Sleep in Menopause

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STATEMENT OF ORIGINAL AUTHORSHIP

I, **Xinzhu Li**, declare that this thesis and the research presented within it are my own work. To the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due acknowledgement has been made. This thesis has not been submitted to any other university or institution as part of or a whole requirement for any degree or other purposes. ChatGPT was used in order to improve readability and language. After using this tool/service, the content was reviewed and edited as needed and I take full responsibility for the content.

I, **Xinzhu Li**, confirm that I was the principal researcher for all work included in this thesis, including any collaborative research or publications with multiple authors. Contributions by others have been explicitly acknowledged where applicable.

I, **Xinzhu Li**, further certify that ethical approval for all studies presented in this thesis was obtained from The University of Sydney Human Ethics Committee and Sydney Local Health District Human Research Ethics Committee - Concord Repatriation General Hospital. Participants involved in the research were provided with a Participant Information Statement, and their informed consent was obtained prior to data collection.

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Abstract

Sleep disturbances are reported to occur in 40-60% of menopausal women. Despite this, the interplay between sleep patterns, vasomotor symptoms, and external factors such as the bedroom environment (including sleepwear and bedding) remain underexplored. This thesis aimed to explore sleeping behaviours, vasomotor symptoms, and the impact of sleepwear on sleep quality in menopausal women through a series of interrelated studies.

The Introduction presented a literature review section, four study chapters, and a final chapter that provided further discussions and future directions.

Study 1 evaluated sleeping behaviours and vasomotor symptoms in peri- and post-menopausal women. Sleep onset time, and sleep offset time were recorded using MotionWatch8 actigraphy. Midsleep time and the intraindividual variabilities for all the timing variables were calculated. Correlation analysis was conducted to investigate their associations with vasomotor symptoms and insomnia severity index (ISI) scores. The menopausal women in this study exhibited moderate menopausal symptoms and some irregularities in sleep-wake timing, but more than half achieved adequate sleep duration of eight hours or more. No significant associations were found between any sleep variables and vasomotor symptoms.

Study 2 validated MotionWatch8 actigraphy against polysomnography (PSG) in menopausal women under warm conditions. The results revealed that MotionWatch8 systematically overestimated total sleep time (TST) and sleep efficiency (SE) while underestimating sleep onset latency (SOL) and wake after sleep onset (WASO) compared to PSG. Significant proportional biases for SOL, WASO, and SE reveal limitations in device's detection of wake periods, especially during episodes of minimal movement.

Study 3, a systematic review, explored how sleepwear and bedding fibre types affect sleep quality, showing wool sleepwear eases sleep onset under cooler conditions ($17°C$) for young adults and under warmer conditions ($30°C$) for older adults. Linen bedsheets demonstrated advantages in warm, humid environments ($29\text{-}30°C$), and goose down duvets improved slow-wave sleep under cool conditions ($11\text{-}17°C$). Although study heterogeneity limited direct comparisons, these findings provide valuable insights for optimising sleep experiences and guiding future research. The review identified a significant gap in the literature, as no studies have specifically evaluated the impact of fabric types on sleep quality in menopausal women. Previous evidence has shown that wool sleepwear promotes shorter sleep onset latency and better sleep quality compared to cotton in older adults under warm conditions ($\sim 30°C$), underscore the potential benefits of sleepwear fabric choice, providing a rationale for further investigation into menopausal women.

Study 4, a pilot study, compared the effects of wool and cotton sleepwear on sleep outcomes and vasomotor symptoms in menopausal women under warm conditions at $30°C$ ($30.1 \pm 0.5°C$) and relative humidity of 50% (46.4±2.7%). No significant differences in objective sleep parameters were observed between the two fabric types. However, despite the small sample size (N=16), participants wearing wool sleepwear reported greater subjective contentedness (more pleasant) on waking, suggesting improved perceived sleep quality, while cotton sleepwear was rated higher for pre-sleep thermal comfort and physical comfort.

In summary, this thesis offers valuable insights into the interplay of menopausal symptoms, sleep patterns, and bedroom environmental factors, offering practical strategies to enhance sleep quality. Future research directions should focus on: (1) developing more accurate sleep monitoring methodologies that can better detect wake episodes and subtle movements during sleep in menopausal women; (2) investigating the relationship between sleeping behaviours and vasomotor symptoms in women with severe vasomotor symptoms, as the current study's non-significant findings might be attributed to the inclusion of women with mild symptoms; and (3) conducting larger-scale clinical trials to validate the effects of different sleepwear fibre types on sleep architecture and thermal comfort in menopausal women.

Publications and Presentations

Parts of the work presented in this thesis have been submitted and/or presented in the following:

Publications

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Table of Contents

LIST OF FIGURES

FIGURE **Page**

List of Tables

ABBREVIATIONS

American Academy of Sleep Medicine - AASM

Australian Eastern Daylight Time - AEDT

Australian Eastern Standard Time - AEST

Australian Wool Innovation - AWI

Cognitive Behavioural Therapy for Insomnia - CBT-I

Confidence Intervals - CI

Central Nervous System - CNS

Electroencephalography - EEG

Electromyographic - EMG

Electrooculography - EOG

False Negative - FN

False Positive - FP

Follicle-Stimulating Hormone - FSH

Generalised Anxiety Disorder - GAD

Hypothalamic-Pituitary-Adrenal - HPA

Hormone Replacement Therapy - HRT

Health Status - HS

Intraclass Correlation Coefficient - ICC

Intraindividual Standard Deviation - IISD

Insomnia Severity Index - ISI

Joanna Briggs Institute - JBI

Luteinising Hormone - LH

Linear Mixed Model - LMM

Limits of Agreements - LOA

Sleep Stage NREM Stage 1 - N1/S1

Sleep Stage NREM Stage 2 - N2/S2

Sleep Stage NREM Stage 3 (S3 + S4) - N3

Not Reported - NR

Non-Rapid Eye Movement - NREM

Polysomnography - PSG

Pittsburgh Sleep Quality Index - PSQI

Rapid Eye Movement - REM

Relative Humidity - RH

Sleep Stage 3 - S3

Sleep Stage 4 - S4

Skin Conductance Level - SCL

Suprachiasmatic Nucleus - SCN

Standard Deviations - SD

Sleep Efficiency - SE

Sleep Fragmentation Index - SFI

Sleep Onset Latency - SOL

Stages of Reproductive Aging Workshop - STRAW

Study of Women's Health Across the Nation - SWAN

Slow-Wave Sleep - SWS

True Negative - TN

True Positive - TP

Total Sleep Time - TST

Visual Analogue Scale - VAS

Awake - W

Wake After Sleep Onset - WASO

CHAPTER 1

Introduction

Sleep is a fundamental physiological process that occupies approximately one-third of an individual's lifetime. It plays a critical role in maintaining physical health, cognitive function, and emotional well-being. Adequate sleep contributes to better physical and immune function, metabolic regulation, and mental health, whereas poor sleep has been associated with adverse health outcomes, including obesity, cardiovascular diseases, depression, and cognitive decline [1, 2]. In menopausal women, sleep disturbances are a prevalent issue, reported by over 50% of this population [3, 4]. The disturbances include difficulty in falling asleep and frequent awakenings, satisfying two of the three insomnia diagnostic criteria outlined in the DSM-5 [5]. These symptoms are often accompanied by dissatisfaction with sleep quality and significant daytime dysfunction, which can severely impact the quality of life for menopausal women.

Vasomotor symptoms, such as hot flushes and night sweats, are the most reported menopausal symptoms and are strongly associated with disrupted sleep patterns [6, 7]. The interplay between these physiological changes and environmental factors, such as the thermal environment, further exacerbates sleep difficulties. Thermoregulation, the body's process of maintaining core temperature, is closely linked to sleep regulation. Effective heat dissipation, particularly through increased skin temperature in distal body regions, promotes sleep onset and maintaining sleep stability [8, 9].

Beyond physiological factors, environmental factors such as room temperature, humidity, and sleepwear and bedding materials can significantly affect the skin's thermal microclimate, thereby impacting sleep quality [10, 11]. Research has shown that materials like wool, due to their superior moisture-wicking and insulation properties, provide a more stable thermal environment compared to cotton or polyester, leading to improved sleep quality [10, 11]. However, despite increasing interest in textile-based sleep interventions, studies focusing on the specific impact of sleepwear materials on menopausal women remain limited.

The role of sleepwear fabrics in mitigating sleep disturbances has gained increasing attention in recent years, particularly for their potential to enhance thermal comfort and improve sleep quality. Research by Chow et al. demonstrated that sleeping in wool significantly reduced sleep onset latency compared with cotton and polyester in older adults, and significantly reduced wakefulness when compared with cotton in poor sleepers [10]. Despite these promising findings, limited research has specifically investigated the impact of sleepwear fabrics on sleep in menopausal women, a population uniquely affected by vasomotor symptoms such as hot flushes and night sweats. These symptoms can disrupt thermoregulation and impair sleep quality, underscoring the need for targeted interventions.

The thesis aims to explore:

Study 1: The sleeping behaviours and vasomotor symptoms of peri- and post-menopausal women.

Question: What are the sleeping behaviours of peri- and post-menopausal women with respect to sleep duration, sleep timing and day-to-day variability and how are vasomotor symptoms associated with these behaviours? The study examined the association between sleeping behaviours (e.g., sleep timing, duration and variability) and vasomotor symptoms in peri- and post-menopausal women. This observational study utilises both objective (actigraphy) and subjective measures (the Modified Greene Climacteric Scale and the Insomnia Severity Index, ISI) to evaluate sleep patterns and vasomotor symptom severity. Sleep onset, offset, midsleep time and sleep duration were extracted from actigraphy records and their intraindividual variability were calculated. Correlation analysis was performed to assess the relationships between sleep parameters and vasomotor symptom. Intraclass correlation coefficient (ICC) was used to assess the consistency and reliability of the sleep parameters measured by actigraphy across multiple nights.

Study 2: The accuracy of MotionWatch8 actigraphy in assessing sleep in menopausal women, comparing its performance against polysomnography

Question: Is the MotionWatch8 actigraphy valid for measuring sleep parameters when compared to polysomnography in menopausal women? The study evaluated the validity of MotionWatch actigraphy in capturing sleep parameters compared to PSG in menopausal women. Through simultaneous data collection from both devices, the study assesses the agreement between actigraphy and PSG using Bland-Altman plots, linear mixed model (LMM) analysis and epoch by epoch comparison.

Study 3: The effects of sleepwear and bedding fibre types on sleep quality, synthesising existing evidence through a systematic review.

> Question: What are the effects of different sleepwear and bedding fibre types on sleep quality, as reported in the existing literature? The study synthesised existing evidence on the effects of sleepwear and bedding fibre types on sleep quality through a systematic review. Conducted according to PRISMA guidelines, this review searched six major databases (MEDLINE, Embase, CINAHL, Web of Science, Scopus, ProQuest) and Google Scholar, evaluating studies that compared at least two fibre types. The findings demonstrate that wool sleepwear offers significant benefits for sleep onset and thermal comfort under specific conditions, while other fibres such as linen bedsheet and goose down show advantages in particular thermal environments. Despite these insights, the review identifies a significant research gap, particularly the lack of studies focusing on menopausal women.

Study 4: The direct impact of wool and cotton sleepwear on sleep outcomes and vasomotor symptoms under warm condition, assessed through a controlled experimental study.

> Question: How do wool and cotton sleepwear compare in their impact on sleep quality and vasomotor symptoms in menopausal women under warm conditions? The study explored the effects of wool and cotton sleepwear on sleep outcomes and vasomotor symptoms in menopausal women through an experimental study. Participants were randomised to wear either wool or cotton sleepwear under controlled warm laboratory conditions. Objective sleep outcome was measured using PSG, and subjective clothing comfort, mood and vasomotor symptoms were assessed through standardised ques-

tionnaires. Linear mixed model (LMM) analysis was performed to access the effect of sleepwear fibre type on sleep outcomes, subjective comfort, mood and symptom severity, while accounting for within-subject variability.

Each study builds upon the previous findings to develop a comprehensive understanding of how vasomotor symptoms, sleep monitoring accuracy, and textile fibre properties contribute to sleep disturbances in menopausal women. By integrating observational, validation, systematic review, and experimental methodologies, the thesis constructs a cohesive narrative that progressively deepens the understanding of menopausal sleep disturbances and explores targeted interventions using sleepwear fibre types to improve sleep quality in this population.

Impact of COVID-19 on Research Plan and Procedure

Throughout the research period, significant disruptions caused by the COVID-19 pandemic and associated regulations in Australia severely impacted the research plan and procedure. The statewide lockdowns implemented in March 2020 and June 2021 across New South Wales severely disrupted sleep study experiments, compelling substantial revisions to both the research timeline and methodology. Additionally, approximately half of the PSG studies were conducted at the Lidcombe sleep laboratory (Cumberland Campus), while the other half at the Sleep Clinic at Concord Hospital due to the closure of the Lidcombe campus. The relocation introduced logistical and administrative challenges, including re-applying for ethics approval and delays in finalising research agreements between Sydney University and Concord Hospital. Challenges also arose with maintaining ambient conditions. Moreover, there was limited access to study rooms due to sharing facilities with clinical patients. Recruitment also declined: research participants might have been less willing to attend studies in hospital settings after the COVID-19 lockdown likely due to health concerns. Despite these challenges, adaptations made to duplicate the study settings in the hospital provided valuable insights into the feasibility of conducting sleep research under restrictive circumstances. These experiences underscored the resilience required for academic research during global disruptions and highlighted the adaptability of both the researchers and the research process.

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CHAPTER 2

LITERATURE REVIEW

2.1 Sleep

2.1.1 Sleep States and Stages

Sleep is a fundamental biological process essential for human health and well-being as it occupies around one-third of a person's lifetime [1]. Human sleep consists of two distinct states: non-rapid eye movement (NREM) sleep and rapid eye movement (REM) sleep [2]. During the sleep period, our brain periodically switches between these states [3]. NREM sleep, which constitutes the majority of sleep, is divided into three stages: N1, N2, and N3 [4]. NREM sleep is thought to contribute to physical restorative and recuperation [5], especially for Stage N3, also known as slow-wave sleep (SWS), which is crucial for physical restoration and immune function [6, 7]. Additionally, NREM sleep plays a critical role in declarative memory consolidation and procedural learning. SWS is associated with motor skill development and cognitive task performance by facilitating synaptic down-scaling and hippocampal-cortical memory transfer, thereby stabilising newly acquired knowledge [6, 8]. NREM Stage 2 sleep, particularly sleep spindles, has been linked to motor sequence learning and perceptual learning tasks [9]. Conversely, REM sleep is more strongly associated with memory reorganisation, emotional regulation, and synaptic plasticity, playing a crucial role in integrating learned experiences and enhancing memory flexibility [6, 8–10]. While REM sleep facilitates the formation of complex memory representations and creative problem-solving, recent studies suggest that it may also contribute to memory distortions due to its role in reconstructing and generalising learned experiences [10]. This suggests that NREM sleep stabilises and consolidates newly learned skills, whereas REM sleep enhances flexibility in memory processing and integration, at the cost of potential distortions.

2.1.2 Regulation of Sleep

2.1.2.1 Sleep Homeostasis and Circadian Processes

Sleep is regulated by two main processes: sleep homeostasis and the circadian rhythms [11]. The homeostatic drive regulates the inclination for sleep: sleep pressure builds up during waking, reaches a peak around the natural bedtime, increasing sleep propensity and sleepiness. Sleep pressure dissipates and reaches the lowest level by the end of sleep [4, 12]. The circadian rhythm is a 24-h endogenous clock-like system that affects the timing and length of sleep [13]. Light is the primary zeitgeber, or time cue, synchronising the circadian system with the external environment [14].

Notably, recent research suggest that sleep regularity may be even more important than sleep duration in predicting long-term health outcomes, including all-cause mortality, emphasising the relevance of evaluating both aspects of sleep health independently [15].

2.1.2.2 Sleep Regularity

Sleep regularity, defined as maintaining consistent sleep and wake times across days, is critical for promoting sleep quality and overall health, as it aligns internal biological rhythms with external environmental cues [16, 17]. Human sleep-wake patterns are governed by the interplay of the solar clock, biological clock, and social clock. The solar clock represents the natural environmental light-dark cycle, which has served as the primary external synchroniser (zeitgeber) for human circadian rhythms throughout evolutionary history. Exposure to natural light, particularly in the morning, anchors the circadian system and promotes alignment between environmental and biological rhythms, ensuring timely sleep onset and wakefulness [16, 18]. This alignment supports not only improved sleep efficiency but also metabolic and immune health by stabilising hormonal rhythms and physiological processes [16, 17].

The biological clock, centred in the suprachiasmatic nucleus (SCN) of the hypothalamus, orchestrates the daily rhythms of sleep-wake cycles and associated physiological processes such as body temperature and hormone secretion [7, 17]. A well-aligned biological clock optimises slow-wave sleep (SWS) during NREM sleep, which is crucial for physical restoration, and facilitates memory consolidation during REM sleep [7, 8]. However, disruptions to this system, such as irregular sleep schedules or nighttime light exposure, can impair cognitive function, emotional regulation, and metabolic processes [18, 19].

In modern society, the social clock, defined by societal schedules such as work hours and cultural norms, often conflicts with the biological clock. Even small inconsistencies in sleep timing across weekdays and weekends can cause misalignment, negatively impacting health. While social jetlag-an extreme form of this misalignment-has been associated with poor sleep quality, obesity, and increased risk of chronic conditions like type 2 diabetes, regular sleep patterns are effective in mitigating these negative effects

[19, 20]. Consistent sleep timing stabilises circadian rhythms, promotes efficient sleep architecture, and enhances overall well-being [7, 18].

Maintaining regular sleep timing yields numerous benefits. It improves sleep quality by fostering consistent sleep cycles and extending periods of restorative slow-wave sleep [7, 8]. Additionally, it supports cognitive performance through enhanced memory consolidation and emotional stability [8, 16]. Regular sleep patterns also reduce the risk of metabolic dysregulation, such as obesity and insulin resistance, by aligning physiological rhythms with environmental and social cues [17, 20]. These findings underscore the critical role of sleep regularity as a foundation for maintaining optimal health and well-being.

2.1.2.3 Sleep Duration

Sleep duration refers to the total amount of time spent asleep during a sleep episode and is a fundamental component of sleep health. While individual needs may vary, the National Sleep Foundation recommends 7 to 9 hours of sleep per night for adults to maintain optimal physiological and cognitive functioning [21]. Both insufficient and excessive sleep durations have been associated with adverse health outcomes, including increased risk of cardiovascular disease, metabolic syndrome, impaired immune function, and all-cause mortality [22, 23].

Sleep duration is regulated by the interaction between the homeostatic and circadian processes. The homeostatic drive determines the level of sleep drive (sleep pressure) to compensate for prior wakefulness, while the circadian system influences the preferred timing of sleep, thus along with 'waking during sleep' they contribute to sleep duration. Factors such as age, sex, hormonal changes, lifestyle, and environmental conditions (e.g., temperature, light exposure) also contribute to individual differences in sleep duration [4, 24].

Emerging research highlights the importance of not only sleep quantity but also its continuity and timing. Fragmented or poorly timed sleep, even when total duration is adequate, may still result in daytime impairments. In menopausal women, for instance, vasomotor symptoms such as night sweats and hot flushes can significantly reduce total sleep time, contributing to fatigue and reduced quality of life [25, 26].

2.1.3 Factors Affecting Sleep

Sleep is a complex physiological process influenced by a myriad of internal and external factors. Sleep duration requirements vary from person to person and reduced with ageing [21]. Sleep quality can be affected by many factors such as health behaviours, physical health, psychological health [22] and external environment [23]. These factors can be broadly categorised into physiological and psychological factors and environmental influences, each of which interacts dynamically to shape sleep quality and patterns.

2.1.3.1 Psychological Factors

Among the various physiological factors influencing sleep, thermoregulation has been identified as a key mechanism of interest in this thesis, particularly due to its interaction with circadian rhythms and relevance to menopausal symptoms. Psychological factors, including stress, anxiety, depression, and coping mechanisms, play a critical role in determining sleep quality. Stress and anxiety are well-established contributors to sleep disturbances. These states activate the hypothalamic-pituitary-adrenal (HPA) axis, resulting in elevated cortisol levels that delay sleep onset and reduce slow-wave sleep, a critical phase for physical restoration [24, 25]. Chronic activation of the HPA axis can lead to persistent insomnia, further exacerbating psychological distress and creating a vicious cycle [26, 27].

Anxiety disorders are strongly associated with increased arousal levels during the pre-sleep period. Individuals with generalised anxiety disorder (GAD) report difficulty in falling asleep due to intrusive thoughts and hyperarousal [28]. This heightened state of arousal disrupts the transition from wakefulness to sleep, leading to prolonged sleep latency and fragmented sleep patterns. Similarly, depressive disorders often result in altered sleep architecture, characterised by reduced slow-wave sleep and shortened REM sleep latency [29]. These alterations not only impair sleep quality but also worsen the symptoms of depression, forming a bidirectional relationship between sleep and mood disorders [30].

Coping mechanisms significantly modulate the impact of psychological stress on sleep. Adaptive coping strategies, such as problem-solving and seeking social support, are associated with better sleep outcomes [27]. In contrast, maladaptive strategies, such as rumination and avoidance, amplify stress and its deleterious effects on sleep [31]. Cognitive behavioural therapy for insomnia (CBT-I) has been shown to effectively address maladaptive thought patterns, reduce pre-sleep arousal, and improve overall sleep quality, particularly in individuals with comorbid anxiety or depression [32, 33].

Furthermore, personality traits, such as neuroticism, are linked to greater vulnerability to stress-induced sleep disturbances [34, 35]. Individuals with high neuroticism tend to perceive stressors as more threatening and exhibit heightened emotional responses, which can prolong pre-sleep arousal and lead to chronic sleep difficulties. Understanding the interplay between psychological factors and sleep provides a foundation for targeted interventions aimed at breaking the cycle of poor sleep and psychological distress.

2.1.3.2 Physiological Factors

Among the various physiological factors influencing sleep, thermal comfort has been identified as a key factor of interest in this thesis, particularly due to its interaction with sleepwear, ambient temperature conditions that are relevant to menopausal women with symptoms. Thermoregulation is a dynamic, homeostatic interaction process to maintain human's core body temperature close to 37°C [36]. According to C. A. Czeisler et al. [13], the body temperature rhythms have a stable internal relationship with the sleep-wake cycle, as the timing of sleep is highly correlated with the phase of body temperature rhythm. Body temperature is a good marker of the circadian rhythm. Sleep duration is extended when bedtime occurs on the decline of the core body temperature, whereas sleep duration is short when bedtime occurred on the next upslope of the temperature curve. This article also states that the temperature and melatonin circadian rhythms are mainly synchronised by the light/dark cycle [13]. Besides, circadian rhythm abnormalities influenced core body temperatures thus reduced sleep quality [37]. That is to say, sleep quality can be regulated by varying core body temperature. Thermoregulation is relatively active during NREM sleep while reduced during REM sleep [38].

Sleep onset coincides with decreases in core body temperature [13] with selective vasodilation of distal skin regions, which contributes to the decrease of core body temperature, thus promotes sleep onset [39]. During the sleep period, the skin temperature remains relatively stable and is slightly raised during REM sleep [38]. Study also shows that skin is very sensitive to temperature changes and skin temperature is affected by ambient temperature while clothing can provide thermal resistance and insulation for the human body [40].

Sweating is an important mechanism for thermoregulation. Night sweating rates are lower during REM sleep than NREM sleep [23, 41]. The lower sweat rates may be the reason for a higher skin temperature during REM sleep [41]. These thermoregulatory characteristics make REM sleep more vulnerable to sleep disturbances because of greater thermal discomfort than in NREM sleep [42].

2.1.3.3 Environmental Factors

Among the external factors, the thermal environment is very important for sleep maintenance [23, 40, 42]. Previous studies have shown that excessively high, low or changing air temperature lower sleep quality [40]. A lower ambient temperature at 23°C supports the best sleep quality when participants wore thick wool, long-sleeve sweater and long pants without bed linens [43]. The thermoneutral temperature is 20-22.2°C under covered conditions [44, 45] and 28-32°C in the naked condition [41, 46].

Many studies have explored the effects of the ambient condition and skin microclimate on sleep. The ambient condition typically includes temperature, humidity, air flow and air pressure [38, 40, 42]. Skin microclimate refers to the temperature and humidity in the space between the skin surface and sleepwear, which is determined by body metabolic rate and clothing [23]. The ideal sleeping skin microclimate is approximately 30°C to 32.5°C [23]. Researchers believe that sleepwear that prevents rapid changes in skin temperature supports optimal sleeping microclimate temperature and humidity levels and moderate their changes to support good sleep pattern [23, 38, 42]. Thus, the thermal properties of bedding are important and critical in supporting thermoregulation and good sleep quality [23, 38].

2.1.4 Sleep measurements

Accurate sleep measurement is fundamental to understanding sleep physiology, diagnosing sleep disorders, and evaluating interventions. There are objective and subjective measurements to quantify sleep.

Polysomnography (PSG) is the gold standard objective technique widely used to investigate and document the sleep activity, including total sleep time (TST), sleep onset latency (SOL), sleep stages and so on [47]. Its measurements include electroencephalography

(EEG), electrooculography (EOG) and electromyographic (EMG), and other parameters to evaluate the function of multiple organ systems and their relationship with different sleep stages and their transition [47]. Despite its comprehensiveness, PSG has limitations. It is resource-intensive, requiring overnight monitoring in a laboratory or sleep clinic by trained technicians. The artificial environment of a sleep lab may also influence natural sleep patterns, necessitating an adaptation night in research settings [48]. Adaptation nights are particularly important for minimising first-night effects, which often involve heightened arousal and atypical sleep architecture due to unfamiliarity with the sleep environment [47]. Including an adaptation night in sleep studies helps ensure that subsequent recordings more accurately reflect participants' habitual sleep patterns, thereby improving the reliability of findings [49].

Actigraphy is another objective measurement of sleep, which is a portable and less intrusive alternative to PSG, suitable for long-term monitoring of sleep patterns in real-world settings. Actigraphy devices use accelerometers to estimate sleep-wake cycles based on movement [50], providing estimates of sleep duration, onset, and efficiency by analysing periods of activity and inactivity [51], and capturing habitual sleep behaviours and circadian rhythms via long-term monitoring [50]. Actigraphy is widely used in populations where PSG may not be feasible, such as children, the elderly, and individuals in remote settings [52, 53]. While actigraphy is highly useful for estimating sleep duration and timing, it has limitations in accuracy compared to PSG. Actigraphy tends to overestimate total sleep time and sleep efficiency, as it cannot distinguish between stillness during wakefulness and actual sleep [54].

In addition to objective methods, subjective sleep measurements, including sleep diary, questionnaires, and various scales provide valuable insights into an individual's perception of sleep quality. The Pittsburgh sleep quality index (PSQI) is one of the most commonly used measure that covers a broad range of indicators relevant to sleep quality and also shows strong reliability and validity [55]. The PSQI is particularly valuable in identifying sleep issues in clinical and research settings across diverse populations [55, 56].

2.2 Menopause

Menopause is the permanent cessation of menstrual cycles due to ovarian failure [57]. It can be categorised into two types: natural menopause and induced menopause. Natural menopause, sometimes described as spontaneous menopause, is defined as the permanent cessation of menstruation resulting from the loss of ovarian follicular activity and without any other apparent pathological or physiological cause; whereas induced menopause, also known as secondary menopause or surgical menopause, is defined as the cessation of menstruation that follows the surgical removal of both ovaries (with or without hysterectomy), or results from iatrogenic ablation of ovarian function by chemotherapy or radiotherapy [57–59]. The gold standard widely used to characterise ovarian ageing is the Stages of Reproductive Ageing Workshop (STRAW) staging system, which divides the adult female life into three broad phases: reproductive, the menopausal transition and postmenopause, with further division into seven segments. However, the STRAW staging mainly applies to natural menopause [58, 60]. The definitive event for the staging system is the final menstrual period (FMP) as denoted in the Figure 2.1 [60, 61].

2.2.1 Hormonal changes during menopause

During menopause, changes in the ovarian structure and function lead to significant hormone levels changes. The ovarian hormones, which are broadly divided into two classes, steroids (estradiol and progesterone) and peptides (inhibins and activins), play critical roles in regulating the hypothalamic-pituitary-ovarian axis [57]. Steroid hor-

Menarche ↓ (at stage -5) | Final Menstrual Period ↓ (at stage +1a)

Stage	-5	-4	-3b	-3a	-2	-1	+1a	+1b	+1c	+2
Terminology	**REPRODUCTIVE**				**MENOPAUSAL TRANSITION**		**POSTMENOPAUSE**			
	Early	Peak	Late		Early	Late	Early			Late
					Perimenopause					
Duration	variable				variable	1-3 years	2 years (1+1)		3-6 years	Remaining lifespan
Criteria and Symptoms										
Menstrual Cycle	Variable to regular	Regular	Regular	Subtle changes in Flow/Length	Variable Length, Persistent ≥7-day difference in length of consecutive cycles	Interval of amenorrhea of >=60 days	None			
FSH (Endocrine)			Low	Variable	↑ Variable	↑ >25 IU/L	↑ Variable		Stabilises	
AMH (Endocrine)			Low	Low	Low	Low	Low		Very Low	
Inhibin B (Endocrine)				Low	Low	Low	Low		Very Low	
Antral Follicle Count			Low	Low	Low	Low	Very Low		Very Low	
Symptoms						Vasomotor symptoms ***Likely***	Vasomotor symptoms ***Most Likely***			***Increasing*** symptoms of urogenital atrophy

Figure 2.1: The STRAW staging system [60, 61]

mones control the secretion of luteinizing hormone (LH) and peptide hormones suppress or stimulate the secretion of follicle-stimulating hormone (FSH) [57]. These hormonal interactions maintain the delicate balance necessary for normal ovarian function [57].

As menopause approaches, the declining number and function of ovarian follicles lead to a marked reduction in circulating estradiol levels. This decline triggers a compensatory increase in FSH secretion due to the diminished inhibitory feedback from ovarian hormones [57, 58]. Notably, FSH levels reach their peak approximately three to four years after the final menstrual period (FMP), a characteristic hallmark of postmenopause [57]. In contrast, LH levels also rise during menopause, albeit to a lesser extent compared to FSH, reflecting the differential regulation of these gonadotropins.

