baseline and after each condition. Analysis of covariance determined whether sleep quality changed between the groups. Logistic regression examined the odds of having poor quantitative or qualitative sleep parameters after the intervention. Results showed a between-group treatment effect for physical activity on the MOS score ($F_{8,428} = 17.35$, $p < 0.001$); only

the 12 KKW group improved significantly compared to the control group (6±2.1-unit improvement vs. 2±2.1-unit improvement, $p < 0.05$). Odds ratios for a MOS score above 25 points post-intervention (indicating significant disturbances in sleep parameters) showed all energy expenditure conditions had lower odds of poor sleep as compared to the control group (12 KKW, OR = 0.34, 95% CI 0.16-0.72; 8 KKW, OR = 0.36, 95% CI 0.17-0.77; 4 KKW, OR = 0.37, 95% CI =0.19-0.73. The authors concluded that increasing energy expenditure through structured physical activity improved quantitative and qualitative sleep parameters and reduced the odds of having poor sleep. The mechanism cited was a possible need for the body's recovery after the exercise.

In summary, increase in energy expenditure, either through structured events or habitual physical activity results in an improvement in sleep. Physical activity improves sleep through mechanisms that include optimal timing and improved rhythms of melatonin release, core body temperature shifts, and blood pressure fluctuations. Therefore, physical activity has gained attention as a treatment to enhance poor sleep parameters.

Relationships between physical activity and insomnia-related sleep parameters

Most studies consistently show that physical activity has a positive association with sleep parameters. Some research suggests that physical activity may interfere with normal sleep. This section briefly reviews several studies showing a negative effect of physical activity on sleep parameters. For a detailed review of this topic, additional studies are highlighted by Youngstedt and Kline[157].

In 1996, Baekeland and Lasky[158] examined the relationship between physical activity and sleep parameters. In 10 male college athletes (ages not reported) the study showed a positive relationship between afternoon and evening exercise and sleep quality on days when the men were active but the beneficial effects of exercise on sleep did not exist on non-active days. In more recent research conducted in 1998, Sherrill et al.[48] examined associations between self-reported physical activity and self-reported sleep maintenance using logistic regression in middle-aged to older men (n = 319; 54.1±2.3 years) and women (n = 403; 59.9±14.4 years). They found that participating in an exercise program reduced odds of having problems with sleep maintenance by 48%. In addition, walking greater than six blocks per day at less than 3.0 mph or walking greater than six blocks per day at 3.0-4.0 mph reduced odds of having problems with sleep maintenance by 33% and 50%, respectively.

The Cardiovascular Health Study, a cross-sectional examination of over 5,200 adults (mean age 72.8±5.6 years, age range 65-100 years), assessed leisure-time physical activity energy expenditure with the Taylor Questionnaire and measured sleep disturbances with self-report questionnaires. Using two-sample *t* tests, the authors determined that energy expenditure was negatively associated with sleep onset latency (men, $p < 0.001$; women, $p < 0.05$; no other statistic reported) and sleep maintenance (men, $p < 0.05$; women, $p \leq 0.001$; no other statistic reported)[159]. Therefore, increased physical activity was related to better sleep parameters. Kline et al.[43], using a subsample of The Study of Women's Health Across the Nation (SWAN) Sleep Study, and Soltani et al.[160] showed similar results.

In 2013, Kline et al.[43] determined the influence of physical activity domains and physical activity levels on sleep outcomes and insomnia using a cross-sectional analysis of 339 women (mean age = 52.2±2.2 years). The Kaiser Physical Activity Survey assessed activity levels in domains of active living, household/caregiving, and sports/exercise. Each respondent was classified as a consistently high, consistently low, or inconsistent/moderate participator of physical activity in each domain. Sleep quality and sleep efficiency were examined by the Pittsburgh Sleep Quality Index survey. Insomnia was assessed with the Insomnia Severity Index. Analysis of covariance determined a significant relationship between greater exercise activity and self-reported sleep quality ($F_{2,317} = 4.17$, $p = 0.02$) and sleep efficiency ($F_{2,316} = 5.25$, $p < 0.01$). Logistic regression results indicated that those reporting consistently high sports/exercise activity had lower odds of insomnia diagnosis (OR = 0.26, 95% CI 0.08, 0.81, p = 0.02) relative to those reporting consistently low sports/exercise activity. Similarly, Soltani et al.[160] examined associations between sociodemographic and lifestyle factors and sleep quality. They conducted a cross-sectional analysis of a sample of 3,655 women (mean age 46.6±5.1 years, age range 34.3-67.4 years) to examine the relationship between physical activity and the sleep outcome of sleep quality. Women were categorized as non-exercisers, moderate exercisers, or vigorous exercisers based on two questions asking the frequency of engaging in 20 minutes or more or less than 20 minutes of vigorous exercise. Women rated their sleep quality using the Pittsburgh Sleep Quality Index and were classified as having normal sleep quality (PSQI global score = 0-5), moderately poor sleep quality (6-10), and very poor sleep quality (11-21). Logistic regression analysis indicated that, compared to non-exercisers, vigorous exercisers had

lower odds of having moderately poor sleep quality (OR = 0.75, 95% CI 0.59-0.94, $p < 0.05$) and very poor sleep quality (OR = 0.69, 95% CI 0.49-0.98, $p < 0.05$). Also, moderate exercisers, compared to non-exercisers, had lower odds of having very poor sleep quality (OR = 0.64, 95% CI 0.45-0.92, $p < 0.05$). These two studies show the relationship between physical activity and sleep quality and demonstrate that consistently high levels of exercise reduces odds of having insomnia symptoms by 74% and reduces odds of having poor sleep quality by up to 36%, respectively, compared to non-exercisers.

In 2001, Ohida et al.[161] surveyed 31,260 adults (52% women) from ages 20 years and older (mean age not reported) on general health, including physical activity, and sleep status. To assess self-reported physical activity, participants were asked if they regularly exercised. Participants responded “always”, “sometimes”, or “never”. To assess sleep quality participants were asked “Do you always get sufficient sleep that you need?” Responses ranged from very sufficient to uncertain on a 5-point scale, with 5 being the highest score. Logistic regression results indicated that participants who reported that they never habitually exercised were 32% more likely to self-report sleeping problems due to insufficient sleep (OR = 1.32, 95% CI 1.19-1.47, $p < 0.01$) as compared to those who reported they always exercised. Higher levels of exercise were not associated with sleep problems ($p > 0.05$). The authors concluded that participants who reported regular physical activity believed they had sufficient sleep.

In 2013, Inoue et al.[162] examined physical activity in relation to insomnia in a sample of 10,211 adults (mean age 73.9±5.4 years; 49.2% women). Data were obtained

from a self-reported questionnaire. Walking and exercise activities were categorized as 1-2, 3-4, or 5 or more days per week. Sleep was expressed as sleep onset latency and sleep maintenance. The odds of poor sleep parameters by days of walking or exercise was computed using logistic regression. Results indicated that exercising or walking five or more days per week resulted in decreased odds for difficulties with sleep onset latency (OR = 0.86, 95% CI 0.76-0.98; OR = 0.75, 95% CI 0.66-0.85, respectively) and sleep maintenance (OR = 0.72, 95% CI 0.64-0.81; OR = 0.89, 95% CI 0.79-1.00, respectively) as compared to those with no physical activity. In addition, a trend analysis was significant ($p < 0.05$) indicating that increased frequency of walking or exercise resulted in decreased odds for sleep onset latency and sleep maintenance problems. The authors concluded that increasing the frequency of walking or exercising may help reduce symptoms of insomnia, especially sleep onset latency and sleep maintenance, demonstrating that physical activity may be an effective treatment for poor sleep.

The benefits of physical activity on sleep parameters are consistent in other populations. In 2013, Kline et al.[43] examined the relationship between habitual physical activity and sleep parameters in a sample of 339 women (52.1±2.1 years). Physical activity included active living, household and caregiving, or sports and exercise and was measured with the Kaiser Physical Activity Survey. Sleep parameters were measured with self-report logs, questionnaires, and polysomnography. Linear regression analysis showed a significant association with sports/exercise domain and self-reported sleep efficiency ($\beta=0.74$, $p < 0.05$) and with restorative sleep stages ($\beta=0.12$, $p < 0.05$). Participants who engaged in sports and exercise had reduced odds for insomnia diagnosis based on the collected sleep parameters (OR = 0.68, 95% CI 0.47-0.99, $p < 0.05$). No

associations were observed for participation in other physical activities and sleep parameters. Kline et al. concluded that regular, habitual activity of beyond that of common household tasks or active travel is required to improved sleep parameters in middle-aged women.

Overall, studies have consistently shown that regular physical activity or exercise is positively associated with better sleep. From these results, interventions have been conducted to examine the effects of physical activity on sleep parameters using longitudinal study designs. The next section describes several formative studies testing these effects.

Interventions

Few interventions were conducted to examine the effects of physical activity on sleep parameters prior to the 21st century. In 1997, King et al.[163] conducted a seminal study examining physical activity effects on sleep. The exercise group included 43 adults (8 men, mean age 62.3±8.4 years; 35 women, mean age 62.4±6.4 years). The comparison group was a wait-listed control group with six men (mean age, 58.8±5.6 years) and 17 women (mean age, 61.2±7.5). Sleep parameters were measured using the PSQI. The experimental group exercised regularly for 16 weeks in addition to their normal routine. The exercise condition consisted of moderate-intensity exercise for four days per week (2 x 40 minutes at home, 2 x 60 minutes at group exercise class). Analysis of variance of within-group differences revealed the PSQI score significantly improved in the exercise group (women, -3.0±2.4; men, 8.5±2.3; $p < 0.001$) after the 16-week trial while the control participants did not show no changes in their PSQI score. Improvements in sleep

parameters were observed following the 16-week trial: sleep onset latency (women, -15.2±12.3 minutes; men, 13.7±13.0 minutes; $p < 0.05$), sleep duration (women, +0.7±1.1 minutes; men +1.2±1.4 minutes; $p < 0.05$), sleep efficiency (women, +9.0±12.9%; men, +8.8±12.9%; $p < 0.05$), and subjective sleep quality (women, +0.6±0.7 units; men +0.3±0.5 units; $p < 0.05$). Analysis of covariance of between-group differences revealed that the PSQI score was improved in the exercise group compared to the control group ($F_{4,38}= 12.86$, $p < 0.001$). In addition, the exercise group showed within-group improvements in sleep onset latency ($F_{4,38}= 7.94$, $p < 0.05$), sleep duration ($F_{4,38}= 4.20$, $p < 0.05$), and subjective sleep quality ($F_{4,38}= 5.09$, $p < 0.05$). The authors concluded that a long-term moderate-intensity exercise program may be an effective treatment for poor sleep.

In 2008, King et al.[37] conducted a randomized controlled trial to examine the effects of a 12-month exercise program on sleep parameters in 36 adults (mean age 61.9±6.3 years; 67% female) compared to a control group of 30 adults engaged in a health education program (mean age 60.9±7.2 years, 67% female). The exercise group participated in two 60-minute, moderate-intensity exercise classes per week and performed three additional 30-minute moderate-intensity exercise sessions on their own. Sleep parameters were measured with in-home polysomnography at baseline, six, and 12 months and with the PSQI at baseline and 12 months. Analysis of covariance determined within-group differences at baseline and 12 months. Results showed the exercise group had improved sleep onset latency (38.44±23.32 minutes to 26.02±18.5 minutes) as compared to the control group (23.08±19.01 minutes to 28.02±21.04 minutes, $p < 0.01$). The exercise group also showed improved sleep in the light-sleep stage from baseline to

12 months (9.13±3.96 minutes to 7.88±3.77 minutes) as compared to the control group (8.24±3.51 minutes to 9.37±5.85 minutes, $p < 0.01$). Analysis of variance examining between-group differences showed the exercise group had better sleep maintenance during the first one-third of nightly sleep duration as compared to the control group ($F_{1,65}= 3.5$, $p < 0.05$). The authors concluded that 12 months of moderate-intensity exercise at the dose of 150 minutes per week recommended by the Physical Activity Guidelines for Americans[42] was beneficial at improving sleep as compared to a control group undergoing health education classes. The results from both trials conducted by King et al. are consistent with other more recent findings in middle-aged to older women[164–166].

The benefits of exercise on sleep parameters have been reported in young adult males. In 2012, Flausino et al.[167] examined whether exercise prior to bedtime influenced sleep parameters in 18 healthy men with good sleep habits (27.2±3.6 years). Sleep parameters were assessed with polysomnography after exercise of varying intensities and durations on five different occasions. Analysis of variance and Wilcoxon tests showed that each of the five training sessions resulted in improved sleep maintenance ($p < 0.05$, other statistics not reported), improved sleep efficiency ($p < 0.05$, other statistics not reported), and improved sleep in light sleep stages ($p < 0.05$, other statistics not reported). The authors concluded that exercise improves sleep parameters in young men with good sleep habits.

Modes of physical activity other than traditional running or cycling also have shown improvements on sleep parameters. In a randomized controlled trial conducted in

2004 by Li et al.[168], 118 elderly adults performed 24 weeks of tai chi (n = 62, mean age 75.3±7.8 years; 84% women) or a low-impact physical activity program (n = 56, mean age 75.45±7.8 years; 79% women) to examine beneficial effects on PSQI-measured sleep parameters. The tai chi group exercised for 60 minutes, three times per week. The low-impact exercise group practiced seated exercises with controlled breathing, stretching, and relaxation techniques for 60 minutes, three times per week. Analysis of variance tests revealed better sleep parameters measured by the PSQI in the tai chi group as compared to the low-impact exercise group. Variables that improved were sleep onset latency (23.44±29.21 minutes vs. -5.55±29.75 minutes, $p < 0.001$), sleep efficiency (+14.07±22.46% vs. +1.72±21.13%, $p < 0.05$), and overall PSQI sleep score (-2.06±2.40 vs. -0.61±2.68, $p < 0.001$). The authors concluded that various types of physical activity, such as tai chi or yoga, might be effective at improving sleep parameters in elderly populations.

In summary, various types of regular physical activity have beneficial effects on sleep parameters in young and old populations. Several syntheses of the literature have examined the effects of a single bout and regular participation in structured and in lifestyle modes of physical activity, on sleep parameters. The next section presents results from these syntheses on the effect of varying durations and modes of physical activity to improve sleep parameters.

Overall effect of physical activity on sleep parameters

A landmark synthesis of physical activity effects on sleep parameters was conducted in 1997 by Youngstedt[169]. Thirty-eight studies totaling 401 participants were

examined to show the effects of exercise compared to no-exercise control conditions on a subsequent night's sleep. The time exercise was performed in relation to sleep, less than four hours, 4-8 hours, or greater than 8 hours prior to sleep, also was examined as a moderator for exercise's effect on a subsequent night's sleep. Sleep parameters included sleep onset latency, time spent in slow wave sleep, sleep duration, and sleep maintenance. Exercise had a positive effect on slow wave sleep time (Hedges and Olkin's $g = 0.19$, $p < 0.01$) compared to no-exercise control conditions. Moderator effects for time-of-day of exercise were significant for sleep onset latency ($F_{1,21} = 6.61$, $p < 0.05$) and sleep maintenance ($F_{1,11} = 7.55$, $p < 0.05$). When performed 4-8 hours prior to bed time, exercise improved sleep onset latency ($g = -0.27$, 95% CI -0.49 to -0.06), sleep maintenance ($g = -0.36$, 95% CI -0.71-0.00) and increased time spent sleeping in slow wave sleep ($g = 0.24$, 95% CI 0.07-0.42). While the synthesis showed that exercise had a positive effect on sleep, the results may have underestimated of the true effect of exercise's effect on sleep due to the inclusion of good sleepers in most of the studies reviewed.

In 2015, Lang et al.[170] compiled a meta-analysis to examine the overall effect of physical activity on sleep parameters in 16,549 adolescents and younger adults (mean age 17.8 years, age range 14-24 years, 52% women). Physical activity was measured using self-report questionnaires, pedometers, and accelerometers. Sleep was measured using sleep diaries, actigraphy, polysomnography, and EEG machines, and sleep diaries. The 12 studies revealed a significant overall effect size ($d = 0.894$, $z = 4.272$, $p < 0.001$, 95% CI 0.484-1.305, $I^2 = 66.44\%$) for the effects of physical activity on monitored sleep parameters. The largest effect was found between objectively-monitored physical activity

and polysomnography- or actigraphy-measured sleep parameters (d = 1.021, z = 1.680, p = 0.091, 95% CI 0.163-2.204). The smallest effect was found between objectively-monitored physical activity and self-reported sleep parameters (d = 0.541, z = 1.291, p = 0.197, 95% CI -0.281-1.364). The overall conclusion of this thorough meta-analysis was that adolescents with higher self-reported and objectively-monitored physical activity were more likely to experience good sleep.

