SLEEP IN COMMUNITY-DWELLING OLDER ADULTS: ISSUES OF MEASUREMENT

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ABSTRACT

BENJAMAS SUKSATIT: Sleep in Community-Dwelling Older Adults: Issues of Measurement (Under the direction of Virginia J. Neelon, RN, PhD)

A secondary data analysis was utilized to explore the first night effect (FNE) among community-dwelling older adults, age 70 years and older. The accuracy of actigraphy when compared with polysomnography (PSG) in measuring sleep and change in sleep in this sample was also explored.

The data were derived from 63 community-dwelling older adults from two studies: PRISM and PTRACS. Two instruments were used, including 1) polysomnograph and 2) wrist actigraph. According to standard PSG, two sleep experts scored sleep states and the inter-rater agreement was acceptable across all records. For wrist actigraph, an actiwatch-light (AW-L) was employed in two original studies. Sleep data from AW-L were retrieved using Actiware-Sleep software v.3.3. This study was conducted under approval from the Institutional Review Board of the University of North Carolina at Chapel Hill. Data entry and analysis were performed using SAS software, version 9.3. All data were double entry and compared for any errors.

FNE occurred in community-dwelling adults age 70 years and older, including more wake after sleep onset (WASO), more stage N1, more REM latency, less total sleep time (TST), less sleep efficiency (SE), and less stage N3. According to the accuracy of actigraphy against PSG, of four sensitivity settings, the high sensitivity setting of actigraphy provided fewer discrepancies. Using high sensitivity settings, actigraphy underestimated sleep onset latency (SOL) by 2 minutes, underestimated WASO by 21 minutes, and overestimated TST by 21 minutes as compared to PSG. For the accuracy of actigraphy when compared to PSG in measuring change in sleep, high sensitivity setting provided fewer discrepancies. Actigraphy with high sensitivity setting overestimated change in SOL by 21 minutes, overestimated change in WASO by 12 minutes, and underestimated change in TST by 41 minutes.

Although PSG is the gold standard in measuring sleep, it has many disadvantages. FNE is one major issue. When FNE occurs, the second night of PSG is needed in order to capture subject's habitual sleep. Although actigraphy is a cost-alternative method in measuring sleep, it appears to underestimate wake and overestimate sleep in community-dwelling older adults, age 70 years and older when compared with PSG. To my mentors, family, and friends, I couldn't have done this without you. Thank you for all of your support.

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LIST OF ABBREVIATIONS

- PSG Polysomnography
- TST Total sleep time
- SE Sleep efficiency
- SOL Sleep onset latency
- WASO Wake after sleep onset
- EEG Electroencephalographic
- EOG Electrooculogram
- EMG Electromyogram
- GDS Geriatric Depression Scale
- PSQI Pittsburgh Sleep Quality Index
- ESS Epworth Sleepiness Scale
- MMSE Mini-Mental State Examination
- IADL Instrumental activities of daily living
- BMI Body mass index
- SD Standard deviation
- ICC Intraclass correlation coefficient
- CI Confidence interval

CHAPTER 1

INTRODUCTION

Sleep plays important role for health and well being throughout our lives. It assumes around one third of the time in our lives. When disturbances in sleep occur, people might get into troubles with physical, psychological, quality of life, and safety. In older adults, sleep disturbance is one of the most common problems and it can lead to more serious consequences that impact older people health and well being.

Insomnia is a symptom, which can accompany several sleep, medical, and psychiatric disorders that result in unrefreshing sleep and functional impairment during the day. It is characterized by unrefreshing sleep plus at least one of the following disturbances in sleep pattern, including difficulty falling asleep, waking up frequently during the night with difficulty returning to sleep, and/or waking up too early in the morning. In general, the goal of treatment for insomnia is to increase the number of hours of sleep a person gets by either lessening the time it takes to fall asleep or lessening the number of awakenings during the night. Thus, it is important to use methods that are sensitive to detect sleep as well as changes in sleep in order to assess individual sleep and the effectiveness of any intervention.

Background and Significance

Insomnia is one of the most common problems reported by older adults. The incidence of insomnia among older adults ranges from 26% to 68.9% (Althuis, Fredman, Langenberg, & Magaziner, 1998; Babar, et al., 2000; Brabbins, et al., 1993; Byles, Mishra, & Harris, 2005;

Byles, Mishra, Harris, & Nair, 2003; Chiu, et al., 1999; Foley, et al., 1995; Kanda, Matsui, Ebihara, Arai, & Sasaki, 2003; Liu & Liu, 2005; Reid, et al., 2006; Schubert, et al., 2002). Even among older people who currently have no sleep problems, 5% can be expected to develop insomnia within one year (Foley, Monjan, Simonsick, Wallace, & Blazer, 1999).

Insomnia is diagnosed based on an individual's complaint of some disturbance in their sleep pattern. However, characteristics of sleep pattern disturbances vary in community-dwelling older adults. According to studies that rely on self-reported sleep measures, older adults might have trouble falling asleep, trouble with early waking, trouble maintaining sleep or any combination of problems (Althuis, Fredman, Langenberg, & Magaziner, 1998; Babar, et al., 2000; Brabbins, et al., 1993; Byles, Mishra, Harris, & Nair, 2003; Chiu, et al., 1999; Foley, et al., 1995; Kanda, Matsui, Ebihara, Arai, & Sasaki, 2003; Reid, et al., 2006). According to studies that use more objective measures of sleep, i.e. actigraphy or polysomnography, sleep pattern disturbances in older adults include decreased total sleep time (Blackwell, et al., 2006; Ohayon, Carskadon, Guileminault, & Vitiello, 2004), decreased percentage sleep efficiency (Blackwell, et al., 2006; Buysse, et al., 1991; Hoch, et al., 1997; Ohayon, et al., 2004), prolonged sleep latency (Blackwell, et al., 2006; Buysse, et al., 1991; Hoch, et al., 1997; Ohayon, et al., 2004), increased awake time (Hoch, et al., 1997), and increased rate of awakening (Klerman, Davis, Duffy, Dijk, & Kronauer, 2004). Changes in sleep architecture are also thought to occur with age and these include: 1) increased percentage stage N1 and percentage stage N2, 2) decreased percentage of stage N3, percentage of stage R, and sleep efficiency (Ohayon, et al., 2004; Redline, et al., 2004). These changes in sleep architecture are thought to promote insomnia in older adults.

Most of the research on sleep disturbances in older adults are epidemiologic and are primarily designed to estimate the prevalence, but not the incidence, of sleep disturbances. Thus,

little is known about the characteristics of changes in sleep among older adults, especially in those who are older than 70 years of age. Of the very few studies that have addressed changes in sleep, the findings tend to be inconsistent and seem to depend upon the sample and the measure used to assess changes in sleep. With this lack of fit between the sample studied and the method used to measure sleep disturbance, one might not be able to detect whether sleep disturbance is present. More importantly, it may make it even more difficult to determine if one's intervention has had any beneficial effect on the person's sleep.

Since sleep measurements play an important role in determining sleep and the effectiveness of intervention on sleep, it is important to know whether or not the method used in assessing sleep as well as changes in sleep is valid and reliable. There are two broad types of methods to assess sleep parameters: subjective measures and objective measures. Subjective sleep measures include sleep quality questionnaires, interview schedules, and sleep diaries while objective sleep measures include polysomnography and actigraphy.

Polysomnography.

Among all of the methods for measuring sleep, polysomnography (PSG) is considered to be the gold standard for evaluating sleep (Buysse, Ancoli Israel, Edinger, Lichstein, & Morin, 2006). PSG combines multiple measures to score sleep states, including electroencephalography (EEG), electrooculography (EOG), and submental electromyography (EMG). As shown in Table 1, sleep stage is scored based on the EEG activities of the brain, the presence and absence of eye movement, and the intensity of muscle activity. A number of sensors, placed along the scalp and face, are used to measure sleep. In order to detect changes in sleep state, at least four sensors are used to measure eye movements; eight sensors are used to measure activity at the midpoint

(central leads) and posterior (occipital leads) areas of the brain; and three additional sensors to measure the muscle activity of the jaw. Other types of physiological activity are also measured. For example, two sensors are often placed on each leg in order to detect leg movements. Continuous cardiac activity is often measured with either a three- or five-lead electrocardiogram (EKG or ECG). Respiratory activity is assessed using a number of different devices including chest and abdominal bands to detect respiratory movements, pulse oximetry to detect oxygen desaturations, capnography to measure end-tidal carbon dioxide, and an oral-nasal airflow sensor to detect the presence or absence of breathing.

Stage of Sleep.

Based on EEG, EMG, and EOG, there are two states of sleep, including non rapid eye movement (NREM) sleep and rapid eye movement (REM) sleep. In 1968, the first standard manual for staging sleep was published by Rechtschaffen and Kales (A. Rechtschaffen, Kales, A., 1968). Sleep stages will be scored for every 30-second epoch. Characteristics of NREM and REM were identified: Stage 1 NREM (transitional sleep), Stage 2 NREM (light sleep), Stage 3 and 4 NREM (slow wave sleep) and Stage REM (paradoxical sleep). Recently, the American Academy of Sleep Medicine (AASM) published the new standard manual for scoring and staging sleep (AASM, 2007). In this most recent version, Stages 3 and 4 are combined into a single stage and then renamed Stage N3 (slow wave sleep). In addition, Stages 1 and 2 are also renamed Stage N1 and Stage N2.

Wakefulness or Stage W is the stage when the individual is awake, regardless of physical activity or inactivity. When one is physically active, movement artifacts and eye blinks are present. Movement artifacts are absent among relaxed individuals. Eye movements and eye

blinks are often seen when subjects have their eyes open. If the subject's eyes are closed, alpha waves (fast EEG waves with a frequency of 8-13 Hz) are present in the anterior EEG leads. Compared to Stage N1, the frequency of EEG during Stage W is much faster.

Stage N1 (formerly Stage 1) occurs when theta waves are seen in the anterior leads of the EEG. Theta waves are relatively low voltage, mixed frequency waves with a frequency between 4-7 Hz. To be scored as Stage N1, theta waves must be counted for at least 50% of the epoch. Vertex sharp waves, with a high voltage and a frequency of less than 0.5 seconds, can also be occasionally seen among the central EEG channels. Slow rolling eye movements (SEM) also define Stage N1. The EMG is slightly decreased as compared to Stage W. In general, stage N1 is a transition stage, where the person moves back and forth between wakefulness and sleep. In this stage, subjects are not completely isolated from their environment and they are still able to hear noises in their room. Thus, subjects might perceive that they are still awake. As a result, subjects with more frequent shifting to or from Stage N1 during the night tend to perceive that they did not fall asleep or slept very little during the night.

While the theta waves are still present, Stage N2 (formerly Stage 2) is characterized by the occurrence of sleep spindles and K-complexes. Sleep spindles are high frequency waves (11-16 Hz); there is no amplitude requirement but the duration should be at least 0.5 seconds. K-complexes consist of a sharp negative wave followed by a slower positive component; again, there is no amplitude requirement but the duration should be at least 0.5 seconds. As with Stage N1, the EMG is also slightly decreased. Compared to Stage N1, Stage N2 is characterized by even greater disengagement with the environment, so it takes stronger stimuli to awaken from Stage N2. Either SEM or no eye movements can be seen in this stage.

Stage N3 (formerly called Stage 3 and Stage 4 NREM) is characterized at least 20% of each epoch containing EEG slow waves (formerly called delta waves). Slow waves have a low frequency (0.5-2 Hz) and high amplitude (at least 75 μ V). As with Stage N1 and N2, the EMG is also slightly decreased. Eye movements are not normally seen in this stage. Compared to the other stages of NREM sleep, Stage N3 is also characterized by very little body movement and almost completes disengagement from the environment.

Stage R (REM sleep) is often referred to as "paradoxical sleep" because the EEG has a similar amplitude (less than 75 μ V) and frequency (8-13 Hz) as wakefulness with eye movements. The eye movements are of a faster frequency and often occur in bursts. For a 30-second epoch to be scored as Stage R, there must be at least three of the following: rapid eye movements, saw tooth waves (trains of sharply contoured or triangular waves of 2-6 Hz), and the loss of voluntary muscle activities.

Table 1

Characteristics	Wakefulness	Stage N1	Stage N2	Stage N3	REM	
EEG	- Alpha waves: low voltage, high frequency (8-13 Hz)	- Theta waves: low voltage, mixed frequency waves (4-7 Hz)	 Theta waves Sleep spindles and K-complexes 	 Slow waves (delta waves): high voltage (>75 μV), low frequency (0.5- 	- Alpha waves: low voltage, high frequency (8-13 Hz)	
		- Vertex sharp waves		2 Hz)	- Saw tooth wave (2-6 Hz)	
EMG	- Normal or high amplitude activity	- Reduced tonic activity	- Reduced tonic activity	- Reduced tonic activity	- Absence of activity or very low amplitude	
EOG	- Eyes blink, reading eye movement, or irregular conjugate rapid eye movements	- Slow eye movements (SEM)	- Slow eye movements can be occasionally seen or no eye movements	- No eye movements	- Rapid eye movements	

Electrographic Characteristic of the Major Sleep-Wakefulness States by PSG (Iber, Ancoli Israel, Chesson, & Quan, 2007)

Characteristics of sleep.

In normal healthy young adults, sleep, as measured by PSG, begins with stage N1 and progresses to stage N2 and N3. Stage N1 comprises less than 10% of the total sleep time. Frequent awakenings and EEG arousals increase the time that an individual spends in Stage N1. Approximately 50% of the total sleep time is categorized as Stage N2. Stage N2 continues until the transition to Stage N3, REM sleep, or Wake. Only after an EEG arousal or an awakening, Stage N2 will transition to Stage N1. Although approximately 25% of the total sleep time of a healthy adult is stage N3, the percentage of stage N3 tends to decrease with advancing age (Bliwise, 2000). Stage R or REM sleep does not occur until 80-110 minutes and is usually preceded by a second period of Stage N1 & N2. This pattern of sleep repeats itself with stage N3 and REM sleep alternating in a cyclical fashion throughout the night, with an average period of 90 minutes. The duration of stage N3 and REM sleep changes over the night; Stage N3 predominates in the first third of the night and stage REM sleep predominates in the last third of the night. The typical pattern of sleep is shown in Figure 1.

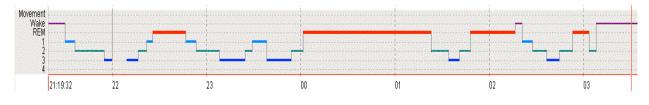
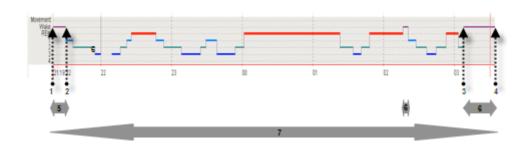


Figure 1. Sleep architecture.

The PSG recording is divided into three key time-based events (Figure 2). The first event, the time of lights out, indicates the time where the lights in the room are turned off and the subject intends to fall asleep. It can also be called "bedtime". The second event, time of sleep onset, marks the onset of sleep and is identified by locating the first consecutive two-minute period of sleep. The start of this two-minute segment is used to determine the time of sleep onset. The third event, time of lights on marks the end of the recording and indicates the time when the subject is no longer trying to sleep. Measured in either seconds or minutes, time in bed (TIB) indicates the time the person spends in bed. It is calculated by determining the time from lights out to lights on.

Three variables are used to estimate the amount of time the person remains awake after lights out. Sleep onset latency (SOL) is defined as the time from lights out to sleep onset. SOL is used to evaluate the degree of difficultly one is having in falling asleep. The second variable, final wake time, precedes lights on and is defined as the time that the subject wakes up for the last time. The last variable, wake after sleep onset (WASO) represents how well the subject is able to maintain sleep throughout the whole night. It is determined by adding all the periods of wakefulness that occur after sleep onset and before final wake time.

The actual time one spent asleep is termed total sleep time (TST), which includes all periods of rapid eye movement (REM) and non-rapid eye movement (NREM) sleep. It is calculated by adding all of the 30-second epochs of sleep. Another way for calculating TST is to subtract the measured sleep latency and WASO from the TIB (TST = TIB – [SOL + WASO]). Since TIB varies across individuals, researchers often use the variable sleep efficiency (SE), to compare subjects. Expressed as a percentage, SE is determined by dividing the TST by the TIB and multiplying by 100 (SE = [TST/TIB] X 100).



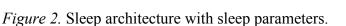
2. Sleep oset

6. Wake after sleep onset (WASO)

4. Light on

Legends

- 1. Light out
- 3. Final wake time
- 5. Sleep onset latency (SOL)
- 7. Time in bed (TIB)



Wrist actigraphy.

Wrist Actigraphy takes advantage of the fact that sleep can also be defined as a reversible behavioral state of perceptual disengagement with the person's environment (Morgenthaler, et al., 2007). Compared to wakefulness, sleep is identified by the closure of the eyes, postural recumbence, but most importantly, it is defined by a decrease or absence of purposeful body movement. In general, the movements observed during sleep are less complex than those seen in wakefulness.

Compared to PSG, actigraphy is less expensive and easier to operate. Resembling a wristwatch, a wrist actigraph monitors gross motor activity and records it in digital form. The actigraph comes with internal memory so that it can collect data continuously for a week or longer, depending on epoch length. Sensitivity levels (wake threshold) and epoch intervals can be pre-programmed by the researcher before applying the device to the subject. Data are downloaded and scored using a program that comes with the device. For the purpose of

illustration, figure 3 shows the activity counts, which are obtained by an actigraph, the Actiwatch L (AW-L).

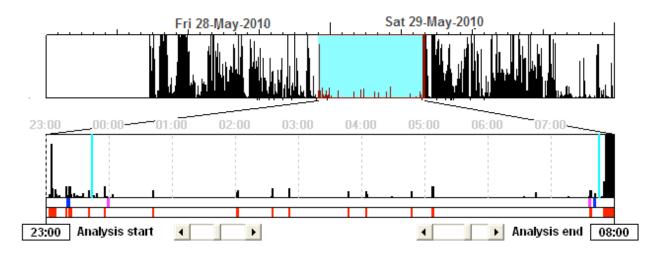


Figure 3. Total activity counts as recorded by actigraph.

For each sampling epoch the activity counts are accumulated. For a particular sampling epoch, the activity count is derived by consideration of the epochs that immediately precede the sampling epoch and the epochs that immediately follow the sampling epoch. For example, with a one-minute sampling epoch, the total activity count for a particular sampling epoch is derived from the activity count from the sampling epoch itself (n), from the two prior epochs (n-1, n-2), and from the two following epochs (n+1, n+2). The total activity count in the sampling epoch is calculated by the following formula:

Total activity counts for sampling epoch (n) =

[(0.04) x count from epoch n-2] + [(0.20) x count from epoch n-1]

+ count from sampling epoch n

+ [(0.20) x count from epoch n+1] + [(0.04) x count from epoch n+2]

There are five choices for sensitivity setting values: low (80), medium (40), high (20), automatic (computed automatically based on activity data), and custom (researcher-selectable value). To score the current epoch as either wake or sleep, the number of total activity counts in each sampling epoch is then compared against a sensitivity level/wake threshold set by the researcher. If the number of activity counts is higher than threshold, that epoch is coded as wake. The epoch is coded as sleep when the number of activity counts is less than or equal to, the threshold. The example of sleep/wake analysis data set is shown in Figure 4.

E	i Sleep w	vake di	spla	y					
F	ïle								
j	Analysis	s Star	st	23:00	Anal	ysis Eı	nd C	08:00	
	Гime	-		No.					
2	23:00	0001	to	0020	SSSWW	uuuus	SSSSS	SSSSW	
	23:20	0021	to	0040		SSSSS			
2	23:40	0041	to	0060	WSSSS	SSSSS	SSSSS	WSSSS	
0	00:00	0061	to	0080	SSSSS	SSSSS	SSSSS	SSSSS	
0	0:20	0081	to	0100		SSSSS		SSSSS	
0	0:40	0101	to	0120	SWSSS	SSSSS	SSSSS	SSSSS	
0	01:00	0121	to	0140	SSSSS	SSSSS	SSSSS	SSSSS	
0	01:20	0141	to	0160	SSSSS	SSSSS	SSSSS	SSSSS	
0	01:40	0161	to	0180	SSSSS	SSSSS	SSSSS	SSSSS	
0	02:00	0181	to	0200	SWWSS	SSSSS	SSSSS	SSSSS	
0	02:20	0201	to	0220	SSSSS	SSSSS	SSSSS	WSSSS	
0	02:40	0221	to	0240	SSSSS	SSSSS	SWSSS	SSSSS	
0	03:00	0241	to	0260	SSSSS	SSSSS	SSSSS	SSSSS	
0	3:20			0280		SSSSS			
	03:40			0300		SSWSS			
0	04:00	0301	to	0320	SSSSW	SSSSS	SSSSS	SSSSS	
	04:20			0340		SSSSS			
	04:40			0360		SSWSS			
0	05:00	0361	to	0380	SSSSS	SSWSS	SSSSS	SSSSS	
)5 : 20			0400		SSSSS			
	05:40			0420		SSSSS			
	06:00			0440		SSSSS		SSSSS	
	06:20			0460		SSSSS			
	06:40			0480		SSSSS			
	07:00			0500		SSSSS			
	07:20			0520		SSSSS		SSWSS	
0	07:40	0521	to	0540	55555	SSSSS	MMMMM	WWWWW	
									-

Figure 4. Sleep/ wake in each sampling epoch as analyzed by Actiware Sleep v. 3.3.

Similar to PSG, the actigraphy software program generates values for all the sleep parameters (Figure 5). The actigraph recording is separated into four key time-based events. The first event, the "bed time" indicates the time when subject intends to fall asleep. The second event, "sleep start" identifies sleep onset by using the immobile minutes method and is identified by the first period of 10 consecutive minutes in which only one epoch contains movement and then marks that first epoch as sleep (T. Stowell, personal communication, January 16, 2014). The third event, "sleep end" occurs before "get up time" and is defined as the time that the subject wakes up for the last time. The last event, "get up time" indicates the end of the recording and indicates the time when the subject is no longer trying to sleep.

As with PSG, time in bed (TIB) is determined by measure the time between the "bed time" and the "get up time". Sleep latency, comparable to SOL from PSG, is defined as the time from "bed time" to "sleep start". Actual wake time, similar to WASO from PSG, represents how well the subject is able to maintain sleep. It is determined by adding all the periods of wakefulness that occur after "sleep start" and before "sleep end". Assumed sleep, equivalent to TST from PSG, is the actual time the subject spent asleep. It is calculated by adding all epochs that are identified as sleep and then multiplying by the epoch length. An alternative method for calculating "assumed sleep" is to subtract minutes of sleep latency and actual wake time from the TIB. Sleep efficiency is determined by the same method with PSG, which is dividing the assumed sleep by the "time in bed" and multiplying this by 100.

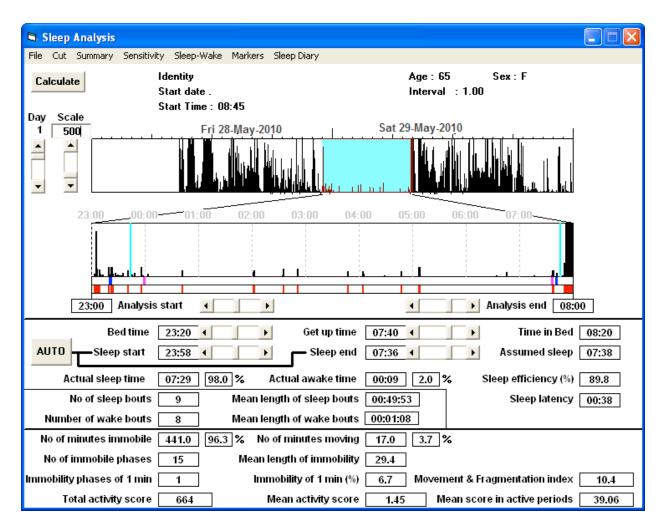


Figure 5. Sleep analysis as computed by Actiware Sleep v. 3.3.

In summary, each method uses different parameters for assessing sleep and there are some common measures that can be assessed by the two methods (i.e. bedtime, SOL, WASO, final wake time, TST, TIB, and SE). Movement, as well as stage of sleep or wake, can be gathered by both PSG and actigraphy. However, sleep stages (i.e. Stage W, Stage N1, Stage N2, Stage N3, and Stage R), arousal, and physiological variables such as ECG and SaO₂ can be collected only by PSG. Table 2 lists all individual sleep parameters that can be obtained by the two different methods in assessing sleep.

Table 2

Comparing Sleep Parameters That can be Obtained by two Different Sleep Measures

Variable	PSG	Actigraphy
Sleep Variables		
- Bed time	Х	Х
- Sleep onset latency (SOL)	Х	Х
- Wake after sleep onset (WASO)	Х	Х
- Sleep state		
• NREM vs. REM vs. Wake	Х	
• Wake vs. Sleep	Х	Х
- Arousal	Х	
- Final wake time	Х	Х
- Total sleep time (TST)	Х	Х
- Time in bed (TIB)	Х	Х
- Sleep efficiency (SE)	Х	Х
Physiological Variables		
- Electrocardiography	Х	
- Oxygen Saturation	Х	
- Respiration	Х	
- Body movements	Х	Х
Sleep quality		

Specific Aims and Research Questions

Numerous studies indicate that the incidence of sleep disturbances increases with advancing age. Although PSG has been regarded as the gold standard for objective assessment of sleep (Buysse, et al., 2006; Sateia, Doghramji, Hauri, & Morin, 2000), PSG is a very expensive method that requires many types of equipment and demands a lot of staff training. In addition, PSG itself can interfere with the subject's sleep. Many adults could not withstand the stress of undergoing a PSG study or afford the cost of the study. With greater attention on the changes in sleep among community-dwelling older adults, especially after receiving sleep intervention, actigraphy may provide an accurate estimate of the changes in sleep in older adults. As I will discuss in greater detail in Chapter 2, there are many factors that might interfere with the accuracy and reliability of this alternative method for measuring differences between individuals. Some of these factors represent lasting subject characteristics, and, as such, one may still be able to use the alternative objective method to detect change in sleep.

Thus, the primary aim of my dissertation were to determine the accuracy of an alternative objective method (i.e. actigraphy in measuring changes in sleep), along with characteristics of sleep in community-dwelling older adults, at least 70 years of age. Data from 63 community-dwelling older adults, at least 70 years of age who participated in either the Respiratory Periodicity and Cognitive Decline in Elders Study (PRISM) (PI: Barbara Carlson NR08032, IRB#01-0666, formerly, 726-01) or the Patterns of Cerebral Oxygenation during Sleep and their Relationship to Markers of Hypoxic Burden and Brain Connectivity in Community Dwelling Older Adults (PTRACS) (PI: Barbara Carlson, NC TraCS: 50K20908, IRB# 09-2129) were analyzed. Differences between actigraphy and PSG were used to evaluate the accuracy for measuring change in the following variables: sleep onset latency (SOL), wake after sleep onset (WASO), and total sleep time (TST).

The study attempts to answer the following questions:

- 1. What are the characteristics of sleep "first night effect" in community dwelling older adults, age 70 years and older?
- 2. How accurate is actigraphy when compared to PSG in measuring sleep in community-dwelling older adults, age 70 years and older?

3. How accurate is an actigraphy, as compared to PSG, in measuring changes in sleep in community-dwelling older adults, age 70 years and older?

Scope of the Study

This research is a secondary data analysis aiming to evaluate the first night effect of PSG on sleep as well as the validity of the actigraphy method in measuring sleep and its changes as compared with the gold standard PSG in community dwelling adults who are 70 years and older. Characteristics of sleep among this specific population were explored. Data from 63 community-dwelling older adults, at least 70 years of age who participated in either the Respiratory Periodicity and Cognitive Decline in Elders Study (PRISM) (PI: Barbara Carlson NR08032, IRB#01-0666, formerly, 726-01) or the Patterns of Cerebral Oxygenation during Sleep and their Relationship to Markers of Hypoxic Burden and Brain Connectivity in Community Dwelling Older Adults (PTRACS) (PI: Barbara Carlson, NC TraCS: 50K20908, IRB# 09-2129) were analyzed in this study.

CHAPTER 2

LITERATURE REVIEW

Growing Number of Older Adults

The elderly population in the U.S. is growing. In 2011, the population aged 65 and older were more than 41 million, representing 13.3% of population (Administration on Aging, 2012). Because of the marked rise in birthrate immediately following the end of World War II, known as the baby boom period, the number of older people will increase significantly in the future. This number is expected to increase to 79.7 millions in 2040 (Administration on Aging, 2012).

The Importance of Sleep and Sleep Quality in Older Adults

Sleep is increasingly recognized as a biological function necessary for optimal daytime functioning, however over 40% of older Americans often get less than 6 hours of habitual sleep at night (National Sleep Foundation, 2005). Sleep appears to affect many processes in the body including energy metabolism (Marshall & Born, 2002; Vgontzas & Chrousos, 2002), immune system function (Vgontzas & Chrousos, 2002), learning/memory (Gais & Born, 2004; Stickgold & Walker, 2005; Wagner, Gais, Haider, Verleger, & Born, 2004), appetite regulation (Spiegel, et al., 2004), and even, gene expression (Cirelli, 2005). Moreover, these same studies show that insufficient sleep as well as or poor sleep quality has been linked to neurocognitive impairments,

possibly due to decreases in both global and regional cerebral metabolism (Thomas, et al., 2000; Thomas, et al., 2003; Wu, et al., 1991).

In addition to having less sleep at night, this overall decline in sleep quality is characterized by a wide variety of sleep. Some might have trouble falling asleep, trouble with early morning waking up, trouble maintaining sleep, or any combination of problems (Althuis, et al., 1998; Babar, et al., 2000; Brabbins, et al., 1993; Byles, et al., 2003; Chiu, et al., 1999; Foley, et al., 1995; Kanda, et al., 2003; Reid, et al., 2006). According to objective measures of sleep disturbances, community-dwelling older adults examined by either actigraphy or PSG, sleep disturbances among older adults included decreased total sleep time (Blackwell, et al., 2006), decreased percentage sleep efficiency (Blackwell, et al., 2006; Buysse, et al., 1991; Hoch, et al., 1997), prolonged sleep latency (Blackwell, et al., 2006; Buysse, et al., 1991; Hoch, et al., 1997), increased awake time (Hoch, et al., 1997), and increased rate of awakening (Klerman, et al., 2004). In addition, Buysse and colleagues (1991) conducted a case-control study between 44 healthy older adults who were older than 80 years old and 35 younger adults who were less than 30 years old. They found several sleep parameters, which older adults were differ than younger adults. They found several sleep parameters, which differed between these two groups: older adults had 1) decreased time spent asleep, 2) decreased sleep efficiency, 3) decreased sleep maintenance, 4) increased Stage 1 and 2 non rapid eye movement (NREM) sleep, 5) decreased delta sleep, 6) decreased rapid eye movement (REM) sleep, and 7) increased number of electroencephalogram arousals (Buysse, et al., 1991). Thus, all these changes in sleep architecture are thought to promote sleep disturbances in older adults.

In order to examine the accuracy of wrist actigraphy to measure change in sleep, this study examined a sleep characteristic termed the "first night effect" in persons who are at least

70 years old, along with the validity of wrist actigraphy for measuring sleep and changes in sleep in this underreported group of older adults. The literature reviewed in this chapter includes papers that first describe the First Night Effect, and then papers that examine the accuracy of actigraphy in determining sleep in older adults.

First Night Effect

It has been long recognized that many adults manifest adaptation responses to the sleep laboratory setting. This is due in part, to the novelty of the laboratory sleeping environment, the presence of laboratory personnel during the sleep period, and the common laboratory practice of maintaining consistent bed-times and wake-times across studies. The most commonly reported adaptation response to the sleep laboratory setting is called the "first night effect" because the sleep on the first night is often worst than subsequent nights.

Although a decline in REM sleep during first night of laboratory based PSG sleep study was reported since 1962 (Antrobus, 1962 cited byA. Rechtschaffen & Verdone, 1964), the term "first night effect" (FNE) was first mentioned in 1964 by Rechtschaffen and Verdone (1964). However, FNE was first thoroughly described in 1966 (Agnew, Webb, & Williams, 1966).

Since FNE is a well-known phenomenon related to sleep study, there are numerous research studies identifying characteristics of FNE across various population (Table 3), including healthy adults (Agnew, et al., 1966; Le Bon, et al., 2001; Lorenzo & Barbanoj, 2002; Moser, Kloesch, Fischmeister, Bauer, & Zeitlhofer, 2010; A. Rechtschaffen & Verdone, 1964; Sharpley, Solomon, & Cowen, 1988; Tamaki, Nittono, Hayashi, & Hori, 2005; Toussaint, et al., 1997), children and adolescent with suspected sleep disordered breathing (Scholle, et al., 2003; Verhulst, Schrauwen, De Backer, & Desager, 2006), adult subjects with suspected obstructive sleep apnea (OSA) (Hutchison, Song, Wang, & Malow, 2008), adults with epilepsy (Marzec, Selwa, & Malow, 2005), adults with epilepsy and OSA (Selwa, et al., 2008), adult subjects with REM sleep disorder (Zhang, et al., 2008), adult subjects with depression (Kupfer, Frank, & Ehlers, 1989; Mendels & Hawkins, 1967; Toussaint, et al., 1995; Toussaint, Luthringer, Staner, Muzet, & Macher, 2000), adults with post traumatic stress disorder (Herbst, et al., 2010; Woodward, Bliwise, Friedman, & Gusman, 1996), adults with insomnia (Coates, et al., 1981; Edinger, Marsh, McCall, Erwin, & Lininger, 1991; Saletu, et al., 1996; Toussaint, et al., 1995), community-dwelling older adults (Aber, Block, Hellard, & Webb, 1989; Edinger, et al., 1997; Wauquier, van Sweden, Kerkhof, & Kamphuisen, 1991; Wauquier, van Sweden, Lagaay, Kemp, & Kamphuisen, 1992), and older adults with insomnia (Edinger, et al., 1997; Riedel, Winfield, & Lichstein, 2001). Except three studies identifying FNE by using home based PSG (Edinger, et al., 1997; Sharpley, et al., 1988; Wauquier, et al., 1992), FNE was the prominent phenomena. Whether it was a laboratory based PSG or a home based PSG, all previously mentioned populations (i.e. healthy individual, subjects with any disorder associated with sleep, subjects with physiological disorder, or subjects with psychological disorder) showed evidence of FNE. In those three studies using home based PSG, no FNE was found (Edinger, et al., 1997; Sharpley, et al., 1988; Wauquier, et al., 1992). The results came from looking at the sample at a whole group level not at the individual. When subjects were studies and reported as a whole group, there was a lack of information concerning individual's differences. Thus, whether each individual subject in the studies had any evidence of FNE remained unclear.

The characteristics of FNE consist of changes in both sleep quality and sleep architecture. In term of sleep quality, FNE is associated with prolonging sleep onset latency (SOL), decreasing total sleep time (TST), increasing wake after sleep onset (WASO), increasing number

of awakenings (NWAK), and decreasing sleep efficiency (SE). For sleep architecture, FNE is represented by decreased % or duration of rapid eye movement (REM) and increased REM latency. However, effects of FNE on changes in NREM sleep remain unclear since there are inconsistent results across different populations. Because the first night does not reflect usual sleep characteristics, it commonly serves as an adaptation night. In the second night, on the other hand, closely represents individual's habitual sleep.

As FNE was associated with individual ability to adapt with unfamiliar sleep environment, FNE was monitored among 12 healthy adults over 3 periods of 4 consecutive nights of laboratory based PSG, with a minimum of 1 month apart. The results were showed that subjects were able to adapt with uncommon sleep environment. Thus, FNE only occurred in the first night of the first period, call "very first night". Only REM sleep-related variables (i.e. REM sleep latency and duration of REM sleep) were statistically significantly differences.

Although there are numerous studies identified characteristics of "first night effect" (FNE) across diverse population, few studies have examined the FNE on community-dwelling older adults, 70 years or older. In relation to laboratory based PSG, 14 community-dwelling older men underwent two consecutive nights of sleep study, although respiratory variables remained consistent across two night, subjects showed evidences of FNE: shorten TST, prolong SOL, prolong % wake, prolong % Stage 1, and shorten %REM during the first night in comparison to the second night (Aber, et al., 1989). Since changes in sleep environment affect individual's sleep and play an important role on creating FNE, two studies examined FNE while using a Home based PSG in order to control the impact of unfamiliar environment. However, the results were inconsistency. One study reported that older adults showed evidence of FNE such as decreased TST, decreased SE, and increased latency to Stage 2 (Wauquier, et al., 1991) while

one year later the same group of investigators found no evidence of FNE (Wauquier, et al., 1992). In Edinger and colleagues' study, comparisons of characteristics of FNE among older adults with good sleep vs. older adults with insomnia were examined, although there were no statistically significant changes in sleep parameters between night 1 and night 2. Older adults with insomnia had greater variation on their sleep parameters than those among good sleeper older adults (Edinger, et al., 1997).

While the first night effect is so common that sleep researchers and clinician have adopted a common practice of ignoring the first night data and relying on findings from subsequent night to address their research and clinical questions. However, this practice may not be appropriate in the case of older adults. In community-dwelling older adults with insomnia, FNE according to laboratory based PSG was evaluated. Although as the whole group, FNE was presented in this sample, not every subject had FNE. Investigators then categorized subjects into 4 groups based on characteristics of their sleep for both nights, including (1) FNE, (2) Reverse FNE (subject who had better slept in the 1st night as compared to the 2nd night), (3) no change, and (4) inconsistent change. Interestingly, anxiety was found to have a positive relationship with FNE (Riedel, et al., 2001).

Table 3

Studies of FNE in Various Populations

No	Authors	Sample	Age (years)	% Older adults ≥ 70 years old	PSG	Characteristics of FNE: Sleep variables during the 1 st night in comparison to the 2 nd night
1	Rechtschaffen and Verdone (1964)	20 healthy males	20-30+	No	- 4 consecutive nights of laboratory based PSG	- \uparrow WASO and \downarrow REM
2	Agnew, Webb, and Williams (1966)	43 healthy young adults	16-31 (mean age 21.1)	No	- 4 consecutive nights of laboratory based PSG	 ↑ WASO, ↓ REM, delay in Stage 4-NREM and Stage REM, and ↑ changes in sleep stages
3	Mendels and Hawkins (1967)	21 depressed subjects and 15 control subjects	NR	NR	- 3 - 6 consecutive nights of laboratory based PSG	 Control subjects had ↑ WASO, ↑ SOL, and ↓ %Stage 3 Depressed subjects had ↓ %Stage 2
4	Coates, George, Killen, Marchini, Hamilton, and Thorensen, (1981)	12 good sleepers and 12 sleep-maintenance insomniacs	23-60	No	- 4 consecutive nights of home based PSG	 Good sleeper had ↓ SE and ↑ WASO Insomniacs had ↑ RL and ↓ REM in the first third of the initial recording night.
5	Sharpley, Solomon, and Cowen (1988)	12 healthy subjects	21-34 (mean age 26.5)	No	- 3 consecutive nights of home based PSG	- No FNE was found.

No	Authors	Sample	Age (years)	% Older adults ≥ 70 years old	PSG	Characteristics of FNE: Sleep variables during the 1 st night in comparison to the 2 nd night
6	Aber, Block, Hellard, & Webb (1989)	14 community- dwelling older men	61-83 (mean age 66.1 ± 5.7)	NR	- 2 consecutive nights of laboratory based PSG	 FNE existed: ↓TST, ↑SOL, ↑% wake, ↑% Stage 1, and ↓%REM during the 1st night. Respiratory variables were stable over two nights.
7	Kupfer, Frank, and Ehlers (1989)	8 non-delusional depressed outpatients and 8 age-matched controls	22-30 (mean age 24.4 ± 2.7)	No	- 2 consecutive nights of laboratory based PSG	- Subjects with depressives showed \uparrow SOL and \downarrow SE.
8	Edinger, Marsh, McCall, Erwin, & Lininger (1991)	20 patients with difficulties initiating and maintaining sleep (DIMS)	45-72 (mean age 62.3)	5%	- 3 consecutive nights of home based PSG	 As a group, there was no evidence of FNE. As individual, half of the sample showed evidence of FNE, including ↓ TST, ↓ SE, ↑ WASO, ↑ %Stage 1, ↑ Stage 1 Latency, ↑ Stage 2 Latency, and ↑ RL
9	Wauquier, van Sweden, Kerkhof, and Kamphuisen (1991)	10 older adults	80-93 (mean age 85.5)	100%	- 2 consecutive 24-h periods of home based PSG	 FNE occurred even when subjects slept in their habitual environment. ↓ TST, ↓ SE, and ↑ latency to Stage 2

No	Authors	Sample	Age (years)	% Older adults ≥ 70 years old	PSG	Characteristics of FNE: Sleep variables during the 1 st night in comparison to the 2 nd night
10	Wauquier, van Sweden, Lagaay, Kemp, and Kamphuisen (1992)	14 older adults	88-102	100%	- 2 consecutive 24-h periods of home based PSG	- No FNE was found.
11	Toussaint and colleagues (1995)	32 control subjects vs. 94 psychiatric inpatients (38 depressives and 56 insomniacs)	18-57	No	- 3 consecutive nights of hospital based PSG	 Control subjects had ↑ RL, ↑ WASO, ↑ TST, and ↓ SE Clinical group had ↓ %REM and ↑ RL. FNE was more pronounced in insomniacs than in depressed subjects.
12	Saletu (1996)	22 DIMS patients with generalized anxiety disorder (GAD)	25-64 (mean age 27 ± 8.2)	No	- 2 consecutive nights of laboratory based PSG	 Insomniacs with GAD showed FNE in both laboratory and home PSG. Subjects showed ↓ TST, ↓
		21 DIMS patients with GAD	$32-64$ (mean age 30 ± 6.9)	No	- 2 consecutive nights of home based PSG	SE \uparrow %Stage 2, \downarrow SWS, \downarrow REM, and \uparrow RL.
13	Woodward, Bliwise, Friedman, and Gusman (1996)	80 PTSD inpatients, 7 PTSD outpatients, 6 combat exposed without Hx of mental illness, and 8 healthy subjects	44-48	No	- 2 consecutive nights of laboratory based PSG	 PTSD subjects showed ↓ SE, ↑ SOL, ↓ %REM, and ↑ RL Subjects with Hx of combat exposed but no Hx of mental illness and healthy subjects showed ↓ SE, and ↑ SOL

No	Authors	Sample	Age (years)	% Older adults ≥ 70 years old	PSG	Characteristics of FNE: Sleep variables during the 1 st night in comparison to the 2 nd night
14	Edinger and colleagues (1997)	32 older adults with insomnia vs.32 age-matched and gender-matched non complaining older adults	67.7 ± 4.8 67.5 ± 5.7	NR	- 3 consecutive nights of laboratory based PSG and 3 consecutive nights of home based PSG	 Laboratory PSG: FNE was similar between two groups. ↓ TST, SWS, SE ↑ RL Home PSG: No FNE. However, insomniacs showed greater variation of sleep parameters than normal sleeper.
15	Toussaint and colleagues (1997)	18 healthy young adults	20-36 (mean age 25.8 ± 5.2)	No	- 3 consecutive nights of hospital based PSG	 ↓ SE, ↑ wake (duration, %), ↑ WASO and ↑ %NREM
16	Toussaint, Luthringer, Staner, Muzet, and Macher (2000)	18 drug-free, depressed inpatients	Mean age 40.8 ± 8.7	No	- 3 consecutive nights of hospital based PSG	 %NREM ↓ TST, ↓ SE, ↑ wakefulness, ↓ REM (% and duration). ↓ delta and theta waves in NREM sleep
17	Le Bon and colleagues (2001)	26 healthy young adults	15-45 (mean age 26.7 ± 9.8)	No	- 4 consecutive nights of home PSG	 ↓ SE,↑ WASO, ↑ NWAK, ↓ SWS, and ↓ REM Prolong RL required monthan one night to recover to the habituation.

No	Authors	Sample	Age (years)	% Older adults ≥ 70 years old	PSG	Characteristics of FNE: Sleep variables during the 1 st night in comparison to the 2 nd night
18	Riedel, Winfield, and Lichstein (2001)	77 older adults with primary insomnia	Mean age 7.5 ± 6.3	NR	- 2 consecutive nights of laboratory based PSG	 FNE occurred. ↓ SE, TST, stage N3, stage R ↑ WASO, REM latency, and stage N1
19	Lorenzo and Barbanoj (2002)	12 healthy young adults	19-27 (mean age 25)	No	- 12 nights (3 periods each of 4 consecutive nights of laboratory based PSG with a minimum of 1 month interval	 FNE was showed only in the first night of the first period. FNE consisted of only REM sleep related variables: % REM, RL, and mean duration of REM sleep
20	Scholle and colleagues (2003)	37 children with suspected sleep disordered breathing	2-6	No	- 2 consecutive nights of laboratory based PSG	- \uparrow WASO and \downarrow %REM
		60 children with suspected sleep disordered breathing	7-12	No	- 2 consecutive nights of laboratory based PSG	- ↓ SE, ↑ WASO, ↑ %Stage 1, ↓ %REM
		34 adolescent with suspected sleep disordered breathing	13-17	No	- 2 consecutive nights of laboratory PSG	- \downarrow SE, \uparrow WASO, \uparrow %Stage 1, \downarrow %Stage 4, and \downarrow %REM
21	Marzec, Selwa, and Malow (2005)	53 epilepsy patients	18-56 (mean age 34 ± 12)	No	- 2 consecutive nights of laboratory based PSG	-↓SWS

No	Authors	Sample	Age (years)	% Older adults ≥ 70 years old	PSG	Characteristics of FNE: Sleep variables during the 1 st night in comparison to the 2 nd night
22	Tamaki, Nittono, Hayashi, and Hori (2005)	11 healthy student volunteers	21-25 (mean age 22.7)	No	- 3 consecutive nights of laboratory based PSG	 ↑ alpha-wave activity during the sleep-onset period
23	Verhulst, Schrauwen, De Backer, and Desager (2006)	22 children with suspected sleep disordered breathing	2-6 (mean age 4.8, SD. 1.3)	No	- 2 consecutive nights of laboratory based PSG	- \downarrow REM and \uparrow RL
		32 children with suspected sleep disordered breathing	7-12 (mean age 9.5, SD. 1.7)	No	- 2 consecutive nights of laboratory PSG	- \uparrow Stage 2 and \downarrow REM
		16 adolescent with suspected sleep disordered breathing	13-17 (mean age 14.4, SD. 1.0)	No	- 2 consecutive nights of laboratory based PSG	- \uparrow Stage 2, \uparrow Stage 4, \downarrow REM, and \uparrow RL
24	Hutchison, Song, Wang, and Malow (2008)	93 patients underwent diagnosis for obstructive sleep apnea (OSA): 44 age and AHI matched hospital-based and 49 hotel-based patients	Median age for hotel based and hospital based group were 45, and 46.5, respectively	NR	- 1 st night of hospital-based PSG vs. 1 st night of hotel-based PSG	- There were no statistically significant differences of SOL, SE, RL, SWS, arousal index, and total Stage 1 between two groups.

No	Authors	Sample	Age (years)	% Older adults ≥ 70 years old	PSG	Characteristics of FNE: Sleep variables during the 1 st night in comparison to the 2 nd night
25	Selwa and colleagues (2008)	40 patients with refractory epilepsy and obstructive sleep apnea (OSA)	19-61 (mean age 40)	No	- 2 nights of laboratory based PSG	 Although subjects showed evidence of FNE on sleep (i.e. ↓TST, ↓SWS (min), ↓REM (min), and ↓%REM), respiratory variable namely AHI just slightly changed. One night of PSG was enough to detect OSA among this sample.
26	Zhang and colleagues (2008)	55 subjects with REM Sleep Behavior Disorder (RBD): 19 without continuous positive airway pressure (CPAP) or clonazepam treatment (CNZ), 28 with CPAP, and 18 with CNZ	Mean age 65.8 ± 11.2	NR	- 2 consecutive nights of video PSG	 As the whole group, subjects showed ↑ RL, ↑ %Stage 1, ↑ and arousal index Only subjects with CPAP titration on N2 showed evidence of FNE: ↑ RL, ↑ %Stage 1, and ↑ arousal index. AHI was also significantly higher in night 1 than night 2. Subjects with CNZ also had significantly higher AHI in night 1 than night 2. A single night was adequate to diagnose of RBD.

No	Authors	Sample	Age (years)	% Older adults ≥ 70 years old	PSG	Characteristics of FNE: Sleep variables during the 1 st night in comparison to
27	Herbst and coworkers (2010)	34 subjects with PTSD 26 healthy control subjects	Mean age 42.2 ± 10.5 Mean age 39.8 ± 11.3	NR	 5 nights of PSG: 2 at home and 3 at hospital laboratory, separated by 3 nights of sleep at home without wearing the sleep equipment Subjects were randomly assigned to begin the study either at home or in the hospital lab 	 the 2nd night For the whole group, there was evidence of FNE: ↓ TST It had a greater impacted on subjects with lab PSG than on subjects with home PSG. It was more noticeable in the initial nights of the study. Subjects with PTSD showed no evidence of FNE in either lab or home based PSG. Control subjects, FNE occurred only among subjects who began the study with lab PSG.
28	Moser, Kloesch, Fischmeister, Bauer, and Zeitlhofer (2010)	28 healthy subjects	21-86 years (mean age 53.3 ± 21.3)	NR	- 2 consecutive nights of laboratory based PSG	 ↑ Stage 1, ↑ RL, and ↑ Cyclic alternating pattern (CAP) Age had no associated with FNE.
29	Ma and colleagues (2011)	68 snorers	21-70 years (mean age 43.3±12.6)	NR	- 2 consecutive nights of laboratory PSG	- ↑ stage N2 (min.)

No	Authors	Sample	Age (years)	% Older adults ≥ 70 years old	PSG	Characteristics of FNE: Sleep variables during the 1 st night in comparison to the 2 nd night
30	Zheng and colleagues (2012)	285 middle-aged women	Median = 52 years	No	- 3 nights of home PSG	- ↑ SOL, WASO - ↓ TST, SE, REM
31	Hasegawa and colleagues (2013)	16 sleep bruxism patients	17-39 years	No	- 2 consecutive night of laboratory PSG	- No FNE

Note. NR = no report; NWAK = number of awakening; REM = Rapid Eyes Movements; RL = REM latency; SE = sleep efficiency; SOL = sleep onset latency; SWS = slow wave sleep; WASO = wake after sleep onset; FNE = first night effect.

Validation of Actigraphy in Determining Sleep in Comparison to PSG

There were many studies aimed to identify the validity of actigraphy as compared against the gold standard PSG (Table 4). Number of studies had been conducted in diverse population, including children (Sitnick, Goodlin-Jones, & Anders, 2008), healthy adults (Jean-Louis, Kripke, Cole, Assmus, & Langer, 2001; Paquet, Kawinska, & Carrier, 2007; Tonetti, Pasquini, Fabbri, Belluzzi, & Natale, 2008), insomniacs (Lichstein, et al., 2006; Vallieres & Morin, 2003), critically ill patients (Beecroft, et al., 2008), post-menopausal women (Jean-Louis, Kripke, Cole, et al., 2001), subjects with sleep disordered breathing (SDB) (Kushida, et al., 2001; Wang, et al., 2008), community-dwelling older women (Blackwell, et al., 2008) and older adults with insomnia (Sivertsen, et al., 2006).

Validity of actigraphy to detect sleep parameters was conducted in many studies. In insomniac subjects, Lichstein and colleagues (2006) conducted a study in 57 insomniacs, ranging in age from 21 to 87 years. PSG and actigraphy were recorded for one night. High sensitivity threshold level of actigraphy was used to analyze sleep parameters. The investigator claimed for validity of actigraphy compared to PSG since (1) there were no statistically significant mean differences of sleep onset latency (SOL), number of awakening (NWAK), wake after sleep onset (WASO), total sleep time (TST), and sleep efficiency (SE) and (2) there were statistically significant relationships of SOL (r = .3, p < .05), NWAK (r = .49, p < .01), WASO (r = .48, p <.01), TST (r = .70, p < .01), and SE (r = .43, p < .01) between actigraphy and PSG. On the other hand, the validity of actigraphy was insufficient when applying it to evaluate sleep among critically ill patients. Beecroft and colleagues (2008) conducted a study among 12 mechanically ventilated patients (Mdn = 68 years). Sleep variables as measured by 5 different level of sensitivity threshold (i.e. low, medium, high, automatic, and custom) were compared against PSG. The results were revealed that actigraphy overestimated TST and SE. However, the investigators did not provide how much actigraphy overestimated TST and SE and which sensitivity threshold level provided the least discrepancies. Although actigraphy had a positive relationship of TST at four different threshold levels of sensitivity (low, medium, high, and automatic) and a positive relationship of SE at medium and automatic levels, the magnitudes of these relationships were too small. In term of accuracy, actigraphy with high level threshold provided highest accuracy in comparison to other sensitivity levels, although, it provided accuracy of only 61% (Beecroft, et al., 2008). Thus, the validity of actigraphy in term of assessing sleep among critically ill patients was somewhat unacceptable.

Ability of actigraphy to detect wakefulness also seems to be an issue of concerns among sleep-investigators when using actigraphy as a method to evaluate sleep. In children, videosomnography and actigraphy were concurrent recorded overnight in 58 subjects, ranging in age from 28 to 73 months. In comparison to videosomnography, actigraphy overestimated SOL by 10 minutes, underestimated TST by 16 minutes, overestimated NWAK by 1 time, and overestimated WASO by 7 minutes. Sleep onset time, SOL, TST, sleep end time, NWAK, and WASO from actigraphy were statistically significant correlated with PSG. Although actigraphy yielded 97% sensitivity, it provided only 24% of specificity (Sitnick, et al., 2008). Since the results were inconsistency, the validity of actigraphy in detecting sleep and wakefulness was concerned. Another study was also conducted to examine actigraphy's ability in detecting wakefulness among 15 healthy adult subjects, ranging in aged between 20 and 60 years (Paquet, et al., 2007). Subject underwent 3 sleep conditions with different amounts of wakefulness: a nocturnal sleep episode and 2 daytime recovery sleep episodes (i.e. with placebo vs. with caffeine). The results revealed that since actigraphy provided the low specificity, it was a

significant decrease in actigraphy accuracy when wakefulness in sleep conditions increased. Additionally, actigraphy overestimated TST and SE especially when sleep conditions was related to more wakefulness. Thus, actigraphy's capacity to detect wakefulness remains questionable.

Only few studies were examined the validity of actigraphy against PSG among older people. Blackwell and coworkers (2008) assessed validity of actigraphy compared with PSG among 68 older women (mean age 81.9 ± 3.8 years). In-home 12-channel PSG and actigraphy were concurrently recorded. Three modes of actigraphy such as proportional mode (PIM), time above threshold (TAT), and zero crossings mode (ZCM) were compared with PSG. Bland-Altman plots were utilized to compare TST between three modes of actigraphy and PSG. PIM mode overestimated TST by 17.9 minutes. TAT also overestimated TST by 33 minutes. On the other hand, ZCM underestimated TST by 25.6. Hence, PIM mode was better corresponded with PSG than other modes. Moderate to high Interclass correlations (ICC) were found between PIM and PSG on TST (0.76), SE (0.61), and WASO (0.58). Additionally, the investigators addressed that when subjects had poor sleep quality, measurement errors increased. Agreement between actigraphy and PSG was identify for two time points: before and after treatment were examined in 34 older adults undergone for chronic primary insomnia (Sivertsen, et al., 2006). Objective sleep estimate and Wilcoxon signed rank test were implemented to examine the agreement between two measures. Actigraphy overestimated TST and SE and underestimated total wake time (TWT) and SOL at before and after treatment time points. In addition, ability of actigraphy to detect changes of sleep parameters after intervention was an issue of concern in this study. Compared with PSG, actigraphy could identify changes in only TWT but failed to capture changes in TST and SE. Additional measures might be needed in order to capture changes of sleep parameters after intervention programs. In contrast, actigraphy was sensitive enough as

compared with PSG to detect treatment effects on TWT, SE, and TST among 17 chronic primary insomniacs (mean age of 41.6 years) even though actigraphy underestimated SOL, TST and SE and overestimated TWT (Vallieres & Morin, 2003). Issues of whether or not actigraphy is able to detect changes in sleep parameter after intervention remains unclear.

Although, actigraphy seems to be useful to assess sleep parameter among diverse population, the validity of actigraphy in assessing sleep among community-dwelling older adults, age 70 years or older is remain unclear. In addition, the issue of type of statistics using in this comparison should be raised up. Investigators from several previously mentioned studies used ttest, ANOVA with post hoc comparison, Kruskal Wallis, Pearson correlation and/or Spearman rank correlation as statistical methods to identify the validity of actigraph against PSG. Those statistics methods might not be appropriately utilized for examining the agreement between two measures. It might be better if the investigator would use Bland-Altman plot to identify all sleep parameters of interest because Bland-Altman plot would provide information related to the bias and well as precision of the actigraph as compared with PSG. In addition, Cohen kappa can be used to examine the agreement of sleep/wake epochs between actigraphy and PSG.