The interactions among ovarian hormones and their regulatory effects on FSH during menopause highlight the complex endocrine changes underlying this transition. The rise in FSH levels, alongside the concurrent decline in estradiol, is not only a defining biochemical feature of menopause but also contributes to the onset of various menopausal symptoms and long-term health consequences [57, 58].

2.2.2 Menopausal symptoms

Hormonal changes during menopause can affect many organ systems thus leading to various menopausal symptoms. These symptoms, often interconnected, are among the most reported experiences during the menopausal transition and postmenopause, with substantial impacts on women's quality of life. Menopausal women also commonly experience different levels of menopausal symptoms. Symptoms of menopause include central nervous system (CNS)-related disorders, bodily alterations related to cardio-metabolic changes, musculoskeletal alterations, urogenital and skin atrophy and sexual dysfunction [62, 63].

2.2.2.1 Vasomotor symptoms

Vasomotor symptoms are the most frequently reported symptoms with a prevalence of 75% [63], which include hot flushes and night sweats, sometimes followed by trembling and a feeling of coldness [58, 62–64]. Hot flushes are sudden, intense sensations of heat, often accompanied by flushing of the face and neck, sweating, and sometimes followed by chills or a sensation of coldness [64]. These episodes are thought to arise from a dysfunction in thermoregulatory control caused by fluctuating or declining oestrogen levels. The physiological response involves a rapid dilation of blood vessels and increased sweating to dissipate heat, which can occur unpredictably and is frequently distressing [62].

Night sweats, the nocturnal manifestation of vasomotor symptoms, often disrupt sleep. They are characterised by excessive sweating during the night, necessitating changes in bedding or sleepwear and causing awakenings. Night sweats are particularly problematic because they not only fragment sleep but also exacerbate other menopausal symptoms, contributing to fatigue and diminished overall well-being [65, 66].

2.2.2.2 Sleep disturbances

Sleep disturbances are another common complaint among menopausal women, with a prevalence of 40-60% [62, 67]. These disturbances encompass difficulty initiating and maintaining sleep, frequent awakenings, and non-restorative sleep. While hormonal changes directly contribute to these issues, vasomotor symptoms, particularly night sweats, are a primary driver of sleep disruption. The sudden onset of sweating and the accompanying rise in skin temperature often trigger arousals, further compounding the difficulty in achieving continuous sleep [68].

Chronic sleep deprivation resulting from repeated nocturnal awakenings can have a cascading effect, amplifying the severity of vasomotor symptoms and leading to impaired cognitive function, mood instability, and decreased daytime productivity. These effects highlight the bidirectional relationship between vasomotor symptoms and sleep disturbances, where each exacerbates the other in a self-perpetuating cycle [66].

2.2.2.3 Interrelations Between vasomotor symptoms and sleep disturbances

The interplay between vasomotor symptoms and sleep disturbances underscores the complexity of menopausal experiences. Hot flushes and night sweats are not only disruptive in isolation but also serve as key contributors to sleep fragmentation. Conversely, poor sleep quality has been shown to heighten sensitivity to vasomotor symptoms, suggesting a feedback loop that intensifies these experiences during menopause. Understanding this interconnectedness is crucial for developing effective interventions aimed at alleviating the burden of menopausal symptoms [62, 64].

2.2.3 Implications and Management of Menopause

Menopausal symptoms extend beyond individual health, exerting significant social and economic consequences. In Australia, women aged between 45 and 64 years represent a substantial portion of the workforce. However, recent national surveys indicate that approximately 25% of women in this age group report experiencing severe menopausal symptoms that hinder daily activities, and 17% have taken extended leave due to these symptoms within the past five years [69]. Additionally, the average retirement age for Australian women is 7.4 years earlier than that of men, a gap partially attributed to the challenges posed by menopausal symptoms [70]. These findings highlight the pressing need for workplace accommodations and policies that support menopausal women to remain productive and healthy during this transition.

The economic burden of menopause also includes healthcare costs associated with managing conditions such as osteoporosis, cardiovascular disease, and mental health issues, all of which are exacerbated by declining oestrogen levels. Furthermore, untreated menopausal symptoms, such as hot flushes and sleep disturbances, can lead to fatigue and reduced cognitive performance, further impacting workplace productivity and personal well-being [62, 71].

On a personal level, the disruptive effects of menopause, including fatigue from sleep disturbances and physical discomfort from vasomotor symptoms, diminish women's quality of life. These challenges are further compounded by emotional and psychological strain, which can interfere with daily functioning and social interactions [72].

Effective management of menopause requires a combination of lifestyle modifications, medical interventions, and environmental adjustments, tailored to address the specific symptoms and improve overall quality of life [73–75].

2.2.3.1 Lifestyle modifications

Adopting a healthy lifestyle is a foundational approach to managing menopausal symptoms and mitigating associated health risks. Dietary changes, such as ensuring adequate intake of calcium and vitamin D, play a critical role in maintaining bone health and reducing the risk of osteoporosis, which is exacerbated by declining oestrogen levels during menopause [76]. Calcium-rich foods, alongside vitamin D to enhance absorption, are particularly beneficial for postmenopausal women in preserving bone density and preventing fractures [77].

Regular physical activity is equally important, contributing to improved cardiovascular function, musculoskeletal strength, and mental health. Weight-bearing exercises, such as walking or resistance training, are especially effective in preventing bone loss and supporting overall physical fitness in postmenopausal women [78]. Exercise has also been linked to reductions in mood disturbances and improved sleep quality, making it a versatile intervention for addressing multiple menopausal symptoms.

Stress reduction techniques, including yoga, mindfulness, and cognitive behavioural therapy, can provide additional benefits. These approaches have been shown to alleviate mood instability and anxiety, which are common during menopause, while also enhancing sleep quality. For instance, yoga has demonstrated efficacy in improving psychological well-being and managing symptoms such as insomnia and fatigue in women facing significant life transitions [79].

2.2.3.2 Medical Interventions

Hormone Replacement Therapy (HRT) is the most effective medical intervention for managing vasomotor symptoms and preventing osteoporosis. HRT options include oestrogen-only or combined oestrogen and progestogen regimens, tailored to individual needs.

While HRT offers significant benefits, such as reduced hot flush frequency, improved bone density, and a lower risk of osteoporosis-related fractures [80], it must be prescribed with caution due to potential risks, including thromboembolism, breast cancer, and cardiovascular events, particularly in women with pre-existing risk factors [58, 81].

For women unable or unwilling to use HRT, non-hormonal pharmacological options are available. Selective serotonin reuptake inhibitors (SSRIs) or serotonin-norepinephrine reuptake inhibitors (SNRIs), such as venlafaxine or paroxetine, have been shown to alleviate vasomotor symptoms by modulating serotonin pathways [67]. In addition, bisphosphonates and selective oestrogen receptor modulators (SERMs) are effective in supporting bone health and reducing fracture risk by preserving bone mineral density in postmenopausal women [82, 83].

2.2.3.3 Environmental and Sleep Management

Environmental adjustments are particularly effective for managing vasomotor symptoms, such as hot flushes and night sweats. Maintaining a cooler ambient temperature has been shown to significantly reduce the frequency of hot flushes [66]. Additionally, appropriate sleepwear plays a critical role in thermal regulation. Wool sleepwear, for example, demonstrates superior moisture-wicking and thermal buffering properties compared to cotton, helping to stabilise skin temperature during hot flushes and improve sleep quality [84, 85].

2.3 Clothing thermal properties and thermal comfort

Thermal comfort refers to a state in which an individual feels thermally satisfied with their surrounding environment, typically influenced by factors such as air temperature, humidity, and clothing insulation [86]. Clothing plays a vital role in achieving thermal comfort by modulating thermal insulation and moisture transfer, thereby maintaining a stable and comfortable microclimate close to the skin [87, 88].

Thermal properties of the fabric are defined by their ability to provide insulation and resist water vapour transfer, which are crucial for thermal comfort. These properties depend on factors such as fibre type, yarn structure and others [89, 90]. For a fabric that delivers thermal comfort, its water vapour permeability should be high to allow sweat to evaporate from the skin to keep the skin dry [90].

Natural fibres, such as wool and cotton, exhibit distinct characteristics that affect their thermal performance. In the dry state, both fibres provide good insulation due to their low thermal conductivity, but their behaviour diverges significantly upon moisture absorption [90]. Wool can absorb up to approximately 36% of its dry weight in moisture, whereas cotton absorbs around 25% [91]. The higher hygroscopicity enables wool to buffer humidity changes more effectively, maintaining a stable skin microclimate even during sweating episodes [92]. Wool's unique ability to absorb and release moisture without retaining liquid sweat on the skin surface is due to its fibre structure, which includes natural crimps that trap air and enhance insulation. These properties make wool effective in maintaining thermal balance, even under conditions of fluctuating temperature and humidity [91]. Previous studies have demonstrated the superior performance of wool sleepwear in supporting better sleep quality compared to in young and older adults [84, 85].

The thermal conductivity of fabrics is also influenced by structural factors such as thickness and bulk density. Wool's natural crimp allows it to trap air, providing better insulation compared to cotton. Thin fabrics, with a thickness of less than 0.9 cm, facilitate more efficient heat transfer (Figure 2.2), whereas fabrics with entrapped air, such as wool, hinder heat flow and enhance thermal comfort [93, 94]. In contrast, synthetic fibres such as polyester and nylon exhibit different thermal and moisture management behaviours. These materials are generally hydrophobic, with low moisture regain and limited breathability, which can hinder evaporative cooling and lead to heat and moisture accumulation near the skin [95–97]. While synthetic fibres are durable and dry quickly, their reduced capacity to absorb and transport moisture may lower thermal comfort in warm or humid environments. This limitation may be particularly significant for individuals experiencing thermoregulatory sensitivity, such as menopausal women. Furthermore, studies have shown that polyester fabrics possess weaker moisture buffering potential compared to natural fibres like wool and cotton [98]. These factors underscore the importance of fibre choice in designing garments that optimise thermal comfort, particularly for individuals experiencing temperature regulation challenges during sleep.

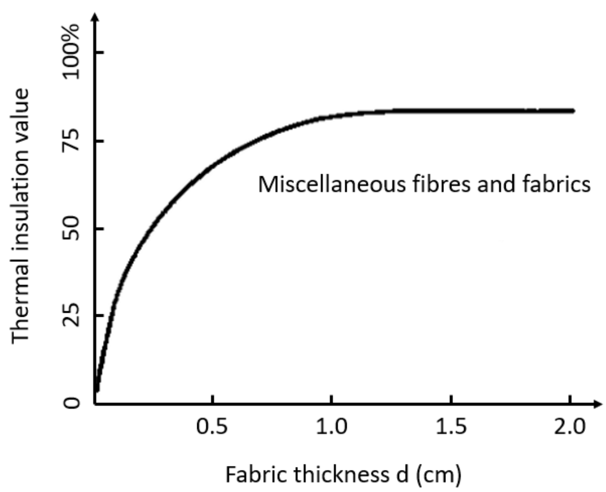

Figure 2.2: Thermal insulation value and fabric thickness.

The thermal and moisture-regulating advantages of wool have been demonstrated in studies comparing wool and cotton sleepwear. Wool has been shown to improve sleep quality by reducing temperature and humidity fluctuations, which are particularly problematic during night sweats and hot flush episodes. As a result, wool may be a more suitable fabric for menopausal women seeking to improve sleep quality and thermal comfort during this transitional period, given its favourable thermal and moisture-regulating properties.

2.4 Integration of Menopausal symptoms, thermal comfort and sleep

Menopausal symptoms, particularly vasomotor symptoms such as hot flushes and night sweats, profoundly impact thermal regulation and sleep quality. Among the various sleep disturbances experienced during menopause, difficulty maintaining sleep – such as frequent night-time awakenings – is the most commonly reported complaint [68, 99]. The interplay between these symptoms and the thermal properties of fabrics highlights the importance of attention to fabric fibre type that supports thermal comfort during sleep for menopausal women.

2.4.1 Thermal Comfort as a Mediator

Hot flush episodes, due to their sudden increases in core and skin temperature that often followed by excessive sweating, disrupt thermoregulation, as the body attempts to dissipate heat through vasodilation and perspiration [64]. The frequency of hot flushes in 24 hours is shown in Figure 2.3. Women with more significant hot flush have a lower core body temperature than asymptomatic women. Besides, the highest hot flushes frequency occurs 1-3 hours after the peak of core body temperature. Moreover, prior to a hot flush, core body temperature increases, which acts as a trigger. Then the temperature significantly drops by 0.1°C in the following 10 minutes, while skin temperature suddenly rises by 0.3°C followed by a drop to baseline within 10 minutes [64]. Measurable sweating occurs in 90% of the hot flushes [64], which restores the skin temperature back to the baseline. During hot flush events, sternal skin conductance level (SCL) increases of ≥2 μmho (electrical unit of conductance) within 30s [100], thus make the increased sternal SCL a gold standard for objectively measuring hot flushes [64, 100, 101].

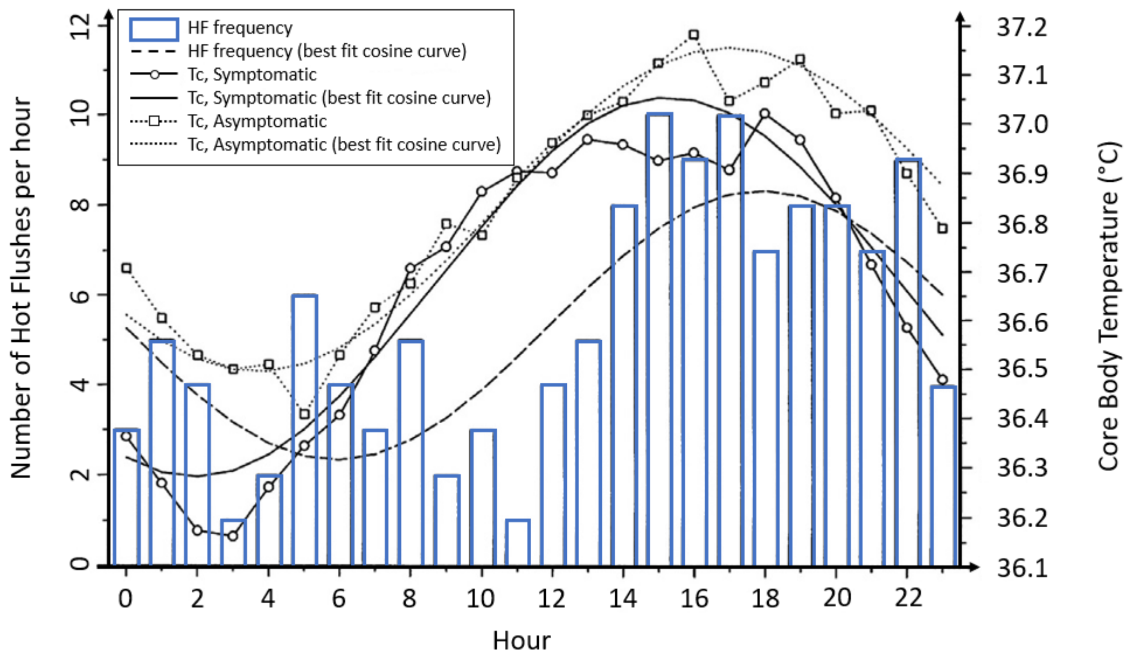

Figure 2.3: Hot flush frequency and core body temperature (Tc) during 24 h. Hot flush frequency in 10 symptomatic women (bars); best-fit cosine curve for hot flush frequency (dashed line); 24 h Tc data for 10 symptomatic women (○) with best fit cosine curve (solid line); 24 h Tc data in 6 asymptomatic women (□) with best-fit cosine curve (dotted line) [64].

2.4.2 Impact of Fabric Properties on Sleep

The choice of fabric is pivotal in mitigating the effects of hot flushes and night sweats during sleep. Wool, with its superior hygroscopicity and thermal insulation, has been shown to absorb and release moisture effectively, thereby reducing skin dampness and maintaining a stable microclimate around the body [92]. This helps prevent rapid cooling after sweating, which is a common discomfort experienced during night sweats. In contrast, cotton, while absorbent, is less efficient at releasing moisture and lacks the thermal buffering capacity of wool, making it less effective in managing the rapid thermal and moisture changes associated with menopausal symptoms [91].

A comparison of moisture diffusion resistance across various fabrics further illustrates the advantages of wool and cotton in managing humidity during sweating episodes. Both wool and cotton exhibit relatively low resistance to moisture diffusion due to their lower fabric bulk density, which facilitates the transfer of water vapour. In contrast, synthetic materials such as nylon, vinyon, and glass fibres exhibit significantly higher resistance to moisture diffusion, making them less effective in maintaining thermal comfort during perspiration (Figure 2.4) [94]. This highlights the importance of fabric selection in ensuring optimal thermal and moisture management for menopausal women.

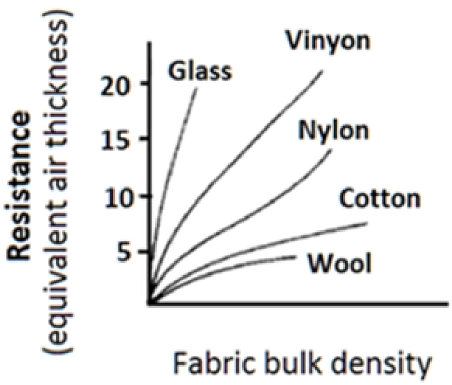

Figure 2.4: Resistance to moisture diffusion and fabric bulk density.

2.4.3 Broader Implications for Symptom Management

As mentioned earlier, rapid skin temperature changes can disturb sleep, vasomotor symptoms further contribute to sleep disturbances in menopausal women apart from other menopausal symptoms [68, 71, 102–104]. Appropriate sleepwear can absorb skin moisture as well as buffer skin temperature changes during a hot flush event. Wool sleepwear, for instance, demonstrates superior moisture-wicking and thermal buffering capabilities compared to cotton. These properties enable wool to absorb skin moisture and buffer temperature fluctuations, potentially reducing the impact of hot flushes on sleep quality. Although previous studies have shown that wool sleepwear may help maintain a more stable skin microclimate and improve overall sleep quality in young and older adults [84, 85], these effects have not yet been confirmed in menopausal women. Therefore, their applicability to menopausal women experiencing vasomotor symptoms including hot flushes remains hypothetical and warrants further investigation.

While the physiological rationale for thermoregulatory sleepwear is well-established, non-pharmacological interventions targeting the sleep environment – such as sleepwear and bedding – have received relatively little empirical attention in the literature. Compared to hormonal or pharmaceutical approaches, the role of thermal comfort in mitigating menopausal sleep disturbances remains underexplored. One recent study by Avis et al. [105] investigated the effect of cooling bedding on sleep and vasomotor symptoms in midlife women, highlighting the potential value of environmental modifications. However, few studies have examined the comparative impact of different fabric types on sleep outcomes in this population. This thesis aims to address this gap by experimentally evaluating the effects of wool versus cotton sleepwear under controlled temperature and humidity conditions.

The broader context of managing menopausal symptoms also involves addressing limitations in current research designs and methodologies. For instance, previous studies, such as the Wisconsin Sleep Cohort study, highlighted several challenges in accurately evaluating menopausal symptoms and sleep quality [106]. These challenges include the inclusion of heterogeneous participant groups, such as those using hormone replacement therapy (HRT) alongside non-users, and the absence of environmental controls during data collection. Moreover, the artificial environment of sleep laboratories may influence natural sleep patterns, necessitating the inclusion of adaptation nights to ensure reliable results [49].

To address these limitations, future research should:

1. **Enhance participant selection**: Exclude individuals with confounding conditions, such as moderate to severe sleep apnea, to improve data clarity and specificity.

2. **Standardise environmental conditions**: Maintain controlled ambient temperatures and humidity levels, such as 30°C with 50% relative humidity, to ensure consistency across studies [66].

3. **Incorporate adaptation nights**: Allow participants time to acclimate to the study environment before data collection, minimising the impact of first-night effects and enhancing data validity [47, 49].

These methodological improvements are essential for generating robust evidence to guide the development of effective interventions, such as optimised sleepwear and environmental adjustments, that address the multifaceted challenges faced by menopausal women.

Building on these recommendations, the present thesis aims to generate new empirical evidence regarding the influence of sleepwear fabric type on thermal comfort and sleep quality in menopausal women. The project comprises a series of interrelated studies, each designed to address a specific aspect of this overarching aim. Chapter 3 characterises the associations between vasomotor symptoms and sleep patterns in peri- and postmenopausal women using actigraphy. Chapter 4 validates an actigraphy device against gold-standard polysomnography under thermally challenging conditions. Chapter 5 systematically reviews existing literature on sleepwear and bedding materials and their impact on sleep. Chapter 6 presents a pilot experimental study comparing wool and cotton sleepwear, focusing on sleep quality, thermal comfort, and vasomotor symptoms. Together, these chapters seek to advance non-pharmacological strategies for improving menopausal sleep health by addressing both measurement and intervention gaps.

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Chapter 3: An Investigation of Sleeping Behaviour and Vasomotor Symptoms in Peri- and Post-Menopausal Women

AUTHORSHIP ATTRIBUTION STATEMENT

This chapter is being prepared for submission for *Menopause*.

I co-designed the study with the co-authors, collected, analysed, and interpreted the data, and wrote the drafts of the manuscript.

In addition to the statements above, in cases where I am not the corresponding author of a published item, permission to include the published material has been granted by the corresponding author.

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CHAPTER 3

An Investigation of Sleeping Behaviour and Vasomotor Symptoms in Peri- and Post-Menopausal Women

Abstract

Objectives: This study aimed to describe sleep patterns and evaluate the associations between menopausal vasomotor symptoms and sleep-related outcomes, including insomnia symptoms, sleep timing and intraindividual sleep variability in peri- and postmenopausal women using actigraphy.

Methods: Thirty-nine peri- and post-menopausal women (mean age: 52.1 ± 3.5 years old) were recruited to record data from at least three nights of actigraphy data. The Insomnia Severity Index (ISI) and the Modified Greene Climacteric Scale were used to assess insomnia and vasomotor symptom severity. Correlation analyses and intra-class correlation coefficients (ICC) were employed to evaluate the relationships between sleep timing, sleep duration, intraindividual sleep regularity, and vasomotor symptoms.

Results: Participants reported mild vasomotor symptoms, with low scores for both hot flushes (mean = 1.2 ± 0.6) and night sweats (mean = 1.2 ± 0.6), according to the Greene Climacteric scale. Sleep patterns exhibited substantial variability across participants, with sleep onset ranging from 8:46 PM to 1:03 AM and midsleep times from 1:28 AM to 4:18 AM. The average sleep duration was 490.3 minutes (SD = 57.4 min), ranging from 361 to 612 minutes. Most participants had sleep onset between 10:00 PM and 10:30 PM, and sleep offset between 7:00 AM and 7:29 AM. Intraindividual variability was also notable, with the intraindividual standard deviation (IISD) for sleep onset averaging 55.3 ± 25.2 minutes. However, no statistically significant associations were identified between vasomotor symptoms and sleep parameters ($p > 0.05$). ICC values for sleep timing ranged from 0.42 to 0.61, indicating moderate consistency in actigraphy-derived sleep metrics across nights.

Conclusions: Women in this study, both peri- and post-menopausal, self-reported mild vasomotor symptoms and exhibited variability in sleep duration and timing, as measured by actigraphy. Although vasomotor symptoms are commonly implicated in menopausal sleep disturbances, this study did not find significant direct associations. Future research with larger samples and multidimensional assessments is warranted to provide further insights into menopausal sleep health.

3.1 Introduction

Sleep quality declines with age, affecting both men and women [1, 2], but women report more sleep complaints than men [3, 4]. Hormonal changes are considered the main drivers of the disparities [4–6]. Research indicates that 40% to 60% of peri- and post-menopausal women experience sleep disturbances [7–9], with vasomotor symptoms such as hot flushes and night sweats being the most frequently reported. These disruptions affect 75% of women during the menopause transition period [7, 10, 11]. Post-menopausal women also face significant sleep challenges. Studies suggest that post-menopausal women experience disrupted sleep due to hormonal changes, which can persist even years after the menopausal transition [12]. For instance, declines in estrogen and progesterone levels during post-menopause contribute to increased sleep fragmentation and a reduction in slow-wave sleep [13].

Previous studies have explored sleep disturbances and their potential causes in menopausal women [4, 5, 14]. For instance, a community-based longitudinal study on healthy middle-aged women (40 to 50 years old) showed that women in early perimenopause experienced more awakenings caused by feeling too hot, resulting in shorter sleep duration and worse sleep quality compared to premenopausal women at similar age [15]. Supporting this, a systematic review concluded that natural menopausal transition is a clear risk factor for sleep disturbance, independent of age, health behaviour, physical and psychological health, previous sleep disturbance, and estradiol and follicular stimulation hormone levels [9]. Shaver et al. [16] reported that perimenopausal status affects sleep patterns. This is primarily due to unstable central thermoregulation, which is often associated with vasomotor symptoms. Additionally, gonadal hormonal instability contributes to this disruption. Mood changes and depression, which are common during this transition, may further exacerbate sleep disturbances.

A study by Gómez-Santos et al. [13] identified menopause status as being associated with both circadian and sleep-related alterations. These alterations, which occur during both peri- and post-menopause, suggest that the onset of menopause brings about significant shifts in circadian rhythms and sleep architecture. Such findings align with the hypothesis that menopausal transition may exert acute and transient effects on sleep, particularly through vasomotor symptoms, while ageing contributes to more gradual and chronic changes.

A 10-year follow-up study by Kalleinen et al. concluded that the effect of menopause on sleep changes was not greater than the ageing effect [17]. However, the two factors may differentially impact sleep disturbances: menopause-related symptoms, such as vasomotor disturbances and hormonal fluctuations, are linked to acute and transient sleep disruptions during the transition period [12, 18]. In contrast, ageing is associated with gradual declines in sleep efficiency, reduced slow-wave sleep, and increased prevalence of sleep-disordered breathing, which contribute to long-term sleep challenges [19]. These findings suggest that while menopause may trigger initial disruptions, ageing eventually plays a more dominant role in shaping sleep patterns over time [18].

Sleep regularity is a key indicator of healthy sleep, aside from sleep quantity, as it is associated with many health-related outcomes such as cardiometabolic health and risk [20], metabolic homeostasis [21], mortality risk [22], performance [23–25], mental health [26] and Delayed Sleep-Wake Phase Disorder [27]. Recent evidence has also shown that for early elder age women, irregular sleep is associated with worse cognitive health [28]. Moreover, Windred et al. found that higher Sleep Regularity Index (SRI) scores were significantly associated with reduced risks of all-cause mortality, cancer-related mortality, and cardiometabolic disease mortality [22]. Notably, sleep regularity was a stronger predictor of mortality risk than total sleep duration [22]. Among menopausal women, sleep regularity has gained increasing attention due to its potential sensitivity to hormonal fluctuations and vasomotor symptoms, both of which may disrupt circadian rhythms and behavioural sleep patterns [29–31]. Thurston et al. (2012) used actigraphy and physiological monitoring to show that self-reported vasomotor symptoms, rather than physiologically measured ones, were associated with poorer objective sleep quality, suggesting that the perception and recall of symptoms may play a key role in menopausal sleep disturbance [32]. Baker et al. similarly found that peri- and postmenopausal women experiencing hot flushes had lower sleep efficiency and greater variability in night-to-night sleep patterns compared to those without hot flushes [33]. However, while Young et al. reported that perimenopausal and postmenopausal women expressed greater dissatisfaction with their sleep compared to premenopausal women, objective sleep measurements did not show significant differences among the groups [34]. These findings suggest that subjective sleep complaints during the menopausal transition may be influenced by factors beyond measurable sleep disruptions, such as hormonal changes and psychological stressors.

Actigraphy, employed since the early 1970s as a widely used methodology for investigating sleep patterns over extended durations [35, 36], is considered a cost-effective way for assessing sleep patterns [29, 35, 37]. Extensive evaluations of its reliability and validity in sleep-wake classification have been conducted across diverse populations across the lifespan and under different conditions, consistently demonstrating high concordance with polysomnography results [38–43].

While previous studies have used actigraphy to examine sleep characteristics in midlife women, few have focused on capturing night-to-night variability in relation to menopausal symptoms. For instance, Thurston et al. used actigraphy to demonstrate that vasomotor symptoms were associated with poorer sleep quality in menopausal women [32]. Similarly, the Study of Women's Health Across the Nation (SWAN) investigated sleep regularity and its association with psychological health in women aged over 60 years, finding that irregular sleep patterns were associated with increased depressive symptoms and reduced quality of life in this population [44]. However, the SWAN study predominantly focused on post-menopausal women and did not specifically address sleep variability or its relationship to menopausal symptoms such as vasomotor disturbances. This leaves a critical gap in understanding sleep patterns in peri-menopausal women, who often experience more pronounced hormonal fluctuations and unique sleep disturbances during the menopausal transition. Given the frequent sleep disturbances and poor sleep quality in menopausal women, it is of particular interest to explore the relationship between menopausal symptoms and sleep regularity over an extended period. This observational study aimed to describe the sleep patterns of a sample of women experiencing menopausal symptoms and explore the potential contribution of menopausal symptoms to insomnia symptoms, sleeping behaviours and intraindividual sleep variability.

3.2 Method

3.2.1 Participants

This study included 39 peri- or post-menopausal women between 45 and 65 years of age (mean age: 52.1 ± 3.5 years old). Participants were recruited via advertisements through local newspapers, social media and referred by a recruiting agency, the Trialfacts (https://trialfacts.com) from the Great Sydney Area, NSW, Australia.

Inclusion criteria required participants to be generally healthy women aged 45 to 65 years with a BMI not exceeding 30 kg/m^2. Eligible participants were defined as: experiencing vasomotor symptoms, or irregular menstruation periods due to menopause transition within the preceding 12 months (peri-menopausal), or having ceased menses for at least 1 year but no more than 2 years (postmenopausal), or had ceased menses for more than 2 years but still experiencing vasomotor symptoms on a daily basis, or had bilateral oophorectomy at least 6 weeks before screening (surgical menopause). Vasomotor symptoms were assessed using the Modified Greene Climacteric Scale (Greene Scale) [45] and self-reported number of hot flushes per day via a screening questionnaire. While hormonal testing (e.g., follicle-stimulating hormone [FSH] levels) was not conducted due to resource constraints, menopausal status was confirmed through self-reported menstrual history and well-established symptoms, and the Greene Scale provides reliability to participant classification [46, 47].