In 2015, Kredlow et al.[171] published a summary of the effects of a single-day or regular physical activity on sleep parameters. Sixty-six studies were identified including 2,863 participants (45±38.4% women) ages 18.3-88.5 years (mean 42.0±20.4 years, gender-specific values not reported). Eligible studies administered physical activity as the independent variable for interventions. Sleep was measured using sleep diaries, self-report questionnaires, sleep-EEG machines, and polysomnography. Cohen's d determined effect sizes and Cochrane's Q test of heterogeneity examined differences between the moderator variable levels. Results showed a single day of physical activity had beneficial effects on sleep duration (d = 0.22, 95% CI 0.10-0.34, p < 0.01), sleep onset latency (d = 0.17, 95% CI -0.02-0.32, p < 0.05), sleep efficiency (d = 0.25, 95% CI 0.12-0.39, p < 0.001), sleep maintenance (d = 0.38, 95% CI 0.21-0.55, p < 0.001), and slow wave sleep (d = 0.19, 95% CI 0.02-0.35, p < 0.05). In addition, regular physical activity had beneficial effects on sleep duration (d = 0.25, 95% CI 0.07-0.43), sleep onset latency (d = 0.35, 95% CI 0.00-0.70, p < 0.05), sleep efficiency (d = 0.30, 95% CI 0.06-0.55), and overall self-reported sleep quality (d = 0.74, 95% CI 0.48-1.00, p < 0.001). Cochrane's Q test of heterogeneity revealed that the time of day of physical activity was performed was a significant beneficial moderator on sleep maintenance (Q = 8.47, df = 1,

$p < 0.005$). Sleep maintenance was significantly improved when physical activity was performed less than three hours before bedtime while physical activity performed 3-8 hours before bedtime showed no effects on sleep maintenance (no statistics reported) in single-day studies only. There were insufficient data to examine time of day as a moderator from studies applying regular physical activity as the independent variable. Meta-regression analyses showed that the duration of physical activity significantly moderated the effects of physical activity on sleep duration ($\beta = 0.005 \pm 0.00$, $p < 0.05$), sleep onset latency ($\beta = 0.009 \pm 0.00$, $p < 0.05$), and slow wave sleep ($\beta = 0.011 \pm 0.00$, $p < 0.01$) in single-day studies only. From studies utilizing regular physical activity, physical activity duration significantly moderated the effect of physical activity on sleep onset latency ($\beta = 0.037 \pm 0.02$, $p < 0.05$) but had no other moderator effects on sleep parameters ($p > 0.05$). The frequency in days per week participants performed physical activity was not a significant moderator on any sleep parameters ($p > 0.05$). The intensity of physical activity performed was not examined as a moderator. The authors concluded that there was a beneficial effect of physical activity on sleep parameters when performed on a single occasion or when performed regularly. The time-of-day and the amount of activity performed were possible moderators of the effect of physical activity on sleep parameters, such that longer bouts of physical activity and physical activity performed 3-8 hours prior to beneficial were most beneficial.

Overall, summaries conducted consistently show that physical activity has a moderate-to-large effect on sleep[172–174]. Positive effects of physical activity on sleep are seen in all age groups and in people with good and poor sleep habits. The largest beneficial effect of physical activity on sleep parameters is found after performing

physical activity approximately four hours prior to bed time, in older adults, and in people with poor sleep habits[17].

The next section will review studies investigating the moderators of time-of-day, duration, and intensity of physical activity on sleep parameters.

Moderators of physical activity effects on sleep

As previously described, the effect of physical activity on improvements in sleep parameters may be modified by the time-of-day and the dose of physical activity performed. This section reviews studies examining time-of-day effects and dose of physical activity on sleep parameters.

Time-of-day

Since the meta-analysis by Youngstedt[169] in 1997, few studies have compared differences in the time-of-day of physical activity on sleep parameters. In 2011, Passos et al.[29] examined these differences in a sample of 10 adults (mean age 42.3±2.6 years, 80% women) performing a structured, moderate-intensity physical activity session in the morning (10:00am±1 hour) and 9 adults (mean age 48.0±2.5 years, 78% women) performing a structured, moderate physical activity session in the evening (6:00pm±1 hour). Sleep parameters was measured using polysomnography. Data were analyzed with Cohen's effect size calculation and repeated measures ANOVA to determine the effect of moderate-intensity training sessions performed in the morning or the late afternoon on sleep parameters. Results showed overall significant effects for performing exercise on sleep onset latency ($d = -0.96$, $p < 0.01$) and sleep maintenance ($d = -1.66$, $p < 0.05$). Comparisons between late-afternoon and morning exercise showed large effects on sleep

onset latency (d = -2.46 vs. -1.67, $p < 0.05$), sleep maintenance (d = -1.82, vs. -1.45, $p < 0.05$), and sleep efficiency (d = -2.16 vs. 1.68, $p < 0.05$). ANOVA analyses showed no significant results for differences in the time-of-day when exercises were performed. These results are similar to other studies as described in the meta-analysis by Kredlow et al.[171], indicating that the time of the day when physical activity is performed is an inconsistent predictor of improved sleep.

Aldemir et al.[175] compared the response mechanism of increased core, sternum, and skin temperatures after evening physical activity as compared to morning physical activity. The sample included 12 male adults (age range 25-30 years, mean age not reported). Exercise consisted of 30 minutes of moderate-intensity exercise performed in the morning (8:00am) or evening (6:00pm). Skin and core temperatures measured by thermistors were examined. Blood flow was measured by laser Doppler flowmetry. Data were analyzed using ANOVA to compare the effects of moderate-intensity exercise in the morning or evening on core and skin temperatures. Analysis of variance showed that the evening exercise group experienced a more rapid rise in peripheral skin blood flow (mean value 74 mL/min vs. 48 mL/min). In addition, core body temperature and sternum temperature were elevated in the evening exercise group compared to the morning exercise group (37.15±0.06 °C vs. 36.77±0.06 °C; 33.60±0.29 °C vs. 32.70±0.38 °C, $p < 0.05$). Based on studies showing that an increase in skin temperature is the main predictor of shorter sleep onset latency, physical activity administered at the appropriate time in the late afternoon or early evening may improve sleep more than physical activity in the morning.

Overall, results remain inconclusive regarding the effects of performing physical activity during different times of day on sleep parameters. While meta-analyses consistently show that time-of-day is a moderator for the beneficial effects of physical activity on sleep parameters, inconsistencies remain on when physical activity is performed relative to bedtime (e.g., less than one hour prior, 3-8 hours prior, greater than 8 hours prior). A lack of well-controlled or long-term studies often are cited as rationale for more studies.

In addition to the timing of day for physical activity, the dose of physical activity administered may result in differing effects of physical activity on sleep. The next section reviews studies examining the dose of physical activity on sleep parameters.

Dose

The duration and intensity of physical activity are cited as moderators for the effect of physical activity on sleep parameters. The product of duration and intensity is physical activity volume[52]. The duration and intensity often are inversely related when performing exercise (i.e., lower intensity and longer duration; higher intensity and shorter duration). The question arises regarding which aspect elicits the greatest improvement in sleep: duration, intensity, or volume? While studies have examined differences between moderate- and vigorous-intensity physical activities on sleep parameters, physical activity volume rarely is examined in relation to sleep parameters. In 2008, Dworak et al.[176] compared moderate- and vigorous-intensity physical activity on sleep parameters in 11 children (mean age 12.6±0.8 years). A 30-minute cycling session at either 65-70% of maximum heart rate or 85-90% maximum heart rate were examined to determine effects

of intensity on sleep parameters, measured with polysomnography. As compared to baseline, analysis of variance tests showed vigorous-intensity physical activity significantly improved sleep-onset latency (22.27±16.26 minutes vs. 6.64±4.88 minutes, $p < 0.05$), sleep efficiency (93.14±5.09 % vs. 97.54±0.82 %, $p < 0.05$) and slow wave sleep (18.58±3.94 % of time asleep vs. 21.48±4.51 % of time asleep, $p < 0.05$). There were no differences in groups for moderate-intensity physical activity compared to baseline for all measures (sleep-onset latency = 9.27±13.57 minutes, sleep efficiency = 96.93±2.88%, slow wave sleep = 13.35±3.92%). Vigorous-intensity physical activity improved sleep parameters in a population of healthy children, confirming that more intense physical activity may be better than less intense physical activity at improving sleep.

A detailed study conducted by Myllymaki et al.[177] in 2012 compared both physical activity intensity and physical activity duration on actigraphy-measured and self-reported sleep parameters. A sample of 14 males (35±4.3 years) performed running activities for 30 minutes at 45%, 60%, and 75% of VO_{2max} to examine physical activity intensity needed to improve sleep parameters. Running activities also were performed for 60 and 90 minutes at 60% of VO_{2max} to examine physical activity duration needed to improve sleep parameters in comparison to a controlled rest day. Using mixed-model variance component models, no significant differences ($p > 0.05$) were found between conditions of 30 minutes of 45%, 60%, and 75% of VO_{2max} and the control condition. However, sleep maintenance was better after the vigorous-intensity condition as compared to the moderate-intensity condition (23.6±9.5 minutes vs. 26.2±7.6 minutes, ns). In addition, no significant differences ($p > 0.05$) were found between conditions of

physical activity performed for 30 minutes, 60 minutes, or 90 minutes at 60% VO_{2max}. Limitations noted for this study included missing data due to exclusion criteria after enrollment, small sample size, a lack of control for time of day the exercise was performed, and a lack of control of the physical activity environment for exercise since the participant was responsible for exercising at home.

In the previously mentioned study by Kline et al.[156], investigators designed a randomized controlled trial to investigate duration of physical activity needed to improve sleep parameters in 437 women (mean age 57.3±6.5 years). Compared to a no-exercise control, moderate-intensity (50% VO_{2max}) cycling sessions of varying durations (exact duration not provided) were prescribed to elicit four kilocalories per kilogram body weight per week (KKW), 8 KKW, and 12 KKW. Training sessions were conducted four times per week for six months. Sleep parameters were measured using the Medical Outcomes Study Sleep scale. Analysis of covariance showed a treatment effect for the 12 KKW condition compared to the control condition for self-reported sleep ($F_{8,428} = 17.35$, $p < 0.001$). Logistic regression revealed the 12 KKW condition had the lowest odds of reporting sleep disturbances (OR = 0.34, 95% CI 0.16-0.72) as compared to the control condition (8 KKW, OR = 0.36, 95% CI 0.17-0.77; 4 KKW, OR = 0.37, 95% CI =0.19-0.73). The authors concluded that longer durations of moderate-intensity physical activity improved self-reported sleep quality and reduced the odds of experiencing poor sleep.

The only study to investigate physical activity volume associated with improved sleep parameters was conducted by Taylor et al.[178] in 1997. In a sample of seven female athletes (mean age 19±2 years), the effect of training volume on polysomnography-

measured sleep parameters was determined by comparing sleep at different phases of the athletes' season. Over a 6-month period, athletes were examined at the start of the season when training volume was mild (e.g., moderate-intensity, cardiorespiratory exercise), at the 3-month interval when training volume was high (e.g., vigorous-intensity cardiorespiratory exercises combined with maximal resistance training), and at the end when the training volume was low and athletes were tapering (e.g., brief vigorous-intensity exercise). Analysis of variance tests showed significantly improved slow wave sleep percentage in the high volume phase (29.4±3.2 % time asleep) and in the mild volume phase (28.7±5.1 % time asleep) as compared to the tapering group (18.4±4.3 % time asleep; $p < 0.05$). The authors concluded that there is a decreased need for restorative sleep during the low-volume training phase resulting in less time spent in slow wave sleep.

In summary, there is a beneficial effect of physical activity on sleep, however the benefits of a single intensity of physical activity on sleep remains unclear as most studies show that both moderate- and vigorous-intensity physical activity result in improved sleep parameters in children, adults, and the elderly.

The literature shows a consistent positive relationship between physical activity and sleep. Studies comparing moderators for the time-of-day and the ideal physical activity dose are equivocal. Moderators of the relationship may depend on the individual, their need for sleep improvements, the quality of sleep obtained the previous night, and their ability to tolerate physical activity[17].

Research within the past three years has emphasized on these individual differences by examining a person's daily routine and the bidirectional relationship between physical activity and sleep. The next section reviews studies discussing these relationships.

Bidirectional relationship between physical activity and sleep

Single-day and regular physical activity consistently are associated with improvements in sleep parameters. Too little sleep, however, may adversely affect physical activity performances. Based on studies describing the effects of sleep deprivation on a subsequent days' mental and physical performance, recent studies have focused on the possibility that poor sleep may result in lower physical activity levels in general[41,179]. In 2014, Holfeld et al.[180] examined the bidirectional relationship between physical activity and sleep in 426 elderly adults (mean age 72.0±7.5 years, range 61-100 years) over two years. Physical activity was measured by self -report with an ordinal scale of extremely inactive to extremely active. Sleep was measured by self-report with an ordinal scale of fair/poor sleep to excellent sleep. A cross-lagged panel analysis using multiple regression steps and analysis of covariance examined the causal relationship between physical activity and sleep parameters. Results showed that the quality of the prior night's sleep significantly predicted subsequent physical activity ($\beta = 0.10$, $p = 0.02$). Adding the prior period sleep quality to the physical activity prediction model significantly increased the amount of variance explained in physical activity ($r^2 = 0.37$-0.38, $p < 0.001$). In the second regression analysis performed, adding the prior night's sleep to the model resulted in a significant model improvement ($F_{1,395} = 6.00$, $p < 0.05$). These results were not replicated ($p > 0.05$) when predicting sleep quality scores from

physical activity scores. The authors concluded that better sleep quality predicted higher levels of physical activity beyond the effects of prior physical activity levels.

Another example of the examination of physical activity as a determinant of sleep quality is the 2014 study conducted by Dzierzewski et al.[181]. The authors conducted a secondary analysis of a randomized controlled trial of a sample that included 79 older adults (mean age 63.58±8.66 years, 83.5% women). Physical activity and self-report measured sleep were obtained from self-report. Data were analyzed using a multi-level model approach similar to multiple regression to determine if exercise behavior predicted sleep quality and if prior-day exercise affected subsequent night's sleep quality. Within-person (individual daily variation) in sleep quality significantly predicted physical activity ($\beta = 0.04 \pm 0.01$, $t_{53.75} = 3.40$, $p = 0.01$) and within-person physical activity significantly predicted sleep quality ($\beta = 0.06 \pm 0.03$, $t_{35.01} = 2.04$, $p = 0.05$). These results indicate that an improvement in self-reported sleep resulted in increased following-day physical activity and that increased physical activity resulted in improved self-reported sleep. Similar results have been found in the few studies that examined the effects of poor sleep parameters, such as sleep onset latency or sleep duration, on subsequent day physical activity. In 2013, Baron et al.[182] evaluated sleep-onset latency, sleep maintenance, and sleep efficiency in association with following day's sleep in a sample of 11 women (61.27±4.15 years) with insomnia. The Pittsburgh Sleep Quality Index was used to evaluate sleep-onset latency. Self-report exercise logs were used to determine exercise the following day. Results from hierarchical linear modeling showed that sleep-onset latency was negatively associated with next day exercise ($\beta = -2.30$, SE = 0.90, p =

0.029). The authors concluded that poor sleep has a negative influence on next-day exercise and that better sleep may encourage next-day exercise.

When examining bidirectional relationships between physical activity and sleep, investigators should consider the moderating effects on physical activity and sleep such as the time of day, eating meals, engaging in regular social interactions, and other types of activity that constitute one's regular daily routine. Having regularity in one's schedule is purported to promote better sleep. In 2015, Moss et al.[183] examined the regularity of daily activities on sleep in 33 insomniacs (mean age 47±12 years, 76% women) as compared to 36 controls with good sleep habits (mean age 32±13 years, 73% women). To determine the regular routine, participants completed the Social Rhythm Metric[184], a survey consisting of 17 daily activities such as out-of-bed time, first contact with person, and time work started. Regularity of the activities over the 2-week study resulted in a computed score from 0 = no regularity to 7 = regular. Sleep parameters were determined from a sleep record kept daily to measure sleep parameters. Participants were classified as normal sleepers or having an insomnia disorder based on the Research Diagnostic Criteria. Data were analyzed using a multivariate analysis of covariance Analysis of covariance (ANCOVA) determined group differences between normal sleepers and those having an insomnia disorder on the Social Rhythm Metric score. Cohens d determined the effect of the Social Rhythm Metric between groups. ANCOVA revealed a significant effect between the insomniacs and the control group on regularity of daily activities with those having an insomnia disorder having lower a total Social Rhythm Metric score for compared to the control group ($F_{1,67}$= 9.12, $p < 0.005$). There was a large effect between groups (d = 0.74) for the Social Rhythm Metric score. The authors concluded that the

insomnia group experienced higher variability in their daily activities compared to the good sleeping control group.

These results provide information on the bi-directional relationship between physical activity and sleep and continue to show inconsistent Results such as these provide rationale for measuring the entire 24-hour day to assess relationships between daily health behaviors, such as physical activity, and nightly behaviors (i.e. sleep parameters)[185].

Summary

A review of literature clearly shows that physical activity positively related positively to optimal sleep in men and women from adolescence to old age. Relationships that examine the physical activity dose required and the optimal time of day performed to maximize benefits on sleep can be strengthened with the development of validated measures that can determine such relationships. Further, the bidirectional relationship between physical activity and sleep warrants additional study as these behaviors likely influence adverse health outcomes such as cardiovascular disease and type 2 diabetes.

CHAPTER 3

METHODS

Sample Recruitment

A convenience sample of 35-60 year-old male and female volunteers were recruited using mass communication methods, including flyers (see Appendix A), emails, and word-of-mouth. Interested volunteers completed an online screening survey that included contact information collection. Internet surveys delivered by the Quatrics survey software (Provo, UT) were collected for all screening information.

Sample size needed to determine the effects of moderate-intensity conditioning (MIC) and high-intensity training (HIT) on sleep-onset latency was based on the effects of exercise on sleep-onset latency. Vigorous exercise has previously resulted in a large effect size for sleep-onset latency ($d = 0.67$)[177], but a more modest, conservative effect size was used ($d = 0.40$) for the power analysis in this study. Based on this effect size and a correlation between repeated measures of $r = 0.5$[17], G*Power (v3.1.3) calculated that 19 subjects would be needed to complete the study.