Table 4

Actigraphy Validity Research

No	Author, year	Device/Company	Sample	% Older adults ≥ 70 years old	Validity
1.	Ancoli-Israel, Clopton, Klauber, Fell, and Mason (1997)	Actillume/ Ambulatory Monitoring	Nursing home patients (N=10)	100%	SUMACT, MAXACT - <i>r</i> for TST: 0.91, 0.81 - <i>r</i> for SE: 0.61, 0.78 - <i>r</i> for TWT: 0.75, 0.67 - Sensitivity = 87% - Specificity = 90%
2.	Colling E. and colleagues (2000)	Actiwatch- AW64/MiniMitter	Healthy older adults with mean age of 74.5 years (N=8)	NR	 Low, medium, high settings high sensitivity setting provided greater accuracy: agreement rate of .84, <i>r_s</i> of .952 (p < .0117) and overestimated TST by 61.32 minutes.
3.	Jean-Louis, Kripke, Cole, Assmus, and Langer (2001)	Actillume/ Ambulatory Monitoring	Post-menopausal women (n=39) between 51 – 77 years old	NR	 Agreement = 85% <i>r</i> for TST = .98 <i>r</i> for SE = .91 ME for TST = 21 minutes ME for SE = 4%
		Actillume/ Ambulatory Monitoring	Healthy adults (n=16)	No	 Agreement: 91% <i>r</i> for TST =.92 <i>r</i> for SE = 0.69 ME for TST = 5 minutes ME for SE = 1%

No	Author, year	Device/Company	Sample	% Older adults \geq 70 years old	Validity
4.	Jean-Louis, Kripke, Mason, Elliott, and Youngstedt (2001)	Actillume/ Ambulatory Monitoring	Healthy adults (N=5)	No	 SUMACT, MAXACT, ZCM, TAT, PIM modes Agreement: 94.4, 91.4, 95.0, 94.6, 96.5 % ME for TST: 8, -10, 12, 6, 2 minutes ME for SE: 1, -2, 2, 1, 0 minutes r for TST: 0.85, 0.85, 0.81, 0.79, 0.94 r for SE: 0.67, 0.69, 0.55, 0.57, 0.87
5.	Kushida and colleagues (2001)	Actiwatch-AW4/ Mini Mitter	Sleep disordered patients (N = 100)	No	 Low, medium, and high sensitivity settings Sensitivity: 92, 96, 98% Specificity: 48, 38, 28% Accuracy: 77, 77, 76% ME for TST: 1, 1.4, 1.8 minutes ME for SE: 12.1, 17.5, 21,9%
6.	Pollak, Tryon, Nagaraja, and Dzwonczyk (2001)	CSA7164/ Computer Science and Applications IM/ ActiTrac, IM system	Healthy young adults $(n = 10)$ and healthy older adults $(n = 4)$	28.57%	 PVS: 83.1% PVW: 47.1% Agreement: 77.9%
7.	De Souza and colleagues (2003)	Actigraph – Basic 32 C/Ambulatory Monitoring	Healthy adults (N = 21)	No	 Cole's and Sadeh's algorithms Agreement: 99, 97% Specificity: 34, 44% ME for SOL: 1.4, 2.5 minutes ME for TST: 18.5, 8.1 minutes ME for IA: -18.6, -10 minutes ME for SE: 4.2, 2.2% <i>r</i> for SOL: 0.69, 0.64 <i>r</i> for TST: 0.89, 0.89 <i>r</i> for SE: 0.39, 0.41

No	Author, year	Device/Company	Sample	% Older adults ≥ 70 years old	Validity
8.	Lotjonen and colleagues (2003)	WristCare/ IST Internatioanl Security Technology	Healthy subjects (N=28)	NR	 <i>r</i> for TST = 0.70 Agreement = 78% Overestimated TST
		Actiwatch- AW4/ActiWatch, Cambridge Neurotechnology			
9.	Vallieres and Morin (2003)	Actigraph/ Individual Monitoring systems	Chronic primary insomniacs (N=17)	No	 ME for TST: -38.29 minutes ME for TWT: 35.36 minutes ME for SE: -8.23 % ME for SOL: -7.01 minutes ME for TIB: 0.39 minute <i>r_s</i> for TWT = 0.52 <i>r_s</i> for TST = 0.71 <i>r_s</i> for SE = 0.57 Actigraphy was sensitive in detecting the effects of treatment on TST, TWT, SE, SOL, and TIB.
10.	Hedner and colleagues (2004)	Watch_PAT100/ Ambulatory Monitoring	Healthy adult (n=38) and sleep apnea patients (n=190)	No	 Normal, mild, moderate, and severe OSA Sensitivity: 91, 90, 89, 85% Specificity: 69, 70, 68, 71% Agreement: 86, 86, 84, 80%

No	Author, year	Device/Company	Sample	% Older adults \geq 70 years old	Validity
11.	Laakso, Leinonen, Lindblom, Joutsiniemi, and	Actiwatch/Actiwatch, Cambridge Neurotechnology	Healthy subjects (n=10)	No	 <i>r</i> for SOL = 0.82 <i>r</i> for TST = 0.88 <i>r</i> for SE = 0.77
	Kaski (2004)		Subjects with sleep disorder (n=13)	No	 <i>r</i> for SOL = 0.73 <i>r</i> for TST = 0.87 <i>r</i> for SE = 0.91
			Subjects with sleep disorder and motor disability (n=16)	No	 No statistics significant relationship of SOL, TST, and SE between two methods.
12.	Lichstein and colleagues (2006)	AW64/ Mini-Mitter	Person with insomnia (N=57)	NR	 High setting No differences between actigraphy and PSG on any sleep variable (i.e. SOL, NWAK, WASO, TST, and SE) <i>r</i> for SOL = 0.30 <i>r</i> for WASO = 0.48 <i>r</i> for TST = 0.70 <i>r</i> for SE = 0.43

No	Author, year	Device/Company	Sample	% Older adults ≥ 70 years old	Validity
13.	Sivertsen and colleagues (2006)	Actiwatch Plus/ Cambridge Neurotechnology	Insomniacs Older adults with insomnia (N=34)	NR	 Medium level Actigraph was 3.6 times more likely to misclassify the epoch as sleep than wake. Sensitivities at before, after, and overall were 94.9, 95.4, and 95.2, respectively. Specificities at before, after, and overall were 34, 38.6, and 36.3, respectively. Accuracies at before, after, and overall were 80.8, 85.3, and 83.1, respectively. The accuracy of the actigraph was significantly higher in subjects with high SE. In comparison to PSG, actigraphy was overestimated TST and SE and underestimated SOL and WASO.
14.	Johnson and colleagues (2007)	Octagonal Sleep Watch 2.01/ Ambulatory Monitoring	Adolescents with (n=17) and without sleep disorder breathing (n=164)	No	 TAT, ZCM, and PIM mode ICC: 0.41, 0.32, 0.34 ME for TST: -11, -33, -54 minutes
15.	Paquet and colleagues (2007)	Actiwatch –L/ Mini Mitter, Respironics	Healthy subjects (N=15)	No	 Act20, Act 40, LötEq, and LötMt Sensitivity: 91.4, 95.3, 94.6, 94.8% Specificity: 65.3, 54.3, 47.3, 52.6 % Accuracy: 88.2, 90.7, 90.3, 90.6% Underestimated SOL and overestimated TST and SE.

No	Author, year	Device/Company	Sample	% Older adults ≥ 70 years old	Validity
16.	Beecroft and colleagues (2008)	Actiwatch- AW64/ Mini Mitter	Mechanically ventilated patients in the ICU (N=12)	NR	Low (20), medium (40), high (80), custom (5), and auto settings - Overestimated TST and SE. - <i>r</i> for TST: 0.14, 0.12, 0.06, 0.08, 0.05 - <i>r</i> for SE: 0.10, 0.09, 0.04, 0.04, 0.18 - Sensitivity: 43, 44, 44, 42, 44% - Specificity: 95, 92, 86, 75, 91% - Accuracy: 57, 57, 61, 58, 51%
17.	Blackwell and colleagues (2008)	Sleepwatch – O/ Ambulatory Monitoring	Community- dwelling women (N=68)	NR	 PIM, TAT, ZCM modes ME for TST: 17.9, 33, -25.6 minutes ME for WASO: -6.7, -20.7, 15.1 minutes ME for SE: 3.9, 7.0, -5.9% ICC for TST: 0.76, 0.66, 0.53 ICC for WASO: 0.58, 0.41, 0.19 ICC for SE: 0.61, 0.44, 0.33
18.	Sitnick and colleagues (2008)	Actiwatch- AW64/ Mini-Mitter	Preschool children (N=58)	No	 Significantly more SOL, nocturnal awakenings, and WASO. Sensitivity: 97% Specificity: 24% Agreement 94%

No	Author, year	Device/Company	Sample	% Older adults ≥ 70 years old	Validity
19.	Wang and colleagues (2008)	Actiwatch- AW64/ Respironics	Subjects with (n=10) and without obstructive sleep apnea (n=11)	No	 Medium setting Agreement: 85% Sensitivity 95% Specificity: 41% Kappa 0.38 Significant less WASO ICC for SOL: 0.35 ICC for TST: 0.27 ICC for SE: 0.23 ICC for WASO 0.18
20.	Tonetti, Pasquini, Fabbri, Belluzzi, and Natale (2008)	Mini-Motionlogger/ Ambulatory Monitoring Actiwatch/ Cambridge Neurotechnology	Healthy adults (N=12)	NR	 MML, low, medium, high, auto SOL: MML and Actiwatch underestimated SOL by 7.35 and 4.45 minutes, respectively. TST: MML and actiwatch with medium and high setting provided significantly higher TST than PSG. WASO: medium and high setting of actiwatch provided significantly higher WASO than PSG SE: MML provided significantly higher while medium and high actiwatch provided significantly lower Among four level of sensitivity, the auto sensitivity provided the best validity; there is no statistically significant difference of TST, WASO, and SE between PSG and actiwatch with auto setting.

No	Author, year	Device/Company	Sample	% Older adults ≥ 70 years old	Validity
21.	Kanady, Drummond, and Mednick (2010)	Actiwatch-64/ Respironics	Subjects in the nap group (n=30) Subjects in the no nap group (n=27)	No	 Low, medium, high setting TST: medium and high sensitivity actigraphy significantly predicted TST by PSG; the high sensitivity setting had the strongest correlation. SE: medium and high sensitivity actigraphy significantly predicted SE by PSG. SOL: only high sensitivity actigraphy significantly predicted SOL by PSG. WASO: actigraphy at all levels did not significantly predict WASO by PSG. High sensitivity actigraphy overestimated TST and SE by PSG. Low sensitivity actigraphy provided highest accuracy, specificity, and kappa while high sensitivity provided highest sensitivity.

No	Author, year	Device/Company	Sample	% Older adults ≥ 70 years old	Validity
22.	Blackwell, Ancoli Israel, Redline, and Stone (2011)	Sleepwatch-O/ Ambulatory Monitoring	Community- dwelling older men (N=889)	NR	 PIM, TAT, and ZCM modes ME for TST: 13.18, 22.12, -59.01 min. ME for SE: 2.55, 4.48, -12.52% ME for SOL: -2.77, -2.43, 17.56 min. ME for WASO: -11.61, -21.79, 31.06 min. <i>r</i> for TST: 0.61, 0.53, 0.39 <i>r</i> for SE: 0.49, 0.42, 0.35 <i>r</i> for SOL: 0.44, 0.39, 0.36 <i>r</i> for WASO: 0.56, 0.47, 0.42 ICC for TST: 0.57, 0.47, 0.21 ICC for SE: 0.46, 0.36, 0.16 ICC for SOL: 0.32, 0.17, 0.36 ICC for WASO: 0.54, 0.42, 0.33
23.	Meltzer, Walsh, Traylor, and Westin (2011)	Motionlogger Sleep Watch/ Ambulatory Monitoring Actiwatch-2/ Respironics	Youths (N=115)	No	 AMI (Sadeh, Cole-Kripke), PRMM (low, medium, high) Sensitivity: 0.89 – 0.97 Specificity: 0.54 – 0.77 Accuracy: 0.87 – 0.90 Both devices overestimated WASO AMI underestimated TST
24.	Rupp and Balkin (2011)	Motionlogger watch/ Ambulatory Monitoring AW-64/ Mini Mitter	Healthy volunteers (N=29)	No	 AW-64 underestimated TST and SE and overestimated number of awakenings for baseline and recovery. It also overestimated SOL at baseline. Motionlogger underestimated TST and SE and overestimated SOL on recovery.

No	Author, year	Device/Company	Sample	% Older adults ≥ 70 years old	Validity
25.	Cellini, Buman, McDevitt, Ricker, and Mednick (2013)	AW-64/ Phillips Respironics GT3X+ / Actilife	Non-smoking adults (N=34)	No	 AW-64 (low, medium, high) and GT3X+ (ACT, LFE) AW-64: No significant differences for any sleep parameter. GT3X+: overestimation SE and underestimation WASO (only ACT). ICC for TST: 0.79, 0.80, 0.80, 0.76, 0.76 ICC for SOL: 0.29, 0.29, 0.29, 0.55, 0.56 ICC for WASO: 0.51, 0.49, 0.46, 0.51, 0.54 ICC for SE: 0.70, 0.68, 0.69, 0.49, 0.50
26.	Maglione and colleagues (2013)	Actiwatch-L/ Philips Respironics	Person with Parkinson's disease (N=61)	NR	 Setting: 0, 5, 10, 20, 40, 60, 80 10 immobile minutes ME for TST: -183.03, -37.08, -6.05, 22.43, 45.81, 57.20, 63.89 min. ME for SE: -38.79, -7.71, -1.10, 4.99, 9.98, 12.21, 13.84% ME for WASO: 172.63, 26.68, -4.35, -32.82, -56.18, -67.60, -74.30 min. 5 immobile minutes ME for TST: -182.15, -36, -5.23, 22.76, 45.52, 56.60, 69.15 min. ME for SE: -39.04, -10.56, -4.96, 0.04, 4.01, 5.94, 7.04% ME for WASO: 135.83, 1.25, 24.66, -48.16, -66.9, -76, -81.2 min. SOL (0, 5, 10 immobile minutes): -14.45, -4.75, -0.65 min.

No	Author, year	Device/Company	Sample	% Older adults ≥ 70 years old	Validity
27.	Marino and colleagues (2013)	AW64/ Minimitter Actiwatch Spectrum/ Philips Respironics	Healthy and insomniacs (N=77)	NR	 Accuracy = 0.86 Sensitivity = 0.97 Specificity = 0.33
28.	Taibi, Landis, and Vitiello (2013)	Actiwatch-64/ Philips Respironics	Older women with insomnia (N=16)	NR	Low (20), medium (40), high (80) setting - ME for TST: 89.15, 107.88, 123.99 min. - ME for SE: 18.91, 22.88, 26.28% - ME for WASO: -75.02, -91.71, -105.47 min. - ME for SOL: -13.39, -13.39, -13.39 min. - Sensitivity = 96.1, 98.1, 99.2% - Specificity = 36.4, 28.1, 19.6% - Agreement = 75.4, 74.3, 72.5% Low (20) setting - β for TST = 0.281 - β for SE = 0.085 - β for SE = 0.085 - β for SOL = 0.669

Note. NR = no report; SUMACT = sum activity setting; MAXACT = maximum activity setting; ME = Mean measurement error (Act – PSG); TST = total sleep time; SE = sleep efficiency; WASO = wake after sleep onset; SOL = sleep onset latency; r = Pearson Correlation Coefficient; r_s = Spearman's rank correlation coefficient; TAT = Time above threshold; ZCM = Zero crossing mode; PIM = Proportional integrations mode; PVS = predictive values for sleep; PVW = predictive values for wake; IA = intermittent awakening; ICC = Intraclass correlation coefficients; ACT = ActiLife 6.4.3 software with Sadeh algorithm without LFE option; LFE = ActiLife 6.4.3 software with Sadeh algorithm and a low-frequency extension option; β = unstandardized Beta

Summary of Review

After the baby boom period after World War II, the number of older people in the US increased significantly, especially ones who are older than 70 years old. This fact implies the need for research studies focusing on understanding and promoting living independently and living well in community in this population. Sleep disturbances are one of the most common symptoms that older adults experience. Additionally, sleep disturbances are associated with both physical and psychological declines. In order to help older adults maintain or improve their sleep quality, it is important to understand characteristics of sleep disturbances and its changes among this specific population. Although polysomnography is a standard tool to evaluate sleep, this method is very expensive; not every older adult is able to afford it. In addition, PSG itself can interfere with the subject's sleep call first night effect. Although PSG is a non-invasive method, it can still pose a physical risk to older adults if they experience agitation, restlessness, or physical aggression. Alternative valid and reliable method with more affordable and more available in older adults is needed. Thus, this study attempts to examine the characteristics of the "first night effect" in community dwelling older adults who are 70 years and older. In addition, the accuracy of actigraphy, an alternative method, in measuring sleep and changes in sleep in community-dwelling older adults who are at least 70 years old is explored in comparison to PSG, the gold standard.

CHAPTER 3

RESEARCH DESIGN AND METHODOLOGY

This secondary research study was used to explore the first night effect of laboratory PSG on sleep, along with the validity of actigraphy in measuring sleep and changes in sleep as compared with PSG in community-dwelling older adults, age 70 years and older. This chapter presents the research design and methodology, such as research design, research questions, sample and subjects, study protocol, protection of the rights of human subjects, and data analysis.

Research Design

This study adds to the existing literature by describing a sleep characteristic termed the "first night effect" in persons who at least 70 years old and the validity of wrist actigraphy for measuring sleep and changes in sleep in this underreported group of older adults. Wrist actigraphy and PSG were performed over two consecutive nights on 47 community-dwelling older adults, who participated in either the Respiratory Periodicity and Cognitive Decline in Elders Study (PRISM) (PI: Barbara Carlson NR08032, IRB#01-0666, formerly, 726-01) or the Patterns of Cerebral Oxygenation during Sleep and their Relationship to Markers of Hypoxic Burden and Brain Connectivity in Community Dwelling Older Adults (PTRACS) (PI: Barbara Carlson, NC TraCS: 50K20908, IRB# 09-2129). Using polysomnography (PSG) as the gold standard for assessing sleep, the aims of this secondary data analysis research are to explore

characteristics of sleep, and to examine the validity of actigraphy for measuring sleep and changes in sleep in community-dwelling older adults, age 70 years and older.

Research Questions

This study answers three research questions, including

- 1. What are the characteristics of sleep "first night effects" in community dwelling older adults, age 70 years and older?
- 2. How accurate is actigraphy when compared to PSG in measuring sleep in community-dwelling older adults, age 70 years and older?
- 3. How accurate is an actigraphy, as compared to PSG, in measuring changes in sleep in community-dwelling older adults, age 70 years and older?

Characteristics of the Sample

Data from 63 older adults were drawn from two samples. The first sample consists of 43 community-dwelling older adults who participated in PRISM project. The second sample consists of 20 additional older adults who participated in PTRACS. In both studies, the subjects were recruited from local senior centers (Hillsborough and Chapel Hill), as well as a retirement community (Carolina Meadows) and two housing projects for low-income residents (Covenant Place and St. Joseph Place). These sites were selected because they provide a representative mix of high and low income Caucasians, African Americans, Hispanics and Asians. The Institutional Review Board of the University of North Carolina at Chapel Hill approved both studies.

Characteristics of the Subjects

There were 63 older adults, ranging in age from 70 to 89 years (M = 79.15, SD = 5.30 years). Fifty-two percent were female. The majority of subjects were Caucasian (92.06%). The subjects' body mass index ranged from 19.43 to 37.21 kg/m² (M = 26.61, SD = 3.72), with 81.36% of values below 30 kg/m². No subject had impairment of everyday function as evidenced by the following: 1) all scores on the Mini Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975)were above 24 points (M = 29.17, SD = 1.43), 2) scores on the Older Adults Resource Services (OARS) Independent Activities of Daily Living Scale (Fillenbaum, 1978) were above 12 points (M = 27.66, SD = 0.73), and 3) all scores on the 15 item Geriatric Depression Scale (GDS) (Yesavage & Sheikh, 1986) were below 5 points (M = 1.15, SD = 1.38). Subjects did complain of sleep problem. Scores on the Pittsburgh Sleep Quality Index (PSQI) (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989) ranged from 0 to 12 (M = 4.17, SD = 2.85) and 15 subjects (23.81%) had scores of at least five points, and indication of poor sleep quality. The Epworth Sleepiness Scale (ESS) (Johns, 1991) scores ranged from 0 to 16 (M = 6.88, SD = 4.04) and 12 subjects (23.08%) reported having daytime sleepiness.

Two-night Sleep Study Protocol

Sleep studies were conducted from 11 pm - 6 am on two consecutive weekday nights in the sleep-monitoring suite at the Biobehavioral Laboratory at the School of Nursing, the University of North Carolina at Chapel Hill. The first night served as a habituation night, allowing the subject to become familiar with sleeping in the laboratory prior to collection of data for analysis on Night 2. During the day between the study nights, subjects were asked to maintain their typical daytime routines between the time they left the sleep laboratory after

breakfast (8:00 am) and their return for dinner (5:00 pm). Since there were two sleep bedrooms, subjects were studied two at a time. The temperature of the room was maintained at 22-24°C, and relative humidity at 19-20%.

Standard procedures were used to apply the sensors for polysomnography (Jasper, 1958). Monitoring began at individual's bedtime and continued until 6:00 am the following morning. Before the sleep study started, a wrist actigraph (Actiwatch L, Respironics, Pittsburgh PA) was set up to record movement counts every 1 minute (Appendix A) and placed on subject's nondominant hand. Carbon dioxide levels were measured using either a capnography (PRISM) or a transcutaneous carbon dioxide monitor (PTRACS). Airflow sensors as well as thermocouple and calibrated inductance plethysmograph sensors to record respiratory movements were used to identify hypopneas and apneas.

The polysomnography recording was digitized and stored on the computer using the AstroMed Grass Software. All of the signals were collected at a rate of 250 samples per second. The night research assistants initiated the recording and were responsible for ensuring the quality of the sleep recordings. At the start of the recording (around 10:00 pm), the subjects were asked to perform a series of biological calibrations (blink, close/open eyes, breathe in and out, hold the breath, sigh and grit the teeth) that were used to evaluate the quality of the waveform signals. Afterwards (around 10:30-11:00 pm), the lights in the subject's room were turned off, and the subject was asked to try to fall asleep.

Throughout the course of the night, the sleep research assistants watched the subject using an infrared camera, mounted at the far end of the room. On the polysomnograph record, the sleep research assistants marked when the subject changes position in bed, speaks, or snores. They also used the time stamp on the videotape to verify the presence of movement artifacts on

the PSG record. Since the tapes can be used to identify subjects, the tapes (PRISM) were stored in a secured, locked cabinet and digital images (PTRACS) were kept on a password-protected network at the School of Nursing.

The recordings continued until the technician awakened the subject. After lights on, the technicians checked impendence of the sensors and ran a second set of biocalibrations. The recordings were stopped around 6:30 am. On the second night, the sensors were reapplied and subjects were allowed to relax until the start of calibrations. Overnight monitoring occurred just as on Night 1.

On both mornings, subjects completed a sleep quality questionnaire that asked them to rate how they slept in the laboratory compared to how they typically sleep at home. In addition to providing a subjective measure of the representativeness of the data collected in the lab, these data were used to determine whether the subject was awake enough to safely find his or her way home. If a subject reported that he or she was groggy or not thinking clearly, the subject was asked to stay and take a nap after breakfast or let us arrange transportation home. In general, this procedure generally restricted subjects' sleep to 7.5 hours, which did not leave subjects so drowsy that they could not safely perform their daytime routines and increased their sleep duration by 5-10% on the second night.

Instrumentations

After each night of recording, the data from polysomnograph and wrist actigraph were backed up and transferred to a second computer for analysis. The following procedures were used to score the two types of recording.

Standard polysomnography.

Standard polysomnography (bilateral eye movement channels, two central and an occipital EEG channels, and one submental EMG channel) was used to score sleep states. Arterial oxyhemoglobin saturation (SaO₂) was measured every 3 seconds with a Nellcor pulse oximeter (Mallinckrodt Inc, St. Louis, MO). Standard measures and criteria set by the American Academy of Sleep Medicine (The Report of an American Academy of Sleep Medicine Task Force, 1999) were used to identify arterial oxygen desaturations, as well as apneas and hypopneas. Respiratory effort was recorded using a calibrated respiratory inductance plethysmograph (Ambulatory Monitoring, Ardsdale, NJ). Airflow at the nose and mouth was monitored using a single-channel oro-nasal thermocouple (Pro Tech, Woodville, WA).

In the PRISM study, the signals were acquired using a Grass Model 15 digital recording system (Astromed Grass, Warwick, RI) at a sampling rate of 250 samples per second. The same sampling rate was used in the PTRACS study, but the signals were collected using a Grass Comet XL digital recording system. Standard scoring rules (A. Rechtschaffen, Kales, A., 1968) were used to score each subsequent 30-second epoch of sleep into one of five categories (Stage 1 NREM, Stage 2 NREM sleep, Stage 3 & 4 NREM sleep, REM sleep, and Wake after Sleep Onset). Inter-rater agreement for scoring sleep states was acceptable across all records (M \pm SD percent agreement=97% \pm 3.5%, Kappa= 0.91 \pm 0.12).

Wrist actigraphy.

The actigraph was worn on the non-dominant wrist for both 2 consecutive nights of the sleep study. In this study, actiwatch-light (AW-L) was used to assess subject's sleep. The size of this device is 28*27*10 mm. It weighs only 16 grams. The AW-L contains an accelerometer, the

sensor integrates the speed and degree of motion, which produces an electrical current that varies in magnitude. It can detect a minimal of force at least or greater then 0.01g. In addition, AW-L contains light sensor. Thus light levels, ranging from 0.1 to 150,000 lux, are also recorded as the same time while movement levels are recorded (Mini Mitter Company Inc., 2003).

Since AW-L has internal memory, either 32K or 64K, it can be programmed for delaying in start time up to 180 days depending upon its battery life. Sampling epoch length, ranging between 15 seconds and 15 minutes, can also be pre-programmed. However, for sleep analysis, an epoch length of one minute or less is recommended since the computer program for sleep analysis called Actiware-Sleep analysis cannot analyze sampling epoch of greater than two minutes (Respironics, 2008).

In the original study, before placing AW-L on the subject's non-dominant wrist, the AW-L was first programmed and calibrated according to the manufacturer's directions by using the specific computer software called Actiware Sleep version 3.3. AW-L was placed on Actiwatch Reader to communicate with a computer and software. After the connection between AW-L and software was established, filename as well as subject information such as age and gender were entered. Data collection parameters such as Start Time, date, and epoch length were selected. In this study, a 1-minute sampling epoch length was selected. After the AW-L was set up, the AW-L was placed on the subject's non-dominant wrist. Subjects were instructed not to remove the device at any time during monitoring. In the following morning after the sleep study, the data from the AW-L were retrieved by using Actiware-Sleep software according to the manufacturer's instructions.

To determine periods of wake and sleep, total activity counts in each 1-minute sampling epoch is compared against threshold. If the number of total activity counts exceed threshold, that

epoch is then coded as wake. On the other hand, the epoch is then coded as sleep when the number of total activity counts is less than or equal to, the threshold. With a one-minute sampling epoch, the total activity count for a particular sampling epoch is derived from the activity count from the sampling epoch itself (n), from the two prior epochs (n-1, n-2), and from the two following epochs (n+1, n+2). The total activity count in the sampling epoch is calculated by the following formula:

Total activity counts for sampling epoch (n) =

[(0.04) x count from epoch n-2] + [(0.20) x count from epoch n-1]

+ count from sampling epoch n

+ [(0.20) x count from epoch n+1] + [(0.04) x count from epoch n+2]

According to Actiware-Sleep software, there are five choices for sensitivity settings: low (80), medium (40), high (20), automatic (computed automatically based on activity data), and custom (researcher-selectable value). Investigator can choose the level of threshold to be compared with total activity counts in each sampling epoch. However, in this study, four different levels of threshold, including low, medium, high, and automatic will be used to identify the one that yields the lowest discrepancies of sleep between PSG and actigraphy.

Results should be also verified for missing data (subject taking off the watch or malfunction in watch) by evaluating the visual graphs produced by the software. Data can be exported into various graphs or spreadsheets for further analysis. Since the validity of actigraph in measuring sleep and changes in sleep are the focus of this study, SOL, WASO, and TST were compared between actigraphy and PSG.

An important issue in doing this comparison is that the time clock as set up on PSG study and on Actigraph must be exactly the same so that investigators can examine epoch by epoch comparison between these two measures. If the time as set up between two measures differ, results from the comparison are worthless. Thus, in this study, the data from both PSG and actigraph will be perfectly synchronized before making comparisons.

Variables and Their Measurement

As discussed in Chapter 1, actigraphy uses an algorithm to measure variables that are similar to that provided by standard PSG such as SOL, WASO, TST, and SE. The operational definitions of these variables, for both the first night and second night, were provided below. Three measures (bedtime, final wake time, and time in bed) by actigraphy were exactly the same for PSG. However they were used to define the other four variables and for this reason they were defined alone with the 4 primary variables that were used to characterize the subject's sleep.

Time in bed (TIB) is defined as time in minutes between lights out (bedtime) and lights on (wake time) as marked on the PSG. Since the time set up by both methods were the same, TIB by PSG and actigraphy was identical.

Sleep-onset latency (SOL) is the time in minutes that the individual takes to fall asleep. SOL by PSG is determined by measuring the time from lights out to the first 2 consecutive minutes of any sleep stage based on the criteria of Rechtschaffen and Kales (1968). SOL by actigraphy is determined by using immobile minutes method. It measured the time from lights out to find the first period of 10 minutes in which only one epoch contains movement and then marked that first epoch as sleep start time. Higher SOL values indicate that the individual is having difficulty falling asleep.

Wake after Sleep Onset (WASO) represents how well subject was able to maintain his/her sleep throughout the whole night. It is determined by measuring a total number of minutes the subject spent awake between sleep onset and final wake time. WASO by PSG is calculated by adding up all epochs scored as state W that occurred between sleep onset and final wake time. WASO by actigraphy is determined by adding all epochs scored as wake that happened after sleep start until sleep end. Higher WASO values indicate that the individual is having difficulty maintaining asleep.

Total sleep time (TST) refers to the actual time in minutes that the subject slept during the night, including only periods of sleep. TST by PSG is calculated by subtracting SOL and WASO from TIB (TIB - (SOL by PSG + WASO by PSG). TST by actigraphy is calculated by subtracting SOL and WASO by actigraphy from TIB (TIB - (SOL by actigraphy + WASO by actigraphy). Higher TST values indicate that the individual is able to maintain his/her sleep.

Sleep Efficiency (SE) refers the quality of sleep that can be used to compare across subjects. SE by PSG is a ratio of the TST by PSG to TIB multiplied by 100 (TST by PSG / TIB * 100). There was no comparison of SE between two methods because subjects had identical TIB. Thus, the comparison of SE between two methods did not provide additional information because it was similar to the comparison of TST between two methods.

Stage N1 refers to the first stage of NREM sleep. It indicates the percentage of time subject stays in the stage N1 sleep as compared to TST. In this study, stage N1 is the ratio of stage N1 in minutes to TST multiplied by 100 (stage N1/TST * 100).

Stage N2 refers to the second stage of NREM sleep. It indicates the percentage of time subject stays in the stage N2 sleep as compared to TST. In this study, stage N2 is the ratio of stage N2 in minutes to TST multiplied by 100 (stage N2/TST * 100).

Stage N3 refers to stage 3 and stage 4 NREM. It indicates the percentage of time subject stays in the stage N3 sleep as compared to TST. In this study, stage N3 is the ratio of stage N3 in minutes to TST multiplied by 100 (stage N3/TST * 100).

Stage R refers to REM sleep. It indicates the percentage of time subject stays in the REM sleep stage as compared to TST. In this study, stage R is the ratio of stage R in minutes to TST multiplied by 100 (stage R/TST * 100).

REM latency referred to the time between sleep start and stage R.

Protection of the Rights of Human Subjects

Although this study was a secondary-data analysis, this study was conducted with the approval of the Institutional Review Board (IRB) of the University of North Carolina at Chapel Hill (UNC-CH) to assure the protection of human subjects. Confidentiality of all information was maintained. All data were analyzed and reported as group data.

Data Analysis

Each subject had sleep data for two nights, including data from PSG and data from actigraphy. Actigraphy was analyzed with four sensitivity settings, (i.e. low, medium, high, and auto). Actigraphy with each sensitivity setting was then compared to its corresponding to PSG measure. Data entry and analysis were performed using SAS software, version 9.3. All data were double entry and compared for any errors. The analyses were aimed at answering the following three research questions:

1. What are the characteristics of "first night effect" in community dwelling older adults, age 70 years and older?

- 2. How accurate is actigraphy when compared to PSG in measuring sleep in community-dwelling older adults, age 70 years and older?
- 3. How accurate is an actigraphy, as compared to PSG, in measuring changes in sleep in community-dwelling older adults, age 70 years and older?

Research question one.

The characteristics of the "first night effect" in community dwelling older adults who are 70 years and older were answered by using comparison of the means, scatter plots, and correlation coefficients between the first and the second nights. Sleep parameters as measured by PSG, including TIB, SOL, WASO, TST, SE, stage N1, stage N2, stage N3, stage R, and REM latency from both the first and second night were examined to characterize the fist night effect (FNE). The following statistics were applied.

- Demographic data, which were continuous, including age, BMI, MMSE, OARS, GDS, PSQI, and ESS, were reported by means and standard deviations.
- Demographic data, which were categorical, including race, were reported by frequencies and percentages.
- All 10 sleep parameters across two nights, including TIB, SOL, WASO, TST, SE, stage N1, stage N2, stage N3, stage R, and REM latency were reported by medians, means, and standard deviations.
- 4. The FNE was examined by using three different approaches. However, the results were based upon the findings from comparison of means method.
 - 4.1 Comparison of means. Mean of each sleep parameter between two nights were compared. Before making a comparison, the differences of each mean

sleep parameter across two nights were examined for their distribution by using Kolmogorov-Smirnov test and histograms. If they were normally distributed, paired-sample t-tests were performed. If data were skewed, a value of skewness was explored. If this value was close to zero, a signed rank test was employed; otherwise, a sign test was used.

- 4.2 Correlation. Scatter plots of each sleep parameter between the first and second night were plotted to show their relationships, along with a regression line. Pearson and Spearman rank correlation coefficients were computed to describe relationships of each sleep parameters across two nights of laboratory sleep PSG. The linear relationship between each parameter was explained by Pearson's coefficient. However, if Pearson provided a correlation coefficient less than what Spearman's rank did, Spearman's rank correlation, which utilizes the rank order of the data, was used to represent the relationship.
- 4.3 Scatter plots: Scatter plots were employed to illustrate change of each sleep parameter from the baseline against the first night sleep parameter or baseline. The zero line and mean were also presented in scatter plots. A positive mean change indicated that sleep parameter during the second night was higher than those during the first night, while a negative mean change indicated that sleep parameter during the second night during the first night.

Research question two.

The accuracy of actigraphy when compared to PSG in measuring sleep in communitydwelling older adults, age 70 years or older were answered by four different methods, including comparison of the means, Intraclass Correlation Coefficients (ICCs), correlation and regression models, and Bland-Altman plots. Since data from actigraphy and PSG were perfectly synchronized. SOL, WASO, and TST by actigraphy were analyzed by using four sensitivity settings, including low (80), medium (40), high (20), and auto and were compared against the gold standard PSG. Since there were two nights of data, data from the first and second night were separately examined in these analyses. The following statistics were applied.

- Demographic data, which were continuous, including age, BMI, MMSE, OARS, GDS, PSQI, and ESS, were separately reported by means and standard deviations.
- Demographic data, which were categorical, including race, were separately reported by frequencies and percentages.
- 3. Three sleep parameters across two methods, including SOL, WASO, and TST were reported by median, mean, and standard deviation.
- 4. The accuracy of actigraphy was examined by using four different approaches. The main findings were reported by using interclass correlations and Bland-Altman plots.
 - 4.1 Comparison of means: Mean of each sleep parameters between two methods were compared. Before making a comparison, the differences of each mean sleep parameter were examined for their distribution by using Kolmogorov-Smirnov test and histogram. If they were normally distributed, pairedsample t-tests with Bonferroni corrections were performed with adjusted significance set at p < .0125. If data were skewed, a value of skewness was

explored. If this value was close to zero, a signed rank test was employed; otherwise, a sign test was used. Since four comparison of means were conducted per sleep variable, Bonferroni corrections were also applied with adjusted significance set at p < 0.0125.

- The intraclass correlation coefficients (ICCs). ICCs were employed to 4.2 explore the strength of a linear relationship between two methods obtained on the same subject. In this analysis, of the six ICC equations described by Shrout and Fleiss (Shrout & Fleiss, 1979), the (3,1) equation was used because each subject was assessed by both PSG and actigraphy, which were the methods of interest. Thus, these two methods were considered to be fixed and the reliability reflected the accuracy of measurement between these two methods. If the two methods aligned the subject data in a similar manner, the ICC would be high. According to ICC values, there are five level of the strength of association. With the ICC less than 0.25, the strength of association is poor. When the ICC is between 0.25 and 0.50, the strength of association is fair. The strength of association is moderate when the ICC is between 0.50 - 0.75. When the ICC is between 0.75 - 0.90, the association is good. The association is excellent only when the ICC is higher than 0.9 (Indrayan, 2013).
- 4.3 Correlation and regression models. These models were employed to examine whether there were relationships of each sleep parameter between actigraphy and PSG.

- 4.3.1 Scatter plots of each sleep parameter between two methods were plotted to show its relationship, along with a regression line.
- 4.3.2 Pearson and Spearman rank correlation coefficients with Bonferroni corrections were performed for each sleep variable (i.e. four correlations per sleep parameter, with adjusted significance set at p < 0.0125). The linear relationship between each parameter was explained by Pearson's coefficient. However, if Pearson provided a correlation coefficient less than what Spearman's rank did, Spearman's rank correlation, which utilized the rank order of the data, was used to represent the relationship. In such cases, scatter plots of ranked sleep parameters were also illustrated with its regression line. The strength of relationship has five levels, including little when r/r_s is less than .25, low when r/r_s is between .26 .49, moderate when r/r_s is between .50 .69, high when r/r_s is between .70 .89, and very high when r/r_s is at least or more than .90 (Munro, 2004).
- 4.3.3 Linear regressions with Bonferroni corrections were performed for each sleep parameters with significance set at p < .0125. In regression models, percentage of variance in sleep parameters from PSG that could be explained by actigraphy were presented, along with predictive value of sleep parameters from PSG by sleep parameters from actigraphy. In these regression models, the minimum value of each sleep parameters by actigraphy were used if

they were different from zero so that value of intercepts in each model represented values of each sleep parameter by PSG when sleep parameter by actigraphy was located at the minimum range of the real data.

4.4 Bland-Altman plots. These plots were also depicted to determine the agreement between methods. The y-axis represented the difference of each sleep parameter between two methods (actigraphy minus PSG). The x-axis represented the mean of each sleep parameter between two methods. In this plot, there were two horizontal dotted lines, which represented upper and lower limit of agreements. The actigraphy bias was represented as the mean difference between actigraphy and PSG. A positive mean difference indicated that actigraphy overestimated sleep parameter compared with PSG while a negative mean difference indicated that actigraphy underestimated sleep parameter compared to PSG.

Research question three.

The accuracy of an actigraphy, as compared to PSG, in measuring changes in sleep in community-dwelling older adults who are at least 70 years old were answered by three different approaches were used, including comparison of the means, correlation and regression models, and Bland-Altman plots. In this question, four sensitivity settings of actigraphy were used to evaluate the validity of actigraphy in measuring sleep and its changes as compared to the standard PSG.

Change was defined as the difference of a given sleep parameter between the two nights of laboratory sleep study. It was calculated by subtracting the value of the second night by the value of the first night, thus a negative change of sleep parameter meant that the value of the second night sleep parameter was less than that of the first night. On the other hand, a positive change in sleep parameter meant that the value of the second night was more than that of the first night.

The following statistics were applied.

- Demographic data, which were continuous, including age, BMI, MMSE, OARS, GDS, PSQI, and ESS, were reported by means and standard deviations.
- Demographic data, which were categorical, including race, were reported by frequencies and percentages.
- Three change in sleep parameters across two methods, including SOL, WASO, and TST were reported by median, mean, and standard deviation.
- The accuracy of actigraphy in measuring changes in sleep was examined by using four different approaches. The main findings were depended upon Bland-Altman plots.
 - 4.1 Figures. Figures were plotted to show change in each sleep parameter between two methods across all subjects. Each subject was then assigned to one of two groups based on the direction of change in sleep parameter between the two methods. For the first group, the change in sleep parameter by the two methods was in the same direction (i.e. either increased or decreased by both methods). For the second group, the change in sleep

parameter by the two methods was in opposite directions (i.e. increased by PSG but decreased by actigraphy, or vice versa).

- 4.2 Comparison of means. Mean of change in each sleep parameters between two methods were compared. Before making a comparison, the differences of each mean sleep parameter were examined for their distribution by using Kolmogorov-Smirnov test and histogram. If they were normally distributed, paired-sample t-tests with Bonferroni corrections were performed with adjusted significance set at p < .0125. If data were skewed, a value of skewness was explored. If this value was close to zero, a signed rank test was employed; otherwise, a sign test was used. Bonferroni corrections with adjusted significance set at p < .0125 were also applied to both a signed rank test and a sign test.
- 4.3 Correlation and regression models. The relationships of change in each sleep parameters across two methods. Correlation and regression models were employed to examine whether there were relationships of change in each sleep parameter between actigraphy and PSG.
 - 4.3.1 Scatter plots of change in each sleep parameter between two methods were plotted to show its relationship, along with a regression line.
 - 4.3.2 Pearson and Spearman rank correlation coefficients with Bonferroni corrections were also computed to describe relationships of change in each sleep parameters across two nights of laboratory sleep PSG with adjusted significance set at p < .0125.

The linear relationship of change in each parameter between two methods was explained by Pearson's coefficient. However, if Pearson provided a correlation coefficient less than what Spearman's rank did, Spearman's rank correlation, which utilized the rank order of the data, was used to represent the relationship. Scatter plots of each ranked change in sleep parameters were also illustrated with its regression line.

- 4.3.3 Regression models with Bonferroni corrections were performed with adjusted significance set at p < .0125. In regression models, percentage of variance in change in sleep parameters from PSG that could be explained by actigraphy were presented, along with predictive value of change in sleep parameters from PSG by change in sleep parameters from actigraphy. In these regression models, the minimum value of each change in sleep parameter by actigraphy was used as a shifting constant if they were different from zero so that value of intercepts in each model were represented values of change in each sleep parameter by PSG when change in sleep parameter by actigraphy was located at the minimum range of the real data.
- 4.4 Bland-Altman plots. Bland-Altman plots were also depicted to determine the agreement between methods. The y-axis represented the difference of change in each sleep parameter between two methods. It calculated by subtracting change in sleep parameter by PSG from sleep parameter by

actigraphy. The x-axis represented the mean of change in each sleep parameter between two methods. In this plot, there were two horizontal dotted lines, which represented upper and lower limit of agreement. Zero line and mean difference of change in sleep parameter were also included in the plot. A positive mean difference indicated that actigraphy overestimated change in sleep parameter compared with PSG while a negative mean difference indicated that actigraphy underestimated sleep parameter compared to PSG.

Importance of the Research

This proposed study provided valuable data for all stakeholders to understand characteristics of first night effect among community-dwelling older adults, at least 70 years old as well as the validity of instrument in measuring sleep disturbances in this specific population. Validity of measurement is very important not only for understanding the nature of sleep disturbances among community-dwelling older adults but also for determining the outcome of any intervention providing to improve sleep among these population.

CHAPTER FOUR RESEARCH QUESTION ONE RESULTS

This chapter presents the results of the secondary data analysis study covering research question one: What are the characteristics of sleep "first night effect" in community dwelling older adults, age 70 years and older? The aim of this study was to explore the presence of a first night effect in two consecutive nights of laboratory polysomnography (PSG) in communitydwelling older adults, age 70 years and older, along with the characteristics of this first night effect. First night effect (FNE) is the set of differences in sleep parameters during the first night in comparison with the second night in the two consecutive nights of laboratory PSG. The FNE may be due to the effects of the laboratory sleep environment and polysomnographic equipment.

Three different approaches were used in this analysis, including comparison of means, scatter plots, and correlation coefficients. In the method of comparison of means, the differences of each sleep parameter across two nights were examined for their distribution by using a Kolmogorov-Smirnov test and histogram. If they were normally distributed, paired-sample t-tests were then performed. If the data were skewed, a value of skewness would then be explored. If skewness was close to zero, a signed rank test was then employed; otherwise, a sign test was used. Scatter plots were employed to illustrate correlation and differences between the data collected on the two nights of observation. Correlation coefficients of each sleep parameter between two nights were also identified. Both Pearson's coefficient and Spearman's rank order coefficients were computed for all 10 parameters. The linear relationship between each

parameter was explained by Pearson's coefficient. If Pearson provided a correlation coefficient less than what Spearman's rank did, then Spearman's rank correlation, which measured the rank order of the data, was used to represent the relationship.

The results were presented in the following order: 1) characteristics of the samples, and 2) the first night effect (FNW) in two consecutive nights of laboratory PSG in communitydwelling older adults, age 70 years and older. According to FNE, the difference between 10 sleep parameters across two consecutive nights of laboratory PSG were compared, including, time in bed (TIB), sleep onset latency (SOL), wake after sleep onset (WASO), total sleep time (TST), sleep efficiency (SE), stage N1, stage N2, stage N3, stage R, and REM latency.

Characteristics of the Samples

To answer this question, data from subjects who had both a first and second night of laboratory PSG were included in the analysis. Of the 63 subjects with sleep data, three subjects did not have first night's sleep data and two other subjects did not have second night's sleep data, thus reducing sample to 58 subjects with complete sleep data. Among these 58 eligible cases, 13 subjects went to the sleep laboratory twice and provided two different sets of data that were acquired 12 months apart. Taking the issue of independence of data into account, the first visit data from these 13 cases were excluded from the analysis. Consequently, 45-paired records (71.43%) were included in the analysis. Figure 6 shows a schematic diagram indicating the flow of study subject selection though the study.

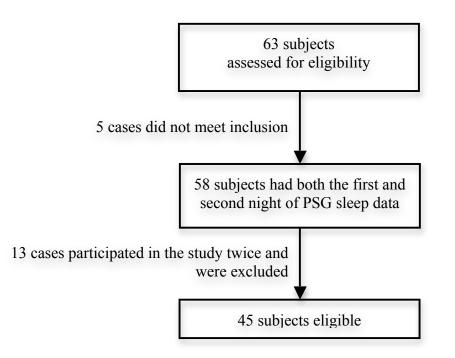


Figure 6. A schematic diagram indicating the flow of study subject selection though the study.

There were 45 older adults with both a first and second night of laboratory PSG sleep data, ranging in age from 70 to 88 years (M = 79.21, SD = 5.07 years). Fifty-six percent were female. The majority of subjects were Caucasian (93.33%). The subjects' body mass index ranged from 19.43 to 37.21 kg/m² (M = 26.51, SD = 3.92), with 80.95% of values below 30 kg/m². No subject had impairment of everyday function as evidenced by the following: 1) all scores on the Mini Mental State Examination (MMSE) were above 24 points (M = 29.07, SD = 1.52), 2) scores on the Older Adults Resource Services (OARS) Independent Activities of Daily Living Scale were above 12 points (M = 27.63, SD = 0.79), and 3) all scores on the 15 item Geriatric Depression Scale (GDS) were below 5 points (M = 1.14, SD = 1.39). Subjects did complain of sleep problem. Scores on the Pittsburgh Sleep Quality Index (PSQI) ranged from 0 to 12 (M = 4.60, SD = 3.01) and 13 subjects (28.89%) had scores of at least five points, and

indication of poor sleep quality. The Epworth Sleepiness Scale (ESS) scores ranged from 0 to 15 (M = 6.44, SD = 3.76) and seven subjects (17.95%) reported having daytime sleepiness. Table 5 shows characteristics of the analysis subset.

Table 5

Characteristics of the Analysis Subset (N=45)

Characteristics	Analysis Subset		
-	n	Value	
Age (year), $M \pm SD$	43	79.21 ± 5.07	
Gender	45		
Female, N (%)		25 (55.56 %)	
Male, N (%)		20 (44.44 %)	
Race	45		
Caucasian, N (%)		42 (93.33 %)	
African American, N (%)		3 (6.67 %)	
BMI (kg/m ²), $M \pm SD$	42	26.51 ± 3.92	
Normal (18.5 – 24.9), N (%)		17 (40.48 %)	
Overweight (25 – 29.9), N (%)		17 (40.48 %)	
Obese (30.0 and above), N (%)		8 (19.05 %)	
MMSE	43	29.07 ± 1.52	
Normal (> 24 points), N (%)		43 (100 %)	
OARS	43	27.63 ± 0.79	
Normal (> 12 points), N (%)		43 (100 %)	
GDS	43	1.14 ± 1.39	
Normal (< 5 point), N (%)		43 (100 %)	
PSQI	45	4.60 ± 3.01	
Good sleep quality (\leq 5 scores), N (%)		32 (71.11 %)	
Poor sleep quality (> 5 scores), N (%)		13 (28.89 %)	
Total sleep time (minute), $M \pm SD$		430.23 ± 66.59	
ESS	39	6.44 ± 3.76	
Normal (< 10 scores), N (%)		32 (82.05 %)	
Sleepy (≥ 10 scores), N (%)		7 (17.95 %)	

Note. BMI = Body Mass Index; MMSE = Mini Mental State Examination; OARS = the Older Adults Resource Services Independent Activities of Daily Living Scale; GDS = Geriatric Depression Scale; PSQI = Pittsburgh Sleep Quality Index; and ESS = Epworth Sleepiness Scale.

The First Night Effect in two Consecutive Nights of Laboratory Sleep PSG in Community-Dwelling Older Adults, age 70 Years and Older

Characteristics of sleep parameters, including the median, mean, and standard deviations, observed in community-dwelling elders, age 70 years and older, are shown in Table 6. To identify a first night effect, the differences between two nights for 10 sleep parameters (TIB, SOL, WASO, TST, SE, stage N1, stage N2, stage N3, stage R, and REM latency) were examined. In addition, the relationships of all 10 parameters were explored by Pearson and Spearman's rank correlation coefficients (Table 7).

Table 6

Characteristics and Differences of Sleep Parameters Between two Consecutive Nights of

Laboratory PSG

Parameter	N	Median	Mean	SD	Difference	t/z	P-value
Time In Bed (minute)							
The first night	45	462.50	462.83	37.89	5.72	1.10	NS
The second night	45	486.00	468.55	38.78	5.12	1.10	110
Sleep Onset Latency (m	inute)						
The first night	45	12.50	32.69	56.29	-19.62	-6.5 ⁺	NS
The second night	45	9.00	13.07	12.06	-19.02	-0.5	IND
Wake After Sleep Onset	(minu	te)					
The first night	45	87.50	96.77	54.76	-20.37	-2.72	< .01
The second night	45	65.50	76.40	47.61	-20.37	-2.12	< .01
Total Sleep Time (minut	te)						
The first night	45	331.00	318.59	82.98	51.48	4.47	< .0001
The second night	45	378.50	370.06	45.06	51.40		
Sleep Efficiency (minute)							
The first night	45	73.30	69.01	17.45	10.24	4 (7	< 0001
The second night	45	80.10	79.25	9.50	10.24	4.67	<.0001
Stage N1 (%)							
The first night	44	17.98	19.24	9.34	2 40	2 2 1	< 05
The second night	45	13.20	15.72	8.89	-3.40	-2.21	< .05

Parameter	N	Median	Mean	SD	Difference	t/z	P-value
Stage N2 (%)							
The first night	45	34.59	35.36	10.17	-2.93	-1.55	NS
The second night	45	31.14	32.44	9.32	-2.95	-1.55	IND
Stage N3 (%)							
The first night	45	27.00	26.36	10.59	2.04	7.50^{+}	< 05
The second night	45	29.67	30.31	10.56	3.94	7.50	< .05
Stage R (%)							
The first night	45	18.51	19.32	7.97	2.22	1.91	NC
The second night	45	21.75	21.54	6.09	2.22	1.91	NS
REM Latency (minute)							
The first night	44	113.50	131.36	88.22	20.65	2.24	< 05
The second night	45	76.00	104.27	74.14	-30.65	-2.34	< .05

Note. ⁺ Sign test was used to analyze data.

Table 7

Correlation of Sleep Parameter Between two Nights

Parameter	Correlation Coefficient		
	Pearson	Spearman	
Time in Bed (TIB)	0.59**	0.46**	
Sleep Onset Latency (SOL)	0.36*	0.38*	
Wake After Sleep Onset (WASO)	0.53**	0.66**	
Total Sleep Time (TST)	0.40**	0.40**	
Sleep Efficiency (SE)	0.54**	0.58**	
Stage N1	0.38*	0.46**	
Stage N2	0.16 ^{ns}	0.16 ^{ns}	
Stage N3	0.42**	0.48**	
Stage R	0.41**	0.43**	
REM Latency	0.42**	0.15 ^{ns}	

Note. * *p* < .05; ** *p* < .01.

Time in bed (TIB).

Overall, subjects spent more than 7.5 hours laid down in bed, from lights out until lights

on. Mean TIB for the first and the second night were 462.83 (SD = 37.89), and 468.55 (SD =

38.78) minutes, respectively. A paired-samples t test was conducted to examine the difference of

TIB between the first and second night and there was no statistically significant difference,

t(44) = 1.10, p > .05.

The relationship of TIB between two consecutive nights was plotted (Figure 7). As shown in Table 7, Pearson provided a correlation coefficient more than what Spearman's rank did, thus, there was a significant moderate positive linear relationship of TIB between the two nights, r = 0.59, p < .01.

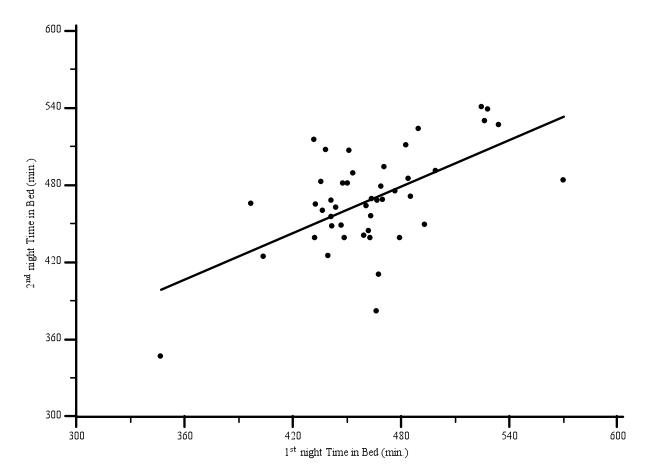


Figure 7. Relationship of time in bed (TIB) between two nights (n=45).

Note. Line represents a regression line of the first night TIB on the second night TIB. Each dot represents each subject.

The mean change between two nights was 5.72 minutes (SD = 34.77), indicating that on average during the second night subjects spent only 5 minutes longer in bed from the lights out

to lights on as compared to the first night. As seen in Figure 8, change from baseline TIB was scattered all over the plot and did not correlate with the magnitude of the first night TIB.

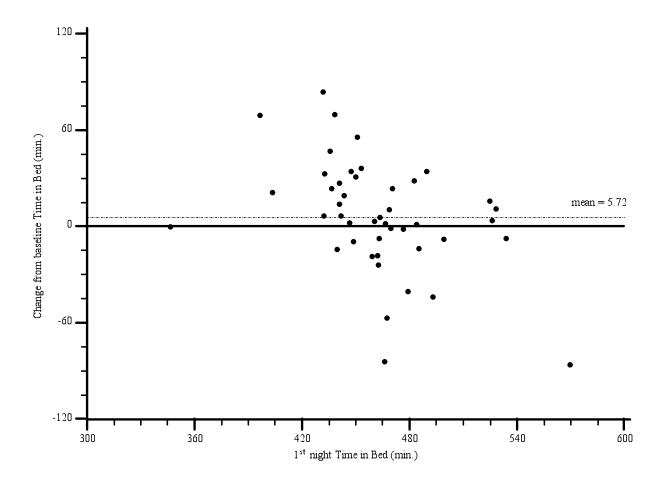


Figure 8. Relationship between change from baseline time in bed (TIB) and the first night TIB (n=45).

Note. Changes were calculated by the second night TIB minus the first night TIB. Each circle represents one subject.

Sleep onset latency (SOL).

During the first night subjects took on average 32.69 minutes (SD = 56.29) until they actually went to sleep, while during the second night, subjects took only 13.07 minutes (SD =

12.06). Differences of SOL between two nights were not normally distributed, D = 0.25, p < .01, as demonstrated by histogram (Figure 9). Using a sign test, there was no statistically significant difference for SOL between the two nights (z = -6.5, p > .05).

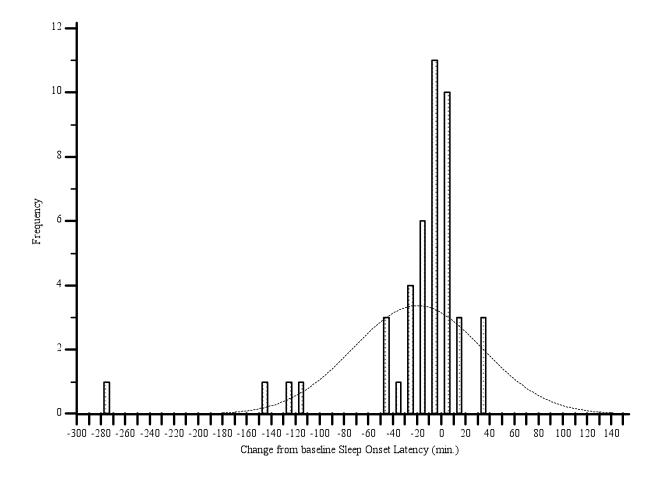


Figure 9. Histogram of change from baseline sleep onset latency (SOL) (n=45). *Note.* Changes were calculated by the first night SOL minus the second night SOL.

The first and second night SOL were plotted to show their relationship (Figure 10). As shown in Table 7, Spearman provided a higher value of correlation coefficient than Pearson, SOL between two nights was then ranked. The relationship of ranked SOL between two nights was illustrated in Figure 11. Using Spearman's rank correlation coefficient, there was a significant but low, positive relationship between the two nights on SOL, $r_s = 0.38$, p < .05.