Individuals were excluded if they were shift workers, had chronic or existing health issues (e.g., cardiovascular diseases, pulmonary diseases, diabetes, or metabolic syndrome), were on hormone replacement therapy (HRT) or were on medications that might impact sleep.

The study was approved by the University of Sydney Ethics Committee (protocol number [2019-151]) and the Sydney Local Health District Human Research Ethics Committee - Concord Repatriation General Hospital (2020/ETH03028).

3.2.2 Materials and Measures

3.2.2.1 Actigraphy

The MotionWatch8 (©2024 CamNtech Ltd and CamNtech Inc, Cambridgeshire, UK) actigraphy was selected for this study due to its widespread clinical and research use, compatibility with legacy actigraphy scoring protocols, and manufacturer-supported algorithms validated for 30-second epochs. It has been previously validated in general adult populations [48], enabling comparisons with earlier work while allowing us to explore its applicability in a thermally challenging setting. Recordings were taken in 30-second epochs using MotionWatch Mode 1, which is an epoch-based recording mode using a single axis algorithm and peak detection. Participants wore it on the non-dominant wrist.

The actigraphy recordings were processed using the software's algorithm (MotionWare

1.2.28, CamNtech Ltd., Cologne, Germany). This algorithm is defined by the manufacture which is not publicly disclosed in detail, and it is designed to mimic legacy actigraphy devices (e.g., Actiwatch). The movement thresholds used for sleep/wake classification are proprietary and cannot be adjusted by the user. Lights-off and lights-on times for each sleep interval were manually checked and marked by reviewing the light level and activity counts and were cross-checked and adjusted based on the participant's documented sleep log to improve the accuracy of the marked rest interval. The software algorithm then automatically calculated the sleep statistic data.

3.2.2.2 Insomnia Severity Index (ISI)

The Insomnia Severity index (ISI) is a 7-item validated tool assessing the severity and impact of insomnia symptoms over the past two weeks [49]. Scores range from 0 to 28, with higher scores indicating more severe insomnia. The ISI has shown high internal consistency (Cronbach's α = 0.90) and strong construct validity in both clinical and non-clinical adult populations [49].

3.2.2.3 Modified Greene Climacteric Scale

The Modified Greene Climacteric Scale is a validated instrument used to assess a range of menopausal symptoms across several domains. For the purposes of this study, only the vasomotor domain was used, which includes two items: hot flushes and night sweats. Each symptom is rated on a 4-point scale (0 = not at all to 3 = extremely). This scale has shown good internal consistency in menopausal populations (Cronbach's α = 0.83–0.87) and has been validated in both Australian and international cohorts [45, 46].

3.2.3 Study Procedures

Participants attended a screening visit, where demographic information and physical measurements (height, weight, waist circumference, neck circumference, and blood pressure) were taken. Participants also completed questionnaires, including the Insomnia Severity index (ISI) [49] and the Modified Greene Climacteric scale [45]. Eligible participants wore a MotionWatch8 actigraphy device on the non-dominant wrist for at least three consecutive days to collect objective actigraphic sleep data. Seven participants were left-handed and the remaining 32 participants right-handed. The device was removed for showering or water-based exercises. Participants were required to press the event marker button when they were in bed and ready to attempt sleep and again upon waking, allowing for more accurate scoring of the rest interval (time-in-bed). During the monitoring period, participants were instructed to adhere to their usual daily routine and sleeping conditions to minimise behavioural variability.

3.2.4 Data processing

3.2.4.1 Scoring of Actigraphy Data

Actigraphy data were recorded in 30-second epochs and manually scored to ensure accuracy. Lights-off and lights-on times were determined based on the event markers pressed by the participants. In cases where event markers were missing, or misaligned with expected reductions in activity or light values, lights-off and lights-on times were manually adjusted based on designated light and/or activity thresholds, which were guided by prior research [25, 50, 51]. Adjustments were made through consensus among the investigators (XL, CMC, and MH). Following manual scoring of the rest intervals, sleep statistics were automatically calculated using the manufacturer's software algorithm (MotionWare 1.2.28, CamNtech Ltd., Cologne, Germany). Actigraphy data were excluded from analysis if dataset were incomplete due to participant non-compliance or technical issues. The time taken to fall asleep and wake up corresponded to the sleep onset time and sleep offset time respectively, and the midsleep time was calculated based on these values. Sleep duration, as used in this study, was calculated as the interval between sleep onset and sleep offset, which corresponds to sleep period time (SPT) and may include brief awakenings.

3.2.4.2 Daylight Saving Adjustment

The research was conducted in Sydney, NSW, Australia, where Daylight Saving Time begins at 2 AM Australian Eastern Standard Time (AEST) on the first Sunday in October and ends at 3 AM Australian Eastern Daylight Time (AEDT) on the first Sunday in April. In this study, four participants' actigraphy records were affected by the Daylight Saving Time transition. For these cases, the participants' wake-up clock time on the Sunday was manually adjusted back by one hour (adjusted light on time) to yield the correct total sleep time, and all the other parameters were calculated based on the adjusted time accordingly.

3.2.5 Statistical analysis

The sleep onset time, sleep offset time, and midsleep time were converted to minutes from midnight (e.g., 11:59 PM was converted to -1 min and 12:01 AM was converted to 1 min). The average for sleep onset time, sleep offset time, midsleep time, sleep duration across all night for each participant were calculated. Sleep duration (total sleep time) is normally calculated as the total time spent asleep within the time in bed period. Given the limited accuracy of the MotionWatch8 in detecting wake, as demonstrated in the validation study in Chapter 4, sleep parameters such as sleep efficiency (SE) and wake after sleep onset (WASO) were not prioritised in the current analysis, and total sleep time (TST) could not be reliably calculated. Therefore, sleep duration in this study represents the full rest interval, that included awakenings during the sleep period. This decision was made to avoid potential misrepresentation of sleep disruption in this population.

The intraindividual standard deviation (IISD) was applied as an overall metric for quantifying sleep regularity [29]. IISD values for sleep onset time, sleep offset time, midsleep time, and sleep duration across all night for each participant were computed.

Shapiro-Wilk test was used to check the normality of all the parameters for sample size less than 50. Based on the results of the Shapiro-Wilk test, parametric Pearson's correlation was applied for normally distributed variables, while non-parametric Spearman's correlation was used for variables that did not meet normality assumptions. For missing values, pairwise exclusion was applied to ensure that cases with missing data in specific variables were not entirely excluded from the analysis, allowing for the inclusion of all available data for each variable. Correlation analyses were used to evaluate the association of vasomotor symptoms from the Greene Climacteric scale, age and BMI with sleep onset time, sleep offset time, midsleep time sleep duration, their intraindividual standard deviations (IISD), and ISI score.

The intraclass correlation coefficient (ICC) [52] was used to assess the consistency of sleep measurements taken on the same participants over time. Due to different number of nights being recorded for each participant with at least 3 nights recorded for 38/39 participants, ICC for sleep onset time, sleep offset time, midsleep time and sleep duration was calculated using a one-way random model by selecting three nights randomly for each participant, and the analysis was repeated across three different random nights for each participant to ensure that the results were reliable. Fisher's Z tests were conducted to evaluate whether the differences in ICC values between the two sets were statistically significant. Data from 38 participants were included in this ICC analysis. ICC values <0.5 were categorised as poor reliability, between 0.5-0.75 as moderate reliability, 0.75-0.9

as good reliability and >0.9 as excellent reliability [53].

All statistical analyses were conducted using SPSS v.29.0.1.0, with the level of significance set at $p < 0.05$.

3.3 Result

3.3.1 Participants

Recordings from a total of 39 participants were included in the analysis (after removing data with technical issues), covering a total of 357 nights of actigraphy recordings (ranging from 2 to 25 nights per participant). Among these, one participant had a surgically induced menopause, while the remaining participants had natural menopause. All participants reported experiencing vasomotor symptoms on a daily basis at screening, although no quantitative frequency data were collected. Participant characteristics are displayed in Table 3.1.

Table 3.1: Participant characteristics

Variable	n (%)	Mean ± SD	Range
Age		52.1 ± 3.5 years	45 - 63 years
BMI		25.6 ± 3.0 kg/m²	20.0 - 30.0 kg/m²
Menopause type			
Natural	38 (97.4%)		
Surgical	1 (2.6%)		
Menopause stage			
last menses <1 year	15 (38.5%)		
1 year < last menses <2 years	18 (46.2%)		
Last menses >2 years	6 (15.4%)		
ISI score		11.0 ± 4.1	2 - 23
Vasomotor score from Greene			
Climacteric Scale		2.4 ± 1.1	0 - 6
Hot flashes		1.2 ± 0.6	0 - 3
Sweating at night		1.2 ± 0.6	0 - 3
Number of nights of recording	357 nights (100%)	9.1 ± 5.6 per participant	2 - 25

3.3.2 Sleep Characteristics

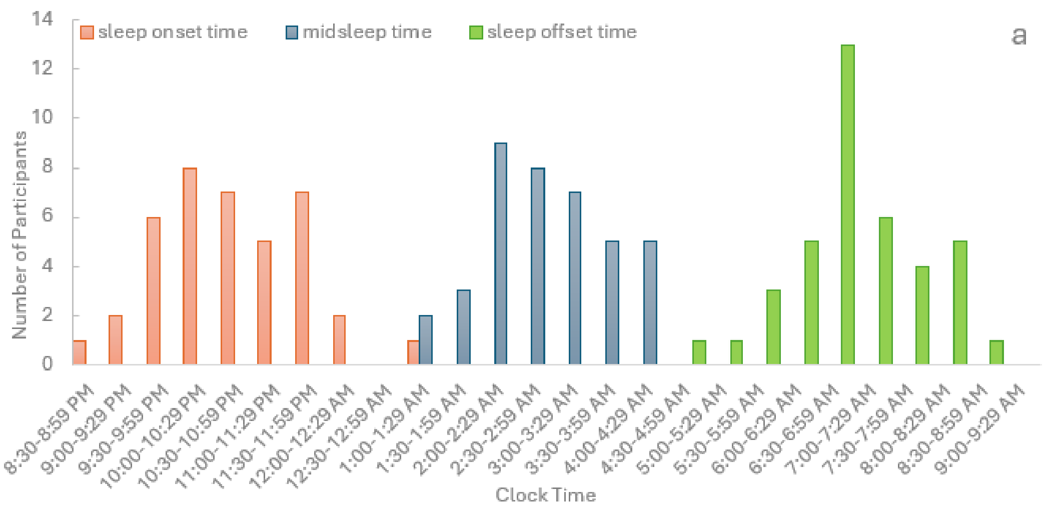
The average sleep onset time, midsleep time, sleep offset time and sleep duration for each participant are displayed in Figures 3.1a and 3.1b, respectively.

Table 3.2 presents the descriptive statistics for sleep timing parameters and their intraindividual standard deviations (IISD) across participants.

Table 3.2: Descriptive Statistics of Sleep Timing Parameters Across Participants (n=39)

	Mean (SD)	Minimum	Maximum	Median
Sleep Onset Time	10:46:42 PM (00:55:12)	8:46:48 PM	1:03:30 AM	10:49:47 PM
Sleep Offset Time	6:57:01 AM (00:49:42)	4:31:40 AM	8:37:43 AM	6:55:15 AM
Mid-Sleep Time	2:54:02 AM (00:44:12)	1:27:53 AM	4:17:44 AM	2:53:55 AM
Sleep Duration (min)	490.3 (57.4)	360.8	611.6	497.5
IISD of Sleep Onset Time (min)	55.3 (25.2)	16.7	129.5	50.8
IISD of Sleep Offset Time (min)	53.3 (25.5)	9.3	149.9	50.3
IISD of Midsleep Time (min)	45.0 (19.7)	9.4	90.6	40.6
IISD of Sleep Duration (min)	63.0 (27.5)	23.3	142.1	56.9

Sleeping behaviour was highly variable among participants, with sleep onset times ranging from 8:46 PM to 1:03 AM and sleep offset times between 4:31 AM and 8:38 AM. Midsleep times varied from 1:28 AM to 4:18 AM, while total sleep duration ranged from



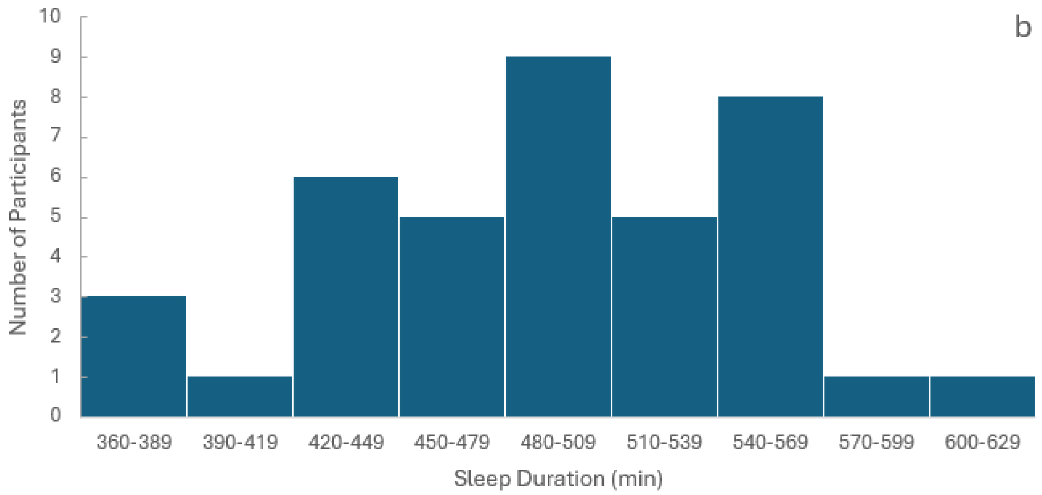


Figure 3.1: Distribution of sleep onset time, mid sleep time, sleep offset time and sleep duration (n=39)
Figure 3.1a: The distribution of average sleep onset, midsleep, and offset times for all participants (N=39).
Figure 3.1b: Frequency plot of average sleep duration distribution for each participant (N=39).

361 to 612 minutes across all nights. Sleep regularity was also very variable with IISD for sleep parameters ranging from 9 to 150 minutes.

3.3.2.1 Correlation analysis of sleep timing and vasomotor symptoms

Normal distribution was confirmed for all variables except IISD of sleep onset time, IISD of sleep offset time, IISD of sleep duration and all the vasomotor scores including hot flushes and sweating at night.

Table 3.3 displays the correlation coefficients (Pearson's r and Spearman's Rho), along with their 95% confidence intervals (CI) and p-values, examining the associations between participant characteristics (age, BMI, vasomotor symptoms derived from the Greene Climacteric Scale) and various sleep parameters.

Participant characteristics and vasomotor symptoms were not significantly ($p>0.05$) associated with any sleep parameters. The results showed weak or negligible associations across all examined variables, with correlation coefficients ranging from -0.21 to 0.31.

Table 3.3: Correlation coefficients between participant characteristics, vasomotor symptoms and sleep parameters

	Age	BMI	Hot flushes score	Sweating at night score	Vasomotor score
Average sleep onset time	0.31 [-0.01, 0.57], p=0.059	-0.20 [-0.49, 0.12], p=0.216	0.04 [-0.29, 0.36], p=0.812^	-0.08 [-0.4, 0.25], p=0.631^	0.00 [-0.33, 0.33], p=0.992^
Average sleep offset time	0.09 [-0.23, 0.40], p=0.570	0.06 [-0.26, 0.37], p=0.728	-0.07 [-0.39, 0.26], p=0.658^	0.03 [-0.31, 0.35], p=0.881^	-0.04 [-0.36, 0.29], p=0.813^
Average mid sleep time	0.24 [-0.08, 0.52], p=0.136	-0.09 [-0.40, 0.23], p=0.569	-0.02 [-0.35, 0.31], p=0.907^	-0.01 [-0.34, 0.32], p=0.952^	-0.01 [-0.34, 0.32], p=0.940^
Average sleep duration	-0.21 [-0.50, 0.11], p=0.189	0.25 [-0.07, 0.52], p=0.128	-0.08 [-0.40, 0.25], p=0.619^	0.06 [-0.27, 0.38], p=0.724^	-0.05 [-0.38, 0.28], p=0.751^
IISD of sleep onset time	-0.13 [-0.44, 0.2], p=0.420^	0.27 [-0.06, 0.55], p=0.092^	-0.14 [-0.45, 0.20], p=0.409^	-0.03 [-0.36, 0.30], p=0.855^	-0.12 [-0.43, 0.22], p=0.486^
IISD of sleep offset time	-0.06 [-0.37, 0.27], p=0.739^	-0.14 [-0.45, 0.19], p=0.387^	-0.14 [-0.45, 0.20], p=0.404^	0.06 [-0.27, 0.38], p=0.706^	-0.08 [-0.40, 0.25], p=0.629^
IISD of mid sleep time	0.08 [-0.24, 0.39], p=0.626	0.02 [-0.30, 0.33], p=0.918	-0.05 [-0.37, 0.28], p=0.770^	0.12 [-0.22, 0.43], p=0.470^	0.02 [-0.31, 0.35], p=0.894^
IISD of sleep duration	-0.15 [-0.45, 0.19], p=0.370^	-0.14 [-0.44, 0.20], p=0.406^	-0.13 [-0.44, 0.20], p=0.422^	-0.11 [-0.42, 0.23], p=0.524^	-0.15 [-0.45, 0.19], p=0.385^
ISI score	-0.05 [-0.36, 0.27], p=0.757	0.2 [-0.12, 0.49], p=0.212	-0.02 [-0.35, 0.31], p=0.889^	0.12 [-0.21, 0.44], p=0.456^	0.07 [-0.27, 0.39], p=0.688^

^ Spearman's Rho was used as variables were not normally distributed

3.3.2.2 Intraclass Correlation Coefficient

Table 3.4 presents the intraclass correlation coefficient (ICC) values and 95% confidence intervals (CI) for sleep onset time, sleep offset time, midsleep time, and sleep duration, calculated from two independent random sets of three nights each, with the p-values derived from Fisher's Z tests indicating the statistical significance of differences in ICC values between the two sets.

Table 3.4: Intraclass Correlation Coefficients (ICCs), 95% Confidence Intervals, and Fisher's Z Test p-values for sleep parameters across two independent sets of nights (n=38)

Variable	3 Random nights (Set 1)		3 Random nights (Set 2)		p
	ICC	95% CI	ICC	95% CI	
Sleep Onset Time	0.66	(0.41, 0.81)	0.59	(0.30, 0.77)	0.982
Sleep Offset Time	0.65	(0.40, 0.80)	0.57	(0.27, 0.76)	0.896
Midsleep Time	0.67	(0.44, 0.82)	0.59	(0.30, 0.77)	0.934
Sleep Duration	0.61	(0.33, 0.78)	0.62	(0.35, 0.79)	0.983

The p-values derived from Fisher's Z tests indicated no significant differences in ICC values between the two sets of 3 random nights, with all p-values exceeding 0.05.

3.4 Discussion

The classification of menopausal status in this study aligns with widely accepted methods used in previous research, which categorise women into premenopausal, perimenopausal, and postmenopausal groups based on menstrual regularity and cessation [46, 54]. Our sample, with an average age of 52.1 ± 3.5 years (range: 45-63 years), primarily represents women in the peri- and early postmenopausal stages.

The low subjective vasomotor scores (mean = 2.4 ± 1.1) in our study are consistent with findings from community-based samples, such as the Dutch study by Barentsen et al. [54], which reported scores of 2.82 ± 1.75 among peri-menopausal women, and the Ecuadorian study by Sierra et al. [55], which reported scores of 2.4 ± 1.61 in the same group. Hot flushes (1.2 ± 0.6) and night sweating (1.2 ± 0.6) in our cohort were within a similar range to those reported in the Ecuadorian population (hot flushes: 1.38 ± 0.85; night sweating: 0.9 ± 0.85). While night sweat scores were slightly higher in our sample, these differences were small considering the scale's range (0–3) and may reflect differences in local ambient temperature conditions and cultural perceptions [32]. The comparison of vasomotor symptom severity across studies is further complicated by differences in the reporting format, as most population-based studies present total Greene scores rather than subscale means. Differences in BMI (mean = 25.6 ± 3.0 kg/m^2 in our study) and exclusion of women with chronic health conditions may have contributed to the lower vasomotor scores in our cohort.

Participants in this study reported a mean Insomnia Severity Index (ISI) score of 11.0 ± 4.1, indicating subthreshold insomnia [56]. Numerous studies have used the ISI to assess sleep disturbances in menopausal populations. Otte et al. [57] demonstrated that ISI is a reliable tool for evaluating the severity of insomnia symptoms and their impact on daytime functioning in middle-aged women with vasomotor symptoms. Similarly, Masoudi et al. [58] reported a significant correlation between ISI scores and perceived stress in postmenopausal women, highlighting the relevance of ISI in capturing the multifaceted nature of sleep disturbances during menopause. Hachul et al. [59] further reported that hot flushes were more prevalent among women with insomnia disorders (25.5%) and those with isolated insomnia symptoms (23.0%) compared to good sleepers (12.6%), emphasising the strong association between vasomotor symptoms and sleep disturbances. These findings suggest that vasomotor symptoms interact with behavioural and physiological factors, contributing significantly to insomnia.

In examining the sleeping behaviour of menopausal women, variability in sleep duration and sleep timing was evident, with interindividual differences comparable to intraindividual variations, as indicated by the similarity between interindividual standard deviations (SD) and intraindividual standard deviations (IISD). This suggests that intraindividual night-to-night variability was as substantial as the differences observed between participants, highlighting the dynamic nature of sleep patterns during menopause. The ICC values (ranging from 0.57 to 0.67) demonstrated a moderate consistency in sleep measurements across different nights, suggesting that while sleep timing exhibited some degree of consistency within individuals, night-to-night variability remained substantial, consistent with the substantial intraindividual variability observed in IISD measures. Sleep regularity, as measured by IISD, has been identified as a critical predictor of health outcomes, including cardiometabolic health, cognitive function, and mortality risk [22, 29]. Research has highlighted the role of circadian rhythm instability in menopausal sleep disturbances [16]. Disrupted wake times are closely linked to circadian misalignment, negatively impacting sleep quality [22, 60–62]. While our study observed average sleep durations within the normal range, the variability in sleep timing may have a more profound impact on sleep quality.

Despite the well-recognised link between vasomotor symptoms and sleep disturbances [46] or reduced sleep quality [9, 10], the current study found no significant correlation between vasomotor symptoms like hot flush or night sweat severity as measured by the Greene Climacteric Scale ($p = 0.680$) and sleep outcomes. This aligns with findings from Kravitz et al. [63], which suggest that vasomotor symptoms alone may not fully explain sleep disturbances in menopausal women. Instead, psychological stress, anxiety, and environmental factors may play a mediating role [32].

A marginally significant correlation ($p = 0.059$) was found between age and average sleep onset time ($r = 0.31$), indicating older participants tended to go to bed earlier. Previous studies have shown that advancing age is associated with earlier sleep onset and wake times, as well as shifts in circadian preference [19]. However, the marginal significance observed in this study indicates that these age-related changes may not be consistent across individuals, particularly in a sample undergoing the hormonal and physiological transitions associated with menopause, which may independently influence sleep timing.

Although preliminary bivariate analyses did not reveal statistically significant associations between vasomotor symptoms and actigraphy-derived sleep parameters, we also conducted exploratory multiple regression models controlling for key covariates such as age and insomnia severity. These models likewise did not yield significant effects, likely due to the limited sample size and weak underlying associations. Future research with larger sample sizes is needed to enable multivariate modelling and more precise investigation of these relationships.

One key limitation of this study is the relatively small sample size (N = 39), which may have reduced the statistical power to detect subtle relationships between vasomotor symptoms and sleep parameters. Additionally, the limited sample size and mild nature of the vasomotor symptoms restrict the generalisability of the findings to broader populations with more diverse demographic and cultural backgrounds. Another limitation concerns the minimum actigraphy recording duration of three nights, which may be insufficient to fully capture night-to-night variability in sleep behaviours. Although participants on average provided over 9 nights of data (mean = 9.1 $\pm$ 5.6), current consensus in actigraphy research recommends at least 7 and preferably 14 nights to obtain stable sleep estimates [29, 35, 37]. Given that SE and WASO are often used to characterise sleep disruption in menopause, their exclusion is acknowledged as a limitation. However, due to poor wake detection accuracy of the MotionWatch8 observed in our validation study (Chapter 4), these measures were deemed unreliable for this sample and therefore omitted. The observed moderate intraclass correlation coefficients in our study suggest acceptable within-subject consistency; however, future research should aim to standardise and extend the duration of actigraphy recordings to enhance reliability and comparability across studies. Future studies with larger, more diverse cohorts are needed to validate these results and explore potential subgroup differences, such as the influence of hormonal therapy, lifestyle factors, or geographic variations on sleep and vasomotor symptoms.

3.5 Conclusion

By integrating objective measures like actigraphy with subjective assessments, this study investigated the sleeping behaviour and the association between vasomotor symptoms and sleep parameters in peri- and postmenopausal women. The women reported mild vasomotor symptoms and variability in sleep duration and sleep timing. The lack of significant correlations suggests that other factors, such as mood changes, lifestyle, and environmental influences, may play a mediating role. Future research should investigate these interactions in diverse populations with a larger sample size, providing a more comprehensive understanding of menopausal sleep health.

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Chapter 4: Validation of MotionWatch8 Actigraphy Against Polysomnography in Menopausal Women Under Warm Conditions

AUTHORSHIP ATTRIBUTION STATEMENT

This chapter is being prepared for submission for *Sensors*.

I co-designed the study with the co-authors, collected, analysed, and interpreted the data, and wrote the drafts of the manuscript.

In addition to the statements above, in cases where I am not the corresponding author of a published item, permission to include the published material has been granted by the corresponding author.

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CHAPTER 4

Validation of MotionWatch8 Actigraphy Against Polysomnography in Menopausal Women Under Warm Conditions

Abstract

Background: Sleep monitoring devices, such as wrist actigraphy, offer a practical alternative to polysomnography (PSG) for large-scale and long-term sleep studies. However, their accuracy and reliability require validation in specific populations and settings. This study evaluates the agreement between MotionWatch8 and PSG in measuring key sleep parameters in menopausal women under controlled laboratory conditions at $30°C$.

Methods: A total of 16 peri- and post-menopausal women (age: 51.4 ± 4.2 years, BMI: 26.0 ± 3.1 kg/m^2) participated in this study, each scheduled for four nights of sleep recordings. After excluding nights with technical issues, a total of 59 nights of valid simultaneous PSG and MotionWatch8 recordings were available for analysis. Sleep parameters, including sleep onset latency (SOL), total sleep time (TST), sleep efficiency (SE), and wake after sleep onset (WASO) were compared using Bland-Altman plots, linear mixed model (LMM) analysis and epoch-by-epoch comparisons.

Results: MotionWatch8 overestimated TST by 18.6 minutes and SE by 3.5%, while underestimating SOL by 11.2 minutes and WASO by 9.1 minutes compared to PSG, with significant differences ($p < 0.05$) observed for TST, SE and SOL with a marginally significant difference observed for WASO ($p = 0.063$) in the LMM analysis. Bland-Altman plots revealed significant proportional errors, particularly for participants with prolonged SOL, high WASO and lower SE. Epoch-by-epoch analysis demonstrated high sensitivity for sleep detection (94.8%) but low specificity for wake detection (33.1%), with an overall accuracy of 87.3%.

Conclusions: MotionWatch8 overestimated total sleep time and sleep efficiency while underestimating sleep onset latency and wake after sleep onset compared to PSG under warm conditions. Proportional biases identified for SOL, WASO and SE indicate that measurement accuracy declines as their values increase, leading to larger discrepancies with PSG. These findings suggest that MotionWatch8 may be less reliable for individuals with more extreme sleep characteristics (e.g., insomnia), highlighting the need for caution in its use for detailed sleep assessments.

4.1 Introduction

Menopause is a significant life transition that can drastically affect a woman's health, with sleep disturbances being one of the most reported issues [1, 2]. Sleep disturbances affect around 40%-60% of menopausal women [3, 4]. Vasomotor symptoms, such as hot flushes and night sweats, reported by 75% of menopausal women, contribute to sleep disturbances [3, 5, 6]. Despite their high prevalence and considerable impact, sleep disturbances in menopausal women are often overlooked or trivialised. Accurately capturing sleep disturbances in menopausal women is critical to understanding their extent and developing effective approaches to address their impact.

While polysomnography (PSG), the gold standard for sleep measurement, captures important data on sleep architecture and patterns [7], it is impractical for tracking sleep over extended periods. Nevertheless, the SWAN Sleep study demonstrated the feasibility of conducting 3-night PSG recordings, albeit in-home studies [8]. Actigraphy, a non-invasive method that tracks movement, offers an accessible alternative in the home and field setting for long-term monitoring [9–11]. Since its introduction in the 1970s, actigraphy has been widely used and validated in diverse populations [9, 12], consistently demonstrating high concordance with PSG results across different conditions, such as insomnia, circadian rhythm disorders, and chronic health conditions, as well as across age groups ranging from children, adolescents to older adults [13–19].

However, despite its widespread application, few studies have specifically validated actigraphy in menopausal women, a population uniquely affected by sleep disturbances due to hormonal fluctuations. The menopausal symptoms of hot flushes and night sweats often lead to fragmented sleep, increased nocturnal movement and frequent arousals, which may not be reliably captured by movement-based sleep detection algorithms [20]. Notably, studies that validated the MotionWatch© consistently reported high sensitivity for detecting sleep, typically ranging from 91% to 96%. However, the specificity for detecting wakefulness was considerably lower, often below 40%. This was observed in various target groups such as non-shift working adult population [19, 21–25], healthy adults [15] and individuals with insomnia [26, 27]. These studies noted an overestimation of total sleep time and an underestimation of wake time in both wrist- and hip-worn accelerometers [27]. These findings suggest that patient groups or individuals with disrupted or poor sleep are likely to experience misclassification of their sleep and wake epochs. These limitations are especially pertinent in populations with disrupted or light sleep – such as menopausal women experiencing vasomotor symptoms – where brief arousals or motionless wakefulness are likely to be misclassified as sleep.