Inclusion Criteria

Volunteers were screened for age, sleeping problems, typical bed times, and physical activity levels. The person was included if he/she was between the ages of 35 and 60, classified as having subclinical insomnia using the Insomnia Severity Index (ISI) or if they were classified as participating in light-intensity physical activity or inactive using the Stanford Brief Activity Survey (SBAS).

Exclusion Criteria

Volunteers completed the American College of Sports Medicine (ACSM) Health History Questionnaire[186] to determine any metabolic, neurological, or disorder other than insomnia known to disrupt sleep. If the person indicated any disorder or were at risk for obstructive sleep apnea measured by the STOP-BANG questionnaire they were excluded from the study. The ACSM Health History Questionnaire also screened for and excluded those taking any medications (e.g., beta-blockers, vasodilators, or hypnotics) or supplements (e.g., vitamin C or melatonin) known to affect sleep or were undergoing hormone replacement therapy. Volunteers also were excluded if they indicated any contraindications to performing moderate- or vigorous-intensity physical activity as defined by the Physical Activity Readiness-Questionnaire (PAR-Q) or were classified as high risk based on signs or symptoms suggestive of cardiovascular, pulmonary, or metabolic disease by the ACSM Guidelines for Exercise Testing[186]. The person also was excluded if they had recently (within seven days) returned from travelling across three or more time zones, were currently working a 2nd or 3rd shift occupation, or self-reported 1:00am or later as their typical bedtime. All screening surveys are described further in the Instruments and Measures section.

The primary investigator contacted volunteers who met the eligibility criteria to schedule a visit to the Exercise Physiology Laboratory at Arizona State University on the Downtown Campus.

Study Design

A baseline measure of sleep preceded a 3-week counter-balanced crossover trial to compare the effects of high-intensity interval exercise (HIT), moderate-intensity continuous exercise (MIC), and a no-exercise control (NEC) on sleep outcomes. Figure 2 shows the study outline.

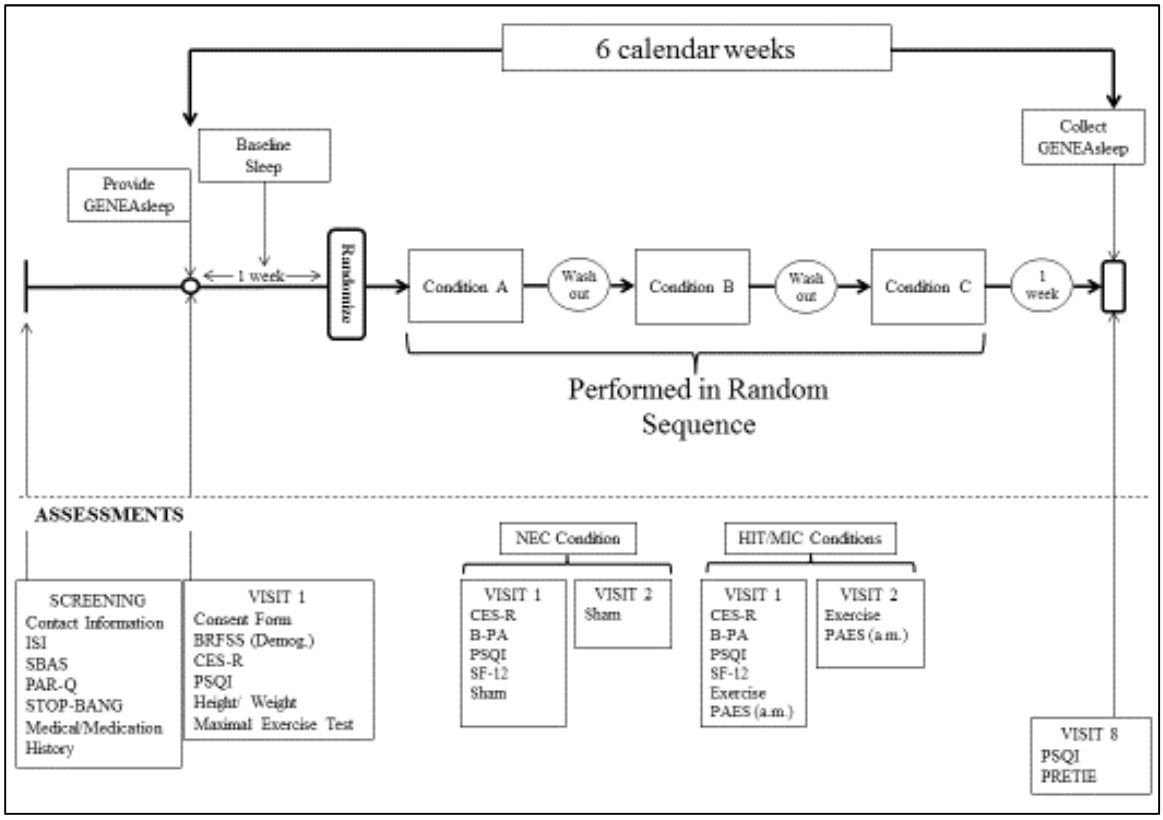

Figure 2. Study Timeline.

The study required eight visits to the Arizona State University Exercise Physiology Laboratory (referred to as the Exercise Physiology Laboratory). The participant performed all study procedures at the same time of day to minimize circadian variation. The study took six calendar weeks to complete following the pre-screening visit. The study included 1-week washout periods, a period between conditions, to allow

participants to recover from any physical fatigue and control for any carry-over that may result from training. At the first visit, participants completed pre-study activities and were given a sleep watch they wore for the next 6 weeks. After a 1-week washout period, participants were randomly assigned to a 3-condition sequence consisting of a no-exercise control, moderate-intensity treadmill walking (MIC), or high-intensity treadmill walking (HIT) delivered in a random, counter-balanced sequence with 1-week washouts. Each condition consisted of two visits completed 3-4 hours prior to typical bedtime on consecutive days. During the last visit, the sleep watch was collected and participants too post-study tests. Details of the activities performed at each visit are described below.

Visit 1: Preliminary Exercise Measurements

During Visit 1, participants read and signed an informed consent form (see Appendix B), completed a demographic data questionnaire, and completed pre-study questionnaires to identify the presence of depression status (revised Center for Epidemiologic Studies Depression Scale, CES-R) and subjective sleep quality (Pittsburgh Sleep Quality Index, PSQI). The Instruments and Measures section describes these measures. The researcher measured the participant's height in inches and weight in pounds using a stadiometer and laboratory scale. The participant performed a maximal treadmill graded exercise test to determine the prescribed exercise heart rate, and received an accelerometer to wear for the duration of the study to monitor their sleep status. Participants refrained from starting an exercise program, consuming caffeine after 12:00pm, or taking any sleep medications on any day throughout the study. At the end of Visit 1, participants scheduled the remaining seven visits with the researcher.

Treadmill Test

A modified Balke maximal treadmill graded exercise test was used to determine the heart rate associated with high- and moderate-intensity workloads needed to prescribe the exercise intensity during the treatment sessions. Participants performed a 5-minute warm-up of treadmill walking at 1.5-2 mph before the exercise test.

The modified Balke treadmill test involved a constant walking speed of 3.0 mph with increases in grade of 1% every one minute. A 12-lead electrocardiogram (EKG) monitor was used to measure the heart rate and rhythm at rest, during, and immediately after the maximal graded exercise test. Participants rated their level of exertion (RPE) with the 15-point Borg scale[187] the end of each stage and walked on the treadmill until volitional fatigue. The researcher recorded heart rate and RPE at the end of each stage (see Appendix C). The treadmill test stopped if the participant requested to stop for any reason, maximal exercise tolerance was reached, or test-termination criteria appeared as described by the American College of Sports Medicine's Guidelines for Exercise Testing[186]. The American College of Sports Medicine's Guidelines for Exercise Testing test-termination criteria include: onset of angina-like symptoms, drop in systolic blood pressure of > 10 mm Hg from rest despite an increase in workload, excessive rise in blood pressure (systolic pressure > 250 mm Hg or diastolic pressure > 115 mm Hg), shortness of breath, wheezing, leg cramps, claudication, signs of poor perfusion, failure of heart rate to increase with increased exercise intensity, noticeable change in heart rhythm, or physical or verbal manifestations of severe fatigue.

Immediately following completion of the treadmill test, participants walked slowly at a self-determined pace ≤ 2 mph until their heart rate returned to pre-exercise levels. An Advanced Cardiac Life Support Certified Exercise Physiologist monitored the participant's EKG throughout the test.

Accelerometer Distribution

Following the graded exercise test, the researcher provided each participant with a GENEAsleep (Activinsights, UK) accelerometer with instructions to wear the monitor for 24 hours per day continuously for two weeks, including during sleep, and to take off the device only if it could be exposed to water (e.g., bathing). The researcher provided a charged device after two weeks. Wearing an accelerometer continuously for four weeks has been deemed feasible in adult women[109]. While wearing the device, participants recorded bed times, wake times, and times/duration during which they remove the device in a personal log (see Appendix D).

Visits 2-7: Randomly Assigned Treatment Conditions

For all conditions, on the first of the consecutive-day visits each participant completed survey assessments of depression status (CES-R), sleep quality (PSQI), and physical activity (Behavioral Risk Factor Surveillance Survey Physical Activity Module; B-PA) during the previous week. For all conditions, on the second of the consecutive-day visits participants completed the treatment only (HIT, MIC, or NEC). At the beginning of each visit a Polar (Kempele, Finland) heart rate monitor was attached around the participant's chest prior to exercise or the sedentary activity to monitor target heart rate. Each morning, after HIT or MIC treatment visits only, participants completed a measure

of their exercise enjoyment (PAES) to assess their enjoyment of the previous days' exercise session. All condition visits occurred 4-6 hours prior to the participant's self-reported typical bedtime obtained from the screening survey.

High-intensity Exercise (HIT) Condition – Independent Variable

The HIT exercise treatments consisted of one 20-minute session of 10 x 1-minute treadmill walking periods at a speed and grade to elicit 90-95% of the participant's maximum heart rate (HR_{max}) achieved during the maximal exercise test. Each HIT walking period was separated by a 1-minute low-intensity active recovery-walking period (~50% HR_{max}). A 10-minute warm-up of treadmill walking at 50% HR_{max} preceded the exercise session and a 5-minute cool-down of treadmill walking at $\leq$ 2.0 mph followed the exercise session. The researcher recorded the exercise heart rate every minute.

Moderate-intensity Continuous Exercise (MIC) Condition – Independent Variable

The MIC exercise condition consisted of approximately 30 minutes of continuous treadmill walking at an intensity of 65-70% of HR_{max} achieved during the maximal treadmill test. A 5-minute warm-up of treadmill walking at 50% HR_{max} preceded each MIC exercise condition. A 5-minute cool down of treadmill walking at $\leq$ 2.0 mph followed each MIC exercise condition. The researcher recorded heart rate every two minutes.

No-exercise Control (NEC) Condition – Independent Variable

The NEC treatment required the participant to sit quietly and do a sedentary activity that excluded eating or the use of electronic equipment. Suitable activities

included reading a book or completing crossword or Sudoku puzzles for 45 minutes. The researcher recorded heart rate every five minutes.

Visit 8: Final Study Visit

Upon completion of the last visit of the final condition, the participant scheduled a final visit to return the accelerometer and turn in the sleep log. In addition, participants completed assessments of sleep quality (PSQI) during the past week and their overall preference of exercise intensity (PRETIE).

Description of Instruments and Measures

Survey Instruments – Screening

The screening survey instruments determined age, sleeping problems, typical bedtimes, physical activity levels, and contraindications for performing a maximal graded exercise test. The screening survey instruments included two questionnaires to assess the participant's ability to complete moderate-to-high intensity physical activity (PAR-Q), and a medication/health history to screen for conditions contraindicative to exercise and medications that may have an impact on sleep. Three questionnaires were used to classify the participant's insomnia status (the Insomnia Severity Index, ISI), habitual physical activity level (Stanford Brief Activity Survey, SBAS), and risk for obstructive sleep apnea (STOP-BANG survey). Participants completed all screening instruments prior to the first visit to the Exercise Physiology Laboratory. The next section describes details on the less commonly known ISI, SBAS, and STOP-BANG surveys.

Insomnia Severity Index

The Insomnia Severity Index (ISI) is a 7-item questionnaire used to identify subclinical to severe insomnia. This questionnaire consisted of questions asking the participant's difficulty with falling asleep, staying asleep, and awaking earlier than preferred. The ISI also asked participants to report current satisfaction with sleep, if sleeping problems interfered with their daily functioning, and how worried they were about their sleeping pattern. ISI responses contain a 5-point scale coded such that higher scores indicated worse sleep. The sum of responses indicated if the participant had no clinically significant insomnia (0-7 points), had sub-threshold insomnia (8-14 points), had clinical insomnia of moderate severity (15-21 points), or had severe clinical insomnia (>21 points). Participants classified as having, at minimum, subthreshold insomnia were eligible for the study. The ISI has good internal consistency ($r = 0.74$) and adequate concurrent validity compared to sleep diary data ($r = 0.65$)[188].

Stanford Brief Activity Survey

Physical activity status was assessed using the Stanford Brief Activity Survey (SBAS) of occupational activity and leisure-time activity. The SBAS is a valid, brief tool that provides an assessment of the usual amount and intensity of physical activity[189]. The survey provides the participant five choices that describe physical activities respective to the occupation and leisure domains. Each choice represents different activity intensity levels that the participant likely accumulates during the week. Participants select which description best matches their habitual activities during the week. Participants were eligible to enroll in the study if they identified as inactive or accruing light-intensity activity either at work (occupation domain) or during leisure time (leisure domain). To be

identified as physically inactive or accruing light-intensity physical activity in the occupation and leisure domains, participants identified as spending most of the day sitting or standing (e.g. writing, typing, talking on the telephone, assembling small parts) while at work and mostly watching television, reading, playing cards, or doing light chores or light exercise during leisure times. Validity of the SBAS was been determined by accurately classifying the association between physical activity levels and coronary heart disease risk factors and with total daily energy expenditure derived from the Stanford Seven-Day Physical Activity Recall in older adults (60-69 years)[189]. Reliability for adults ages 60-70 years is $r = 0.62$[190].

STOP-BANG Survey

To screen out participants at risk for obstructive sleep apnea, participants completed the STOP-BANG questionnaire as part of initial screening[191]. The name of the instrument is created from the first letter for the domains measured (Snoring, Tired, Obstruction, blood Pressure, Body mass index, Age, Neck circumference, and Gender). The questionnaire includes 8 items regarding snoring, being tired during the day, cessation of breathing during sleep due to an obstruction, taking medication to control high blood pressure, body mass index > 28, age ≥ 50, male with neck circumference > 17 inches or female with neck circumference > 16 inches, and male gender formatted so responses are yes/no. Used as a screening instrument, participants were eligible for the study if the sum of 'yes' responses totaled ≤ 3 for all questions. The STOP-BANG questionnaire is valid in detecting obstructive sleep apnea from monitored polysomnography in a clinically obese population. The total score of 3 has high sensitivity (90%) and high positive predictive value (85%) for obstructive sleep apnea[191].

Survey Instruments - Demographics

The Qualtrics survey software administered all demographic survey instruments to the participant on a laptop computer during the Exercise Physiology Laboratory visits. The survey instruments included the demographic information module, the Pittsburgh Sleep Quality Index (PSQI) for determining self-reported sleep parameters, the Physical Activity Enjoyment Scale (PAES) to determine satisfaction of exercise sessions, and the Preference for Exercise Intensity (PRETIE) survey to determine overall preference of intensity at which to perform physical activity.

Participants provided demographic information from the demographics module of the 2011 Behavioral Risk Factor Surveillance system (www.cdsc.gov/brfss, BRFSS). The participant reported age in years, race/ethnicity, marital status, education level, occupation status, and income, which have been associated with sleep quality[10,192,193,194,195,196]. Data analysis models controlled for all demographic variables.

Survey Instruments - Covariates

The Qualtrics survey software administered all survey instruments to the participant on a laptop computer during the Exercise Physiology Laboratory visits. The covariate survey instruments included the SF-12 to determine self-rated health status of the participant, the physical activity module from the 2001 Behavioral Risk Factor Surveillance System to assess weekly physical activity levels (BRFSS-PA), and the Center for Epidemiologic Depression Scale (CESD-1) for assessing depression status. Data analysis models controlled for all covariates.

Physical Activity

The participant indicated self-reported leisure-time physical activity prior to exercise on Visit 2, Visit 4, and Visit 6 by completing the 2001 BRFSS Physical Activity Module (BRFSS-PA). Regular physical activity is related to sleep quality[48]. The BRFSS-PA is a 6-item questionnaire designed to assess leisure-time, household, and transportation activities the participant performed during a usual week. Items asked if the participant performed moderate or vigorous activities for recreation, exercise, to get to and from places or for any other reason for at least 10 minutes over a usual week and to indicate how many days (1-7) and how much total time (hours and minutes per day) was spent active. These questions are fair at estimating moderate ($\kappa = 0.31$) and vigorous ($\kappa = 0.17$) intensity physical activity compared to accelerometers with good test-retest reliability in estimating moderate- ($\kappa = 0.53$) and vigorous- ($\kappa = 0.86$) intensity activity[197]. The summary score includes three categories: inactive, insufficiently active, meets recommendations.