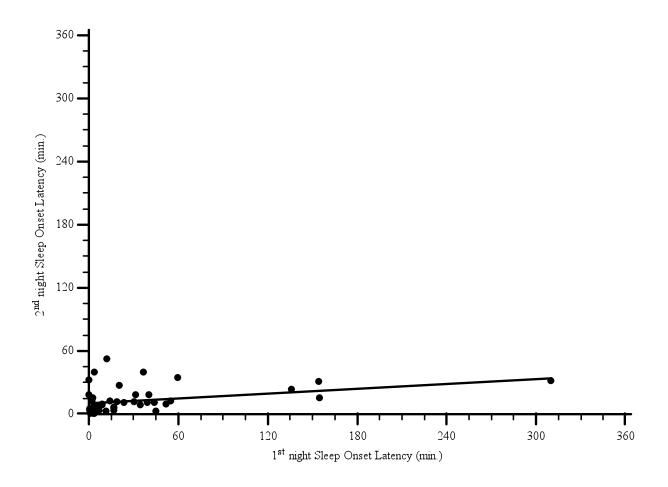


Figure 10. Relationship of sleep onset latency (SOL) between two nights (n=45). *Note.* Line represents a regression line of the first night SOL on the second night SOL. Each dot represents each subject.

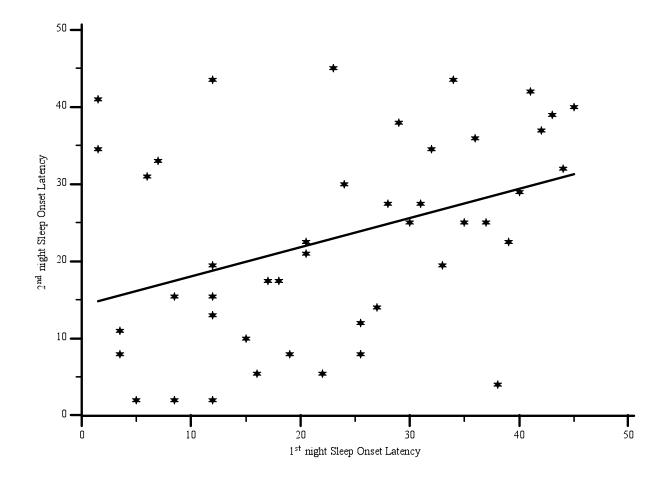


Figure 11. Relationship of ranked sleep onset latency (SOL) between two nights (n=45). *Note.* Line represents a regression line of the first night's ranked SOL on the second night's ranked SOL. Each star represents one subject.

A scatter plot of how SOL changed from the baseline against the first night SOL was shown in Figure 12. The mean change between two nights was -19.62 minutes (SD = 53.19), indicating that subject had spent approximately 20 minutes less than the first night in order to fall asleep. Change in SOL from baseline had a negative linear relationship with the magnitude of the first night SOL; when the magnitude of the first night SOL increased, the magnitude of changes from baseline also increased in the opposite direction. Using 30 minutes as a cut point, when a subject had a first night SOL of less than 30 minutes, the change of SOL from baseline was not specific, and the second night SOL could either increase or decrease from what subjects had during the first night. On the other hand, when a subject had a first night SOL of more than 30 minutes, the change of SOL from baseline was located under the zero line, indicating that subject would have fewer minutes of SOL during the second night.

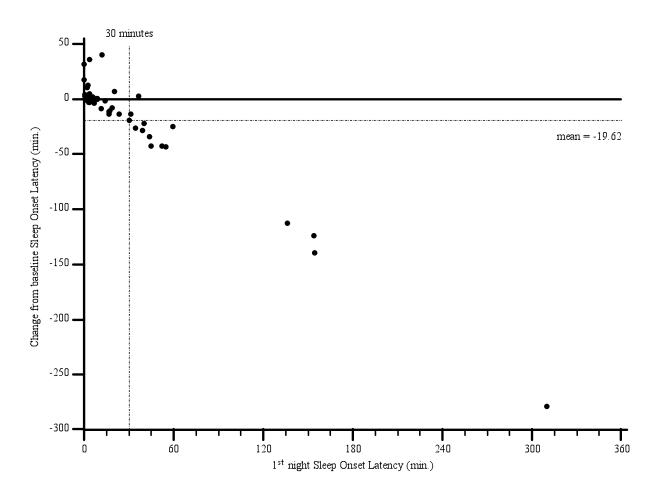


Figure 12. Relationship between change from baseline sleep onset latency (SOL) and the first night SOL (n=45).

Note. Changes were calculated by the second night SOL minus the first night SOL. Each dot represents one subject.

Wake after sleep onset (WASO).

Average WASO for the first and second night were 96.77 (SD = 54.76) and 76.40 (SD = 47.61), respectively. During the second night, subjects demonstrated statistically significantly less WASO than what they had during the first night, t(44) = -2.72, p < .01.

A scatter plot of WASO between the two nights is shown in Figure 13. As seen in Table 7, Spearman's rank provided a correlation coefficient more than what Pearson did, so WASO between the two nights was ranked and their relationship is shown in Figure 14. Using Spearman's rank correlation coefficient, there was a significant moderate positive relationship between the first and second night on WASO, $r_s = 0.66$, p < .01.

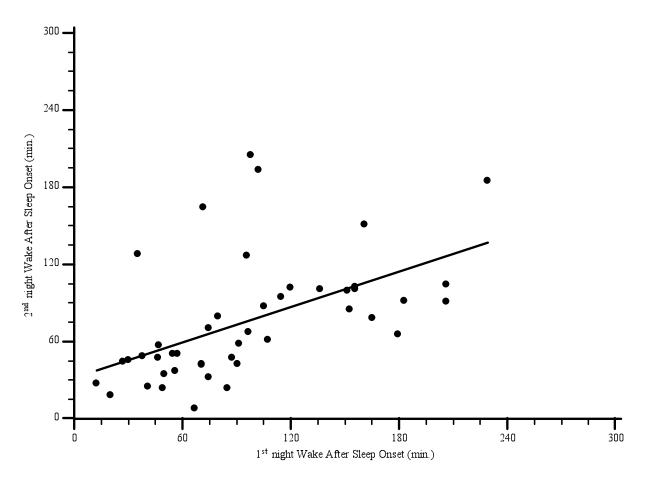


Figure 13. Relationship of wake after sleep onset (WASO) between two nights (n=45).

Note. Line represents a regression line of the first night WASO on the second night WASO. Each dot represents each subject.

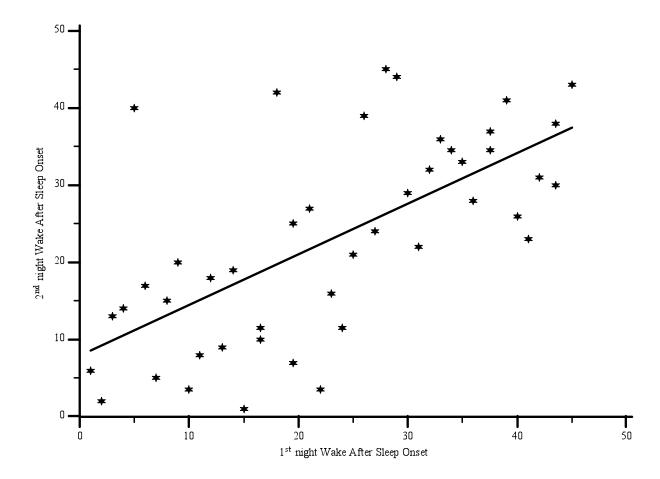


Figure 14. Relationship of ranked wake after sleep onset (WASO) between two nights (n=45) *Note.* Line represents a regression line of the first night ranked WASO on the second night ranked WASO. Each star represents each subject.

The relationship between change from the baseline WASO and the first night WASO is illustrated in Figure 15. The mean change of WASO between two nights was -20.37 minutes (*SD* = 50.21), indicating that on average during the second night subjects spent around 20 minutes less time awake than what they did during the first night. Change in WASO from baseline had a negative linear relationship with the magnitude of the first night WASO; when the magnitude of the first night WASO increased, the magnitude of changes from baseline also increased in the

opposite direction. A cut point of 105 minutes was identified. When the subject had a first night WASO of less than 105 minutes, the second night WASO was not specific; it could be better or worse than what they had on the first night. However, when subjects had a first night WASO of more than 105 minutes, then during the second night they awoke less often after they went to sleep.

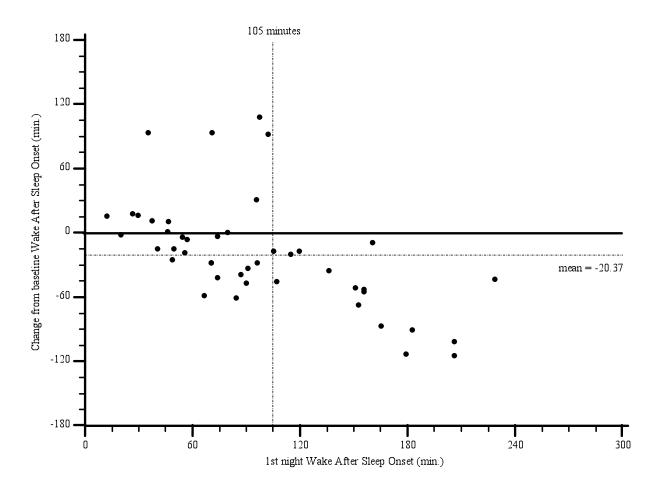


Figure 15. Relationship between change from baseline wake after sleep onset (WASO) and the first night WASO (n=45).

Note. Changes were calculated by the second night WASO minus the first night WASO. Each dot represents one subject.

Total sleep time (TST).

On average, during the first night subjects slept for 318.59 minutes (SD = 82.98), or slightly less than 5.5 hours. During the second night, subjects had a better sleep and on average they slept for 370.06 minutes (SD = 45.06), or more than 6 hours. A paired-sample t-test confirmed significant differences between the two nights, t(44) = 4.47, p < .0001.TST during the second night was significantly higher in comparison to the first night.

Figure 16 shows the relationship of TST between the first and second nights. As seen in Table 7, there was a significant low positive linear relationship between the first and second night on TST, r = 0.40, p < .01.

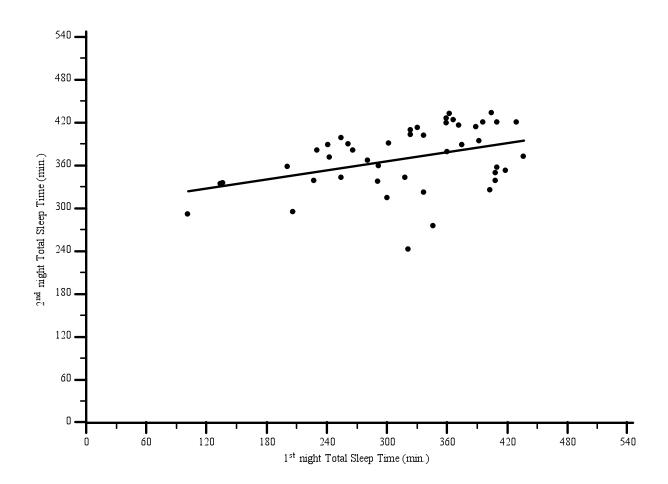


Figure 16. Relationship of total sleep time (TST) between two nights (n=45). *Note.* Line represents a regression line of the first night TST on the second night TST. Each dot represents each subject.

As seen in Figure 17, there was a negative linear relationship between change from the baseline TST and the first night TST. Mean change in TST from baseline was 51.48 minutes, indicating that during the second night, subjects slept around 52 minutes more than what they had during the first night. Change in TST from baseline declined as the magnitude of the first night TST increased. During the first night, when subjects slept less than 7 hours, the majority of change from baseline TST was positive, which revealed that when subject had less than 7 hours

of sleep during the first night, they had longer sleep during the second night. However, when subject slept more than 7 hours during the first night, the second night TST declined and was less than the first night TST.

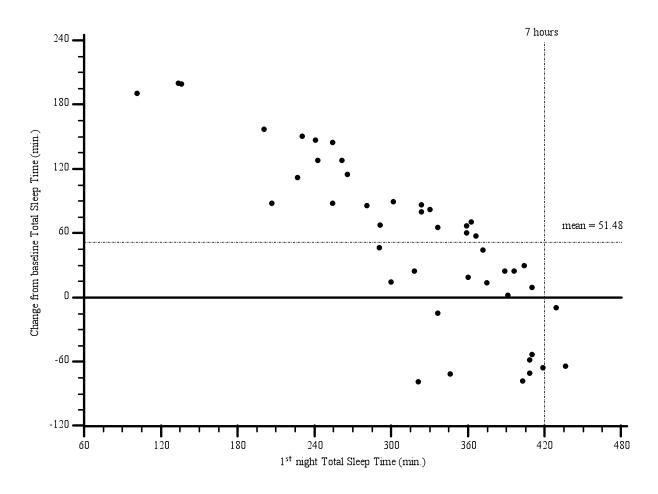


Figure 17. Relationship between change from baseline total sleep time (TST) and the first night TST (n=45).

Note. Changes were calculated by the second night TST minus the first night TST. Each dot represents one subject.

Sleep efficiency (SE).

On average subjects' SE was at least 70% for both consecutive nights. Mean SE for the first and the second night were 69.01 (SD = 17.45) and 79.25 (SD = 9.50), respectively. A paired-sample t-test showed that subjects' SE during the second night was statistically significantly different than those during the first night, t(44) = 4.67, p < .0001. During the second night, SE was significant higher in comparison to the first night.

Figure 18 shows a scatter plot of SE between the first and second night of the sleep study. As seen in Table 7, the value of Pearson correlation coefficient was less than the value of Spearman's rank correlation coefficient, indicating that the relationship of SE between the two nights was monotonic. Thus, SE was ranked. A scatter plot (Figure 19) represents the relationship of ranked SE between the two nights. Using a Spearman's rank correlation, there was a significant moderate positive relationship between the first and second night on SE, $r_s =$ 0.58, p < .01.

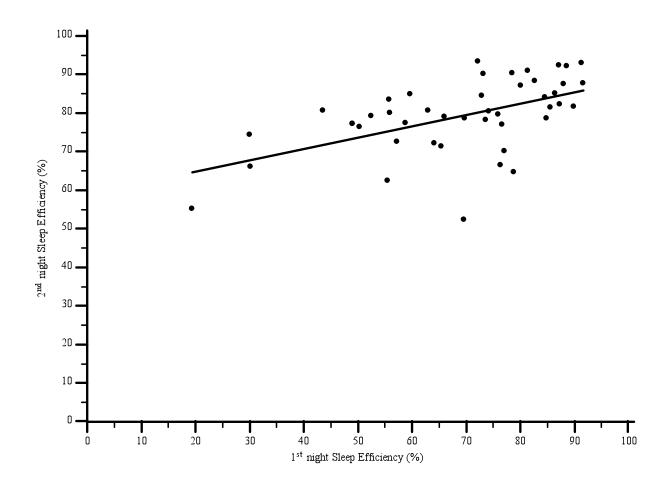


Figure 18. Relationship of sleep efficiency (SE) between two nights (n=45).

Note. Line represents a regression line of the first night SE on the second night SE. Each dot represents each subject.

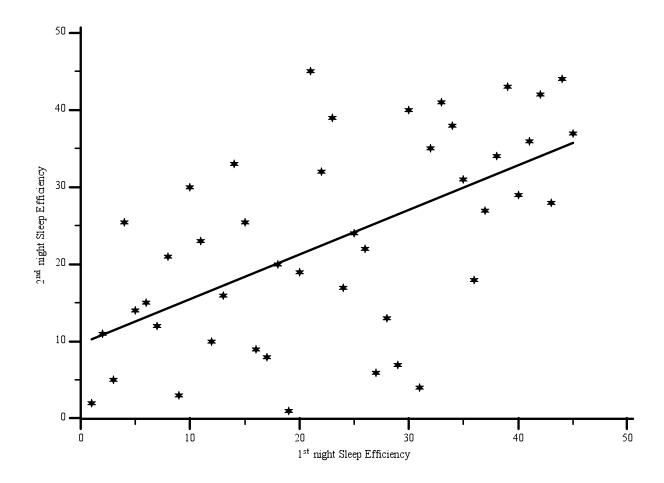


Figure 19. Relationship of ranked sleep efficiency (SE) between two nights (n=45). *Note.* Line represents a regression line of the first night ranked SE on the second night ranked SE. Each star represents each subject.

A negative linear relationship between change from the baseline SE and the first night SE is demonstrated in Figure 20. The mean change of SE between two nights was 10.24 percent (*SD* = 14.70), meaning that on average during the second night subjects had SE more than what they had during the first night. Change in SE from baseline declined when the magnitude of the first night SE increased. An SE cut point of 75% could be used to determine the direction of change in SE. When subjects had a first night SE of less than 75%, the majority of changes from

baseline SE were more than zero, implying that a subject tended to have always had more SE on the second night if his/her first night SE was less than 75%. However, when the first night SE was more than 75%, the second night SE could be either better or worse than that of the first night.

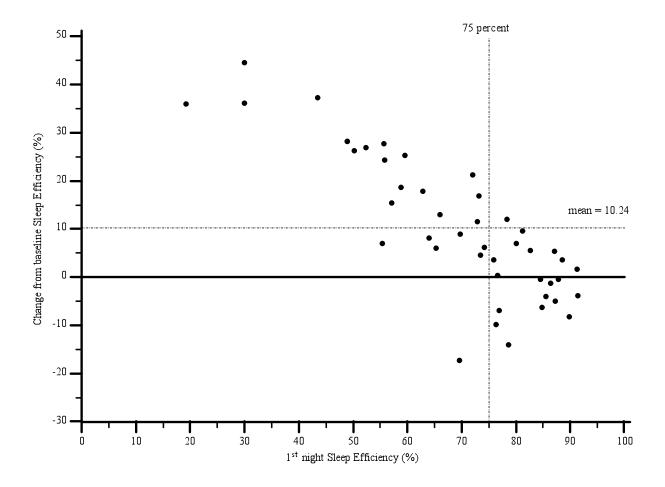


Figure 20. Relationship between change from baseline sleep efficiency (SE) and the first night SE (n=45).

Note. Changes were calculated by the second night SE minus the first night SE. Each dot represents one subject.

Stage N1.

On average, subjects spent 17.54 % of their actual sleep time in stage N1 sleep. Mean percentage of stage N1 for the first and second night was 19.24 % (SD = 9.34) and 15.72 % (SD = 8.89), respectively. A paired-sample t-test showed that the percentage of time subjects spent in stage N1 during their actual sleep was statistically differently different between the two nights, t(43) = -2.21, p < .05. Subject spent time in stage N1 on the first night significantly more than what they did during the second night.

The first and second night stage N1 were plotted to illustrate their relationship (Figure 21). As seen in Table 7, Spearman's rank correlation provided higher value of correlation coefficient than what Pearson correlation did, thus the relationship was monotonic. Stage N1 data were then ranked. A scatter plot was drawn to represent the relationship of ranked stage N1 between the two nights (Figure 22). There was a significant low positive relationship between the first and second night on stage N1 sleep, $r_s = 0.46$, p < .01.

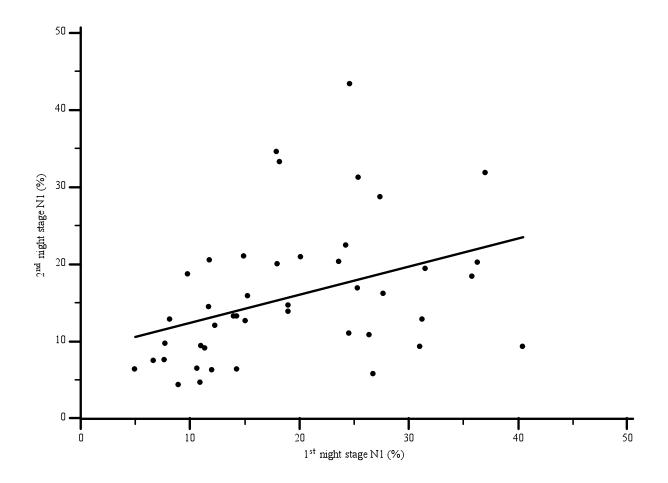


Figure 21. Relationship of stage N1 between two nights (n=44).

Note. Line represents a regression line of the first night stage N1 on the second night stage N1. Each dot represents each subject.

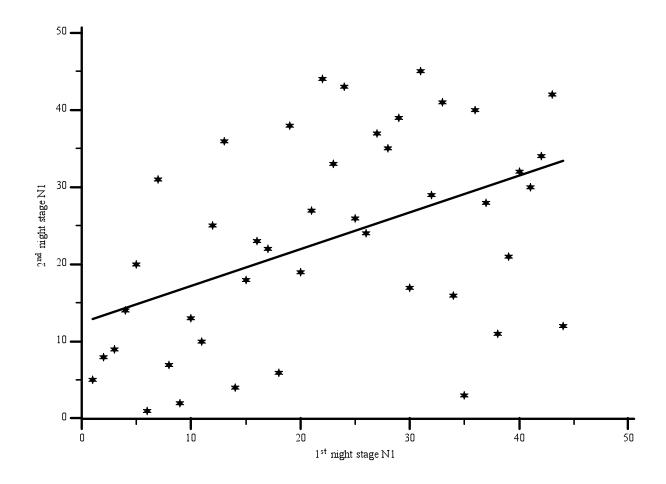


Figure 22. Relationship of ranked stage N1 between two nights (n=44).

Note. Line represents a regression line of the first night ranked stage N1 on the second night ranked stage N1. Each star represents each subject.

The mean change of stage N1 sleep between two nights was -3.40 percent (SD = 10.18), indicating that on average during the second night subjects had 3 percent less of stage N1 sleep than what they had during the first night. When a relationship between change from the baseline stage N1 and the first night stage N1 was examined, change in stage N1 from baseline declined when the magnitude of the first night SE increased (Figure 23). Twenty-eight percent of stage N1 could be used as a cut point to determine the direction of change in stage N1. When subjects had

a first night stage N1 of less than 28%, changes from baseline SE were scattered; it could be better or worse compared to the baseline. However, when the first night stage N1 was more than 25%, changes from baseline were located below the zero line. This finding implies that when a subject had first night stage N1 of more than 28%, then during the second night the subject spent less percentage of total sleep time on stage N1.

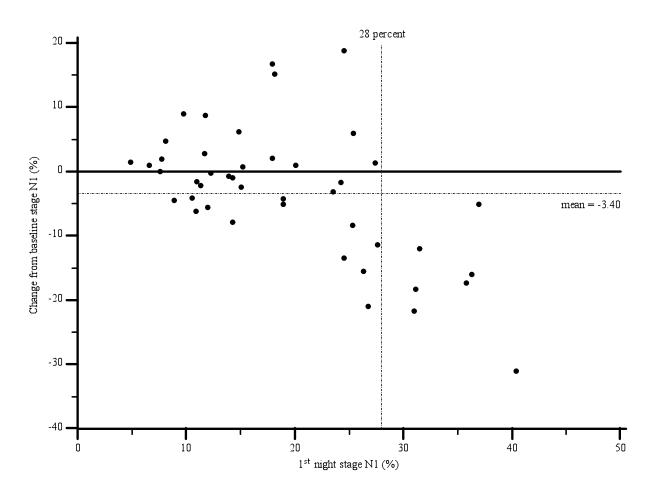


Figure 23. Relationship between change from baseline stage N1 and the first night stage N1 (n=44).

Note. Changes were calculated by the second night stage N1 minus the first night stage N1. Each dot represents one subject.

Stage N2.

Average stage N2 sleep during the first and second night were 35.36 percent (SD = 10.17) and 32.44 percent (SD = 9.32), respectively. A paired-sample t-test showed that the percentage of actual sleep time that subjects spent in stage N2 between two nights was not statistically different, t(44) = -2.93, p > .05.

A scatter plot was drawn to show the relationship of stage N2 between the two nights (Figure 24). As seen in Table 7, correlation coefficient by Pearson and Spearman's rank was identical, so stage N2 data were then ranked. Figure 25 shows the relationship between two nights on ranked stage N2 data. However, both Pearson and Spearman's rank showed that this relationship was not statistically significant.

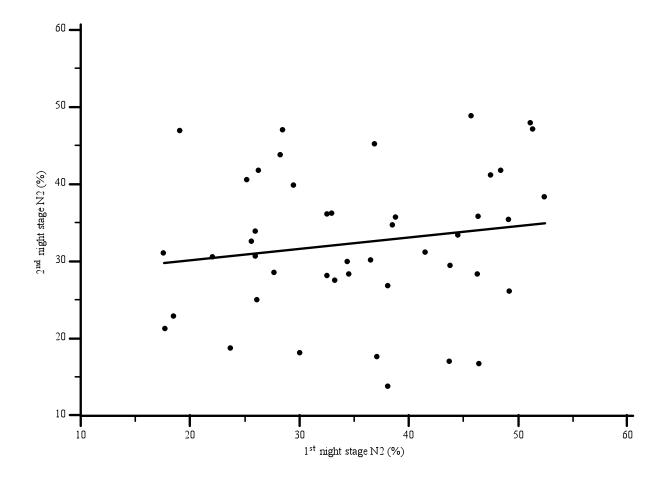


Figure 24. Relationship of stage N2 between two nights (n=45).

Note. Line represents a regression line of the first night stage N2 on the second night stage N2. Each dot represents each subject.

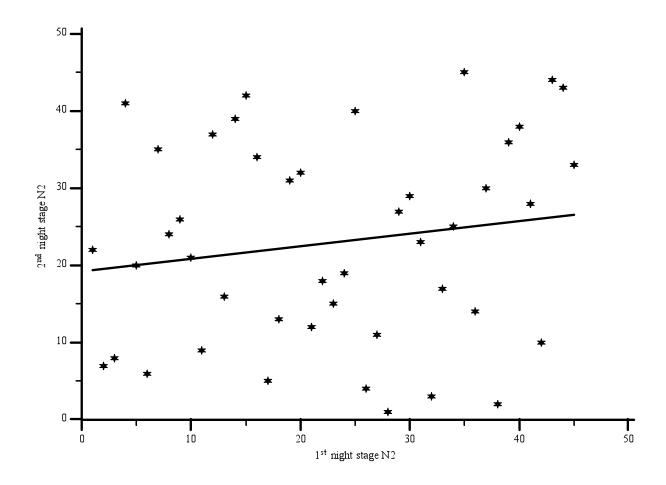


Figure 25. Relationship of ranked stage N2 between two nights (n=45). *Note.* Line represents a regression line of the first night ranked stage N2 on the second night ranked stage N2. Each star represents each subject.

The mean change of stage N2 sleep between the two nights was -2.93 percent (SD = 12.65), meaning that on average during the second night subjects had 3 percent less of stage N2 than during the first night. There was a negative linear relationship between change from the baseline stage N2 and the first night stage N2 (Figure 26), meaning change in stage N2 from baseline decreased when the magnitude of the first night stage N2 increased. Based on this Figure, 46% of stage N2 during the first night could be used as a cut point to determine the

direction of change in stage N2 from baseline. When subjects had a first night stage N2 of less than 46%, the majority of changes from baseline stage N2 were not specific; it could be improve or decline. However, when the first night stage N2 was more than 46%, all changes from baseline were located below the zero line. Thus, when subject had the first night stage N2 of more than 46%, the second night stage N2 would be less than what they had on the first night.

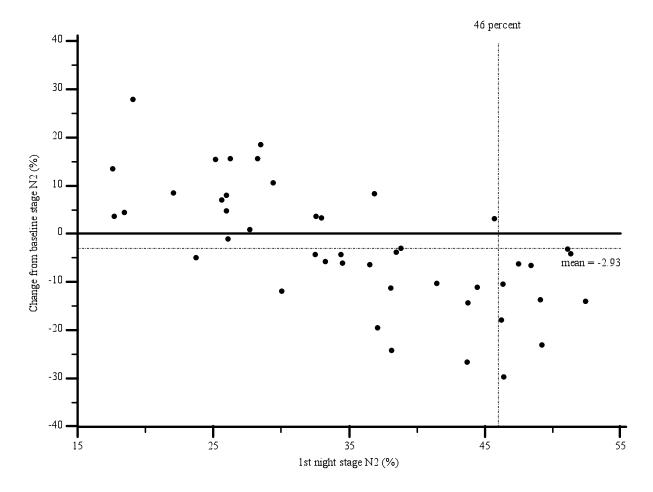


Figure 26. Relationship Between change from baseline stage N2 and the first night stage N2 (n=45).

Note. Changes were calculated by the second night stage N2 minus the first night stage N2. Each dot represents one subject.

Stage N3.

Subjects had a median of 27 percent (M = 26.36, SD = 10.59) for the first night stage N3 and a median of 29.67 percent (M = 30.31, SD = 10.56) for the second night stage N3. The differences of stage N3 between two nights were not normally distributed, D = 0.15, p < .05. A histogram was illustrated to present how the data were distributed (Figure 27). Using a sign rank test, the difference of stage N3 between the two nights was statistically significant, z = 7.5, p <.05. Subjects had more percentage of stage N3 on the second night more than what they had during the first night.

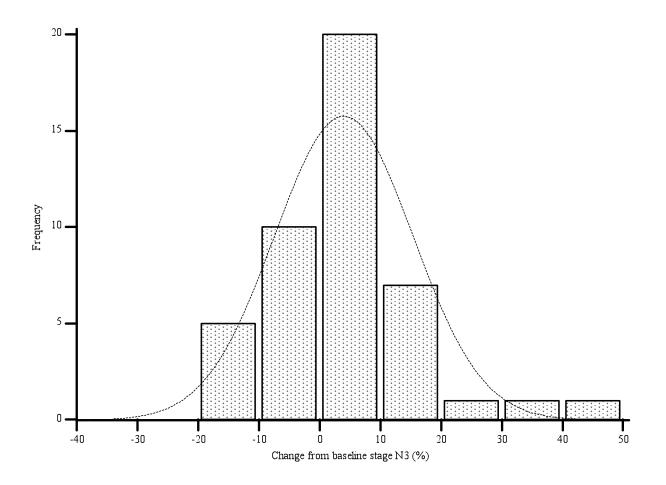


Figure 27. Histogram of change from baseline stage N3 (n=45).

Note. Changes were calculated by the first night stage N3 minus the second night stage N3.

Figure 28 shows the relationship of stage N3 between two nights. However, this relationship was better explained by monotonic relationship (Table 7). Thus, stage N3 data were ranked. A scatter plot of ranked stage N3 was drawn (Figure 29). Using Spearman's rank correlation, there was a significant low positive relationship between stage N3, $r_s = 0.48$, p < .01.

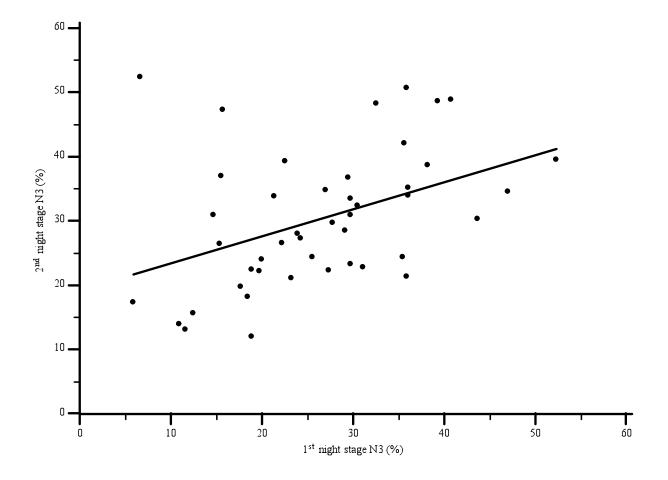


Figure 28. Relationship of stage N3 between two nights (n=45).

Note. Line represents a regression line of the first night stage N3 on the second night stage N3. Each dot represents each subject.

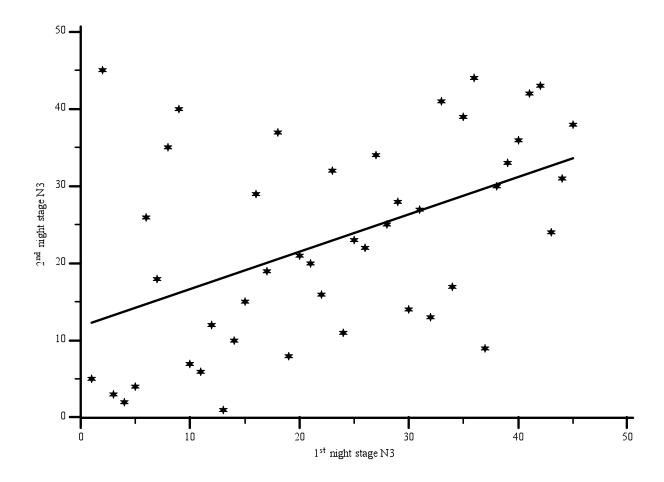


Figure 29. Relationship of ranked stage N3 between two nights (n=45).

Note. Line represents a regression line of the first night ranked stage N3 on the second night ranked stage N3. Each star represents each subject.

The mean change of stage N3 sleep between two nights was 3.94 percent (*SD* = 11.39), meaning that on average during the second night subjects had 4 percent more stage N3 than what they had during the first night. There was a negative linear relationship between the change from the baseline stage N3 and the first night stage N3 (Figure 30). Change in stage N3 from baseline decreased when the magnitude of the first night stage N3 increased. When the first night stage N3 was more than 41%, change from baseline stage N3 was located under the zero line,

indicating that the second stage N3 was less than the first night stage N3. However, when the first night stage N3 was less than 41%, change from baseline was not specific and was scattered all over the plot.

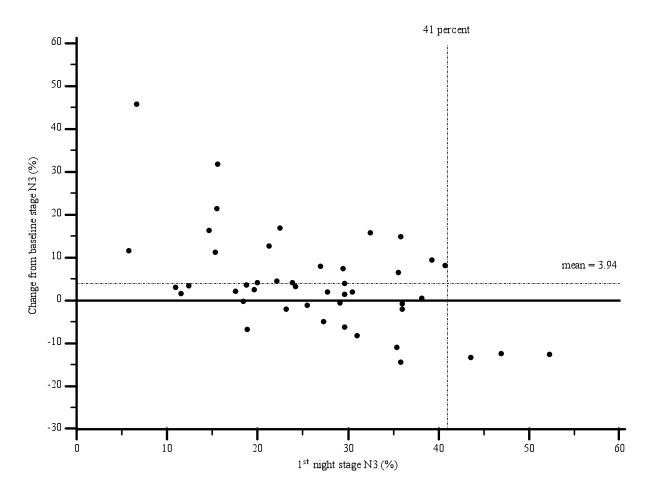


Figure 30. Relationship between change from baseline stage N3 and the first night stage N3 (n=45).

Note. Changes were calculated by the second night change in stage N3 minus the first night stage N3. Each dot represents one subject.

Stage R.

On the first night, mean percentage of stage R from total sleep time was 19.32 percent

(SD = 7.97), while the second night showed a higher percentage of stage R, with a mean of 21.54 percent (SD = 6.09). A paired-sample t-test showed that there was no statistically significant difference for stage R between the two nights, t(44) = 1.91, p > .05.

A positive relationship of stage R between the two nights is shown in Figure 31. As seen in Table 7, the relationship of stage R between two nights was monotonic but not necessarily linear. Thus, stage R data were ranked and their relationship is shown in Figure 32. Using Spearman's rank correlation, there was a significant but small positive relationship of stage R between two nights, $r_s = 0.43$, p < .01.

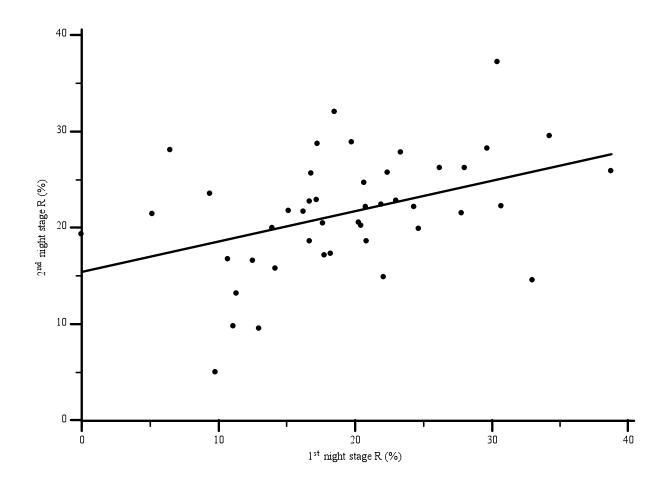


Figure 31. Relationship of stage R between two nights (n=45).

Note. Line represents a regression line of the first night stage R on the second night stage R. Each dot represents each subject.

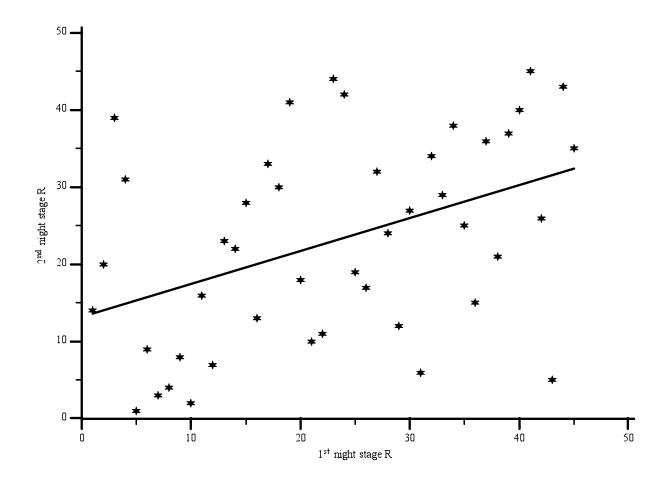


Figure 32. Relationship of ranked stage R between two nights (n=45).

Note. Line represents a regression line of the first night ranked stage R on the second night ranked stage R. Each star represents each subject.

The mean change of stage R sleep between the two nights was 2.22% (SD = 7.77), meaning that on average during the second night subjects had 2 percent more stage R than what they had during the first night. There was negative linear relationship between change from the baseline stage R and the first night stage R (Figure 33). Change in stage R from baseline decreased when the magnitude of the first night stage R increased. When the first night stage R was more than 31%, change from baseline stage R was located under the zero line, indicating that the second night stage R was less than the first night stage R. However, when the first night stage R was less than 31%, change from baseline was not specific and was scattered all over the plot, either above or below the zero line.

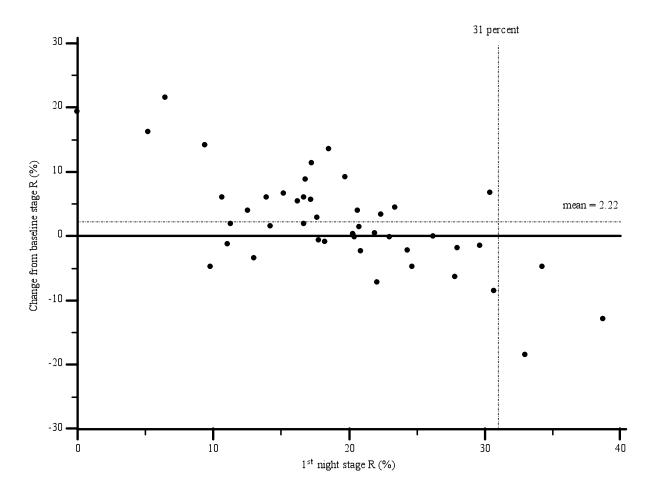


Figure 33. Relationship between change from baseline stage R and the first night stage R (n=45). *Note.* Changes were calculated by the second night change in stage R minus the first night stage R. Each dot represents one subject.

REM latency.

Average REM latencies for the first and the second night were 131.36 (SD = 88.22), and 104.27 (SD = 74.14), respectively. There was significantly more REM Latency on the first night then on the second night, t(43) = -2.34, p < .05.

REM latency was plotted to show its relationship between the first and second night (Figure 34). As seen in Table 7, there was a significant low positive linear relationship of REM latency between the two nights, r = 0.42, p < .01.

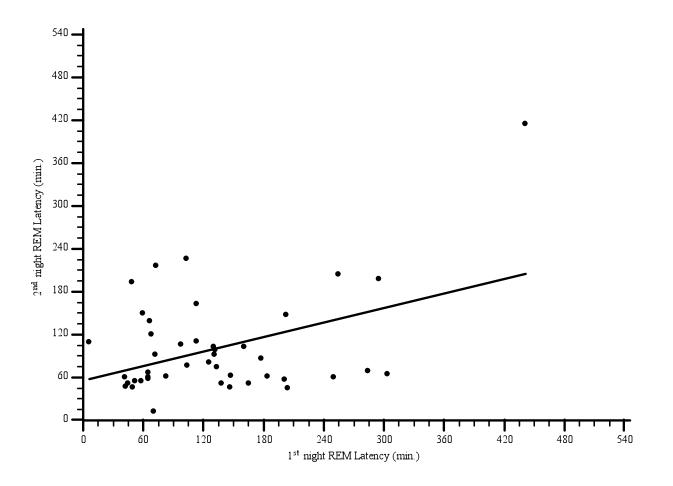


Figure 34. Relationship of REM latency between two nights (n=45). *Note.* Line represents a regression line of the first night REM latency on the second night REM latency. Each dot represents each subject.

The mean change of REM latency between the two nights was -30.65 percent (*SD* = 86.97), meaning that on average during the second night subjects had 31 minutes less REM latency than what they had during the first night. There was a negative linear relationship between the change from the baseline REM latency and the first night REM latency (Figure 35). Change in REM latency from baseline decreased when the magnitude of the first night REM latency increased. When the first night REM latency was more than 120 minutes, change from baseline REM latency was located under the zero line, indicating that the second REM latency was less than the first night REM latency. However, when the first night REM latency was less than 120 minutes, change from baseline was not specific; it was located either above or below the zero line, indicating that the second night REM latency could be shorter or longer.

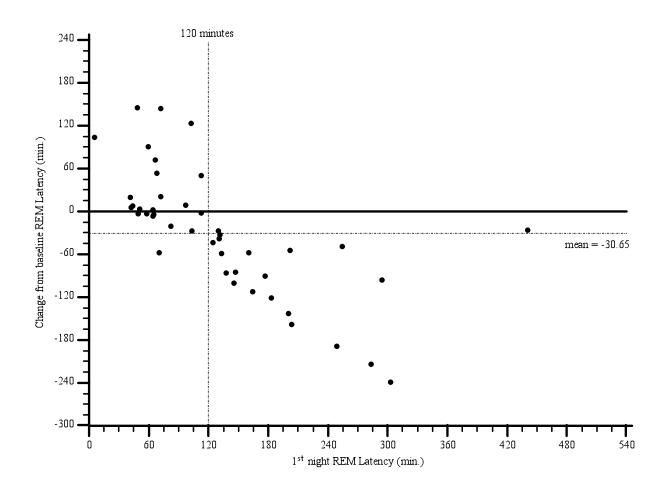


Figure 35. Relationship between change in REM latency and the first night REM latency (n=45). *Note.* Changes were calculated by the second night REM latency minus the first night REM latency. Each circle represents one subject.

Summary of Results

During two consecutive nights of laboratory polysomnography (PSG), Time in Bed (TIB), Sleep Onset Latency (SOL), stage N2, and stage R were similar on both nights. However, there was significantly more Wake After Sleep Onset (WASO), stage N1 and REM latency during the first night. On the other hand, Total Sleep Time (TST), Sleep Efficiency (SE), and stage N3 during the second night was significantly higher than those on the first night. Thus,

First Night Effect (FNE) occurred in community-dwelling older adults, age 70 years and older, who had undergone a laboratory PSG.

Characteristics of Sleep in Community-Dwelling Older Adults

Since we found a first night effect in this study, characteristics of sleep in communitydwelling older adults in this study is presented based on the second night PSG sleep data. Of those 63 subjects with PSG sleep data, two subjects did not have the second night sleep data. Among 61 eligible cases, 13 subjects went to the PSG sleep laboratory twice. Thus, the first visit data from these 13 were eliminated from the analysis. The second night PSG sleep parameters were reported based on 48 community-dwelling older adults, age 70 years and older. During the second night of laboratory PSG sleep, subjects spent approximately 466.28 minutes (SD = 39.48) or almost 8 hours in bed with the intention to sleep. After they went to bed, on average, they took 13.35 minutes (SD = 11.75) until they actually felt asleep. The WASO was 80.02 minutes (SD = 50.46) or almost one and a half hours. The TST was 364.11 (SD = 50.33) or more than 6 hours. Their SE was quite high with 78.31 percent (SD = 10.28). The proportions of sleep stages to TST (i.e. stage N1, stage N2, stage N3, and stage R) were 15.14 (SD = 8.90), 32.13 (SD = 9.13), 30.37 (SD = 10.57), and 22.36 (SD = 7.15), respectively. The REM latency was 101.57 minutes (SD = 72.61).

CHAPTER FIVE RESEARCH QUESTION TWO RESULTS

This chapter presents the results of the secondary data analysis study covering research question two: How accurate is actigraphy when compared to polysomnography (PSG) in measuring sleep in community-dwelling adults, age 70 years and older? Since there were two sets of sleep data during the first and second nights, separate analyses were performed for each night to examine whether or not there were similar patterns of results between the two sets of data.

Since this was a method-comparison study, four different approaches were used, including comparison of means, Intraclass Correlation Coefficients (ICCs), correlation and regression models, and Bland-Altman plots. In the method of comparison of means, differences of each sleep parameter across two methods were examined for their distribution by using a Kolmogorov-Smirnov test and histogram. If they were normally distributed, then paired-sample t-tests were performed. If the data were skewed, then a value of skewness was explored. If skewness was closed to zero, then a signed rank test was employed; otherwise, a sign test was then used. The ICCs were also employed to explore the similarity in value between two methods obtained on the same study subject. If the two methods aligned the subject data in a similar manner, the ICC would be high. Correlation and regression models were employed to examine whether there were linear relationships for each sleep parameter between actigraphy and PSG. In regression models, percentage of variance in sleep parameters from PSG that could be explained by actigraphy were presented, along with predictive value of sleep parameters from PSG by sleep parameters from actigraphy. In these regression models, minimum values of each sleep parameter by actigraphy were used if they were different from zero. In doing so, the value of the intercepts in each model represented values of each sleep parameter by PSG when sleep parameter by actigraphy was located at the minimum range of the real data. Bonferroni corrections were employed with significance set at p < .0125 for all inferential statistics. Bland-Altman plots were also depicted to determine the agreement between methods because Bland-Altman plots could represent both bias and precision.

The results presented the accuracy of actigraphy to measure sleep when compared to PSG in community-dwelling adults, age 70 years and older during the first and second night. Differences between three sleep parameters obtained by PSG and actigraphy were evaluated, including sleep onset latency (SOL), wake after sleep onset (WASO), and total sleep time (TST), and the findings were examined to evaluate the accuracy of actigraphy against PSG in measuring sleep. Since actigraphy has four sensitivity settings (i.e. low, medium, high, and auto), all thresholds were applied to obtain different values in order to explore the best sensitivity level that would provide less discrepancy with PSG.

The Accuracy of Actigraphy to Measure the First Night Sleep Parameters When Compared to PSG in Community-Dwelling Older Adults, age 70 Years and Older

Of the 63 subjects with sleep data, only 43 subjects had both laboratory PSG and actigraphy data collected for the first night. Of those 43 subjects, four subjects went to the sleep laboratory twice and provided 2 different sets of data that were acquired 12 months apart. Taking the issue of independence of data into account, the first visit data from these four cases were

excluded from the analysis, reducing the sleep data to 39 subjects that were included in the analysis. Figure 36 shows a schematic diagram indicating the flow of study subject selection though the study.

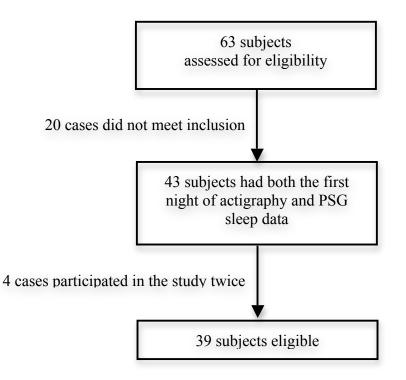


Figure 36. A schematic diagram indicating the flow of study subject selection though the study.

Characteristics of the samples.

There were 39 older adults with both actigraphy and PSG sleep data, ranging in age from 71 to 88 years (M = 79.68, SD = 5.04 years). Fifty-six percent were female. The majority of subjects were Caucasian (94.87%). Body mass indexes ranged from 19.49 to 37.21 (M = 26.63, SD = 3.81) kg/m²; 80.56% had values below 30 kg/m². No subject had impairments of everyday function: all Mini-Mental State Examination (MMSE) scores were above 24 points (M = 29.19, SD = 1.37), all scores on the Older Adults Resource Services (OARS) Independent Activities of Daily Living Scale were above 12 points (M = 27.59, SD = 0.83), and all Geriatric Depression

Scale (GDS) scores were below 5 points ($M = 0.92$, $SD = 1.23$). Subjects complained of having
sleep problems: Pittsburgh Sleep Quality Index (PSQI) scores varied from 0 to 12 ($M = 4.41$, SD
= 2.94): 10 subjects (25.64%) had PSQI scores of at least five points, indicating that they had
poor sleep quality. The Epworth Sleepiness Scale (ESS) scores ranged between 0 and 15 (M =
6.53, $SD = 3.75$) and seven subjects (20.59%) reported having daytime sleepiness. Table 8 shows
characteristics of the analysis subset.

Table 8

Characteristics of the Analysis Subset

Characteristics	Analysis Subset			
-	n	Value		
Age (year), $M \pm SD$	37	79.68 ± 5.04		
Gender	39			
Female, N (%)		22 (56.41%)		
Male, N (%)		17 (43.59%)		
Race	39			
Caucasian, N (%)		37 (94.87%)		
African American, N (%)		2 (5.13%)		
BMI (kg/m ²), $M \pm SD$	36	26.63 ± 3.81		
Normal (18.5 – 24.9), N (%)		14 (38.89%)		
Overweight (25 – 29.9), N (%)		15 (41.67%)		
Obese (30.0 and above), N (%)		7 (19.44%)		
MMSE	37	29.19 ± 1.37		
Normal (> 24 points), N (%)		37 (100%)		
OARS	37	27.59 ± 0.83		
Normal (> 12 points), N (%)		37 (100%)		
GDS	37	0.92 ± 1.23		
Normal (< 5 point), N (%)		37 (100%)		
PSQI	39	4.41 ± 2.94		
Good sleep quality (\leq 5 scores), N (%)		29 (74.36%)		
Poor sleep quality (> 5 scores), N (%)		10 (25.64%)		
ESS	34	6.53 ± 3.75		
Normal (< 10 scores), N (%)		27 (79.41%)		
Sleepy (≥ 10 scores), N (%)		7 (20.59%)		

Note. BMI = Body Mass Index; MMSE = Mini-Mental State Examination; OARS = the Older Adults Resource Services Independent Activities of Daily Living Scale; GDS = Geriatric Depression Scale; PSQI = Pittsburgh Sleep Quality Index; and ESS = Epworth Sleepiness Scale.

Characteristics of sleep.

The time in bed (TIB) was the time between lights out and lights on as recorded in the laboratory sleep study. During the first night, subjects' time in bed was 465.94 minutes (SD = 39.21 minutes). Since PSG and actigraphy was set up with the exact same time clock, TIB measurements between the two methods were identical. Only three sleep parameters, including SOL, WASO, and TST, were compared. Table 9 shows the difference in three sleep parameters as measured by PSG and four different sensitivity settings of actigraphy. Relationships between each sleep parameter by PSG and actigraphy were explored by using both Pearson's and Spearman's rank correlation coefficients (Table 10).

Table 9

Sleep				Difference (Actigraphy - PSG)			ICC	
Parameters	Median	Mean	SD	Mean	SD	t/z	р	(95% CI)
SOL (minute)								
PSG	14.50	35.27	59.75					
Actigraphy								
Low sensitivity	2.00	14.82	37.28	-20.45	48.95	-13.50^{+}	< .0001	0.52 (0.25, 0.71)
Medium sensitivity	2.00	14.82	37.28	-20.45	48.95	-13.50^{+}	< .0001	0.52 (0.25, 0.71)
High sensitivity	2.00	14.82	37.28	-20.45	48.95	-13.50^{+}	< .0001	0.52 (0.25, 0.71)
Auto sensitivity	2.00	14.82	37.28	-20.45	48.95	-13.50^{+}	< .0001	0.52 (0.25, 0.71)
WASO (minute)								
PSG	96.00	103.44	55.19					
Actigraphy								
Low sensitivity	29.00	31.23	19.12	-72.21	52.43	-386.00^{++}	< .0001	0.19 (-0.12, 0.47)
Medium sensitivity	47.00	49.13	23.98	-54.31	51.23	-6.62	< .0001	0.28 (-0.03, 0.54)
High sensitivity	64.00	70.44	31.08	-33.00	52.73	-243.50^{++}	< .001	0.31 (0.00, -0.56)
Auto sensitivity	28.00	32.23	15.99	-71.21	52.24	-370.50^{++}	< .0001	0.17 (-0.14, 0.46)
TST (minute)								
PSG	324.00	315.13	85.63					
Actigraphy								
Low sensitivity	415.00	410.08	60.84	94.95	78.18	375.00^{++}	< .0001	0.45 (0.16, 0.66)
Medium sensitivity	396.00	392.15	62.35	77.03	78.21	6.15	< .0001	0.45 (0.17, 0.67)
High sensitivity	382.00	370.87	65.36	55.74	80.79	11.50^{+}	< .001	0.44 (0.15, 0.66)
Auto sensitivity	416.00	409.08	60.76	93.95	79.15	07.41	<.0001	0.43 (0.15, 0.65)

Characteristics and Differences of the First Night Sleep Parameters by PSG and Actigraphy (n = 39)

Note. SOL = Sleep Onset Latency; WASO = Wake After Sleep Onset; TST = Total Sleep Time; SE = Sleep Efficiency; ICC = Intraclass correlation coefficient; 95% CI = 95% Confidence Interval; ⁺ Sign test was used to analyze data; ⁺⁺ Signed Rank test was used to analyze data.

Table 10

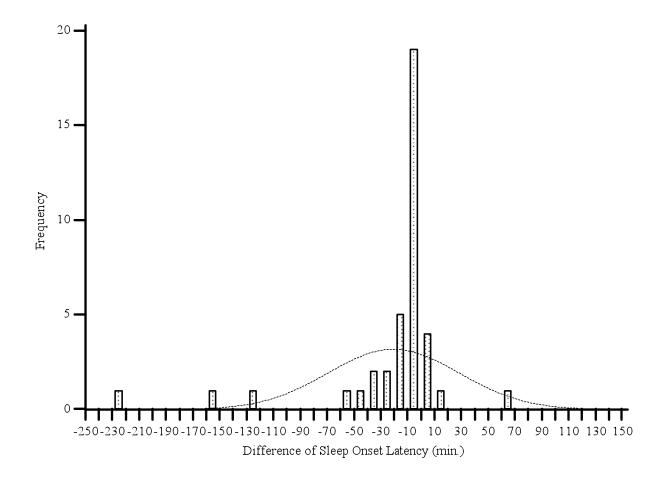
Parameter	Correlation Coefficient				
	Pearson	Spearman			
Sleep Onset Latency (SOL)					
Low sensitivity	0.58*	0.52*			
Medium sensitivity	0.58*	0.52*			
High sensitivity	0.58*	0.52*			
Auto sensitivity	0.58*	0.52*			
Wake After Sleep Onset (WASO)					
Low sensitivity	0.31 ^{ns}	0.27^{ns}			
Medium sensitivity	0.38 ^{ns}	0.32 ^{ns}			
High sensitivity	0.36^{ns}	0.31 ^{ns}			
Auto sensitivity	0.32^{ns}	0.29^{ns}			
Total Sleep Time (TST)					
Low sensitivity	0.47*	0.45*			
Medium sensitivity	0.48*	0.43*			
High sensitivity	0.45*	0.40*			
Auto sensitivity	0.46*	0.48*			

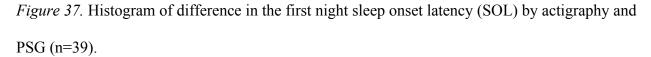
Correlation of the First Night Sleep Parameters Between PSG and Actigraphy (n=39)

Note. * p < .0125; ns = not statistically significant.

Sleep onset latency (SOL).

The mean first night SOL by PSG was 35.27 minutes (SD = 59.75). Although four different sensitivity settings were applied to actigraphy, the measured values of the first night SOL from all four thresholds were identical: (M = 14.82, SD = 37.28 minutes). Differences in the first night SOL between actigraphy and PSG was not normally distributed, D = 0.29, p < .01. A histogram shows the distribution of these data (Figure 37). Using a sign test with Bonferroni correction, the first night SOL by actigraphy and PSG was significantly different, z = -13.5, p < .0001. Actigraphy scored significantly lower SOL in comparison to PSG. The association between the first night SOL measures was moderate with an ICC value of 0.52 and the 95% CI of 0.25 and 0.71.





Note. Differences were calculated as the first night SOL by actigraphy minus the first night SOL by PSG.

The significant relationships of the first night SOL measured by PSG and actigraphy is shown in Figure 38. Pearson and Spearman's rank correlation coefficients with Bonferroni corrections were performed to examine the relationship between the first night SOL by PSG and actigraphy (Table 10). Pearson provided correlation coefficients greater than Spearman's rank did. However, there were many outliers in this data. Spearman's rank correlation was reported because it would help with outlier issues. The first night SOL between two methods was then ranked. The relationship of ranked SOL between two methods is illustrated in Figure 39. Using a Spearman's rank correlation coefficient, there was a significant moderate positive linear relationships of the first night SOL between two methods, $r_s = .52$, p < .0125.