The performance of actigraphy under warm environmental conditions also remains unclear. This issue is particularly important in regions regularly experiencing summer temperatures exceeding $30°C$, such as Sydney and Melbourne (Australia) [28, 29], Cancun (Mexico) with an average temperature of $30.5°C$ in January [30], many coastal cities in China [31] and eastern United States [32]. Countries with this average temperature all year round include Qatar and Kenya [33, 34]. Warm conditions are often a trigger for hot flushes [35–37]. However, the ambient temperature of $30°C$ for this study was not selected to provoke vasomotor symptoms, but rather to minimise thermal variability caused by bedding or external insulation. Participants in this study wore only long-sleeved sleepwear without blankets, ensuring that the thermal environment remained standardised across individuals. This temperature closely mimics the typical thermoneutral skin microclimate under bedding, which has been reported to range from $30°C$ to $32.5°C$, supporting thermal comfort during sleep [38]. This approach allowed for a controlled environment that minimised thermal noise and enabled an accurate validation of the MotionWatch8's performance under conditions mimicking typical sleep microclimates.

In addition to affecting human physiology, elevated ambient temperatures can impair the performance of actigraphy devices themselves. Specifically, prolonged exposure to heat and humidity can degrade the signal fidelity, bandwidth, and overall stability of MEMS-based accelerometers, which are the core sensing units in actigraphy devices [39–41]. MEMS-based accelerometers, the sensing units embedded in actigraphy, exhibit temperature-related drift in sensitivity and bias [42–44], and this drift may be exacerbated under thermally unstable conditions, such as those commonly experienced by menopausal women during hot flush episodes [20, 39]. Supporting this, previous research by Shin et al. [45] demonstrated that ambient temperature can influence the behaviour and accuracy of actigraphs in sleep measurements, suggesting that environmental conditions must be considered when validating these devices.

Taken together, these physiological and technological challenges underscore the necessity of evaluating actigraphy performance specifically in menopausal women under warm conditions. This study therefore aims to address this gap by validating the effectiveness of the MotionWatch8© (CamNtech Ltd, Cambridgeshire, UK) against PSG in measuring sleep parameters among menopausal women under controlled warm laboratory conditions.

4.2 Method

4.2.1 Participants

A total of 16 peri- or post-menopausal women from the Great Sydney Area, NSW, Australia, participated in this study. Participant characteristics are summarised in Table 4.1.

Inclusion criteria: Participants were required to be experiencing vasomotor menopausal symptoms, defined as a vasomotor scale score ≥2 on the Modified Greene Climacteric Scale [46] or with self-reported daily hot flashes or night sweats. Additional criteria included irregular menstruation period due to menopause transition over the past 12 months (perimenopausal), cessation of menstruation for at least one year (post-menopausal), or bilateral oophorectomy (surgically induced menopause) at least six weeks prior to screening.

Exclusion criteria: Individuals were excluded if they were shift workers, had sleep difficulties or sleep disorders, chronic health conditions affecting sleep (e.g., cardiovascular diseases, pulmonary diseases, diabetes or metabolic syndrome), were on hormone replacement therapy (HRT) or were taking medications that could impact sleep.

Recruitment strategy: Participants were mainly recruited via advertisements through flyers, local newspapers, social media and referrals from a recruiting agency, the Trialfacts (https://trialfacts.com).

Actigraphy and PSG data were collected simultaneously during overnight sleep studies.

Table 4.1: Participant characteristics

Variable	n (%)	Mean ± SD	Range
Age		51.4 ± 4.2 years	45-63 years
BMI		26.0 ± 3.1 kg/m²	20.7-30.0 kg/m²
Menopause type			
Natural	15 (93.8%)		
Surgical	1 (6.3%)		
Menopause stage			
last menses <1 year	8 (50.0%)		
1 year < last menses <2 years	6 (37.5%)		
Last menses >2 years	2 (12.5%)		
Dominant Hand			
Right	13 (81.3%)		
Left	3 (18.8%)		
Ethnicity			
Asian	4 (25.0%)		
Caucasian	12 (75.0%)		

4.2.2 Study procedures

During the laboratory visits, participants underwent screening by completing several questionnaires about health history, sleep-related scales, menopausal status and menopause symptoms. Demographic information was collected. Physical measurements, including height, weight, waist and neck circumference, and blood pressure were recorded.

Eligible participants completed four overnight sleep studies inconsecutively with at least one night interval between studies in a controlled laboratory environment. The bedroom was maintained at a temperature of $30°C$ ($30.1±0.5°C$) and relative humidity of 50% (46.4±2.7%) as part of a broader investigation into the effects of sleepwear fibre type on sleep quality.

On each study night, participants arrived approximately 4.5-5 hours before their usual bedtime. A standardised dinner was served at 4 hours before their usual bedtime, following a physical examination. Participants were encouraged to maintain adequate fluid intake during the day but to restrict water consumption within two hours before bedtime to minimise nocturnal awakenings. PSG setup, including electrode and sensor placement, began 1.5-2 hours before bedtime. Participants remained in the waiting area before transitioning to the sleeping room 20 minutes prior to lights-off. The lights-off and lights-on times corresponded to participants' usual bedtimes and wake-up times, ensuring adherence to their typical sleep routines. During the PSG study, participants wore the MotionWatch8© on their non-dominant wrist for the entire sleep period to capture actigraphy data concurrently.

4.2.3 PSG recording

Overnight PSG sleep data were collected using Compumedics E-series or W-series Sleep system (Compumedics Australia Pty Ltd., Australia). A standardised procedure for the placement of 10-20 electrodes was followed according to the American Academy of Sleep Medicine (AASM) guidelines [47].

Electrode placement included the following:

Electroencephalogram (EEG): Five scalp electrodes referenced to mastoid processes (C3-M2, C4-M1, O1-M2, O2-M1, F3-M2), Cz on the scalp as reference and one ground electrode Fpz on forehead.

Electrooculogram (EOG): Bilateral electrodes placed near the outer canthus of each eye.

Electromyogram (EMG): Submental electrodes placed under the chin to record muscle activity.

Electrocardiogram (ECG): Electrodes placed on the chest to monitor heart activity.

All signals were sampled at a frequency of 256Hz.

4.2.4 PSG data scoring

The PSG recordings were scored by an external independent experienced scorer according to the AASM manuscript [47]. A report was generated using the Compumedics Profusion PSG4 software including the following items: report start and end time/duration, lights-off and lights-on time, time available for sleep, sleep latency, REM latency, sleep period start and end time/duration, wake after sleep onset, total sleep time (minutes), NREM sleep, sleep stages (N1/N2/N3/REM) time and proportion, and sleep efficiency. The stage of each epoch was also exported.

4.2.5 MotionWatch8 recording and scoring

The MotionWatch 8 employs a tri-axial accelerometer. Recordings were taken in 30-second epochs using MotionWatch Mode 1, which used a single axis algorithm and peak detection. Participants wore it on the non-dominant wrist.

The actigraphy recordings were processed using the software's algorithm (MotionWare 1.2.28, CamNtech Ltd., Cologne, Germany). Lights-off and lights-on times for each sleep interval were manually checked and marked by reviewing the light level and activity counts and were cross-checked and adjusted based on the participant's documented sleep log to improve the accuracy of the marked rest interval. The software algorithm then automatically calculated the sleep statistic data.

4.2.6 Data analysis

To assess the agreement between PSG and actigraphy, both sleep summary statistics and epoch-by-epoch analyses were performed using data across the sleep period. Nights with incomplete actigraphy or PSG recordings were excluded from the analysis.

Bland-Altman plots were used to assess the agreements between MotionWatch8 and PSG for the sleep outcome variables of total sleep time (TST), sleep efficiency (SE), sleep onset latency (SOL) and wake after sleep onset (WASO). Each night's data was treated as an independent observation in the analysis, meaning that data from different nights for the same participant were analysed separately, rather than averaged or combined. Given the relatively small sample size (n = 16), more complex multilevel or nested Bland-Altman models were not statistically appropriate, as such models require larger samples to yield stable and interpretable estimates [48]. In the Bland-Altman plots, each data point represents the sleep parameters recorded for a single night, regardless of whether the nights belonged to the same or different participants. The differences for each sleep variable (displayed on the y-axis) were calculated as actigraphy outcome minus PSG outcome, and the mean of the two measures was displayed on the x-axis. The limits of agreements (LoA) were calculated as the mean difference $\pm 1.96 \times$ standard deviation, which indicated the range of values expected for 95% of individuals. To further evaluate the systematic bias and potential dependency of measurement differences on the size of the measurement, statistical significance tests were performed using SPSS. A one-sample t-test was used to examine whether the mean difference (offset) for each sleep variable significantly deviated from zero. Linear regression analyses were conducted to assess whether the differences (dependent variable) were significantly associated with the mean values (independent variable). The regression slope was tested for significance to determine if the measurement bias varied across the range of measurement values.

To assess the agreement between PSG and MotionWatch8, sleep parameters, including SOL, TST, SE, and WASO were compared using a linear mixed model (LMM) in SPSS. The LMM approach was chosen to account for the repeated measures design as each participant contributed up to four nights of data, and to incorporate both fixed and random effects. The model included device (PSG vs. MotionWatch8) as a fixed factor to evaluate the main effects of measurement method and visit number (night-to-night variability) as a repeated fixed factor. Study ID was included as a random intercept to account for within-subject correlation across repeated measures, with a first order autoregressive covariance structure (AR1) specified. Estimated Marginal Means (EM Means) were generated for device to compare main effects. The model employed restricted maximum likelihood estimation (REML) for parameter estimation and used the Satterthwaite approximation for calculating degrees of freedom.

Epoch-by-epoch comparison was made to calculate sensitivity, specificity and accuracy. Only the epochs that both the actigraphy and PSG have stages were analysed. Sleep epochs were coded as 1 and awake epochs were coded as 0. Sensitivity reflects sleep agreement and was calculated as the number of true sleep (TP) / (TP+ number of false wake epoch (FN)). Specificity measures wake agreement and was calculated as the number of true wake epoch (TN)/ (TN + number of false sleep epoch (FP)). Accuracy shows the overall performance of sleep and wake detection for the actigraphy against PSG, which was calculated as (TP + TN) / (TP + TN + FP + FN).

All the analysis were conducted using SPSS v.29.0.1.0 and Microsoft Excel. The level of significance was set at $p < 0.05$.

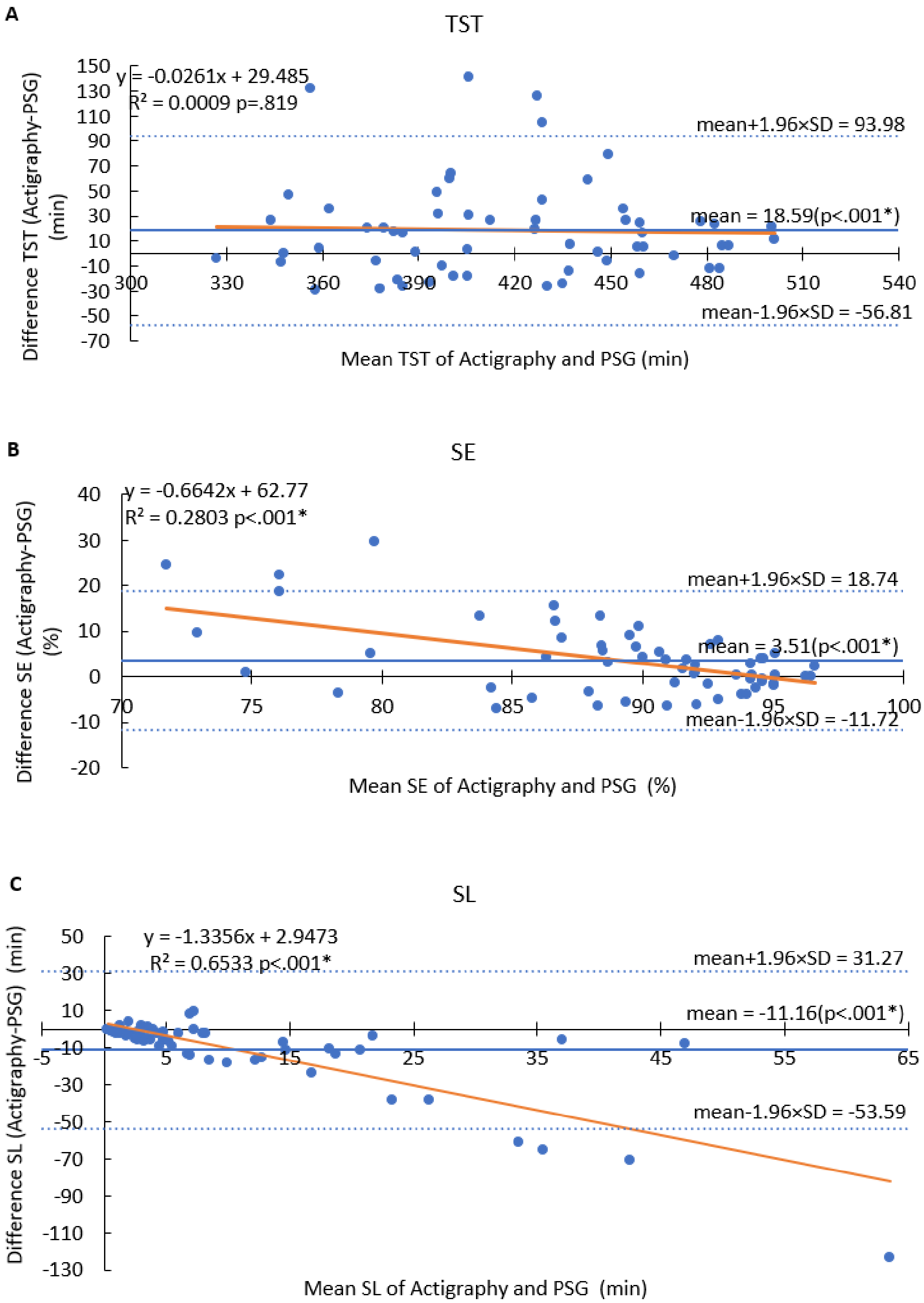
4.3 Result

After excluding nights with technical issues, a total of 59 nights of valid recordings from 16 participants were included for analysis. Participants' ages ranged from 45 to 63 years old (51.4 ± 4.2 years).

4.3.1 Bland-Altman plots

The Bland-Altman plots for SOL, TST, SE and WASO are displayed in Figure 4.1. The MotionWatch8 tended to overestimate TST by an average of 18.6 minutes, with LOA ranging from -56.8 minutes to 94.0 minutes. No proportional bias was found for TST ($p = 0.819$, $R^2 = 0.0009$). It overestimated SE by 3.5%, with LOA between -11.7% and 18.7% and a significant proportional bias. On the other hand, the MotionWatch8 underestimated SOL by an average of 11.2 minutes, with LOA from -53.6 to 31.3 minutes. The proportional error was significant, particularly for participants with sleep onset latency was greater than 30 minutes. Similarly, WASO was underestimated by 9.06 minutes, with LOA ranging from -74.80 minutes to 56.68 minutes, with a significant dispersion from the mean where WASO was greater than 55 minutes. Supplementary

Table S4.1 provides the mean differences, lower and upper limits of agreement (LOA), ranges, the p value for offset and regression line for SOL, TST, SE and WASO.



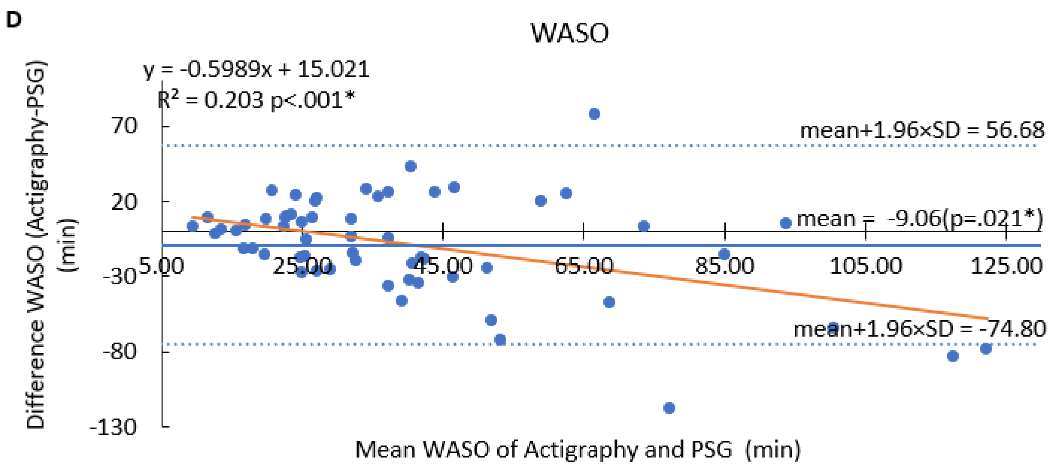


Figure 4.1: Bland-Altman Analysis of Agreement Between MotionWatch8 and PSG for TST, SE, SOL and WASO
Significant results (p<0.05) are marked with*

4.3.2 Linear mixed model

Table 4.2 summarises the linear mixed model (LMM) analysis results for sleep onset latency (SOL), wake after sleep onset (WASO), total sleep time (TST), and sleep efficiency (SE). The table displays the estimated marginal means (Mean ± Std. Error) for each device (PSG and MotionWatch8), along with the F-values and p-values for the main effect of device.

Table 4.2: Result of Linear Mixed Model Analysis

Sleep Parameter	Device (Mean ± Std. Error)		F-value	Devices
	PSG	MotionWatch8		
SOL (minutes)	16.0 ± 3.2	5.1 ± 3.2	9.835	.004*
WASO (minutes)	45.9 ± 6.6	36.2 ± 6.6	3.729	.063
TST (minutes)	408.1 ±11.0	426.8 ±11.0	11.677	.002*
SE (%)	87.3 ± 1.6	90.9 ± 1.6	10.458	.003*

Significant results (p<0.05) are marked with *

Significant differences were observed between PSG and MotionWatch8 for SOL, TST, SE and as indicated by p-values below 0.05. Additionally, a marginally significant difference was observed for WASO between the two devices (p = .063).

4.3.3 Epoch-by-epoch comparison

Table 4.3 displays the comparison results for sensitivity for sleep, specificity for wake, and accuracy between the classifications of sleep and wake.

Table 4.3: Sensitivity, Specificity, and Accuracy of MotionWatch8 Compared to PSG

	Mean±SD	Range	95%CI
Sensitivity	94.8%±3.2%	85.8%-100%	94.0%, 95.6%
Specificity	33.1%±19.5%	0.0%-82.2%	28.1%, 38.1%
Accuracy	87.3%±6.6%	65.8%-96.8%	85.6%, 88.9%

4.4 Discussion

The present study highlights the utility and limitations of MotionWatch8 for sleep assessment in menopausal women under controlled laboratory, warm conditions. Our study validated the MotionWatch8 against PSG, revealing that MotionWatch8 systematically overestimates sleep duration and underestimates wakefulness-related metrics, particularly in participants with higher SOL, WASO and lower SE values.

Specifically, Bland-Altman plots revealed that MotionWatch8 overestimated total sleep time (TST) and sleep efficiency (SE), while underestimating sleep latency (SOL) and wake after sleep onset (WASO), with significant proportional errors observed for SE, SOL and WASO. The linear mixed model (LMM) analysis results indicated significant differences between PSG and MotionWatch8 for TST, SE and SL, with MotionWatch8 tending to overestimate TST and SE while underestimating SOL compared to PSG. Additionally, a trend toward significance was observed for WASO between the two devices ($p = 0.063$), with MotionWatch8 tending to underestimate WASO compared to PSG.

Significant proportional biases were observed for SOL, SE, and WASO as indicated by their regression slopes, while no proportional bias was found for TST ($p = 0.819$, R^2 =

0.0009). This indicates that while MotionWatch8 performs satisfactorily for objective measurement of sleep parameters in individuals with regular sleep patterns, it may not be suitable for populations with disrupted sleep, e.g. insomnia. Specifically, individuals with prolonged sleep latency (>30 minutes) or high wake after sleep onset (WASO) (criteria that fall under insomnia in DSM-5) [49, 50] are likely to experience larger measurement errors due to the device's reliance on movement-based algorithms. These limitations stem from MotionWatch8's tendency to misclassify periods of quiet wakefulness as sleep and its difficulty in detecting fragmented or disrupted sleep patterns.

Epoch-by-epoch comparisons demonstrated high sensitivity (94.8%) and overall moderate accuracy (87.3%), but low specificity (33.1%) for wake detection. These findings align with previous validation studies of actigraphy devices [19]. Marino et al. [15] and Lichstein et al. [26] both reported similar trends in Actiwatch devices, attributing these overestimations to the reliance on movement-based algorithms that often misclassify quiet wakefulness as sleep. Likewise, studies [27, 51] highlighted actigraphy's inherent limitations in distinguishing wake epochs during periods of minimal movement. Our study extended these findings by observing more pronounced proportional errors for SOL and WASO compared to prior research, potentially due to the controlled laboratory environment and population characteristics. For instance, Full et al. [27] found that SOL errors were less severe in healthy adult populations, potentially due to their shorter sleep latency ranges. While MotionWatch8 demonstrated high sensitivity (94.8%) for sleep detection, its low specificity (33.1%) for wake detection highlights its limitations in distinguishing wake epochs during periods of minimal movement [52]. These findings align with Kosmadopoulos et al. [51], who observed similar challenges in shift workers with irregular schedules. The lack of significant differences in WASO observed in our study differs from some previous findings, potentially due to differences in laboratory conditions or sample characteristics. Moreover, our findings suggest that MotionWatch8's accuracy diminishes significantly in participants with extended SOL or fragmented sleep patterns, which may be a result of its algorithmic limitations under fixed laboratory conditions. These discrepancies highlight the importance of considering device-specific calibration and population-specific factors when interpreting actigraphy data.

Compared to previous validation studies conducted under standard room-temperature conditions (typically 20–24$°C$) [15, 26, 27, 51], the present study demonstrated more pronounced proportional biases, particularly for sleep onset latency (SOL) and wake after sleep onset (WASO). Several factors may contribute to these differences. First, the sample consisted of peri- and post-menopausal women, who were more likely to experience thermoregulatory instability and fragmented sleep due to hormonal fluctuations [53]. These physiological changes may result in extended periods of quiet wakefulness, which actigraphy often misclassified as sleep. Second, a number of participants exhibited extended sleep latency and elevated WASO, sleep patterns commonly associated with insomnia [50]. As actigraphy relies heavily on movement, its performance tends to decline in the context of long periods of motionless wakefulness, leading to overestimated total sleep time and sleep efficiency. Third, the ambient temperature of 30$°C$, although chosen to simulate thermoneutral skin microclimate, may have affected both physiology and sensor accuracy. Elevated temperatures are known to reduce sleep depth and increase arousals, especially in older adults, potentially altering movement patterns and undermining the reliability of movement-based detection [54]. These findings underscore the importance of considering population characteristics and environmental context when interpreting actigraphy-based sleep estimates.

The findings of this study may have broader implications for the use of commercial wearable devices now widely adopted in community and consumer health settings, such as Fitbit, Apple Watch, Oura Ring, Xiaomi Mi Band, Huawei Watch, and Samsung

Galaxy Watch. These devices primarily rely on movement-based algorithms using built-in accelerometers, and in some cases incorporate additional sensors such as photoplethysmography (PPG) to enhance sleep estimation [55–57]. While some platforms like Oura also integrate body temperature and heart rate, movement remains the primary signal for sleep-wake classification [58]. Multiple validation studies have consistently shown that commercial sleep trackers overestimate total sleep time and underestimate wake periods, with accuracy further declining in individuals with fragmented or pathological sleep [55, 59–62]. The performance of commercial wearable is comparable to that of actigraphs. However, their lack of raw data availability to researchers and the continuous updates to their software remain significant drawbacks.

A key strength of this study is the use of simultaneous PSG and actigraphy recordings over multiple nights, providing robust data for analysis. Furthermore, this study uniquely employs multiple statistical methods, including Bland-Altman plots, linear mixed models, and epoch-by-epoch comparisons, offering a comprehensive evaluation of MotionWatch8's performance. These statistical approaches are particularly well-suited to the experimental design and population in this study, enhancing the validity of the findings. However, the controlled laboratory environment may limit generalisability, as natural sleep patterns could be influenced by fixed bedtimes. Additionally, MotionWatch8's reliance on movement-based algorithms poses challenges in detecting wake epochs during periods of quiet rest, which remains a limitation of this device.

4.5 Conclusion

MotionWatch8 demonstrated overestimations for total sleep time (TST) and sleep efficiency (SE) and underestimations for sleep onset latency (SOL) and wake after sleep onset (WASO) compared to PSG. Bland-Altman plot analysis revealed significant proportional biases for SE, SOL, and WASO, while no proportional bias was observed for TST. Linear mixed model (LMM) analysis confirmed significant differences between the two devices for SOL, TST, and SE, and a marginally significant difference for WASO indicating that MotionWatch8 and PSG do not produce interchangeable measurements for these parameters. Epoch-by-epoch comparisons revealed high sensitivity for sleep (94.8%) but low specificity (33.1%) for wake detection, underscoring the device's challenges in accurately identifying wake epochs during periods of minimal movement. These findings suggest that while MotionWatch8 has potential for monitoring overall sleep patterns under warm laboratory conditions, it may be less reliable for individuals with more extreme sleep characteristics (e.g., insomnia), highlighting the need for caution in its use for detailed sleep assessments.

Table S4.1: Bland-Altman Analysis Summary for Sleep Variables

Variable	Mean Difference	Lower LOA	Upper LOA	Range	p (offset)	p (regression slope)
SOL (min)	-11.2	-53.6	31.3	84.9	<.001*	<.001*
WASO (min)	-9.1	-74.8	56.7	131.5	.021*	<.001*
TST (min)	18.6	-56.8	94.0	150.8	<.001*	.819
SE (%)	3.6	-11.7	18.7	30.5	<.001*	<.001*

Significant results (p<0.05) are marked with *

4.6 References

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Chapter 5: How Do Sleepwear and Bedding Fibre Types Affect Sleep Quality: A Systematic Review

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Xinzhu Li co-designed the study with the co-authors, collected, analysed, and interpreted the data, and wrote the drafts of the manuscript.

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Chapter 5

How do sleepwear and bedding fibre types affect sleep quality: a systematic review

Abstract

Sleepwear and bedding materials can affect sleep quality by influencing the skin and body temperature and thermal comfort. This review systematically evaluates the impact of sleepwear or bedding of different fibre types on sleep quality. A systematic search was conducted in six data bases plus Google Scholar and manual searches. Original articles that compared human sleep quality between at least two fibre types of bedding or sleepwear were included, resulting in nine eligible articles included in the review. The fibre types included cotton, polyester, wool and blended materials for sleepwear; cotton, duck down, goose down, polyester and wool for duvet; and linen and a combination of cotton and polyester for bedding. The interplay between fibre materials and sleep quality is complex. Blended sleepwear demonstrated potential benefits for specific populations. Wool sleepwear showed benefits for sleep onset in adults (cool conditions) and in older

adults (warm conditions). Linen bed sheets improved sleep quality under warm conditions in young adults. Goose down-filled duvets increased slow-wave sleep under cool conditions in young adults. However, a systematic comparison of fibre types is challenging due to the diverse nature of the studies evaluating sleep quality. Further research employing standardised methodologies with standard fibre samples in different populations and at different temperature conditions is imperative to comprehensively elucidate the effects of fibre choices on sleep quality. Despite the limitations and heterogeneity of the included studies, this analysis offers valuable insights for individuals seeking to optimise their sleep experiences and for manufacturers developing sleep-related products.

5.1 Introduction

Sleep, accounting for approximately one-third of an individual's lifespan, plays a fundamental role in maintaining human health and overall well-being [1]. Inadequate or poor sleep has been associated with detrimental effects on both cognitive and motor performance, mood regulation, as well as disruptions in metabolic, hormonal, and immunological systems [2, 3]. The body temperature rhythms have a stable internal relationship with the sleep-wake cycle, as the timing of sleep is highly correlated with the phase of body temperature rhythm [4]. Sleep duration is extended when bedtime occurs on the falling limb of the core body temperature curve, whereas sleep duration is short when bedtime occurred on the rising limb of the curve. There is a strong tendency for sleep termination when sleep occurs at the temperature peak (acrophase) [4]. Hence, sleep timing and duration are closely associated with changes in circadian core body temperature.

Sleep quality can be affected by many factors such as health behaviours, physical health, psychological health [5], as well as environmental factors like light, noise, temperature, air pollution, social neighbourhood safety, etc. [6, 7]. Among the environmental factors, the thermal environment is very important for sleep maintenance [6, 8, 9]. Previous studies have shown that excessively high, low, or fluctuating air temperature can compromise sleep quality [8, 10–12].

Sleepwear and bedding types can have an impact on sleep quality by affecting thermal comfort. Skin temperature plays an essential role in thermoregulation, as receptors for warmth and cold detection found in the skin help adjust peripheral blood flow and control heat loss [13, 14]. The skin's sensitivity to temperature fluctuations and the pervasive effect of ambient temperature on skin temperature have been well-documented [8].

Sleep onset coincides with decreases in core body temperature, which is supported by selective vasodilation of distal skin regions to contribute to the decrease of core body temperature and promote sleep onset [13]. During the sleep period, the skin temperature remains relatively stable, with a slight increase during rapid eye movement (REM) sleep [15]. Clothing provides thermal resistance and insulation for the human body, which is important for maintaining the thermal balance of the body during sleep.

Achieving thermal comfort plays a vital role in maintaining good sleep quality [9, 14, 16]. Thermal comfort is a condition of mind that expresses satisfaction with the thermal environment [17] with a need to maintain a stable core body temperature [18], in this way, it varies from person to person [19]. The thermal exchange between a human body and the environment includes sensible heat loss from the skin, evaporative heat loss from the skin and respiratory losses [19]. Sleepwear and bedding insulate the body and influence skin and body temperature, and therefore can significantly affect sleep. Notably, the thermal properties of fabric fibres, including insulation and water vapour resistance, influenced by factors like fibre type, thickness, and yarn structure, play a pivotal role. Specifically, natural fibres such as cotton and wool exhibit lower thermal conductivity when dry, but this can increase significantly after moisture absorption [20]. To optimise thermal comfort under normal or warm condition, a fibre's water vapour permeability should be high to allow sweat to evaporate from the skin and keep the skin dry [20], for example, wool has a higher water vapour permeability than cotton and polyester, which allows efficient sweat evaporation, keeping the skin dry and enhancing thermal comfort [21].