Depression

The participant indicated depression status on Visit 2, Visit 4, and Visit 6 with a short form of the Centers for Epidemiologic Studies Depression Scale-Revised (CESD-R). The CESD-R is a 20-item survey asking participants to list how they felt or behaved over the previous week, such as feeling depressed, feeling happy, feeling lonely, enjoying life, feeling sad, and having restless sleep[198]. Dichotomous responses are assigned numeric values (yes = 1, no = 0) and coded so that smaller values reflect a more positive profile. The total score was calculated as a sum of responses to all questions. The 20-item survey is valid compared to the Diagnostic and Statistical Manual of Mental Disorders at

identifying depression in adults age 60 and older. A cut-off score of four or greater has sensitivity and specificity values of 100% and 92%[199]. Reliability of the 20-item survey is also good ($\alpha = 0.80$)[200]. The summary score is expressed as a number from 0-20 with smaller values indicating a lack of depression symptoms.

Survey Instruments – Dependent Variables

Pittsburgh Sleep Quality Index

The Pittsburgh Sleep Quality Index (PSQI) assessed participant's subjective sleep for the previous week at Visit 1 and Visit 5 prior to exercise and at Visit 8. The PSQI measures subjective sleep habits over the previous month with scores computed for sleep-onset latency, sleep disturbances (sleep maintenance), sleep efficiency, sleep quality, and a global sleep score. The participant completed a modified version to indicate sleep over the previous week. The modified instrument (assessment of previous week) is a valid measure compared to the 28-day instrument (previous month)[201]. Clinical psychologists have found the modified version useful in assessing subjective sleep complaints. The PSQI is a valid 10-item questionnaire asking the participant to report information regarding bed time (Q1), time is takes to fall asleep (Q2), sleep time (Q3 and Q4), trouble sleeping (Q5a-Q5j), overall sleep quality (Q6), use of sleeping medication (Q7), and daytime dysfunction due to sleepiness (Q8 and Q9) [114]. If a range was provided for time, such as 30 to 60 minutes, the difference was recorded as the mid-point time. Questions 5a-5j and Question 7 assess frequency of occurrences using a 4-point scale ranging from "Not during the past month" to "Three or more times a week" coded as 0-3 respectively. To score overall sleep quality Q6-responses were coded 0-3. All scored categorical

responses were set 0-3 with minimum score reflecting better sleep. To score sleep latency, Q2-responses were recoded from ≤ 15 minutes, 16-30 minutes, 31-60 minutes, and > 60 minutes to 0-3 respectively. The recoded Q2-responses were added to the coded Q5a response. The resultant value was recoded from 0, 1-2, 3-4, and 5-6 points to 0-3, respectively. To score sleep duration, Q4-responses of greater than seven hours, 6-7 hours, 5-6 hours, and greater than five hours were coded as 0-3, respectively. To score sleep efficiency, Q4 was divided by the difference in time between Q1 and Q3 and multiplied by 100. The resultant value was recoded from ≥ 85%, 75-84%, 65-74%, and < 65% to 0-3 points respectively. To score sleep disturbances, the sum of Q5b-Q5j responses was recoded from 0, 1-9, 10-18, and 19-27 to 0-3 respectively. To score daytime dysfunction, the sum of Q8 and Q9 was recoded from 0, 1-2, 3-4, and 5-6 to 0-3 respectively. The global PSQI score is the sum of each component score. The original PSQI has test-retest reliabilities of $r = 0.87$ for the overall score, $r = 0.79$ for sleep-onset latency, $r = 0.81$ for sleep efficiency, and $r = 0.69$ for sleep disturbances in a population of diagnosed insomniacs. A global sleep quality score > 5 points has a sensitivity of 98.7% and specificity of 84.4% as a marker for sleep disturbances in primary insomniacs[114]. The component scores are expressed as integers with values closer to 0 indicating better sleep outcomes.

Physical Activity Enjoyment Scale

The participant completed the Physical Activity Enjoyment Scale (PAES), an 18-item questionnaire, the morning after each exercise session. The participant responded to a 7-point bipolar rating scale to rate how they felt now about their past physical activity. The survey required the participant to report feelings of pleasure, fun, pleasantness,

invigoration, gratification, exhilaration, stimulation, and refreshment directed toward the physical activity most recently performed. A higher PAES score reflects greater levels of enjoyment. The PAES has demonstrated excellent structural validity (Comparative Fit Index = 0.99; Root Mean Squared Error of Approximation = 0.04) and good internal reliability (r = 0.93) in older adults (66.4 years). The instrument is not subject to longitudinal invariance (i.e. does not lose structural validity when taken more than once)[202]. The summary score was expressed as the median of the 18 item responses across the 18 items.

Preference for the Intensity of Exercise Questionnaire

The Preference for Intensity of Exercise Questionnaire (PRETIE) is an 16-item measure of individual preference for intensity of exercise and the tolerance of exercise[202]. The preference scale of the instrument has eight items that identify one's preference for high intensity/short duration and eight items that identify one's preference for low intensity/longer duration. Item-responses range from totally disagree (1) to totally agree (5) and was recoded so minimum numbers reflect preference for lighter intensity exercise. The summary score was expressed as the median of the 16 items. The Preference scale and Tolerance scale have internal consistency (r = 0.89 and r = 0.86) and structurally valid (Comparative Fit Index = 0.97; Root Mean Squared Error of Approximation = 0.04) in college females[203].

GENEAsleep Measurements – Dependent Variables

Sleep Outcomes

The GENEAsleep measured the dependent variables of sleep-onset latency (time spent from getting into bed to sleep-onset), sleep maintenance (time spent awake between sleep-onset and last awakening), and sleep efficiency (ratio of time spent asleep to time spent in bed; expressed as a percentage) for Aim 1A. The GENEAsleep monitor (Activinsights, UK), an objective measure of sleep, reflected sleep quantity and sleep quality. The GENEAsleep is a +/- 8g wrist-worn, splash-proof accelerometer. It is a valid measure of physical activity compared to the ActiGraph accelerometer ($r = 0.92$)[204], and sleep outcomes compared to the Actiwatch accelerometer using Bland-Altman plot inspections[205]. The instrument is a thin profile device, similar in shape to a commonly worn wristwatch. The GENEAsleep has a rechargeable lithium polymer battery and a 0.5 GB memory capable of logging various frequencies (10-100Hz) or movement. The frequency for measuring movement was 40 Hz. The researcher downloaded GENEAsleep data and saved it using the GENEAsleep software, a free download from the website (www.geneactive.co.uk). Each file consisted of approximately 1-2 weeks of data saved in .csv format. Data were imported to SAS (SAS Institute, Cary, NC) for data processing and scoring.

The researcher developed a SAS program macro that read in each file, reformatted the timestamped accelerometer data, read in the sleep log bed and wake times for all participants, and output a data set consisting of nightly sleep periods, termed sleep windows, for each participant. To score the dependent variables of nightly sleep-onset latency, sleep maintenance, and sleep efficiency, the researcher developed an

independent SAS program macro (see Appendix E) based on a combination of previously tested equations supplied by the Activinsights Ltd. manufacturer and previously conducted studies using wrist-worn accelerometers[76,205]. Utilizing the non-filtered, z-axis (palmar-dorsal) data collected at the original epoch (40 times per second), movement between epochs was the premises for the calculations. For example, each 40th of a second z-axis value was assigned a positive or negative integer between 0 and 128, termed bin, such that a bin value of ±25 represented ±1 g. The largest absolute bin value (value furthest from zero) was retained within each second and the standard deviation of bin values within a 15-second epoch, representing the extent of movement from one second to the next, was calculated. The standard deviation of 15-second epoch bin values, termed count, was used to determine movement versus sleep within the sleep window of each night for each participant. These calculations were created from a movement-based perspective using the assumption that lying in bed attempting to fall asleep initially (sleep onset latency) involves different movement patterns compared to waking in the middle of the night (sleep maintenance).

The dependent variable of sleep-onset latency time was calculated by comparing the time the person reported going to bed (first epoch of each night) to the first 15-second epoch value at which the proceeding 20 epochs (5 minutes) were < 0.5 counts.

The dependent variable of sleep maintenance was calculated by summing the 15-second epoch values that were assigned as wake. Wake was assigned, using a 1-minute moving window, if the two epochs prior (30 seconds) and two epochs after (30 seconds) were all > 1 count.

The dependent variable of sleep efficiency, expressed as a percentage, was calculated by dividing the number of minutes asleep by the number of minutes spent in bed, multiplied by 100. The newer algorithms for determining sleep onset latency and wakefulness after sleep onset resulted in similar results for sleep onset latency, sleep maintenance, and sleep efficiency compared to previously conducted methods[76].

The dependent variable of total sleep time was calculated from the sum of non-wake epochs between the sleep onset latency epoch and the final sleep maintenance epoch. Time spent in bed was calculated from the first epoch and last epoch of each night. Sleep outcome variables sleep-onset latency, sleep efficiency, sleep maintenance, and total sleep time for each participant per night were output to a final sleep metrics data set organized by participant ID and date.

Body Temperature

Peripheral body temperature during sleep measured by the GENEAsleep is a dependent variable for Aim 2A. The stainless steel temperature plate backing on the GENEAsleep is capable of measuring peripheral heat loss within normal body ranges (0° to 60° C) with +/- 1° C accuracy. The GENEAsleep recorded temperature every 30 seconds with a resolution of 0.25° C. Device specifications indicate it is capable of measuring the rate of decline in peripheral skin temperature within expected physiological values. Participants took the device off during showers and water-based activities but wore the device at all other times throughout the four-week study.

The researcher downloaded body temperature from the GENEAsleep monitor as previously described. The researcher developed a SAS program code to aggregate the

time-stamped temperature measurements. The SAS code retained the maximum temperature collected per second and calculated the average temperature over the 1-minute epoch. The algorithm compared each epoch's temperature value to the value 10 minutes in advance and calculated the difference between the two, expressed as percent change. The SAS code retained the largest percent change in temperature over a 10-minute epoch in the span of one evening along with the time at which the 10-minute epoch begin.

Data Management

The researcher created an information form for each participant that included participant ID, laboratory visit date, laboratory visit start time and end time, indication of exercise protocol sequence (ABC, ACB, BAC, BCA, CAB, or CBA), indication of exercise protocol (HIT=1; MIC=2; NEC=3), exercise session number (1 or 2), and HR during exercise (see Appendix F). Each participant's ID matched the exercise information sheet to all Qualtrics administered surveys and the GENEAsleep data. The researcher input the laboratory information sheet containing the treadmill test results and condition results into an Excel file organized by participant ID and date of the Exercise Physiology Laboratory visit.

The researcher downloaded and input results of each Qualtrics survey into different worksheets in the same Excel file, organized by participant ID and date the survey was completed. The researcher scored survey responses using Microsoft Excel software individually using the scoring methods described previously. The researcher input the sleep log information for each participant of each date of the study into a

separate worksheet in the same Excel file, with missing bed times and wake times left blank. The researcher imported each Excel worksheet containing all Exercise Laboratory visit results, online survey results, and sleep log results into the data analysis software and match-merged by ID and date.

The final data set used for data analysis was created by match-merging the sleep metrics data set and the body temperature data set with the condition and survey data set by participant ID and date. This resulted in a time-series data set organized by calendar date for the whole sample.

Data Analysis

Data were analyzed using descriptive measures for mean, standard deviation, range, and percent values to characterize the sample. Mixed effects models (SAS, Proc Mixed) tested each alternate hypothesis with the intercept as the random effect and the covariates, independent variables, and interaction terms as the fixed effects. All models used restricted maximum likelihood to determine estimates, the Satterthwaite method to determine degrees of freedom, and a power spatial covariance structure to account for within-subject correlated time points with the p-value set at 0.05.

Hypothesis 1A

For hypothesis 1A, a multi-level mixed effects repeated measures model tested the alternate hypothesis that high-intensity interval training would result in superior sleep outcomes of actigraphy-measured sleep-onset latency, sleep maintenance, and sleep efficiency compared to a continuous moderate-intensity training or a no-exercise control. The dependent variables included GENEAsleep-measured sleep variables of sleep-onset

latency, sleep maintenance, and sleep efficiency. The fixed effects included condition (high-intensity interval training, continuous moderate-intensity condition, or a no-exercise control), night, and covariates of age, body mass index (BMI), the number of children in the household, education, occupation status, income, marital status, race, depression, and physical activity level. The interaction terms included condition by night. The intercept was used as the random effect.

Hypothesis 1B

For hypothesis 1B, a multi-level mixed effects model tested the alternate hypothesis that high-intensity interval training would result in superior sleep outcomes of PSQI-measured sleep outcomes compared to a continuous moderate-intensity training or a no-exercise control. The dependent variables included PSQI-measured sleep-onset latency, sleep disturbances (i.e., sleep maintenance), sleep efficiency, sleep duration, sleep quality, and the global PSQI score. The fixed effects included condition (high-intensity interval training, continuous moderate-intensity condition, or a no-exercise control), and covariates of age, body mass index (BMI), the number of children in the household, education, occupation status, income, marital status, race, depression, and physical activity level. The intercept was used as the random effect.

Hypothesis 2

For hypothesis 2, a mixed effects model tested the alternate hypothesis that the high-intensity interval condition would result in a greater change in peripheral distal body temperature compared to MIC and a NEC, thereby predicting improved actigraphy-measured sleep-onset latency. The dependent variable included actigraphy-measured

sleep-onset latency. The fixed effects included condition, the maximum change in GENEAsleep-measured distal skin temperature prior to bed time, and covariates of age, BMI, number of children in the household, education, occupation status, income, marital status, race, depression, and physical activity level. The intercept was used as the random effect.

Hypothesis 3

For hypothesis 3, a mixed effects repeated measures model tested the alternate hypothesis that participants would prefer the high-intensity interval training over the continuous moderate-intensity training as a method of improving sleep outcomes. The dependent variable was the score on the self-reported Physical Activity Enjoyment Scale. The fixed effects included condition, condition number (e.g. first visit, second visit), and covariates of age, BMI, number of children in the household, education, occupation status, income, marital status, race, depression, and physical activity level. The interaction effects included condition-by-condition number. The intercept was used as a random effect. To investigate individual preferences for high-intensity interval training or continuous moderate-intensity training, measures of central tendency of the 16-item Preference for Exercise Intensity (PRETIE) questionnaire were examined. The median value from the Likert-type 1-5 scale of each of the 16 items represented each participant's training intensity preference such that a higher score indicates preference for more intense training.

CHAPTER 4

RESULTS

The primary purpose of this research was to compare the effects of two consecutive days of moderate-intensity continuous exercise and high-intensity interval training with a no-exercise control group on actigraphy-measured sleep outcomes in inactive adults with self-reported sleep problems. The secondary purpose of this research was to examine changes in thermoregulation following moderate- and high-intensity exercise sessions as a mechanism of improving the sleep outcome of sleep-onset latency. The tertiary purpose of this research was to examine the participant's subjective preference of an exercise intensity in improving sleep.

Sample descriptive information is available in Table 1. Three hundred eight-five volunteers completed the screening surveys. Twelve adults met the inclusion criteria. Of those who failed to meeting the inclusion criteria, 86 were outside the age range, 101 did not meet the criteria for subclinical insomnia, 118 indicated they obtained moderate-intensity activity during work or exercised regularly, 22 indicated a bedtime after 11:00pm, 7 indicated they recently returned from travel across three or more time zones, seven worked 2nd or 3rd shift occupations, and 32 that indicated contraindications to exercise testing. Those who met the inclusion criteria were invited to the facility for graded maximal exercise test. The supervising exercise physiologist excluded one person due to contraindications to performing maximal exercise. The lead researcher enrolled eleven adults in the study (see Appendix G) whom were provided a GENEAsleep monitor and sleep log.

All enrolled participants were female with average age of 46.9±7.0 years (range 35-58 years) and a BMI of 29.2±6.0 (range 24.1-40.1). One participant was of African-American race and all others were Caucasian. All participants had a household income of greater than $25,000. All were employed for wages except one, who was a homemaker.

Table 1. Descriptive and Demographic Data on Study Participants (n = 11).

Demographic Characteristic	*Descriptive Data* *N (%) or mean* ± SD (range)
Gender	
Female	11 (100%)
Age	46.9 ± 7.0 years (35 – 58)
Body Mass Index	29.2 ± 6.0
Self-Reported Race	
White	10 (91%)
Black or African American	1 (9%)
Marital Status	
Married	7 (64%)
Single/Divorced	4 (36%)
Number of children	
None	6 (54.5%)
One or more child	5 (45.5%)
Education	
High school	1 (9%)
Some college	3 (27%)
College graduate	7 (64%)
Employment	
Employed for wages	10 (91%)
Homemaker	1 (9%)
Income	
Median annual salary	$50,000 - $75,00 USD ($25.000-$35,000 – $85,000 or more)
Maximal Oxygen Uptake	21.7 ± 3.1 $ml \cdot kg^{-1} \cdot min^{-1}$

Figure 3 displays the night-to-night and condition mean estimates in the actigraphy-measured sleep outcome of sleep-onset latency. Results showed no significant effect in night-to-night actigraphy measured sleep-onset latency for the HIT condition ($F_{3, 66.4} = 0.61$, $p > 0.05$), the MIC condition ($F_{3, 66.4} = 1.84$, $p > 0.05$), and the NEC condition ($F_{3, 69} = 0.31$, $p > 0.05$). The interaction term of night-to-night sleep-onset latency between the three conditions was not significant ($F_{6, 68.4} = 0.83$, $p > 0.05$).