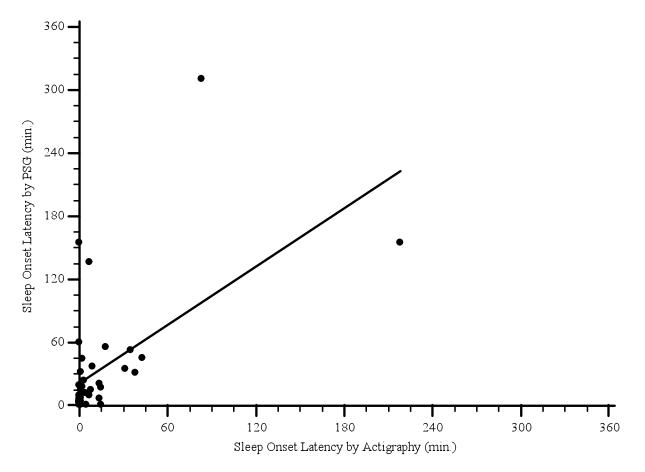


Figure 38. Relationship of the first night sleep onset latency (SOL) between PSG and actigraphy (n=39).

Note. Line represents a regression line of the first night SOL by actigraphy on the first night SOL by PSG. Each dot represents one subject.

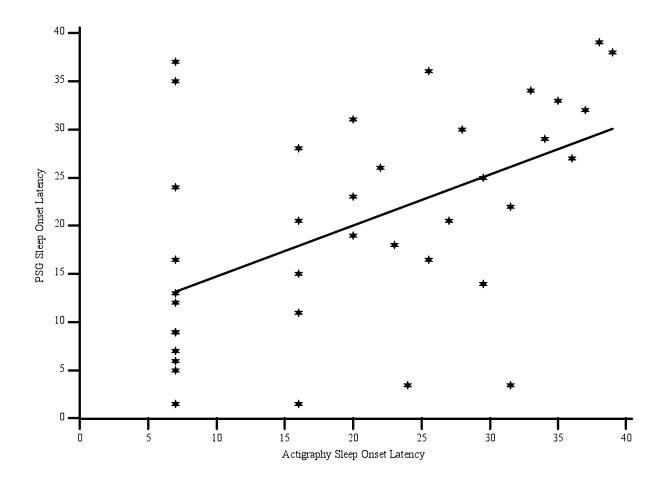


Figure 39. Relationship of the first night ranked sleep onset latency (SOL) between PSG and actigraphy (n=39).

Note. Line represents a regression line of the first night SOL by actigraphy on the first night SOL by PSG. Each star represents one subject.

A simple linear regression with Bonferroni correction was performed to identify the predictive effect of the first night SOL by actigraphy on the first night SOL by PSG (Table 11). Approximately 33% of variance in the first night SOL by PSG was explained by the first night SOL by actigraphy, $R^2 = 0.33$, p < .0125. The first night SOL by PSG was estimated to be 21.60 minutes when subjects had zero first night SOL by actigraphy. In addition, the first night SOL by

PSG was estimated to increase 0.92 minute for each additional minute increase in the first night

SOL by actigraphy.

Table 11

Regression Analysis for the First Night Sleep Onset Latency (SOL) by Actigraphy as a

Predicting Factor for SOL by PSG (n=39)

Variable	В	SE B	β
Intercept	21.60 ^{ns}	8.55	
SOL by Actigraphy	0.92*	0.21	0.58*

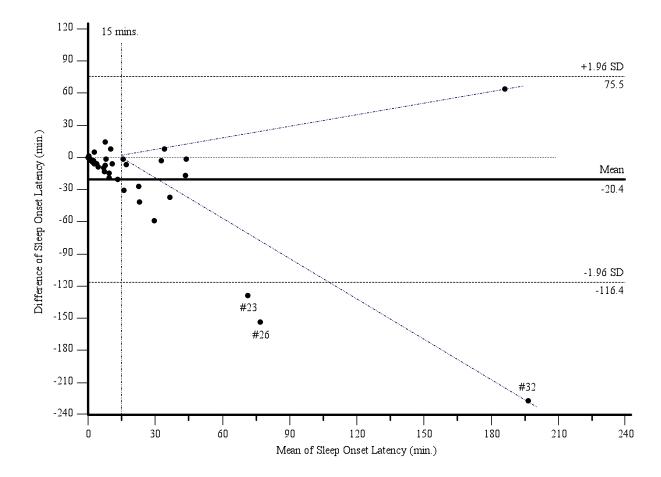
Note. PSG = Polysomnography; SOL = Sleep Onset Latency; B = Unstandardized Beta; *SE* B = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125; ns = not statistically significant.

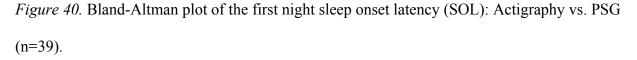
The agreement of the first night SOL by actigraphy and PSG is presented in a Bland-Altman plot (Figure 40). The x-axis represents the average first night SOL obtained by two methods across the range of 0.25 and 196.75 minutes. The y-axis represents the difference in the first night SOL by actigraphy and PSG. In this study, the differences varied from -227.50 to 63.00 minutes. All but six subjects (84.62%) had negative differences, which meant that actigraphy always provided a lower value of the first night SOL than the PSG method in this sample.

The mean difference between these two methods, or bias, was -20.45 minutes (95% CI = -36.32 to -4.58). A negative mean difference indicates that on average actigraphy underestimated the first night SOL by PSG approximately 20 minutes. The horizontal dotted lines show the 95% limits of agreement. Since the standard deviation for the mean difference of the first night SOL was 48.95, the upper and lower limits of agreement were 75.50 and -116.40 minutes, respectively. Based on these limits of agreement, there were three outliers (7.69%) with values

beyond the lower limit of agreement: subjects #23, #26, and #32.

There was a possible trend in the bias. When the mean first night SOL was less than 15 minutes, the difference or bias was small and values clustered around the zero line. However, when the magnitude of the first night SOL was more than 15 minutes, the majority of differences also increased farther from the zero line, towards the right side of the graph in both positive and negative directions.





Note. Differences were calculated as the first night SOL by actigraphy minus the first night SOL by PSG (actigraphy – PSG). Means were calculated as the mean of the first night SOL by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

In summary, although different sensitivity settings were applied to actigraphy, the first night SOL was the same for all thresholds, indicating that any changes in sensitivity would not impact the value of the first night SOL taken by actigraphy. Compared with PSG, actigraphy tended to underestimate the first night SOL by 20 minutes. Although there was a moderate linear

relationship for first night SOL between these two methods, the first night SOL by actigraphy could explain only 33% of the variance in the first night SOL measured by PSG. In addition, measurement error varied over the measurement scale, especially when subjects had mean SOL more than 15 minutes.

Wake after sleep onset (WASO).

The first night WASO by PSG was 103.44 minutes (SD = 55.19), and the mean first night WASO by actigraphy for the four-sensitivity settings were 31.23 (SD = 19.12), 49.13 (SD = 23.98), 70.44 (SD = 31.08) and 32.23 (SD = 15.99) minutes, respectively. The WASO of the first night by four actigraphy thresholds were compared to those taken by PSG on the same night, and significant differences were revealed as shown in Table 9. The first night WASO by all four sensitivity settings did not have statistically significant relationships with the first night WASO by PSG. More detail is elaborated in the following section.

Low sensitivity actigraphy.

When comparing the first night WASO by PSG to those by low sensitivity actigraphy, differences were not normally distributed, D = 0.14, p < .05. A histogram illustrates how these data were distributed (Figure 41). Using a signed rank test with Bonferroni correction, the differences of the first night WASO between two methods was statistically significant, z = .386, p < .0001. Low sensitivity actigraphy scored WASO significantly The association between these two methods in measuring the first night WASO was poor, with an ICC value of 0.19 and the 95% CI of -0.12 and 0.47.

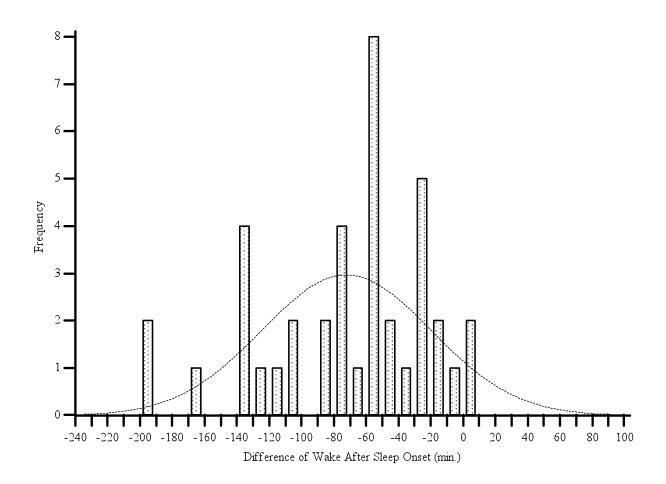


Figure 41. Histogram of differences in the first night wake after sleep onset (WASO) by low sensitivity actigraphy and PSG (n=39).

Note. Differences were calculated as the first night WASO by actigraphy minus the first night WASO by PSG.

Scatter plot of the relationship between the first night WASO from PSG and low sensitivity actigraphy is shown in Figure 42. However, this relationship was not significant as seen in Table 10.

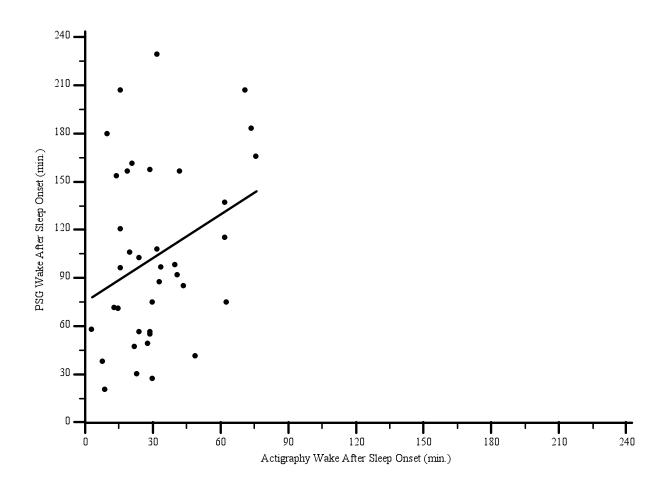


Figure 42. Relationship of the first night wake after sleep onset (WASO) between PSG and low sensitivity actigraphy (n=39).

Note. The x-axis and y-axis is displayed in the same scale. Line represents a regression line of the first night WASO by actigraphy on the first night WASO by PSG. Each dot represents one subject.

Bland-Altman plot shows the agreement between the low sensitivity actigraphy and PSG on the first night WASO (Figure 43). The x-axis represents the average first night WASO obtained by two methods across the range of 14.75 and 138.75 minutes. The y-axis represents the difference in first night WASO between two methods, which varied from -197.00 to 8.00

minutes. The majority of subjects (94.87%) had negative differences, indicating that the low sensitivity actigraphy always provided a lower value for first night WASO as compared to PSG.

The mean difference between these two methods, or bias, was -72.21 minutes (95% CI = -89.20 to -55.21), indicating that on average low sensitivity actigraphy underestimated the first night WASO measured by PSG by approximately 72 minutes. The horizontal dotted lines show 95% limits of agreement. Since the standard deviation of the mean difference of the first night WASO was 52.43, the upper limit and lower limit of agreement was 30.56 and -174.97 minutes, respectively. Two outliers (5.13%) exceeded the lower limit of agreement: subjects #18, and #33.

There was a possible trend in the bias. Using a 45-minutes mean first night WASO between two methods as a cut point, when the mean first night WASO was less than 45 minutes, the bias between two methods was not specific and could be either over or underestimated. However, when the mean first night WASO was more than 45 minutes, all differences were located under the zero line, indicating that low sensitivity actigraphy always underestimated the first night WASO in those instances.

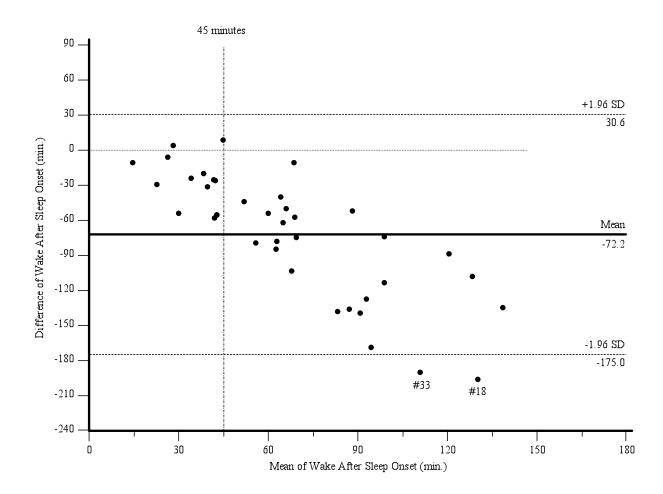


Figure 43. Bland-Altman plot of the first night wake after sleep onset (WASO): Low sensitivity actigraphy vs. PSG.

Note. Differences were calculated as the first night WASO by actigraphy minus the first night WASO by PSG (actigraphy - PSG). Means were calculated as the mean of the first night WASO by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

Medium sensitivity actigraphy.

The first night WASO by PSG and medium sensitivity /wake threshold actigraphy was compared by a paired-sample t-test with Bonferroni correction and a statistically significant difference was found, t(38) = -6.62, p < .0001. The association between these two methods in

measuring the first night WASO was fair, with an ICC value of 0.27 and 95% CI of -0.03 and 0.54.

Scatter plot (Figure 44), and correlation analysis with Bonferroni corrections (Table 10) were performed to examine the relationship between the first night WASO taken by medium sensitivity actigraphy and those taken by PSG. However, this relationship was not significant, r = .38, p > .0125.

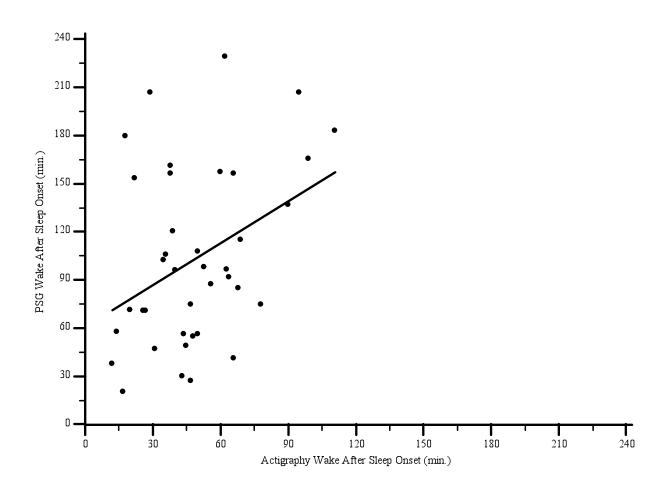


Figure 44. Relationship of the first night wake after sleep onset (WASO) between PSG and medium sensitivity actigraphy (n=39).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the first night WASO by actigraphy on the first night WASO by PSG. Each dot represents one subject.

The Bland-Altman plot illustrates the agreement of the first night WASO by the medium sensitivity actigraphy and by PSG (Figure 45). The average first night WASO obtained by two methods were between 18.75 and 150.75 minutes. The differences of first night WASO varied from -177.50 to 25.00 minutes. Nearly 90% of subjects had negative differences, which meant

that the medium sensitivity actigraphy always provided lower value of the first night WASO than then PSG method.

The mean difference, or bias, of these two methods was -54.31 minutes (95% CI = -70.91 to -37.70), indicating that on average the medium sensitivity actigraphy underestimated the first night WASO from PSG by around 54 minutes. Since the standard deviation for the mean difference of the first night WASO was 51.23, the upper limit and lower limits of agreement were 46.10 and -154.72 minutes, respectively. Three outliers (7.69%) exceeded the lower limit of agreement: subjects #12, #18, and #33.

There was a possible trend in the bias. Using 80-minute cut point, when the mean first night WASO was less than 80 minutes, difference of the first night WASO was not specific. However, when the mean WASO was more than 80 minutes, the difference of first night WASO was located under the zero line, indicating that medium sensitivity actigraphy always underestimated the first night WASO by PSG if the mean first night WASO between two methods was more than 80 minutes. Also, when the mean first night WASO was more than 80 minutes, the magnitude of underestimated WASO increased.

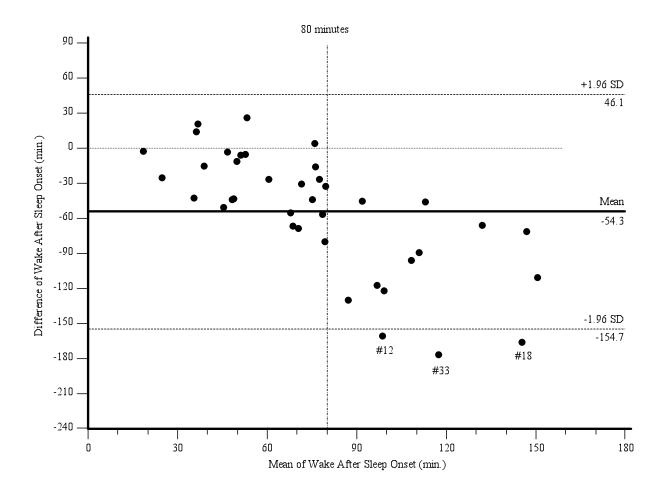


Figure 45. Bland-Altman plot of the first night wake after sleep onset (WASO): Medium sensitivity actigraphy vs. PSG.

Note. Differences were calculated as the first night WASO by actigraphy minus the first night WASO by PSG (actigraphy - PSG). Means were calculated as the mean of the first night WASO by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

High sensitivity actigraphy.

Differences in first night WASO by PSG and high sensitivity actigraphy were not normally distributed, D = 0.16, p < .01, as illustrated by histogram (Figure 46). Using a sign rank test with Bonferroni correction, the first night WASO by two methods was statistically

significantly different, z = -243.5, p < .001. The association between these two methods in measuring the first night WASO was fair with an ICC value of 0.30 and the 95% CI of 0.00 and 0.56.

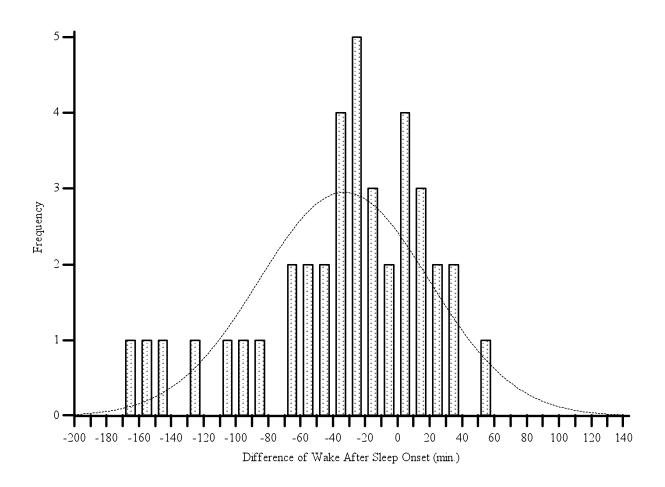


Figure 46. Histogram of difference in the first night wake after sleep onset (WASO) by high sensitivity by PSG and by actigraphy (n=39).

Note. Differences were calculated as the first night WASO by actigraphy minus the first night WASO by PSG.

Scatter plot (Figure 47) and correlation analysis (Table 10) were performed to examine the relationship between the first night WASO by high sensitivity actigraphy and PSG. However, with Bonferroni Correction, this relationship of the first night WASO between two methods was not significant, r = .36, p > .0125.

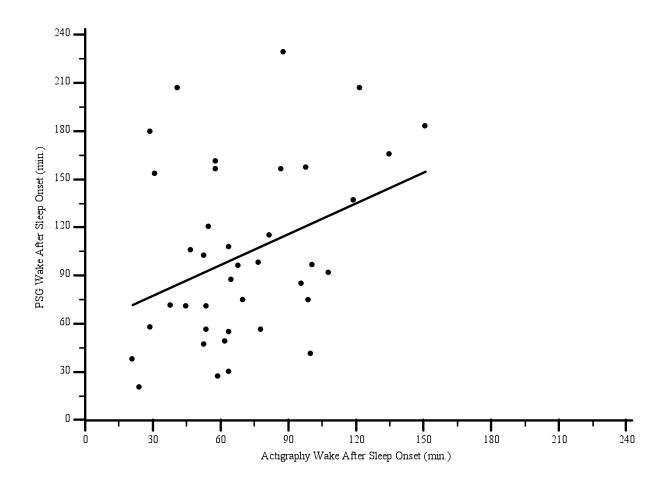


Figure 47. Relationship of the first night wake after sleep onset (WASO) between PSG and high sensitivity actigraphy (n=39).

Note. Line represents a regression line of the first night WASO by actigraphy on the first night WASO by PSG. Each dot represents one subject.

The agreement of the first night WASO obtained by two methods is presented using a Bland-Altman plot (Figure 48). The mean first night WASO by two methods was between 22.25 and 167.00 minutes while the differences varied from -165.50 to 59.00 minutes. The majority of

subjects (69.23%) had negative differences, indicating that the high sensitivity actigraphy always provided a lower value for first night WASO than the PSG method. However, among the four sensitivity settings, the high threshold had the greatest number of subjects with a positive difference.

The bias of these two methods was -33.00 minutes (95% CI = -50.09 to -15.91), indicating that on average the high sensitivity actigraphy underestimated the first night WASO by approximately one-half hour. Since the standard deviation for the mean difference of the first night WASO was 52.73, the upper and lower limits of agreement were 70.35 and -136.36 minutes, respectively. Three outliers (7.69%) exceeded the lower limit of agreement: subjects #12, #18, and #33.

There was a possible trend of bias. When the magnitude of WASO increased, the underestimation of the first night WASO also increased. Using 100-minutes as a cut point, when the mean first night WASO was less than 100 minutes, the difference was not specific. However, when the mean WASO was more than 100 minutes, all differences were located under the zero line. Thus, high sensitivity actigraphy always underestimated the first night WASO when the mean first night WASO between two methods was more than 100 minutes.

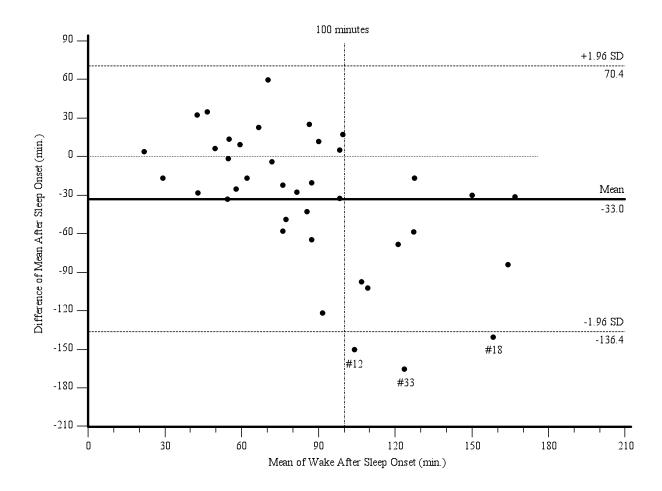


Figure 48. Bland-Altman plot of the first night wake after sleep onset (WASO): High sensitivity actigraphy vs. PSG (n=39).

Note. Differences were calculated as the first night WASO by actigraphy minus the first night WASO by PSG (actigraphy - PSG). Means were calculated as the mean of the first night WASO by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

Auto sensitivity actigraphy.

Differences of the first night WASO by auto sensitivity actigraphy and PSG were not normally distributed, D = 0.14, p < .05, as depicted in a histogram (Figure 49). Using a signed rank test with Bonferroni correction, the differences of the first night WASO between these two

methods was a statistically significant, z = -370.5, p < .0001. The association between these two methods in measuring the first night WASO was poor, with an ICC value of 0.17 and the 95% CI of -0.14 and 0.46.

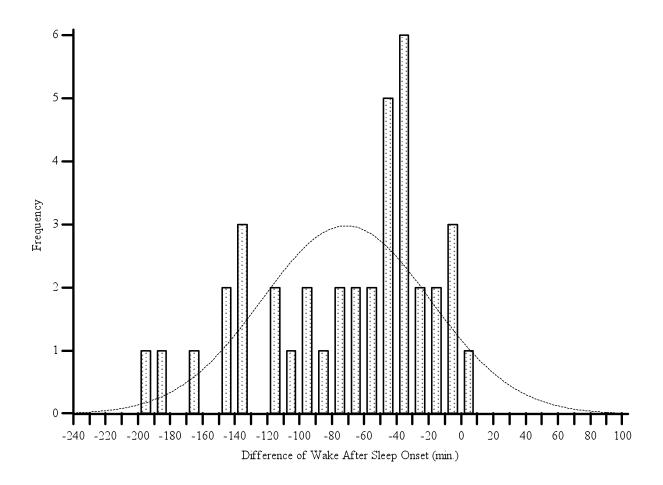


Figure 49. Histogram of difference in the first night wake after sleep onset (WASO) by auto sensitivity actigraphy and by PSG (n=39).

Note. Differences were calculated as the first night WASO by actigraphy minus the first night WASO by PSG.

Scatter plot (Figure 50) and correlation analysis (Table 10) were performed to examine the relationship between the first night WASO taken by auto sensitivity actigraphy and those taken by PSG. However, with Bonferroni correction, this relationship was not statistically significant, r = .32, p > .0125.

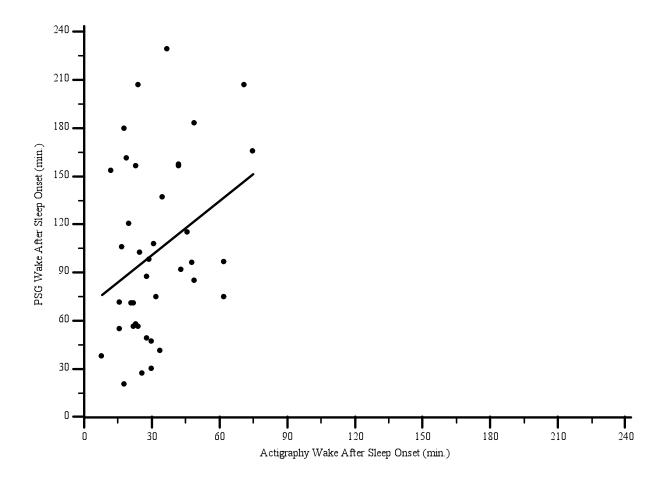


Figure 50. Relationship of the first night wake after sleep onset (WASO) between PSG and auto sensitivity actigraphy (n=39).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the first night WASO by actigraphy on the first night WASO by PSG. Each dot represents one subject.

Bland-Altman plot illustrates the agreement of the first night WASO between two methods (Figure 51). The mean first night WASO was between 19.25 and 138.75 minutes and

the differences of the first night WASO varied from -192.00 to 0.00 minutes. Thirty-eight subjects (97.44%) had negative differences, indicating that auto sensitivity actigraphy almost always provided a lower value of the first night WASO than PSG. One subject had exactly the same value of the first night WASO between two methods.

The difference in first night WASO obtained with two methods was -71.21 minutes (95% CI = -88.14 to -54.27), indicating that on average auto sensitivity actigraphy underestimated the first night WASO by 71 minutes, or more than one hour. Since the standard deviation for the mean difference of the first night WASO was 52.24, the upper and lower limits of agreement were 31.18 and -173.59 minutes, respectively. Two outliers (5.13%) exceeded the lower limit of agreement: subjects #18, and #33.

There was a possible trend in the bias. When the magnitude of the first night WASO increased, the underestimation of the first night WASO also increased. Using 30-minutes as a cut point, when the mean first night WASO was less than 30 minutes, the differences were not specific and could be either over or underestimated. However, when the mean WASO was more than 30 minutes, all differences were located under the zero line, thus auto sensitivity actigraphy always underestimated the first night WASO when the mean first night WASO between two methods was more than 30 minutes.

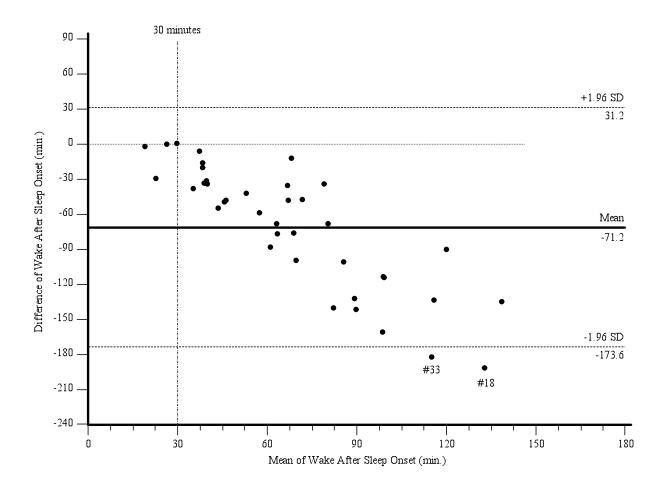


Figure 51. Bland-Altman plot of the first night wake after sleep onset (WASO): Auto sensitivity actigraphy vs. PSG (n=39).

Note. Differences were calculated as the first night WASO by actigraphy minus the first night WASO by PSG (actigraphy - PSG). Means were calculated as the mean of the first night WASO by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

As shown in Table 12, four different methods were employed to examine the agreement of the first night WASO between four sensitivity settings of actigraphy and PSG. When taking differences of the mean/median between two methods into account, there were statistically significantly differences in the first night WASO from four sensitivity settings and PSG. ICCs between two methods were between poor and fair; medium and high sensitivity provided better values of ICCs than those with low and auto sensitivity. There were low positive linear relationships for first night WASO between two methods but they were not statistically significant. All sensitivity settings of actigraphy underestimated the first night WASO compared to PSG. However, the high sensitivity provided the least bias as it underestimated the first night WASO by 33 minutes.

Table 12

Sensitivity settings Actigraphy	Comparison of the mean/median	Method Correlation and ICC Regression		Bland-Altman Plots (Bias)	
	(p value)		r/r_s	R^2	
Low	<.0001	Poor	NS	NS	-72.21
Medium	<.0001	Fair	NS	NS	-54.31
High	<.001	Fair	NS	NS	-33.00
Auto	< .0001	Poor	NS	NS	-71.21

Agreement of the First Night Wake After Sleep Onset (WASO) by PSG and Actigraphy (n=39)

Note. PSG = Polysomnography; r = Pearson Coefficient; r_s = Spearman's Rank Coefficient; R^2 = coefficient of determination; NS = not statistically significant.

Total Sleep Time (TST).

On average, during the first night subjects slept for 315.13 minutes (SD = 85.63) or slightly less 5.5 hours by PSG. However, the first night TST by four sensitivity settings (i.e. low, medium, high, and auto) was more than those by PSG with the values of 410.08 (SD = 60.84), 392.15 (SD = 62.35), 370.87 (SD = 65.36) and 409.08 (SD = 60.76) minutes, respectively. The first night TST by PSG was compared to those taken by four sensitivity settings of actigraphy and there were statistically significant differences for all four thresholds (Table 10). More detail was elaborated in the following section.

Low sensitivity actigraphy.

Differences of the first night TST by low sensitivity actigraphy and PSG were not normally distributed, D = 0.17, p < .01, as depicted in a histogram (Figure 52). With a signed rank test with Bonferroni correction, there was a statistically significant difference of the first night TST between two methods, z = 375, p < .0001. The association between these two methods in measuring the first night TST was fair, with an ICC value of 0.44 and the 95% CI of 0.16 and 0.66.

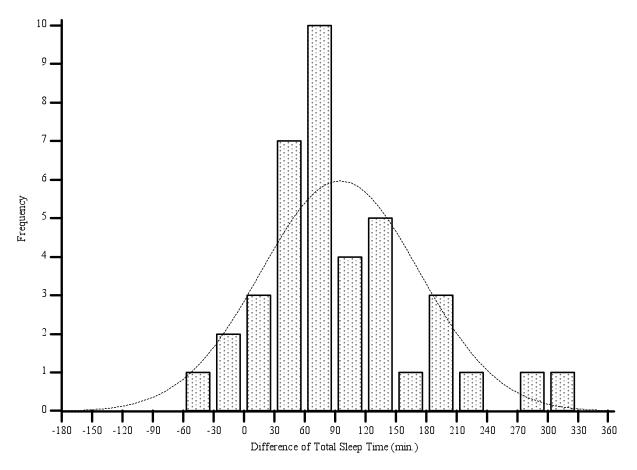


Figure 52. Histogram of difference in the first night total sleep time (TST) by PSG and low sensitivity actigraphy (n=39).

Note. Differences were calculated as the first night TST by actigraphy minus the first night TST by PSG.

As seen in Table 10, Pearson correlation with Bonferroni correction revealed that the first night TST by actigraphy had a significant low positive linear relationship with the first night TST by PSG, r = .47, p < .0125. Scatter plot illustrates this relationship (Figure 53).

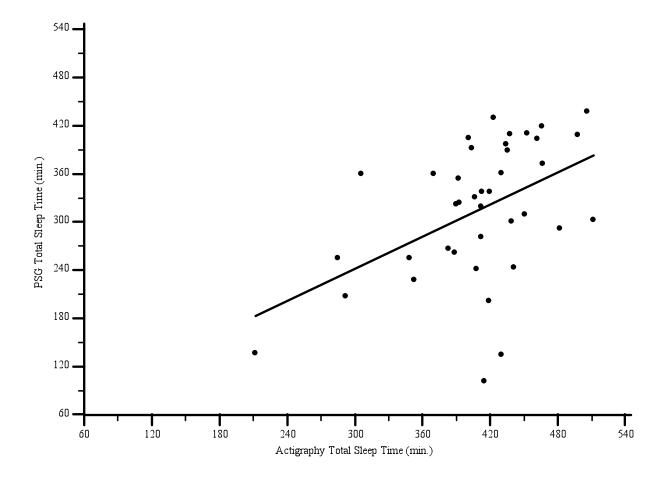


Figure 53. Relationship of the first night total sleep time (TST) between PSG and low sensitivity actigraphy (n=39).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the first night TST by actigraphy on the first night TST by PSG. Each dot represents one subject.

A simple linear regression with Bonferroni correction was performed, with significance set at p < .0125, to identify the predictive effect of the first night TST by actigraphy, on the first night TST by PSG (Table 13). Approximately 22% of variance in the first night TST by PSG was explained by the first night TST by low sensitivity actigraphy, $R^2 = 0.22$, p < .0125. The first night TST by PSG was estimated to be 158.29 minutes when subjects had a minimum value of 212 minutes for the first night TST by actigraphy. The first night TST by PSG was estimated to increase 0.67 minute for each minute of increase in the first night TST by actigraphy.

Table 13

Regression Analysis for the First Night Total Sleep Time (TST) by low Sensitivity Actigraphy as a Predicting Factor for the First Night TST by PSG (n=39)

Variable	В	SE B	β
Intercept	158.29*	49.63	
TST by Actigraphy	0.67*	0.20	0.47*

Note. PSG = Polysomnography; TST = Total Sleep Time; B = Unstandardized Beta when TST by actigraphy equaled minimum value of 212 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

A relative agreement of the first night TST between two methods is illustrated by Bland-Altman plot (Figure 54). The x-axis represents the average first night TST by low sensitivity actigraphy and PSG across the range of 174.25 and 471.50 minutes. The y-axis represents difference of the first night TST by two methods and it varied from -53.50 to 313 minutes. The majority of subjects (92.31%) had positive differences, indicating that the low sensitivity actigraphy provided higher value of the first night TST than PSG method.

The mean difference between these two methods, or bias, was 94.95 minutes (95% CI = 69.61 to 120.29). A positive mean difference indicated that on average actigraphy overestimated

the first night TST by approximately 95 minutes or more than one and one-half hour as compared to those taken by PSG. The limits of agreement are represented by the two horizontal dotted lines. Because the standard deviation for the mean difference of TST was 78.18, the upper and lower limits of agreement were 248.17 and -58.28 minutes, respectively. Two outliers (5.13%) exceeded the upper limit of agreement: subjects #26, and #32.

Based on the Bland-Altman plot there was no obvious pattern of overestimation of TST; differences of TST were distributed all over the graph and did not relate to the magnitude of TST.

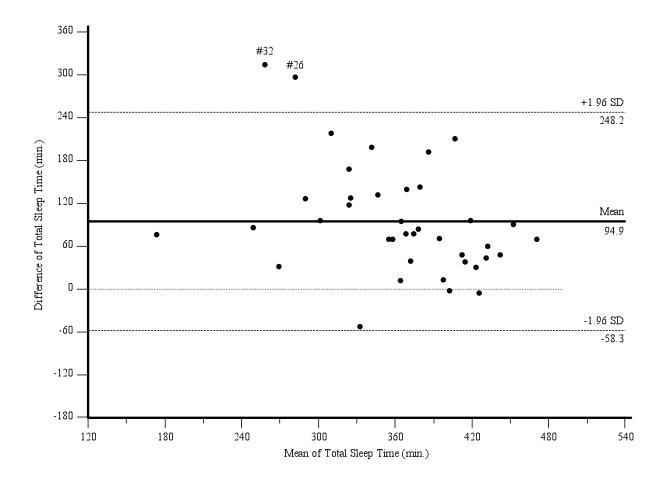


Figure 54. Bland-Altman plot of the first night total sleep time (TST): Low sensitivity actigraphy vs. PSG (n=39).

Note. Differences were calculated as the first night TST by actigraphy minus the first night TST by PSG (actigraphy - PSG). Means were calculated as the mean of the first night TST by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

Medium sensitivity actigraphy.

The first night TST by medium sensitivity actigraphy was compared to the first night TST by PSG. Using a paired-sample t-test with Bonferroni correction, there was a statistically significant difference of TST, t(38) = 6.15, p < .0001. The result revealed that the first night TST

by medium sensitivity was more than by PSG. The association between these two methods in measuring the first night TST was fair, with an ICC value of 0.45 and the 95% CI of 0.17 and 0.67.

As seen in Table 10, the first night TST by actigraphy had a significant relationship with the first night TST by PSG, r = .47, p < .01. Figure 55 illustrates this relationship.

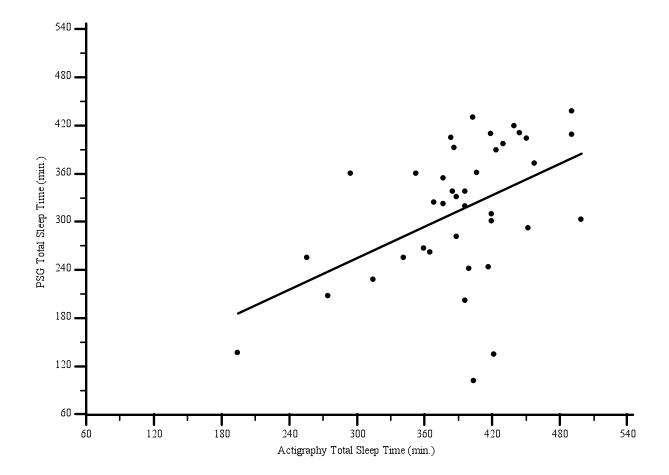


Figure 55. Relationship of the first night total sleep time (TST) between PSG and medium sensitivity actigraphy (n=39).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the first night TST by actigraphy on the first night TST by PSG. Each dot represents one subject.

The predictive effect of the first night TST by actigraphy on the first night TST by PSG was tested (Table 14). Approximately 23% of variance in the first night TST by PSG was explained by the first night TST by medium sensitivity actigraphy, $R^2 = 0.23$, p < .0125. The first night TST by PSG was estimated to be 166.53 minutes when subjects had a minimum value of 195 minute for the first night TST by actigraphy. In addition, the first night TST by PSG was estimated to increase 0.66 minute for each minute of increase in the first night TST by actigraphy.

Table 14

Regression Analysis for the First Night Total Sleep Time (TST) by Medium Sensitivity

Actigraphy as a Predicting Factor for the First Night TST by PSG (n=39)

Variable	В	SE B	β
Intercept	166.53*	46.53	
TST by Actigraphy	0.66*	0.20	0.48*

Note. PSG = Polysomnography; TST = Total Sleep Time; B = Unstandardized Beta when TST by actigraphy equaled minimum value of 195 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

The Bland-Altman plot illustrates the agreement of the first night TST by medium sensitivity actigraphy and PSG methods (Figure 56). The average first night TST obtained by two methods were between 165.75 and 464.00 minutes. The difference in first night TST by two methods varied from -54.50 to 302.00 minutes. Nearly 90% of subjects had positive differences, indicating that medium sensitivity actigraphy usually provided a higher value of the first night TST than PSG.

The mean difference between these two methods, or bias, was 77.03 minutes (95% CI = 51.67 to 102.38). A positive mean difference indicates that on average actigraphy overestimated the first night TST by approximately 77 minutes, or more than one hour, as compared to those taken by PSG. The two horizontal dotted lines show 95% limits of agreement. Since the standard deviation for the mean difference of first night TST was 78.21, the upper and lower limits of agreement were 230.33 and -76.27 minutes, respectively. Two outliers (5.13%) exceeded the upper limit of agreement: subjects #26, and #32.

Based on a Bland-Altman plot there was no obvious pattern of overestimation of the first night TST; differences of the first night TST were distributed all over the graph and did not related to the magnitude of the first night TST.

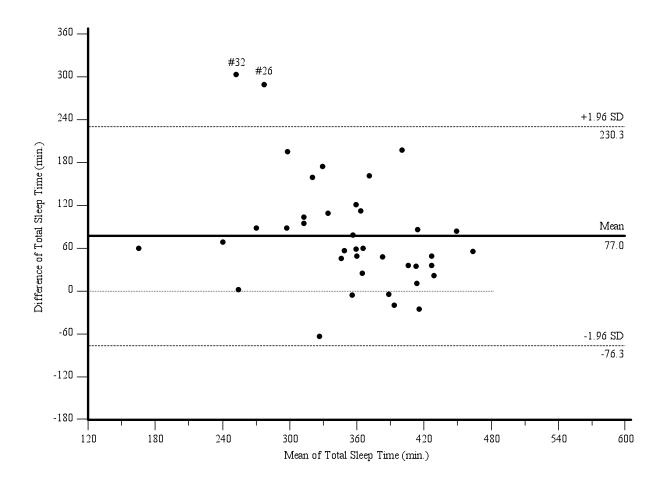


Figure 56. Bland-Altman plot of the first night total sleep time (TST): Medium sensitivity actigraphy vs. PSG (n=39).

Note. Differences were calculated as the first night TST by actigraphy minus the first night TST by PSG (actigraphy - PSG). Means were calculated as the mean of the first night TST by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

High sensitivity actigraphy.

Differences of the first night TST by high sensitivity actigraphy and PSG were not normally distributed, D = 0.17, p < .01, as shown in a histogram (Figure 57). Using a rank test with Bonferroni correction, there was a statistically significantly difference in TST between two

methods, z = 11.5, p < .001. It indicated that the first night TST obtained by high sensitivity actigraphy was more than that obtained by PSG. The association between these two methods in measuring the first night TST was fair, with an ICC value of 0.44 and the 95% CI between 0.15 and 0.66.

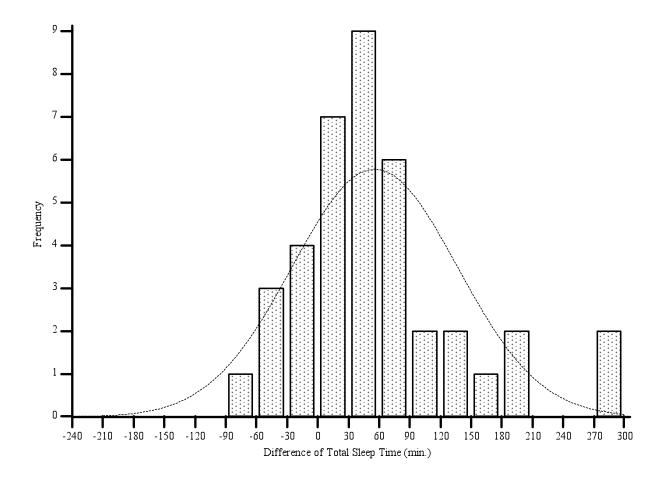


Figure 57. Histogram of differences in the first night total sleep time (TST) by high sensitivity actigraphy and the first night TST by PSG (n=39).

Note. Differences were calculated as the first night TST by actigraphy minus TST by PSG.

As seen in Table 10, the first night TST by actigraphy had a significant positive linear relationship with the first night TST by PSG, r = .45, p < .0125. The scatter plot also illustrates this relationship (Figure 58).

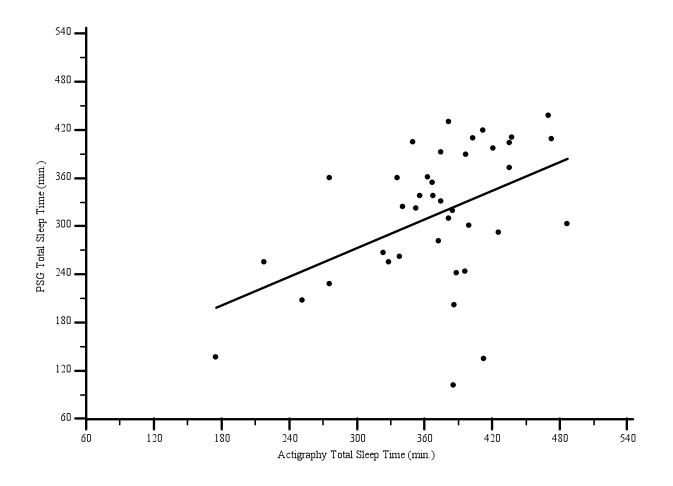


Figure 58. Relationship of the first night total sleep time (TST) between PSG and high sensitivity actigraphy (n=39).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the first night TST by actigraphy on the first night TST by PSG. Each dot represents one subject.

With a simple regression with Bonferroni correction, approximately 21% of variance in the first night TST by PSG could be explained by the first night TST by high sensitivity actigraphy, $R^2 = 0.21$, p < .0125. As seen in Table 15, the first night TST by PSG was estimated to be 187.28 minutes when subjects had a minimum value of 175 minutes for the first night TST by actigraphy. Additionally, the first night TST by PSG was estimated to increase 0.59 minutes for each minute of increase in the first night TST by actigraphy.

Table 15

Regression Analysis for the First Night Total Sleep Time (TST) by High Sensitivity Actigraphy as a Predicting Factor for the First Night TST by PSG (n=39)

Variable	В	SE B	β
Intercept	187.28*	43.11	
TST by Actigraphy	0.59*	0.19	0.45*

Note. PSG = Polysomnography; TST = Total Sleep Time; B = Unstandardized Beta when TST by actigraphy equaled minimum value of 175 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

The agreement of the first night TST by high sensitivity actigraphy and PSG is illustrated by a Bland-Altman plot (Figure 59). The average first night TST by the two methods was between 155.75 and 453.50 minutes. The difference in first night TST by the two methods varied from -83.50 to 284.00 minutes. Nearly 80% of subjects had positive differences, indicating that the high sensitivity actigraphy often provided a higher value of the first night TST than PSG method. However, among the four threshold levels, high sensitivity had the highest number of subjects with a negative difference.

The mean difference between two methods was 55.74 minutes (95% CI = 29.55 to 81.93). A positive value of the mean difference indicates that on average actigraphy

overestimated the first night TST by approximately 56 minutes or almost one hour as compared to those taken by PSG. The limits of agreement are presented by the two horizontal dotted lines. Since the standard deviation for the mean difference of the first night TST was 80.79, the upper and lower limits of agreement were 214.10 and -102.61 minutes, respectively. Two outliers (5.13%) exceeded the upper limit of agreement: subjects #26, and #32.

Based on the Bland-Altman plot there was no clear pattern of overestimation of the first night TST; differences of the first night TST distributed all over the plot and did not relate to the magnitude of the first night TST.

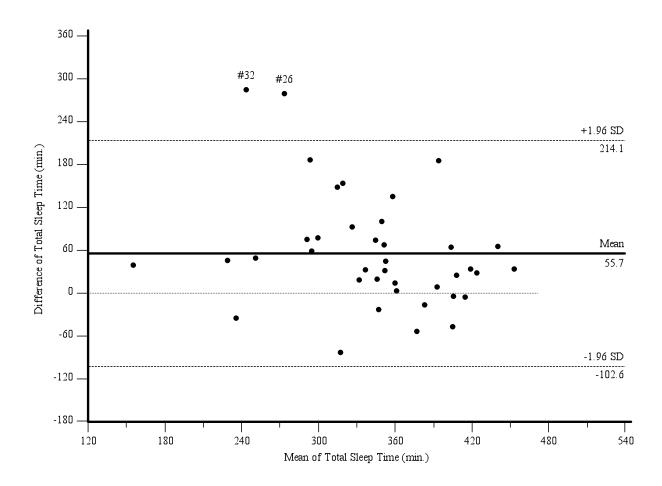


Figure 59. Bland-Altman Plot of the first night total sleep time (TST): High sensitivity actigraphy vs. PSG (n=39).

Note. Differences were calculated as the first night TST by actigraphy minus the first night TST by PSG (actigraphy - PSG). Means were calculated as the mean of the first night TST by actigraphy and PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

Auto sensitivity actigraphy.

The first night TST obtained by PSG was compared to those obtained by auto sensitivity actigraphy. Using a paired-sample t-test with Bonferroni correction, a statistically significant difference of TST was found, t(38) = -7.41, p < .0001. It indicated that the first night TST by

auto sensitivity was more than that by PSG. The association between these two methods in measuring the first night TST was fair, with an ICC value of 0.43 and the 95% CI between 0.15 and 0.65.

The first night TST between PSG and auto sensitivity actigraphy were plotted to show their relationship (Figure 60). As shown in Table 10, Spearman provided a higher value of correlation coefficient than what Pearson did. The first night TST between two methods was then ranked. The relationship of ranked TST between two methods is illustrated in Figure 61. Using Spearman's rank correlation coefficient, there was a significant relationship of the first night TST between two methods, $r_s = 0.48$, p < .0125.

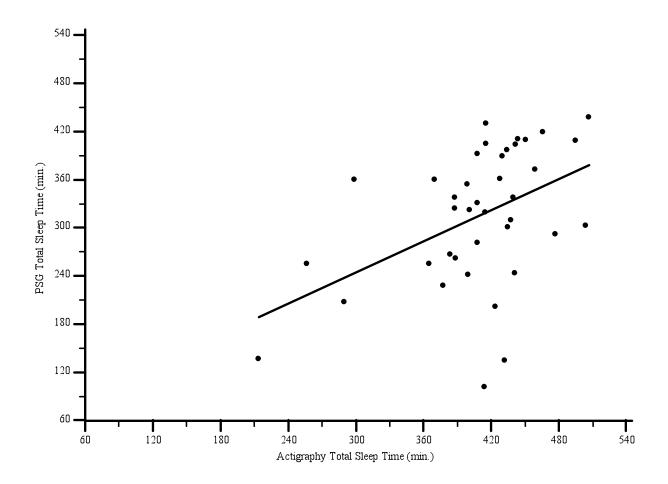


Figure 60. Relationship of the first night total sleep time (TST) between PSG and auto sensitivity actigraphy (n=39).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the first night TST by actigraphy on the first night TST by PSG. Each dot represents one subject.

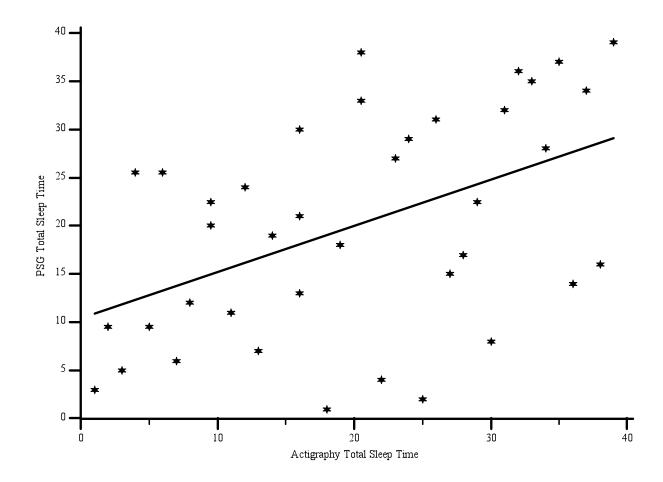


Figure 61. Relationship of the first night ranked total sleep time (TST) between PSG and auto sensitivity actigraphy (n=39).

Note. Line represents a regression line of the first night TST by actigraphy on the first night TST by PSG. Each star represents one subject.

Twenty-one percent of variance in the first night TST from PSG could be explained by the first night TST from auto sensitivity actigraphy, $R^2 = 0.21$, p < .0125. The first night TST by PSG was estimated to be 164.28 minutes when subjects had 214 minutes of the first night TST by actigraphy, which was the minimum value in this dataset. Additionally, the first night TST by PSG was estimated to increase 0.64 minutes for each minute of increase in the first night TST by actigraphy. Simple regression analysis is shown in Table 16.

Table 16

Regression Analysis for the First Night Total Sleep Time (TST) by Auto Sensitivity Actigraphy as a Predicting Factor for the First Night TST by PSG (n=39)

Variable	В	SE B	β
Intercept	164.38*	49.74	
TST by Actigraphy	0.64*	0.21	0.46*

Note. PSG = Polysomnography; B = Unstandardized Beta when TST by actigraphy equaled minimum value of 214 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

The agreement of the first night TST between two methods is presented in a Bland-Altman plot (Figure 62). The average first night TST obtained by two methods were between 175.25 and 472.00 minutes. The difference in first night TST by two methods varied from -60.50 to 312.00 minutes. Nearly 95% of subjects had positive differences, which meant that auto sensitivity actigraphy always provided a higher value of the first night TST than PSG method.

The mean difference between these two methods was 93.95 minutes (95% CI = 68.29 to 119.61). A positive mean difference indicated that on average actigraphy overestimated the first night TST by approximately 94 minutes or more than one and one-half hour as compared to PSG. The limits of agreement are presented by the two horizontal dotted lines. Since the standard deviation for the mean difference of the first night TST was 79.15, the upper and lower limit of agreement was 249.08 and -61.19 minutes, respectively. Two outliers (5.13%) exceeded the upper limit of agreement: subjects #26, and #32.

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Based on Bland-Altman plot there was no clear pattern of overestimation of the first night TST; differences of the first night TST were distributed all over the plot and did not relate to the magnitude of the first night TST.

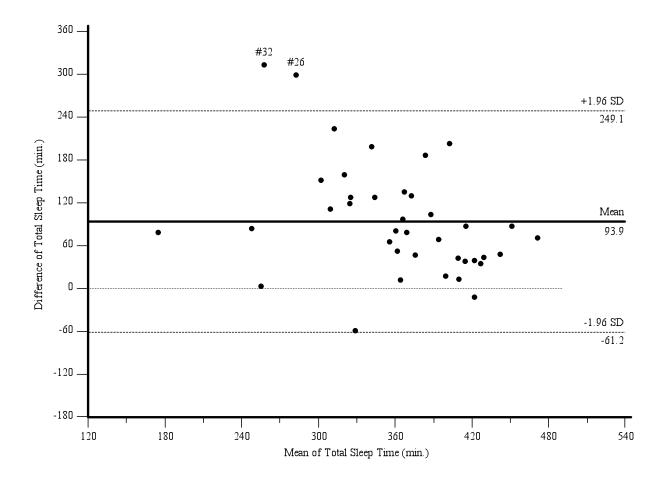


Figure 62. Bland-Altman plot of the first night total sleep time (TST): Auto sensitivity actigraphy vs. PSG (n=39).

Note. Differences were calculated as the first night TST by actigraphy minus the first night TST by PSG (actigraphy - PSG). Means were calculated as the mean of the first night TST by actigraphy and PSG [(actigraphy + PSG) /2]. Each dot represented one subject.

In summary, four different approach methods (i.e. comparison of the means, ICCs, correlation and regression models, and Bland-Altman Plots) were employed to examine the agreement of the first night TST by PSG and four sensitivity settings of actigraphy (Table 17). According to the comparison of the mean/median method, the four sensitivity settings provided statistically significantly different TST as compared with PSG. The ICCs between the two methods were fair. The relationships of the first night TST between two methods were statistically significant for all four sensitivity settings, but the strength of these relationships was low. In addition, regardless of sensitivity, actigraphy always overestimated the first night TST when compared to PSG. Actigraphy with high sensitivity provided the least bias, as it overestimated the first night TST by 56 minutes.

Table 17

Sensitivity settings Actigraphy	Comparison of the mean/median	±		Bland-Altman Plots (Bias)	
	(p value)		r/r_s	R^2	
Low	<.0001	Fair	Low	0.22	94.95
Medium	<.0001	Fair	Low	0.23	77.03
High	<.001	Fair	Low	0.21	55.74
Auto	<.0001	Fair	Low	0.21	93.95

Agreement of the First Night Total Sleep Time (TST) by PSG and Actigraphy (n=39)

Note. PSG = Polysomnography; r = Pearson Coefficient; r_s = Spearman's Rank Coefficient; R^2 = coefficient of determination; NS = not statistically significant.

The Accuracy of Actigraphy to Measure the Second Night Sleep Parameters When Compared to PSG in Community-Dwelling Older Adults, age 70 Years and Older

Of the 63 subjects with sleep data, only 39 subjects had both the second night of laboratory PSG and actigraphy. Of the 39 pairs, one subject went to the sleep laboratory twice and provided two different sets of data that were acquired 12 months apart. Taking the issue of independence of data into account, the first visit data from this case was excluded from the analysis, reducing the sleep data to 38 subjects that were included in the analysis Figure 63 showed a schematic diagram indicating the flow of study subject selection though the study.

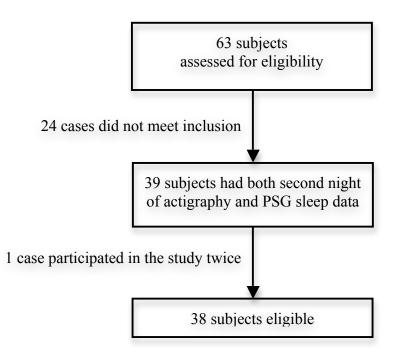


Figure 63. A schematic diagram indicating the flow of study subject selection though the study.