Although there have been numerous studies investigating the effects of various fibre types of sleepwear and bedding on sleep quality, to the best of our knowledge, no systematic reviews have been conducted on this topic. Therefore, this review aims to systematically evaluate the impact of sleepwear or bedding of different fibre types on sleep quality by summarising the existing evidence. By analysing the effects of fibre types and thermal properties of sleepwear and bedding on sleep outcomes, this review aims to provide insights into selecting appropriate materials for better sleep quality.

5.2 Method

This systematic review was conducted in accordance with the recommendations outlined in the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement [22]. The study protocol was registered with PROSPERO under the registration number CRD42021204652.

5.2.1 Study search

Systematic literature searches were conducted using six electronic databases (MEDLINE, Embase, CINAHL, Web of Science, Scopus, Proquest) and additional searches were conducted in Google Scholar with the first 17 pages and via citation searches. These data were added to the search results. An initial search was conducted on August 18, 2021 and updated every month by search alerts until November 2023. The search strategy contained four concepts with their combinations (bedding OR sleepwear) AND fibre AND sleep quality. For each concept, both text words and MeSH terms (controlled vocabulary) were searched where applicable.

The detailed keywords for each concept were as follow:

bedding – "bedding and linen*" OR bed?sheet* OR "bed linen*" OR bedding* OR "quilt cover*" OR bedspread* OR "fitted sheet*" OR "top sheet*" OR "bed cover*" OR coverlet* OR comforter* OR quilt* OR duvet* OR blanket* OR underlay;

sleepwear – pajama* OR pyjama* OR cloth* OR night?dress* OR nighti* OR nightshirt* OR nightcloth* OR night?gown* OR Sleep?wear* OR "night garment*" OR lounge?wear;

fibre – cotton* OR wool* OR "Merino wool*" OR flannelette* OR hemp OR viscose* OR modal* OR lycra* OR lyocell* OR polyester* OR polycotton* OR rayon* OR synthetic* OR silk* OR linen* OR bamboo OR textile* OR fibre* OR fibre* OR fabric* OR flax*;

sleep quality – "sleep qualit*" OR "quality of sleep*" OR "sleep efficienc*" OR sleep* OR polysomnograph* OR "Pittsburgh Sleep Quality Index" OR "PSQI" OR "Insomnia severity index" OR "ISI" OR "Insomnia index" OR Actigraph* OR "sleep assessment*" OR Polygraph* OR "Sleep Stage*" OR "sleep diar*" OR "sleep quality scale*" OR "sleep monitoring".

The search included all studies that had English title and abstract without other limitation. All results were exported into EndNote X9 for selection.

5.2.2 Study selection

After removing duplicates, all titles and abstracts were screened independently by two reviewers (XL and CMC or MH) for inclusion. Disagreements between individual judgements were resolved via discussion within the team. Studies were included in the review if they satisfied the following criteria: study was conducted on humans of any age; reported sleep quality outcome measures (objective or subjective), eg. PSG, PSQI, questionnaire; the study investigated fibre type of the bedding or sleepwear, compared at least two fibre types (eg. cotton vs wool). Studies were excluded if they only investigated one fibre type (e.g. cotton only); investigated the effect of chemical or medicinal fibre coatings; investigated only pillows, mattresses, or other supporting systems (weighted blankets, clothes with different tightness). If an article potentially matched the inclusion criteria, full text was reviewed using the same process and criteria. References where a full text could not be accessed were excluded [23]. If separate references examining the same study, the most updated data was included [24, 25]. Articles written in languages other than English were translated via Google translate, and the accuracy of the translated information was corroborated by individuals proficient in the respective language.

5.2.3 Quality assessment

The methodological quality of each study was assessed using Joanna Briggs Institute (JBI) Critical Appraisal Tools (quasi experiments and randomised controlled trials). Two reviewers (CMC and XL) independently evaluated the quality of included articles. Disagreements in scoring were discussed until consensus was reached.

5.3 Data extraction and analysis

The following information was extracted from each study: (1) publication information: title, author(s), publish year, doi or url; (2) participants: number, age, sex, health conditions; (3) study design; (4) sleepwear, bedding, and fibre types; (5) sleep outcomes: measurement method (subjective or objective), parameters and data. Data presented in figures were extracted using GetData Graph Digitizer 2.26 software. XL extracted data and CMC or MH checked all extracted data. Disagreements between individual judgements were resolved via discussion within the team. For missing data, the corresponding author was contacted for unreported data. If unreachable, the data was recorded as missing (not reported, NR).

The data were analysed in Microsoft Excel. Computation of effect sizes (Hedges' g) of differences in sleep parameters between fibre types was made to facilitate data interpretation, where Hedges' g values of 0.20, 0.50, and 0.80 are considered to be indicative of small, medium, and large effect sizes [26]. A p-value less than 0.05 is considered to indicate a statistically significant difference.

$$\text{Hedges' } g = \frac{M_1 - M_2}{\sqrt{\frac{SD_1^2 + SD_2^2}{2}}} \tag{5.1}$$

M_1 and M_2 refer to the mean value of fibre 1 and fibre 2; SD_1 and SD_2 refer to the standard deviation of fibre 1 and fibre 2.

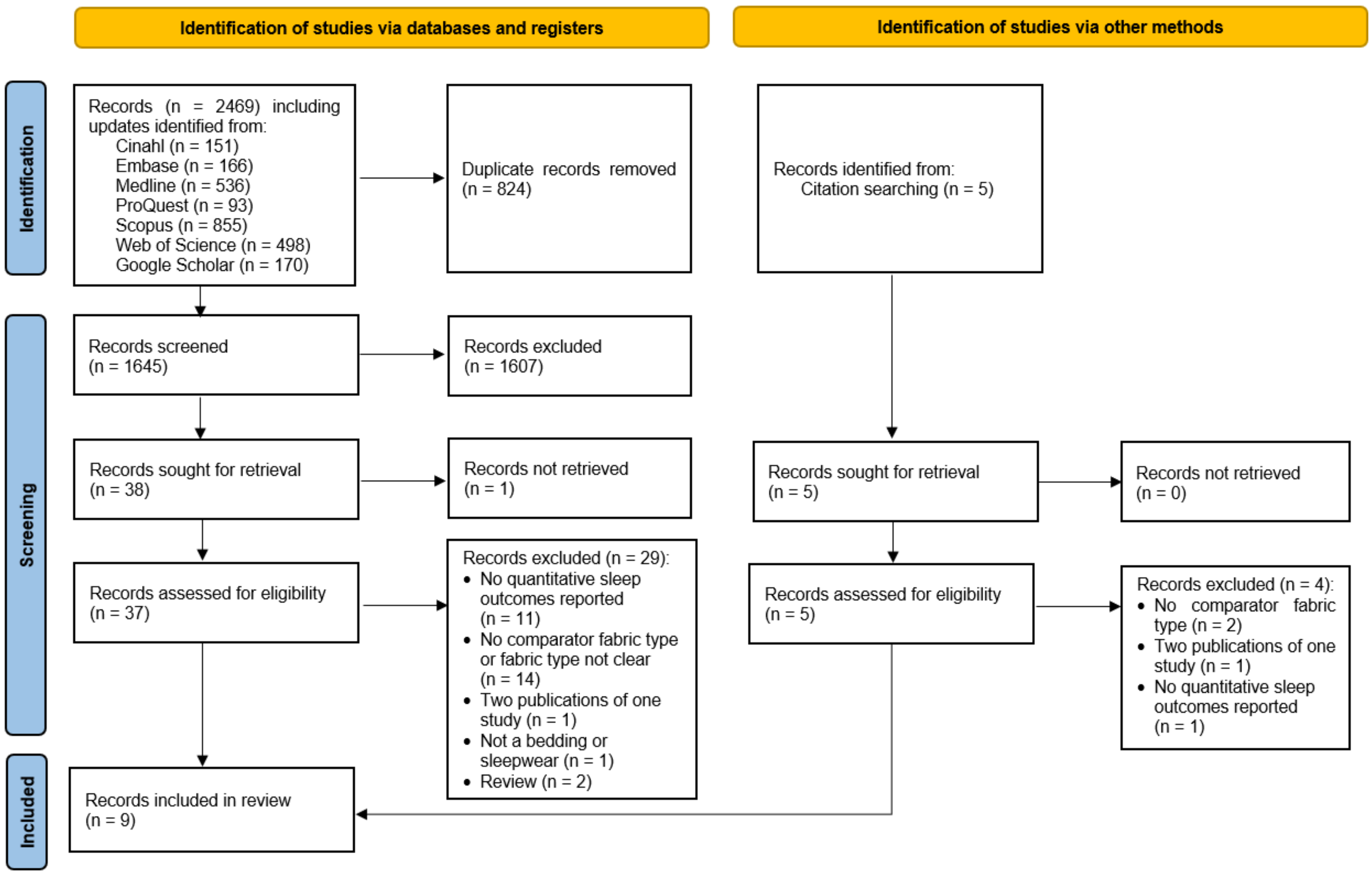

Figure 5.1: PRISMA flow chart of study selection in the systematic review

Table 5.1: Summary of included studies [25, 27–36]

Authors Year Country	Participants	Method				Outcomes (only statically significant data are reported)
		Design	Ambient condition	Study procedures	Comparators	
M. S. Lee, Song, Kim, Park, and Moon (2004) Republic of Korea	N=9 0 male Age: 12±2 years BMI: 24.3±0.8 Healthy	Cross-over, counter-balanced	NR	3 consecutive days in sleep laboratory, 2 consecutive nights in cotton and 2 consecutive nights with experimental wear. (5 control, 4 MFF) 2-week wash out then switch.	Sleepwear control fibre: 100% cotton; MFF: super-absorptive and fast-drying capacities, anti-bacterial, sun-blocking, and far-infrared radiation	**S1** (%) Blended: 9.4±3.1, Cotton: 15.2±2.5, p<0.05, Hedges' g=-1.96 **S2** (%) Blended: 36.1±4.5, Cotton: 44.1±9.3, p<0.01, Hedges' g=-1.02 **SWS** (%) Blended: 35.0±2.9, Cotton: 18.4±6.5, p<0.01, Hedges' g=3.14 **subjective sleep quality on a VAS** (with 0 representing "feel very bad after sleep" and 100 representing "feel very good after sleep") Blended: 83.2±7.3, Cotton: 73.2±8.2, p<0.01, Hedges' g=1.22
Araujo et al. (2013) Portugal	N = 18 61.1% male Age: 7 years BMI: NR All with atopic dermatitis (AD), 33.3% with personal history of atopy (Allergic rhinoconjunctivitis & asthma)	RCT	NR	From D0 the clothes were used continuously (24 h/d) for 7 days. After D7, the clothes was only used overnight, until D90. Clinical assessments took at D0, D7 and D90. Participants slept in their own home.	Babygrows (long sleeve no pants) for babies around 1-year-old and pyjamas (short top long pants) and sockets for older patients Trial group: 70% cotton fibres, 20% cellulose fibres with algae extracts and 10% silver activated algal cellulose fibres; control group: 100% cotton	**VAS of sleep disturbances** from 0 (lowest) to 10 (highest) points no significant differences were recorded

Okamoto-Mizuno et al. (2013) Japan	N = 8 100% male Age: 22.5±3.5 years BMI: 20.3±1.28 Healthy	Cross-over, counter-balanced	29±0.5 °C 70±3%RH	The interval between the two conditions was between 2 and 6 days. nap sleep study between 13:00 and 15:00.	Sheet, bad pad and pillowcase: Cotton: cotton sheets, polyester bed pads and cotton pillowcases; Linen: linen (hemp) sheets, bed pads and pillowcases	**Wakefulness** (N) Linen: 7.9±1.7, Cotton: 11.1±2.5, p<0.05, Hedges' g=-1.42 **S1** (min) Linen: 17.8±3.1, Cotton: 23.7±3.9, p<0.05, Hedges' g=-1.58
Okamoto-Mizuno et al. (2015) Japan	N = 10 100% male Age: 23±4 years BMI: 21.5±2.1 Healthy	Cross-over, counter-balanced	29±0.5 °C RH: 70±3%	Study conducted during August and September, before wearing, the sleepwear were conditioned at 5°C for at least 24 hours. Crossover design for the 2 sleepwear types. The interval between the two conditions was between 2 and 6 days. Nap sleep study between 13:00 and 15:00.	Sleepwear: short sleeve and long pants type C: 100% cotton; type L: polyamide-based elastomer fibre 45%, rayon 55%	**S3 (min)** Cotton: 16.5±3.3, Blended: 9.1±3.1, p<0.05, Hedges' g=-2.21
Emine Utkun, Öndoğan, Yalaz, and Sözmen (2015) Turkey	N = 8 50% male Age: 6 - 12 months BMI: NR HS: NR	Cross-over, counter-balanced	22 - 24°C RH: 40% - 65%	1st, 3rd, 5th, 7th night: own underwear; 2nd, 4th, 6th, 8th night: test two-piece pyjama set over own underwear: 2nd night D6; 4th night D6-6, 6th night D2-3; 8th night Ö4. Infant's sleep time, wakeup times during the night, duration of being awake, and wakeup time were followed by the mother.	Two-piece pyjama set: top and bottom, long sleeve D6, D6-6, Ö4: 100% cotton with different weaves D2-3: Blended (50% cotton + 25% Tencel LF® + 25% Bamboo)	**average sleep duration (min):** Cotton (D6): 659±60.822, Cotton (D6-6): 715±46.664, Cotton (Ö4): 665±82.412 Blended (D2-3): 700±77.068, ANOVA main effect p=0.037 Hedges' g: Blended (D2-3) vs Cotton(D6): 0.56 Blended (D2-3) vs Cotton (D6-6): -0.22 Blended (D2-3) vs Cotton (Ö4): 0.41
Nejedlá and Minařík (2016) Czech Republic	N = 1 male Age: young BMI: NR Healthy	single case	NR	The test was carried out on 2 defined days during 3 weeks, in total 6 measurements. Time in bed: 10pm - 6am	Sleepwear: 100% cotton vs 60% TencelC + 40% Tencel+PADh	**PSG** no significant differences were recorded

Shin, Halaki, Swan, Ireland, and Chow (2016) Australia	N = 17 58.8% male Age: 24.6±6.9 years BMI: 23.7±2.2 Healthy (all females were on contraceptives)	Randomised, cross-over, counter-balanced	17.4°C±0.3°C and 22.4°C±0.5°C RH: 60.3%±2.0%	1 familiarisation night + 8 nonconsecutive test nights no more than a week apart	Sleepwear (long sleeve and long pants): 100% cotton vs 100% Merino wool Duvet: wool vs polyester	**SOL (min)** wool sleepwear: 11.0±8.2, cotton sleepwear: 15.0±18.0, p=0.043, Hedges' g=-0.28 **SOL (at the ambient condition of 17°C)** wool sleepwear: 9.9±6.6 minutes, cotton sleepwear: 18.1±0.9 minutes, p=0.006, Hedges' g=-1.70 **%N3 at 22°C** wool sleepwear: 18.0±1.2, cotton sleepwear: 19.6±1.2, p<0.05, Hedges' g=-1.30

Chow, Shin, Mahar, Halaki, and Ireland (2019) Australia	N = 36 50% male Age: 60.0±6.2 years BMI: 25.6±4.1 Healthy (female participants were tested on the follicular phase)	Randomised, cross-over, counter-balanced	30.1±0.5 °C RH: 50.2±2.9%	Study process: 1 adaptation night + 3 testing nights randomly slept in cotton, polyester or wool sleepwear	Sleepwear: long sleeve and pants, loose-fitting: cotton vs wool vs polyester	**SOL (min)** Cotton: 18.5±23.5; Polyester: 18.2±15.5; Wool: 16.0±15.5, ANOVA main effect p=0.04 Hedges' g: Polyester vs Cotton: -0.01 Wool vs Cotton: -0.12 Wool vs Polyester: -0.14 SOL (min) in Old age subgroup (≥65 years, n=13) Cotton: 26.7±36.1 Polyester: 21.6±21.0 Wool: 12.4±13.4, ANOVA main effect p=0.001 (p=0.011 for difference between wool and cotton, p=0.011 for difference between wool and polyester) Hedges' g: Polyester vs Cotton: -0.17 Wool vs Cotton: -0.51 Wool vs Polyester: -0.51 **SFI (number. hour^{-1})**, sleep fragmentation index Cotton: 13.3±5.8; Polyester: 13.7±4.4*; Wool: 12.1±4.2*, ANOVA main effect p=0.01, (*p<0.05 for difference between polyester and wool.) Hedges' g: Polyester vs Cotton: 0.08 Wool vs Cotton: -0.23 Wool vs Polyester: -0.37

He et al. (2019) China	N = 8 50% male Age: 23±3 years BMI: 21.8±2.1 Healthy	Cross-over, counter-balanced	11.52±0.85 °C RH: 58.91±7.52%	Every day, 2 subjects (1 male and 1 female) participated in the experiment. For each subject, three kinds of quilts were applied respectively to three-night sleeping test in a fixed sleep chamber. The experimental conditions were presented in Latin-square design. Time in bed: 23:30pm – 7:30am	Quilts (150 *210 cm2) with cotton cover: 90% white duck down, 90% white goose down or 100%cotton.	**Subjective sleep quality** (5-point scale, -2 very uncomfortable to +2 very comfortable) duck down: -0.03±0.35, goose down: 0.48±0.25, cotton: -0.25±0.44, ANOVA main effect p<0.05 (p=0.077 for difference between duck down and goose down, p<0.05 for difference between cotton and goose down) Hedges' g: Duck down vs Cotton: 0.52 Goose down vs Cotton: 1.93 Goose down vs Duck down: 1.59 **PSG: N3%** duck down: 28.35±1.07, goose down: 29.58±0.91, cotton: 26.05±1.23 (p=0.083 for difference between duck down and cotton, p <0.01 for difference between cotton and goose down) Hedges' g: Duck down vs Cotton: 1.89 Goose down vs Cotton: 3.08 Goose down vs Duck down: 1.17

NR: not reported
RH: relative humidity
HS: health status
SOL: sleep onset latency
TST: total sleep time
SE: sleep efficiency
W: awake
N1/S1, sleep stage NREM stage 1
N2/S2, sleep stage NREM stage 2

N3: sleep stage NREM stage 3, the merging of stage S3 and S4

N1/N2/N3 are standard from AASM from 2005(Medicine, 2005), S1/S2/S3/S4 are standard from Rechtschaffen and Kales (R&K) from 1968(Rechtschaffen, 1968)

SWS: slow wave sleep,

VAS: Visual Analogue Scale

SFI: sleep fragmentation index

5.4 Result

5.4.1 Study selection

Literature search across databases yielded 2362 references. After duplicates were removed, abstract and full text screening, nine studies [25, 27–34, 37, 38] were included for the systematic review. 25 studies were excluded by full text for: no quantitative sleep outcomes reported for nine records, no control fibre for nine records, no clear fibre details for three records, with more updated results in another publication for one record, not a bedding or sleepwear for one record, or review articles for two records. Figure 5.1 represents the detailed PRISMA flow chart of the study screening and selection process. All the nine included articles were experimental studies. A detailed description of the included studies is given in Table 5.1.

5.4.2 Risk of bias of included studies

In adherence to the CONSORT statement [39], crossover studies of randomised design are an extension of RCT, therefore the risk-of-bias of 3 studies [28, 33, 34] were evaluated using JBI-RCT tool. The rest of the studies [25, 27, 29–32] were assessed using the JBI quasi-experimental tool. The ranking results were presented in table 5.2 and 5.3.

Nejedlá's [32] study only included one participant and statistical analysis could not be performed. Four studies [25, 29–31] did not apply multiple measurements on the outcomes. The rest of the studies [27, 28, 33, 34] were considered to have "good" methodological quality. These studies were by robust controls, meticulous experimental design, and comprehensive statistical analyses, collectively underscoring their methodological rigour and capacity to yield reliable insights.

Table 5.2: Joanna Briggs Institute (JBI) Critical Appraisal Tools for RCT studies

JBI-RCT	Araujo et al. (2013)	Shin et al. (2016)	Chow et al. (2019)
1. Was true randomisation used for assignment of participants to treatment groups?	YES	YES	YES
2. Was allocation to groups concealed?	YES	YES	YES
3. Were treatment groups similar at the baseline?	YES	YES	YES
4. Were participants blind to treatment assignment?	YES	NOT CLEAR	NOT CLEAR
5. Were those delivering treatment blind to treatment assignment?	YES	NOT CLEAR	NOT CLEAR
6. Were outcomes assessors blind to treatment assignment?	NOT CLEAR	YES	YES
7. Were treatment groups treated identically other than the intervention of interest?	YES	YES	YES
8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analysed?	NOT CLEAR	Not Applicable	Not Applicable
9. Were participants analysed in the groups to which they were randomised?	YES	YES	YES
10. Were outcomes measured in the same way for treatment groups?	YES	YES	YES
11. Were outcomes measured in a reliable way?	YES	YES	YES
12. Was appropriate statistical analysis used?	YES	YES	YES
13. Was the trial design appropriate for the topic, and any deviations from the standard RCT design accounted for in the conduct and analysis?	YES	YES	YES

5.4.3 Study characteristics

The geographical distribution of the included studies reflects a diverse global perspective. Notably, two studies [33, 34] were conducted in Australia, three studies [28, 31, 32] were conducted within the European region, while four studies [25, 27, 29, 30] were conducted in East and Southeast Asia. As we included human studies covering the lifespan, the participants' age ranged from 6 months to 66 years: three studies investigated infants [31] and children (age < 18y) [27, 28]; five studies investigated adults (age: 18-50y) [25, 29, 30, 32, 33]; and one study investigated older adults (age: 50-70y) [34]. There were 115 participants (66 males and 49 females) included in total; one study included all female participants [27], three studies included all male participants [29, 30, 32] and five studies included both genders [25, 28, 31, 33, 34]. In addition, one study investigated participants

Table 5.3: Joanna Briggs Institute (JBI) Critical Appraisal Tools for quasi experimental studies

JBI-quasi-experiment	M. S. Lee et al. (2004)	Okamoto-Mizuno et al. (2013)	Okamoto-Mizuno et al. (2015)	Emine Utkun et al. (2015)	Nejedlá and Minařík (2016)	He et al. (2019)
1. Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?	YES	YES	YES	YES	YES	YES
2. Were the participants included in any comparisons similar?	YES	YES	YES	YES	YES	YES
3. Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	YES	YES	YES	YES	YES	YES
4. Was there a control group (control treatment)?	YES	YES	YES	YES	YES	YES
5. Were there multiple measurements of the outcome both pre and post the intervention/exposure?	YES	NO	NO	NO	YES	NO
6. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analysed?	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
7. Were the outcomes of participants included in any comparisons measured in the same way?	YES	YES	YES	YES	YES	YES
8. Were outcomes measured in a reliable way?	YES	YES	YES	YES	YES	YES
9. Was appropriate statistical analysis used?	YES	YES	YES	YES	NO	YES

with a skin condition (atopic dermatitis) [28], others are all healthy participants. Of all the product types, seven were sleepwear [27, 28, 30–34], two included quilt filler [25, 33] and one included bedsheets [29].

Cotton emerged as the fibre type commonly used either as a control or an investigated fibre. The fibre types of sleepwear include cotton, wool, polyester, and five different types of blended materials [27, 28, 30–32] (three studies with cellulose-based fibres made from natural sources [28, 31, 32], one with synthetic materials of polyester Healtha and polyolefin [27], and one with natural and synthetic materials [30]). Two studies [25, 33] compared duvet fibre type between wool and polyester and between cotton and down fibres separately. One study compared bedsheets [29] fibre type between linen and a combination of cotton bed sheet and polyester bed pad. Detailed material properties are displayed in Table 5.4.

Of the included studies, seven reported the bedroom ambient conditions. For the room temperature, two studies [25, 33] were conducted below 20°C, two studies [31, 33] were between 21-25°C and 3 studies [29, 30, 34] at 29-30°C. Most studies which reported relative humidity (RH) were conducted at a RH between 40-65%, except for two studies [29, 30] which were conducted at a RH of 70%.

Two studies [29, 30] were daytime nap sleep studies of fixed time of 2-hour while all others were overnight sleep studies, of which, three studies [25, 27, 32] had fixed sleep time of 8 hours, with the others being sleep ad libitum. Of the nine studies, one study [28] was conducted at the participants' own home, whereas all other studies were conducted in a sleep laboratory.

Eight studies used objective measurements (actigraphy and/or polysomnography) while one study [31] only using a sleep diary to assess sleep quality. The main sleep outcomes reported included sleep efficiency (SE) in six studies [27, 29, 30, 32–34], total sleep time (TST) in five studies [27, 30, 31, 33, 34], proportion of sleep stages in six studies [25, 27, 29, 30, 32, 34], sleep onset latency (SOL) and REM sleep and latency in five studies [29, 30, 32–34], wake after sleep onset (WASO) in four studies [29, 32–34] and Pittsburgh Sleep Quality Index (PSQI) score in two studies [25, 33]. Other sleep outcomes reported includes sleep fragmentation index [34], arousal index, subjective rated sleep quality [27], sleep disturbance [28], and sleep comfort [25], each with one report.

5.4.4 Fibre properties

Seven articles [25, 27, 29–31, 33, 34] provided the texture properties of the sleepwear, bedding or duvet used in the study. A summary of the material properties is provided in Table 5.4.

Table 5.4: Summary of fibre material properties used in the included articles

Product	Author, year	Fibre component	Weight (g·m⁻²)	Thickness (mm)	Water vapor permeability / Moisture transmission (g·m⁻²·24h⁻¹)	Vapor resistance (m²·Pa·W⁻¹)	Water spreading transport capacity	Air permeability / Air transmission (l·m⁻²·s⁻¹)	Thermal resistance (m²·K·W⁻¹)	Thermal conductivity (W·m⁻¹·K⁻¹)	Thermal insulation value (%)	Clo value Cloth insulation (clo)	thermal character q-max (W·cm⁻²)	Moisture Regain (%)
Sleepwear	M. S. Lee et al. (2004)	Standard	NP	NP	-	-	NP	-	-	NP	-	-	-	-
		100% cotton	165	0.7	-	-	0.5	-	-	19.76[A]	-	-	-	-
		Polyester Healtha & Polyolefin	168	0.71	-	-	1.5	-	-	6.97[A]	-	-	-	-
	Araujo et al. (2013)	-	-	-	-	-	-	-	-	-	-	-	-	-
	Okamoto-Mizuno et al. (2015)	Standard	NP	NP	JIS L 1099 A	-	-	JIS L 1096 A	-	-	ThermoLab oII	-	NP	gravimetric method under 27°C RH90%
		100% cotton	100	0.42	10675.2[A]	-	-	1148[A]	-	-	23.1	-	0.15	12.5
		polyamide-based elastomer fibre 45%, rayon 55%	160	0.18	10560[A]	-	-	104[A]	-	-	13.1	-	0.27	15.8

Emine Utkun et al. (2015)	Standard	SFS 3192:1974 standard	SFS-EN ISO 5084:1997 standard	Gore cup method	-	-	SFS-EN ISO 9237:1996	Alambeta (manufactured by Czech SENSORA Company	Alambeta (manufactured by Czech SENSORA Company	-	-	-	-
	D2-3: 50% cotton, 25% Tencel LF®,25% Bamboo	142	0.61	4975	-	-	1345	0.019	0.047	-	-	-	-
	D6: 100% cotton, structure : Plain weave	69.9	0.30	5643	-	-	1610	0.01	0.04	-	-	-	-
	D6-6: 100% cotton, first-type modified twill weave	79.4	0.49	4961	-	-	2780	0.01	0.04	-	-	-	-
	Ö4: 100% cotton, interlock knitted	216	0.80	4663	-	-	390	0.02	0.07	-	-	-	-
Nejedlá and Minařík (2016)	-	-	-	-	-	-	-	-	-	-	-	-	-
Shin et al. (2016)	Standard Cotton sleepwea	NP 153.80± 0.45	NP 0.51±0.00	- -	NP 3.532±0.07	- -	NP 181.70±7.32	NP 0.021±0.0001	- -	- -	- -	- -	- -

		r: 100% cotton												
		Wool sleepwear: 100% wool	161.40±0.89	0.41±0.00	-	2.820±0.06	-	347.74±7.32	0.023±0.0032	-	-	-	-	-
	Chow et al. (2019)	Standard	NP	NP	-	-	-	-	NP	-	-	-	-	-
		100% Cotton	140.0±0.0	0.57±0.03	-	-	-	-	0.030	-	-	-	-	-
		100% Wool	143.5±2.1	0.52±0.01	-	-	-	-	0.025	-	-	-	-	-
		100% polyester	150.5±0.7	0.49±0.04	-	-	-	-	0.030	-	-	-	-	-
Bedsheets	Okamoto-Mizuno et al. (2013)	Standard	NP	NP	JIS L 1099	-	-	-	-	-	ThermoLab oII	-	KES	-
		sheet linen 100%	234.6	0.44	480^A	-	-	-	-	-	36.4	-	0.12	-
		bed pad 100% linen	1345.1	14.8	302.4^A	-	-	-	-	-	80.7	-	0.09	-
		sheet 100% cotton	123.5	0.2	528^A	-	-	-	-	-	29.0	-	0.12	-
		bed pad 100% polyester	1245	24	307.2^A	-	-	-	-	-	85.9	-	0.12	-
Duvets and quilts	Shin et al. (2016)	Standard	NP	NP	-	NP	-	-	NP	-	-	-	-	-
		Wool	694	15.7±1.0	-	60.09	-	-	0.54	-	-	-	-	-
		Polyester	933	17.3±7.6	-	20.51	-	-	0.38	-	-	-	-	-
	He et al. (2019)	Standard	NP	NP	-	-	-	-	-	NP	-	NP	-	-
		100% cotton	133.2	4.18	-	-	-	-	-	4.5	-	1.433	-	-

		90% white duck down	200	8.7	-	-	-	-	-	1.102	-	7.583	-	-
		90% white goose down	Air density 200	8.7	-	-	-	-	-	1.102	-	7.583	-	-

Entries marked with ^ have been converted from their original units.