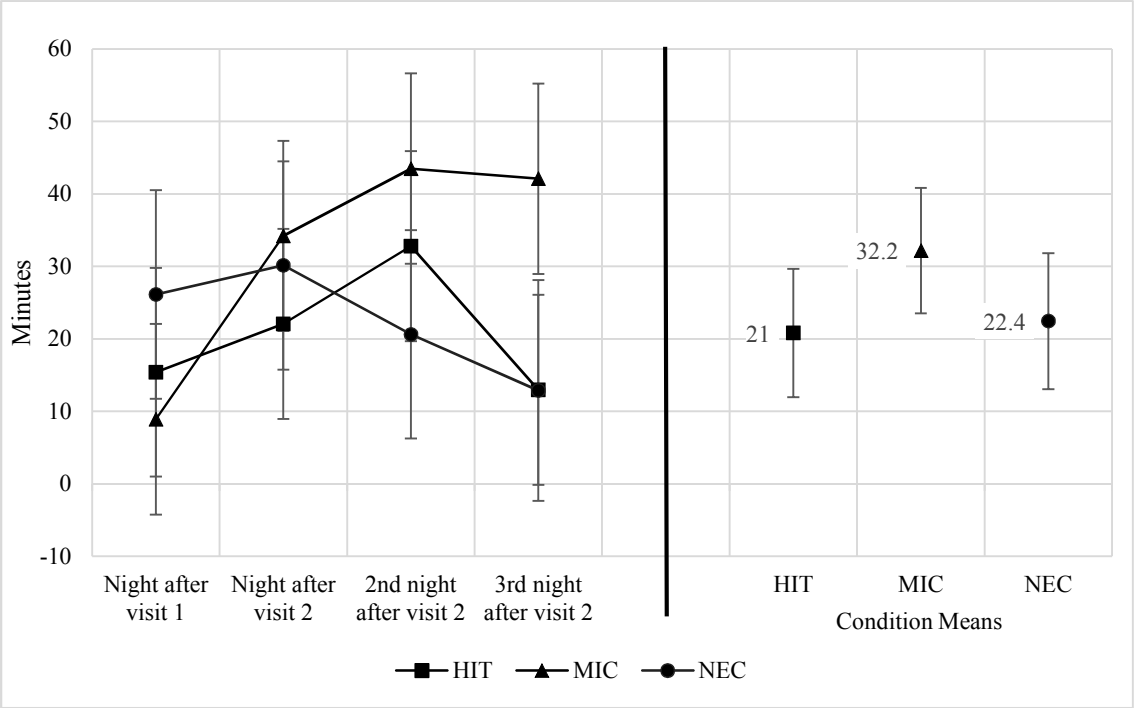

Figure 3. Mean Sleep-onset Latency with 95% Confidence Intervals for High-intensity (HIT), Moderate-intensity (MIC) and Non-exercise Control (NEC) Conditions. Values closer to 0 minutes indicates less time spent in bed prior to sleep onset. Values further from 0 minutes indicate more time spent in bed prior to sleep onset.

Figure 4 displays the night-to-night and condition mean estimates in the actigraphy-measured sleep outcome of sleep maintenance. Results showed no significant effect in night-to-night actigraphy measured sleep maintenance for the HIT condition ($F_{3, 72} = 0.02$, $p > 0.05$), the MIC condition ($F_{3, 71.6} = 0.91$, $p > 0.05$) and the NEC condition

($F_{3, 72.2} = 0.07$, $p > 0.05$). The interaction term of night-to-night sleep maintenance between the three conditions was not significant ($F_{6, 72.3} = 0.26$, $p < 0.05$).

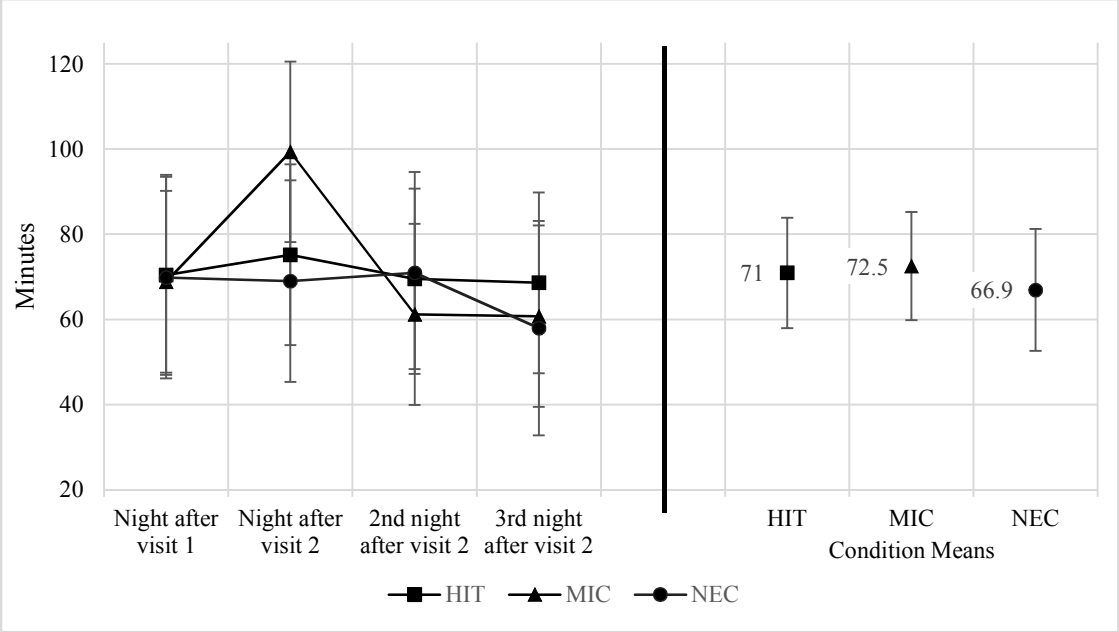

Figure 4. Mean Sleep Maintenance with 95% Confidence Intervals for High-intensity (HIT), Moderate-intensity (MIC) and Non-exercise Control (NEC) Conditions.

Figure 5 displays the night-to-night and condition mean estimates in the actigraphy-measured sleep outcome of sleep efficiency. Results showed no significant effect in night-to-night actigraphy measured sleep efficiency for the HIT condition ($F_{3, 65.1} = 0.35$, $p > 0.05$), the MIC condition ($F_{3, 65} = 0.40$, $p > 0.05$) and the NEC condition ($F_{3, 66.4} = 0.21$, $p > 0.05$). The interaction of night-to-night sleep efficiency between the three conditions was not statistically significant ($F_{6, 66.3} = 0.25$, $p > 0.05$).

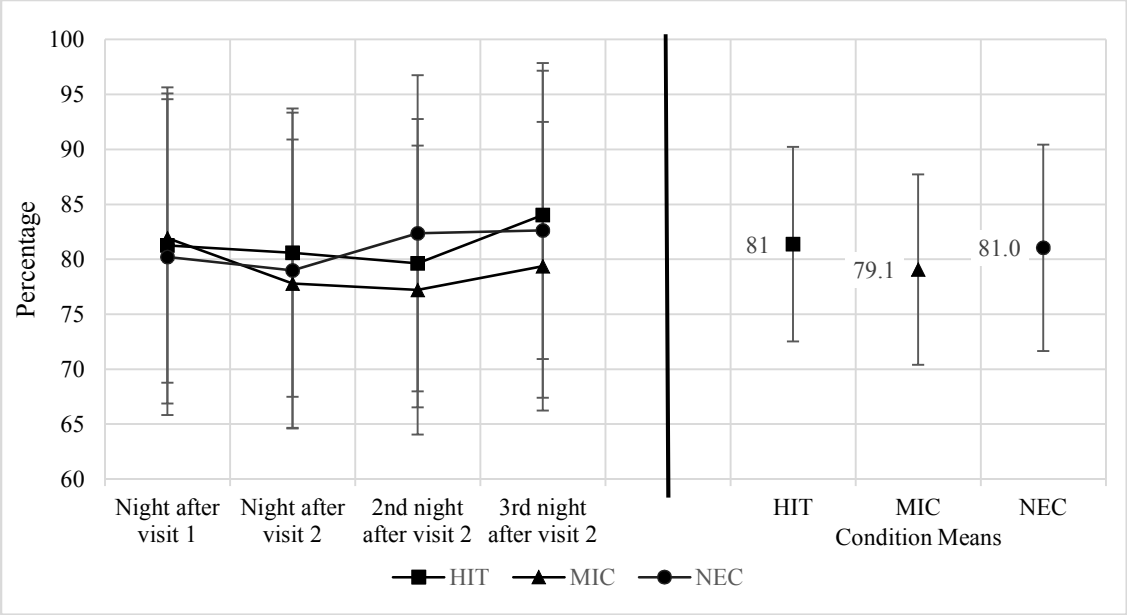

Figure 5. Mean Sleep Efficiency with 95% Confidence Intervals for High-intensity (HIT), Moderate-intensity (MIC) and Non-exercise Control (NEC) Conditions.

Figure 6 displays the night-to-night and condition mean estimates in actigraphy-measured total sleep time. Results showed a significant effect in night-to-night actigraphy measured total sleep time for the HIT condition ($F_{3, 61.2} = 3.08$, $p < 0.05$). No significant changes in night-to-night actigraphy measured total sleep time for the MIC condition ($F_{3, 61.2} = 0.76$, $p > 0.05$) and the NEC condition ($F_{3, 65.5} = 0.78$, $p > 0.05$) were found. The interaction of night-to-night sleep efficiency between the three conditions was not statistically significant ($F_{6, 64.4} = 1.47$, $p > 0.05$).

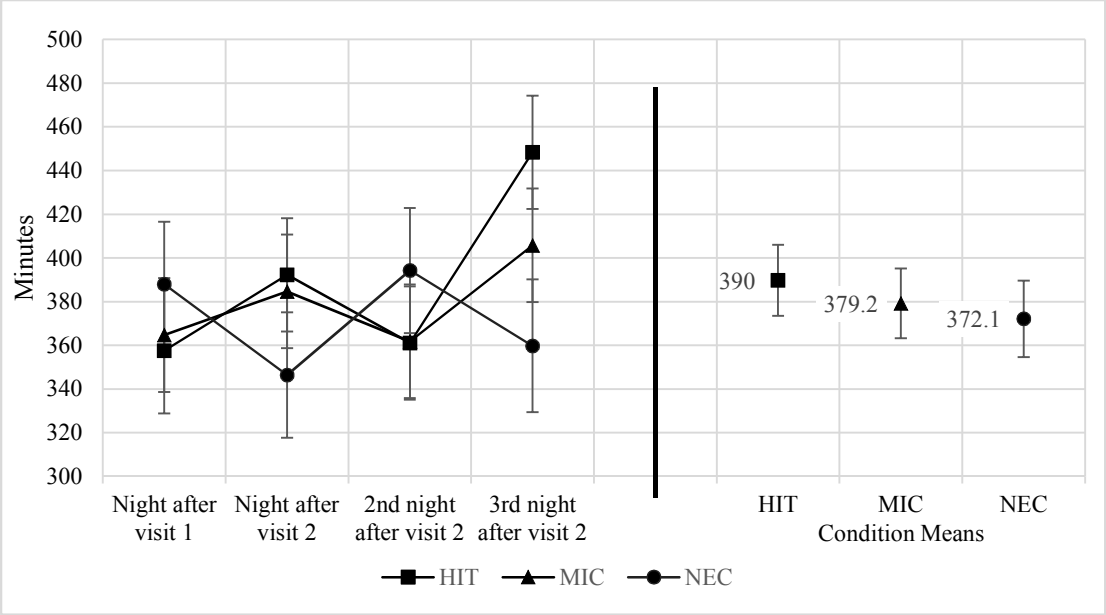

Figure 6. Mean Total Sleep Time in Minutes with 95% Confidence Intervals for High-intensity (HIT), Moderate-intensity (MIC) and Non-exercise Control (NEC) Conditions.

Table 2 displays differences between conditions for the PSQI-measured sleep outcomes and PAES-measured enjoyment of the condition. Results showed no significant differences between conditions for PSQI-measured sleep-onset latency, sleep disturbances, sleep efficiency, sleep quality, or the global PSQI sleep score ($p > 0.05$).

Table 2. Comparisons of Subjectively-Measured Sleep Measures (n = 11)

	Baseline	HIT	MIC	NEC	P-value
PSQI					
Sleep-onset Latency	1.77	1.50	1.70	1.66	0.89
Sleep Disturbances	1.76	1.66	1.60	1.35	0.65
Sleep Efficiency	0.77	1.18	0.64	0.99	0.39
Sleep Quality	1.34	1.38	0.92	1.28	0.18

Global Sleep Score	7.43	7.22	6.12	6.67	0.80
PAES	N/A	5.74	5.50	N/A	0.49

PSQI = Pittsburgh Sleep Quality Index. Sleep parameter scores range from 0-3 with a score closer to 0 indicating a better outcome. The Global Sleep Score ranges from 0-21 with a score ≤ 5 indicating good sleep quality and a score > 5 indicating poor sleep quality; PAES = Physical Activity Enjoyment Survey

Temperature change was not a significant predictor of sleep-onset latency ($p > 0.05$). Table 3 shows the mean percent temperature change prior to sleep onset for the HIT, MIC, and NEC conditions only on nights following laboratory visits. No differences existed between conditions ($p > 0.05$).

Table 3. Percent Increase in Peripheral Skin Temperature in Celsius between Conditions (n = 11)

	HIT	MIC	NEC	P-value
Temperature Change	19.8%°C (15.5-24.2)	17.2%°C (12.9-21.4)	17.5%°C (12.4-22.5)	0.65

Mean percent increase in peripheral skin temperature prior to sleep onset with 95% confidence intervals for the high-intensity interval (HIT), continuous moderate-intensity (MIC), and no-exercise control (NEC) conditions.

Figure 7 shows results of the Preference for Exercise Intensity survey rescaled so that a score of 3 (on a scale of 1-5) was a reference value set to 0. One participant responded with a median score of 1, indicating a preference for more intense exercise. This was the only responder reporting a median score greater than 0. Three participants reported a median score less than 0 and five participants reported a median score of 0. The median score of all responses for all completed surveys was 0.

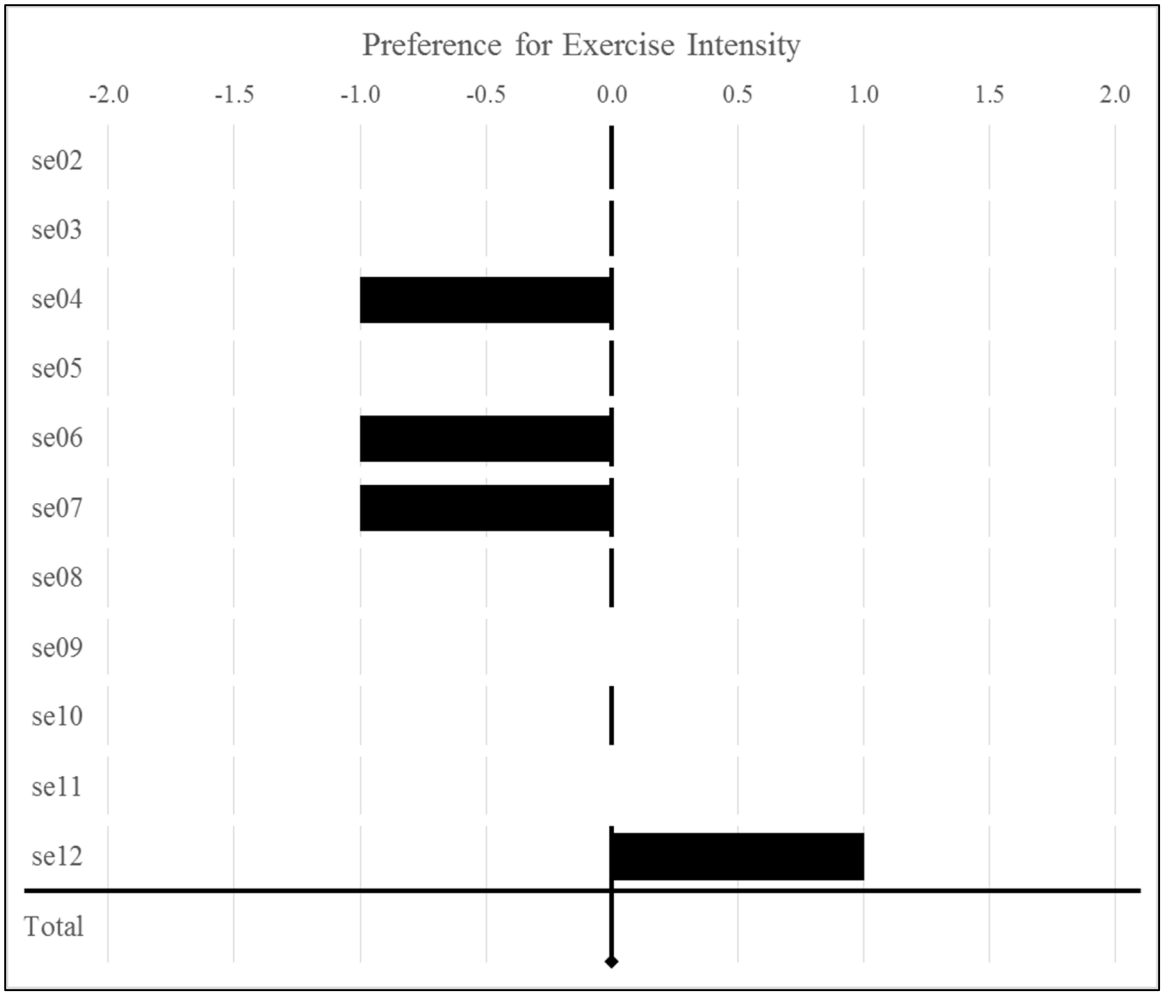

Figure 7. Self-reported Preference for Exercise Intensity. Higher numbers indicate a preference for higher-intensity exercise. Values that are above the reference median score (0.0) reflect a typical response that was a certain number of units above the reference median value; suggesting participants preferred higher intensity exercise. Values that are below the median reference score reflect a typical response that was a certain number of units below the reference median value; suggesting participants preferred lower or more moderate intensity exercise.