Characteristics of the samples.

There were 38 older adults with both actigraphy and PSG sleep data, ranging in age from 71 to 89 years (M = 79.81, SD = 5.55 years). Fifty-eight percent of subjects were female. The majority of subjects were Caucasian (92.11%). Body mass indexes ranged from 19.49 to 37.21 kg/m² (M = 26.71, SD = 3.69). No subject had impairments of everyday function: all Mini-Mental State Examination (MMSE) scores were above 24 points (M = 29.17, SD = 1.38), all scores on the Older Adults Resource Services (OARS) Independent Activities of Daily Living Scale were above 12 points (M = 27.62, SD = 0.82), and all scores on the Geriatric Depression Scale (GDS) were below 5 points (M = 1.08, SD = 1.32). Some subjects reported sleep problems. The Pittsburgh Sleep Quality Index (PSQI) scores varied from 0 to 12 points (M = 4.50, SD = 3.06) and 11 subjects (28.95%) had a PSQI score of more than 5 points. The Epworth Sleepiness Scale (ESS) scores ranged from 0 – 15 points (M = 6.63, SD = 3.77), with 7 subjects (18.42%) having a score over 10, and indication of daytime sleepiness. Table 18 shows characteristics of the analysis subset.

Table 18

Characteristics of the Analysis Subset

Characteristics	Analysis Subset		
	n	Value	
Age (year), $M \pm SD$	36	79.81 ± 5.55	
Gender	38		
Female, N (%)		22 (57.89%)	
Male, N (%)		16 (42.11%)	
Race	38		
Caucasian, N (%)		35 (92.11%)	
African American, N (%)		3 (7.89%)	

Characteristics		Analysis Subset
	n	Value
BMI (kg/m ²), $M \pm SD$	35	26.71 ± 3.70
Normal (18.5 – 24.9), N (%)		12 (34.39%)
Overweight (25 – 29.9), N (%)		17 (48.57%)
Obese (30.0 and above), N (%)		6 (17.14%)
MMSE	36	29.17 ± 1.38
Normal (> 24 points), N (%)		36 (100%)
OARS	37	27.62 ± 0.83
Normal (> 12 points), N (%)		37 (100%)
GDS	37	1.08 ± 1.32
Normal (< 5 point), N (%)		37 (100%)
PSQI	38	4.50 ± 3.06
Good sleep quality (≤ 5 scores), N (%)		27 (71.05%)
Poor sleep quality (> 5 scores), N (%)		11 (28.95%)
ESS	33	6.64 ± 3.77
Normal (< 10 scores), N (%)		26 (78.79%)
Sleepy (≥ 10 scores), N (%)		7 (21.21%)

Note. BMI = Body Mass Index; MMSE = Mini-Mental State Examination; OARS = the Older Adults Resource Services (OARS) Independent Activities of Daily Living Scale; GDS = Geriatric Depression Scale; PSQI = Pittsburgh Sleep Quality Index; and ESS = Epworth Sleepiness Scale.

Characteristics of sleep.

Time in bed (TIB) for the second night of laboratory sleep study was 468.85 minutes (*SD* = 45.35 minutes) and was identical for both actigraphy and PSG methods. Three sleep parameters (i.e. SOL, WASO, and TST) were compared as measured by PSG and by four-sensitivity settings of actigraphy; the differences in these parameters are indicated in Table 19. Relationships between each sleep parameter by PSG and actigraphy during the second night were explored by using both Pearson's and Spearman's rank correlation coefficients (Table 20).

Table 19

Characteristics and Difference of the Second Night Sleep Parameters by PSG and Actigraphy (n = 38)

Sleep				Dif	ference (PSC	G – Actigra	phy)	ICC
Parameters	Median	Mean	SD	Mean	SD	t/z	P-Value	(95% CI)
SOL (minute)								
PSG	11.00	14.71	12.03					
Actigraphy								
Low sensitivity	4.00	12.58	26.28	-2.13	27.96	- 11 ⁺	< .001	0.06 (-0.25, 0.37)
Medium sensitivity	4.00	12.58	26.28	-2.13	27.96	- 11 ⁺	< .001	0.06 (-0.25, 0.37)
High sensitivity	4.00	12.58	26.28	-2.13	27.96	- 11 ⁺	< .001	0.06 (-0.25, 0.37)
Auto sensitivity	4.00	12.58	26.28	-2.13	27.96	- 11 ⁺	< .001	0.06 (-0.25, 0.37)
WASO (minute)								
PSG	75.25	85.71	52.50					
Actigraphy								
Low sensitivity	26.00	26.45	13.39	-59.26	48.27	-18 ⁺	< .0001	0.21 (-0.11, 0.49)
Medium sensitivity	40.00	44.16	20.17	-41.55	45.84	-5.59	< .0001	0.34 (0.03, 0.58)
High sensitivity	64.00	65.11	28.11	-20.61	42.69	-2.98	< .0125	0.49 (0.21, 0.69)
Auto sensitivity	28.50	29.26	14.96	-56.45	48.98	-17 ⁺	< .0001	0.20 (-0.12, 0.48)
TST (minute)								
PSG	363.25	360.08	51.82					
Actigraphy								
Low sensitivity	420.00	419.71	52.14	59.63	55.67	6.60	< .0001	0.43 (0.13, 0.65)
Medium sensitivity	398.50	402.00	53.53	41.92	53.67	4.82	< .0001	0.48 (0.20, 0.69)
High sensitivity	385.00	381.05	54.42	20.98	51.11	2.53	NS	0.54 (0.27, 0.73)
Auto sensitivity	420.00	416.89	50.78	56.82	54.76	6.40	< .0001	0.43 (0.14, 0.65)

Note. SOL = Sleep Onset Latency; WASO = Wake After Sleep Onset; TST = Total Sleep Time; SE = Sleep Efficiency; ICC = Intraclass correlation Coefficient; 95% CI = 95% Confidence Interval; $^+$ Sign test was used to analyze data; NS = not statistically significant.

Table 20

Parameter	Correlation	n Coefficient
	Pearson	Spearman
Sleep Onset Latency (SOL)		
Low sensitivity	0.09 ^{ns}	0.21^{ns}
Medium sensitivity	0.09 ^{ns}	0.21^{ns}
High sensitivity	0.09 ^{ns}	0.21 ^{ns}
Auto sensitivity	0.09 ^{ns}	0.21^{ns}
Wake After Sleep Onset (WASO)		
Low sensitivity	0.43*	0.49*
Medium sensitivity	0.50*	0.49*
High sensitivity	0.58*	0.58*
Auto sensitivity	0.37*	0.44*
Total Sleep Time (TST)		
Low sensitivity	0.43*	0.47*
Medium sensitivity	0.48*	0.47*
High sensitivity	0.54*	0.56*
Auto sensitivity	0.47*	0.48*

Note. * p < .0125; ns = not statistically significant.

Sleep Onset Latency (SOL).

The mean second night SOL from PSG was 14.71 minutes (SD = 12.03) while the mean second night SOL by actigraphy was 12.58 minutes (SD = 26.28 minutes). The differences of the second night SOL between two methods were not normally distributed, D = 0.28, p < .01. Figure 64 shows how these data were distributed. Using a sign test, the second night SOL by actigraphy was significantly less than by PSG, z = -11, p < .0001. The association between the second night SOL measures was poor, with an ICC value of 0.06 and the 95% CI of -0.25 and 0.37.

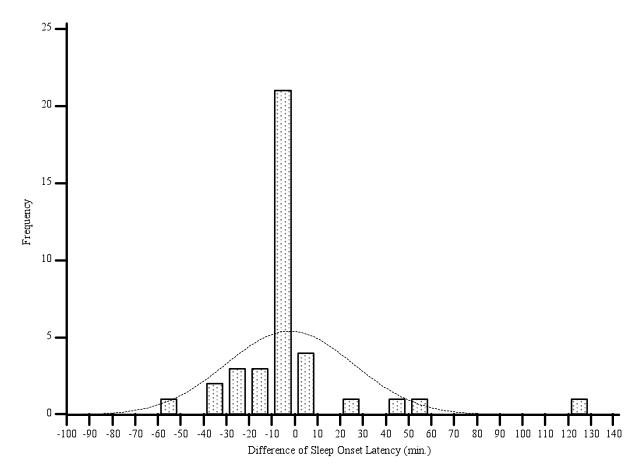


Figure 64. Histogram of differences in the second night sleep onset latency (SOL) by actigraphy and by PSG (n=38).

Note. Differences were calculated as the second night SOL by actigraphy minus the second night SOL by PSG.

The relationship of the second night SOL between actigraphy and PSG was illustrated in Figure 65; this relationship was not statistically significant (Table 20).

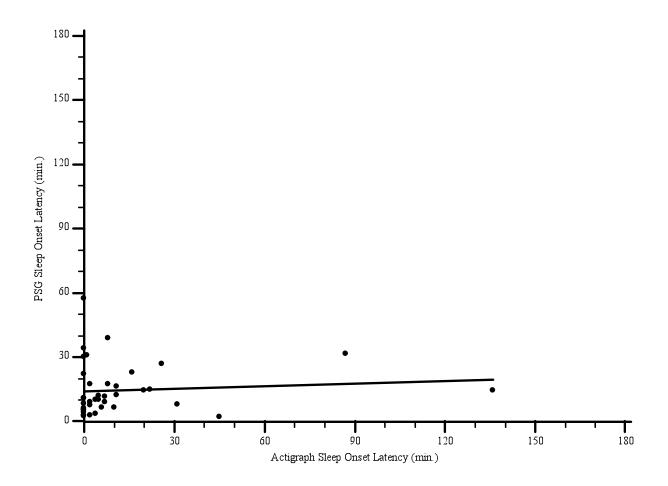


Figure 65. Relationship of the second night sleep onset latency (SOL) between PSG and high sensitivity actigraphy (n=38).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the second night SOL by actigraphy on the second night SOL by PSG. Each dot represents one subject.

The agreement of the second night SOL by actigraphy and by PSG is presented in a Bland-Altman plot (Figure 66). The x-axis represents the mean second night SOL between two methods across the range of 1.25 and 75.25 minutes. The y-axis represents the difference in the second night SOL between two methods and it varied from -57.50 to 121.50 minutes.

The mean difference between these two methods, or bias, was -2.13 minutes (95% CI = - 11.32 to 7.06), indicating that on average actigraphy underestimated SOL by approximately 2 minutes as compared to PSG. The standard deviation for the mean difference of SOL was 22.96. Since the horizontal dotted lines show a 95% limits of agreement, the upper and lower limits of agreement were 52.67 and -56.93 minutes, respectively. Based on these limits of agreement, there were 2 outliers (5.26%) with values beyond the upper limit of agreement: subjects #11 and #27.

In addition, there was a possible trend in the bias. When the mean second night SOL was less than 10 minutes, difference or bias was small and clustered around the zero line. However, when the magnitude of mean SOL increased beyond 10 minutes, the bias was larger and was either positive or negative from the zero line.

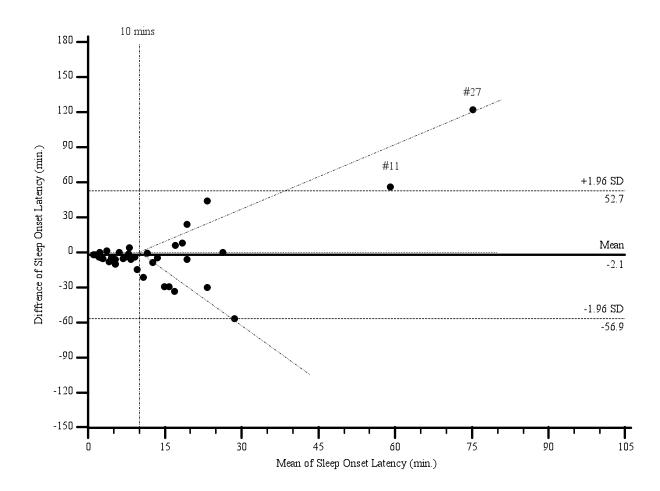


Figure 66. Bland-Altman plot of the second night sleep onset latency (SOL): Actigraphy vs. PSG (n=38).

Note. Differences were calculated as the second night SOL by actigraphy minus the second night SOL by PSG (actigraphy - PSG). Means were calculated as the mean of the second night SOL by actigraphy and PSG [(actigraphy + PSG) /2]. Each dot represented one subject.

In summary, although different sensitivity settings were applied to actigraphy, the second night SOL was identical for all four thresholds. Actigraphy underestimated the second night SOL from PSG by 2 minutes. Although there was a linear relationship for the second night SOL between these two methods, it was not statistically significant. In addition, measurement error

occurred and varied over the measurement scale: the more SOL subjects had, the more bias occurred in both positive and negative directions.

Wake after sleep onset (WASO).

While the second night WASO by PSG was 85.71 minutes (SD = 52.50), the mean second night WASO by actigraphy for low, medium, high, and auto sensitivity settings were 26.45 (SD = 13.39), 44.16 (SD = 20.17), 65.11 (SD = 28.11) and 29.26 (SD = 14.96) minutes, respectively. There were statistically significant differences for all four sensitivity levels of actigraphy compared to PSG for second night WASO.

Pearson and Spearman's rank correlation coefficients were implemented to examine relationships of the second night WASO between two methods (Table 20). More detail is elaborated in the following section.

Low sensitivity actigraphy.

Differences of the second night WASO between low sensitivity actigraphy and PSG were not normally distributed, D = 0.15, p < .05, as illustrated in a histogram (Figure 67). A signed test with Bonferroni correction was performed with significance set at p < .0125 and showed that the differences of the second night WASO between these two methods was statistically significant, z = .18, p < .0001. The association between these two methods in measuring WASO was poor, with an ICC value of 0.21 and the 95% CI of -0.11 and 0.49.

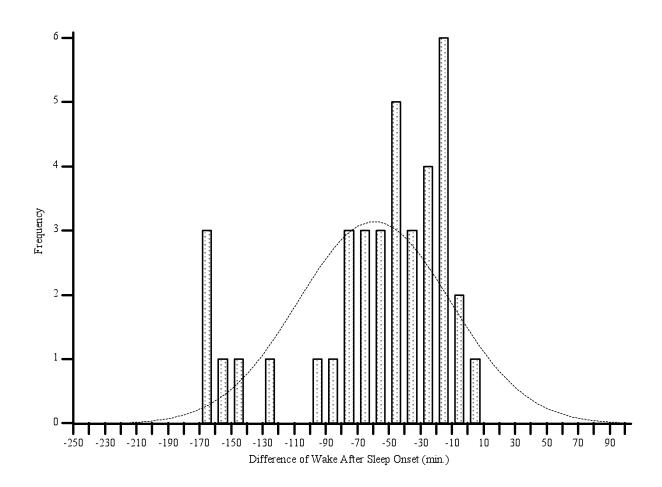


Figure 67. Histogram of Differences in wake after sleep onset (WASO) by low sensitivity actigraphy and PSG (n=38).

Note. Differences were calculated as WASO by actigraphy minus WASO by PSG.

The second night WASO between PSG and low sensitivity actigraphy were plotted to show their relationship (Figure 68). As shown in Table 20, Spearman provided a higher value of correlation coefficient than what Pearson did. The second night WASO from two methods were then ranked. The relationship of ranked WASO between two methods is illustrated in Figure 69. Using Spearman's rank correlation coefficient, there was a significant relationship of the second night WASO between two methods, $r_s = 0.49$, p < .0125.

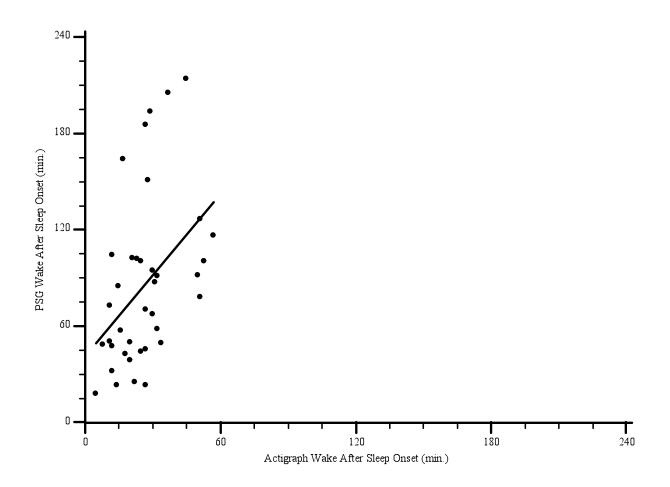


Figure 68. Relationship of the second night wake after sleep onset (WASO) between PSG and low sensitivity actigraphy (n=38).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the second night WASO by actigraphy on the second night WASO by PSG. Each dot represents one subject.

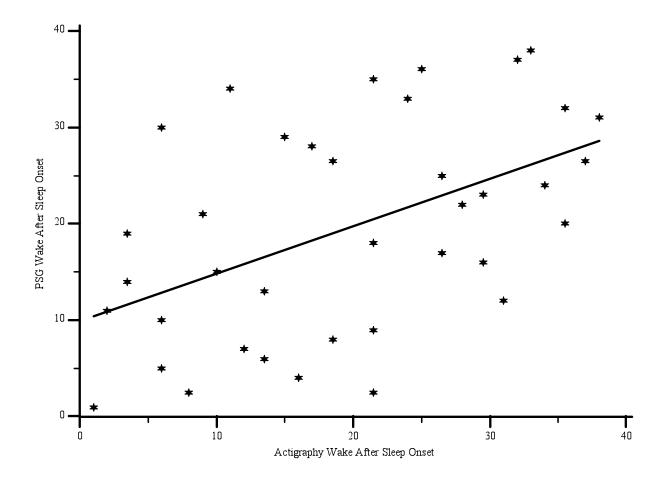


Figure 69. Relationship of the second night ranked wake after sleep onset (WASO) between PSG and low sensitivity actigraphy (n=38)

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the second night ranked WASO by actigraphy on the second night ranked WASO by PSG. Each star represents one subject.

A simple regression revealed that approximately 19% of variance in WASO by PSG could be explained by WASO from actigraphy, $R^2 = 0.19$, p < .0125. As seen in Table 21, the second night WASO by PSG was expected to be 49.47 minutes when WASO by actigraphy

reached a minimum value of 5 minutes. In addition, WASO by PSG was expected to increase by

1.69 minute for each 1 minute of increase in WASO by actigraphy.

Table 21

Regression Analysis for the Second Night Wake After Sleep Onset (WASO) by low Sensitivity

Actigraphy as a Predicting Factor for the Second Night WASO by PSG (n=38)

Variables	В	SE B	β
Intercept	49.47*	14.85	
WASO by Actigraphy	1.69*	0.59	0.43*

Note. PSG = Polysomnography; WASO = Wake After Sleep Onset; B = Unstandardized Beta when WASO by actigraphy equaled minimum value of 5 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125; ns = not statistically significant.

A Bland-Altman plot illustrates the agreement of the second night WASO from low sensitivity actigraphy and PSG (Figure 70). The mean WASO varied from 11.15 to129.50 minutes while the difference in WASO varied from -169.00 to 3.50 minutes. More than 97% of subjects had negative differences, indicating that low sensitivity actigraphy almost always underestimated WASO by PSG.

The mean difference between these two methods, or bias, was -59.26 minutes (95% CI = -75.13 to -43.40). A negative mean difference meant that on average actigraphy underestimated WASO by approximately one hour as compared to WASO by PSG. The standard deviation for the mean difference of WASO was 48.27 thus the 95% limits of agreement was 35.34 for upper limit and -153.87 minutes for lower limit. Four outliers (10.53%) had differences that exceeded the lower limit of agreement: subjects #6, #14, #19 and #31.

There was a possible trend in this bias. Using 30-minutes as a cut point, when the mean second night WASO was less than 30 minutes, an overestimation of actigraphy on WASO was

found in one case. However, when the mean second night WASO was at least 30 minutes or more, all differences were below the zero line, with increasing distance from the zero line towards the right side of the graph.

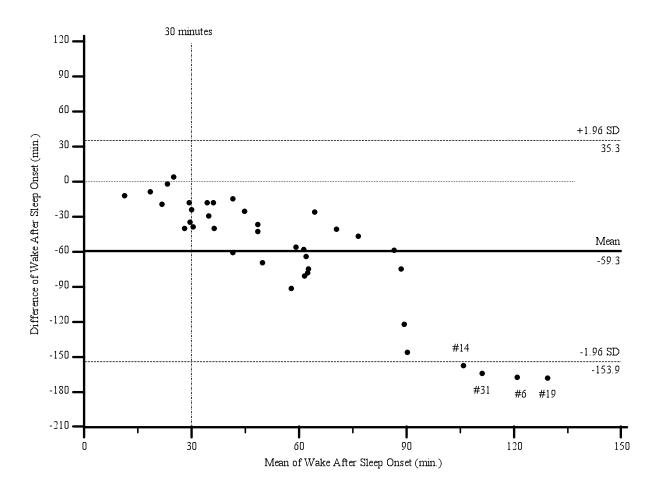


Figure 70. Bland-Altman plot of the second night wake after sleep onset (WASO): Low sensitivity actigraphy vs. PSG (n=38).

Note. Differences were calculated as WASO by actigraphy minus WASO by PSG (actigraphy - PSG). Means were calculated as the mean of WASO by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represented one subject.

Medium sensitivity actigraphy.

Differences of the second night WASO from actigraphy and PSG were examined by a paired-sample t-test with Bonferroni correction, revealing a statistically significant difference, t(37) = -5.59, p < .0001. The association between these two methods in measuring WASO was fair, with an ICC value of 0.34 and the 95% CI of 0.03 and 0.58.

A scatter plot (Figure 71) and correlation models (Table 20) were performed to examine the relationship of the second night WASO between two methods. There was a significant moderate positive linear relationship of the second night WASO between two methods, r = .50, p< .0125.

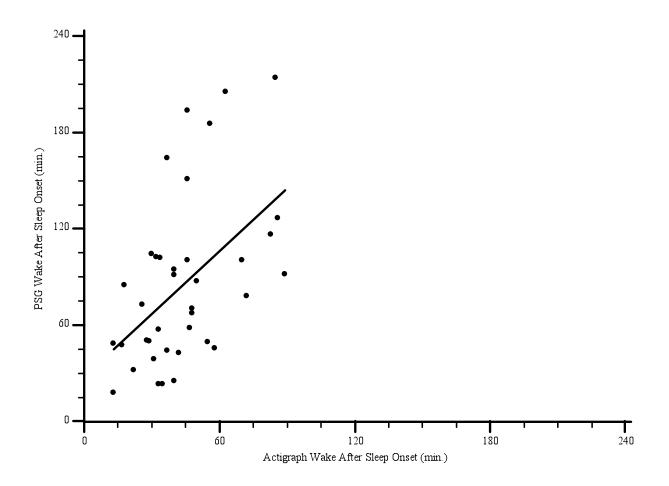


Figure 71. Relationship of the second night wake after sleep onset (WASO) between PSG and medium sensitivity actigraphy (n=38).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the second night WASO by actigraphy on the second night WASO by PSG. Each dot represents one subject.

Approximate 25% of variance in the second night WASO from PSG could be explained by the second night WASO from actigraphy, $R^2 = 0.25$, p < .0125. As seen in Table 22, the second WASO by PSG was expected to be 45.04 minutes when the second night WASO by actigraphy was 13 minutes. In addition, for each 1 minute increase in the second night WASO by

actigraphy, the second night WASO by PSG was expected to increase 1.30 minutes.

Table 22

Regression Analysis for the Second Night Wake After Sleep Onset (WASO) by Medium

Sensitivity Actigraphy as a Predicting Factor for the Second Night WASO by PSG (n=38)

Variables	В	SE B	β
Intercept	45.04*	13.87	
WASO by Actigraphy	1.30*	0.38	0.50*

Note. PSG = Polysomnography; WASO = Wake After Sleep Onset; B = Unstandardized Beta when WASO by actigraphy equaled minimum value of 13 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

The agreement of the second night WASO from actigraphy and PSG is illustrated by Bland-Altman plot (Figure 72). The average second night WASO was between 15.50 and 149.50 minutes while the difference of the second night WASO varied from -147.50 to 15.00 minutes. Nearly 87% of subjects had negative differences, indicating that the medium sensitivity actigraphy always provided a lower value of the second night WASO compared to PSG.

The mean difference, or bias, between these two methods was -41.55 minutes (95% CI = -56.62 to -26.49). A negative value indicated that on average the medium sensitivity actigraphy underestimated the second night WASO from PSG by 42 minutes. Since the standard deviation for the mean difference of the second night WASO was 45.84, the upper and lower limits of agreement are 48.29 and -131.40 minutes, respectively. Two outliers (5.26%) exceeded the lower limit of agreement: subjects #6, and #31.

There was a possible trend in the bias. When the magnitude of WASO increased, the underestimations of WASO were also increased. Using a 60-minutes of mean WASO between

the two methods as a cut point, when the mean WASO was less than 60 minutes, the bias was not specific. However, when the mean WASO was at least or more than 60 minutes, all differences were located under the zero line, indicating that medium sensitivity actigraphy always underestimated WASO in those cases.

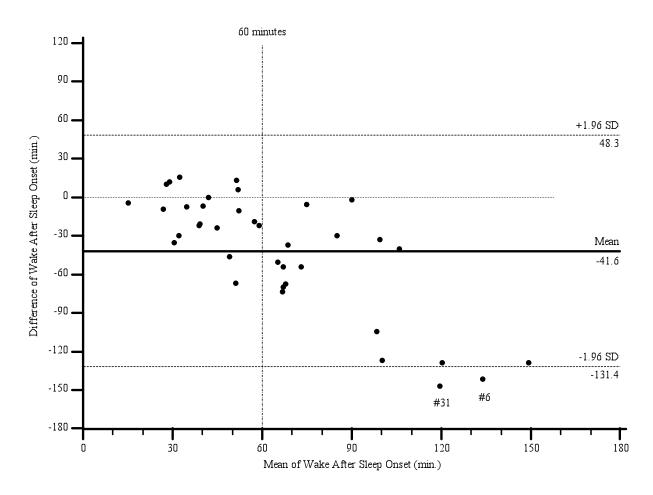


Figure 72. Bland-Altman plot of the second night wake after sleep onset (WASO): Medium sensitivity actigraphy vs. PSG.

Note. Differences were calculated as WASO by actigraphy minus WASO by PSG (actigraphy - PSG). Means were calculated as the mean of WASO by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

High sensitivity actigraphy.

The differences of WASO obtained by actigraphy and PSG were examined by a pairedsample t test with Bonferroni correction and these differences were statistically significant, t(37)= -2.98, p < .001. The association between these two methods in measuring WASO was fair, with an *ICC* value of 0.49 and the 95% CI of 0.21 and 0.69.

A scatter plot (Figure 73) and correlation analysis (Table 20) were performed to examine the relationship of the second night WASO between two methods. There was a significant moderate positive linear relationship between the second night WASO by actigraphy and by PSG, r = .58, p < .01.

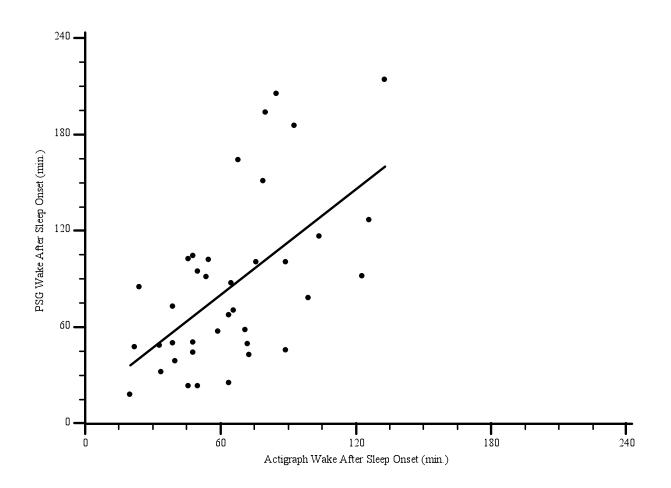


Figure 73. Relationship of the second night wake after sleep onset (WASO) between PSG and high sensitivity actigraphy (n=38).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the second night WASO by actigraphy on the second night WASO by PSG. Each dot represents one subject.

Approximately 34% of variances in the second night WASO by PSG could be explained by the second night WASO by actigraphy, $R^2 = 0.34$, p < .0125. As seen in Table 23, the second night WASO by PSG was expected to be 36.50 minutes when the second night WASO by actigraphy was 20 minutes. In addition, second night WASO by PSG was expected to increase

1.09 minutes for each minute increase in the second night WASO by actigraphy.

Table 23

Regression Analysis for the Second Night Wake After Sleep Onset (WASO) by High Sensitivity

Actigraphy as a Predicting Factor for the Second Night WASO by PSG (n=38)

Variables	В	SE B	β
Intercept	36.50*	13.38	
WASO by Actigraphy	1.09*	0.25	0.58*

Note. PSG = Polysomnography; Wake After Sleep Onset; B = Unstandardized Beta when WASO by actigraphy equaled minimum value of 8 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

The agreement of the second night WASO obtained by two methods is presented using Bland-Altman plot (Figure 74). The mean second night WASO by two methods was between 19.00 and 173.50 minutes while the differences of WASO varied from -120.00 to 43.50 minutes. Although more than half of subjects (63.16%) had negative differences, meaning high sensitivity actigraphy provided a lower value of WASO than PSG method, among the four thresholds, the group had the highest number of subjects with a positive difference.

The bias of these two methods was -20.61 minutes (95% CI = -34.64 to -6.57), indicating that on average the high sensitivity actigraphy underestimated the second night WASO by 21 minutes as compared to PSG. Since the standard deviation for the mean difference of the second night WASO was 42.69, the upper and lower limits of agreement are 63.07 and -104.28 minutes, respectively. Two outliers (5.26%) exceeded the lower limit of agreement: subjects #6 and #31.

There was a possible trend in the bias. When the magnitude of the second night WASO increased, the magnitude of underestimation of the second night WASO also increased. Using

120-minutes as a cut point, when the mean second night WASO was less than 120 minutes, the bias was not specific. However, when the mean second night WASO was more than 120 minutes, all differences were located under the zero line, indicating that high sensitivity actigraphy always underestimated WASO in such cases.

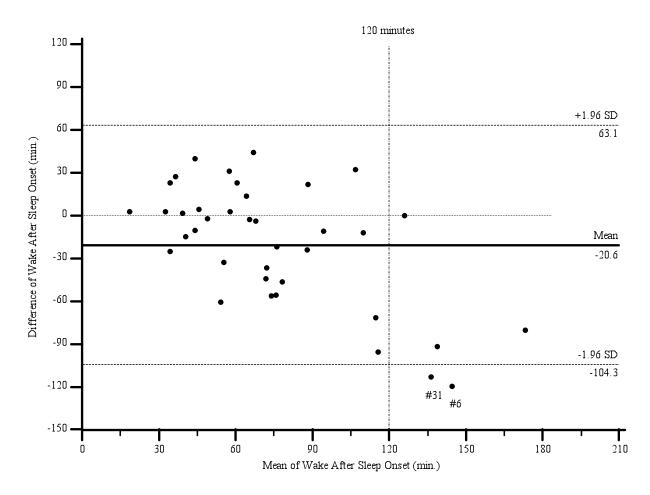


Figure 74. Bland-Altman plot of wake after sleep onset (WASO): High sensitivity actigraphy vs. PSG (n=38).

Note. Differences were calculated as WASO by actigraphy minus WASO by PSG (actigraphy – PSG). Means were calculated as the mean of WASO by actigraphy and by [(actigraphy + PSG) /2]. Each dot represents one subject.

Auto sensitivity actigraphy.

The distribution of differences of the second night WASO by auto sensitivity actigraphy and PSG was not normal, D = 0.15, p < .05, as depicted in a histogram (Figure 75). Using a signed test with Bonferroni correction, the differences of the second night WASO between two methods was statistically significant, z = -17, p < .0001. The association between these two methods in measuring the second night WASO was poor, with an ICC value of 0.20 and the 95% CI of -0.12 and 0.48.

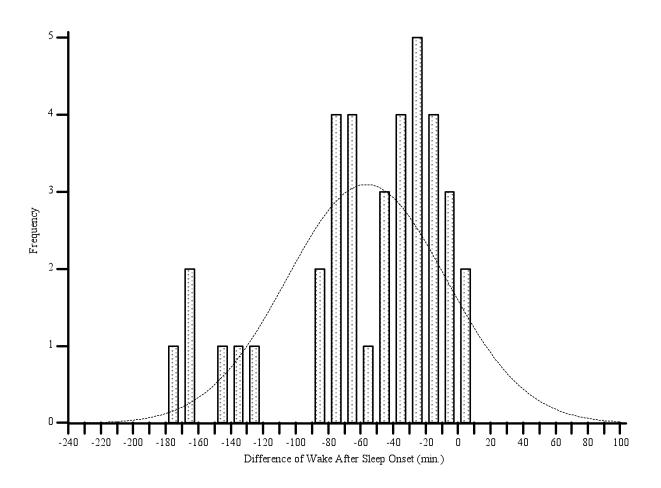


Figure 75. Histogram of differences in wake after sleep onset (WASO) by auto sensitivity actigraphy and by PSG (n=38).

Note. Differences were calculated as WASO by actigraphy minus WASO by PSG.

The second night WASO between PSG and auto sensitivity actigraphy were plotted to show their relationship (Figure 76). As shown in Table 20, Spearman provided a higher value of correlation coefficient than what Pearson did. The second night TST between two nights was then ranked. The relationship of ranked TST between two nights is illustrated in Figure 77. Using Spearman's rank correlation coefficient, there was a significant relationship of the second night TST between two methods, $r_s = 0.44$, p < .0125.

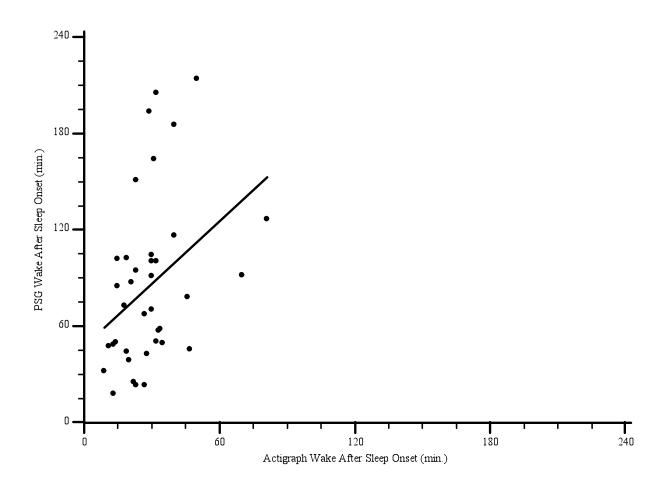


Figure 76. Relationship of the second night wake after sleep onset (WASO) between PSG and auto sensitivity actigraphy (n=38).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the second night WASO by actigraphy on the second night WASO by PSG. Each dot represents one subject.

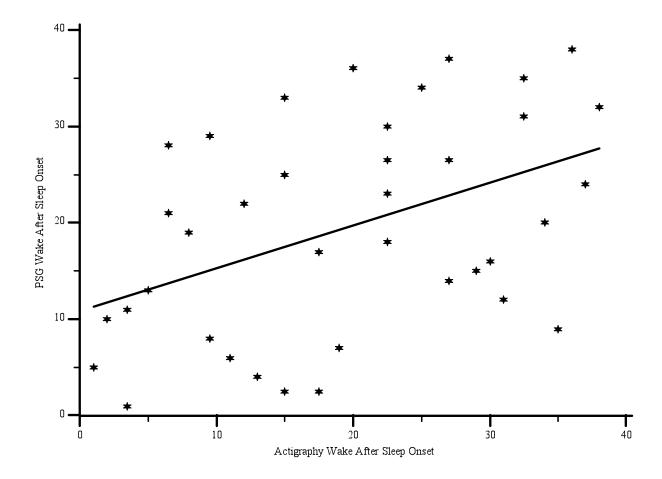


Figure 77. Relationship of the second night ranked wake after sleep onset (WASO) between PSG and auto sensitivity actigraphy (n=38).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the second night ranked WASO by actigraphy on the second night ranked WASO by PSG. Each star represents one subject.

As seen in Table 24, approximately 14% of variance in the second night WASO by PSG could be explained by the second night WASO from actigraphy, $R^2 = 0.14$, p < .0125. The second night WASO by PSG was expected to be 59.39 minutes when the second night WASO

by actigraphy was nine minutes. In addition, the second night WASO by PSG was expected to

increase 1.30 minutes for each minute of increase in the second night WASO by actigraphy.

Table 24

Regression Analysis for the Second Night Wake After Sleep Onset (WASO) by Auto Sensitivity

Actigraphy as a Predicting Factor for the Second Night WASO by PSG (n=38)

Variables	В	SE B	β
Intercept	59.39*	13.63	
WASO by Actigraphy	1.30*	0.54	0.37*

Note. PSG = Polysomnography; WASO = Wake After Sleep Onset; B = Unstandardized Beta when WASO by actigraphy equaled minimum value of 8 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

A Bland-Altman plot illustrates the agreement of the second night WASO between two methods (Figure 78). The mean second night WASO varied from 15.50 to 132.00 minutes while the differences of WASO were between 173.00 and 3.50 minutes. More than 90% of subjects had negative differences, indicating that auto sensitivity actigraphy almost always provided a lower value of the second night WASO than what PSG did.

The mean difference in the second night WASO, or bias, was -56.47 minutes (95% CI = -72.55 to -40.35), indicating that on average auto sensitivity actigraphy underestimated the second night WASO by approximately one hour. Since the standard deviation for the mean difference of the second night WASO was 52.24, the upper and lower limits of agreement are 39.55 and -152.45 minutes, respectively. Three outliers (7.89%) had differences exceeded the lower limit of agreement: subjects #6, #19, and #31.

There was a possible trend of bias. When the magnitude of the second night WASO increased, the underestimations of the second night WASO were also increased. Using a 50

minutes as a cut point, when the mean WASO was less than 50 minutes, bias was not specific. However, when the mean second night WASO was at least or more than 50 minutes, all differences were located under the zero line, indicating that auto sensitivity actigraphy was always underestimated WASO in such cases.

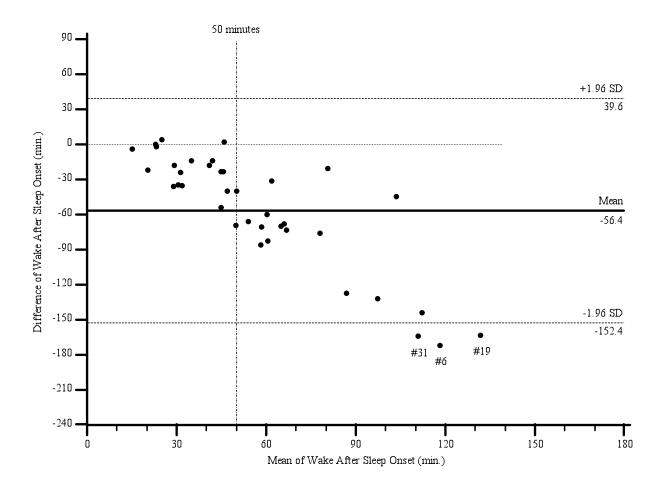


Figure 78. Bland-Altman plot of wake after sleep onset (WASO): Auto sensitivity actigraphy vs. PSG (n=38).

Note. Differences were calculated as WASO by actigraphy minus WASO by PSG (actigraphy - PSG). Means were calculated as the mean of WASO by actigraphy and by PSG [(actigraphy + PSG)/2]. Each dot represented one subject.

As shown in Table 25, four approaching methods were employed to examine the agreement of the second night WASO between four sensitivity settings of actigraphy and PSG. When taking differences of the mean/median between two methods into account, there were statistically significantly difference in the second night WASO from four sensitivity settings and PSG. The ICCs between two methods were between poor and fair; medium and high sensitivity provided better values of ICCs than those with low and auto sensitivity. There were statistically low positive linear relationships for the second night WASO between two methods across four levels of threshold. Regardless of the different sensitivity settings, actigraphy underestimated the second night WASO by PSG. However, of all the sensitivity settings, the high sensitivity provided the least bias, as it underestimated WASO by 21 minutes.

Table 25

Agreement of the Second Night Wake After Sleep Onset (WASO) by PSG and Actigraphy

(n=38)
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Sensitivity			Method		
settings	Comparison of		Correlation	Bland-Altman Plots	
Actigraphy	the mean/median	ICC	Regression		(Bias)
	(p value)		r/r_s	R^2	
Low	<.0001	Poor	Low	0.19	-59.26
Medium	<.0001	Fair	Moderate	0.25	-41.55
High	<.0125	Fair	Moderate	0.34	-20.61
Auto	<.0001	Poor	Low	0.14	-56.45

Note. PSG = Polysomnography; r = Pearson Coefficient; r_s = Spearman's Rank Coefficient; R^2 = coefficient of determination.

Total sleep time (TST).

On average, subjects slept for 360.08 minutes (SD = 51.82) or around 6 hours by PSG during the second night. However, the second night TST from four sensitivity settings (i.e. low,

medium, high, and auto) was higher than those taken by PSG with values of 419.71 (SD = 52.14), 402.00 (SD = 53.52), 381.05 (SD = 54.42) and 416.89 (SD = 50.78) minutes, respectively. The second night TST from PSG and actigraphy was compared. Except for high sensitivity level, there were statistically significant differences between TST by actigraphy and PSG (Table 19). The relationships of the second night TST between two methods were tested and the second night TST by actigraphy had a significant relationship with the second night TST by PSG (Table 20). More detail was elaborated in the following section.

Low sensitivity actigraphy.

Differences in the second night TST between two methods were tested. Using a pairedsample t-test with Bonferroni correction, there was a statistically significant difference of the second night TST between actigraphy and PSG, t(37) = 6.60, p < .0001. The association between these two methods in measuring the second night TST was fair, with an ICC value of 0.43 and the 95% CI of 0.13 and 0.65.

A relationship of the second night TST between PSG and low sensitivity is shown in Figure 79. As seen in Table 20, Spearman's rank provided higher value of correlation coefficient that what Pearson did. Data were then ranked. Scatter plot illustrates the relationship between ranked TST from PSG and actigraphy (Figure 80). There was a significant low positive relationship between ranked TST by actigraphy and by PSG, $r_s = .47$, p < .01.

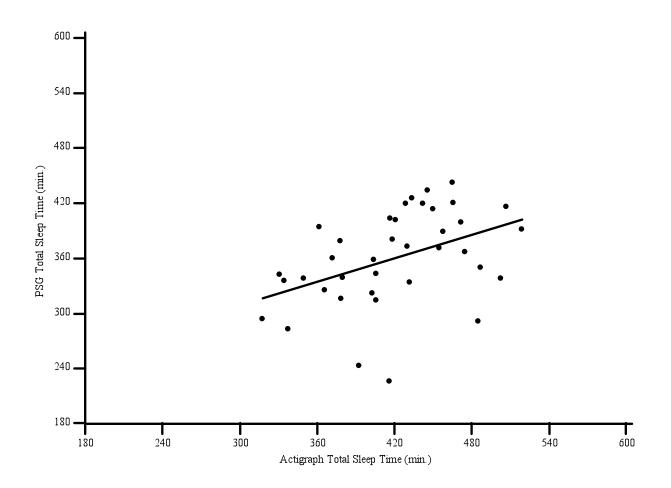


Figure 79. Relationship of the second night total sleep time (TST) between PSG and low sensitivity actigraphy (n=38).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the second night TST by actigraphy on the second night TST by PSG. Each dot represents one subject.

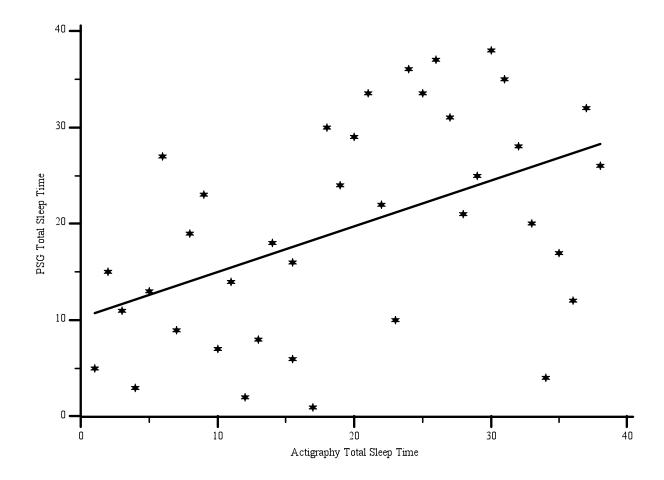


Figure 80. Relationship of the second night ranked total sleep time (TST) between PSG and low sensitivity actigraphy (n=38).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the second night TST by actigraphy on the second night TST by PSG. Each star represents one subject.

A simple regression was employed to identify the predictive value of the second night TST by actigraphy on the second night TST by PSG (Table 26). Approximately 18% of variance in the second night TST by PSG was explained by the second night TST from actigraphy, $R^2 = 0.18$, p < .01. The second night TST by PSG was expected to be 316.97 minutes when the second

night TST by actigraphy was 318 minutes. In addition, the second night TST by PSG was expected to increase 0.42 minute for each minute of increase in the second night TST by actigraphy.

Table 26

Regression Analysis for the Second Night Total Sleep Time (TST) by low Sensitivity Actigraphy as a Predicting Factor for the Second Night TST by PSG (n=38)

Variables	В	SE B	β
Intercept	316.97*	17.08	
TST by Actigraphy	0.42*	0.15	0.43*

Note. PSG = Polysomnography; TST = Total Sleep Time; B = Unstandardized Beta when TST by actigraphy equaled minimum value of 318 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

A relative agreement of the second night TST between two methods is illustrated by Bland-Altman plot (Figure 81). The x-axis represents the average TST obtained from low sensitivity actigraphy and PSG methods. The range of TST varied between 306.00 and 461.50 minutes. The y-axis represents the difference in TST measured with the low sensitivity actigraphy and PSG methods. In this study, the differences varied from -31.50 to 193.50 minutes. Ninety-five percent of subjects had positive differences, which meant that the low sensitivity actigraphy always provided higher value of TST than PSG method.

The mean difference between these two methods, or bias, was 59.63 minutes (95% CI = 41.34 to 77.93). A positive value of the mean difference indicated that on average actigraphy overestimated the second night TST by approximately one hour as compared to those taken by PSG. The 95% limits of agreement are represented by the two horizontal dotted lines shown. Because the standard deviation for the mean difference of TST was 55.67, the upper and lower

limits of agreement are 137.20 and -49.48 minutes, respectively. Two outliers (5.26%) exceeded the upper limit of agreement: subjects #19, and #31.

Based on the Bland-Altman plot there is no obvious pattern of overestimation of the second night TST; differences of the second night TST distributed all over the graph and did not relate to the magnitude of the mean second night TST.

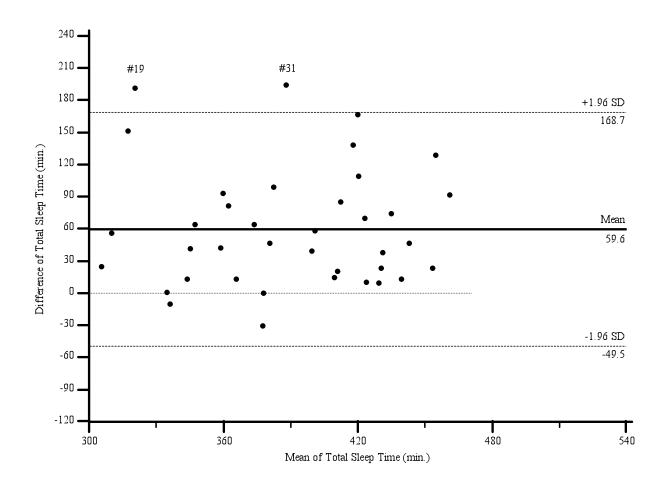


Figure 81. Bland-Altman plot of total sleep time (TST): Low sensitivity actigraphy vs. PSG (n=38).

Note. Differences were calculated as TST by actigraphy minus TST by PSG (actigraphy - PSG). Means were calculated as the mean of TST by actigraphy and PSG [(actigraphy + PSG) /2]. Each dot represented one subject.

Medium sensitivity actigraphy.

The second night TST obtained by medium sensitivity /wake threshold actigraphy was compared to the second night TST taken by PSG. Using a paired-sample t-test with Bonferroni correction, there was a statistically significant difference for the second night TST, t(38) = 4.82, p < .0001. The result revealed that TST by medium sensitivity was more than that measured by PSG. The association between these two methods in measuring the second night TST was fair, with an ICC value of 0.48 and the 95% CI of 0.20 and 0.69.

A scatter plot shows the relationship between the second night TST from medium sensitivity actigraphy and PSG (Figure 82). Using a Pearson correlation, there was a significant low positive linear relationship between TST by actigraphy and by PSG, r = .48, p < .01.

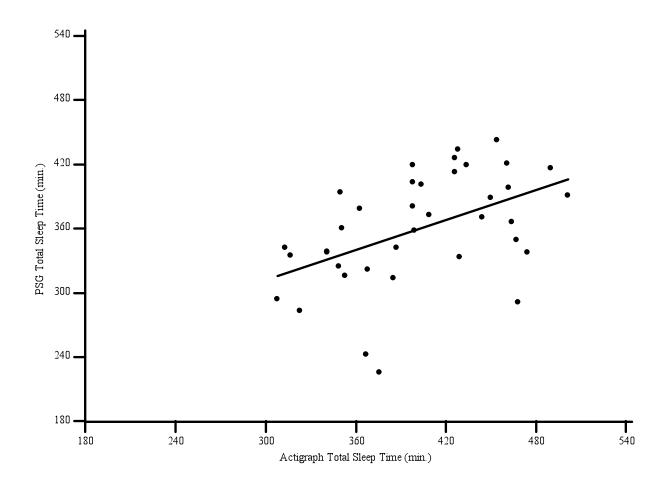


Figure 82. Relationship of the second night total sleep time (TST) between PSG and medium sensitivity actigraphy (n=38).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the second night TST by actigraphy on the second night TST by PSG. Each dot represents one subject.

The predictive value for the second night TST by PSG is shown in Table 27. Approximately 23% of variance in the second night TST by PSG could be explained by the second night TST from actigraphy, $R^2 = 0.23$, p < .0125. The second night TST by PSG was expected to be 316.28 minutes when the second night TST by actigraphy was 308 minutes. In addition the second night TST by PSG was expected to increase 0.47 minute for each minute of

increase in the second night TST by actigraphy.

Table 27

Regression Analysis for the Second Night Total Sleep Time (TST) by Medium Sensitivity

Actigraphy as a Predicting Factor for the Second Night TST by PSG (n=38)

Variables	В	SE B	β
Intercept	316.28*	15.25	
TST by Actigraphy	0.47*	0.14	0.48*

Note. PSG = Polysomnography; TST = Total Sleep Time; B = Unstandardized Beta when TST by actigraphy equaled minimum value of 308 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

A Bland-Altman plot illustrates the agreement of the second night TST by medium sensitivity actigraphy and PSG methods (Figure 83). The average second night TST obtained by two methods were between 300.75 and 453.00 minutes. The difference in the second night TST by two methods varied from -54.50 to 142.50 minutes. Approximately 80% of subjects had positive differences, indicating that medium sensitivity actigraphy always provided higher values for the second night TST than PSG method.

The mean difference between these two methods, or bias, was 41.93 minutes (95% CI = 24.28 to 59.56). A positive mean difference indicates that on average actigraphy overestimates TST by approximately 42 minutes as compared to PSG. The two horizontal dotted lines show 95% confidence limits, or limits of agreement. Since the standard deviation for the mean difference of TST was 53.67, the upper and lower limits of agreement are 147.12 and -63.27 minutes, respectively. Two outliers (5.26%) exceeded the upper limit of agreement: subjects #19, and #31.

Based on the Bland-Altman plot there was no obvious pattern of overestimation of TST; differences of the second night TST were distributed all over the graph and did not relate to the magnitude of the mean second night TST.

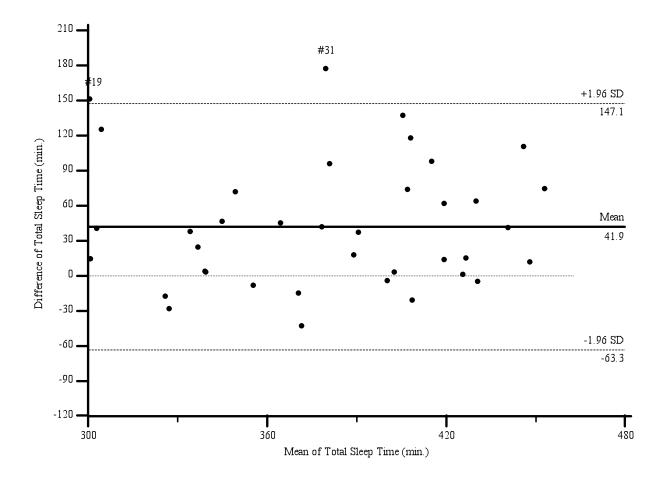


Figure 83. Bland-Altman plot of the second night total sleep time (TST): Medium sensitivity actigraphy vs. PSG (n=38).

Note. Differences were calculated as the second night TST by actigraphy minus the second night TST by PSG (actigraphy - PSG). Means were calculated as the medium of the second night TST by actigraphy and PSG [(actigraphy + PSG) /2]. Each dot represented one subject.

High sensitivity actigraphy.

Differences of the second night TST taken by high sensitivity actigraphy and by PSG were compared. Using a paired-sample t-test with Bonferroni correction, TST by two methods were similar, t(37) = 2.53, p > .0125. The association between these two methods in measuring the second night TST was moderate, with an ICC value of 0.54 and the 95% CI between 0.27 and 0.73.

Figure 84 shows a relationship of the second night TST by PSG and high sensitivity actigraphy. As seen in Table 20, Spearman's rank correlation provided higher value of correlation coefficient than what Pearson did, so the data were ranked. Scatter plot shows the relationship between the second night TST from actigraphy and PSG (Figure 85). Using Spearman's rank correlation, there was a significant moderate positive relationship between TST by actigraphy and PSG, $r_s = .56$, p < .01.

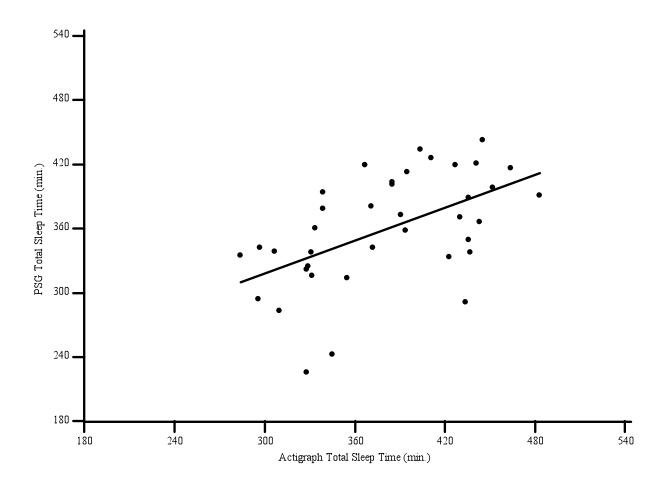


Figure 84. Relationship of the second night total sleep time (TST) between PSG and high sensitivity actigraphy (n=38).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the second night TST by actigraphy on the second night TST by PSG. Each dot represents one subject.

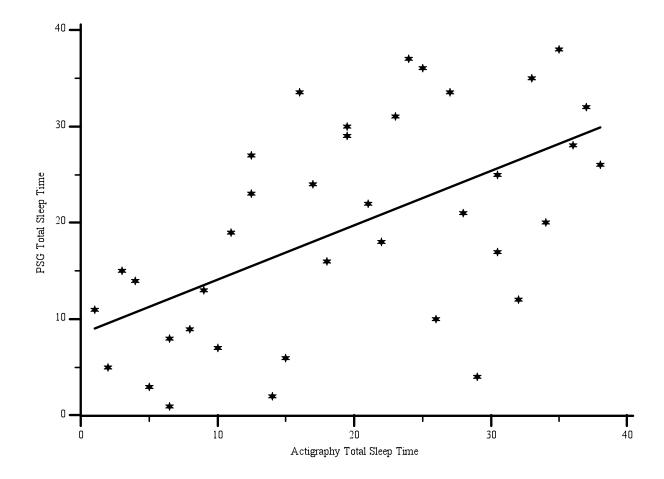


Figure 85. Relationship of the second night ranked total sleep time (TST) between PSG and high sensitivity actigraphy (n=38).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the second night ranked TST by actigraphy on the second night ranked TST by PSG. Each star represents one subject.

Approximately 29% of variance in the second night TST by PSG could be explained by the second night TST from actigraphy, $R^2 = 0.29$, p < .0125. As seen in Table 28, the second night TST by PSG was expected to be 310.36 minutes when the second night TST by actigraphy was 284 minutes. In addition, TST by PSG was expected to increase 0.51 minute for each minute of increase in the second night TST by actigraphy.

Table 28

Regression Analysis for the Second Night Total Sleep Time (TST) by High Sensitivity

Actigraphy as a Predicting Factor for the Second Night TST by PSG (n=38)

Variables	В	SE B	β
Intercept	310.36*	14.84	
TST by Actigraphy	0.51*	0.13	0.54*

Note. PSG = Polysomnography; TST = Total Sleep Time; B = Unstandardized Beta when TST by actigraphy equaled minimum value of 284 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

The agreement of the second night TST obtained by high sensitivity actigraphy and those obtained by PSG is illustrated by a Bland-Altman plot (Figure 86). The average second night TST obtained by two methods were between 276.75 and 443.75 minutes. The difference in the second night TST by two methods varied from -25.50 to 193.50 minutes. Sixty-three percent of subjects had positive differences, which meant that the high sensitivity actigraphy usually provided higher values of TST than PSG method. However, among the four levels of threshold, the high sensitivity had the highest number of subjects with a negative difference.