NP: standard used to obtain the measure was not provided.

5.4.5 Sleep outcomes using different fibres

5.4.5.1 Sleepwear

Cotton vs Blended materials. Five studies [27, 28, 30–32] compared the sleep outcome between blended sleepwear and cotton sleepwear, and only Lee's study [27] reported the blended sleepwear (Polyester Healtha & Polyolefin) promoted significantly shorter N1% and N2%, longer SWS% and higher subjective sleep quality on VAS compared with cotton sleepwear. Although Okamoto-Mizuno's study [30] reported a significant difference in Stage 3 but no significant differences in the combined stage 3 + stage 4, or other sleep variables. All the other studies did not report any significant differences in sleep outcomes between cotton and blended sleepwear [28, 31, 32].

Utkun et al. [31] compared infant sleep quality when wearing underwear made of cotton fibres with three different weave structures and those of blended materials (50% cotton + 25% Tencel LF® + 25% Bamboo). No consistent finding was found for sleep outcome between cotton and blended sleepwear. It was found that the D2-3 showed a medium positive effect on TST compare with D6 and a small positive effect compared to Ö4, which indicated that D2-3 promoted longer total sleep time than D6 and O4.

Nejedlá, M. and R. Minařik [32] reported non-significant differences in sleep quality between 100% cotton sleepwear and blended sleepwear (60% TencelC /40% Tencel+PADh) across three nights each in one healthy young man, although participants reported the blended sleepwear was nicer and finer for sensation. Of the six sleep study nights, the participant's sleep was disrupted by a siren on one night. Statistical analysis was not conducted.

Araujo et al. [28] reported non-significant differences in sleep outcomes between biofunctional textile (consisting of 70% cotton fibres, 20% cellulose fibres with algae extracts and 10% silver activated algal cellulose fibres) and all-cotton sleepwear.

A nap study investigated the effects of pajamas made of cotton and blended material (45% polyamide-based elastomer fibre and 55% rayon) on sleep under mild humid heat exposure [30] and reported a significant reduction with a large effect in Stage 3 when sleeping in the blended pajama compared to sleeping in cotton ($p<0.05$), while there were no significant differences in SWS (stage 3 + stage 4) and other sleep variables between the blended pajamas and cotton pajamas.

Cotton vs Polyester. Chow et al. [34] conducted a study to determine the influences of sleepwear made of cotton, wool and polyester on sleep quality for adults aged 50-70 years old, with different BMI (>25 vs ≤25 $kg \cdot m^{-2}$) and PSQI (poor sleepers vs good sleepers whose PSQI score ≤ 5). When comparing cotton and polyester, there was no significant differences reported for all the sleep parameters. However, with the interaction between sleepwear and PSQI group, poor sleepers had significantly longer REM sleep latency when sleeping in polyester than in cotton ($p=0.037$).

Cotton vs Wool. Two studies compared Merino wool sleepwear [33, 34] with cotton sleepwear with both showing wool sleepwear promoted shorter SOL than cotton sleepwear.

Shin et al. [33] conducted a study among young adults which evaluated sleepwear, bedding at two temperature conditions [33]. The results showed that wool sleepwear produced a significantly shorter SOL than cotton sleepwear with a small effect overall, with a large effect at $17°C$. However, a marginal significant interaction was observed under $22°C$ that sleeping in cotton produced more N3% than wool with a large effect. All the rest sleep parameters were not significantly different between cotton and wool sleepwear.

Study conducted among older adults [34] also showed similar result that sleepwear significantly reduced the SOL compared with cotton (p=0.044) with no effect. Subgroup analysis showed significant differences in the following parameters: for age>65 years old, SOL was significantly reduced when sleeping in wool compared to sleeping in cotton (p=0.011) with a medium effect; poor sleepers (PSQI>5) had significantly reduced WASO when sleeping in wool than in cotton (p=0.047).

Wool vs Polyester. In the same study [34] that showed significant effect of sleepwear on SOL (p=0.044), sleeping in wool sleepwear contributed to a lower SOL than sleeping in polyester sleepwear with no effect. Moreover, the sleep fragmentation index (SFI) was significantly lower when sleeping in wool (12.1±4.2) than polyester (13.7±4.4*) with a small effect (p=0.005). When considering interaction effects with subgroups, for older adults (age>65 years old), sleeping in wool significantly reduced SOL than sleeping in polyester (p=0.011); for poor sleepers (PSQI>5), sleeping in polyester significantly prolong REM sleep latency compared to sleeping in wool (p=0.036).

5.4.5.2 Bedsheets

One study [29] investigated the effect of bedsheet on sleep quality under warm condition (29°C - 30°C). The fibres included 100% linen and 100% cotton. The results showed that linen bedsheets promoted better sleep than cotton bedsheets (see below).

Linen bed sheet and pad vs Cotton sheet + Polyester bed pad. In the nap study [29] conducted under mild humid heat condition that compared 100% cotton sheet and pillowcases with 100% polyester bed pad and with 100% linen sheet, pillowcases and bed pad on sleep quality. The condition with cotton sheets had significantly increased number of awakenings and N1% compared to linen sheets and pillowcases with a large effect (p<0.05). There were no significant differences for any other sleep variables.

5.4.5.3 Duvets and quilts

Two studies investigated quilt materials and sleep quality [25, 33]. The materials as a filler include duck down, goose down, cotton, polyester and wool. The studies were conducted under the ambient conditions of $11°C$, $17°C$ and $22°C$. Goose down promoted longer SWS compared to cotton, and no significant differences were found between other materials.

Cotton vs Duck Down vs Goose Down. The study [25] showed quilt materials had a significant and large effect on sleep quality. Goose down promoted significantly longer SWS (N3%) compared to cotton with a large effect ($p<0.01$), with no difference between duck down and cotton, or duck down and goose. No significant differences were shown for other PSG outcomes.

Wool vs Polyester. From Shin's study [33], non-significant differences were observed between wool and polyester quilts.

5.5 Discussion

Six of the nine included studies reported that different fibre types that make up sleepwear or bedding significantly ($p \leq 0.05$) affected sleep quality measured using various sleep outcomes with medium to large effect [25, 27, 29, 30, 33, 34]. However, the relationship between sleep quality and the type of fibre used in sleepwear and bedding is intricate. Blended fibre sleepwear has shown potential advantages for certain groups. In cool environments, wool sleepwear has been found to aid sleep onset in adults, while in warm environments, it benefits older adults. Young adults experienced better sleep quality with linen sheets in hot conditions. Goose down duvets, under cool conditions, enhanced slow-wave sleep in young adults. However, comparing different fibre types systematically is difficult due to the varied nature of studies on sleep quality.

5.5.1 The performance of different sleepwear fibres on sleep quality

5.5.1.1 Cotton vs Blended materials

Despite five studies employing blended materials, comparisons between studies to derive a systematic sleep outcome is challenging for a diversity of methodological issues, namely 1) the blended fibre type differs, e.g., Lee's study [27] used synthetic sources of polyester Healtha and polyolefin, while the other studies employed natural cellulose-based fibres [28, 31, 32] or natural and synthetic materials [30], 2) target populations and study environment differed in that Lee et al [27] studied healthy girls aged 12±2 years in a sleep laboratory, while two studies conducted home studies in young children (7 years) with atopic dermatitis (AD) [28], and or in infants (aged between 6 months to 12 months) [31]. A further two studies performed studies in young male adults (age < 30 years) in a sleep laboratory [30, 32]. One study was conducted in warm conditions [30], one in cool conditions [32] and three studies [27, 28, 31] did not report the ambient conditions.

It can only be concluded that for adolescent girls, sleepwear made of materials blended from synthetic sources [27] with the merits of super-absorptive and fast-drying capacities was effective in inducing more deep sleep and improving sleep quality compared to cotton sleepwear. This study [27] along with [28, 31] were considered to have "good" methodological quality, although only study [27] yielded significant sleep changes with blended materials. The study suggests that blended fibres, with superior absorption, quick-drying properties, and lower thermal conductivity than cotton, enhance sleep quality, particularly SWS when the body temperature was usually lower than other sleep stages [40], in girls aged 12±2 years, possibly by better maintaining body temperature.

However, the ambient temperature during the study was not reported. No differences in sleep outcomes were observed between cotton and other blended sleepwear in infants, children and young men.

In sum, these diverse studies underscore the intricate interplay between fibre composition, weave structure, and their combined influence on sleep outcomes. The findings highlight both similarities and disparities in sleep quality between cotton and blended materials, contextualizing the multifaceted factors influencing sleep experiences within varying populations.

5.5.1.2 Pure materials

Two studies [33, 34], both considered to have "good" methodological quality, investigated the sleep effect among sleepwear made of cotton, polyester, and Merino wool, with significant differences reported. Shin's study [33] was conducted among young (25±7 years) health adults at 17°C and 22°C, while Chow's study [34] was conducted among relatively older adults (60±6 years) at 30°C. The comparisons between materials are discussed below.

Cotton vs Wool

Significant sleep benefits were observed with wool compared to cotton, including shortened sleep onset in young adults in cooler conditions (17°C) [33] and in older adults in warmer conditions (30°C) [34]. Wool also led to decreased N2% and increased N3% sleep stages in young adults at 17°C but not at 22°C [33]. Interestingly, cotton sleepwear showed a greater N3% at 22°C [33]. These findings indicated that wool sleepwear perform better under cooler conditions while cotton sleepwear would be more suitable for warmer thermal conditions in young adults. In Chow's study [34] that compared cotton sleepwear with wool sleepwear, older adults and poor sleepers (with a PSQI>5) benefited more from wool, showing shorter SOL, lower WASO, and shorter REM latency. This suggests that these individuals may prefer sleeping at a higher ambient temperature for more favourable thermal comfort [41, 42] which wool sleepwear can provide due to its superior insulation and moisture transport properties [43]. Additionally, wool sleepwear can help regulate the body temperature and prevent overheating or getting too cold by trapping air and moisture, creating a favourable microclimate between the skin and garment [44].

In summary, wool sleepwear is favourable for cooler condition, older population and poorer sleepers for a faster sleep onset and more consolidated sleep. For healthy young adult under normal ambient temperatures, cotton sleepwear would be better for a deeper sleep.

Cotton vs Polyester

Sleepwear made of cotton and polyester was compared in one study [34] in older adults under warm conditions but no significant differences in sleep outcomes were reported.

Wool vs Polyester

In this comparisons, one study [34] found that older adults who slept in wool under warmer conditions experienced significant improvements in their sleep. Specifically, they had a shortened SOL and a decrease in SFI, indicating fewer disruptions during sleep compared polyester. Furthermore, among older adults with poor sleep quality, those who slept in wool had decreased REM latency, meaning they entered the REM sleep stage quicker compared to those who slept in polyester. However, in young adults, non-significant differences were observed between wool and polyester quilts under cool and comfortable conditions [31]. These findings suggested that wool sleepwear performed better than polyester sleepwear by contributing to a shorter sleep onset and maintaining a less fragmented sleep, especially for older adult in warmer conditions.

Taken together, material properties like weight and thermal resistance can determine the thermo-physiological wear comfort and skin sensation wear comfort [36, 37] and can in turn affect sleep quality. In Chow's study [34], the weight and thickness of the wool sleepwear lies in between cotton and polyester sleepwear, while the thermal resistance values were similar. The higher moisture buffering of wool sleepwear (9.9 $KJ \cdot m^{-2}$) compared with polyester (0.6 $KJ{\cdot}m^{-2}$) or cotton (6.9 $KJ{\cdot}m^{-2}$) [45] potentially contributed to a faster sleep onset, which was associated with a fall in core body temperature and a rise in distal skin temperature [9, 46, 47]. Sleeping in wool also showed the lowest SFI compared to cotton and polyester sleepwear. A lower SFI reflected less stages shifts and less thermal stress under hot humid conditions [48], which may be linked to the beneficial moisture transfer and the wicking properties of wool. While in Shin's study [31], the wool sleepwear was a little heavier and thinner than the cotton sleepwear, with a higher air permeability, lower vapour resistance and similar thermal resistance value compared to cotton sleepwear. A previous study [9] showed that slight warming of proximal skin in the comfortable range would decrease SOL and enhance SWS. The wool sleepwear might perform better in keeping the proximal skin warm.

5.5.2 The performance of different bedsheet materials on sleep quality

Only one study [29] investigated the effect of bed sheet on sleep quality under a warm/hot condition, which compared a composite of linen (hemp) bed sheets, bed pads and pillowcases with a composite of cotton sheets, polyester bed pads and cotton pillowcases. The results indicated that the linen composite promoted a better sleep through a significantly shorter W%, N1% and less numbers of awakenings compared to cotton composite. Given the bed pads were different between conditions, it is difficult to establish whether the bedsheet fibre type or bed pad played a more important role in this situation.

5.5.3 The performance of different duvets and quilts materials on sleep quality

Based on the studies reviewed, only He's study [25] reported a significant impact of duvet material on sleep quality. Duvets filled with goose down promoted a longest N3% compared to duvets filled with cotton when sleeping under cool condition ($11°C$). Duvets filled with duck down also showed a longer N3% compared to that with cotton but non-significant differences reported. This difference may be explained by the higher insulation value and lower thermal conductivity of feather down compared to cotton, which would have created a thermal comfort bed micro-climate for people under a cool condition. Conversely, uncomfortable cool condition would increase muscle activity, stimulate wakefulness, and improve the frequency of the arousals or stage transition from SWS to shallow sleep [45]. Meanwhile, there was no significant differences founded between wool and polyester quilts under normal ambient condition ($17°C$ and $22°C$) [33].

5.5.4 Limitations of the included studies

Although the studies included in this review shed light on the potential impact of sleepwear and bedding materials on sleep quality, there are some limitations that should be noted. Firstly, the sample sizes in some studies were relatively small, like Nejedlá's study [32] included one participant. Four studies [25, 27, 29, 31] had sample sizes of less than 10 participants, which may limit the generalisability of the findings. However, by comparison, the studies by Shin et al. [33] and Chow et al. [34] reported a sample size of N=17 and N=36 respectively. Secondly, the studies employed different materials under different ambient conditions. A recent review has demonstrated the relationship between thermal environment, body temperature, human's thermal comfort and sleep quality

[14]. Since humans are sensitive to temperature differences [46] which influence thermal comfort and sleep propensity and quality [9, 47], sleep outcomes from different studies are not directly comparable. Some studies did not report the temperature conditions [27, 28, 32] or fibre material properties [28, 32, 37], making it difficult to draw definitive conclusions about the effects of specific materials or conditions on sleep. However, other studies [25, 27, 29–31, 33, 34] clearly presented the fibre properties of fibres. Finally, some studies had limitations in their methodology.

Specifically, Utkun's study [31] used fibres with different structure and yarn, thus making it difficult to determine the specific characteristics of the fibres and compare the fibre properties. Sleep duration was reported by the mother, which may introduce biased reporting and errors.

Araujo's study [28] did not report the material properties of the sleepwear and did not conduct objective sleep measurement in the experiment. Furthermore, it is worth noting that there was a difference in sleep disturbances between the blended and cotton sleepwear groups at baseline (Day 0), with values of 5.2 ± 2.3 and 4.7 ± 2.4, respectively. This finding raises the possibility of introducing bias and reduced the accuracy and reliability of the study's results.

Okamoto-Mizuno's studies [29, 30] investigated the effects of different sleepwear and beddings under hot and humid conditions during daytime naps, which may not be representative of nighttime sleep, as human's body temperature would change according to the thermoregulatory system.

Nejedlá's study [32], as mentioned earlier, is considered to have a high risk of bias due to the small sample size and lack of proper statistical analysis. This paper did not report any material properties and the bedroom's environment condition as well.

5.5.5 Limitation of this review and implications for future research

This review has several limitations that should be considered when interpreting the findings. Firstly, the inclusion criteria only considered papers with English abstracts, which may have resulted in the exclusion of relevant studies published in other languages. Additionally, two of the included papers [29, 30] were translated using Google Translate, which may have led to some misinterpretation or omission of key information. Furthermore, publication bias may have influenced the results, as studies with statistically significant results are more likely to be published.

Moreover, due to the heterogeneity of the studies included in this review, such as varying designs, materials, and outcome measures, it was not possible to conduct a meta-analysis, thus limiting the generalisability of the findings. Most studies were conducted in laboratory settings, which may not reflect real-world sleeping conditions.

Sleep quality can be affected by the performance of different fibre types (along with their material properties, fibre weave types and blending) in different ambient conditions. Material properties like weight and thermal resistance can determine the thermo-physiological wear comfort and skin sensation wear comfort [48, 49] and can in turn affect sleep quality. Other physiological factors such as sex, age and metabolic rates can also impact the interaction with microclimate and sleep quality [50, 51]. Human's metabolic processes would generate heat and moisture, which would interact with the clothing with respect to its dissipation and affect comfort [21]. These factors were not considered in this review.

Future research should include larger and more diverse samples, standardised study designs with specific types of fibres for sleepwear/ bedding, and objective outcome measures of sleep (using polysomnography and actigraphy) to provide a more comprehensive understanding of the effects of sleepwear and bedding materials on sleep quality. The authors recommend testing the difference between two ensembles (for example): one with cotton sleepwear, bedding and pillowcases, and another with wool sleepwear, bedding and pillowcases.

5.5.6 Conclusion

Overall, the reviewed studies suggest that different types of sleepwear, bed sheets, and duvet materials can affect sleep outcomes, and selecting appropriate materials for sleepwear, bed sheets, and duvets can have a positive impact on sleep quality. However, based on the limited evidence from this review, it is hard to draw an overall conclusion. Some points can be drawn from the comparison of subgroups. For sleepwear, wool sleepwear appears to be the most beneficial for promoting sleep quality compared to cotton or polyester sleepwear, while sleepwear made of materials blended from synthetic sources was effective in inducing more deep sleep and improving sleep quality compared to cotton sleepwear for adolescent girls. There were no significant differences reported or no evidence for other fibre or condition. For bedding, as only one study was included in this review, which showed under hot condition, linen promoted less W%, N1% and awakening in health young men compared to a combination of cotton and polyester bedding, no conclusion can be drawn for this section for the lack of evidence. For the duvets, under cool conditions, duvets filled with goose down were preferable than cotton-filled duvets, while there was no significant difference between cotton and duck down. Meanwhile, under normal temperature, there was no significant difference found between wool and polyester quilts either. However, the heterogeneity of the studies included, and limitations of this review indicate a need for more standardised research with larger and more diverse samples to fully understand the effects of sleepwear and bedding fibre materials on sleep quality. Nonetheless, the findings of this review provide valuable insights for individuals seeking to improve their sleep quality and for companies designing sleep products.

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Chapter 6: A Pilot Study Comparing the Effects of Wool and Cotton Sleepwear on Sleep Outcomes and Vasomotor Symptoms

AUTHORSHIP ATTRIBUTION STATEMENT

This chapter is being prepared for submission for *Sleep Advances*.

I co-designed the study with the co-authors, collected, analysed, and interpreted the data, and wrote the drafts of the manuscript.

In addition to the statements above, in cases where I am not the corresponding author of a published item, permission to include the published material has been granted by the corresponding author.

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CHAPTER 6

A Pilot Study Comparing the Effects of Wool and Cotton Sleepwear on Sleep Outcomes and Vasomotor Symptoms

Abstract

Menopause is a critical life transition that significantly impacts sleep quality and thermal comfort due to hormonal fluctuations and vasomotor symptoms, such as hot flushes and night sweats. These symptoms exacerbate sleep disturbances, affecting 40-60% of menopausal women.

This pilot study utilised a randomised, crossover, triple-blind design to evaluate the effects of wool and cotton sleepwear on sleep quality, vasomotor symptoms, and subjective comfort in 16 peri- and postmenopausal women under a controlled bedroom temperature of 30°C (30.1±0.5°C) and relative humidity of 50% (46.4±2.7%). Polysomnography (PSG) was employed to assess objective sleep outcomes. Subjective measures were captured

using the Modified Greene Climacteric Scale to evaluate vasomotor symptoms and the Clothing Comfort Mood Scales to assess thermal comfort, and mood states.

Results revealed no significant differences in PSG parameters between wool and cotton sleepwear. However, wool sleepwear was associated with greater subjective contentedness (more pleasant) on waking, suggesting improved perceived sleep quality, while cotton sleepwear was rated higher for pre-sleep thermal comfort and physical comfort.

A key strength of this study was the use of polysomnography (PSG) in a controlled sleep laboratory, combined with a randomised, crossover, repeated-measures, and triple-blind design, ensuring reliable physiological measurements while minimising confounding factors and reducing inter-individual variability and bias. The small sample size and inclusion of participants with mild to moderate symptoms may limit generalisability. Future studies should include those with severe vasomotor symptoms and assess adaptation effects over multiple nights. These findings provide insights into the impact of sleepwear on subjective sleep experiences and thermal comfort in menopausal women.

6.1 Introduction

Menopause is a significant transition in a woman's life, characterised by hormonal changes that impact various organ systems. Menopause can lead to diverse symptoms. These include central nervous system (CNS)-related disturbances, cardio-metabolic changes, musculoskeletal alterations, urogenital and skin atrophy, and sexual dysfunction [1, 2]. Among these, vasomotor symptoms-comprising hot flushes and night sweats-are the most frequently reported, affecting up to 75% of menopausal women. Such symptoms can disrupt daily functioning, impair sleep quality, and contribute to broader social and personal impacts [2–4]. Sleep disturbances, reported by 40-60% of menopausal women, are particularly significant as they exacerbate the burden of menopausal symptoms and negatively affect overall quality of life [1, 5]. The relationship between body temperature regulation and sleep is well-established. Circadian rhythms govern core body temperature fluctuations, which in turn influence sleep onset, duration, and quality. Sleep onset typically coincides with the decline in core body temperature [6, 7]. Thermoregulation is more active during non-REM (NREM) sleep, where the body can regulate temperature more effectively, compared to REM sleep, which is less responsive to thermal changes due to altered thermoregulatory sensitivity and mechanisms [8, 9]. External factors, such as the thermal environment in the bedroom including sleepwear and bedding type, play a contributory role in maintaining sleep. Sleeping too hot (excessively high temperature) or sleeping too cold (low temperatures) and abrupt temperature changes can reduce sleep quality. Thermoneutral conditions for optimal sleep occur within a skin microclimate of approximately 30-32.5°C, while the ambient temperature range conducive to sleep is generally between 20°C and 26°C [10–12].

The role of sleepwear in influencing the thermal microclimate and supporting sleep quality has received increasing attention. The thermal properties of sleepwear and bedding materials are particularly important under varying ambient temperature conditions. For example, Shin et al. demonstrated that materials with superior moisture-wicking and thermal insulation properties improved sleep quality by maintaining an optimal thermal microclimate and minimising skin temperature fluctuations at ambient temperatures of 17°C and 22°C in young adults [13]. Similarly, a recent systematic review highlighted that different types of sleepwear or bedding materials can significantly affect sleep quality [14]. Sleepwear materials with superior moisture absorption and thermal insulation properties can prevent rapid skin temperature changes and support thermoregulation during sleep [12]. In menopausal women, vasomotor symptoms, including hot flushes and night sweats, further challenge thermal regulation during sleep, exacerbating sleep disturbances [5, 15–18]. Wool fibres, known for their superior moisture-wicking and thermal-insulating properties, have demonstrated benefits in facilitating faster sleep onset and providing better thermal comfort in young and older adults [13, 19]. Specifically, wool can absorb up to 36% of its dry weight in moisture compared to cotton 25%, showcasing its superior hygroscopicity, which allows them to buffer humidity changes more effectively [20]. This enhanced moisture management allows wool to buffer humidity fluctuations more effectively, reducing skin wetness and discomfort caused by night sweats. By efficiently wicking away moisture, wool helps to keep the skin dry, enhancing overall sleep comfort. Additionally, wool's better moisture-wicking capacity makes it more effective in thermoregulation during sleep than cotton [21, 22]. These unique thermal and moisture-handling properties are particularly relevant for menopausal women, who often experience vasomotor symptoms such as hot flushes and night sweats that disrupt sleep. Evaluating whether wool sleepwear offers tangible advantages over cotton in alleviating these symptoms and supporting sleep quality is, therefore, a critical area of investigation. To enable a focused examination of sleepwear effects, the ambient temperature was held constant at 30.1±0.5°C across all nights. This decision was based on the need to minimise variability introduced by external bedding and to replicate the thermoneutral skin microclimate typically present under covered sleeping conditions. Although ambient temperatures between 20°C and 26°C are generally considered optimal for sleep, previous research indicates that temperatures beneath bedding can reach 30–32.5°C [23], supporting the relevance of this choice. By standardising the thermal environment, the influence of fabric properties on sleep and vasomotor outcomes could be more clearly isolated. Accordingly, the study aimed to determine whether wool sleepwear, compared to cotton, would enhance sleep quality and thermal comfort, and reduce vasomotor symptoms in peri- and post-menopausal women under warm, controlled conditions.

This pilot study investigated the impact of wool and cotton sleepwear on sleep quality and vasomotor symptoms in menopausal women. Utilising objective measures of sleep and subjective vasomotor symptoms, mood and thermal comfort, this study examined how sleepwear fibre type, namely cotton versus wool, influenced the sleep quality of menopausal women and inform lifestyle strategies for managing menopausal symptoms.

6.2 Methodology

6.2.1 Study Design

This study was a randomised, crossover, repeated-measures and triple-blind trial designed to compare the sleep quality and vasomotor symptoms of menopausal women between cotton and wool sleepwear. A computer-generated randomisation sequence was created by an independent researcher not involved in data collection or analysis. On each testing day, when a participant confirmed their attendance, the study researcher opened a sealed opaque envelope to determine the assigned sleepwear condition. While full participant blinding was limited due to textile texture differences, participants were not informed of the study's fibre comparison focus. Sleep scoring was performed by an independent scorer and the researcher who collected the PSG data, both of whom were blind to the study condition.

The primary outcome was objective sleep quality, assessed via polysomnography-derived measures, including total sleep time (TST), sleep onset latency (SOL), sleep efficiency (SE), wake after sleep onset (WASO), and sleep fragmentation index. Secondary outcomes comprised the number of objectively recorded nocturnal hot flushes (using a sternal Bahr monitor), sweat loss (based on pre- and post-sleep body and garment weights), and subjective ratings of thermal comfort and mood.

While the initial study protocol aimed to recruit 35 participants, due to COVID-related disruptions and resource limitations, only 16 participants completed the full experimental protocol. As such, this study is best interpreted as a pilot study, providing preliminary findings and informing the feasibility of a larger-scale trial.

The study was approved by the Institutional Ethics Committee of the University of Sydney (protocol number [2019-151]) and the Concord Repatriation General Hospital Human Research Ethics Committee (2020/ETH03028).

6.2.2 Participants

A total of 39 peri- or post-menopausal women volunteered to take part in the study of which 16 met the inclusion criteria. Eligible participants' characteristics are summarised in Table 6.1.

Table 6.1: Participant characteristics (N=16).

Variable	N (%)	Mean ± SD	Range
Age		51.4 ± 4.2 years	45-63 years
BMI		26.0 ± 3.1 kg/m²	20.7-30.0 kg/m²
Menopause type			
Natural	15 (93.8%)		
Surgical	1 (6.3%)		
Menopause stage			
Last menses <1 year	8 (50.0%)		
1 year < last menses <2 years	6 (37.5%)		
Last menses >2 years	2 (12.5%)		
Dominant Hand			
Right	13 (81.3%)		
Left	3 (18.8%)		
Ethnicity			
Asian	4 (25.0%)		
Caucasian	12 (75.0%)		

Inclusion criteria: Participant were required to be experiencing vasomotor menopausal symptoms, defined as a vasomotor score ≥2 on the Modified Greene Climacteric Scale [24] or with self-reported daily hot flushes or night sweats. Additional criteria included irregular menstruation period due to menopause transition over the past 12 months (perimenopausal), cessation of menstruation for at least one year (postmenopausal), or bilateral oophorectomy at least six weeks prior to screening (surgical menopause).

Exclusion criteria: Individuals were excluded if they were shift workers, had sleep difficulties or sleep disorders, chronic health conditions affecting sleep (e.g., cardiovascular diseases, pulmonary diseases, diabetes or metabolic syndrome), on hormone replacement therapy (HRT), or were taking medications that could impact sleep.

Recruitment strategy: Participants were mainly recruited via advertisements through flyers, local newspapers, social media and referrals from a recruiting agency, the Trialfacts (https://trialfacts.com).

6.2.3 Research Sites and Bedroom environments

Research data collection was conducted at Delta Sleep Research Unit at the Cumberland campus of the University of Sydney from January 1, 2020, to January 31, 2021, and Concord Repatriation General Hospital Sleep Study Unit from February 1, 2021 to March 21, 2023.

The overnight PSG sleep studies were conducted in a controlled laboratory environment. The bedroom was maintained at a temperature of 30°C (30.1±0.5°C) and relative humidity of 50% (46.4±2.7%).

Each participant slept on identical mattresses covered with waterproof mattress protectors, topped with 100% cotton bed sheets and pillowcases to ensure consistency across study nights. Participants wore standardised long-sleeved sleepwear sets provided by the researchers, and no additional blankets or duvets were used. This setup was designed to minimise thermal variability and simulate a thermoneutral microclimate close to the skin, allowing the influence of sleepwear fabric on sleep and thermoregulation to be assessed under uniform environmental conditions.

6.2.4 Sleepwear

Participant slept in sleepwear set in long sleeves and long pants. The sleepwear types were made of natural fibre (100% cotton or 100% Merino wool). Both types of sleepwear were available in 4 sizes (S, M, L, and XL). Cotton and wool sleepwear were closely matched for fabric thickness and mass per unit area.

6.2.5 Questionnaires

A participant screening questionnaire was administered to assess eligibility criteria. A similar pre-screening questionnaire was used in Trialfacts to assess the eligibility of participants during the pre-screening process.

The Insomnia Severity Index (ISI), a tool for assessing the severity of insomnia symptoms [25], was completed by participants to establish baseline data.

The Modified Greene Climacteric Scale was used to assess eligibility and was also administered each morning following the completion of sleep studies to evaluate symptom changes [26]. The scale was completed each morning, to capture perceived symptom intensity over the previous night, and did not serve as a real-time measure of acute vasomotor symptoms.