CHAPTER 5

DISCUSSION

The purpose of this research was to examine the relationship between physical activity intensity on changes in sleep-onset latency, sleep maintenance, and sleep efficiency. Secondary and tertiary aims included determining if temperature rate-of-change predicted sleep-onset latency and determining the preferred intensity of physical activity to improve sleep outcomes in sedentary adults with subclinical insomnia. In a sample of sedentary women self-reporting problems with sleep, the high-intensity interval training condition had a significant effect on actigraphy-measured total sleep time resulting in an increase in total sleep time on the fourth night of the condition; it had no effect on the other actigraphy-measured sleep parameters measured. The moderate-intensity condition had no significant effect on actigraphy-measured sleep-onset latency, sleep maintenance, sleep efficiency, or total sleep time, but did result in a 30-minute sleep onset delay on the third and fourth nights compared to the first night of the moderate-intensity condition. The no-exercise control had no effect on actigraphy-measured sleep-onset latency, sleep maintenance, sleep efficiency, and total sleep time and no significant differences were found between nights. The high-intensity, moderate-intensity, and no-exercise control conditions had no effect on any of the self-reported sleep parameters. The rate-of-change in body temperature had no effect on sleep-onset latency and the maximum body temperature increase post-exercise was similar between the three conditions. Last, most women preferred moderate-intensity physical activity compared to high-intensity training as a means of improving sleep.

The alternate hypothesis of Aim 1A was that two consecutive nights of high-intensity interval training or two consecutive nights of continuous moderate-intensity training sessions would result in superior sleep outcomes of actigraphy-measured sleep-onset latency, sleep maintenance, and sleep efficiency, compared to two consecutive nights of a no-exercise control. The null hypothesis that no differences would exist between the high-intensity exercise, moderate-intensity exercise, and no-exercise control conditions was not rejected for the dependent variables of actigraphy-measured sleep-onset latency, sleep maintenance, sleep efficiency. One factor that may have resulted in failing to reject the null hypothesis for the actigraphy-measured dependent variables of sleep-onset latency, sleep maintenance, and sleep efficiency may have been the mode of physical activity eliciting energy expenditure to affect sleep. While not performed in this study, using a greater volume of resistance training with intermediate-level weights at lower intensities can improve metabolic conditioning and may result in increased metabolic costs of activity, an increase in muscle fatigue, increase in core body temperature, and a smaller increase in cytokines, thereby preparing the body for an improved sleep drive. Resistance training has shown promise to improve other sleep disorders, such as restless leg syndrome. In a cross-sectional analysis of a population-representative sample, Loprinzi et al.[206] reported that those participating in muscular strengthening activities had 19% increased odds of meeting the sleep duration guidelines of 7-8 hours per night. In 2015, Alley et al.[207] confirmed these results in an experiment testing the effects of resistance exercise (9 exercises performed to a 10 repetition maximum) and timing of resistance exercise on sleep disturbances. Results showed that resistance exercise resulted in fewer sleep disturbances compared to a no-exercise control

and that resistance exercise performed in the evening resulted in improved sleep disturbances compared to training at mid-day or in the morning.

Night-by-night comparisons of sleep onset latency represented in Figure 3 show a worsening of sleep onset latency by 30 minutes on the third and fourth nights compared to the first night of the moderate-intensity condition. One factor that may have influenced the worsening of sleep onset latency was a physiological excitement reaction to the activity. Physical activity results in increased heart rate and increased release of cytokines, possibly exacerbating sleep problems in sedentary, poor sleepers resulting in the worsening of sleep outcomes. The high-intensity condition resulted in statistically similar sleep onset latency each night, however the changes in night-to-night sleep-onset latency show a visually similar pattern over the four post-exercise nights to that of the moderate-intensity condition. In 2014, Oda and Shirakawa[208] demonstrated that physical activity, particularly high-intensity physical activity, performed in the evening resulted in an elevated heart rate at bed time and an increased sleep-onset latency in comparison to a no-exercise control. In 2007, Santos et al.[209] described a positive dose response relationship between physical activity intensity and the release of cytokines interleukin-1, interleukin-6, and tumor necrosis factor-alpha. The increase in cytokines may result in decreased sleepiness. In addition, drowsiness may be a result of decreased levels of these cytokines. Because these cytokines typically require several hours to return to normal post-exercise, the authors recommended performing physical activity in the morning. Additionally, performing physical activity in the morning may improve sleep due to the body's increased demand for sleep from additional energy expenditure while allowing sufficient recovery post-training[210].

The night-to-night comparisons of total sleep time in Figure 6 indicate the fourth night of the high-intensity condition resulted in improved total sleep time by 91 minutes, a 25% increase compared to the first night of the high-intensity condition. The 25% improvement in total sleep time on the fourth night may be explained by a possible combined effect from the release of exercise-related hormones followed by muscular relaxation from accumulated evening exercise. No research has reported this type of theoretical combined effect from evening exercise. However, previous research described by Santos et al.[209] demonstrated the exercise-induced hormone release and resultant decrease in sleepiness. In addition, in 2012, Morris et al.[211] reported that the muscular relaxation response following high-intensity exercise was greater compared to low-intensity exercise. Also, the recovery profile of the high-intensity exercise was delayed despite the same total work accumulated compared to the low-intensity training. These reports indicate the possibility that sleep may be unimproved on the night immediately following an evening exercise session, but may result in a delayed muscular relaxation response on the second night following evening exercise, thereby ultimately improving sleep.

The alternate hypothesis of aim 1B was that two consecutive nights of high-intensity interval training sessions or two consecutive nights of continuous moderate-intensity training sessions would result in superior self-reported sleep-onset latency, sleep maintenance, sleep efficiency, sleep quality, and the PSQI global sleep score as compared to a no-exercise control condition. The null hypothesis was not rejected as no differences were observed between the three conditions for any of the self-reported dependent variables.

One factor that may have resulted in failing to reject the null hypothesis for aim 1B was that the physical activity volume prescribed to increase energy expenditure was not high enough to result in an increased desire to sleep. Thus, the improvement in sleep quality within each condition was too similar between conditions to result in differences between conditions. Sleep is a period of rest during which the body recuperates from daily physical exertion[212]. It makes sense that additional physical activity should facilitate better sleep, particularly in those who subjectively rate their sleep as non-restorative and often wake not feeling rested[213,214]. In an exercise study completed in 2011, Myllymaki et al.[215] also found no differences in subjectively rated sleep quality after moderate- and vigorous-intensity early-evening physical activity. However, the moderate-intensity physical activity was performed at 60% of maximal oxygen uptake for 30 minutes and the high-intensity physical activity was performed at 75% maximal oxygen consumption for 30 minutes. These conditions have lower intensities than the similarly named conditions in the current study. Other studies failing to find significant differences between high-intensity training and sleep outcomes required exercise until volitional fatigue or less intense continuous bouts[30,177,216]. Thus, the alternate hypothesis that high-intensity interval training would result in superior sleep outcomes compared to a no-exercise control was based on increasing the intensity of physical activity to near maximal and including intervals of light activity for the accumulation of more high-intensity exercise. Unfortunately, this effect did not occur in the present study.

The alternate hypothesis of aim 2 was that two consecutive nights of high-intensity interval training or two consecutive nights of continuous moderate-intensity training would result in a greater change in peripheral distal body temperature predicting

improved sleep-onset latency compared to a no-exercise control. There was insufficient evidence to reject null hypothesis that distal skin temperature rate-of-change would predict improved sleep-onset latency. The percent increase in peripheral skin temperature after the HIT and MIC conditions was similar to the percent increase after the NEC condition. The high-intensity exercise resulted in nearly a 20% increase in wrist skin temperature. The moderate-intensity and no-exercise control resulted in nearly a 18% increase in peripheral skin temperature. The percent increase in peripheral skin temperature was greater than that found in previous studies. In 2008, Sarabia et al.[217] showed an increase in peripheral skin temperature of approximately 10% preceding sleep onset. In 2014, Rubio-Sastre et al.[218] examined wrist skin temperature in adult women after 45 minutes of morning or evening running and found an approximate 10% increase in temperature prior to sleep. The evening after morning running elicited the greatest increase in wrist skin temperature (12%) in addition to more exaggerated temperature change.

One factor that possibly influenced the results for aim 2 was habitual diet. Participants were instructed to continue with their regular daily habits outside of the study visits. However, food and energy intake was not recorded or controlled for in this study. Driver et al.[219] found evening meals with greater energy content increased body temperature, but had no effect on sleep outcomes. Food intake and the timing of the evening meal may have influenced body temperature differently each night. However, this is speculation since dietary intake was not measured in the study.

It also is speculated that failing to reject the null hypothesis for aim 2 may have been due to women being in different phases of their menstrual cycle while performing each exercise condition. Menstrual cycle phase is typically not measured unless examining the relationship between physical activity and state anxiety[220]. The random assignment of training condition order possibly controlled for any effects that menstrual cycle phase may have had on the relationship between physical activity and temperature shift. Parry et al.[221] reported that women experiencing moderate-to-severe premenstrual symptoms experienced no differences in temperature reduction or timing in relation to sleep throughout their menstrual cycle compared to age-matched controls. However, the phase of a woman's menstrual cycle also has resulted in alterations in body temperature regulation[222] and blood flow[223] and therefore could affect the physical activity-temperature shift relationship. Menstrual cycle phase may have influenced the relationship between physical activity and peripheral temperature shift as skin blood flow is affected by menstrual cycle phase during physical activity. Hayashi et al.[224] found the menstrual luteal phase to be associated with higher mean body temperature threshold for cutaneous vasodilatory response than the follicular phase of the menstrual cycle during 1-hour of moderate-intensity exercise. However, there was no difference in the peak value of body temperature threshold in the current study. Since menstrual cycle was not measured in this study, it is impossible to determine possible effects of menstrual cycle variation on the study outcomes.

A final factor that possibly many have influenced failing to reject the null hypothesis for aim 2 was ambient room or seasonal temperature variations. The current study required all participants to complete the study physical activity conditions in a

temperature-controlled environment. However, the time lapse between the enrollment of the first participant and the completion of the final participant was 17 months that resulted in wide variations in ambient temperatures. In 2007, Buguet[225] summarized how excessively hot external temperatures result in sleep disturbances and reduces sleep quality indicating this is commonly found in laboratory-based studies. They also indicated that sleep improved during extended exposure to a hot external environment followed by sleep in a controlled, cooler environment. These researchers demonstrated that performing physical activity adds to the heat load on the body resulting in differing effects between training and sleep at during different seasons[226].

The alternate hypothesis of aim 3 was that the high-intensity interval training condition would be the preferred mode of physical activity to improve sleep outcomes compared to the continuous moderate-intensity condition. The null hypothesis was that no differences would exist between the two training conditions. The study results failed to reject the null hypothesis as no differences were observed between the Physical Activity Enjoyment Scale scores after each condition and the sample median score for the Preference for Exercise Intensity survey, indicating no preference for either lower intensity or higher intensity of exercise.

One possible factor that may have resulted in failing to reject the null hypothesis for aim 3 was the inclusion criteria requiring participants to be sedentary. This may have resulted in a sample of participants not having ample time to acclimate to the intensity. These results are in contrast to results of other studies. In 2015, Hartescu et al. [227] found that moderate-to-vigorous physical activity improved insomnia symptoms, anxiety, and

depression in a sample of sedentary insomniacs after 6 months. It is possible that the brief experience with high-intensity interval training in the current study did not allow participants to become acclimated to the physical activity intensity.

Limitations

This study has several limitations that should be noted. First, the decisions to fail to reject the null hypotheses for the study aims were based on overlapping standard errors of the dependent variables, thus indicating more variability and lack of differences in these dependent variables. The lack of differences between the values may have been due to the study's small sample size, resulting in low power[228] and risk of type II error. Power calculations indicated 19 participants would be needed for vigorous physical activity to have an effect of Cohen's $d = 0.40$ on sleep-onset latency. Only eleven women, comprising 58% of the desired sample, completed the study. A post-hoc analysis to compute the achieved power indicated $1-\beta=0.69$. Therefore, a larger sample size was needed to reduce probability type II error[229].

Another factor that may have influenced results was the algorithms used to calculate actigraphy-measured dependent variables. The algorithms were based on other valid and reliable data reduction methods developed by other researchers[204,205,230]. However, they have not been validated on the current sample of participants and, accordingly, may have been too sensitive in detecting actigraphy-measured sleep parameters. Further, while the GENEActive temperature sensor may be useful in accurately capturing actigraphic movement[231], it has not been used previously to measure skin temperature in relation to sleep-onset latency.

Last, a limitation that may have influenced results was insufficient volume of physical activity to elicit the energy expenditure desired to improve sleep. Physical activity-focused guidelines recommend that adults accrue 150 minutes per week of moderate-intensity physical activity or 75 minutes of vigorous-intensity physical activity[37] or expend 8 kilocalories per kilogram body weight per week[232]. In the current study, the moderate-intensity and vigorous-intensity conditions were prescribed a total of 60 minutes and 20 minutes, respectively. Kline et al.[156] demonstrated that expending more energy throughout the week improves sleep in sedentary women. Passos et al.[30] also found improvements in sleep outcomes after 50 minutes of moderate-intensity physical activity. In the current study, the high-intensity interval condition consisted of 10 x 1-minute bouts of high-intensity walking with 1-min bouts of active recovery. Due to the brief minute of activity followed by the active recovering, the participant did not reach the target heart rate of 90% of maximum heart rate until over halfway through the training session. This shorter exercise time resulted in reduced volume spent at the target heart rate. This study used interval training to increase high-intensity exercise time. However, sleep improvements may depend on greater daily energy expenditure than expended in the current study. Studies utilizing high-intensity interval training to improve other health outcomes have found a session of four rounds of 4-minute exercise bouts followed by 4-minute active recovery bouts to be beneficial. This would result in increased volume and more total time spent walking at higher intensities.

Conclusion

This study examined the relationship between physical activity intensity, objectively measured and subjectively measured sleep outcomes. In addition, the body

temperature rate-of-change was examined as a predictor of sleep-onset latency, as was the participant's preference of physical activity intensity. Following high-intensity physical activity, objectively measured total sleep time was significantly better following the fourth night of the condition, but sleep onset latency, sleep maintenance, and sleep efficiency were unaltered. Also, following moderate-intensity physical activity, objectively measured sleep-onset latency, sleep maintenance, and sleep efficiency were unaltered. No significant differences were found between moderate- or high-intensity physical activity and subjective sleep outcomes as compared to a no-exercise control. Temperature rate-of-change also was not significantly associated with sleep-onset latency. There was no significant difference in physical activity enjoyment between the three experimental conditions. However, the single rating of physical activity intensity preference indicated most participants preferred moderate-intensity physical activity as compared with high-intensity physical activity.

The recommended dose and mode of physical activity to optimize sleep outcomes remains to be determined. Future studies should examine physical activity conditions that may affect sleep. These include investigating different intensities of physical activity associated with improved sleep, comparing physical activity levels performed at different times of day, such as comparing morning and early evening activity, and comparing the effects of different modes of physical activity, such as resistance training, on sleep.

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APPENDIX A

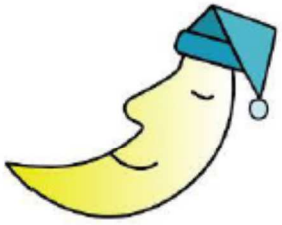
RECRUITMENT FORMS

How is Your Sleep?

Are you currently inactive?

Do you have difficulty falling asleep or staying asleep?

Are you satisfied with your sleep overall?



You may be eligible for a research study

Men and women 35-60 years of age are being recruited to examine evening physical activity or rest on sleep.
No drugs or supplements will be used and there's no cost to you for participating!

You will be compensated $100 for this 7-visit study

Online Pre-screening at
http://bit.ly/ASUsleep

Principle Investigator:
Jonathan Kurka, PhD Candidate
ASU School of Nutrition & Health Promotion
jkurka@asu.edu

ASU School of Nutrition & Health Promotion
ARIZONA STATE UNIVERSITY

How is Your Sleep?

Can I be in this study?

- Physically inactive
- Do you have some difficulty sleeping
- Age 35-60

What are the details?

- 7 total visits to the conveniently located ASU Phoenix Campus
- Complete a short exercise test
- Wear a small activity monitor on the wrist the study - 5 weeks

How will I be compensated for my time?

You will be compensated for 3 visits and upon returning the activity monitor **– Total = $200**

To see if you qualify please visit:

Just click or type in this link: **http://bit.ly/ASUsleep**

For additional information please contact:

Jonathan Kurka
ASU School of Nutrition & Health Promotion
Ph: 602-496-1608, Email: jkurka@asu.edu

ASU School of Nutrition & Health Promotion
ARIZONA STATE UNIVERSITY

How is Your Sleep?

Can I be in this study?

- Physically inactive
- Do you have some difficulty sleeping
- Age 35-60

What are the details?

- 7 free exercise training sessions
- Short exercise test at the convenient ASU Phoenix Campus
- Wear a small activity monitor on the wrist for 5 weeks

How will I be compensated for my time?