The mean difference between these two methods, or bias, was 20.68 minutes (95% CI = 4.18 to 37.78). A positive mean difference indicated that on average actigraphy overestimated the second night TST by approximately 21 minutes as compared to PSG. The limits of agreement are presented by the two horizontal dotted lines. Since the standard deviation for the mean difference of the second night TST was 51.11, the upper and lower limits of agreement are

121.15 and -79.20 minutes, respectively. One outlier (2.63%) exceeded the upper limit of agreement: subject #31.

Based on Bland-Altman plot there was no clear pattern of overestimation of the second night TST; differences of the second night TST were distributed all over the plot and did not relate to the magnitude of the mean second night TST.

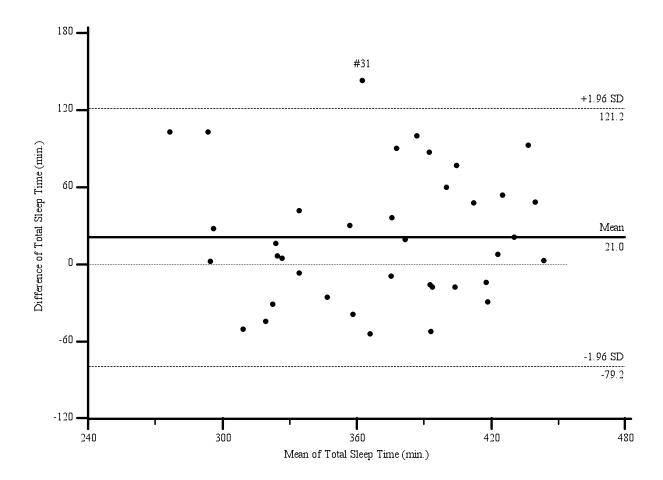


Figure 86. Bland-Altman plot of the second night total sleep time (TST): High sensitivity actigraphy vs. PSG (n=38).

Note. Differences were calculated as the second night TST by actigraphy minus the second night TST by PSG (actigraphy - PSG). Means were calculated as the mean of the second night TST by actigraphy and PSG [(actigraphy + PSG) /2]. Each dot represented one subject.

Auto sensitivity actigraphy.

A paired-sample t-test with Bonferroni correction was conducted to examine the difference of the second night TST between two methods. Statistically significant differences for the second night TST were found, t(37) = 6.40, p < .0001. It indicated that the second night TST by auto sensitivity was more than by PSG. The association between these two methods in measuring the second night TST was fair, with an ICC value of 0.43 and the 95% CI between 0.14 and 0.65.

Figure 87 shows a relationship of the second night TST between PSG and auto sensitivity actigraphy. As seen in Table 20, Spearman's rank provided a higher value of correlation coefficient than what Pearson did, so the data were then ranked. A scatter plot shows the relationship between ranked the second night TST from auto sensitivity actigraphy and PSG (Figure 88). There was a significant low positive linear relationship between TST by actigraphy and by PSG, $r_s = .48$, p < .01.

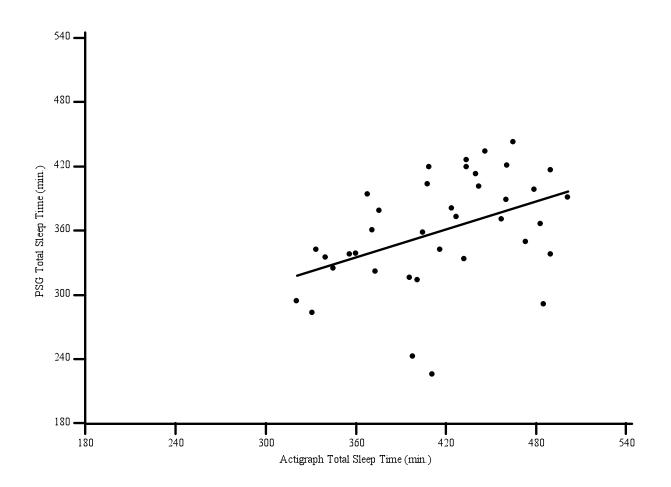


Figure 87. Relationship of the second night total sleep time (TST) between PSG and auto sensitivity actigraphy (n=38).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the second night TST by actigraphy on the second night TST by PSG. Each dot represents one subject.

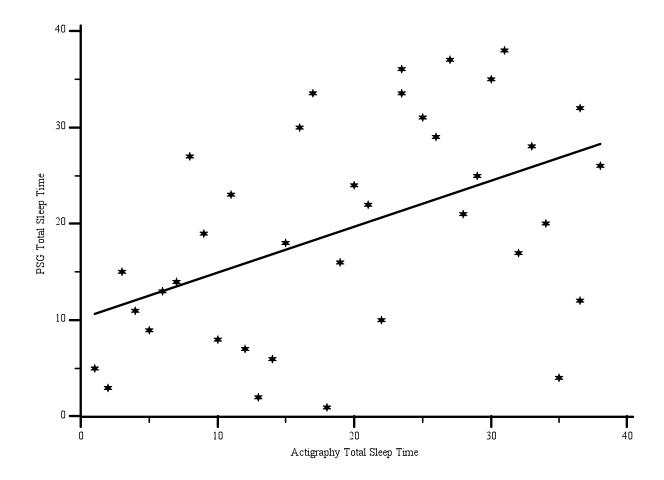


Figure 88. Relationship of the second night ranked total sleep time (TST) between PSG and auto sensitivity actigraphy (n=38).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of the second night ranked TST by actigraphy on the second night ranked TST by PSG. Each star represents one subject.

Approximately 19% of variance in TST by PSG could be explained by TST from actigraphy, $R^2 = 0.19$, p < .0125. As seen in Table 29, the TST by PSG was expected to be 317.96 minutes when TST by actigraphy was 321 minutes. In addition, TST by PSG was expected to increase 0.44 minute for each minute of increase in TST by actigraphy.

Table 29

Regression Analysis for the Second Night Total Sleep Time (TST) by Auto Sensitivity

Actigraphy as a Predic	ting Factor fo	or the Second N	Jight TST by	PSG(n=38)
i teugruphi y us u i teute			inghie i b i b j	100(11.00)

Variables	В	SE B	β
Intercept	317.96*	16.61	
TST by Actigraphy	0.44*	0.15	0.43*

Note. PSG = Polysomnography; TST = Total Sleep Time; B = Unstandardized Beta when TST by actigraphy equaled minimum value of 321 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

The agreement of the second night TST between two methods is presented in a Bland-Altman plot (Figure 89). The average second night TST obtained by two methods were between 307.00 and 453.75 minutes. The difference in TST by two methods varied from -25.50 to 193.50 minutes. Nearly 90% of subjects had positive differences, which meant that auto sensitivity actigraphy always provided higher values of TST than PSG.

The mean difference between these two methods, or bias, was 56.82 minutes (95% CI = 38.82 to 74.82). A positive value of the mean difference indicated that on average actigraphy overestimated the second night TST by approximately one hour as compared to PSG. The two horizontal dotted lines show 95% limits of agreement. Since the standard deviation for the mean difference of TST was 54.76, the upper and lower limits of agreement are 164.15 and -50.51 minutes, respectively. Two outliers (5.26%) exceeded the lower limit of agreement: subjects #19, and #31.

Based on the Bland-Altman plot there was no clear pattern of overestimation of the second night TST; differences of the second night TST distributed all over the plot and did not relate to the magnitude of the mean second night TST.

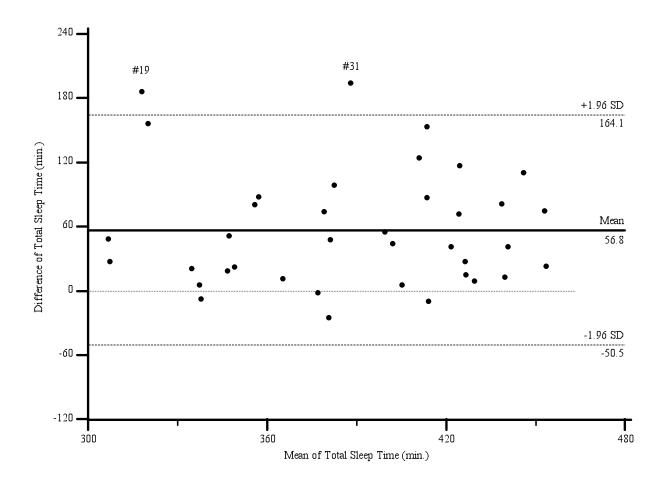


Figure 89. Bland-Altman plot of the second night total sleep time (TST): Auto sensitivity actigraphy vs. PSG (n=38).

Note. Differences were calculated as the second night TST by actigraphy minus the second night TST by PSG (actigraphy - PSG). Means were calculated as the mean of the second night TST by actigraphy and PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

In summary, four different approach methods (i.e. comparison of the means, ICC, generalized linear models, and Bland-Altman Plots) were employed to examine the agreement of the second night TST taken by PSG and those taken by four sensitivity settings of actigraphy (Table 30). According to the comparison of the mean/median method, four sensitivity settings

provided statistically significantly different TST compared with PSG. The ICCs between each sensitivity actigraphy and PSG were fair to moderate, with high sensitivity having the highest ICC among the four thresholds. The linear relationships of the second night TST between two methods were statistically significant for all four sensitivity settings. The strength of these relationships was low to moderate, with high sensitivity yielding the strongest relationship among the four thresholds. In addition, regardless of the different sensitivity settings, actigraphy always overestimated TST compared to PSG. However, actigraphy with high sensitivity provided the least bias, as it overestimated TST by 21 minutes.

Table 30

Agreement of the Second Night Total Sleep Time (TST) by PSG and Actigraphy (n=38)

Sensitivity settings	Comparison of		Method Correlation	n and	Bland-Altman Plots
Actigraphy	the mean/median	ICC	C Regression		(Bias)
	(p value)		r/r_s	R^2	
Low	<.0001	Fair	Low	0.18	59.63
Medium	<.0001	Fair	Low	0.23	41.92
High	NS	Moderate	Moderate	0.29	20.98
Auto	<.0001	Fair	Low	0.19	56.82

Note. PSG = Polysomnography; r = Pearson Coefficient; r_s = Spearman's Rank Coefficient; R^2 = coefficient of determination; NS = not statistically significant.

Summary of Results

The data presented examine the validity of actigraphy against PSG from two separate analyses from two separate nights of laboratory sleep study (Table 31). Except the second night TST by PSG and high sensitivity actigraphy, there were statistically significant differences between actigraphy and PSG for all sleep parameters. However, actigraphy data showed less discrepancy during the second night as compared to the first night. SOL was equal across all four different levels of sensitivity settings for actigraphy. Compared to PSG, SOL taken by actigraphy during the second night provided smaller discrepancy than those taken from the first night. The minutes of underestimate SOL declined from 21 minutes on the first night to 2 minutes on the second night.

WASO values, on the other hand, were influenced by different sensitivity settings of actigraphy. High sensitivity provided the smallest discrepancies among all four thresholds of actigraphy when compared to WASO taken by PSG. In addition, the validity of actigraphy during the second night of laboratory sleep was better than during the first night, as the discrepancy dropped from 33 minutes to 21 minutes.

Except high sensitivity, TST taken by actigraphy were different across other three sensitivity settings (i.e. low, medium and auto). The high sensitivity also yielded the smallest discrepancies. Additionally, the validity of actigraphy during the second night was better than those during the first night. The overestimate of TST decreased from 56 minutes during the first night to 21 minutes during the second night.

Table 31

Sleep	Comparison	Comparison of	ICC	r/r_s	Bland-
parameter	(PSG vs.	the	(strength of	(strength of	Altman Plots
from different	actigraphy)	mean/median	agreement)	linear	(Bias: PSG -
sensitivity				relationship)	Actigraphy)
levels					
SOL					
Low	1 st night	< .0001	Moderate	Moderate*	-20.45 min
	2 nd night	< .0001	Poor	Little ^{ns}	- 2.13 min
Medium	1 st night	<.0001	Moderate	Moderate*	-20.45 min
	2 nd night	< .0001	Poor	Little ^{ns}	- 2.13 min
High	1 st night	< .0001	Moderate	Moderate*	-20.45 min
	2 nd night	< .0001	Poor	Little ^{ns}	- 2.13 min
Auto	1 st night	< .0001	Moderate	Moderate*	-20.45 min
	2 nd night	< .0001	Poor	Little ^{ns}	- 2.13 min
WASO					
Low	1 st night	< .0001	Poor	Low ^{ns}	-72.21 min
	2 nd night	< .0001	Poor	Low*	-59.26 min
Medium	1 st night	< .0001	Fair	Low ^{ns}	-54.31 min
	2 nd night	< .0001	Fair	Moderate*	-41.55 min
High	1 st night	< .001	Fair	Low ^{ns}	-33.00 min
-	2 nd night	< .01	Fair	Moderate*	-20.61 min
Auto	1 st night	< .0001	Poor	Low ^{ns}	-71.21 min
	2 nd night	< .0001	Poor	Low*	-56.45 min
TST					
Low	1 st night	< .0001	Fair	Low*	+94.95 min
	2 nd night	< .0001	Fair	Low*	+59.63 min
Medium	1 st night	< .0001	Fair	Low*	+77.03 min
	2 nd night	<.001	Fair	Moderate*	+41.92 min
High	1 st night	< .001	Fair	Low*	+55.74 min
-	2 nd night	ns	Moderate	Moderate*	+20.98 min
Auto	1 st night	< .0001	Fair	Low*	+93.95 min
	2 nd night	< .0001	Fair	Low*	+56.82 min

Summary of the Results From Separate Analyses for Each Night

Note. SOL = Sleep Onset Latency; WASO = Wake After Sleep Onset; TST = Total Sleep Time; 1^{st} night = a comparison of first night sleep parameter from PSG and actigraphy; 2^{nd} night = a comparison of first night sleep parameter from PSG and actigraphy; ICC = Intraclass Correlation Coefficient; r = Pearson Product Moment Coefficient; r_s = Spearman's Rank Correlation Coefficient; * p < .0125; ns = Not statistically significant; - = underestimated, and + = overestimated.

CHAPTER SIX

RESEARCH QUESTION THREE RESULTS

This chapter presents the results of the secondary data analysis study covering research question three: How accurate is actigraphy, as compared to polysomnography (PSG), in measuring change in sleep in community-dwelling adults age 70 years and older? Since this was a method-comparison study, three different approaches were used, including comparison of the means, correlation and regression models, and Bland-Altman plots.

In this study, change was defined as the difference of a given sleep parameter between two nights of laboratory sleep study for the same individual. It was calculated by subtracting one's value on the second night by his value on the first night, thus a negative change of sleep parameter meant that the value of the second night sleep parameter was less than that of the first night. On the other hand, a positive change in sleep parameter meant that the value of the second night was more than that of the first night. According to simple linear regression, the intercepts of each model were adjusted based on the minimum value of change of each sleep parameter by actigraphy.

Below, the results are presented in the following order: 1) characteristics of the samples, and 2) the accuracy of actigraphy to measure change in sleep when compared to PSG in community-dwelling adults age 70 years and older. In this comparison, the differences between three sleep parameters, including sleep onset latency (SOL), wake after sleep onset (WASO), and total sleep time (TST) that were obtained by both PSG and actigraphy methods were examined to

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evaluate the accuracy of actigraphy against PSG for measuring change in sleep. Four sensitivity settings (i.e. low, medium, high, and auto) were applied to actigraphy to assure the best sensitivity setting that would provide less discrepancy with PSG.

Characteristics of the Samples

To answer this question, data from subjects who had both the first and second night of laboratory PSG and actigraphy were included in the analysis. Of the 63 subjects with sleep data, only 36 subjects had both nights of PSG and actigraphy. Among these 36 eligible cases, one subject went to the sleep laboratory twice and provided two different sets of data that were acquired 12 months apart. Taking the issue of independence of data into account, the first visit data from this case were excluded from the analysis. Consequently, 35 subjects (55.56%) were included in the analysis. Figure 90 shows a schematic diagram indicating the flow of study subject selection though the study.

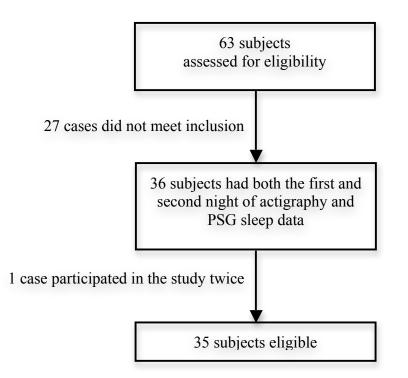


Figure 90. A schematic diagram indicating the flow of study subject selection though the study.

There were 35 older adults in this analysis, ranging in age from 71 to 88 years (M = 79.48, SD = 5.14 years). Fifty-seven percent were female. The majority of subjects were Caucasian (94.29%). Body mass indexes ranged from 19.49 to 37.21 (M = 26.67, SD = 3.86) kg/m²; 81.25% had BMI below 30 kg/m². No subject had impairments of everyday function: all Mini-Mental State Examination (MMSE) scores were above 24 points (M = 29.12, SD = 1.43), all scores on the Older Adults Resource Services (OARS) Independent Activities of Daily Living Scale scores were above 12 points (M = 27.59, SD = 0.86), and Geriatric Depression Scale (GDS) were below 5 points (M = 1.09, SD = 1.36). However, subjects reported that they had sleep problem. Pittsburgh Sleep Quality Index (PSQI) scores varied from 0 to 12 (M = 4.71, SD = 3.08) and 11 subjects (31.43%) had PSQI scores at least or more than five points, indicating

that they had poor sleep quality. The Epworth Sleepiness Scale (ESS) scores ranged between 0 and 15 (M = 6.67, SD = 3.94) and seven subjects (23.33%) reported having daytime sleepiness. Table 32 shows characteristics of the analysis subset.

Table 32

Characteristics of the Analysis Subset

Characteristics	Analysis Subset			
-	N	Value		
Age (year), $M \pm SD$	33	79.48 ± 5.14		
Gender	35			
Female, N (%)		20 (57.14%)		
Male, N (%)		15 (42.86%)		
Race	35			
Caucasian, N (%)		33 (94.29%)		
African American, N (%)		2 (5.71%)		
BMI (kg/m ²), $M \pm SD$	32	26.67 ± 3.86		
Normal (18.5 – 24.9), N (%)		12 (37.50%)		
Overweight (25 – 29.9), N (%)		14 (43.75%)		
Obese (30.0 and above), N (%)		6 (18.75%)		
MMSE	33	29.12 ± 1.43		
Normal (> 24 points), N (%)		33 (100%)		
OARS	34	27.59 ± 0.86		
Normal (> 12 points), N (%)		34 (100%)		
GDS	34	1.09 ± 1.36		
Normal (< 5 point), N (%)		34 (100%)		
PSQI	35	4.71 ± 3.08		
Good sleep quality (≤ 5 scores), N (%)		24 (68.57%)		
Poor sleep quality (> 5 scores), N (%)		11 (31.43%)		
ESS	30	6.67 ± 3.94		
Normal (< 10 scores), N (%)		23 (76.67%)		
Daytime Sleepiness (≥ 10 scores), N (%)		7 (23.33%)		

Note. BMI = Body Mass Index; MMSE = Mini-Mental State Examination; OARS = the Older Adults Resource Services Independent Activities of Daily Living Scale; GDS = Geriatric Depression Scale; PSQI = Pittsburgh Sleep Quality Index; and ESS = Epworth Sleepiness Scale.

Accuracy of Actigraphy to Measure Change in Sleep When Compared to PSG in Community-Dwelling Adults, age 70 Years and Older

Characteristics of sleep parameters, including the median, mean, and standard deviations, observed in community-dwelling elders, age 70 years and older, are shown in Table 33. The mean change in time in bed (TIB) during two nights of laboratory sleep study was 4.23 (*SD* = 37.79) minutes. Since the time clock on PSG and actigraphy was identical, TIB between the two methods were the same. Only three sleep parameters, including SOL, WASO, and TST, were compared. Table 33 also shows differences in three sleep parameters as measured by PSG and four different sensitivity settings of actigraphy.

Relationships between changes in each sleep parameter across two methods were examined by correlation analysis, including Pearson and Spearman's rank correlation coefficients; (Table 34). Simple regression analyses were also employed to identify actigraphy as a predictive factor for PSG on three sleep parameters. Bonferroni corrections were applied to all statistics with significance set at p < .0125.

Table 33

Sleep				Dif	ference (Actigraphy -	PSG)
Parameters	Median	Mean	SD	Mean	SD	t/z	p
TIB (minute)	3.00	4.23	37.79				
SOL (minute)							
PSG	-8.50	-24.91	59.21				
Actigraphy							
Low sensitivity	0.00	-3.94	27.23	20.97	46.18	10.50^{+}	< .001
Medium sensitivity	0.00	-3.94	27.23	20.97	46.18	10.50^{+}	< .001
High sensitivity	0.00	-3.94	27.23	20.97	46.18	10.50^{+}	< .001
Auto sensitivity	0.00	-3.94	27.23	20.97	46.18	10.50^{+}	< .001
WASO (minute)							
PSG	-20.50	-22.53	52.91				
Actigraphy							
Low sensitivity	-4.00	-7.51	16.15	15.01	46.96	1.89	NS
Medium sensitivity	-6.00	-8.80	21.18	13.73	43.45	1.87	NS
High sensitivity	-11.00	-10.40	29.34	12.13	42.12	1.70	NS
Auto sensitivity	-2.00	-5.23	16.99	17.30	48.09	154.50^{++}	NS
TST (minute)							
PSG	46.00	55.68	79.20				
Actigraphy							
Low sensitivity	14.00	11.91	50.83	-43.77	56.07	-4.62	<.0001
Medium sensitivity	19.00	13.23	52.29	-42.45	51.78	-4.85	< .0001
High sensitivity	11.00	14.80	53.64	-40.88	51.11	-259.50^{++}	<.0001
Auto sensitivity	2.00	9.63	52.12	-46.05	56.33	-4.84	< .0001

Characteristics and Differences of Change in Sleep Parameters by PSG and Actigraphy (n = 35)

Note. SOL = Sleep Onset Latency; WASO = Wake After Sleep Onset; TST = Total Sleep Time; SE = Sleep Efficiency; ICC = Intraclass correlation coefficient; 95% CI = 95% Confidence Interval; ⁺ Sign test was used to analyze data; ⁺⁺ Signed Rank test was used to analyze data; NS = not statistically significant; Bonferroni corrections were applied with significance set at p < .0125.

Table 34

Correlation of C	Change in Sleer	Parameters Betwee	n PSG and Actigra	aphy (n=35)
• • • • • • • • • • • •				······································

Parameter	Correlation Coefficient		
	Pearson	Spearman	
Sleep Onset Latency (SOL)			
Low sensitivity setting	0.66*	0.44*	
Medium sensitivity setting	0.66*	0.44*	
High sensitivity setting	0.66*	0.44*	
Auto sensitivity setting	0.66*	0.44*	
Wake After Sleep Onset (WASO)			
Low sensitivity setting	0.50*	0.47*	
Medium sensitivity setting	0.61*	0.60*	
High sensitivity setting	0.61*	0.62*	
Auto sensitivity setting	0.43*	0.37*	
Total Sleep Time (TST)			
Low sensitivity setting	0.71*	0.70*	
Medium sensitivity setting	0.76*	0.78*	
High sensitivity setting	0.77*	0.79*	
Auto sensitivity setting	0.70*	0.69*	

Note. * *p* < .0125.

Sleep onset latency (SOL).

A mean change in SOL from PSG was -24.91 minutes (SD = 59.21). Although four different sensitivity settings were applied to actigraphy, the values of change in SOL were identical (M = -3.94, SD = 27.23 minutes) for all four settings.

Individual's change in SOL between PSG and actigraphy is shown in Figure 91. Each subject was then assigned to one of two groups based on the direction of change in SOL between the two methods. For the first group, the change in SOL by the two methods was in the same direction (i.e. either increased or decreased by both methods). For the second group, the change in SOL by the two methods was in opposite directions (i.e. increased by PSG but decreased by actigraphy, or vice versa). As seen in Table 35, 19 subjects (54.29%) had similar direction of change in SOL between two methods across two nights. However, of those 19, one subject had

more than 1 hour of change in SOL across two methods. Among the 16 subjects (45.71%) that had different direction of change in SOL between two methods, five cases had less than five minutes difference.

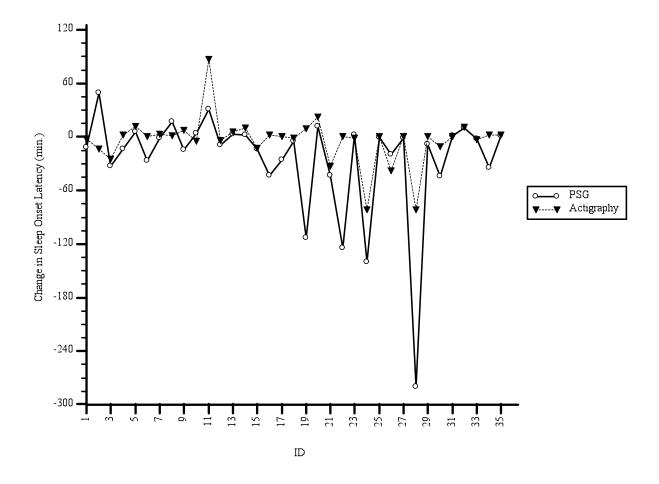


Figure 91. Individual's changes in sleep onset latency (SOL) by PSG and actigraphy. *Note.* Each circle represents an individual's change in SOL by PSG. Each triangle represents an individual's change in SOL by actigraphy (n=35).

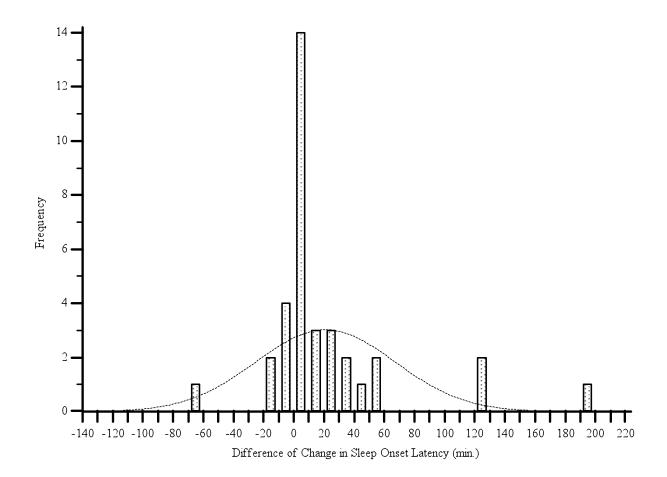
Table 35

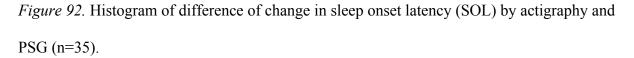
Magnitude of Difference of Change and Direction of Change in Sleep Onset Latency (SOL) by

Magnitude of difference	Direction		
	Similar	Different	
0 - 5 minutes	6	5	
5.01 – 15 minutes	7	2	
15.01 – 30 minutes	2	4	
30.01 – 60 minutes	3	2	
More than 1 hour	1	3	
Total	19	16	

Actigraphy and PSG (n=35)

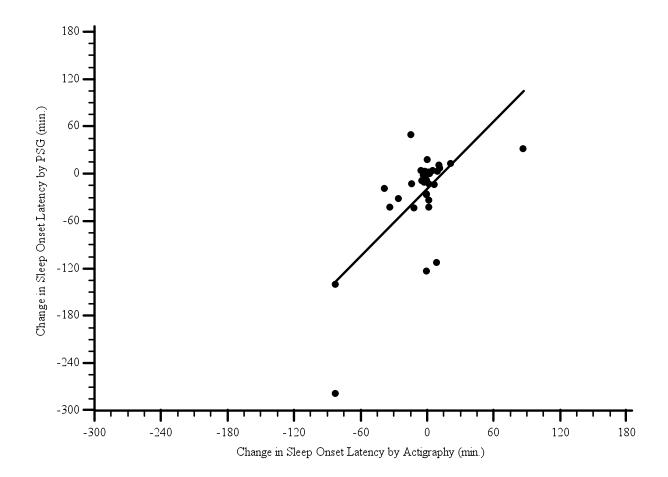
The differences of these changes were not normally distributed, D = 0.25, p < .01. A histogram was depicted to show how these data were distributed (Figure 92). Using a sign test with Bonferroni correction, change in SOL by actigraphy was significantly different from those by PSG, z = 10.50, p < .0125.

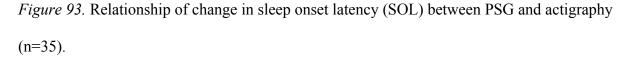




Note. Differences were calculated as change in SOL by actigraphy minus change in SOL by PSG.

Scatter plots illustrate the positive relationship of change in SOL between two methods (Figure 93). Pearson and Spearman's rank correlation coefficients with Bonferroni correction were performed to examine this relationship. As seen in Table 34, change in SOL by actigraphy had a significant moderate positive relationship with change in SOL by PSG, r = .66, p < .0125.





Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of change in SOL by actigraphy on change in SOL by PSG. Each dot represents one subject.

A simple linear regression with Bonferroni correction was performed to identify the predictive effect of change in SOL by actigraphy on change in SOL by PSG (Table 36). Approximately 43% of variance of change in SOL by PSG was explained by change in SOL by actigraphy, $R^2 = 0.43$, p < .0125. Change in SOL by PSG was estimated to be -136.17 when subjects had -82 minute of change in SOL by actigraphy. Change in SOL by PSG was estimated to increase 1.43 minutes for each additional minute of increase in change in SOL by actigraphy.

Table 36

Regression Analysis for Change in Sleep Onset Latency (SOL) by Actigraphy as a Predicting

Factor for Change in SOL by PSG (n=35)

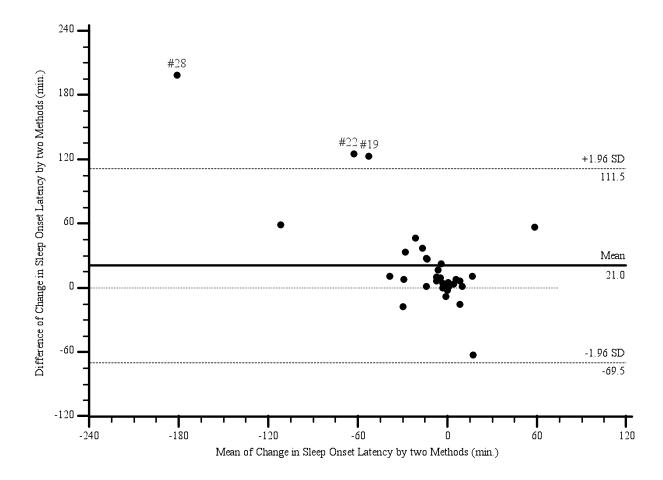
Variables	В	SE B	β
Intercept	-136.17*	25.59	
Change in SOL by Actigraphy	1.43*	0.29	0.66*

Note. PSG = polysomnography; SOL = sleep onset latency; B = unstandardized Beta when change in SOL by actigraphy equaled a minimum value of -82 minutes; *SE B* = standard error of unstandardized Beta; β = standardized Beta; * p < .0125.

The agreement of change in SOL by actigraphy and PSG is presented in a Bland-Altman plot (Figure 94). The x-axis represents the average change in SOL by two methods across the range of -180.75 and 59.00 minutes. The y-axis represents the difference of change in SOL, which varied from -63.00 to 197.50 minutes.

The mean difference between these two methods, or bias, was 20.97 minutes (95% CI = 5.11 to 36.84). A positive mean difference indicated that on average actigraphy overestimated change in SOL by PSG approximately 21 minutes. The horizontal dotted lines shows the 95% limits of agreement. Since the standard deviation for the mean difference of change in SOL was 46.18, the upper and lower limit of agreement was 111.49 and -69.55 minutes, respectively. Based on these limits of agreement, three outliers (8.57%) exceeded the lower limit of agreement: subjects #23, #26, and #32.

Based on the Bland-Altman plot, there is no obvious pattern of overestimation of change in SOL; differences of change in SOL are distributed all over the graph and are not related to the



magnitude of mean change in SOL between two methods.

Figure 94. Bland-Altman plot of change in sleep onset latency (SOL): Actigraphy vs. PSG (n=35).

Note. Differences were calculated as change in change in SOL by actigraphy minus SOL by PSG (actigraphy - PSG). Means were calculated as the mean of change in SOL by actigraphy and PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

In summary, although different sensitivity settings were applied to actigraphy, SOL was the same for all four levels of sensitivity settings. Based on a paired-sample t-test, there was a significant different of change in SOL between the two methods. According to Pearson correlation, there was a moderate linear relationship of change in SOL between these two methods. Change in SOL by actigraphy explained 43% of variances of change in SOL by PSG. Based on Bland-Altman plot, measurement error varied over the measurement scale without any trend in bias. Overall, actigraphy overestimated change in SOL by 21 minutes.

Wake after sleep onset (WASO).

While mean change in WASO by PSG was -22.53 minutes (SD = 52.91), mean change in WASO for the four sensitivity settings (i.e. low, medium, high, and auto) were -7.51 (SD = 16.15), -8.80 (SD = 21.18), -10.40 (SD = 29.34) and -5.23 (SD = 16.99) minutes, respectively. Change in WASO from four sensitivity settings of actigraphy and those from PSG were compared. Only auto sensitivity setting provided a significant difference while low, medium, and high sensitivity settings provided change in WASO similar to PSG.

The relationships of change in WASO by PSG and by four sensitivity settings of actigraphy are shown in Table 34. Change in WASO by actigraphy for all four settings showed statistically significant relationships with change in WASO by PSG. More detail is provided in the following session.

Low sensitivity setting Actigraphy.

Individual's change in WASO between two methods is shown in Figure 95. As seen in Table 37, 23 subjects (65.71 %) had similar direction of change in WASO between two methods. However, of those 23, seven subjects had a difference of more than one hour. Although 34.29 percent of subjects had different direction, two subjects had less than 15 minutes difference.

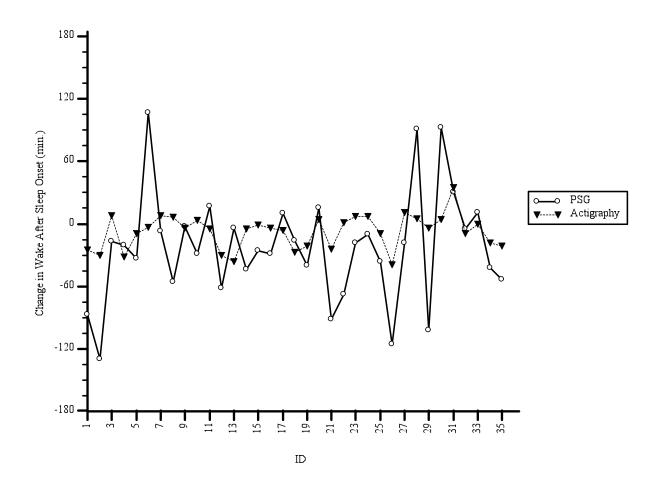


Figure 95. Individual's change in wake after sleep onset (WASO) by PSG and low sensitivity actigraphy (n=35).

Note. Each circle represents individual's change in WASO by PSG. Each triangle represents individual's change in WASO by low sensitivity actigraphy.

Table 37

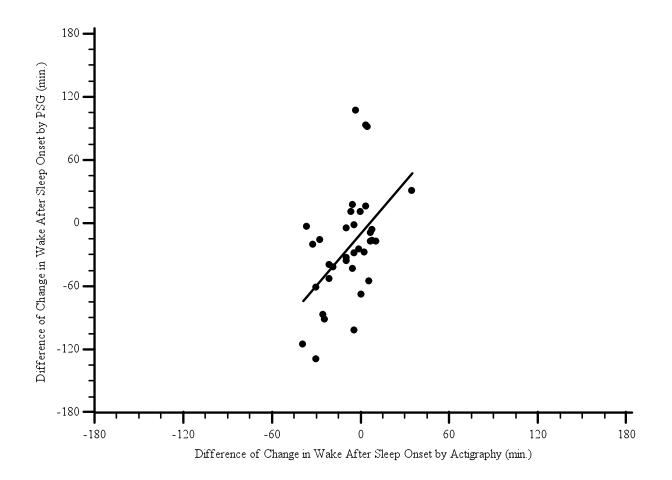
Magnitude of Difference of Change and Direction of Change in Wake After Sleep Onset

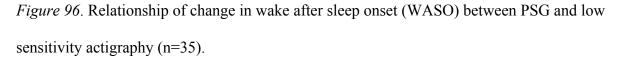
Magnitude of difference	Direction		
	Similar	Different	
0 - 5 minutes	3	0	
5.01 – 15 minutes	3	2	
15.01 – 30 minutes	6	6	
30.01 – 60 minutes	4	1	
More than 1 hour	7	3	
Total	23	12	

(WASO) by Low Sensitivity Actigraphy and PSG (n=35)

A paired-sample t-test with Bonferroni correction was employed to examine the differences of change in WASO between two methods. It revealed that change in SOL by two methods was not statistically significantly different, t(34) = 1.89, p > .0125.

The relationship of change in WASO by PSG and by actigraphy was explored. Scatter plot of this relationship is shown in Figure 96. As seen in Table 34, Pearson correlation coefficient with Bonferroni correction showed that there was a moderate positive relationship of change in WASO between PSG and low sensitivity actigraphy, r = 0.50, p < .0125.





Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of change in WASO by actigraphy on change in WASO by PSG. Each dot represents one subject.

Change in WASO by actigraphy was included in a simple linear regression model to identify its predictive effect on change in WASO by PSG (Table 38). Approximately 25% of variance in change in WASO by PSG was explained by change in WASO from actigraphy, $R^2 = 0.25$, p < .0125. The change in WASO by PSG was expected to be -74.17 minutes when change

in WASO by actigraphy was -39 minutes. Every one additional minute increase of change in

WASO by actigraphy, change in WASO by PSG was expected to increase 1.64 minutes.

Table 38

Regression Analysis for Change in Wake After Sleep Onset (WASO) by Low Sensitivity

Actigraphy as a Predicting Factor for Change in WASO by PSG (n=35)

Variables	В	SE B	β
Intercept	-74.17*	17.42	
Change in WASO by Actigraphy	1.64*	0.49	0.50*

Note. PSG = Polysomnography; WASO = Wake After Sleep Onset; B = Unstandardized Beta when change in WASO by actigraphy equaled a minimum value of -39 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

A Bland-Altman plot illustrates the agreement of change in WASO by low sensitivity actigraphy and PSG (Figure 97). The x-axis represents the average change in WASO by two methods across the range of change in WASO between -80.00 and 52.00 minutes. The y-axis represents the difference in change in WASO, which varied from -110.00 to 100.00 minutes.

The mean difference between these two methods, or bias, was 15.01 minutes (95% CI = -1.12 to 31.15) with a standard deviation of 46.96 minutes. A positive mean difference indicated that on average actigraphy overestimated change in WASO by approximately 15 minutes as compared to PSG. The upper and lower limit of agreement was 107.06 and -77.03 minutes, respectively. Three outliers (8.57%) exceeded the lower limit of agreement: subjects #6, #28 and #30.

In addition, there was a possible trend in the bias. The overestimation of change in WASO was greater for lower values of change in WASO by the two methods. When the magnitude of average change in WASO increased, the magnitude of difference of change in

WASO declined. When the mean change in WASO between two methods was zero, there was no bias and after the mean change in WASO was higher than zero, instead of overestimating, actigraphy underestimated change in WASO by PSG.

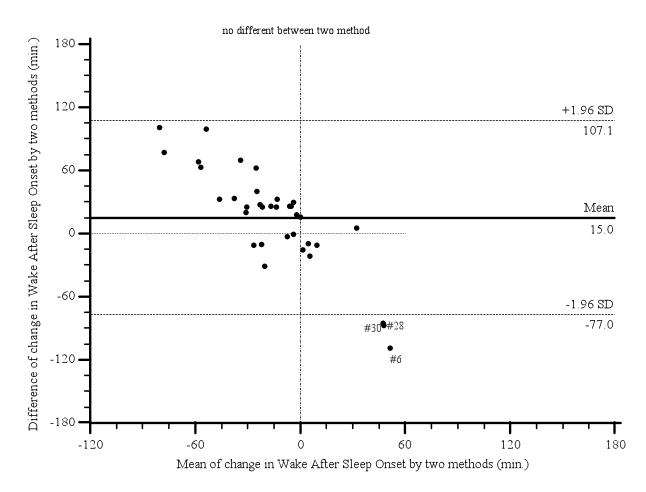


Figure 97. Bland-Altman plot of change in wake after sleep onset (WASO): Low sensitivity actigraphy vs. PSG (n=35).

Note. Differences were calculated as change in WASO by actigraphy minus change in WASO by PSG (actigraphy - PSG). Means were calculated as the mean of WASO by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

Medium sensitivity actigraphy.

Figure 98 shows each individual's change in WASO between two methods. As seen in Table 39, 28 subjects (80%) had similar direction of change in WASO across two measures. However, of those 28, eight subjects had more than one hour difference of change in WASO between two methods. Among 20 percent who had different direction, three subjects had at least or less than 30 minutes difference.

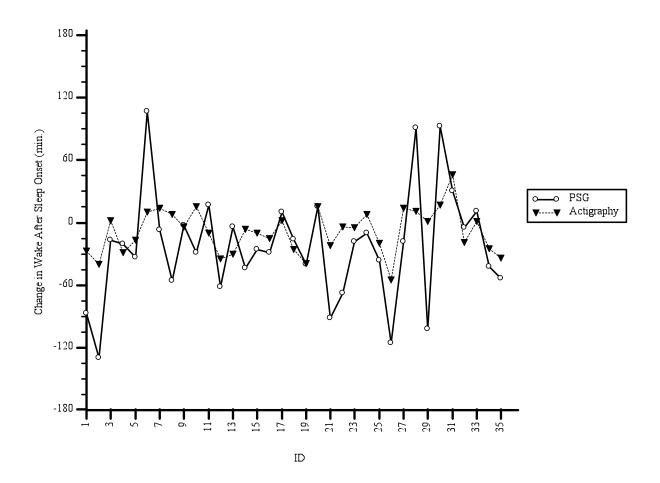


Figure 98. Individual's change in wake after sleep onset (WASO) by PSG and medium sensitivity actigraphy (n=35).

Note. Each circle represents individual's change in WASO by PSG. Each triangle represents individual's change in WASO by medium sensitivity actigraphy.

Table 39

Magnitude of Difference of Change and Direction of Change in Wake After Sleep Onset

Magnitude of difference	Direction	
	Similar	Different
0 - 5 minutes	3	0
5.01 – 15 minutes	7	0
15.01 – 30 minutes	9	3
30.01 – 60 minutes	1	2
More than 1 hour	8	2
Total	28	7

(WASO) by Medium Sensitivity Actigraphy and PSG (n=35)

The change in WASO from PSG and actigraphy was compared using a paired-sample ttest. No statistically significant difference of change in WASO was found, t(34) = 1.87, p > .05. As seen in Table 34, there was a significant moderate positive linear relationship between WASO by actigraphy and by PSG, r = .61, p < .0125. A scatter plot shows the relationship of change in WASO between two methods (Figure 99).

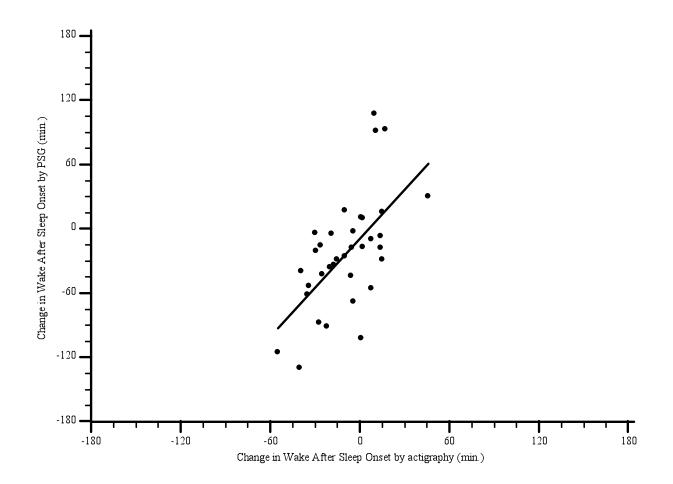


Figure 99. Relationship of change in wake after sleep onset (WASO) between PSG and medium sensitivity actigraphy (n=35).

Note. Line represents a regression line of change in WASO by actigraphy on change in WASO by PSG. Each dot represents one subject.

Approximately 37% of variance in change in WASO by PSG was explained by change in WASO from actigraphy, $R^2 = 0.37$, p < .0125. As seen in Table 40, the change in WASO by PSG was expected to be -92.61 minutes when change in WASO by actigraphy was -55 minutes (the second night WASO was 55 minutes less than the first night WASO). For every one additional

minute increase of change in WASO by actigraphy, change in WASO by PSG was expected to

increase 1.51 minutes.

Table 40

Regression Analysis for Change in Wake After Sleep Onset (WASO) by Medium Sensitivity

Actigraphy as a Predicting Factor for Change in WASO by PSG (n=35)

Variables	В	SE B	β
Intercept	-92.61*	17.52	
Change in WASO by Actigraphy	1.51*	0.35	0.61*

Note. PSG = Polysomnography; WASO = Wake After Sleep Onset; B = Unstandardized Beta when change in WASO by actigraphy equaled a minimum value of -39 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

A Bland-Altman plot illustrates the agreement of change in WASO by two methods (Figure 100). The mean change in WASO between two methods was between -85.25 and 58.50 minutes. The difference of change in of WASO varied from -97.00 to 103.50 minutes.

The mean difference in change of WASO between two methods was 13.73 minutes (95% CI = -1.20 to 28.65). This positive mean indicates that on average medium sensitivity actigraphy overestimated change in WASO by 14 minutes as compared to PSG. Since the standard deviation for the mean difference of WASO was 43.45, the upper limit and lower limit of agreement was 98.89 and -71.43 minutes, respectively. There were four outliers (11.43%). Three subjects had value exceed the lower limit of agreement: subjects #6, #28, and #30 while one subject had value more than the upper limit of agreement: subject #29.

The plot shows a possible trend in the bias. The overestimation of change in WASO was greater for lower values of change in WASO by two methods. When the magnitude of mean change in WASO increased, the magnitude of difference of change in WASO declined. When

the mean change in WASO between two methods was approximately 15 minutes, there was no bias and after the mean change in WASO was higher than 15 minutes, instead of overestimation, actigraphy underestimated change in WASO by PSG.

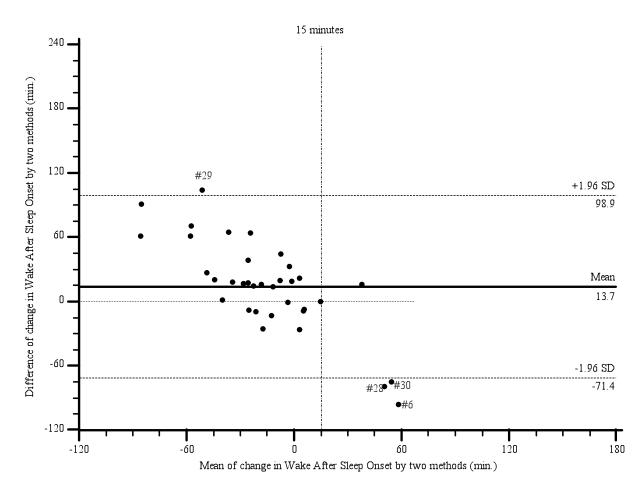


Figure 100. Bland-Altman plot of change in wake after sleep onset (WASO): Medium sensitivity actigraphy vs. PSG (n=35).

Note. Differences were calculated as change in WASO by actigraphy minus change in WASO by PSG (actigraphy – PSG). Means were calculated as the mean of change in WASO by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

High sensitivity actigraphy.

Individual's change in WASO between two methods is illustrated in Figure 101. As seen in Table 41, the majority of subjects (74.29%) had similar direction of change in WASO across two methods. Although they had similar direction of change, six subjects had more than one hour difference of change in WASO by two methods. There were nine subjects with different direction of change. Of those nine, two subjects had less than 30 minutes different.

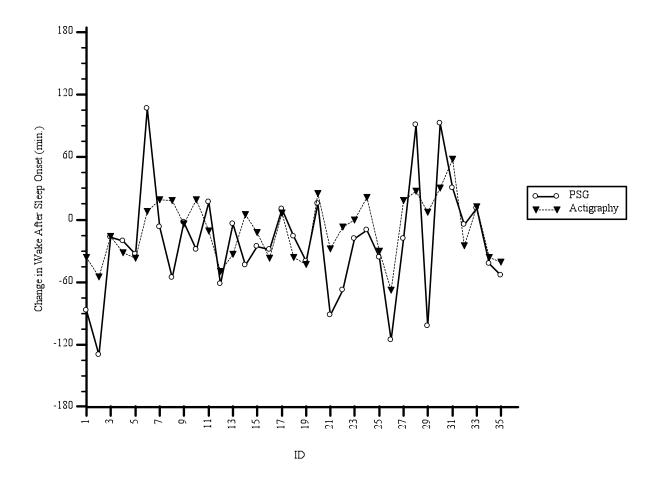


Figure 101. Individual's change in wake after sleep onset (WASO) by PSG and high sensitivity actigraphy (n=35).

Note. Each circle represents individual's change in WASO by PSG. Each triangle represents individual's change in WASO by high sensitivity actigraphy.

Table 41

Magnitude of Difference of Change and Direction of Change in Wake After Sleep Onset

Magnitude of difference	Dire	ection
	Similar	Different
0 - 5 minutes	6	0
5.01 – 15 minutes	8	0
15.01 – 30 minutes	4	3
30.01 – 60 minutes	2	4
More than 1 hour	6	2
Total	26	9

(WASO) by High Sensitivity Actigraphy and PSG (n=35)

The difference of change in WASO by PSG and high sensitivity actigraphy was tested by a paired-sample t-test. It showed that this difference was not statistically significant, t(34) = 1.70, p > .05.

Change in WASO between two methods was plotted to show their relationship (Figure 102). As seen in Table 34, although both Pearson and Spearman's rank showed a significant relationship of change in WASO between two methods, Spearman provided correlation coefficient more than what Pearson did. Change in WASO between two methods was then ranked; the relationship of ranked change in WASO between two methods is illustrated in Figure 103. Using Spearman's rank correlation coefficient, ranked change in WASO by actigraphy had a moderate positive relationship with ranked change in WASO from PSG, $r_s = 0.62$, p < .0125.

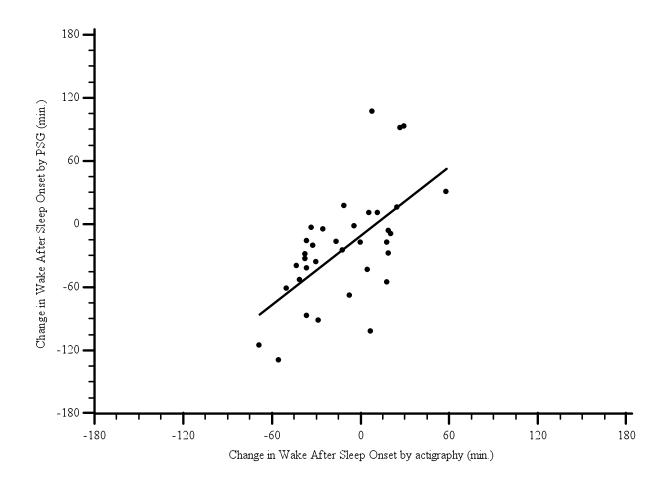


Figure 102. Relationship of change in wake after sleep onset (WASO) between PSG and high sensitivity actigraphy (n=35).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of change in WASO by actigraphy on change in WASO by PSG. Each dot represents one subject.

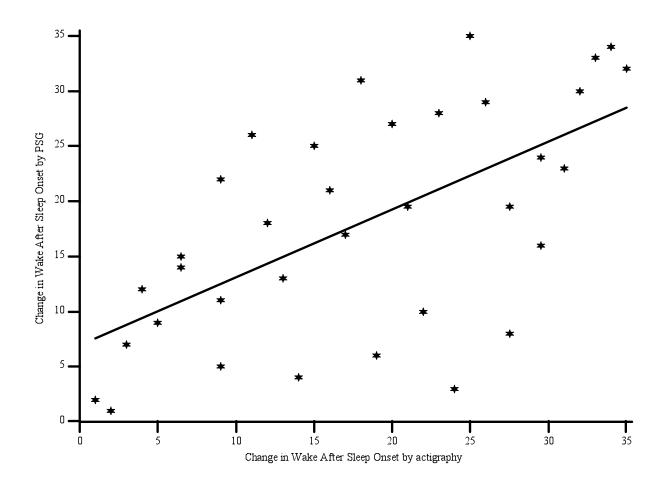


Figure 103. Relationship of ranked change in wake after sleep onset (WASO) between PSG and high sensitivity actigraphy (n=35).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of ranked change in WASO by actigraphy on ranked change in WASO by PSG. Each star represents one subject.

As seen in Table 42, the change in WASO by PSG was expected to be -85.65 minutes when change of WASO by actigraphy was -68 minutes. For every one additional minute increase of change in WASO by actigraphy, change in WASO by PSG was expected to increase 1.10 minute.

Table 42

Regression Analysis for Change in Wake After Sleep Onset (WASO) by High Sensitivity

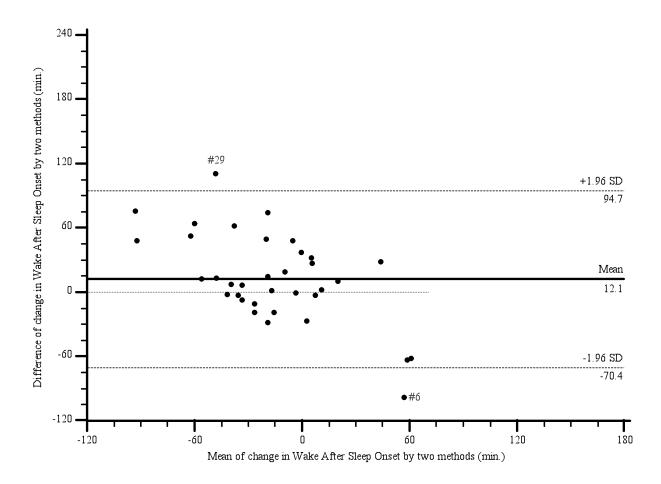
Actigraphy as a Predicting Factor for Change in WASO by PSG (n=35)

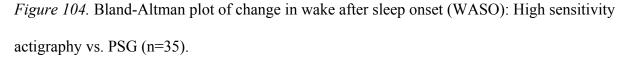
Variables	В	SE B	β
Intercept	-85.65*	16.07	
Change in WASO by Actigraphy	1.10*	0.25	0.61*

Note. PSG = Polysomnography; WASO = Wake After Sleep Onset; B = Unstandardized Beta when change in WASO by actigraphy equaled a minimum value of -68 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .01.

The agreement of change in WASO obtained by two methods is presented by Bland-Altman plot (Figure 104). The mean change in WASO between these two methods varied from -92.50 and 61.25 minutes while the difference of change in WASO ranged from -99.00 to 109.50 minutes. The bias of these two methods was 12.13 minutes (95% CI = -2.34 to 26.60). A positive value indicated that on average the high sensitivity actigraphy overestimated change in WASO by 12 minutes. When examining the plot, there was no obvious trend of bias.

The standard deviation for the mean difference of change in WASO was 42.12. Thus, the upper limit and lower limit of agreement was 94.68 and -70.42 minutes, respectively. There were two outliers (5.71%). One subject had a value exceeding the upper limit of agreement: subject #29, while another subject had a value exceeding the lower limit of agreement: subject #6.





Note. Differences were calculated as change in WASO by actigraphy minus change in WASO by PSG (actigraphy - PSG). Means were calculated as the mean of change in WASO by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

Auto sensitivity actigraphy.

Individual's change in WASO by PSG and medium sensitivity actigraphy is presented in Figure 105. As seen in Table 43, 25 subjects (71.43%) had similar direction of change in WASO across two methods. However, of those 25, five subjects had more than one hour of difference in

change of WASO. Among ten subjects who had different direction of change across two methods, four subjects had less than 30 minutes different.

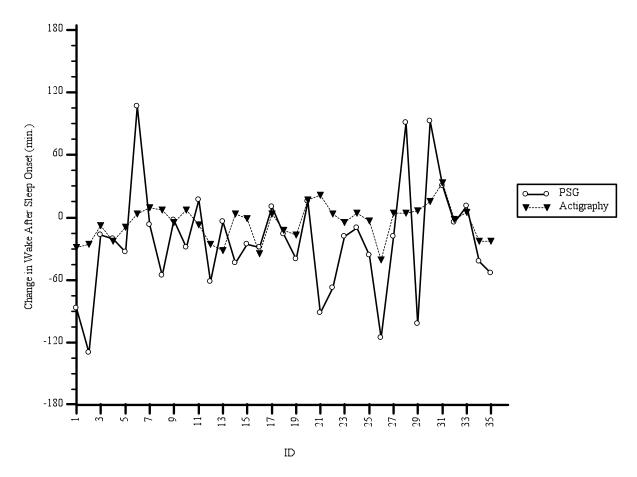


Figure 105. Individual's change in wake after sleep onset (WASO) by PSG and auto sensitivity actigraphy (n=35).

Note. Each circle represents individual's change in WASO by PSG. Each triangle represents individual's change in WASO by auto sensitivity actigraphy.