The Clothing Comfort and Mood Scales [27, 28] were used to subjectively assess the comfort of sleepwear and to measure participants' mood at the time of completion. The scales consisted of three parts: Part 1 evaluated the wetness perception, overall warm/cool sensation and thermal comfort of the sleepwear fabric (Figure 6.1a); Part 2 evaluated the thermal sensation of the different skin sites of neck, chest, upper back, upper inner thigh, hand and feet (Figure 6.1b); Part 3 evaluates the instant mood condition at the time of completion (Figure 6.1c). Participants completed the scales after changing into the designated sleepwear (2.5 hours before bedtime), 10 minutes prior to bedtime, and upon waking during all sleep studies (Visit 2 to 6).

6.2.6 General procedures

Eligible participants underwent six clinic visits within a six-week period, including Visit 1 as an initial clinical screening, Visit 2 as a familiarisation night and PSG screening, Visit 3 to 6 as randomised test nights. There were at least 24 hours separating each sleep study trial. Adherence monitoring was not applied since this was a study of short-term outcomes.

6.2.6.1 Visit 1 Clinical Screening

Participants attended a screening visit, where demographic information and physical measurements (height, weight, waist circumference, neck circumference, and blood pressure) were taken. Participants also completed questionnaires, including the Insomnia Severity index [25] and Modified Greene Climacteric scale (Greene, 2008). Eligible participants wore a MotionWatch8 (©2024 CamNtech Ltd and CamNtech Inc, Cambridgeshire, UK) actigraph device on the non-dominant wrist for at least three consecutive days to check baseline sleep pattern. Seven participants were left-handed, and the remaining 32 participants were right-handed. The device was removed for showering or water-based exercises. Participants were required to press the event marker button when they were in bed and ready to attempt sleep and again upon waking, allowing for more accurate scoring of the rest interval (time-in-bed). During the monitoring period, participants were instructed to adhere to their usual daily routine and sleeping conditions, to minimised behavioural variability.

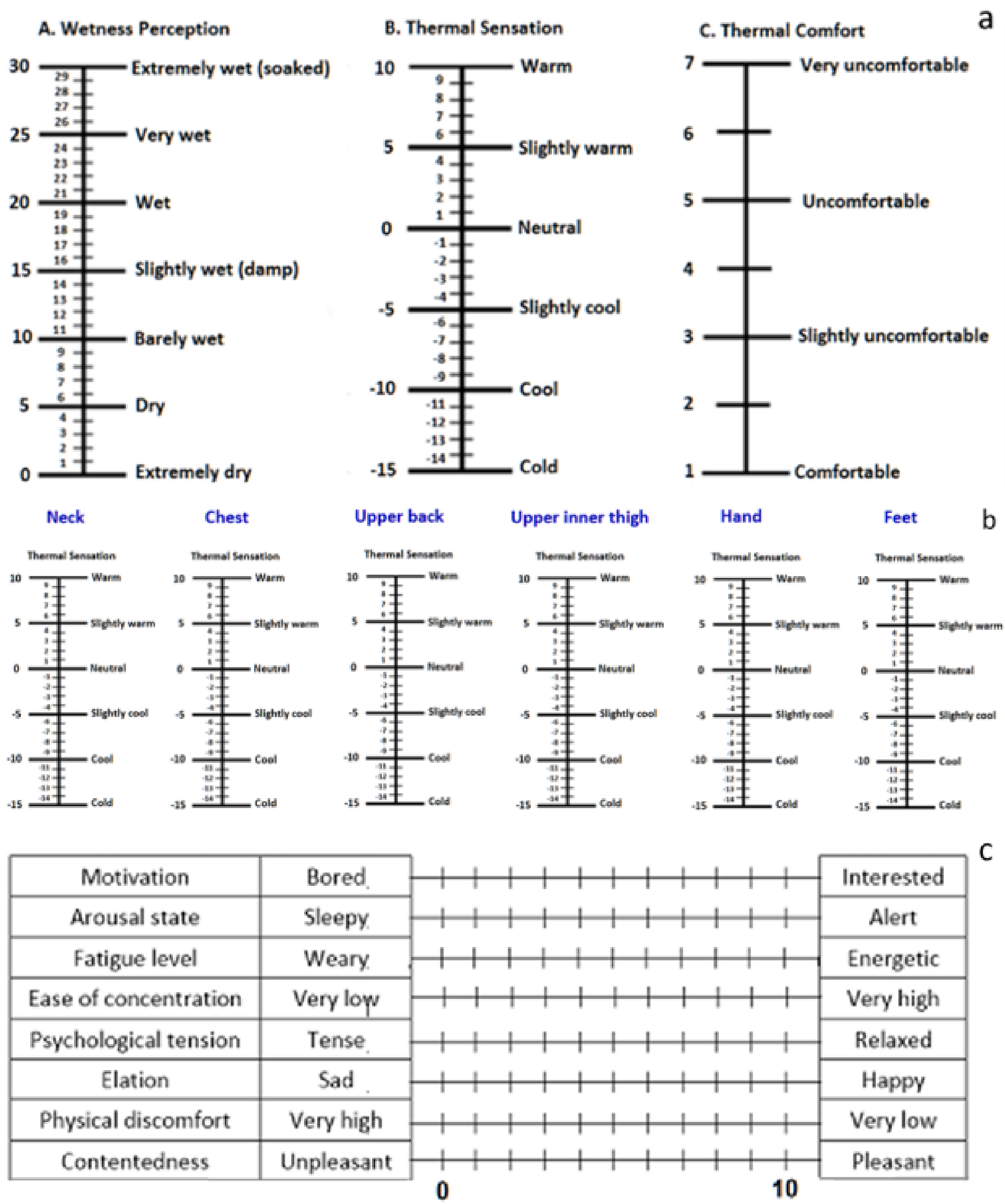

Figure 6.1: Clothing Comfort and Mood Scale used in this study.
Figure 6.1a: wetness perception, overall warm/cool sensation and thermal comfort of the sleepwear fabric
Figure 6.1b: thermal sensation of the different skin sites
Figure 6.1c: mood scale

6.2.6.2 Visit 2 Familiarisation PSG study

Participants returned the MotionWatch8 at the end of the monitoring period and underwent a familiarisation PSG study (Visit 2) if the actigraphy showed a general regular nocturnal sleep pattern (non-shift worker). The procedures and environmental conditions during Visit 2 were identical to those used in the subsequent test nights (Visit 3 to 6). However, for Visit 2, additional PSG signals were recorded to screen out participants who had sleep disturbances which could mask the study findings. The criteria used were SE<85%, Apnea-hypopnea index (AHI) > 15 and periodic limb movement index (PLMI) > 15.

Participants who were eligible completed four overnight sleep studies inconsecutively with at least one night separating each study (Visit 3 to 6), which were randomised to two nights sleeping in cotton sleepwear and two nights in wool sleepwear. To maintain control over the intervention, the test sleepwear (wool or cotton) was provided only at the sleep laboratory. Participants wore the sleepwear exclusively during PSG study nights (Visits 3 to 6) and did not take the garments home.

6.2.6.3 Overnight Sleep Study Procedures

On the morning of each study trial, the researcher contacted the participant to ask about their sleep on the previous night. If the participant reported significantly atypical sleep patterns – such as sleep deprivation (e.g., staying up very late) or compensatory oversleeping – the scheduled study night was cancelled and rescheduled. This was done to ensure that sleep outcomes would not be confounded by irregular prior sleep.

On each study night, participants arrived approximately 4.5-5 hours before their usual bedtime (calculated from the MotionWatch 8 data). Upon arrival, basic physical examinations, including measurements of body weight, blood pressure, waist circumference and neck circumference, were conducted. A standardised dinner was served at 4 hours before their usual bedtime. In the meantime, the bedroom was set at target temperature and humidity conditions and the sleepwear for the night was put in the bedroom for conditioning. 2.5 hours before their usual bedtime, the sleep wear was weighted and the participant changed into the allocated sleepwear. After changing into the sleepwear, the participant remained in the laboratory and completed the Clothing Comfort and Mood Scales [28]. A Bahr MonitorTM (Simplex Scientific, USA) was attached to the sternum to monitor skin conductance overnight. However, the results were not reported due to technical issues resulting in data interpretation challenging and substantial data loss. Participants were encouraged to maintain adequate fluid intake during the day but to restrict water consumption within two hours before bedtime to minimise nocturnal awakenings. PSG setup, including electrode and sensor placement, began 1.5-2 hours before bedtime. Participants remained in the waiting area and were kept awake. Approximately 20 minutes prior to the usual bedtime, the participant was weighed and was transitioned to the sleeping room. Approximately 10 minutes prior to bedtime, the participant completed the Clothing Comfort and Mood scales again while the researcher checked the PSG signals via bio-calibration. The lights-off and lights-on times corresponded to participants' usual bedtimes and wake-up times. Overnight urine was collected and measured to account for fluid loss, enabling the calculation of sweat loss by comparing changes in body weight before and after sleep. The participant completed the Clothing Comfort and Mood scales and Greene Climacteric scale on waking and then body weight again was taken. With all the sensors disconnected, the participant could leave the laboratory.

6.2.7 PSG recording

Overnight PSG sleep data were collected using Compumedics E-series or W-series Sleep system (Compumedics Australia Pty Ltd., Australia). A standardised procedure for the placement of 10-20 electrodes was followed according to the American Academy of Sleep Medicine (AASM) guidelines [29]. All signals were sampled at a frequency of 256Hz.

Electrode placement included the following:

Electroencephalogram (EEG): Five scalp electrodes were referenced to mastoid processes (C3-M2, C4-M1, O1-M2, O2-M1, F3-M2), with Cz on the scalp as reference and a ground electrode Fpz on forehead.

Electrooculogram (EOG): Bilateral electrodes placed near the outer canthus of both eyes to record eye movements.

Electromyogram (EMG): Submental electrodes were placed under the chin to record muscle activity.

Electrocardiogram (ECG): Electrodes placed on the chest to monitor heart activity.

Visit 2 only signals:

Electromyogram (EMG):

Leg electromyography involved placing electrodes on the anterior tibialis muscles of both legs to detect periodic leg movements or muscle activity associated with sleep disorders.

Electrodes positioned over the diaphragm to assess electrical activity associated with respiratory muscle function.

Respiratory signals:

Nasal Pressure Transducer: Placed at the nostrils to measure airflow via pressure changes during breathing.

Thermistor Flow Sensor: Positioned at the nose and mouth to detect airflow and differentiate between inhalation and exhalation.

Effort Bands: Elasticized respiratory inductance plethysmography (RIP) bands were placed around the chest and abdomen to measure thoracic and abdominal movement, reflecting respiratory effort.

6.2.8 PSG scoring

The PSG recordings (familiarisation night) for Visit 2 were reviewed by XL to screen for potential sleep disturbances and sleep disorders. The PSG recordings for Visit 3 to 6 were scored by an external independent experienced scorer according to the AASM manuscript [29]. A report was generated using the Compumedics Profusion PSG4 software including the following items: report start and end time/duration, lights-off and lights-on time, time available for sleep, sleep latency, REM sleep latency, sleep period start and end time, wake after sleep onset, total sleep time, sleep efficiency, NREM sleep, stages (N1/N2/N3) and REM sleep duration and proportion.

6.2.9 Statistical Analysis

Descriptive statistics with confidence intervals were used to summarise data. Linear mixed model (LMM) analysis were conducted on the PSG sleep outcomes including SOL, REM latency, WASO, TST, SE, and proportion of sleep stages as a percentage of TST (NREM%, N1%, N2%, N3% and REM% sleep), sweat loss, vasomotor score from the Greene Climacteric Scale, and clothing comfort and mood scales outcomes, to test the main effects of sleepwear (wool and cotton), visit number, and their interaction, with adjustments for within-subject correlations. The effect sizes for those outcomes were calculated using Cohen's d, which is defined as the difference between the means of the two groups divided by the pooled standard deviation, as shown in the formula below [30]. Cohen's d values of 0.20, 0.50, and 0.80 are considered to be indicative of small, medium, and large effect sizes [30].

$$d = \frac{M_1 - M_2}{SD_p} \tag{6.1}$$

M_1 and M_2 represent the means of the two groups, and SD_p denotes the pooled standard deviation, calculated as:

$$SD_p = \sqrt{\frac{(n_1 - 1)SD_1^2 + (n_2 - 1)SD_2^2}{n_1 + n_2 - 2}} \tag{6.2}$$

SD_1 and SD_2 are the standard deviations of the two groups, and n_1 and n_2 are the respective sample sizes.

All the analysis were conducted using SPSS v.29.0.1.0 and Microsoft Excel. The level of significance was set at $p < 0.05$.

6.3 Result

6.3.1 Objective Sleep Parameters

The objective sleep data, derived from polysomnography (PSG) measurements, provide detailed insights into participants' sleep characteristics. A total of 64 study nights were analysed. The values for sleep parameters across the four nights were averaged for each subject, and the average and SD across subjects were calculated and presented in Table 6.2.

Table 6.2: The average PSG outcomes and SD across all subjects (N=16)

Variable	Mean ± SD	Min	Max
Sleep pattern			
Time in Bed (min)	470.2 ± 51.6	360.6	561.3
Sleep Onset Latency (min)	15.7± 16.0	1.9	54.3
REM Sleep Latency (min)	90.5 ± 46.7	57.4	241.9
Total Sleep Time (min)	409.1 ± 40.3	345.8	469.4
Wake After Sleep Onset (min)	45.4 ± 29.8	9.6	141.5
Sleep Efficiency (%)	87.5 ± 7.1	66.7	95.9
Sleep architecture			
NREM Sleep (min)	323.5 ± 33.8	263.6	392.5
NREM Sleep (%)	79.1 ± 3.1	74.1	84.0
N1 (min)	12.4 ± 6.0	2.6	27.6
N1 (%)	3.0 ± 1.4	0.7	6.3
N2 (min)	227.0 ± 28.0	175.6	287.4
N2 (%)	55.5 ± 5.3	48.9	67.6
N3 (min)	84.1 ± 22.6	44.4	128.1
N3 (%)	20.5 ± 4.9	12.0	29.4
REM Sleep (min)	85.6 ± 15.9	60.6	116.1
REM Sleep (%)	20.9 ± 3.1	16.1	25.9

The results demonstrate variability in sleep pattern and architecture among the participants, with overall adequate sleep efficiency and a balanced distribution between NREM and REM sleep stages.

6.3.2 Comparison of PSG outcome between different sleepwear and visits

The results of the linear mixed model (LMM) analysis and the effect sizes (Cohen's d) for PSG sleep outcomes are presented in Table 6.3.

Overall, none of the main effects or interaction effects were statistically significant for any of the sleep measures. These findings suggest that neither test visits nor fibre types significantly influenced sleep parameters in this study.

Table 6.3: LMM results and effect sizes (Cohen's d) for PSG outcomes (N=16)

	Mean ±SD				
Variable	Wool	Cotton	F	p	Cohen's d
Sleep Onset Latency (min)	16.6 ± 21.0	14.7 ± 23.3	0.02	0.897	0.09
REM Sleep Latency (min)	87.6 ± 47.4	93.5 ± 60.6	0.07	0.793	-0.11
Wake after sleep onset (min)	47.5 ± 40.5	43.4 ± 31.8	0.31	0.580	0.11
Total Sleep (min)	407.5 ± 48.1	410.6 ± 50.1	0.23	0.631	-0.06
Sleep Efficiency (%)	87.0 ± 10.0	87.9 ± 7.6	2.09	0.154	-0.10
NREM Sleep (min)	324.0 ± 44.7	323.1 ± 40.4	0.03	0.858	0.02
NREM Sleep (%)	79.4 ± 4.3	78.8 ± 4.7	0.32	0.577	0.13
Stage 1 (min)	11.8 ± 6.2	12.9 ± 8.6	1.23	0.274	-0.15
Stage 1 (%)	2.9 ± 1.4	3.2 ± 2.2	0.38	0.543	-0.16
Stage 2 (min)	228.2 ± 34.1	225.9 ± 39.9	0.01	0.941	0.06
Stage 2 (%)	56.0 ± 6.0	55.1 ± 7.5	0.51	0.478	0.13
Stage 3 (min)	84.0 ± 27.8	84.3 ± 27.6	0.09	0.762	-0.01
Stage 3 (%)	20.5 ± 6.0	20.5 ± 6.3	0.02	0.893	0.00
REM Sleep (min)	83.5 ± 18.9	87.6 ± 23.6	0.99	0.325	-0.19
REM Sleep (%)	20.6 ± 4.3	21.2 ± 4.7	0.32	0.577	-0.13

6.3.3 Comparison of vasomotor symptom and sweat loss between different sleepwear and visits

The comparison of vasomotor symptoms as measured by the Greene Climacteric scale between wool (2.2 ± 1.0) and cotton (2.2 ± 1.1) sleepwear revealed no significant difference (F = 0.04, p = 0.850). The comparison of sweat loss as measured by a body weight change overnight between wool (0.458 ± 0.138) and cotton (0.502 ± 0.225) sleepwear revealed no significant difference (F = 1.08, p = 0.308).

6.3.4 Comparison of clothing comfort and mood questionnaire outcome between different sleepwear and visits

Table 6.4 displays the LMM result for comfort and mood questionnaire, only variables with p < 0.1 and their effect sizes (Cohen's d) at any given time were displayed in the table, no other significant differences were found in any other variables. The complete table can be found in Supplementary Table S6.1.

Thermal Comfort

Significant differences were found for thermal comfort 2.5 hours before bedtime and at bedtime between wool and cotton sleepwear, with wool sleepwear showed more uncomfortable compared to cotton sleepwear.

Mood Scale

A significant difference was observed in physical discomfort at bedtime (pre-sleep), with participants reporting lower levels of discomfort when wearing cotton sleepwear. However, a significant difference was observed in contentedness on waking (post-sleep), with participants reporting more pleasant when wearing wool sleepwear.

Furthermore, some other mood variables showed marginal significances ($p < 0.1$). Motivation level was approaching significance ($p = 0.080$) with wearing cotton showing more interested. Arousal state showed a marginal significance of 0.074 with wearing cotton showing more alert at changing sleepwear (2.5h before bedtime).

Given the small sample size and the number of comparisons, these results should be interpreted with caution as they may reflect statistical trends rather than robust effects.

Table 6.4: LMM result for comfort and mood questionnaire outcome with $p < 0.1$ and their effect sizes

Variable	2.5h Before Bedtime					At Bedtime					On Waking				
	Mean ±Sd					Mean ±Sd					Mean ±Sd				
	Wool	Cotton	F	p	Cohen's d	Wool	Cotton	F	p	Cohen's d	Wool	Cotton	F	p	Cohen's d
Thermal Comfort	2.4±2.0	1.5±1.0	8.21	0.006*	0.57	2.8±1.6	2.3±1.3	5.92	0.019*	0.34	3.9±2.2	3.3±1.9	1.85	0.181	0.29
Mood Scale-Motivation	6.7±2.1	6.9±2.1	0.48	0.491	-0.10	4.8±2.3	5.2±2.4	3.21	0.080	-0.17	6.1±2.3	5.8±2.3	0.39	0.538	0.13
Mood Scale-Arousal State	5.6±2.7	6.3±2.7	3.36	0.074	-0.26	3.4±2.5	3.5±2.5	0.25	0.618	-0.04	5.5±2.8	4.7±3.0	1.75	0.192	0.28
Mood Scale-Physical Discomfort	7.4±2.0	7.4±1.9	0.11	0.746	0.00	5.3±2.3	6.0±2.3	4.75	0.035*	-0.30	5.5±2.5	5.3±2.6	0.34	0.566	0.08
Mood Scale-Contentedness	7.1±1.9	7.3±2.0	0.27	0.603	-0.10	6.0±1.9	6.3±1.9	1.15	0.289	-0.16	6.4±2.1	5.6±2.2	4.15	0.048*	0.37

6.4 Discussion

6.4.1 Overall sleep pattern and sleep architecture

The sleep patterns of the participants demonstrated generally "normal" sleep, with an average total sleep time (TST) of 409.1 ± 40.3 minutes, sleep onset latency (SOL) of 15.7 ± 16.0 minutes, and sleep efficiency (SE) of 87.5 ± 7.1%. When compared to similar menopausal cohorts, the TST in this study was longer than the 404.9 minutes reported for premenopausal women and 384.7 minutes for postmenopausal women [31], as well as the 380.1 minutes for perimenopausal women and 383.8 minutes for postmenopausal women not receiving HRT [32]. The relatively higher SE (87.5%) compared to other studies, which reported ranges from 80.2% to 86.5% [31, 32], may be influenced by multiple factors. The lower severity of vasomotor symptoms among participants may have resulted in fewer nocturnal awakenings and less sleep fragmentation, contributing to the relatively high SE. Additionally, the small sample size in this study may have contributed to greater variability in sleep outcomes, making the observed SE less representative of the broader menopausal population.

Interestingly, the study cohort demonstrated a higher proportion of slow-wave sleep (SWS, N3% = 20.5%) compared to the Wisconsin cohort (16-17.4%) [32]. This increased proportion of SWS could be attributed to the controlled thermal environment at 30°C, which may have optimised the skin microclimate, as prior research has suggested that thermoregulatory stability supports deeper sleep stages [8]. Additionally, the exclusion of participants with severe sleep disorders may have helped in preserving higher SWS percentages. The lower severity of vasomotor symptoms in this study cohort may have also contributed to reduced SWS, as more severe hot flushes and night sweats have been linked to increased nocturnal awakenings and interrupting sleep continuity [33–35].

These findings suggest that despite the physiological challenges associated with menopause, such as vasomotor symptoms linked to hormonal fluctuations, the SWS patterns in this cohort appears relatively well preserved. The longer TST and higher SE observed here may also reflect the participants' mild menopausal symptoms, which could have resulted in fewer nocturnal awakenings and reduced sleep fragmentation. Additionally, the controlled laboratory environment ensured minimal external confounders, allowing for a precise evaluation of sleep parameters across different sleepwear conditions.

This study did not find significant differences in objective sleep parameters between wool and cotton sleepwear or across test visits. Both fibre types supported comparable sleep quality, and no interaction effects between visits and fibre types were observed. The effect sizes (Cohen's d) observed in PSG outcomes were small, ranging in absolute value from 0.00 to 0.19, indicating minimal differences between wool and cotton sleepwear [30]. Based on these effect sizes, the power analysis showed that the current sample size (N=16) is insufficient to reliably detect significant differences, with actual power values remaining low (≤ 0.08). Future studies investigating such difference in PSG outcomes between cotton and wool sleepwear will require at least 436 participants to achieve 80% power (based on REM Sleep (min)). While previous research emphasises the critical role of thermoregulation in sleep quality - particularly for menopausal women experiencing vasomotor symptoms [9, 12] - and suggests that wool sleepwear may improve sleep in older adult under warm condition [19], the subtle effects of fibre type may require a larger sample size or more targeted subgroups to detect. For instance, individual differences in thermoregulatory responses and vasomotor activity, such as variations in skin temperature and sweat rate, could influence how sleepwear fibre types interact with sleep outcomes. These factors were not fully addressed in this study, which may limit the generalisability of the findings.

6.4.2 The effect of sleepwear on vasomotor symptoms, thermal comfort and mood

No significant differences were found for the items on the vasomotor scale following the sleep study on waking between sleeping in wool and cotton sleepwear.

The thermal comfort variables were detected before bedtime (pre-sleep). Two and a half hours before sleep, when participants changed into sleepwear, and at bedtime, they reported higher comfort when wearing cotton sleepwear. A lower physical discomfort on mood scale was also detected for cotton sleepwear at bedtime. This preference for cotton aligns with previous research, which has shown that cotton fabrics are perceived as smoother and less likely to evoke fabric-induced prickle compared to wool fabrics [36, 37]. The prickle sensation has been attributed to the neurophysiological activation of cutaneous mechanoreceptors caused by fibre stiffness and diameter [38]. Wool fabrics, particularly those with coarser fibres, tend to evoke more frequent prickle responses compared to finer wool or cotton fabrics [39, 40]. Nevertheless, the thermal comfort scores for wool sleepwear were generally within the range of "comfortable" to "slightly uncomfortable," indicating that wool remains an option for maintaining overall comfort. Advancements in wool fabric technology, such as finer yarns and improved fibre finishes, have been shown to reduce prickle and enhance wearer comfort [36, 37].

Subjective measures of mood variables indicated sleeping in wool showed a significantly higher contentedness score (more pleasant) upon waking (post-sleep) compared to sleeping in cotton, suggesting improved subjective sleep quality. This effect may be attributed to wool's hygroscopic properties and its ability to regulate skin microclimate by efficiently managing moisture and temperature variations [38]. This capacity for moisture buffering is particularly advantageous during sleep, when maintaining stable skin conditions is critical for comfort and sleep quality [9, 12]. The literature has shown discrepancies between subjective and objective sleep measures that subjective assessments of sleep often do not align with objective measures, especially for older adults [41, 42]. Psychosocial and mood factors like anxiety, depression, and work stress can amplify sleep perception biases [43].

6.4.3 Strengths, limitations and future directions

One of the key strengths of this study is the use of PSG in a controlled sleep laboratory environment, minimising external confounding factors such as variations in ambient temperature, humidity, and external disturbances. Conducting such a study in home settings would introduce significant variability, making it challenging to detect the subtle effects of sleepwear on sleep quality. The controlled conditions in this study provide a robust framework for assessing the physiological impacts of different sleepwear materials, ensuring the reliability of the findings. Another major strength of this study is its randomised, crossover within subject, repeated measure, and triple-blind design. The design allowed each participant to act as their own control, minimising inter-individual variability and enhancing the statistical power to detect differences between sleepwear conditions. Additionally, repeated assessments across multiple nights improved the reliability of the results, ensuring that observed effects were not due to random night-to-night fluctuations in sleep quality. The triple-blind approach further ensured that neither the participants, the data collectors, nor the PSG scorers were aware of the sleepwear conditions, reducing the risk of bias and enhancing the study's internal validity. Additionally, this study incorporated both objective (PSG) and subjective (self-reported questionnaires) measures, providing a comprehensive assessment of sleep and comfort.

As a pilot study, this research has several limitations that should be acknowledged. First and foremost, the small sample size limits the generalisability of the findings.

With only 16 participants completing the study, the statistical power to detect small or nuanced effects of sleepwear fibre type on sleep outcomes and menopausal symptoms is reduced. Additionally, the small sample may not capture the full variability of menopausal symptoms or individual differences in thermoregulation and sleep patterns, which could influence the outcomes. Another limitation involves the lack of reliable direct monitoring of vasomotor activity. Although a Bahr Monitor,Ñ¢ was used to measure skin conductance, technical issues led to substantial data loss, preventing its use in the analysis. Instead, overnight sweat loss was calculated, but no significant differences were observed. More comprehensive monitoring of these physiological markers, particularly in conjunction with PSG, could have provided more precise insights into the relationship between vasomotor activities and nocturnal arousals. By capturing dynamic changes in these markers throughout the night, the study could have better elucidated the mechanisms underlying sleep disturbances associated with vasomotor symptoms, offering a more comprehensive understanding of their impact on sleep quality.

To address these limitations, future studies should increase sample size and participant diversity, particularly by including individuals with more severe menopausal symptoms, to improve the generalisability of findings and detect subtle effects of sleepwear materials on sleep outcomes and menopausal symptoms. In this study, the majority of participants exhibited mild to moderate vasomotor symptoms, which may have influenced the results. Women with mild symptoms may experience fewer hot flashes and night sweats, leading to reduced sweat loss and a less pronounced impact of sleepwear on thermoregulation and sleep quality. Including participants with severe symptoms would allow for a more comprehensive assessment of the potential benefits of sleepwear in managing nocturnal vasomotor symptoms, particularly in individuals who experience significant night sweats. Additionally, future studies should incorporate continuous monitoring of vasomotor activity using physiological measures such as sternal skin conductance, infrared thermography, or temperature sensors, alongside with PSG. These measures would help capture real-time changes in thermoregulation and their impact on sleep architecture, providing a more detailed understanding of how different sleepwear materials influence menopausal sleep disturbances. Lastly, longer-term studies, defined as lasting at least two weeks, are needed to assess how habitual use of different sleepwear materials influences sleep quality and comfort over time. A longer study duration would allow for adaptation effects, as participants may experience initial discomfort with a new sleepwear material that diminishes after several nights. A hybrid study design could be considered: PSG assessments conducted in a controlled sleep laboratory on the first night, followed by home-based monitoring using actigraphy and subjective sleep diaries, with the option of including a single night of home-based PSG in the middle or towards the latter part of the trial, if feasible, then conducting with a final PSG re-evaluation in the laboratory. Conducting repeated assessments over multiple nights in both controlled laboratory and real-world home settings would provide a more ecologically valid understanding of the relationship between sleepwear materials, vasomotor symptoms, and sleep quality. This approach would allow researchers to track adaptation effects while maintaining the rigour of objective sleep assessments. Such a design balances ecological validity with controlled measurement, providing deeper insights into the long-term impact of sleepwear materials on menopausal sleep quality.

6.5 Conclusion

This pilot study compared the effects of wool and cotton sleepwear on sleep quality, thermal comfort, and menopausal symptoms under controlled laboratory conditions. While no significant differences in objective sleep parameters were found between fibre types, wool sleepwear was associated with higher subjective pleasantness on waking (post sleep), suggesting potential benefits for perceived sleep quality. Cotton sleepwear, however, showed advantages in pre-sleep thermal comfort and arousal state, highlighting individual preferences for thermal and tactile properties. Limitations such as a small sample size and the inclusion of generally healthy participants with mild to moderate symptoms may have restricted the generalisability of the findings. Future studies should include a more diverse sample, particularly individuals experiencing more severe vasomotor symptoms, to better capture the full impact of sleepwear on sleep quality. These findings contribute to a better understanding of how sleepwear fabrics may influence sleep-related experiences in menopausal women, providing a basis for future investigations into optimising sleepwear choices for improved comfort and sleep quality.