You will be compensated for 3 visits and upon returning the activity monitor

Total = $100 cash AND Fitbit activity/sleep monitor

To see if you qualify please visit:

Just click or type in this link: **http://bit.ly/ASUsleep**

For additional information please contact:

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How is Your Sleep?

Can I be in this study?

- Not regularly active
- Do you have some difficulty sleeping
- Age 35-60

What are the details?

- 7 free exercise training sessions
- Short exercise test at the convenient ASU Phoenix Campus
- Wear a small activity monitor on the wrist for 5 weeks

How will I be compensated for my time?

You will be compensated for 3 visits and upon returning the activity monitor

Total = $100 cash AND Fitbit activity/sleep monitor

To see if you qualify please visit:

Just click or type in this link: http://bit.ly/ASUsleep

For additional information please contact:

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APPENDIX B

CONSENT FORM

CONSENT TO PARTICIPATE IN RESEARCH

Introduction

The purpose of this form is to provide you (as a prospective research study participant) information that may affect your decision to participate in this research project and to record your consent to be involved in the study. The researchers will explain this study to you. Your participation is voluntary

Researchers

Jonathan Kurka (Doctoral Candidate) and Dr. Barbara Ainsworth, Professor (Mentor) have invited your participation in a research study at the ASU School of Nutrition and Health Promotion's Healthy Lifestyles Research Center.

Why is this study being done?

Some scientists believe that exercise is helpful for sleep; others believe that it has little effect on sleep; and others think that it can impair sleep; particularly if it is performed a few hours before bedtime. Likewise, some scientists think that quiet activity close to bedtime is helpful for sleep, whereas others think that it has little effect on sleep; and others think that it is harmful for sleep.

The purpose of this study is to examine the effects of different exercise sessions and quiet rest on sleep and body temperature. We will ask which of the exercise or quiet rest conditions you prefer.

How long will this research last?

Participation in this research study will last at least approximately *6 weeks*. You will be asked to report to the Research Center on *one occasion* for to determine your eligibility, *six separate occasions* for treatment, and *one final occasion* to complete the study.

How many people will be studied?

We expect about *20* people to participate in this research study.

What happens if I say yes, I want to be in this research?

If you decide to participate, you will join a study that will require you to report to the Healthy Lifestyles Research Center (Research Center) in the 1st floor of the Arizona Biomedical Collaborative building on *eight total occasions* approximately 3-4 hours prior to your usual bedtime over a period of *five weeks*. You will be asked to wear a watch-like device on your non-dominant wrist throughout the four week study.

Exercise Test (duration of visit: 1 hour)

On the first visit (today) you will undergo:
Demographic information survey
Survey to identify your depression status
Survey to identify your sleep quality
Height and weight measurement
Maximal exertion graded exercise test
GENEActiv Sleep (watch-like device) fitting and initialization

Visit Details
The maximal exertion graded exercise test under the supervision of an Exercise Physiologist. This exercise test requires that you wear a blood pressure cuff and EKG monitors to monitor you before, during, and after exercise. The goal of this test is to walk on a treadmill at the highest heart rate you can achieve. We will record the speed and grade of the treadmill at which you achieved this heart rate. There will be a 5-minute warm up period and 5-min cool down period.
At the conclusion of the session you will *schedule the next six visits*.

Treatments- Visits 2-7 (duration of visits: 45 minutes each)

You will be asked to schedule 6 more visits to this lab for a treatment that will improve, impair, or have no effect on your sleep. Each visit needs to take place 3-4 hours before your normal bed time.

On these visits, we will undergo:
Surveys to identify regular physical activity and depression status
Exercise or Quiet session

Visit Details
It is recommended that you not eat or drink anything other than water for the 2 hours leading up to any of the exercise sessions to avoid illness due to exercise.
The exercise sessions require you to wear a heart rate monitor. The goal of these exercise sessions if for you to walk on a treadmill at either 90-95% of your maximum heart rate for 1-minute intervals separated by 1-minute light walking intervals for a total of 20 minutes or to exercise at 65-70% of your maximum heart rate for a period of 30 continuous minutes. All exercise sessions will be preceded by a 5-minute warm up and a 5-minute cool down.
The quiet sessions require you to sit with the option of reading, or completing cross-words or puzzles.
At the conclusion of the final treatment you will *schedule the final visit.*

The morning after each exercise or quiet session, you will be asked to complete a survey to determine your enjoyment of the exercise or quiet rest session that took place the night before.

Exit Meeting (duration of visit: 15 minutes)

On the final visit, you will undergo:
Return the GENEAsleep device
Complete a survey to identify your sleep quality
Complete a survey to assess your preference of the exercise or quiet rest session

Visit Details:
You will complete the surveys and return the device. You will receive the monetary incentive on this visit if you have completed all previous visits.

What happens if I say yes, but change my mind later?

You can leave the research at any time and it will not be held against you. If you decide to leave the research, contact the lead investigator so the investigator can remove you from the study schedule. Your relationship with Arizona State University will not be affected now or later.

What are the possible risks or discomforts if I participate?

If you decide to participate in this study, then you may face physical risk of injury or illness associated with all exercise sessions. These risks are the same as those encountered with any vigorous training session. It is possible there may be side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

Maximal Exertion Treadmill Test
There are risks of walking briskly such as a pulled or torn muscle or tendonitis (pain in the tendon). However, these symptoms subside after adequate rest. It is very unlikely that this will occur, but if it does, you will be attended to and provided first-aid treatment and referral of treatment if necessary. High intensity walking can cause high or low blood pressure, fainting, irregular heart rhythm, chest pain, heavy fatigue, cramping, and very rarely, heart attack, stroke, cardiac arrest, or death. You will be monitored for heart rhythm abnormalities with a 12-lead electrocardiogram (ECG) during the maximal exercise test to ensure that no complications due to exercise are present. An Advanced Cardiac Life Support Certified physiologist will monitor your ECG during the test to ensure safety.

These risks are no greater than when you perform high intensity exercise on your own.

Exercise Sessions

With any exercise, there is a risk of muscle strain and tendonitis (pain in the tendon).
However, these symptoms subside after adequate rest. There is a risk of high or low blood pressure, fainting, irregular heart rhythm, chest pain, and very rarely, heart attack, stroke, cardiac arrest, or death. You will be monitored during your exercise session for any unusual symptoms such as excessive shortness of breath, dizziness, and chest discomfort.

These risks are no greater than when you perform high intensity exercise on your own.

GENEAsleep Sleep Monitor

There is a slight risk of developing skin irritation due to wearing the device on your wrist. This risk is no greater than when you wear a common wrist watch.

Survey Questions

Some survey questions ask you to divulge personal information such as race/ethnicity, income, education level, and feelings regarding depression. While this information is important to the study, you do not have to answer any questions you do not feel comfortable answering and will not be excluded for refusing to respond. Exclusion from the study will be based solely on your compliance with the study procedures described above.

What are the possible benefits if I participate?

There is no direct benefit from participating in the study.

What happens to the information collected for the research?

All information obtained in this study is strictly confidential unless disclosure is required by law. The results of this research study may be used in reports, presentations, and publications, but the researchers will not identify you. Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. You will be provided a unique identification number that will link all of your demographic information to your exercise and sleep results. A list linking your identifiable information and your ID number will be kept separate from the research data. Your personal contact information will be kept in a locked file cabinet and will not be shared with those outside the research project without your permission. If the researchers find new information during the study that would reasonably change your decision about participating, then they will provide this information to you. In the future, data collected for this study may be shared with other researchers for other studies that are unknown at this time. Any data shared with other researchers will not include your name or other personal identifying information.

What choices do I have if I do not want to participate?

It is ok for you to say no. Even if you say yes now, your participation is voluntary and you are free to withdraw from the study at any time.

Will I be paid for my participation?

You will be compensated up to $100 and a Fitbit for your participation. You will receive compensation in the following order:
$10 after completing the 1st office visit
$15 after completing the 2nd office visit
$25 after completing the 5th office visit
$50 and a Fitbit activity/sleep monitor on the final visit when you return the device

What happens if I believe I am injured because I took part in this study?

If you agree to participate in the study, then your consent does not waive any of your legal rights. It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed above. However, no funds have been set aside to compensate you in the event of injury.

Who can I talk to?

Any questions you have concerning the research study or your participation in the study, before or after your consent, will be answered by the study staff, Jonathan Kurka at 309-657-3538 or Dr. Barbara Ainsworth at 480-208-5877.

If you have questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Research Compliance Office, at 480-965-6788.

How do I indicate my agreement to participate?

This form explains the nature, demands, benefits and any risk of the project. By signing this form you agree knowingly to assume any risks involved. Remember, your participation is voluntary. You may choose not to participate or to withdraw your consent and discontinue participation at any time without penalty or loss of benefit. In signing this consent form, you are not waiving any legal claims, rights, or remedies. A copy of this consent form will be given (offered) to you.

Your signature documents your permission to take part in this research study.

_____ _____

Signature of participant Date

_____

Printed name of participant

INVESTIGATOR'S STATEMENT

"I certify that I have explained to the above individual the nature and purpose, the potential benefits and possible risks associated with participation in this research study, have answered any questions that have been raised, and have witnessed the above signature. These elements of Informed Consent conform to the Assurance given by Arizona State University to the Office for Human Research Protections to protect the rights of human subjects. I have provided (offered) the subject/participant a copy of this signed consent document."

_____ _____

Signature of Investigator Date

_____

Printed name of Investigator

APPENDIX C

MAXIMAL GRADED EXERCISE TEST RECORDING FORM

ASU School of Nutrition & Health Promotion
ARIZONA STATE UNIVERSITY

Examining Effects of Rest vs. Exercise on Sleep

MAXIMAL GRADED EXERCISE TEST (GXT)
Using Modified Balke Protocol:

BASELINE TEST

Patient ID _____ Date Form Completed __/__/__

Visit # __ Reviewed by __

I. Resting Measurements

1. **Gender**: Male / Female
2. **Age**: _____
3. **Wt**: _____lbs **Ht**: _____in **BMI**: _____ kg/m^2
4. **Blood Pressure:** **Supine** _____/_____**mmHg**
5. **Predicated HR_{max} (220 - age) =** _____
6. **Target HR =** _____ **(Transfer to next page)**

Patient ID

II. Exercise Measurements

Lead Technician: _____ **Target HR =** ____ **bpm**

Stage	Time (min)	Speed (mph) Male / Female	Grade (%)	HR (b/min)	RPE	Other Notes
Warm up	0:00-0:59	2.5 / 2.5	0%			
Warm Up	1:00-1:59	2.5 / 2.5	0%			
1	2:00-2:59	3.3 / 3.0	0%			
2	3:00-3:59	3.3 / 3.0	2%			
3	4:00-4:59	3.3 / 3.0	3%			
4	5:00-5:59	3.3 / 3.0	4%			
5	6:00-6:59	3.3 / 3.0	5%			
6	7:00-7:59	3.3 / 3.0	6%			
7	8:00-8:59	3.3 / 3.0	7%			
8	9:00-9:59	3.3 / 3.0	8%			
9	10:00-10:59	3.3 / 3.0	9%			
10	11:00-11:59	3.3 / 3.0	10%			
11	12:00-12:59	3.3 / 3.0	11%			
12	13:00-13:59	3.3 / 3.0	12%			
13	14:00-14:59	3.3 / 3.0	13%			
14	15:00-15:59	3.3 / 3.0	14%			
15	16:00-16:59	3.3 / 3.0	15%			
16	17:00-17:59	3.3 / 3.0	16%			
17	18:00-18:59	3.3 / 3.0	17%			
18	19:00-19:59	3.3 / 3.0	18%			
19	20:00-20:59	3.3 / 3.0	19%			

Patient ID

III. Post Exercise Measurements

	Speed (mph)	HR (bpm)	BP (mmHg)	Additional Comments (if appropriate)
Immediate	2.0		/	
1 minutes	2.0		/	
2 minutes	2.0		/	
3 minutes	2.0		/	
4 minutes	2.0		/	
5 minutes	Seated		/	

IV. Test Summary

1. Reason(s) for termination:
   - ☐ Participant requested to stop (% of HR_{max} achieved:_____)
   - ☐ Other reason: _____
2. HR_{Max} achieved: _____ Max RPE achieved: _____ Total exercise time: _____
3. Estimated VO_{2max}: ({0.694 * [(0.1 * speed) + (1.8 * speed * grade) + 3.5]} + 3.33) =

APPENDIX D

SLEEP LOG

Participant ID:_____

GENEActiv LOG

PLEASE RECORD ANY TIMES DURING WHICH YOU WERE NOT WEARING YOUR GENEActiv FOR AT LEAST 20 MINUTES. PLEASE ENTER THE **EXACT** TIME AND ONE OF THE FOLLOWING CODES:

1 - BATHING/SHOWERING 2 – SWIMMING/WATER ACTIVITIES 3 – FORGOT 4 – OTHER

(indicate reason)

Date **Time**	**Day you receive monitor** Bedtime: _____	Waketime: _____ Bedtime: _____	Waketime: _____ Bedtime: _____	Waketime: _____ Bedtime: _____	Waketime: _____ Bedtime: _____	Waketime: _____ Bedtime: _____	Waketime: _____ Bedtime: _____	Waketime: _____ Bedtime: _____	Waketime: _____ **Day you return monitor**
12:00 am									
01:00 am									
02:00 am									
03:00 am									
04:00 am									
05:00 am									
06:00 am									
07:00 am									
08:00 am									
09:00 am									
10:00 am									
11:00 am									
12:00 pm									
01:00 pm									
02:00 pm									
03:00 pm									
04:00 pm									
05:00 pm									
06:00 pm									
07:00 pm									
08:00 pm									
09:00 pm									
10:00 pm									
11:00 pm									

Your next scheduled appointment is:_____.