Table 43

Magnitude of Difference of Change and Direction of Change in Wake After Sleep Onset

Magnitude of difference	Direction		
	Similar	Different	
0 - 5 minutes	6	0	
5.01 – 15 minutes	5	1	
15.01 – 30 minutes	5	3	
30.01 – 60 minutes	4	2	
More than 1 hour	5	4	
Total	25	10	

(WASO) by Auto Sensitivity Actigraphy and PSG

The distribution of the difference of change in WASO between these methods were not normally distributed, D = 0.16, p < .05, as seen in Figure 106. Using a signed rank test, the differences of WASO between these methods was statistically significant, z = -154.50, p < .01.

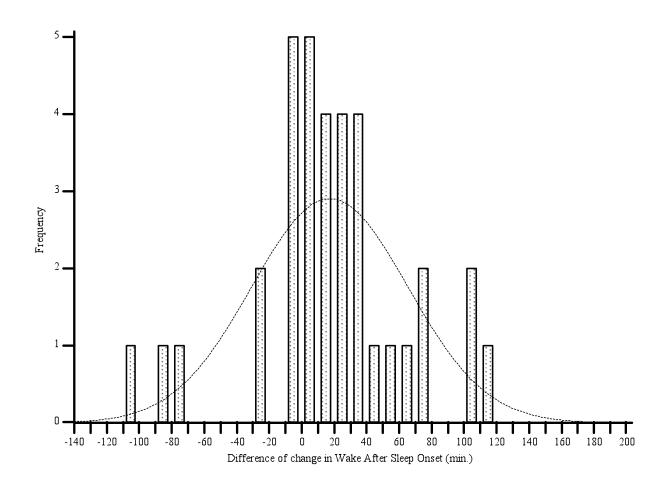


Figure 106. Histogram of differences in change in wake after sleep onset (WASO) by auto sensitivity actigraphy and by PSG (n=35). *Note.* Differences were calculated as Change in WASO by actigraphy minus Change in WASO

by PSG.

The scatter plot shows a relationship of change in WASO from PSG and auto sensitivity actigraphy (Figure 107). As seen in Table 34, change in WASO from actigraphy had a low positive relationship with change in WASO from PSG, r = 0.43, p < .01.

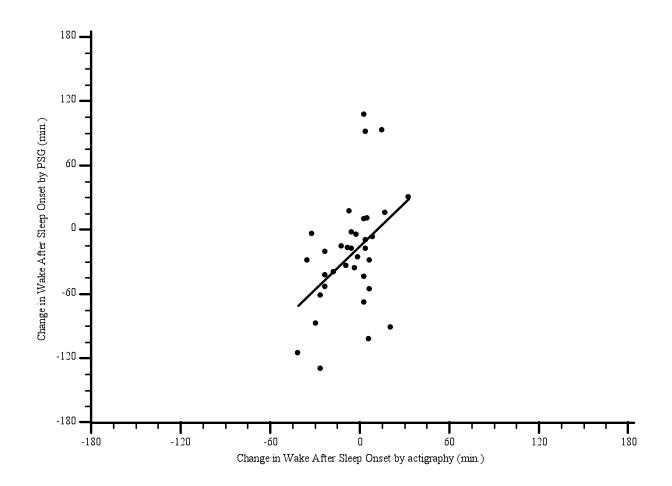


Figure 107. Relationship of change in wake after sleep onset (WASO) between PSG and auto sensitivity actigraphy (n=35).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of change in WASO by actigraphy on change in WASO by PSG. Each dot represents one subject.

Change in WASO by actigraphy was included in a simple linear regression model to identify its predictive effect on change in WASO by PSG. Approximately 19% of variance of change in WASO by PSG was explained by change in WASO from actigraphy, $R^2 = 0.19$, p < .0125. As seen in Table 44, the change in WASO by PSG was expected to be -70.60 minutes

when change in WASO by actigraphy was -41 minutes. For each additional minute of increasing in change in WASO by actigraphy, change in WASO by PSG was expected to increase by 1.34 minutes.

Table 44

Regression Analysis for Change in Wake After Sleep Onset (WASO) by Auto Sensitivity

Actigraphy as a Predicting Factor for Change in WASO by PSG (n=35)

Variables	В	SE B	β
Intercept	-70.60*	19.32	
Change in WASO by Actigraphy	1.34*	0.49	0.43*

Note. PSG = Polysomnography; WASO = Wake After Sleep Onset; B = Unstandardized Beta when change in WASO by actigraphy equaled a minimum value of -41 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

Bland-Altman plot illustrates the agreement of change in WASO between two methods (Figure 108). The mean change in WASO was between -78.25 and 55.00 minutes. The difference of change in WASO varied from -104.00 to 112.50 minutes.

The mean difference of change in WASO by two methods, or bias, was 17.30 minutes (95% CI = 0.78 to 33.82). A positive mean difference indicated that on average auto sensitivity actigraphy overestimated change in WASO by 17.30 minutes. Since the standard deviation for the mean difference of WASO was 48.09, the upper and lower limit of agreement was 111.57 and -76.97 minutes, respectively. There were four outliers (11.43%). Three subjects had values exceeding the lower limit of agreement: subjects #6, #28, and #30. Another subject had value exceeding the upper limit: subject #21.

Furthermore, there was a possible trend in the bias. The overestimation of change in WASO was greater for lower values of change in WASO by two methods. When the magnitude

of average change in WASO increased, the magnitude of difference of change in WASO declined. When the mean change in WASO between two methods was zero, there was no bias and after the mean change in WASO was higher than zero, instead of overestimation, actigraphy underestimated change in WASO by PSG.

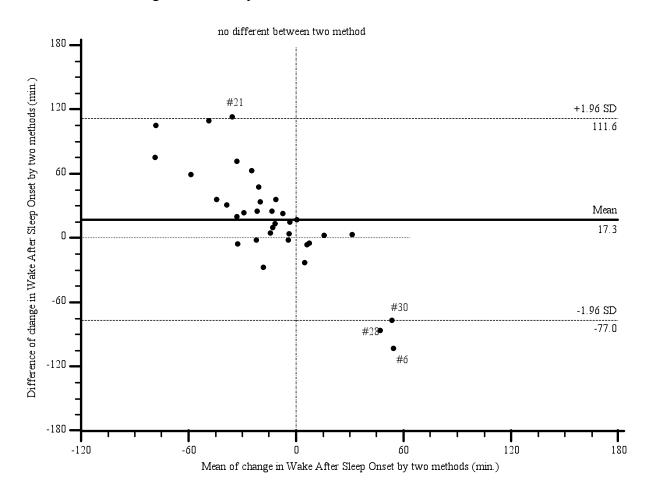


Figure 108. Bland-Altman plot of change in wake after sleep onset (WASO): Auto sensitivity actigraphy vs. PSG (n=35).

Note. Differences were calculated as change in WASO by actigraphy minus change in WASO by PSG (actigraphy - PSG). Means were calculated as the mean of change in WASO by actigraphy and by PSG (actigraphy - PSG) [(actigraphy + PSG) /2]. Each dot represents one subject.

As shown in Table 45, three different approaches were employed to examine the agreement of change in WASO between four sensitivity settings of actigraphy and PSG. When taking differences of the mean/median between two methods into account, change in WASO by PSG and actigraphy (low, medium, and high sensitivity setting) did not show a significant difference (p > .0125); only auto sensitivity setting was statistically significantly different. There were statistically moderate positive linear relationships of change in WASO between PSG and all four sensitivity settings of actigraphy. Medium and high sensitivity settings of actigraphy explained around 37% of variance in change in WASO by PSG. Despite the different sensitivity setting, actigraphy overestimated change in WASO compared to PSG. However, of all four sensitivity settings, a high sensitivity setting provided the least bias, as it overestimated change in WASO by 12 minutes.

Table 45

Sensitivity	Method			
settings	Comparison of the	Correlation	n and	Bland-Altman Plots
Actigraphy	mean/median (p value)	Regressi	on	
		r/r_s	R^2	Bias
Low	NS	Moderate	0.25	15.01
Medium	NS	Moderator	0.37	13.73
High	NS	Moderate	0.37	12.13
Auto	< .0125	Low	0.19	17.30

Agreement of Change in Wake After Sleep Onset (WASO) by PSG and Actigraphy (n=35)

Note. WASO = Wake After Sleep Onset; PSG = Polysomnography; r = Pearson Coefficient; r_s = Spearman's Rank Coefficient; R^2 = coefficient of determination; NS = not statistically significant.

Total sleep time (TST).

A mean change in TST by PSG was 55.68 minutes (SD = 79.20) while mean change in

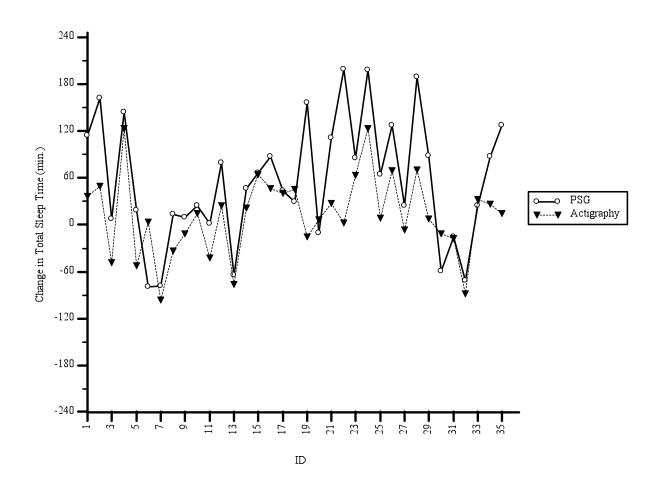
TST for four-sensitivity settings were 11.91 (SD = 50.83), 13.23 (SD = 52.29), 14.80 (SD =

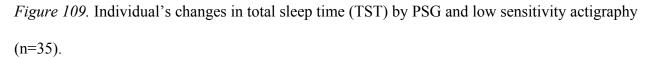
53.64) and 9.63 (SD = 52.12) minutes, respectively. The change in TST from four different sensitivity /wake thresholds of actigraphy and those from PSG were compared and significant differences were found.

The relationships of change in TST by PSG and by four sensitivity settings of actigraphy are shown in Table 34. Change in TST by actigraphy at all levels had statistically significant relationships with change in TST by PSG. More detail is provided in the following section.

Low sensitivity actigraphy.

Individual's change in TST by PSG and low sensitivity actigraphy are shown in Figure 109. As seen from Table 46, 25 subjects had similar direction of change in TST for both methods. However, of those 25, nine subjects had more than 60 minutes of difference of change in TST between two methods. There were 10 cases that had different direction of change across two methods. However of those 10, three subjects had less than 30 minutes difference.





Note. Each circle represents an individual's change in TST by PSG. Each triangle represents an individual's change in TST by low sensitivity actigraphy.

Table 46

Magnitude of Difference of Change and Direction of Change in Total Sleep Time (TST) by Low Sensitivity Actigraphy and PSG (n=35)

Magnitude of difference	Direction	
	Similar	Different
0 - 5 minutes	3	0
5.01 – 15 minutes	2	1
15.01 – 30 minutes	6	2
30.01 – 60 minutes	5	4
More than 1 hour	9	3
Total	25	10

Using a paired-sample t-test, there was a statistically significant difference of change in TST between two methods, t(34) -4.62, p < .0001. Change in TST from low sensitivity actigraphy was less than that by PSG.

The relationship between change in TST by PSG and low sensitivity actigraphy is represented in Figure 110. As seen in Table 34, change in TST by low sensitivity actigraphy had a high positive significant relationship with change in TST by PSG, r = .71, p < .01.

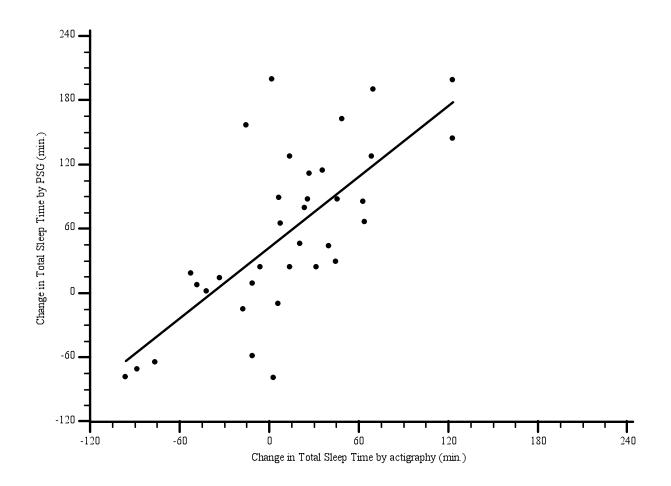


Figure 110. Relationship of change in total sleep time (TST) between PSG and low sensitivity actigraphy (n=35).

Note. Line represents a regression line of change in TST by actigraphy on change in TST by PSG. Each dot represents one subject.

A simple linear regression was performed to identify the predictive effect of change in TST by actigraphy on change in TST by PSG (Table 47). Approximately 50% of the variance of change in TST by PSG was explained by change in TST by low sensitivity actigraphy, $R^2 = 0.50$, p < .0125. The change in TST by PSG was estimated to be -63.61 minutes when subjects had change in TST by actigraphy of -96 minutes (TST during the second night was 96 minutes less

than the those during the first night). For any additional minute increase of change in TST by

actigraphy, change in TST by PSG was estimated to increase 1.11 minutes.

Table 47

Regression Analysis for Change in Total Sleep Time (TST) by Low Sensitivity Actigraphy as a

Predicting Factor for Change in TST by PSG (n=35)

Variables	В	SE B	β
Intercept	-63.61*	22.74	
Change in TST by Actigraphy	1.11*	0.19	0.71*

Note. PSG = Polysomnography; TST = Total Sleep Time; B = Unstandardized Beta when change in TST by actigraphy equaled a minimum value of -96 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125.

A relative agreement of change in TST between two methods is illustrated by Bland-Altman plot (Figure 111). The x-axis represents the mean change in TST by two methods, which varied between -87.25 and 160.75 minutes. The y-axis represents the difference in change in TST by two methods, which ranged from -197.00 to 82.00 minutes.

The mean difference between these two methods (bias) was -43.77 minutes (95% CI = -63.03 to -24.51). A negative mean difference indicated that on average actigraphy underestimated change in TST by approximately 44 minutes as compared to PSG. The 95% confidence limits (limit of agreement) are represented by the two horizontal dotted lines as shown in Figure 6.19. Since the standard deviation for the mean difference of TST was 56.06, the upper limit and lower limit of agreement was 66.12 and -153.66 minutes, respectively. There were three outliers (8.57%). Two subjects exceeded the lower limit of agreement: subjects #19, and #22 while another subject had value more than the upper limit of agreement: subject #6. The Bland-Altman plot shows no obvious pattern of overestimation of change in TST; differences of change in TST are distributed all over the graph and do not relate to the magnitude of mean change in TST.

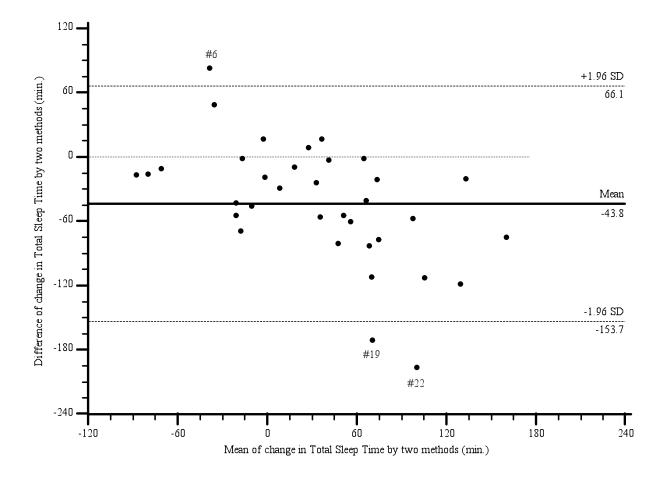


Figure 111. Bland-Altman plot of change in total sleep time (TST): Low sensitivity actigraphy vs. PSG (n=35).

Note. Differences were calculated as change in TST by actigraphy minus change in TST by PSG (actigraphy - PSG). Means were calculated as the mean of change in TST by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

Medium sensitivity actigraphy.

Figure 112 illustrates individual's change in TST by two methods. As seen in Table 48, 29 subjects had similar direction of change in TST for both methods. However, of those 29, 10 subjects had more than 60 minutes different of change in TST between two methods. Although there were six subjects with different direction of change, one subject had less than 30 minutes difference.

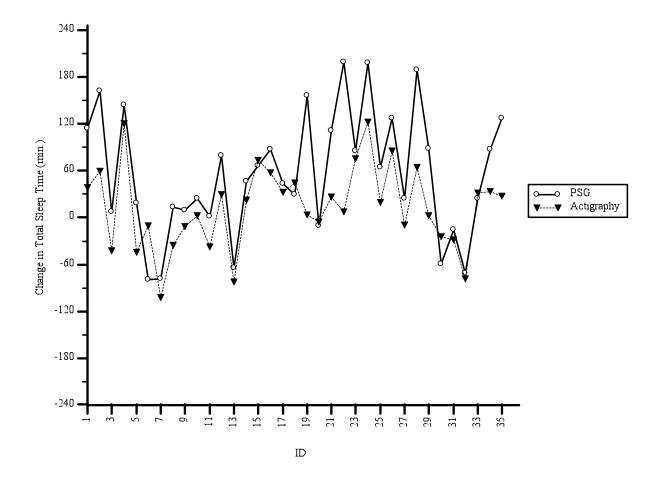


Figure 112. Individual's change in total sleep time (TST) by PSG and medium sensitivity actigraphy (n=35).

Note. Each circle represents individual's change in TST by PSG. Each triangle represents individual's change in TST by medium sensitivity actigraphy.

Table 48

Magnitude of Difference of Change and Direction of Change in Total Sleep Time (TST) by

Magnitude of difference	Direction		
	Similar	Different	
0 - 5 minutes	1	0	
5.01 – 15 minutes	7	0	
15.01 – 30 minutes	5	1	
30.01 – 60 minutes	6	4	
More than 1 hour	10	1	
Total	29	6	

Medium Sensitivity Actigraphy and PSG (n=35)

A paired-sample t test was employed to examine the difference of change in TST by medium sensitivity /wake threshold actigraphy and PSG. There was statistically significant difference of TST, t(34) = -4.85, p < .0001. The result revealed that change in TST by medium sensitivity setting was less than those by PSG.

Change in TST between PSG and medium sensitivity actigraphy is shown in Figure 113. As seen in Table 34, although both Pearson and Spearman's rank showed a significant relationship of change in TST between two methods, Spearman provided correlation coefficient more than what Pearson did. Change in TST between two methods was then ranked. The relationship of ranked change in TST between two methods is illustrated in Figure 114. Using Spearman's rank correlation coefficient, ranked change in TST by actigraphy had a high positive relationship with ranked change in TST from PSG, $r_s = 0.78$, p < .01.

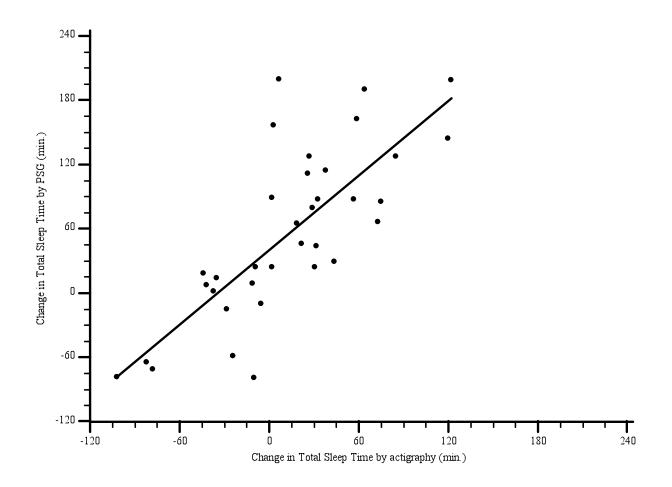


Figure 113. Relationship of change in total sleep time (TST) between PSG and medium sensitivity actigraphy (n=35).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of change in TST by actigraphy on change in TST by PSG. Each dot represents one subject.

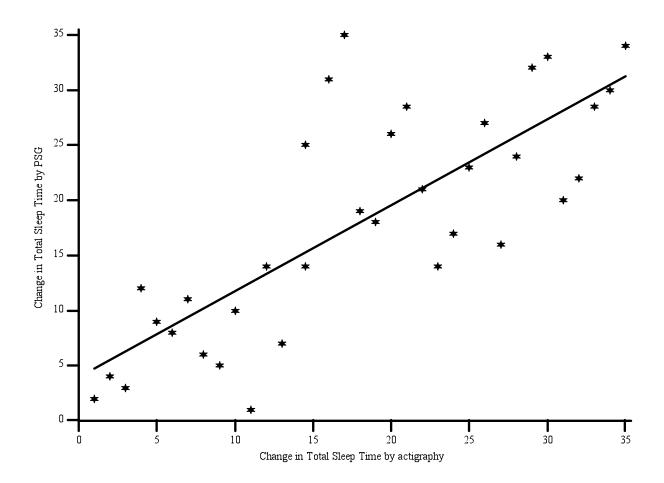


Figure 114. Relationship of ranked change in total sleep time (TST) between PSG and medium sensitivity actigraphy (n=35).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of ranked change in TST by actigraphy on ranked change in TST by PSG. Each star represents one subject.

The predictive effect of change in TST by actigraphy on change in TST by PSG was tested by a simple linear regression (Table 49). Approximately 58% of the variance in change in TST by PSG was explained by change in TST by medium sensitivity actigraphy, $R^2 = 0.58$, p <.0125. The TST by PSG was estimated to be -77.60 minutes when subjects had change in TST by actigraphy of -102 minutes (TST during the second night was 102 minutes less than the first

night). For each additional minute increase in change in TST by actigraphy, change in TST by

PSG was estimated to increase 1.16 minutes.

Table 49

Regression Analysis for Change in Total Sleep Time (TST) by Medium Sensitivity Actigraphy as a Predicting Factor for Change in TST by PSG (n=35)

Variables	В	SE B	β
Intercept	-77.60*	21.48	
Change in TST by Actigraphy	1.16*	0.17	0.76*

Note. PSG = Polysomnography; TST = Total Sleep Time; B = Unstandardized Beta when change in TST by actigraphy equaled a minimum value of -102 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .01.

A Bland-Altman plot illustrates the agreement of change in TST by medium sensitivity actigraphy and PSG methods (Figure 115). The mean change in TST obtained by two methods was between -90.25 and 160.25 minutes. The difference in TST by two methods varied from - 192.00 to 69.00 minutes.

The mean difference between these two methods (bias) was -42.45 minutes (95% CI = -60.24 to -24.67). A negative mean difference showed that on average actigraphy underestimated change in TST by approximately 42 minutes as compared to PSG. The two horizontal dotted lines show 95% limit of agreement. Since the standard deviation for the mean difference of change in TST was 51.78, the upper limit and lower limit of agreement was 59.03 and -143.94 minutes, respectively. Three outliers (5.13%) exceeded the lower limit of agreement: subjects #19, #22, and #28. Another subject exceeded the upper limit of agreement: subject #6. Based on the Bland-Altman plot there is no obvious pattern of overestimation of change in TST; difference of change in TST is distributed all over the graph and does not relate to the magnitude of mean change in TST.

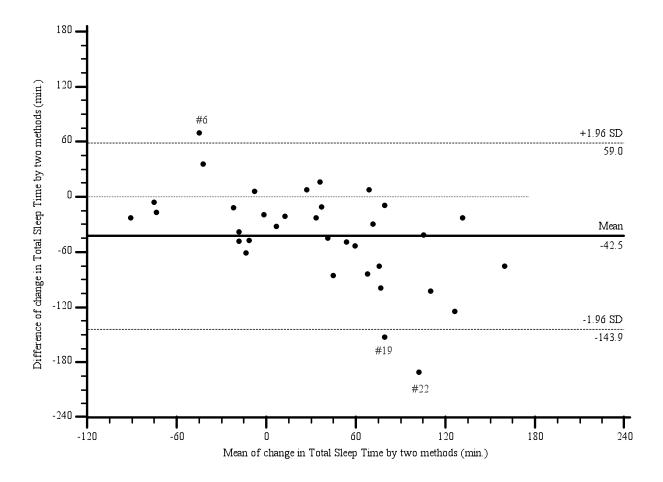


Figure 115. Bland-Altman plot of change in total sleep time (TST): Medium sensitivity actigraphy vs. PSG (n=35).

Note. Differences were calculated as change in TST by actigraphy minus change in TST by PSG (actigraphy - PSG). Means were calculated as the average change in TST by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

High sensitivity actigraphy.

Figure 116 shows individual's change in TST by two methods. As seen in Table 50, 27 subjects had similar direction of change. However of those 27, nine subjects had more than 60 minutes different in change in TST between two methods.

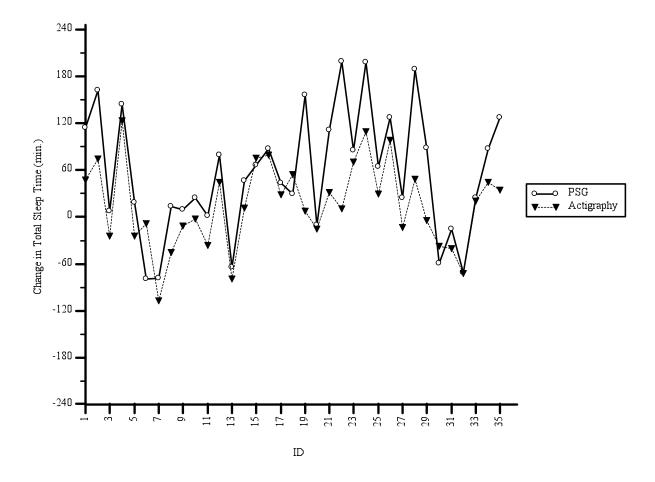


Figure 116. Individual's change in total sleep time by PSG and high sensitivity actigraphy (n=35).

Note. Each circle represents individual's change in TST by PSG. Each triangle represents individual's change in TST by high sensitivity actigraphy.

Table 50

Direction of Change and Magnitude of Difference in Total Sleep Time (TST) by High Sensitivity

Magnitude of difference	Direction		
	Similar	Different	
0 - 5 minutes	3	0	
5.01 – 15 minutes	4	0	
15.01 – 30 minutes	7	2	
30.01 – 60 minutes	4	5	
More than 1 hour	9	1	
Total	27	8	

Actigraphy and PSG (n=35)

The differences of change in TST taken by high sensitivity actigraphy and by PSG were not normally distributed, D = 0.20, p < .01. A histogram was drawn to show how these data were distributed (Figure 117). Using a signed rank test, there was a statistically significantly different of change in TST taken by two different methods, z = -259.50, p < .0001. It indicated that change in TST obtained by high sensitivity actigraphy was higher than those obtained by PSG.

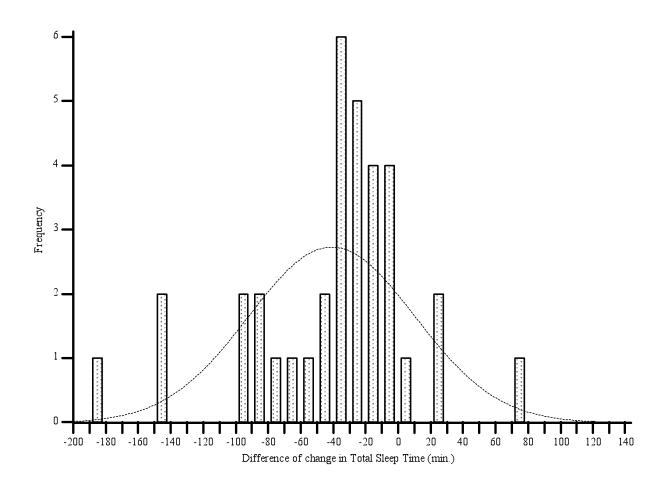


Figure 117. Histogram of difference of change in total sleep time (TST) by high sensitivity actigraphy and by PSG (n=35).

Note. Differences were calculated as change in TST by actigraphy minus change in TST by PSG.

As seen in Table 34, Spearman's rank provided correlation coefficient more than what Pearson did. Data were ranked and there was a statistically significantly high positive correlation of change in TST by actigraphy and PSG, $r_s = .79$, p < .0125. Scatter plots were employed to illustrate these relationships (Figures 118 - 119).

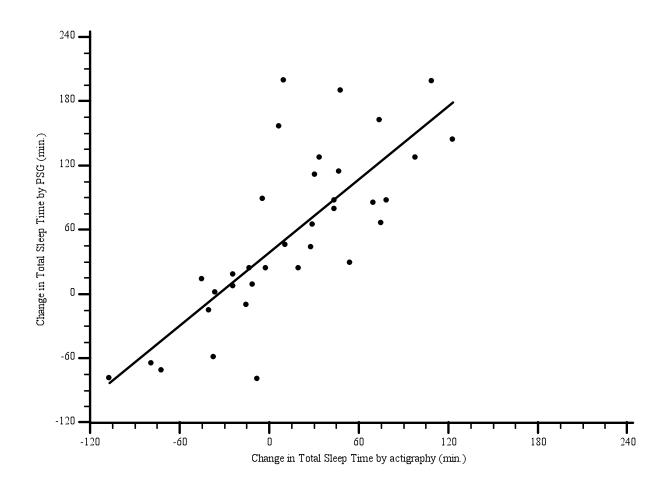


Figure 118. Relationship of change in total sleep time (TST) between PSG and medium sensitivity actigraphy (n=35).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of change in TST by actigraphy on change in TST by PSG. Each dot represents one subject.

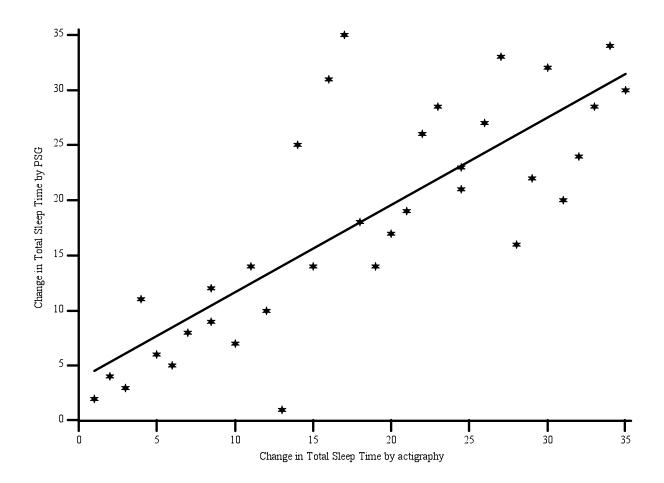


Figure 119. Relationship of change in ranked total sleep time (TST) between PSG and medium sensitivity actigraphy (n=35).

Note. The x-axis and the y-axis are displayed in the same scale. Line represents a regression line of ranked change in TST by actigraphy on ranked change in TST by PSG. Each dot represents one subject.

With a simple linear regression, approximately 59% of variance of change in TST by PSG was explained by change in TST by high sensitivity actigraphy, $R^2 = 0.59$, p < .0125. The change in TST by PSG was estimated to be -82.69 minutes when subjects had change in TST by actigraphy of -107 minutes (change in TST during the second night was 107 minutes less than

those during the first night). Change in TST by PSG was estimated to increase 1.14 minutes for each minute of increase in change in TST by actigraphy. A simple regression analysis is shown in Table 51.

Table 51

Regression Analysis for Change in Total Sleep Time (TST) by High Sensitivity Actigraphy as a Predicting Factor for Change in TST by PSG (n=35)

Variables	В	SE B	β
Intercept	38.87*	9.01	
Change in TST by Actigraphy	1.14*	0.16	0.80*

Note. PSG = Polysomnography; TST = Total Sleep Time; B = Unstandardized Beta when change in TST by actigraphy equaled a minimum value of -107 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .01.

The agreement of change in TST obtained by high sensitivity actigraphy and that obtained by PSG is illustrated by a Bland-Altman plot (Figure 120). The average change in TST obtained by two methods was between -92.75 and 153.75 minutes. The difference in change in TST by two methods varied from -189.00 to 71.00 minutes.

The mean difference between these two methods (bias) was -40.88 minutes (95% CI = -

58.44 to -23.32). A negative mean difference indicated that on average actigraphy

underestimated change in TST by approximately 41 minutes as compared to PSG. Based on the Bland-Altman plot, there is no clear pattern of underestimation of change in TST; differences of change in TST are distributed all over the plot and do not relate to the magnitude of mean change

in TST.

The limits of agreement are presented by the two horizontal dotted lines. With the standard deviation for the mean difference of change in TST of 51.11, the upper limit and lower

limit of agreement was 59.30 and -141.06 minutes, respectively. There were four outliers (11.43%). Three exceeded the lower limit of agreement: subjects #19, #22, and #28. Another subject exceeded the upper limit: subject #6.

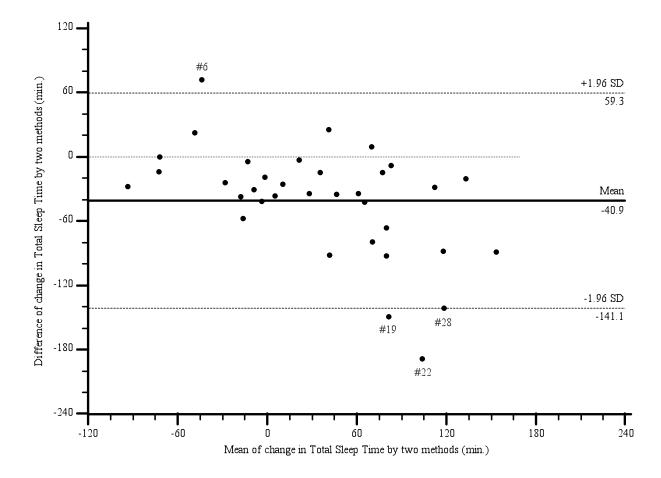


Figure 120. Bland-Altman plot of change in total sleep time (TST): High sensitivity actigraphy vs. PSG (n=35).

Note. Differences were calculated as change in TST by actigraphy minus change in TST by PSG (actigraphy - PSG). Means were calculated as the mean of change in TST by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

Auto sensitivity actigraphy.

Individual's change in TST by two methods was shown in Figure 121. As seen in Table 52, 27 subjects had similar direction of change in TST between two methods. However of those 27, eight subjects had more than 60 minutes different in change in TST.

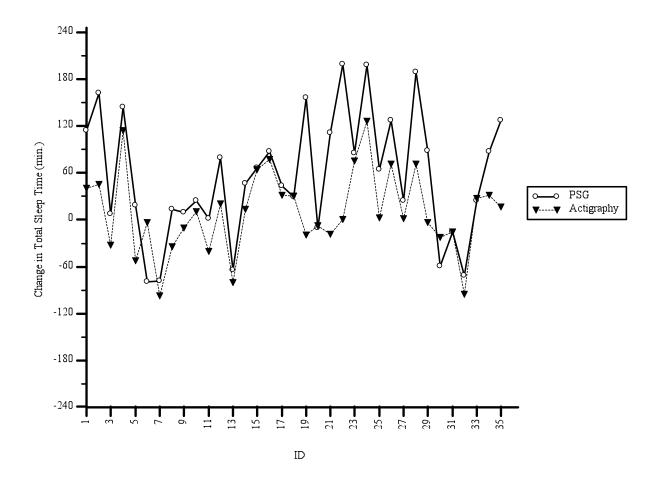


Figure 121. Individual's changes in total sleep time (TST) by PSG and auto sensitivity actigraphy (n=35).

Note. Each circle represents an individual's change in TST by PSG. Each triangle represents an individual's change in TST by auto sensitivity actigraphy.

Table 52

Direction of Change and Magnitude of Difference in Total Sleep Time (TST) by Auto Sensitivity Actigraphy and PSG

Magnitude of difference	Direction		
	Similar	Different	
0 - 5 minutes	5	0	
5.01 – 15 minutes	4	0	
15.01 – 30 minutes	5	1	
30.01 – 60 minutes	5	3	
More than 1 hour	8	4	
Total	27	8	

A paired-sample t-test was conducted to examine the difference of change in TST between two methods. Statistically significant difference of change in TST was found, t(34) =-4.84, p < .0001. It indicated that change in TST by auto sensitivity setting was less than that by PSG.

Change in TST between two methods was plotted to show their relationship (Figure 122). As seen in Table 34, change in TST by actigraphy had a significant moderate positive linear relationship with change in TST by PSG, r = 0.70, p < .01.

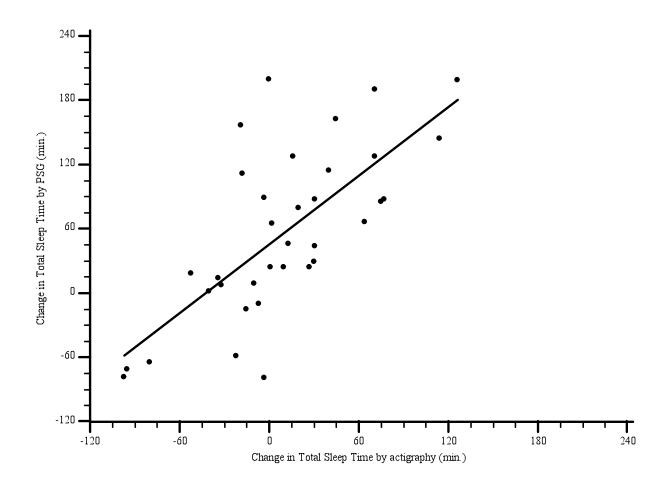


Figure 122. Relationship of change in total sleep time (TST) between PSG and auto sensitivity actigraphy (n=35).

Note. Line represents a regression line of change in TST by actigraphy on change in TST by PSG. Each dot represents one subject.

Fifty percent of variance of change in TST from PSG was explained by change in TST from auto sensitivity actigraphy, $R^2 = 0.50$, p < .01. As seen in Table 53, the change in TST by PSG was estimated to be -58.46 minutes when subjects had change in TST by actigraphy of -97 minutes. Change in TST by PSG was estimated to increase 1.07 minutes for each minute of increase in change in TST by actigraphy.

Table 53

Regression Analysis for Change in Total Sleep Time (TST) by Auto Sensitivity Actigraphy as a Predicting Factor for Change in TST by PSG (n=35)

Variables	В	SE B	β
Intercept	-58.46 ^{ns}	22.22	
Change in TST by Actigraphy	1.07*	0.19	0.70*

Note. PSG = Polysomnography; TST = Total Sleep Time; B = Unstandardized Beta when change in TST by actigraphy equaled a minimum value of -97 minutes; *SE B* = Standard Error of Unstandardized Beta; β = Standardized Beta; * p < .0125; ns = not statistically significant.

The agreement of change in TST between two methods is presented in a Bland-Altman plot (Figure 123). The average change in TST obtained by two methods was between -87.75 and 162.25 minutes. The difference in change in TST by two methods varied from -199.00 to 76.00 minutes.

The mean difference between these two methods, or bias, was -46.05 minutes (95% CI = -65.40 to -26.70). A negative mean difference indicates that on average actigraphy underestimates change in TST by approximately 46 minutes as compared to PSG. The limits of agreement are presented by the two horizontal dotted lines. Since the standard deviation for the mean difference of change in TST was 56.33, the upper limit and lower limit of agreement was 64.36 and -156.47 minutes, respectively. There were three outliers (8.57%). Two exceeded the lower limit of agreement: subjects #19, and #22. Another exceeded the upper limit: subject #6. The Bland-Altman plot showed no clear pattern of underestimation of change in TST.

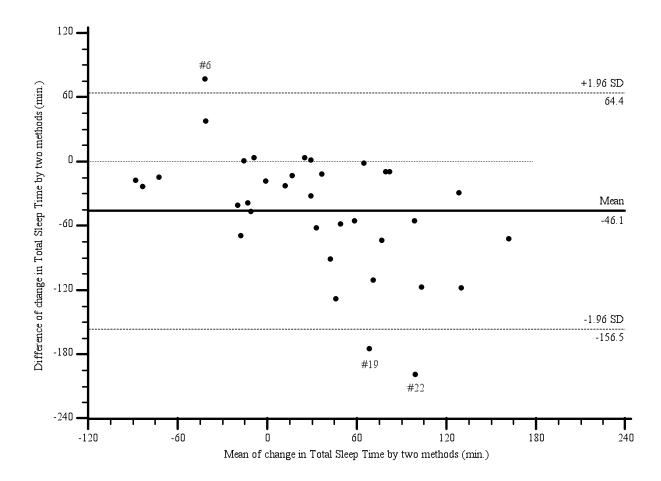


Figure 123. Bland-Altman plot of change in total sleep time (TST): Auto sensitivity actigraphy vs. PSG (n=35).

Note. Differences were calculated as change in TST by actigraphy minus change in TST by PSG (actigraphy - PSG). Means were calculated as the mean of change in TST by actigraphy and by PSG [(actigraphy + PSG) /2]. Each dot represents one subject.

In summary, three different approach methods (i.e. comparison of the means, correlation and regression models, and Bland-Altman Plots) were employed to examine the agreement of TST taken by PSG and those taken by four sensitivity settings of actigraphy (Table 57). According to the comparison of the mean/median method, four sensitivity settings provided statistically significantly different change in TST compared to PSG. The intraclass correlations between each sensitivity actigraphy and PSG were moderate. The linear relationships of TST between two methods were statistically significant for all four sensitivity settings. However, medium and high sensitivity provided the strongest relationship between all four sensitivity levels. In addition, in spite of the different sensitivity settings, actigraphy always underestimated change in TST compared to PSG. However, actigraphy with high sensitivity setting provided the least bias; it underestimated change in TST by 41 minutes.

Table 54

Agreement of Chan	ge in Total Slee	ep Time (TST)	by PSG and Ac	tigraphy (n=35).
	0			

Sensitivity	Method			
settings	Comparison of the	Correlation and		Bland-Altman Plots
Actigraphy	mean/median (p value)	Regression		
		r/r_s	R^2	Bias
Low	< .0001	Moderate	0.50	-43.77
Medium	< .0001	Moderate	0.58	-42.45
High	< .0001	Moderate	0.59	-40.88
Auto	< .0001	Moderate	0.50	-46.05

Note. TST = Total Sleep Time; PSG = Polysomnography; r = Pearson Coefficient; r_s = Spearman's Rank Coefficient; R^2 = coefficient of determination.

Summary of Results

During the two consecutive nights of polysomnography (PSG) and actigraphy, change in wake after sleep onset (WASO) between two methods was similar. However, actigraphy showed statistically significantly different changes in sleep onset latency (SOL) and total sleep time (TST) when compared to PSG. Of the four-sensitivity settings, high sensitivity provided the least discrepancy for change in sleep parameters as compared to PSG.

CHAPTER 7 DISCUSSION

This study examines 1) a first night effect of laboratory polysomnography on sleep, 2) the accuracy of actigraphy when compared to PSG in measuring sleep, and 3) the accuracy of actigraphy when compared to PSG in measuring change in sleep, in community-dwelling older adults, age 70 years and older. A secondary data analysis was conducted with the data from 63 community-dwelling older adults, at least 70 years of age who participated in either the Respiratory Periodicity and Cognitive Decline in Elders Study (PRISM) (PI: Barbara Carlson NR08032, IRB#01-0666, formerly, 726-01) or the Patterns of Cerebral Oxygenation during Sleep and their Relationship to Markers of Hypoxic Burden and Brain Connectivity in Community Dwelling Older Adults (PTRACS) (PI: Barbara Carlson, NC TraCS: 50K20908, IRB# 09-2129).

This chapter discusses the findings from this study. First, the discussion focuses the characteristics of sleep first night effect (FNE), followed by the characteristics of sleep in community-dwelling older adult, age 70 years and older. Second, it discusses the accuracy of actigraphy when compared to PSG in measuring sleep. Finally, it discusses the accuracy of actigraphy when compared to PSG in measuring change in sleep. Limitation of the study and implications for future research are also included in the discussion.

Research Question one: The First Night Effect

These findings present first night effect (FNE) related to laboratory polysomnography (PSG) from 45 community-dwelling older adults, age 70 years and older. The aim of this study was to explore the presence of a FNE in two consecutive nights of laboratory PSG in community-dwelling older adults, age 70 years and older. Although three different approaches were employed to in this research question, including 1) comparisons of means, 2) scatter plots of each sleep parameters between the first and second night, along with correlation coefficients, and 3) scatter plots of change of each sleep parameter from the baseline against the first night sleep parameter or baseline. Comparison of means method was used as a key method to identify FNE. Ten sleep parameters, including 1) time in bed (TIB), 2) sleep onset latency (SOL), 3) wake after sleep onset (WASO), 4) total sleep time (TST), 5) sleep efficiency (SE), 6) stage N1, 7) stage N2, 8) stage N3, 9) stage R, and 10) REM latency between two nights were tested to identify and describe FNE.

The results revealed that TIB, SOL, stage N2, and stage R were comparable on both nights. However during the first night, subjects demonstrated statistically significantly more wake after sleep onset (WASO), proportion of stage N1, REM latency than what they had during the second night. On the other hand, they showed statistically significantly less total sleep time (TST), sleep efficiency (SE), and proportion of stage N3 during the first night than what they had during the second night. Thus, first night effect (FNE) occurred in community-dwelling older adults, age 70 years and older, who undergone for a laboratory PSG.

According to SOL, although the different of SOL between two nights was 19.62 minutes, there was no statistically significantly different. Two issues might impact on this topic, including 1) variability of SOL, and 2) sample size in this analysis. When the variability of SOL was

examined, the different of SOL between two nights was not normally distributed. Its standard deviation was almost two times of its mean. When power analysis was calculated based on the value of SOL of each night, the power of this analysis was only .71 with 45 subjects. In order to achieve the power of .80, the total number of at least 56 subjects is needed.

For stage N2 and stage R, the total number of 45 cases was not enough to provide the power of .80. Based on the value from this study, the analyses of stage N2 and stage R provided power of .50, and .52, respectively. If the sample size increases to be at least 90 cases, we might be able to see the different of these stages between two nights of laboratory PSG.

Overall, FNE in this study is consistent with prior studies with a typical first night effect that during the first night older adults had more awake and less sleep (Aber, et al., 1989; Edinger, et al., 1997). Aber and colleagues conducted a study in 14 community-dwelling older men. Two consecutive nights of laboratory PSG were employed. FNE was reported, including significantly increased SOL and stage N1 and significantly decreased TST and stage R during the first night as compared to the second night (Aber, et al., 1989). Similar findings were presented by Edinger's study. Thirty-two older adults with insomnia and 32 age and gender matched older adults without insomnia participated in three consecutive nights of laboratory PSG. FNE was found in both groups, which included significant decreased TST, slow wave sleep, and SE while REM latency was significantly increased during the first night as compared to the second and the third night (Edinger, et al., 1997).

Characteristics of Sleep in Community-Dwelling Older Adults, age 70 Years and Older.

Since FNE occurred in this population, second night PSG sleep data from 48 subjects were employed to describe the characteristics of sleep in community-dwelling older adults, age

70 years and older. The average time in bed (TIB) was almost 8 hours. The mean SOL was 13.35 minutes (SD = 11.75), which was located within the normal range of less than 30 minutes. It represented that the subjects in this study did not have problem falling asleep. The WASO was 80.02 minutes (SD = 50.46), which was more than 30 minutes. It indicated that subjects had problems staying asleep. The TST was 364.11 (SD = 50.33), or approximately 6 hours. Their SE was quite high with 78.31 percent (SD = 10.28). The percentages of sleep stages (i.e. stage N1, stage N2, stage N3, and stage R) were 15.14 (SD = 8.90), 32.13 (SD = 9.13), 30.37 (SD = 10.57), and 22.36 (SD = 7.15), respectively. The REM latency was 101.57 minutes (SD = 72.61).

These findings of sleep architecture in this study are inconsistent with a prior study (Redline, et al., 2004) that investigated the variation in sleep architecture across the population. In Redline's study, 2,685 subjects were participated in the study. Of those, there were 649 older adults, age 70 years who went to a one-night home PSG study. According to Redline's study, stage N1, N2, N3, and R were 5.7%, 57.3%, 18.2%, and 18.8%, respectively. The percentage of stage N1, stage N3, and stage R in this study were higher than those from Redline's study while the percentage of stage N2 in Redline's study was higher than those in this study. There are three possible reasons why the findings in this study were different from the Redline's study: because 1) Redline and colleagues measured individual sleep by using only one night home PSG. Although there was numerous studies reported that there was no FNE (Edinger, et al., 1997; Edinger, et al., 1991; Sharpley, et al., 1988; Wauquier, et al., 1992), the occurrence of FNE in home PSG were reported in several studies (Coates, et al., 1981; Le Bon, et al., 2001; Saletu, et al., 1996; Wauquier, et al., 1991). Thus, whether FNE occurs in home PSG is controversy. If FNE exists in the sample of Redline's study, their findings might not represent individual's habitual sleep architecture; 2) the sample size in this current study was small; and 3) different

PSG equipment was used between these studies. Although sleep recording and scoring were similar, there was no information whether or not these two methods would provide identical sleep architecture.

Although FNE occurred and subjects had better sleep during the second night, whether the second night sleep data could represent subjects' habitual sleep remains unclear since there were a possibility of incongruent of subjects' bedtime and wake up time between laboratory sleep and their usual sleep in their place. At the laboratory sleep study, subjects' bedtime and wake up time were based on the protocol of sleep lab that normally subjects would probably go to bed sometime around 10 pm and wake up around 6 am in the following day. These laboratory sleep schedule might not be identical to their sleep schedule when they were at home. To clarify this issue, TST by PSQI was compared to TST by the first and second night PSG. TST by PSQI was statistically significantly more than TST by the first night PSG, t(44) = 7.72, p < .01. TST by PSQI was also statistically significantly more than TST by the second night PSG, t(44) = 5.23, p< .01. Thus, whether the second night sleep from PSG could represent subject's habitual sleep remains indeterminate.

Research Question Two: The Accuracy of Actigraphy When Compared to PSG in Measuring Sleep in Community-Dwelling Older Adults, age 70 Years and Older

Since the issue of whether actigraphy has the potential to provide useful sleep information similar to PSG in community-dwelling older adults, age 70 years and older, remains unclear, this secondary study was then conducted to examine the accuracy of actigraphy against the gold standard PSG. The best sensitivity setting that can provide less discrepancy of three sleep parameters (i.e. SOL, WASO, TST) was also identified for both the first and the second

night. Three sleep parameters obtained by PSG and actigraphy with four different sensitivity setting (i.e. low (80), medium (40), high (20), and auto) were compared on the basis of its value during the first and second night of two consecutive nights of sleep study.

Four different approaches were employed to identify the accuracy, including comparison of means, intraclass correlation coefficients (ICC), correlation and regression models, and Bland-Altman plots. Bonferroni corrections were applied with the significance set at p < .0125. However, since this analysis is a method-comparison, the main findings are presented based only the ICC and Bland-Altman plots.

Sleep onset latency (SOL).

Since actigraphy uses immobile minutes method as the strategy to identify sleep start, SOL from four settings of actigraphy were identical. According to SOL, during the first night the association between two methods to measure SOL was moderate while it was poor during the second night, representing that actigraphy might be more association with PSG in determining SOL when subjects had prolong SOL. The strength of this association was somewhat similar to the study by Blackwell and colleagues (2011), which conducted among 668 community-dwelling older men. However, in that study, they used a different actigraphy device, which was the sleepwatch-O with three modes (i.e. PIM, TAT, and ZCM). Of those three modes, TAT mode provided the smallest ICC, which was comparable to what AW-L did. However, when PIM and ZCM modes of sleepwatch-O were employed, these two modes provided ICC values of 0.32 and 0.36, which were more than what AW-L did. It implies the need for actigraphy to develop a new method to determine sleep starts rather that the immobile minutes method that actiware program currently employs so that it might be able to improve ICC between AW-L and PSG.

Even when actigraphy from the same company but different model was used, the strengths of association were different (Cellini, et al., 2013; Wang, et al., 2008). However, the samples in these two studies were different than those in this study. In Wang' study, samples were 21 young adults with obstructive sleep apnea while samples of Cellini's study were 34 non-smoking young adults. AW-64 was employed for both studies. The association of SOL between AW-64 and PSG was fair, which was more than the ICC in this study. The reasons behind different results may come from one major reason that both studies were conducted in young adults. Age may impact on the estimation of SOL by PSG and/or SOL by actigraphy. If so, the ICC between two methods may be differ from other age group.

During the first and second night of laboratory PSG, actigraphy overestimated SOL by 20 and 2 minutes, respectively. Only the bias of 2 minutes during the second night might not be significant because it is unlikely that this average bias between two methods in measuring SOL would be considered clinically significant or would affect diagnosis and treatment decisions. The finding during the second night is consistent with previous studies that actigraphy underestimated SOL (Blackwell, Ancoli-Israel, et al., 2011; Taibi, et al., 2013; Vallieres & Morin, 2003). Blackwell and colleagues (2011) tested Sleepwatch-O in 889 community-dwelling older men and reported an underestimated of SOL similar to this study. When actigraphy was tested in people with insomnia, the values of underestimation were higher than what reported in this study (Taibi, et al., 2013; Vallieres & Morin, 2003).

Wake after sleep onset (WASO).

Of those four sensitivity settings, actigraphy with high sensitivity setting provided highest ICC value between actigraphy and PSG on WASO. According to high sensitivity setting, the

ICCs of WASO between two methods across two nights were similar, representing that the association between two methods in measuring WASO was fair. However, the value of ICC during the second night was a little bit more than the ICC value during the first night. The ICCs in this study were somewhat as similar as those found in previous studies (Blackwell, Ancoli-Israel, et al., 2011; Blackwell, et al., 2008; Cellini, et al., 2013).

Blackwell and colleagues conducted two studies in 2008 and 2011 to investigate the accuracy of Sleepwatch-O with three different modes (i.e. PIM, TAT, and ZCM) against PSG in community-dwelling older women. The strength of associations of WASO between TAT mode of sleepwatch-O and PSG for both studies were similar to the ICC that report here while PIM mode provided slightly higher and ZCM mode provided slightly less than what reported here. Cellini and coworkers (2013), who validated AW-64 and GT3X+ against PSG in 34 non-smoking young adults during daytime nap, reported similar ICCs when AW-64 was employed. However, GT3X+ provided ICC values a little bit more than what reported here. Since the samples were different, whether GT3X+ could provide ICC value more than AW-L in community-dwelling older adults, 70 years and older needs to be studied. Wang and coworkers (2008), who used the medium setting of AW-64 in young adults with sleep apnea, reported a lesser degree of ICC than what reported here. However, whether this difference came from a different device, different sensitivity setting, different age group, different health problem, or a combination of all listed issues remains unclear.

Actigraphy with high sensitivity setting underestimated WASO by 33 minutes during the first night and by 21 minutes during the second night. During the second night, actigraphy provided a lesser degree than that reported during the first night, representing that actigraphy might be more accurate when subject has less awake. However, the bias of 21 minutes during the

second night is likely to be considered clinically significant or effect diagnosis and treatment decisions. The finding during the second night is consistent with previous studies that actigraphy underestimated WASO (Blackwell, Ancoli-Israel, et al., 2011; Blackwell, et al., 2008; Taibi, et al., 2013; Vallieres & Morin, 2003). When Sleepwatch-O with TAT mode was tested in community-dwelling older adults, similar values of underestimation of WASO were reported (Blackwell, Ancoli-Israel, et al., 2011; Blackwell, et al., 2008). However with PIM mode, lesser degrees were reported while ZCM mode was applied, sleepwatch-O was overestimated WASO. Vallieres and Morin (2003) also reported underestimated of WASO with actigraphy (Individual Monitoring systems), but with a lesser degree than that reported here, with a mean underestimation of 7 minutes. However, this study was conducted in 17 chronic primary insomniacs and did not include community-dwelling older adults. Greater degree of underestimation was reported when Actiwatch-64 with 20 activity counts threshold was employed in 16 older women with insomnia (Taibi, et al., 2013). Although this samples were older adults, having insomnia might allow them to have higher variability of WASO.

Total sleep time.

Of those four sensitivity settings, actigraphy with high sensitivity setting provided highest ICC value between actigraphy and PSG on TST. According to high sensitivity setting, the ICC of TST during the second night was higher than those during the first night. This finding was different to previous studies (Blackwell, Ancoli-Israel, et al., 2011; Blackwell, et al., 2008; Johnson, et al., 2007; Wang, et al., 2008). Lesser degree of association of TST between two methods was reported in two studies (Johnson, et al., 2007; Wang, et al., 2008). Wang and colleagues validated Actiwatch-64 in adults with or without obstructive sleep apnea while

Johnson and coworkers (2007) validated Octagonal Sleep Watch 2.01 (Ambulatory Monitoring) in 181 adolescents with and without sleep disorder breathing. However, it might not be able to make a statement that high setting of AW-L provided better ICC than what Actiwatch-64 and Octagonal Sleep Watch 2.01 did since the samples and also their characteristics were different in term of age group and health status.

Incongruent degree of association was reported in two studies (Blackwell, Ancoli-Israel, et al., 2011; Blackwell, et al., 2008), when sleepwatch-O was used in community-dwelling older adults across three modes (i.e. PIM, TAT, ZCM), the PIM mode provided the highest ICC of 0.76 (Blackwell, et al., 2008) and 0.57 (Blackwell, Ancoli-Israel, et al., 2011). The ICC of TST from PIM mode of sleepwatch-O was higher than the ICC from high setting of AW-L in the first study and was similar to the later study. Then whether the PIM mode of sleepwatch-O would provide better ICC than what high setting of AW-L did remains unclear.

For mean bias, actigraphy with high sensitivity setting overestimated TST with the mean bias of 56 minutes during the first night and 21 minutes during the second night. Actigraphy provided better accuracy during the second night than those during the first night. The bias of 21 minutes might be unlikely to be considered clinically significant or would affect diagnosis and treatment decisions. The finding during the second night is consistent with previous studies that actigraphy overestimated TST (Blackwell, Ancoli-Israel, et al., 2011; Blackwell, et al., 2008; Jean-Louis, Kripke, Cole, et al., 2001; Jean-Louis, Kripke, Mason, et al., 2001; Kushida, et al., 2001; Taibi, et al., 2013). In community-dwelling older adult, Sleepwatch-O was employed in two studies (Blackwell, Ancoli-Israel, et al., 2011; Blackwell, et al., 2008) with three different modes (i.e. PIM, TAT, and ZCM), degree of overestimation was similar when TAT mode was applied. Taibi and coworkers (2013), who validated Actiwatch-64 in older women with

insomnia, reported greater degree of overestimation with the value of 89.15 minutes with 20 activities counts threshold.

Research Question Three: The Accuracy of Actigraphy When Compared to PSG in Measuring Change in Sleep in Community-Dwelling Older Adults, age 70 Years and Older

These findings present the results of research question three. The aim of this research question is to identify the accuracy of actigraphy, as compared to PSG, in measuring change in sleep in community-dwelling older adults, age 70 years old. In this analysis, data from subjects who had both the first and second night of laboratory PSG and actigraphy were included. Data from 35 subjects were included in this analysis.

In this analysis, change was defined as the difference of given sleep parameter between two nights of laboratory study. The value of the second night was subtracted by the value of the first night. A negative change indicated that the value of the second night sleep parameter was less than that of the first night. On the other hand, a positive change indicated that the value of the second night was more than that of the first night.

Four different approaches were employed in this study, including 1) figures of change in each sleep parameter between two methods across all subjects, 2) comparison of means, 3) correlation and regression models, and 4) Bland-Altman plot. However, the findings were based on only the Bland-Altman plots. Other three approaches were additional methods for explaining more information about these data.

According to Bland-Altman plots, all four sensitivity settings of actigraphy overestimated change in SOL and change in WASO, and underestimated change in TST, when compared with

PSG. However, among all four sensitivity settings, high sensitivity setting provided the smallest discrepancies between actigraphy and PSG.

Sleep onset latency.

According to SOL, since actigraphy uses immobile minutes method as the strategy to identify sleep start, SOL from four settings of actigraphy were identical. Overall, the mean bias of change in SOL between two methods was 21 minutes, indicating that actigraphy overestimated change in SOL by PSG approximately 21 minutes.

Wake after sleep onset.

For change in WASO, the mean biases of change in WASO between two methods across four-sensitivity settings (i.e. low, medium, high, and auto) were 15, 14, 12, 17 minutes, respectively. These indicated that overall, actigraphy overestimated change in WASO by PSG.

Total sleep time.

According to change in TST, the mean biases of change in TST between two methods across four-sensitivity settings (i.e. low, medium, high, and auto) were -43.77, -42.45, -40.88 and -46.05 minutes, respectively. These indicated that overall actigraphy overestimated TST by PSG.

These findings indicate that, while there are substantial discrepancies between actigraphy and PSG in measuring change in three sleep parameters, both measures tend to provide sleep parameter in the same direction. However, these discrepancies are too large, indicating that actigraphy might not be sensitive enough to pick up change in sleep parameters. However, there is a limitation in these findings since this study is a secondary data analysis. Change of each sleep parameter as defined in this study was only the difference of each sleep parameter between two consecutive nights. There are three major issues with how change was defined and measured in this analysis: 1) there was FNE related to PSG in this study and the FNE included difference in WASO and TST but not on SOL, 2) there was also FNE related to actigraphy and the FNE happened only on WASO and 3) change in sleep parameter between the period of two nights could be defined as night to night variability and that may occur in individual's habitual sleep.

There was one study that compared the accuracy of actigraphy against PSG in detecting the effects of treatment (Vallieres & Morin, 2003). Seventeen subjects with chronic primary insomnia were participated in this study. According to their findings, the researchers stated that actigraphy was sensitive in detecting the effects of treatment on SOL, TWT, SE, and TST. However, this study had some concerning issues since 1) they used repeated-measures ANOVAs as the strategy for this method comparison study and 2) Bonferroni corrections were not applied in this study. Repeated-measures ANOVA is not appropriate to use for method comparison study and without Bonferroni correction, the researchers increased the likelihood of having type I error in this study. Thus, it is still unclear whether or not actigraphy is accurate in measuring change in sleep.

Limitations of the Study

The first limitation is about the research design. This study was a secondary research study. Beside the advantages that data has been collected and are available to use, there were some disadvantages because the researcher could not control how data were collected: 1) as seen in the result chapters, the number of samples in each research question differed since there were

some missing sleep data and some data were not normally distributed. Instead of using parametric statistics, the researcher had to use non-parametric statistics to analyze data; 2) according to research question number two, epoch by epoch comparisons were not performed between PSG and actigraphy because each method had different epoch lengths. In these two original studies, PSG was scored with 30-second epoch length while actigraphy was scored with one-minute epoch length. Thus, sensitivity, specificity, and agreement analysis cannot be performed; and 3) according to research question number three, the accuracy of actigraphy in measuring change in sleep when compared to the gold standard PSG, at the time to do a research proposal, the researcher was not fully familiar with the data and did not expect any error on PSG sleep data that may come from FNE. When FNE occurred, it impacted on the first night PSG sleep data more than what it did with actigraphy sleep data. Thus, the methodology for that research question, it might be preferable if the researcher anticipates concerns about FNE and designs a study to prevent any error on PSG sleep from FNE.

The second limitation is about sample size. Sample size in this study was not too small but was not too large either. Sample size is important because small sample size will limit the power of the statistical analyses. According to research question one, sleep data from 45 subjects were analyzed to identify FNE. If the sample size in this analysis increased, we might be able to see other significantly differences such as SOL.

The third limitation is about population validity. The majority of subject in this study was female, Caucasian. This study is lack of ethnic and gender diversity, which limits the generalizability of the findings from the sample to the population. In addition since this study

focuses on community-dwelling older adults, age 70 years and older, the results of this study might not be able to generalize across other populations.

The fourth limitation is that this study did not to control for any subjects with untreated sleep apnea. Untreated sleep apnea may cause subject to toss and turn during the night more often than normal sleeper and it might be related to variability of sleep data.

The fifth limitation is related to the method of applying Bonferroni correction. In this study, Bonferroni correction was applied for only research question number two and three with the significant level of p value set up at less than .0125 (0.05/4) since their were four different value for each sleep parameter from actigraphy. If different family of tests were applied with different significant set up of p value, different results might be seen.

The last limitation is about the actigraphy device. In this study only one type of actigraphy that was actiwatch-light (AW-L) was tested in this study. Although Philips Respironics company (2014) stated that the performance of AW-64, AW-2, and AW-Spectrum were similar, there was no information related to the performance of Actiwatch-L to other models. In addition, there are several types of actigraphy devices from different companies. Performance of different actigraphy devices were tested in several study, including Basic Mini-Motionlogger and Actiwatch-L (Benson, et al., 2004), Basic Mini-Motionlogger vs. Actiwatch (Tonetti, et al., 2008) and Motionlogger watch vs. Actiwatch-64 (Rupp & Balkin, 2011) were tested. Although all three studies were conducted among healthy adults, results of these three studies were incongruent. Benson and colleagues (2004) found that Actiwatch-L provided similar performance with Mini-Motionllogger only when Actiwatch-L was set up at medium setting. When Actiwatch-L was set up at high setting, the Mini-Motionlogger reported more TST and less WASO. Although Tonetti and coworkers (2008) found that both devices had similar

performance in assessing sleep as compared to PSG, they failed to report what type of specific actiwatch that they used. On the other hand, Rupp and Balkin (2011) reported that Motionlogger provided better agreement with PSG than AW-64 did. Thus, whether or not the performances of all actigraphy devices in assessing sleep as compared to PSG are similar remains unclear. Thus, the results of this study might not be able to generalize across other actiwatch models and other actigraphic devices. In addition, different results may be expected if other model of actigraphy and other analyzing program are employed.

Conclusions

A secondary data analysis was utilized to explore the first night effect (FNE) among community-dwelling older adults, age 70 years and older. In addition, the accuracy of actigraphy when compared with polysomnography (PSG) in measuring sleep and change in sleep was also explored.

The data in this study were derived from 63 community-dwelling older adults from two studies: PRISM and PTRACS. The number of subjects analyzed for each research question was different depending upon the criteria for each research question. For the first research question, the first night and second night PSG from 45 subjects were analyzed to describe the FNE in community-dwelling older adults, age 70 years and older. For the second research question, the accuracy of actigraphy in measuring sleep when compared to PSG, there were two separate analyses for each night of sleep data. During the first night, PSG and actigraphy data in 39 cases were compared while sleep data from two methods in 38 cases were compared during the second night to identify the accuracy of actigraphy against PSG. For the last research question, 35 subjects who had both the first and second night of PSG sleep and the first and second night of

actigraphic sleep were included in this analysis to identify the accuracy of actigraphy in measuring change in sleep against PSG.

Two instruments were used in the study, PSG and wrist actigraph. According to standard PSG, two sleep experts scored sleep states and the inter-rater agreement was acceptable across all records with 97% of agreement and a kappa of 0.91. For wrist actigraph, an actiwatch-light was employed in two original studies. Sleep data from the actigraph were retrieved by using Actiware-Sleep software v.3.3.

After receiving approval from the Institutional Review Board of the University of North Carolina at Chapel Hill, data entry and analysis were performed using SAS software, version 9.3. All data were double entered and compared for any errors. The results of the study are presented below.

According to research question one, FNE occurred in community-dwelling older adults, age 70 years and older. The FNE included more of the following parameters: wake after sleep onset (WASO), proportion of stage N1 and REM latency, and less of the following parameters: total sleep time (TST), sleep efficiency (SE), and proportion of stage N3.

For research question two, the accuracy of actigraphy was compared to the gold standard PSG in measuring three sleep parameters (i.e. SOL, WASO, and TST). For SOL, the mean bias of SOL between two methods was -2.13 minutes, indicating that overall actigraphy underestimated SOL by PSG approximately two minutes. The difference of 2 minutes is not significant because it is likely that this difference would not be considered clinically significant or effect diagnosis and treatment decisions. Thus, actigraphy might be useful for measuring SOL in community-dwelling older adults, age 70 years and older. For WASO, the mean biases of WASO between two methods across four-sensitivity settings (i.e. low, medium, high, and auto)

were as follows: -59.26, -41.55, -20.61, and -56.45 minutes, respectively. These results indicate that overall actigraphy underestimated WASO by PSG. Although of those four settings, high sensitivity setting of actigraphy provided less discrepancy of WASO, the difference of 20.61 minutes is significant because it is likely that this difference would be considered clinically significant or effect diagnosis and treatment decisions. Thus, actigraphy might not be useful for measuring WASO in community-dwelling older adults, age 70 years and older. For TST, the mean biased of TST between two methods across four- sensitivity settings (i.e. low, medium, high, and auto) were as follows: 59.63, 41.92, 20.98, and 56.82 minutes, respectively. These results indicate that overall actigraphy overestimated TST by PSG. Although of those four settings, high sensitivity setting of actigraphy provided less discrepancy of TST between two methods, the difference of 21 minutes is not significant because it is unlikely that this difference would be considered clinically significant or effect diagnosis and treatment actigraphy provided less discrepancy of TST between two methods, the difference of 21 minutes is not significant because it is unlikely that this difference would be considered clinically significant or effect diagnosis and treatment decisions. Thus, actigraphy might be useful for measuring TST in community-dwelling older adults, age 70 years and older.

For research question three, the accuracy of actigraphy was compared to the gold standard PSG in measuring change in three sleep parameters (i.e. SOL, WASO, and TST). The mean bias of change in SOL between two methods was 21 minutes, indicating that on average actigraphy overestimated change in SOL by PSG by approximately 21 minutes. The difference of 21 minutes is significant because it is likely that this difference would be considered clinically significant or effect diagnosis and treatment decisions. Thus, actigraphy might not be useful for measuring change in SOL in community-dwelling older adults, age 70 years and older. For change in WASO, the mean biases of change in WASO between two methods across four-sensitivity settings (i.e. low, medium, high, and auto) were as follows: 15.01, 13.73, 12.13 and

17.30 minutes, respectively. These results indicate that overall actigraphy overestimated change in WASO by PSG. Although of those four settings, high sensitivity setting of actigraphy provided less discrepancy of WASO, the difference of 12.13 minutes is significant because it is likely that this difference would be considered clinically significant or effect diagnosis and treatment decisions. Thus, actigraphy might not be useful for measuring change in WASO in community-dwelling older adults, age 70 years and older. According to change in TST, the mean biases of change in TST between two methods across four- sensitivity settings (i.e. low, medium, high, and auto) were as follows: -43.77, -42.45, -40.88, and -46.05 minutes, respectively. These results indicate that overall actigraphy underestimated change in TST by PSG. Although of those four settings, high sensitivity setting of actigraphy provided less discrepancy of change in TST between two methods, the difference of 40.88 minutes is significant because it is likely that this difference would be considered clinically significant or effect diagnosis and treatment decisions. Thus, actigraphy might not be useful for measuring change in TST in community-dwelling older adults, age 70 years and older.

Recommendation for Further work

There are nine recommendations for future investigation. The first recommendation is to replicate this study with a prospective approach, analyzing a larger sample size and a more diverse sample.

The second recommendation is to find an alternative method to identify actigraphy sleep start. Currently, the Actiware sleep program uses the immobile minutes method as the strategy to identify sleep start. The immobile minutes method uses the first period of 10 minutes in which no more than one epoch contains movement as the time when sleep starts. Despite any change in

sensitivity setting, SOL from actigraphy remains the same. Since we now know that actigraphy always underestimates SOL by PSG, an alternative strategy is needed to come up with the time of sleep start.

The third recommendation is to set up epoch lengths to be identical between the two methods so that sensivity, specificity, and percent of agreement could be computed.

The fourth recommendation is to refine actigraphy sensitivity settings to achieve closer value of sleep parameters with PSG. By doing this, custom settings would be applied to select the different activity-count thresholds that provide the least discrepancy when compared with sleep parameter by PSG.

The fifth recommendation is to combine other measurements (e.g. electrooculogram or electromyogram) with actigraphy to verify whether or not these could improve accuracy of actigraphy in detecting wake/sleep state.

The sixth recommendation is to attempt a different research design in order to identify the accuracy of actigraphy in measuring change in sleep against PSG. Specifically, the period between time one and time two that will be used to identify change should be longer than one day. In addition, sleep data used for comparison should come from the second night of each time in order to prevent the FNE effect that might interfere with PSG sleep data.

The seventh recommendation is to test the accuracy of PSG, actigraphy, and subjective data (i.e. sleep diary) at the same time or the combination of actigraphy and subjective data against the gold standard PSG.

The eighth recommendation is to validate other actigraphy devices that might be available in the market. If possible, it might be better to validate multiple devices against PSG at the same time.

Finally, the last recommendation is to identify the relationship between subjects' characteristics such as age, gender, and race, on sleep parameters with measurements by PSG and actigraphy.

APPENDIX 1: INSTITUIONAL REVIEW BOARD APPROVALS



OFFICE OF HUMAN RESEARCH ETHICS Medical School Building 52 Mason Farm Road CB #7097 Chapel Hill, NC 27599-7097 (919) 966-3113 Web site: ohre.unc.edu Federalwide Assurance (FWA) #4801

To: Benjamas Suksatit School of Nursing 600 Martin Luther King Jr. Blvd. Apartment 523 Chapel Hill, NC 27514

From: Public Health-Nursing IRB

Authorized signature on behalf of IRB

Approval Date: 7/28/2010 Expiration Date of Approval: 7/27/2011

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110) Submission Type: Initial Expedited Category: 5.Existing or non-research data Study # 10-1359 Study Title: The Accuracy of Wrist Actigraphy in Measuring Sleep Characteristics Among Community-Dwelling Older Adults Without Insomnia

This submission has been approved by the above IRB for the period indicated. It has been determined that the risk involved in this research is no more than minimal.

Study Description:

Purpose: The primary aim of this secondary analysis is to examine the accuracy of wrist actigraphy to measure sleep characteristics in community dwelling older adults (age 70+ years) without insomnia Participants: Two nights of electroencephalography and wrist actigraphy data previously collected from 63 community-dwelling older adults, 70 years of age and older. Procedures (methods): Data were collected under standard procedures at the School of Nursing, Biobehavioral Laboratory. Six variables, which can be obtained by both methods, will be used to measure the following sleep characteristics: (1) total time in minutes spent in bed, (2) total time in minutes spent asleep, (3) sleep onset latency, (4) time spent awake after sleep onset, (5) time between final wake time and out of bed, and (6) sleep efficiency. The association and level of agreement of wrist actigraphy to measure sleep characteristics, as compared to electroencephalography, will be determined using descriptive statistics, Bland-Altman plots, and interclass correlations. All of these analyses will be performed separately for Night 1 and Night 2. A combination of graphic and statistical (i.e. paired t-tests) analyses will be used to determine the magnitude of change in electroencephalographic sleep characteristics. Using the change in sleep characteristics by encephalography as the standard, the accuracy of wrist actigraphy for detecting change in sleep characteristics will be determined by measuring the change in variables derived by wrist actigraphy and using interclass correlations (interval or ration measures) and Cohen Kappa coefficients (categorical measures) to test the level of association and agreement between measures.

Regulatory and other findings:

This research meets criteria for a waiver of informed consent according to 45 CFR 46.116(d).

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Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

When applicable, enclosed are stamped copies of approved consent documents and other recruitment materials. You must copy the stamped consent forms for use with subjects unless you have approval to do otherwise.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented (use the modification form at ohre.unc.edu/forms). Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at https://irbis.unc.edu/irb.

Researchers are reminded that additional approvals may be needed from relevant "gatekeepers" to access subjects (e.g., principals, facility directors, healthcare system).

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC: Barbara Carlson, School Of Nursing

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OFFICE OF HUMAN RESEARCH ETHICS Medical School Building 52 Mason Farm Road CB #7097 Chapel Hill, NC 27599-7097 (919) 966-3113 Web site: ohre.unc.edu Federalwide Assurance (FWA) #4801

To: Benjamas Suksatit School of Nursing 600 Martin Luther King Jr. Blvd. Apartment 523 Chapel Hill, NC 27514

From: Public Health-Nursing IRB

Approval Date: 6/17/2011 Expiration Date of Approval: 6/15/2012

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110) Submission Type: Renewal Expedited Category: 5.Existing or non-research data Study # 10-1359 Study Title: The Accuracy of Wrist Actigraphy in Measuring Sleep Characteristics Among Community-Dwelling Older Adults Without Insomnia

This submission has been approved by the above IRB for the period indicated.

Study Description:

Purpose: The primary aim of this secondary analysis is to examine the accuracy of wrist actigraphy to measure sleep characteristics in community dwelling older adults (age 70+ years) without insomnia. Participants: Two nights of electroencephalography and wrist actigraphy data previously collected from 63 community-dwelling older adults, 70 years of age and older. Procedures (methods): Data were collected under standard procedures at the School of Nursing, Biobehavioral Laboratory. Six variables, which can be obtained by both methods, will be used to measure the following sleep characteristics: (1) total time in minutes spent in bed, (2) total time in minutes spent asleep, (3) sleep onset latency, (4) time spent awake after sleep onset, (5) time between final wake time and out of bed, and (6) sleep efficiency. The association and level of agreement of wrist actigraphy to measure sleep characteristics, as compared to electroencephalography, will be determined using descriptive statistics, Bland-Altman plots, and interclass correlations. All of these analyses will be performed separately for Night 1 and Night 2. A combination of graphic and statistical (i.e. paired t-tests) analyses will be used to determine the magnitude of change in electroencephalographic sleep characteristics. Using the change in sleep characteristics by encephalography as the standard, the accuracy of wrist actigraphy for detecting change in sleep characteristics will be determined by measuring the change in variables derived by wrist actigraphy and using interclass correlations (interval or ration measures) and Cohen Kappa coefficients (categorical measures) to test the level of association and agreement between measures.

Regulatory and other findings:

This research meets criteria for a waiver of informed consent according to 45 CFR 46.116(d).

page 1 of 2

Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

IF YOU SUBMITTED ON PAPER, enclosed are stamped copies of approved consent documents and other recruitment materials (when applicable). You must copy the stamped consent forms for use with subjects unless you have approval to do otherwise. IF YOU SUBMITTED ONLINE (Behavioral and Public Health-Nursing IRBs Only), your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/eform_routing.cfm?masterid=101110&Section=attachments.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented (use the modification form at ohre.unc.edu/forms). Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at https://irbis.unc.edu/irb.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

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OFFICE OF HUMAN RESEARCH ETHICS Medical School Building 52 Mason Farm Road CB #7097 Chapel Hill, NC 27599-7097 (919) 966-3113 Web site: ohre.unc.edu Federalwide Assurance (FWA) #4801

To: Benjamas Suksatit School of Nursing 600 Martin Luther King Jr. Blvd. Apartment 523 Chapel Hill, NC 27514

From: Non-Biomedical IRB

Approval Date: 5/14/2012 Expiration Date of Approval: 5/13/2013

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110) Submission Type: Renewal Expedited Category: 5.Existing or non-research data Study # 10-1359 Study Title: The Accuracy of Wrist Actigraphy in Measuring Sleep Characteristics Among Community-Dwelling Older Adults Without Insomnia

This submission has been approved by the IRB for the period indicated.

Study Description:

Purpose: The primary aim of this secondary analysis is to examine the accuracy of wrist actigraphy to measure sleep characteristics in community dwelling older adults (age 70+ years) without insomnia. Participants: Two nights of electroencephalography and wrist actigraphy data previously collected from 63 community-dwelling older adults, 70 years of age and older. Procedures (methods): Data were collected under standard procedures at the School of Nursing, Biobehavioral Laboratory. Six variables, which can be obtained by both methods, will be used to measure the following sleep characteristics: (1) total time in minutes spent in bed, (2) total time in minutes spent asleep, (3) sleep onset latency, (4) time spent awake after sleep onset, (5) time between final wake time and out of bed, and (6) sleep efficiency. The association and level of agreement of wrist actigraphy to measure sleep characteristics, as compared to electroencephalography, will be determined using descriptive statistics, Bland-Altman plots, and interclass correlations. All of these analyses will be performed separately for Night 1 and Night 2. A combination of graphic and statistical (i.e. paired t-tests) analyses will be used to determine the magnitude of change in electroencephalographic sleep characteristics. Using the change in sleep characteristics by encephalography as the standard, the accuracy of wrist actigraphy for detecting change in sleep characteristics will be determined by measuring the change in variables derived by wrist actigraphy and using interclass correlations (interval or ration measures) and Cohen Kappa coefficients (categorical measures) to test the level of association and agreement between measures.

Regulatory and other findings:

This research meets criteria for a waiver of informed consent according to 45 CFR 46.116(d).

Investigator's Responsibilities:

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You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at http://irbis.unc.edu.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

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OFFICE OF HUMAN RESEARCH ETHICS Medical School Building 52 Mason Farm Road CB #7097 Chapel Hill, NC 27599-7097 (919) 966-3113 Web site: ohre.unc.edu Federalwide Assurance (FWA) #4801

To: Benjamas Suksatit School of Nursing

From: Non-Biomedical IRB

Approval Date: 4/01/2013 Expiration Date of Approval: 3/31/2014

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110) Submission Type: Renewal Expedited Category: 5.Existing or non-research data Study # 10-1359

Study Title: The Accuracy of Wrist Actigraphy in Measuring Sleep Characteristics Among Community-Dwelling Older Adults Without Insomnia

This submission has been approved by the IRB for the period indicated.

Study Description:

Purpose: The primary aim of this secondary analysis is to examine the accuracy of wrist actigraphy to measure sleep characteristics in community dwelling older adults (age 70+ years) without insomnia. Participants: Two nights of electroencephalography and wrist actigraphy data previously collected from 63 community-dwelling older adults, 70 years of age and older. Procedures (methods): Data were collected under standard procedures at the School of Nursing, Biobehavioral Laboratory. Six variables, which can be obtained by both methods, will be used to measure the following sleep characteristics: (1) total time in minutes spent in bed, (2) total time in minutes spent asleep, (3) sleep onset latency, (4) time spent awake after sleep onset, (5) time between final wake time and out of bed, and (6) sleep efficiency. The association and level of agreement of wrist actigraphy to measure sleep characteristics, as compared to electroencephalography, will be determined using descriptive statistics, Bland-Altman plots, and interclass correlations. All of these analyses will be performed separately for Night 1 and Night 2. A combination of graphic and statistical (i.e. paired t-tests) analyses will be used to determine the magnitude of change in electroencephalographic sleep characteristics. Using the change in sleep characteristics by encephalography as the standard, the accuracy of wrist actigraphy for detecting change in sleep characteristics will be determined by measuring the change in variables derived by wrist actigraphy and using interclass correlations (interval or ration measures) and Cohen Kappa coefficients (categorical measures) to test the level of association and agreement between measures.

Regulatory and other findings:

This research meets criteria for a waiver of informed consent according to 45 CFR 46.116(d).

Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date.

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You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at http://irbis.unc.edu.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

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OFFICE OF HUMAN RESEARCH ETHICS Medical School Building 52 Mason Farm Road CB #7097 Chapel Hill, NC 27599-7097 (919) 966-3113 Web site: ohre.unc.edu Federalwide Assurance (FWA) #4801

To: Barbara Carlson School Of Nursing

From: Non-Biomedical IRB

Approval Date: 5/09/2013 Expiration Date of Approval: 3/31/2014

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110) Submission Type: Modification Expedited Category: Minor Change to Previously Approved Research Study # 10-1359

Study Title: The Accuracy of Wrist Actigraphy in Measuring Sleep Characteristics Among Community-Dwelling Older Adults Without Insomnia

This submission has been approved by the IRB for the period indicated. It has been determined that the risk involved in this modification is no more than minimal. Unless otherwise noted, regulatory and other findings made previously for this study continue to be applicable.

Submission Description:

Changing PI status to me, Barbara Carlson. The original PI, Benjamas Suksatit, has left the university.

Investigator's Responsibilities:

Your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/irb event.cfm?actn=info&irbid=10-1359.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.



OFFICE OF HUMAN RESEARCH ETHICS Medical School Building 52 Mason Farm Road CB #7097 Chapel Hill, NC 27599-7097 (919) 966-3113 Web site: ohre.unc.edu Federalwide Assurance (FWA) #4801

To: Benjamas Suksatit School of Nursing

From: Non-Biomedical IRB

Approval Date: 9/03/2013 Expiration Date of Approval: 3/31/2014 RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110) Submission Type: Modification Expedited Category: Minor Change to Previously Approved Research Study # 10-1359

Study Title: The Accuracy of Wrist Actigraphy in Measuring Sleep Characteristics Among Community-Dwelling Older Adults Without Insomnia

This submission has been approved by the IRB for the period indicated. It has been determined that the risk involved in this modification is no more than minimal. Unless otherwise noted, regulatory and other findings made previously for this study continue to be applicable.

Submission Description:

This modification address changes in project personnel

1. Reinstatement of Ms. Benjamas Suksatit as PI of the project. Ms. Suksatit had to step down as PI because she left UNC by the order of her government. She has been readmitted to UNC, to complete her dissertation based on the data covered under this project.

2. Dr. Barbara Carlson, currently listed as the PI, is leaving UNC, effective 2nd Summer Session. She will remain on Ms. Suksatit's committee and will be a CoPI in this project.

3. Dr. Virginia Neelon, who was a member of Ms. Suksatit's dissertation committee will now serve as her Research advisor for the project and chair of her dissertation committee.

4. Two member of her committee, Dr. Todd Schwartz (biostatis) and Dr. Heidi Roth (neurology) has been added to assist Ms. Suksatit with the analysis and interpretation of the data.

Investigator's Responsibilities:

Your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/irb event.cfm?actn=info&irbid=10-1359

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

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CC: Barbara Carlson, School Of Nursing Virginia Neelon, School of Nursing

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OFFICE OF HUMAN RESEARCH ETHICS Medical School Building 52 Mason Farm Road CB #7097 Chapel Hill, NC 27599-7097 (919) 966-3113 Web site: ohre.unc.edu Federalwide Assurance (FWA) #4801

To: Benjamas Suksatit School of Nursing

From: Non-Biomedical IRB

Approval Date: 3/06/2014 Expiration Date of Approval: 3/05/2015 RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110) Submission Type: Renewal Expedited Category: ,5.Existing or non-research data Study # 10-1359

Study Title: Sleep in Community-dwelling Older Adults: Issues of Measurement.

This submission has been approved by the IRB for the period indicated.

Study Description:

Purpose: The primary aim of this secondary analysis is to examine the accuracy of wrist actigraphy to measure sleep characteristics in community dwelling older adults (age 70+ years) without insomnia. Participants: Two nights of electroencephalography and wrist actigraphy data previously collected from 63 community-dwelling older adults, 70 years of age and older. Procedures (methods): Data were collected under standard procedures at the School of Nursing, Biobehavioral Laboratory. Six variables, which can be obtained by both methods, will be used to measure the following sleep characteristics: (1) total time in minutes spent in bed, (2) total time in minutes spent asleep, (3) sleep onset latency, (4) time spent awake after sleep onset, (5) time between final wake time and out of bed, and (6) sleep efficiency. The association and level of agreement of wrist actigraphy to measure sleep characteristics, as compared to electroencephalography, will be determined using descriptive statistics, Bland-Altman plots, and interclass correlations. All of these analyses will be performed separately for Night 1 and Night 2. A combination of graphic and statistical (i.e. paired t-tests) analyses will be used to determine the magnitude of change in electroencephalographic sleep characteristics. Using the change in sleep characteristics by encephalography as the standard, the accuracy of wrist actigraphy for detecting change in sleep characteristics will be determined by measuring the change in variables derived by wrist actigraphy and using interclass correlations (interval or ration measures) and Cohen Kappa coefficients (categorical measures) to test the level of association and agreement between measures.

Regulatory and other findings:

This research meets criteria for a waiver of informed consent according to 45 CFR 46.116(d).

Investigator's Responsibilities:

page 1 of 2

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

Your approved consent forms and other documents are available online at <u>http://apps.research.unc.edu/irb/irb_event.cfm?actn=info&irbid=10-1359</u>.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at http://irbis.unc.edu.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40CFR 26 (EPA), where applicable.

CC: Virginia Neelon, School of Nursing

page 2 of 2

APPENDIX 2: SLEEP PROTOCOL AND WORKSHEETS

PRISM Project		ID: Date:	R/P		
Sleep: Protocol	& Worksheets	Time:	Baseline, 12M, 24M		
	Sleep Protocol & Worksheets				
N1 N2] Label VHS tapes (8-hr, 160 minutes) and put i Participant ID Date Night Session	n VCR:	Room #		
	Turn on notebooks activate hyperterminal: Set up file in prism-invos Filename, Subject ID, Session, Night numl Turn on INVOS and see data on hypertermina	•	002base1.txt)		
	Turn on grass computer Verify equipment setup: Sampling rate at 250s/s Correct montage—version: 3	Chest	Circumf: Circumf:		
	Enter subject information: Name Date of birth Age Height Weight Gender Subject ID number Complaint: R01 Primary Care: B. Carlson Tech: (Your Name) Meds				
] Run Cals				
	Check switch box keys				
	Enter channel settings.				
] Turn on bedside equipment				

Run a 0 and 1 volt cal signal on the BCI capnograph. Make sure the Grass machine displays a zero at the 0 volt cal and record the 1 volt digital output readings below:

Night	Room	SaO2	EtCO2
1			
2			

PRISM Project		ID: R/P Date://
Sleep: Protocol & Worksheets		Time: Baseline, 12M, 24M
Sensor Attributes		
Invos Sensors:		
Must be labeled (R for Rig	ht and L for Left) and come from	om the same lot.
Right Lot Number:	N1	N2
Left Lot Number:	N1	N2
Respitrace:		
Chest Band Size:	N1	N2
Abdominal Band Size:	N1	N2 N2
Pulse Oximeter:		
Lot Number:	N1	N2
Capnograph		
Lot Number:	N1	N2
Time Synchronizations		
PSG:	N1	N2
VCR:	N1	N2
Hyperterm:	N1	N2

Place EKG/Respitrace after pajamas are on. Hook up PSG sensors and use the following table to place sensors in head box. Record impedances. Place INVOS, thermocouple, capnograph and oximeter sensors when subject is in bed.

		Prestudy Impedance	Prestudy Impedance
Sensor	Head Box	Night 1	Night 2
Ground	Ground		
C3	1		
C4	2		
Oz	17		
Al	A1		
A2	A2		
R-eye	3		
L-eye	4		
Left Jaw	5		
Right Jaw	6		
Chin	15		
Thermocouple	13 & 14	NA	NA
EKG	9 & 10	NA	NA

Head Box Sensor Assignments and Impedance Worksheet

PRISM Project

			_
ID:	R	/P	
Date:		//	
Time	Baseline	12M 24M	

Sleep: Protocol & Worksheets

Night 1 I	Documentation			
Night	Systolic	Diastolic	MAP	Heart Rate
1				

Hour	Time	Pulse ox	ETCO2	Body Position	IVOS sync	Narrative
		+		TOSITION	Sync	LIGHTS OUT
	15	+				
	30					
	45					
	60					
	1-15					
	1-13					
	1-30					
	2-00					
	2-15					
	2-30					
	2-45					
	3-00					
	3-15					
	3-30					
	3-45					
	4-00					
	4-15					
	4-30					
	4-45					
	5-00					
	5-15					
	5-30					
	5-45					
	6-00					
	6-15					
	6-30					
	6-45					
	7-00					
	7-15					
	7-30	-				
	7-45					
	8-00					
						LIGHTS ON

PRISM Project	ID: Date:	R/P
Sleep: Protocol & Worksheets	Time:	Baseline, 12M, 24M

Post Study Instrument and Biocals

Action	Completed N1
Press the cal buttons on the display to show the upward and downward 50	
microvolt deflection	
Press the zero and calibration buttons on the Respitrace	
Press the zero and 1 volt calibration button on the pulse oximeter	

Post Study Biocalibrations

Record Post-sleep Vital Signs

	Systolic	Diastolic	MAP	Heart Rate
N1.Pre ortho				
N1.Post ortho				
N1. 1min ortho				

Sensor	Head Box	Post-study Impedance Night 1
Ground	Ground	
C3	1	
C4	2	
Oz	17	
A1	A1	
A2	A2	
R-eye	3	
L-eye	4	
Left -Jaw	5	
Right-Jaw	6	
Chin X	15	
Thermocouple	13 & 14	NA
EKG	9 & 10	NA

PRISM Project	ID: R/P
	Date: / /
Sleep: Protocol & Worksheets	Time: Baseline, 12M, 24M

Post Sleep Study Questionnaire-Night 1

<u>Description:</u> The post sleep study questionnaire is designed to detect people who are too sleepy to safely drive home.

Instructions to Technician:

- 1. Have subject complete questionnaire after breakfast but before leaving the lab.
- 2. Make sure subjects who select **Response 2** for any item have someone drive them home.
 - a. If they have not made arrangements for someone to drive them home, make arrangements for a taxi or senior transportation services to drive the subject back and forth from the BBL.
 - b. If they plan to take public transportation (Chapel Hill bus system), ask that they take a nap before leaving. Call Dr. Carlson if they refuse a nap and still want to take the bus.
- 3. Call Dr. Carlson if the subject does not feel better after a nap or refuses our offer to arrange transportation to home and, if necessary, back to the BBL.

Technician Post Sleep Study Assessment		
Any answer of choice 2	Yes	No
Called Dr. Carlson because		
I think the subject is too sleepy to go home alone	Yes	No
The subject did not feel better after his/her nap	Yes	No
The subject refused a nap and is taking the bus	Yes	No
The subject refused our offer to arrange transportation	Yes	No

Extra	Notes:

LAna Ivo

PRISM Project	ID: R /P
	Date: / /
Sleep: Protocol & Worksheets	Time: Baseline, 12M, 24M

Post-Sleep Study Questionnaire (Waag, 1994)

We would like to know how you would evaluate your sleep last night.

Please choose the best response to the following questions.

<u>Question</u>	Response 1		Response 2
1. How alert do you feel?	Wide awake	or	Sleepy or drowsy
2. How clear are you thinking?	Clear as a bell	or	Sort of fuzzy
3. Do you have a headache?	No	or	Yes
4. How do you feel compared to the way you usually feel when you wake up?	Same or better	or	Much worse
5. How soundly did you sleep?	Very soundly (like a rock)	or	Slept very little
6. How tired are you?	I am full of energy	or	I feel very weak

PRISM Project	ID: R /P
	Date: / /
Sleep: Protocol & Worksheets	Time: Baseline, 12M, 24M

Night 2 Documentation

Night	Systolic	Diastolic	MAP	Heart Rate
2				

Hour	Time	Pulse ox	ETCO2	Body Pos	IVOS sync	Narrative
					sync	LIGHTS OUT
	15					
	30					
	45					
	60					
	1-15					
	1-30					
	1-45					
	2-00					
	2-15					
	2-30					
	2-45					
	3-00					
	3-15					
	3-30					
	3-45					
	4-00					
	4-15					
	4-30					
	4-45					
	5-00					
	5-15					
	5-30					
	5-45					
	6-00					
	6-15					
	6-30					
	6-45					
	7-00					
	7-15					
	7-30					
	7-45					
	8-00					
						LIGHTS ON

PRISM Project	ID: R /P
	Date: / /
Sleep: Protocol & Worksheets	Time: Baseline, 12M, 24M

Post Study Instrument and Biocals

Action	Completed N2
Press the cal buttons on the display to show the upward	
and downward 50 microvolt deflection	
Press the zero and calibration buttons on the Respitrace	
Press the zero and 1 volt calibration button on the pulse	
oximeter	

Post Study Biocalibrations

Record Post-Sleep Vital Signs

	Systolic	Diastolic	MAP	Heart Rate
N2. Pre ortho				
N2. Post ortho				
N2. 1min ortho				

Sensor	Head Box	Post-study Impedance Night 2
Ground	Ground	
C3	1	
C4	2	
Oz	17	
A1	A1	
A2	A2	
R-eye	3	
L-eye	4	
Left -Jaw	5	
Right-Jaw	6	
Chin X	15	
Thermocouple	13 & 14	NA
EKG	9 & 10	NA

PRISM Project	ID: R /P
	Date: / /
Sleep: Protocol & Worksheets	Time: Baseline, 12M, 24M

Post Sleep Study Questionnaire-Night 2

Description: The post sleep study questionnaire is designed to detect people who are too sleepy to safely drive home.

Instructions to Technician:

- 1. Have subject complete questionnaire after breakfast but before leaving the lab.
- 2. Make sure subjects who select **Response 2** for any item have someone drive them home.
 - a. If they have not made arrangements for someone to drive them home, make arrangements for a taxi or senior transportation services to drive the subject back and forth from the BBL.
 - b. If they plan to take public transportation (Chapel Hill bus system), ask that they take a nap before leaving. Call Dr. Carlson if they refuse a nap and still want to take the bus.
- 3. Call Dr. Carlson if the subject does not feel better after a nap or refuses our offer to arrange transportation to home and, if necessary, back to the BBL.

Technician Post Sleep Study Assessment		
Any answer of choice 2	Yes	No
Called Dr. Carlson because		
I think the subject is too sleepy to go home alone	Yes	No
The subject did not feel better after his/her nap	Yes	No
The subject refused a nap and is taking the bus	Yes	No
The subject refused our offer to arrange transportation	Yes	No

Date: //////	PRISM Project	ID: R /P	
Sleep: Protocol & Worksheets Time: Baseline, 12M, 24M		Date: / / /	
•	Sleep: Protocol & Worksheets	Time: Baseline, 12M, 24M	

Post-Sleep Study Questionnaire (Waag, 1994)

We would like to know how you would evaluate your sleep last night.

Please choose the best response to the following questions.

Question	Response 1		Response 2
1. How alert do you feel?	Wide awake	or	Sleepy or drowsy
2. How clear are you thinking?	Clear as a bell	or	Sort of fuzzy
3. Do you have a headache?	No	or	Yes
4. How do you feel compared to the way you usually feel when you wake up?	Same or better	or	Much worse
5. How soundly did you sleep?	Very soundly (like a rock)	or	Slept very little
6. How tired are you?	I am full of energy	or	I feel very weak

APPENDIX 3: PROTOCOL FOR ACTIWATCH-L

Biobehavioral Laboratory School of Nursing University of North Carolina at Chapel Hill

Actiwatch-L Model # AWLP

*COMPONENTS: Actiwatch, Actiwatch reader unit, Actiware-sleep software program, and diary

*<u>COMMUNICATIONS WORKSHEETS</u> : Before checking out any watches from the BBL, each watch must have a communication worksheet filled out before initialization. The worksheet is located in the watch checkout book.

I. Set up the Actiwatch

1. Check the battery of Actiwatch.

- Loosen the 4 retaining screws on the Actiwatch-L bottom. These screws retain the strap holder. Rotate the strap holder counterclockwise and remove.
- Check the battery voltage with a multimeter.
- If the voltage is less than 2.60, discard and replace it with a new battery.

Note that the negative side of the battery should be facing down towards the gold plate in the watch. The positive (+) side of the battery is labeled and should be facing upwards.

When you check and/or replace the battery, make sure that the gold contact is extended up and not stuck in the down position to have proper battery contact.

- Tighten the four screws
- 2. Connect the Actiwatch-L reader to a Com port on your computer. Open the *Actiware Sleep* program on the toolbar. Click on *Reader* and select *Com Port*. Select the COM port which is connected to the Actiwatch reader (typically COM 1 or 2).

3. Position the Actiwatch on the reader.

- The metal plated side should be facing up. Match the small dot on the Actiwatch-L to the diagram on the reader.

- If you are using a laptop PC and it is working off its battery (not plugged into an outlet), move the switch on the end panel of the reader from PC Power to Battery Power. When the reader is not in use, make sure to switch this back to PC power to conserve the battery.

- The green LED light is on when it is correctly positioned.

1

4. Select *Reader* on the toolbar and choose *Test Actiwatch-L*. The flickering LED light indicates communication. Wait for the message *Actiwatch test passed*.

MACINTOSH:Users:suksatit:Dropbox:full dissertation:appendix:Actiwatch.doc

Biobehavioral Laboratory School of Nursing University of North Carolina at Chapel Hill

- 5. Select *Reader* and then choose *Write*. Enter the information on Actiwatch setup menu.
 - Enter User ID, Start date, Start time.
 - Epoch length is the period of time the watch will accumulate activity counts before saving the sample and resetting the counter to zero. Select the epoch length by clicking in this field. The choices are 0.25, 0.5, 1, 2, 4, 10, 15 minutes.
 - Recording time displays the time before the watch memory is full with samples based on the epoch length selected and will no longer record data.

Memory	0.25	0.5	1	2	5	10	15min.
	min.	min.	min.	min.	min.	min.	
AW-L	2.8	5.6	11.2	22.4	56	112	168

Logging Capacity (days) by Epoch Length

- Any letters in red indicate the field can be changed. However, DO NOT click on "Battery fitted" unless you have just changed the battery. Any field in black letters indicates that field cannot be changed.
- 6. Press Send button.
- 7. Wait for the message *Actiwatch verified & ready. Remove from Reader* to appear.
- II. Put the Actiwatch-L on the wrist.

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III. Download Data/ Reading from the Actiwatch-L.

- 1. Open the program.
- 2. Place the Actiwatch on the reader. Once the Ready LED illuminates you are ready to download data.
- 3. Select *Reader* and choose *Read* from the menu.
 - Once communication is established, *setup information* for the current Actiwatch-L will be displayed in the lower portion of the screen.
 - When data downloading has been successfully completed, the message *Actiwatch read completed*. *Please remove from reader*. *Do you want to save data now*? To save the data, select *Yes*. If you select not to save the data, they will be lost.

IV. Save the Data

- 1. By default, all data files are saved with an *.awd* extension. The first eight characters of the User Identity entered during setup will be used for the filename unless you enter another.
- 2. The file format is a *return delimited text* file. These data files may easily be imported into various applications for additional analysis or graphing.
- 3. Data are maintained in the Actiwatch-L memory until you write or test the Actiwatch-L.

Originally developed by Suhyun Kim June 17, 2003

Revised Aug. 28, 2003

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APPENDIX 4: DATA MANAGEMENT PLAN

Data Set Information

In the original data folder, there are 3 subfolders, including cytokine I, cytokine II, and PTRACS. Information of each subfolder is described below.

Cytokine I

Cytokine I folder consists of data from 23 subjects from Cytokine Study Phase I: C01-C23. Within Cytokine I folder, there are three subfolders, including actigraphy, night 1, and night 2.

Actigraphy folder includes actigraphic data from 7 subjects. Each subject has one file containing two-nights of actigraphic data. Since actiwatch L was applied for all subjects, the actigraphic file type is .awd, which is a default actiwatch data. AWD files will be processed with Actiware-Sleep Version 3.3.

Night 1 and Night 2 folders includes of subfolders for each subjects. Under each subject folder, there are at least 10 different extension files.

- MTG file is a montage file from grass system. It provides information related to PSG data in which what specific channel types provide which waveforms. It stores the PSG data for retrieval during review or in the future when reviewing archived data.
- 2. CAL file is a calibration file. It is used by Grass to determine the amplitude of the waveforms and the units of measurement
- 3. PSG file is a raw data file of polysomnography.
- 4. RPT file is a report file in which only grass system can open.

- STA file is a sleep state file. It lists the state code for each consecutive 30-second interval. The state codes are 0=awake, 7=not applicable, 1=Stage 1 & 2 NREM sleep, 2=Stage 3 & 4 NREM sleep, 5=REM sleep.
- 6. SCO file is a sleep score file.
- XLS file is a sleep report of each subject. It is generated from Grass Gamma Review Program.
- 8. EKG file contains measures (minimum, maximum and mean) of heart rate measure and is derived from the subject's EKG waveform.
- TND file contains measures (minimum, maximum, and mean) of end tidal carbon dioxide, measured at consecutive 30-second intervals.
- 10. OXI file contains measures (minimum, maximum, and mean) of arterial oxyhemoglobin saturation, measured at consecutive 30-second intervals.

Cytokine II

Cytokine II folder consists of data from 20 subjects from the Cytokine Study Phase II. Subjects are given the new ID: C24-C43. Within Cytokine II folder, there are three subfolders, including actigraphy, night 1, and night 2. Beside that data came from different subjects, information of all files are exactly the same with files from the Cytokine I. There are 20 actigraphic data files from all subjects.

PTRACS

PTRACS folder consists of data from 17 subjects from the PTRACS study. Subject will be given the new ID C44-C60. Within PTRACS folder, there are three subfolders, including actigraphy, PTRACS notes, and PTRACS summaries. Actigraphy folder consists of 17 data from all subjects in the PTRACS study. PTRACS note contains the .csv file type, which can be opened by Microsoft excel. It provides the information about all activities during sleep record start until the end of the record. For PTRACS summaries, it contains sleep report in the .doc file type, which can be simply opened by Microsoft word.

Data Management Plan

- Under each folder, files inventory will be made to ascertain that there is no missing file (Appendix I). All missing file, if available, will be processed. If not, the reason why the file is missing will be noted.
- 2. Under the Cytokine I and the Cytokine II folder, the sleep results of each subject in each night was reported with the xls file, which can be opened with Excel. Before extra copies of xls file will be made, all xls file will be checked for any sensitive information that can be linked to the subjects in the original studies. Originally, there are 12 places that contain subject identifiers: two in the list page and ten in the report page. File inventory will be made to ascertain that the sensitive information from 12 places in the xls file is removed. (Appendix II).
- This file inventories will be given to Dr. Carlson and she will verify that all of the sensitive information has been removed before given her permission to take a copy the files back to Thailand.
- 4. Hard copy of sleep reports will be printed and checked for any errors it may have.
- Copies of electronics data will be made once it is ascertained the completeness and accuracy (removal or verification of outliers) of the sleep reports.

- a. Copies of all electronic files will be made and restored in three different data storages: hard drive of computer laptop, external hard drive, and DVD.
- b. Copies of only sleep data reports and actigraphic data summary reports, with subject identifiers removed, will be made and restored in five different data storages: hard drive of computer laptop, external hard drive, DVD, USB flash drive, and dropbox online backup website. Hard copy of these files will also be made.
- Data will be primarily entered into the excel file and then imported to the SAS v9.2 later for data analysis.
- 7. Archive and working data
 - a. Four sets of archive data will be made in the DVD format. All DVDs will be password protected. No one could open it without the password. During my trip back to Thailand, each set of archive data will be stored in four different suitcases: two loading bags and two carry on bags. In Thailand, two sets of archive data will be stored at my office at the Department of Medical Nursing, the Faculty of Nursing, Chiang Mai University. All DVDs will be kept in the cabinet with lock key. The remaining DVDS will be stayed in the cabinet with lock key at my house.
 - b. Working data will be backup every time after I finish doing any data analysis.
 Working data will be located in the hard drive of my computer while the backup will be stored in the external hard drive that has no files other than my dissertation data on it. After final analysis is made, all data will be written in

the DVDs. Four sets of DVDs will be made: two for Dr. Carlson and two for myself.

- 8. The security system of Dropbox website (<u>https://www.dropbox.com/help/27</u>)
 - a. Encryption method is used for transferring and storing data.
 - b. Except the owner, no one can see or access files in private folders, unless that folder is either shared or set up as public.
 - c. Password is required while assessing online data.
 - d. For public folder, only people who have a link to the file(s) in that folder can assess it. All files in public folders are not browsable or searchable by any kind of method.
 - e. Even Dropbox employees are unable to access user files, and when troubleshooting an account they only have access to file metadata (filenames, file sizes, etc., not the file contents). They cannot access the content within the file.

Completeness of the Data for Analysis

Overall, there are 63 subjects in this study. However, due to the missing data, the number of subjects who participated in each research question is different. Details are described in the following session (Appendix III).

Research question 1: What are the characteristics of sleep "first night effects" in community dwelling older adults, age 70 years and older?

To answer this question, sleep results from actigraphy and from polysomnography of each night will be compared separately. In this study, actigraphy was applied in 45 subjects.

Research question 2: How accurate is actigraphy when compared to PSG in measuring sleep in community-dwelling older adults, age 70 years and older?

For first night, data from three subjects in the PTRACS study were missing due to technical errors. Thus, data from 39 subjects will be used to identify the accuracy of actigraphy as compared to polysomnography.

For second night, data from 38 subjects will be compared since there were two missing polysomnographic data. There were technical errors in one case while there was a snowstorm at that time so that another subject called to cancel the study.

Research question 3: How accurate is actigraphy when compared to PSG in measuring change in sleep in community-dwelling older adults, age 70 years and older?

To answer this question, polysomnographic data from 35 subjects will be used to examine the first night effect among this specific population.

NO	ID	Subject ID	Actig	raphy		nography
			1 st night	2 nd night	1 st night	2 nd night
1	1	C001	<mark>MISSING</mark>	<mark>MISSING</mark>	Х	Х
2	2	C002	<mark>MISSING</mark>	<mark>MISSING</mark>	Х	Х
3	3	C003	<mark>MISSING</mark>	<mark>MISSING</mark>	Х	Х
4	4	C004	<mark>MISSING</mark>	<mark>MISSING</mark>	Х	Х
5	5	C005	<mark>MISSING</mark>	<mark>MISSING</mark>	Х	Х
6	6	C006	<mark>MISSING</mark>	MISSING	Х	Х
7	7	C007	<mark>MISSING</mark>	<mark>MISSING</mark>	Х	Х
8	8	C008	<mark>MISSING</mark>	MISSING	Х	Х
9	9	C009	<mark>MISSING</mark>	MISSING	Х	Х
10	10	C010	<mark>MISSING</mark>	MISSING	Х	Х
11	11	C011	<mark>MISSING</mark>	MISSING	Х	Х
12	12	C012	<mark>MISSING</mark>	MISSING	Х	Х
13	13	C013	<mark>MISSING</mark>	MISSING	Х	Х
14	14	C014	<mark>MISSING</mark>	MISSING	Х	Х
15	15	C015	Х	Х	Х	Х
16	16	C016	MISSING	MISSING	Х	Х
17	17	C017	<mark>MISSING</mark>	MISSING	Х	Х
18	18	C018	Х	Х	Х	Х
19	19	C019	Х	MISSING	Х	Х
20	20	C020	Х	Х	Х	Х
21	21	C021	Х	Х	Х	Х
22	22	C022	Х	MISSING	Х	MISSING
23	23	C023	Х	Х	Х	Х
24	24	P201	Х	Х	Х	Х
25	25	P202	Х	Х	Х	Х
26	26	P203	Х	Х	Х	Х
27	27	P204	Х	Х	Х	Х
28	28	P205	Х	MISSING	Х	Х
29	29	P206	Х	Х	Х	Х
30	30	P207	MISSING	MISSING	Х	Х
31	31	P208	Х	MISSING	Х	Х
32	32	P209	Х	Х	Х	Х
33	33	P210	Х	MISSING	Х	Х
34	34	P211	Х	MISSING	Х	Х
35	35	P212	Х	Х	Х	Х
36	36	P213	Х	MISSING	Х	MISSING
37	37	P214	X	X	X	X
38	38	P215	X	X	X	X
39	39	P217	X	X	X	X
40	40	P218	X	X	X	X
41	41	P219	X	X	X	X
42	42	P220	X	X	X	X

APPENDIX 5: COMPLETENESS OF THE DATA

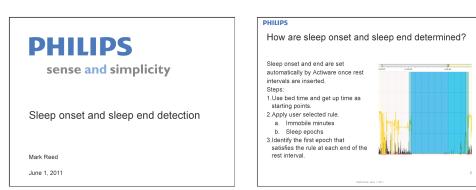
NO	ID	Subject ID	Actig	Actigraphy		nography
		_	1 st night	2 nd night	1 st night	2 nd night
43	43	P221	Х	Х	Х	Х
44	44	PT001	MISSING	Х	MISSING	Х
45	45	PT002	MISSING	Х	MISSING	Х
46	46	PT003	MISSING	Х	MISSING	Х
47	47	PT004	Х	Х	Х	Х
48	48	PT005	Х	Х	Х	Х
49	49	PT006	Х	Х	Х	Х
50	50	PT007	Х	Х	Х	Х
51	51	PT008	Х	Х	Х	Х
52	52	PT009	Х	Х	Х	Х
53	53	PT010	Х	Х	Х	Х
54	54	PT011	Х	Х	Х	Х
55	55	PT012	Х	Х	Х	Х
56	56	PT013	Х	Х	Х	Х
57	57	PT014	Х	Х	Х	Х
58	58	PT015	Х	Х	Х	Х
59	59	PT016	Х	Х	Х	Х
60	60	PT017	Х	Х	Х	Х
61	61	PT018	Х	Х	Х	Х
62	62	PT019	Х	Х	Х	Х
63	63	PT020	Х	Х	Х	Х

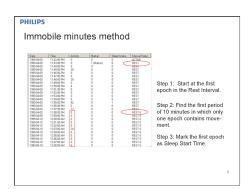
No	ID	_	Actig	Actigraphy		nography
		-	1 st night	2 nd night	1 st night	2 nd night
1	P003	C011	MISSING	MISSING	X	X
		P210	Х	MISSING	Х	Х
2	P007	C012	MISSING	MISSING	Х	Х
		P205	Х	MISSING	Х	Х
3	P009	C013	MISSING	MISSING	Х	Х
		P204	Х	Х	Х	Х
4	P020	C014	MISSING	<mark>MISSING</mark>	Х	Х
		P203	Х	Х	Х	Х
5	P024	C017	MISSING	MISSING	Х	Х
		P202	Х	Х	Х	Х
6	P031	C002	MISSING	MISSING	Х	Х
		P201	Х	Х	Х	Х
7	P032	C019	Х	MISSING	Х	Х
		P209	Х	Х	Х	Х
8	P036	C020	Х	Х	Х	Х
		P211	Х	MISSING	Х	Х
9	P056	C006	MISSING	MISSING	Х	Х
		P212	Х	Х	Х	Х
10	P060	C007	<mark>MISSING</mark>	<mark>MISSING</mark>	Х	Х
		P206	Х	Х	Х	Х
11	P068	C008	MISSING	MISSING	Х	Х
		P207	MISSING	MISSING	Х	Х
12	P083	C015	X	X	Х	Х
		P218	Х	Х	Х	Х
13	P094	C021	Х	Х	Х	Х
		P208	Х	MISSING	Х	Х

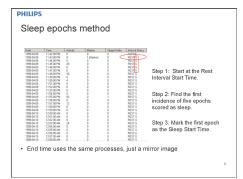
APPENDIX 6: SUBJECTS THAT WERE ENROLLED TWICE

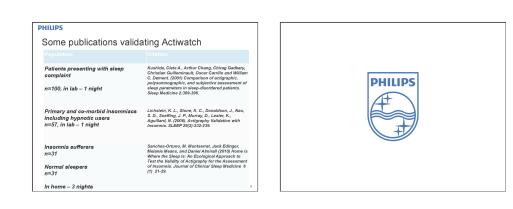
APPENDIX 7: SLEEP ONSET AND SLEEP DETECTION

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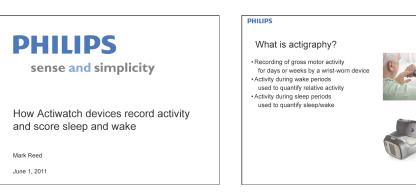


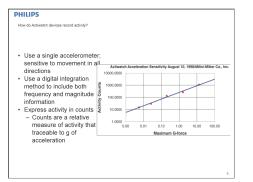


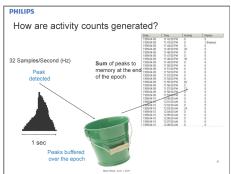
APPENDIX 8: HOW ACTIWATCH DEVICES RECORD ACTIVITY AND SCORE

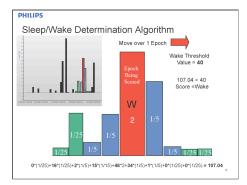
SLEEP AND WAKE

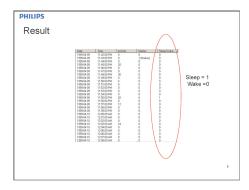
3/11/14











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