APPENDIX E

SAS DATA PROCESSING

```
/*- Scoring Sleep -*;
%macro GAscoring (id,run);
*- Indicate device data collection parameters ;
%let hz = 40 ;              * # of sampling rate (per second, hz)
;
%let epoch = 15 ;           * # of seconds per epoch (put 60 for
1-min epochs) ;

*- input values for detecting movement or non-movement as needed
* based on teLindert and Huberty papers ;
%let still_sense = 0.5 ;    *Indicate sensitivity for detecting
non-movement - StD above this value is considered being awake ;
%let still_epochs = 20 ;    *Indicate length of time stillness is
required to be considered sleep ;
%let move_sense = 1 ;       *Indicate sensitivity for detecting
movement during sleep - StD below this value is considered sleep
;
%let move_epochs = 5 ;           *Indicate length of time
movement is found to be considered awake between sleep periods ;

     *- create bin then find max bin within each second ;
DATA SLEEP_work1 ;
     set data_fin.SLEEP_&id ;
     by id ;
     if z > 5 then z = 5 ;
     if z < -5 then z = -5 ;
     bin= floor(z/(5/128))+ 1 ;
     datetimestamp = floor(datetimestamp) ;
RUN;
PROC SUMMARY data= SLEEP_work1 ;
     by id datetimestamp ;
     var temp ;
     output out=SLEEP_work2 (drop= _type_ _freq_)
     std=temp
     idgroup (max(bin) min(bin) out(id datetimestamp sleep_h lux
temp )= )
                max(bin)=bin_max min(bin)=bin_min ;
RUN ;
     *- calculating epochs and nights ;
DATA SLEEP_epochs1 ;
     set SLEEP_work2 ;
     by id ;
     epoch + mod(_n_,&epoch) eq 1 ;
     if first.id OR (dif(datetimestamp) > 60) then night + 1 ;
retain night ;
     if abs(bin_min) > abs(bin_max) then bin = bin_min ; else
bin = bin_max ;
RUN ;
     *- summary values for temp, bin, and lux for each epoch ;
PROC SUMMARY data= SLEEP_epochs1;
```

```
      by id epoch ;
      var temp bin lux ;
      output out=SLEEP_epochs2 (drop= _type_ _freq_)
      sum(temp)=temp std(bin)=bin_std max(lux)=lux
      idgroup (min(datetimestamp) out(id datetimestamp sleep_h
lux temp bin night)= );
RUN ;
      *- determining movement vs. still ;
DATA is_sleep1 ;
      set SLEEP_epochs2 ;
      by id night ;
      if bin_std >= &still_sense then isstill = 0;
            else isstill = 1 ;
      if bin_std <= &move_sense then isasleep = 1;
            else isasleep = 0 ;
proc expand out=is_sleep2 (drop= time);
      by id night ;
      convert isstill = still_cnt / transformout= ( reverse
movsum &still_epochs reverse ) ;
      convert isasleep = sleep_cnt / transformout= ( cmovsum
&move_epochs ) ;
RUN ;
      *- determining sleep vs. wake ;
DATA is_sleep3 ;
      set is_sleep2 ;
      by id night ;
      if still_cnt >= &still_epochs then sol_time = datetimestamp
;
      if sleep_cnt >= &move_epochs then not_waso = datetimestamp
; else not_waso = . ;
            format sol_time not_waso datetime21.3 ;
RUN ;
      *- summarizing sleep ;
PROC SQL ;
      CREATE TABLE is_sleep4 as select
      id, night, temp, lux, bin_std, sleep_h,
      datetimestamp, round(min(datetimestamp),'0:01:00't) as
beddatetime format= datetime21.3, not_waso,
      min(sol_time) as sol_time format= datetime21.3,
      max(not_waso) as snooze_time format= datetime21.3,
      intck('minutes', min(datetimestamp), max(datetimestamp)) as
tib,
      intck('minutes', min(datetimestamp),min(sol_time)) as sol,
      intck('minutes', max(not_waso),max(datetimestamp)) as
snooze
      from is_sleep3 GROUP by id, night ORDER by id, night,
datetimestamp;

      CREATE TABLE is_sleep5 as select
      id, night, temp, lux, bin_std, sleep_h,
```

```
      datetimestamp, sol_time, snooze_time, beddatetime,
      sol, not_waso, snooze, tib,
      nmiss(not_waso)/4 as waso,
      count(not_waso)/4 as tst
      from is_sleep4 WHERE datetimestamp between sol_time and
snooze_time
      GROUP by id, night ORDER by id, night, datetimestamp;

      CREATE TABLE SLEEP_METRICS as select
      id, night, beddatetime,
      TIB, TST, SOL, WASO, SNOOZE, round((tst/tib*100),0.01) as
SE
      from is_sleep5
      GROUP by id, night ORDER by id, night ;
QUIT;
PROC SUMMARY data= sleep_metrics;
      by id night ;
      output out= metrics_master_&id
      (drop= _type_ _freq_)
      idgroup (out(id--se)= );
RUN;

%if 1 = &run  %then %do;
DATA METRICS_MASTER ;
      set metrics_master_&id ;
RUN ;
%end;

%if 1 ne &run %then %do;
PROC APPEND base= METRICS_MASTER data= metrics_master_&id;
RUN ;
%end;
DATA METRICS_MASTER ;
      set metrics_master;
RUN ;
%mend ;
%GAscoring (id=se02, run=1);
%GAscoring (id=se03, run=2);
%GAscoring (id=se04, run=2);
%GAscoring (id=se05, run=2);
%GAscoring (id=se06, run=2);
%GAscoring (id=se07, run=2);
%GAscoring (id=se08, run=2);
%GAscoring (id=se09, run=2);
%GAscoring (id=se10, run=2);
%GAscoring (id=se11, run=2);
%GAscoring (id=se12, run=2);

*- Creating Master Dataset - Merging Metrics with Surveydata ;
PROC SQL ;
```

```
     CREATE TABLE data_fin.GRADUATE1 (rename=(night=night1))
          as select *, day+1 as night
     from data_fin.surveydata t1
     LEFT JOIN METRICS_MASTER t2
          on (t1.id = t2.id) and (t1.beddatetime =
t2.beddatetime)
     ORDER by id, date;
QUIT ;
*/
/*- Calculating temperature changes -*;
%macro GAtemp (id,run);
     *- Indicate summarizing parameters ;
%let epoch = 60 ;          * # of seconds per epoch (put 60 for
1-min epochs) ;
%let perc_epoch = 30 ;     * # of epochs to calculate % change
over ;

     *- aggregating timestamp into seconds then summarizing
alternate variables ;
DATA ALT_work1 ;
     set data_fin.ALT_&id;
     by id ;
     datetimestamp = floor(datetimestamp) ;
proc summary ;
     by id datetimestamp ;
     output out=ALT_work2 (drop= _type_ _freq_)
     idgroup (max(temp) out(id datetimestamp sleep_h lux temp )=
);
RUN ;
     *- calculating epochs, days ;
DATA ALT_epochs1 ;
     set ALT_work2 ;
     by id ;
     epoch + mod(_n_,&epoch) eq 1 ;
     if first.id OR (dif(datetimestamp) > 60) then day + 1 ;
retain day ;
     *- summary values for temp and lux for each epoch ;
proc summary;
     by id epoch ;
     var temp lux ;
     output out=ALT_epochs2 (drop= _type_ _freq_)
     mean(temp)=temp max(lux)=lux
     idgroup (min(datetimestamp) out(id datetimestamp sleep_h
lux temp day)= );
RUN ;
     *- calculating temperature change over time ;
PROC EXPAND data= ALT_epochs2 out= ALT_tempchange (drop=time) ;
     by id day ;
     convert temp = temp_change / transformout= ( pctdif 10 ) ;
RUN ;
```

```
PROC SUMMARY data= ALT_tempchange ;
      by id day ;
      var temp ;
      output out= ALT_tempchange2 (drop= _type_ _freq_)
      max(datetimestamp)=beddatetime
      idgroup (max(temp_change) out(id--sleep_h)= ) ;
RUN;
      *- summarizing temperature ;
PROC SQL ;
      CREATE TABLE ALT_temp1 as select
      id, day, temp, lux, temp_change, sleep_h,
      datepart(beddatetime) as beddate format=date9.2,
datetimestamp as temptime
      from ALT_tempchange2 GROUP by id, day ORDER by id, day;
QUIT ;
DATA ALT_temp2 ;
      merge ALT_temp1
                  ALT_temp1 (firstobs=2 keep=beddate
rename=(beddate=lead_beddate));
RUN ;
DATA ALT_temp_&id (drop= lead_beddate);
      set ALT_temp2 ;
      if beddate = lead_beddate then beddate =
intnx('day',beddate,-1);
RUN;
%if 1 = &run  %then %do;
DATA ALT_MASTER ;
      set ALT_temp_&id ;
RUN ;
%end;
%if 1 ne &run %then %do;
PROC APPEND base= ALT_MASTER data= ALT_temp_&id ;
RUN ;
%end;

%mend ;
%GAtemp (id=se02, run=1);
%GAtemp (id=se03, run=2);
%GAtemp (id=se04, run=2);
%GAtemp (id=se05, run=2);
%GAtemp (id=se06, run=2);
%GAtemp (id=se07, run=2);
%GAtemp (id=se08, run=2);
%GAtemp (id=se09, run=2);
%GAtemp (id=se10, run=2);
%GAtemp (id=se11, run=2);
%GAtemp (id=se12, run=2);

*- Creating Master Dataset - Merging Temperature with Master ;
PROC SQL ;
```

```
      CREATE TABLE GRADUATE2 (rename=(night1=night))
           as select *
      from data_fin.GRADUATE1 t1
      LEFT JOIN ALT_MASTER t2
           on (t1.id = t2.id) and (t1.date = t2.beddate)
      ORDER by id, date;
QUIT ; RUN ;

PROC SQL;
   CREATE TABLE sleep_vs_hit AS
   SELECT  id, date, day, night, wakedatetime, beddatetime,
                sleep_h, tst as tst_ga, sol as sol_ga, waso as
waso_ga, snooze as snooze_ga, SE as se_ga, temp_change, temptime,
lux,
                psqi_global, psqi_meds, psqi_qual, psqi_se,
psqi_days, psqi_sol, psqi_dist, psqi_dur, TIB as TIB_psqi,
                cond_time, cond, cond_num, seq, mph, grade,
ave_hr,
           paes_date, paes_q1,  paes_q2,  paes_q3,  paes_q4,
paes_q5,  paes_q6,  paes_q7,  paes_q8, paes_q9, paes_q10,
                              paes_q11, paes_q12, paes_q13,
paes_q14, paes_q15, paes_q16, paes_q17, paes_q18,
           pretie_q1,  pretie_q2,  pretie_q3,  pretie_q4,
pretie_q5,  pretie_q6, pretie_q7, pretie_q8, pretie_q9,
pretie_q10,
            pretie_q11, pretie_q12, pretie_q13, pretie_q14,
pretie_q15, pretie_q16,
           csd_tot,
                pa_1, pa_2, pa_3, pa_4, pa_5, pa_6, pa_7,
             sf_score, sf_q1, sf_q2, sf_q3, sf_q4, sf_q5, sf_q6,
sf_q7, sf_q8, sf_q9, sf_q10, sf_q11, sf_q12,

                base_time,
                age, wt_lbs, ht_in, isfemale,
                ishispanic, race, marital, num_chld, educ, empl,
income,
            ap_hrmax, hr_max, mph_max, grade_max, rpe_max,
vo2max,
            hr_90, mph_90, grade_90, rpe_90, hr_65, mph_65,
grade_65, rpe_65
      FROM WORK.GRADUATE2
      ORDER BY id, date ;
QUIT; RUN ;
```

APPENDIX F

PARTICIPANT VISIT RECORDING FORM

Participant ID: _____ HIIT for Sleep
GENEActiv #: _____
Protocol Sequence : _____

HR_{max} : _____ $HR_{90\text{-}95\%}$: _____ $HR_{65\text{-}70\%}$: _____
Speed/Grade: _____ Speed/Grade : _____ Speed/Grade : _____

A

1) Speed: _____ Grade: _____
Visit Date: _____ Start Time: _____ End Time: _____ HR_{rest} _____

HR bout	Warm-up 0	1	2	3	4	5	6	7	8	9	10
4min@2.5/0% 1min@3.0/0%		/	/	/	/	/	/	/	/	/	/

*HI / LI

2) Speed: _____ Grade: _____
Visit Date: _____ Start Time: _____ End Time: _____ HR_{rest} _____

HR bout	Warm-up 0	1	2	3	4	5	6	7	8	9	10
4min@2.5/0% 1min@3.0/0%		/	/	/	/	/	/	/	/	/	/

*HI / LI

B

1) Speed: _____ Grade: _____
Visit Date: _____ Start Time: _____ End Time: _____ HR_{rest} _____

HR minute	Warm-up 0	2	4 / 6	8 / 10	12 / 14	16 / 18	20 / 22	24/ 26	28	30	Cool down
3min@2.5/0%			/	/	/	/	/	/			3min@ 2.5/0%

2) Speed: _____ Grade: _____
Visit Date: _____ Start Time: _____ End Time: _____ HR_{rest} _____

minute	Warm-up 0	2	4 / 6	8 / 10	12 / 14	16 / 18	20 / 22	24/ 26	28	30	Cool down
			/	/	/	/	/	/			3min@ 2.5/0%

C

Activity: _____

1) Visit Date: _____ Start Time: _____ End Time: _____

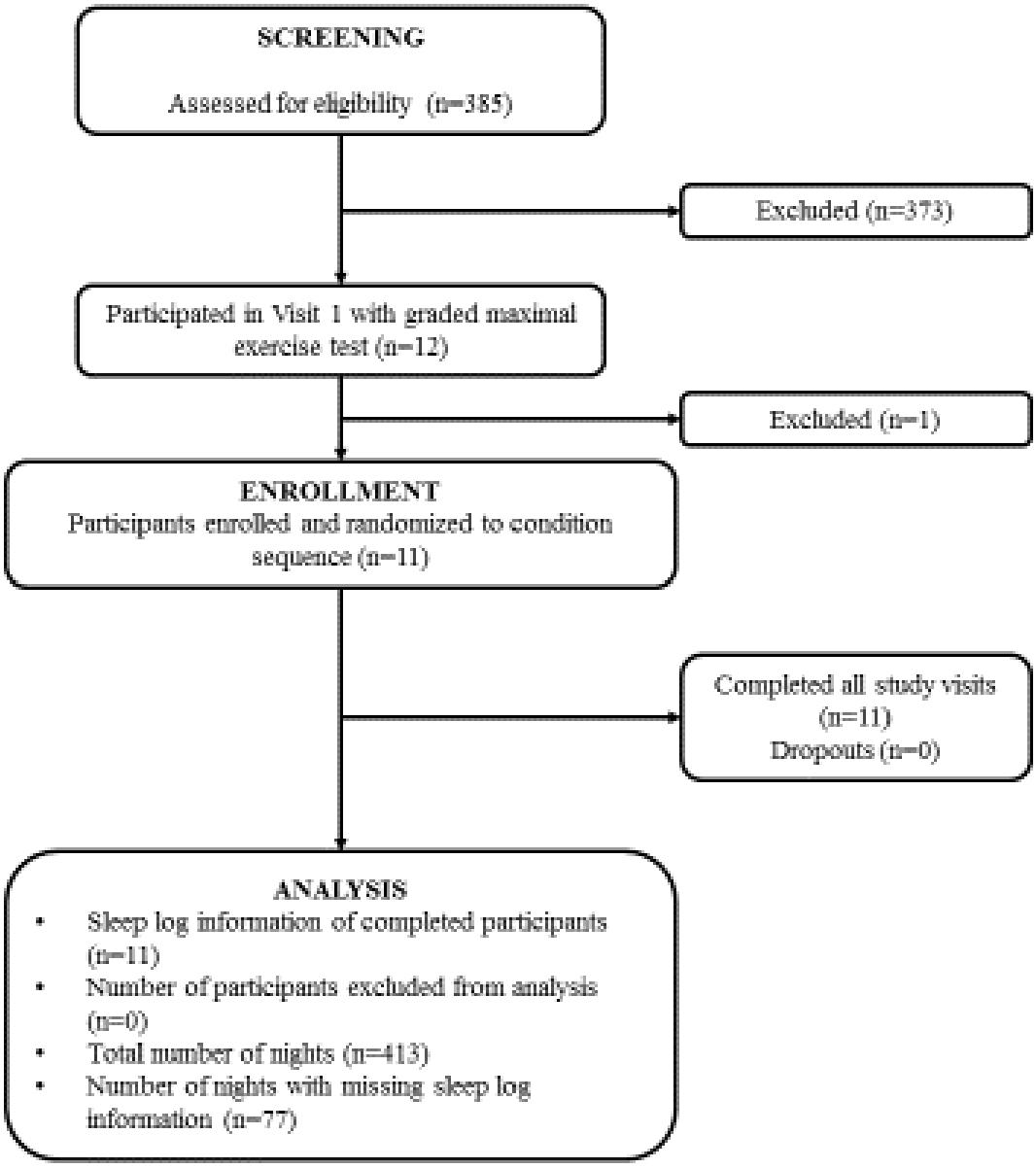
minute	0	5	10	15	20	25	30	35	40	45
HR										

2) Visit Date: _____ Start Time: _____ End Time: _____

minute	0	5	10	15	20	25	30	35	40	45
HR										

APPENDIX G

RECRUITMENT FLOW CHART AND ELIGIBILITY


SCREENING
Assessed for eligibility (n=385)
Excluded (n=373)
Participated in Visit 1 with graded maximal exercise test (n=12)
Excluded (n=1)
ENROLLMENT
Participants enrolled and randomized to condition sequence (n=11)
Completed all study visits (n=11)
Dropouts (n=0)
ANALYSIS
• Sleep log information of completed participants (n=11)
• Number of participants excluded from analysis (n=0)
• Total number of nights (n=413)
• Number of nights with missing sleep log information (n=77)

APPENDIX H

IRB APPROVAL

ASU Knowledge Enterprise Development

APPROVAL: EXPEDITED REVIEW

Barbara Ainsworth
SNHP - Exercise and Wellness
602/827-2291
Barbara.Ainsworth@asu.edu

Dear Barbara Ainsworth:

On 4/29/2014 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Effects of High-intensity Interval Exercise and Continuous Moderate Exercise versus a No-exercise Control on Sleep Outcomes in Post-menopausal Women
Investigator:	Barbara Ainsworth
IRB ID:	STUDY00000932
Category of review:	(4) Noninvasive procedures, (7)(b) Social science methods, (7)(a) Behavioral research
Funding:	Name: Graduate Education;
Grant Title:	
Grant ID:	
Documents Reviewed:	• Consent Form_revised 4.28.14.pdf, Category: Consent Form; • IRB_Sleep HIIT and MOD_final_4.4.2014.docx, Category: IRB Protocol; • PRETIEonly_Ekkaakis et al. 2007.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Demographics Survey, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Physical Activity, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • PSQI.pdf, Category: Measures (Survey

	questions/Interview questions /interview guides/focus group questions); • CESD-R-1.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • SF-12_Ware et al. 1996.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • PAESonly_Kendzierski and DeCarlo 1991.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Little et al. 2011_Low-volume high-intensity interval training reduces hyperglycemia and increases muscle mitochondria capacity in patients with type 2 diabetes.pdf, Category: Other (to reflect anything not captured above); • Rognmo et al. 2012_Cardiovascular risk of high- versus moderate-intensity aerobic exercise in coronary heart disease patients.pdf, Category: Other (to reflect anything not captured above); • Wisloff et al. 2007_Superior cardiovascular effect of aerobic interval training versus moderate continuous training in heart failure patients. RCT.pdf, Category: Other (to reflect anything not captured above); • Adams CITI Ethics Certificate 2013 (expires 2016).pdf, Category: Other (to reflect anything not captured above); • Ainsworth, Barbara CITI 2012.pdf, Category: Other (to reflect anything not captured above); • Angadi CITI 2013.pdf, Category: Other (to reflect anything not captured above); • Buman CITI 2013.09.25.pdf, Category: Other (to reflect anything not captured above); • Kurka CITI 2014.pdf, Category: Other (to reflect anything not captured above); • Youngstedt CITI 2014.pdf, Category: Other (to reflect anything not captured above); • Flyer.pdf, Category: Recruitment Materials; • Survey Screening.pdf, Category: Screening forms; • Script to determine if eligible sample is willing to participate, Category: Screening forms; • ACSM Risk Stratification - prior to Max test, Category: Screening forms; • ACSM - Signs and Symptoms, Category: Screening forms; • ACSM - Risk Factors, Category: Screening forms;

	• ACSM - Risk Stratification_2, Category: Screening forms; • GPSA Grant_submitted 12.20.2013.pdf, Category: Sponsor Attachment; • Data Collection Sheet, Category: Technical materials/diagrams;

The IRB approved the protocol from 4/29/2014 to 4/28/2015 inclusive. Three weeks before 4/28/2015 you are to submit a completed "FORM: Continuing Review (HRP-212)" and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 4/28/2015 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the "Documents" tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Jonathan Kurka
Marc Adams
Jonathan Kurka
Shawn Youngstedt
Matthew Buman
Siddhartha Angadi
Barbara Ainsworth