Table S6.1: LMM result and effect sizes (Cohen's d) for comfort and mood questionnaire outcome

variable	2.5h before bedtime					at bedtime					on waking				
	mean ±SD				Cohen's	mean ±SD				Cohen's	mean ±SD				Cohen's
	wool	cotton	F	p	d	wool	cotton	F	p	d	wool	cotton	F	p	d
wetness perception	4.3±2.8	4.7±1.7	0.88	0.353	-0.17	7.8±4.7	7.7±4.3	1.94	0.171	0.02	13.3±6.8	14.1±5.1	0.87	0.355	-0.13
thermal sensation	-1.0±6.2	-0.3±5.6	0.55	0.464	-0.12	3.9±4.0	4.0±3.4	0.01	0.936	-0.03	5.9±3.5	6.6±2.8	1.06	0.308	-0.22
thermal comfort	2.4±2.0	1.5±1.0	8.21	0.006*	0.57	2.8±1.6	2.3±1.3	5.92	0.019*	0.34	3.9±2.2	3.3±1.9	1.85	0.181	0.29
thermal sensation-neck	-1.1±5.2	-0.9±4.8	0.68	0.415	-0.04	3.3±3.8	2.2±4.1	1.06	0.308	0.28	5.5±4.1	5.7±3.4	0.04	0.840	-0.05
thermal sensation-chest	-0.5±5.5	0.5±5.8	0.77	0.386	-0.18	3.8±3.2	4.1±3.5	0.25	0.622	-0.09	6.7±3.3	6.9±2.3	0.15	0.703	-0.07
thermal sensation-upper back	-0.5±5.8	0.2±5.8	0.04	0.840	-0.12	4.5±3.5	3.7±3.3	1.53	0.222	0.24	5.9±3.9	7.0±2.3	1.98	0.166	-0.34
thermal sensation-upper inner thigh	0.4±4.7	0.7±5.0	0.37	0.546	-0.06	3.7±3.9	4.0±3.4	0.05	0.831	-0.08	4.8±4.8	6.1±2.9	2.27	0.139	-0.33
thermal sensation-hand	-1.8±4.7	-0.7±4.8	1.06	0.310	-0.23	2.9±2.6	3.0±3.2	0.27	0.607	-0.03	4.3±3.4	5.2±3.5	1.02	0.318	-0.26
thermal sensation-feet	-2.1±5.1	-0.6±4.4	1.25	0.271	-0.31	2.3±3.7	2.3±3.9	0.59	0.448	0.00	3.9±3.9	4.7±3.7	0.31	0.581	-0.21
mood scale-motivation	6.7±2.1	6.9±2.1	0.48	0.491	-0.10	4.8±2.3	5.2±2.4	3.21	0.080	-0.17	6.1±2.3	5.8±2.3	0.39	0.538	0.13
mood scale-arousal state	5.6±2.7	6.3±2.7	3.36	0.074	-0.26	3.4±2.5	3.5±2.5	0.25	0.618	-0.04	5.5±2.8	4.7±3.0	1.75	0.192	0.28
mood scale-fatigue level	5.3±2.4	5.8±2.3	2.14	0.150	-0.21	3.6±2.4	3.7±2.3	0.40	0.529	-0.04	5.5±2.6	4.7±2.5	2.33	0.135	0.31
mood scale-ease of concentration	6.0±2.1	6.3±2.4	1.72	0.196	-0.13	3.8±2.5	4.2±2.2	2.36	0.131	-0.17	5.6±2.3	5.2±2.7	0.94	0.338	0.16
mood scale-psychological tension	7.8±1.4	7.9±1.2	0.12	0.729	-0.08	7.4±1.5	7.6±1.6	0.66	0.420	-0.13	6.9±1.7	6.9±2.2	0.36	0.554	0.00
mood scale-elation	6.8±1.9	7.1±2.0	1.29	0.263	-0.15	6.1±1.9	6.1±1.9	0.00	0.986	0.00	6.7±1.8	6.5±1.8	0.26	0.613	0.11
mood scale-physical discomfort	7.4±2.0	7.4±1.9	0.11	0.746	0.00	5.3±2.3	6.0±2.3	4.75	0.035*	-0.30	5.5±2.5	5.3±2.6	0.34	0.566	0.08
mood scale-contentedness	7.1±1.9	7.3±2.0	0.27	0.603	-0.10	6.0±1.9	6.3±1.9	1.15	0.289	-0.16	6.4±2.1	5.6±2.2	4.15	0.048*	0.37
mood scale-trouble falling asleep	6.9±1.5	6.5±1.9	1.80	0.188	0.23	6.5±1.9	6.6±2.0	0.15	0.699	-0.05	6.5±2.4	5.8±2.3	2.97	0.092	0.30

6.6 References

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CHAPTER 7

Discussion and Future Directions

7.1 Summary

This thesis investigated the interrelated factors among sleeping behaviour, vasomotor symptoms, sleep monitoring accuracy, textile fibre properties and sleepwear fibre types in peri- and post-menopausal women. By integrating observational, validation, systematic review, and experimental methodologies, this thesis presents a cohesive framework that progressively deepens the understanding of menopausal sleep disturbances and evaluates targeted interventions using sleepwear fibre types to improve sleep quality in this population.

The first study described the sleep patterns and vasomotor symptoms and examined their associations in menopausal women. Participants reported mild vasomotor symptoms, with low scores for both hot flushes (mean = 1.2 ± 0.6) and night sweats (mean = 1.2 ± 0.6). Sleep patterns exhibited substantial variability, with sleep onset ranging from 8:46 PM to 1:03 AM and midsleep times ranging from 1:28 AM to 4:18 AM with considerable intraindividual variability. No statistically significant associations were found between vasomotor symptoms and sleep parameters. ICC analysis demonstrated moderate reliability of actigraphy recordings, suggesting some consistency in individual sleep timing across nights. These findings indicated that while vasomotor symptoms are often linked to menopausal sleep disturbances, their direct impact may vary according to the severity of vasomotor symptoms.

The second study assessed the accuracy of MotionWatch8 actigraphy compared to polysomnography (PSG) in menopausal women under warm conditions (30.1 ± 0.5°C, 46.4 ± 2.7%RH). The results demonstrated that MotionWatch8 systematically overestimated total sleep time and sleep efficiency while underestimating sleep onset latency and wake after sleep onset. These findings indicated the limitations of actigraphy in detecting wakefulness accurately and emphasise the need for caution when interpreting sleep data collected via actigraphy especially in individuals with severe sleep disturbances.

The third study, a systematic review, examined the effects of sleepwear and bedding fibre types on sleep quality. The findings indicated that wool sleepwear shortened sleep onset latency and enhanced thermal comfort compared to other fibres, particularly in older adults [1, 2]. Linen bedding demonstrated benefits in warm, humid environments by promoting better sleep quality [3], while goose down increased slow-wave sleep under cool conditions [4], suggesting that different fibre types may play a role in influencing thermal comfort and sleep architecture.

The final study was a pilot study comparing the effects of wool and cotton sleepwear on sleep outcomes in menopausal women under warm conditions (30.1 ± 0.5°C, 46.4 ± 2.7%RH). Although objectively measured sleep parameters did not reveal significant differences between the two fibre types, participants reported higher pre-sleep comfort when wearing cotton sleepwear, and improved mood upon waking when sleeping in wool. These results suggest that subjective perceptions of sleep quality may be enhanced by wool's thermal properties, albeit objective measures of sleep architecture remain unchanged.

7.2 Interpretations and implications

The findings of this thesis suggest that vasomotor symptoms alone may not be the primary drivers of menopausal sleep disturbances. Instead, sleep variability and individual responses to menopause (from mild to severe) differences in thermal sensitivity may play a role. Thermal sensitivity, which refers to an individual's ability to perceive and respond to temperature fluctuations, may significantly influence sleep quality during menopause. Research suggests that menopausal women exhibit altered thermoregulation, particularly in response to heat, which could contribute to sleep disturbances independently of vasomotor symptoms [5]. Aging-related reductions in thermoreceptor density and skin blood flow may impair the ability to regulate body temperature efficiently, leading to increased susceptibility to environmental heat and discomfort during sleep [5]. Moreover, differences in skin thermal sensitivity across body regions may further impact thermoregulatory responses and sleep, as heat dissipation plays a key role in sleep initiation and maintenance, a heightened or blunted thermal response in specific skin regions could contribute to variations in sleep disturbances among menopausal women [6]. Studies indicate that certain areas of the body exhibit greater thermal sensitivity than others, with distal extremities typically being more responsive to temperature changes [7]. Furthermore, the relationship between core body temperature and hot flushes remains complex. While some studies suggest that hot flushes may be triggered by slight increases in core temperature, this is not consistently observed, and other physiological mechanisms may be involved [8]. Temperature-sensing approaches have been explored to detect the onset of hot flushes more accurately, highlighting the importance of continuous monitoring for understanding thermoregulatory disruptions during menopause [9, 10].

Chronotype differences also appear to influence sleep disturbances and psychological responses during menopause. Evidence suggests that menopausal transition is associated with a shift towards morningness, likely driven by hormonal changes rather than ageing alone [11]. This shift aligns with findings that postmenopausal women exhibit phase-advanced circadian rhythms, leading to earlier sleep and wake times [12]. Despite this general trend, chronotype differences appear to influence sleep disturbances and psychological responses during menopause. Evening chronotypes tend to experience worse sleep quality, likely due to greater misalignment between biological and social schedules [13]. Given that menopausal sleep complaints often include delayed sleep onset, increased night-time awakenings, and reduced sleep efficiency, evening-oriented women may be particularly vulnerable to exacerbated sleep fragmentation and daytime fatigue. Additionally, chronotype may play a role in vasomotor symptom severity, as circadian misalignment could influence core body temperature regulation and exacerbate night sweats [12]. Moreover, psychological health during menopause appears to be chronotype-dependent. Eveningness has been consistently associated with higher rates of depressive symptoms, a pattern also observed in menopausal women [14]. As mood disturbances are a significant contributor to perceived sleep quality, this association further supports the need for considering circadian preferences when assessing sleep-related challenges in menopause. Additionally, the interaction between chronotype, obesity, and metabolic health-all of which influence menopausal well-being-has been highlighted as an important factor in postmenopausal sleep disorders [15]. Several questions emerge from this literature, for example, how do hormonal fluctuations during menopause specifically contribute to shifts in chronotype? This question would help clarify whether hormonal changes directly impact the circadian system, and if so, how this might vary by individual or across different stages of menopause. Understanding the hormonal role could lead to more targeted interventions for sleep issues in menopausal women. Additionally, can interventions aimed at realigning circadian rhythms improve sleep quality and reduce vasomotor symptoms in evening chronotypes? Examining the effectiveness of light therapy, behavioural adjustments, or pharmacological interventions to realign circadian rhythms in evening chronotypes could potentially reduce sleep disturbances and night sweats, improving overall quality of life.

The validation of MotionWatch8 emphasises the need for caution when using actigraphy in populations with fragmented sleep [16], as its limitations in detecting wakefulness may lead to inaccurate assessments of sleep duration and efficiency. Future improvements could focus on refining movement detection algorithms, integrating physiological sensors such as heart rate or skin temperature monitoring, and enhancing data interpretation methods to better distinguish between quiet wakefulness and actual sleep, thereby reinforcing PSG as the gold standard for sleep assessment. In light of these limitations, sleep efficiency (SE) and wake after sleep onset (WASO) were not selected as key outcome measures in the observational study reported in Chapter 3. Given actigraphy's known tendency to overestimate SE and underestimate WASO – particularly in individuals with frequent nocturnal awakenings – we prioritised reporting sleep timing and total duration measures, which are less sensitive to inaccuracies in wake detection.

From a textile and sleep science perspective, our systematic review demonstrated the role of sleepwear and bedding materials in influencing thermoregulation, sleep quality and subjective sleep experience. These findings reinforce the role of sleepwear and bedding on optimising thermoregulation and improving sleep outcomes. This is particularly relevant in warm environments, where inappropriate fabric choices may lead to increased wakefulness and sleep fragmentation. Studies have shown that elevated ambient temperatures can lead to prolonged sleep onset latency and increased nocturnal awakenings, whereas cooler temperatures that facilitate core body temperature reduction promote deeper sleep stages [17]. Similarly, improper bedding and sleepwear choices can disrupt thermoregulation, leading to discomfort and fragmented sleep [18]. These insights further inform the development of adaptive textile technologies that cater to individual thermal needs, particularly for vulnerable populations such as menopausal women, older adults, and individuals experiencing temperature-related sleep disturbances. Due to the heterogeneity of the current studies investigating the impact of sleepwear or bedding of different fibre types on sleep quality, such as varying designs, materials, and outcome measures, it was not possible to conduct a meta-analysis, thus limiting the generalisability of the findings. Further research employing standardised methodologies with comparable fibre samples such as fabric thickness and thermal resistance at different temperature conditions and in different populations are imperative to comprehensively elucidate the effects of fibre choices on sleep quality. Despite the limitations and heterogeneity of the included studies, this analysis offers insights for industry partners to work closely with researchers to investigate sleep-related products to optimise sleep experiences

The findings from this research hold several important implications across multiple domains. From a clinical and practical perspective, they emphasise the necessity for personalised sleep strategies for menopausal women, focusing on optimising thermal comfort alongside addressing vasomotor symptoms as part of a comprehensive approach. Given the demonstrated effects of different sleepwear and bedding fibres on sleep quality, this research highlights the need to further explore how textile-based modifications may optimise thermal comfort and improve perceived sleep quality in temperature-sensitive individuals. The findings reinforce the continued need for PSG in menopausal sleep research, particularly given the challenges identified in actigraphy-based sleep monitoring. While PSG offers superior accuracy, improving wearable technology remains critical for large-scale, long-term sleep assessments in this population.

7.3 Limitations and future directions

While this research offers valuable insights, several limitations should be acknowledged. The sample size in both the observational and experimental studies was relatively small, limiting the generalisability of the findings. Additionally, actigraphy exhibited limitations in detecting wakefulness and sleep fragmentation in menopausal women under warm conditions.

Future research should focus on expanding the study sample to include a larger and more diverse population, which would improve the generalisability of the findings. Additionally, further refinement and validation of wearable sleep monitoring devices are necessary, focusing on improving their accuracy in detecting wakefulness and sleep fragmentation, particularly in menopausal women who often experience disrupted sleep patterns.

Longitudinal research should assess the sustained impact of sleepwear and bedding materials on sleep quality, thermoregulation, and overall well-being. Understanding whether prolonged exposure to specific bedding and sleepwear textiles would lead to adaptive physiological responses or long-term improvements in sleep could provide further evidence for their therapeutic potential. Moreover, interdisciplinary collaborations between sleep scientists, textile engineers, and healthcare professionals could drive innovation in sleepwear technology, leading to the development of adaptive textiles that dynamically regulate body temperature and moisture levels to optimise sleep, particularly for menopausal women, older adults, and individuals with sleep disorders.

Based on the findings and limitations of this thesis, the following recommendations for future research are proposed:

Larger-Scale Clinical Trials: Future studies should include larger, more diverse samples to validate the effects of sleepwear on sleep quality in menopausal women.

Longitudinal Sleep Studies: Investigating long-term sleep patterns in menopausal women using both PSG and actigraphy can provide deeper insights into sleep variability and adaptation to interventions.

Mechanistic Studies on Thermoregulation: Further research should explore the physiological mechanisms through which different sleepwear fabrics influence sleep, particularly in relation to menopausal thermoregulatory changes. This includes examining skin temperature regulation, heat dissipation via peripheral vasodilation, and the moisture-wicking properties of fabrics that impact sweat evaporation and overall thermal comfort.

Expanded Populations: Future research should assess the impact of wool sleepwear in populations with specific vulnerabilities, such as older adults with impaired thermoregulation, individuals with insomnia, and night shift workers who experience circadian misalignment.

Microclimate Studies: Understanding the interaction between skin temperature, clothing insulation, and bedroom conditions will improve fabric selection recommendations for optimising sleep environments.

Portable Sleep Monitoring Validation: Further validation studies should refine wearable sleep monitoring devices for detecting wake episodes more accurately in women experiencing sleep disturbances.

7.4 Conclusion

This thesis contributes to a growing body of research on sleep and menopause, providing novel insights into sleep variability, the limitations of actigraphy, and the potential benefits of wool sleepwear. By integrating objective and subjective sleep measures, it underscores the need for multifaceted, personalised approaches to managing menopausal sleep disturbances. The findings suggest that optimising sleepwear choices presents a practical, non-pharmacological intervention for improving sleep quality, particularly in populations with thermoregulatory challenges.

Future research should explore these findings in broader populations and develop tailored interventions that leverage fabric properties to enhance sleep outcomes. These efforts will not only improve sleep health in menopausal women but also extend to other groups experiencing temperature-related sleep disturbances, such as older adults, individuals with insomnia, and shift workers.

7.5 References

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APPENDIX

A

QUESTIONNAIRES AND FORMS USED IN THIS STUDY

Activity record for whole night study

Clothing comfort and Mood Scale

Clothing comfort and Mood Scale - Qualtrics

Modified Greene Climacteric Scale

Modified Greene Climacteric Scale - Qualtrics

Insomnia severity index

Participant Screening Questionnaires

Case Report Form

Statement of Consent - Re: MotionWatch8

Participant information statement

Participant Consent Form

Participant information - COVID-19 supplement

COVID-19 Symptoms Pre-Screen for Face-to-Face Visits

Sleep Quality and Menopause

Food Intake, Physical Activity and Clothing Record

Study code: | | | | | | | | | |

Item	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
Date					
Food intake: *Breakfast* *Morning tea* *Branch* *Lunch* *Afternoon tea* *Snacks* *Medication/ supplement* *Alcohol* *caffeine* *Etc.*					
Physical Activity: *Walking* *Jogging* *House working* *Etc.*					
Clothing worn (socks, sweater, dressing gown) when waiting at the lab:					

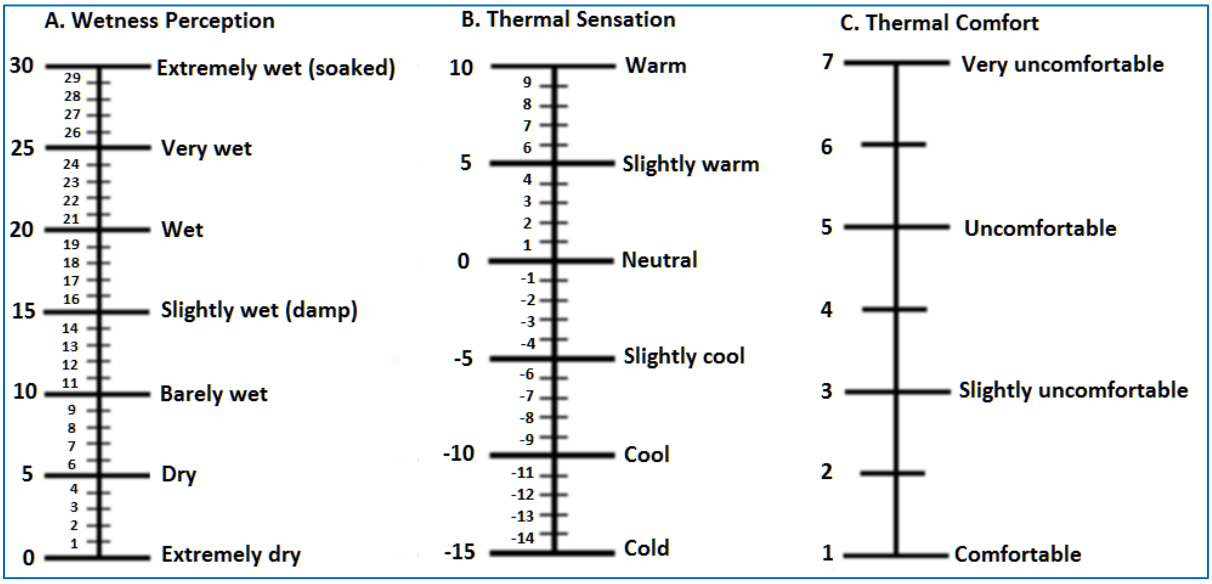
Sleep Quality and Menopause

Clothing comfort Scale

2.5h before bedtime
(immediately after donning sleepwear)

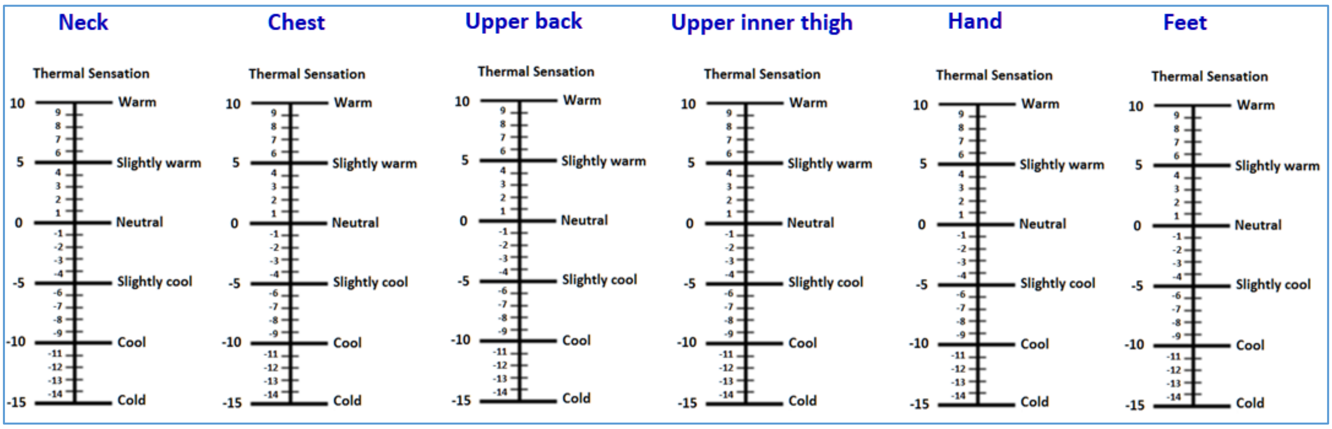
Your Study Code: ☐☐☐☐☐☐☐☐☐

Please mark on each of the scales below how you feel about the wetness perception, warm/cool sensation, and thermal comfort of the sleepwear fabric:



Interval scales for wetness perception, thermal sensation and thermal comfort (Raccuglia et al 2017).

Please mark on each of the scales below how you feel about the warm/cool sensation of the sleepwear fabric at different skin sites:



2.5h before bedtime
(immediately after donning sleepwear)

Mood Scale

Please mark on the scales below a point between 0 - 10, which best describes HOW YOU HAVE BEEN FEELING RIGHT NOW.

Motivation	Bored	0 ——————————— 10	Interested
Arousal state	Sleepy	0 ——————————— 10	Alert
Fatigue level	Weary	0 ——————————— 10	Energetic
Ease of concentration	Very low	0 ——————————— 10	Very high
Psychological tension	Tense	0 ——————————— 10	Relaxed
Elation	Sad	0 ——————————— 10	Happy
Physical discomfort	Very high	0 ——————————— 10	Very low
Contentedness	Unpleasant	0 ——————————— 10	Pleasant
Trouble falling asleep	Much worse	0 ——————————— 10	Much better

Page 2 of 6 pages

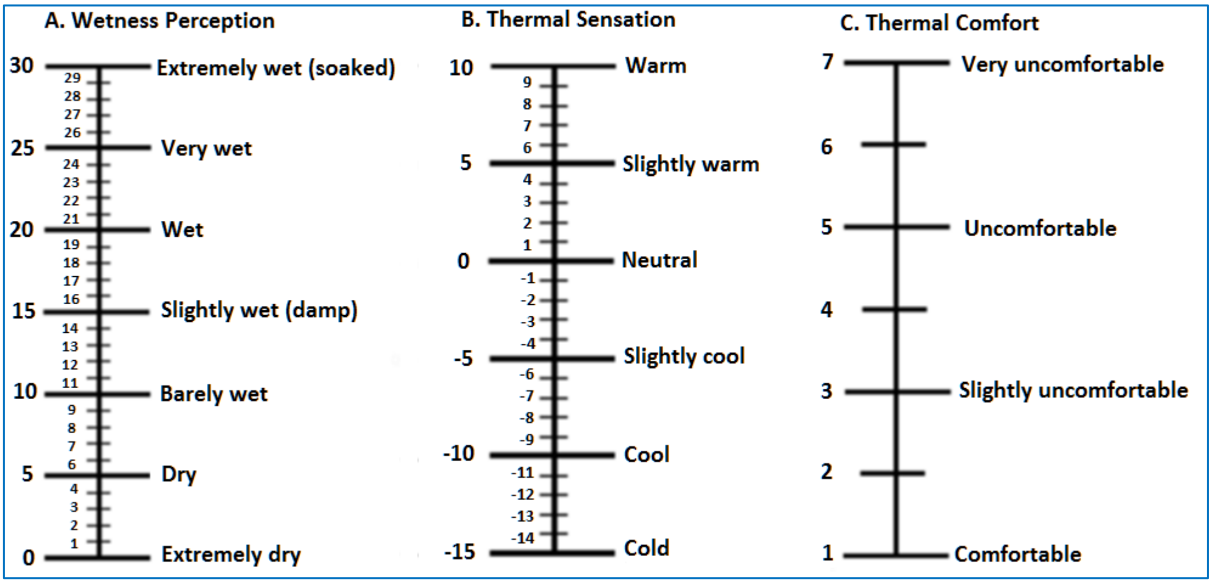
Sleep Quality and Menopause

Clothing comfort Scale

At bedtime
(10 mins prior to bed time)

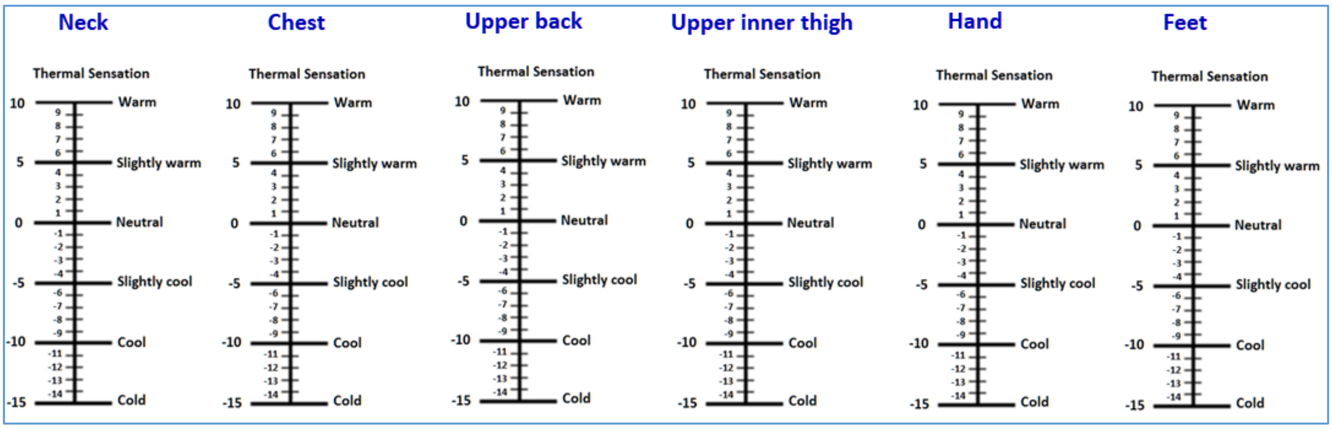
Your Study Code: | | | | | | | | | |

Please mark on each of the scales below how you feel about the wetness perception, warm/cool sensation, and thermal comfort of the sleepwear fabric:



Interval scales for wetness perception, thermal sensation and thermal comfort (Raccuglia et al 2017).

Please mark on each of the scales below how you feel about the warm/cool sensation of the sleepwear fabric at different skin sites:



Page 3 of 6 pages

At bedtime

Mood Scale

Please mark on the scales below a point between 0 - 10, which best describes HOW YOU HAVE BEEN FEELING RIGHT NOW.

Motivation	Bored		Interested
Arousal state	Sleepy		Alert
Fatigue level	Weary		Energetic
Ease of concentration	Very low		Very high
Psychological tension	Tense		Relaxed
Elation	Sad		Happy
Physical discomfort	Very high		Very low
Contentedness	Unpleasant		Pleasant
Trouble falling asleep	Much worse		Much better
		0 … **10**	

An Investigation of the Impact of Sleepwear Fibre Type On Menopausal Sleep Quality

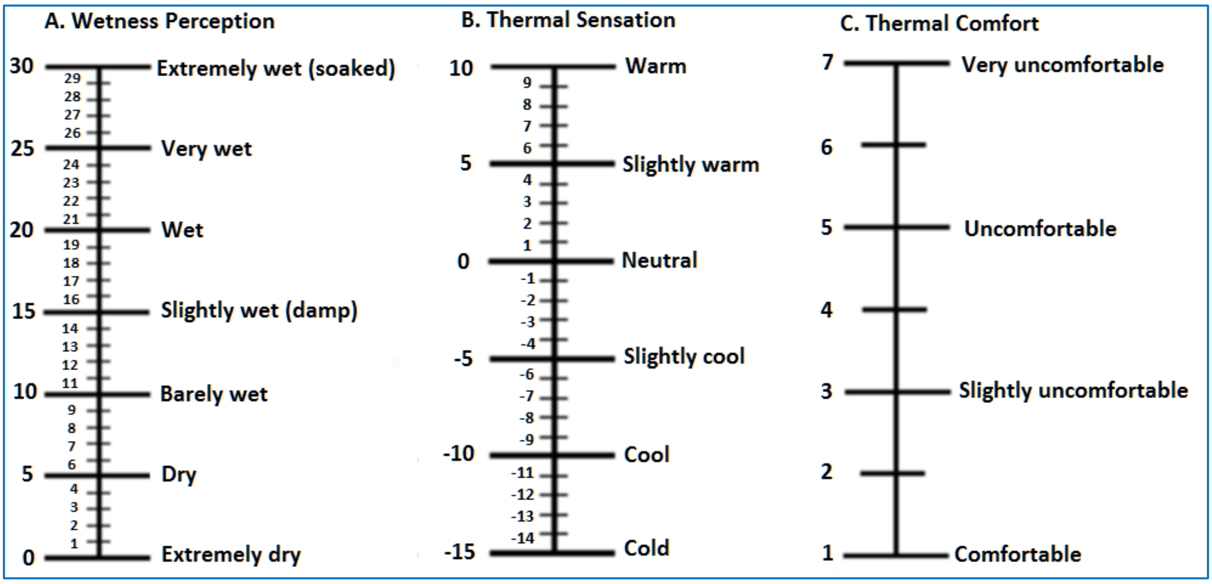
Clothing comfort Scale

On waking

Your Study Code: | | | | | | | | | |

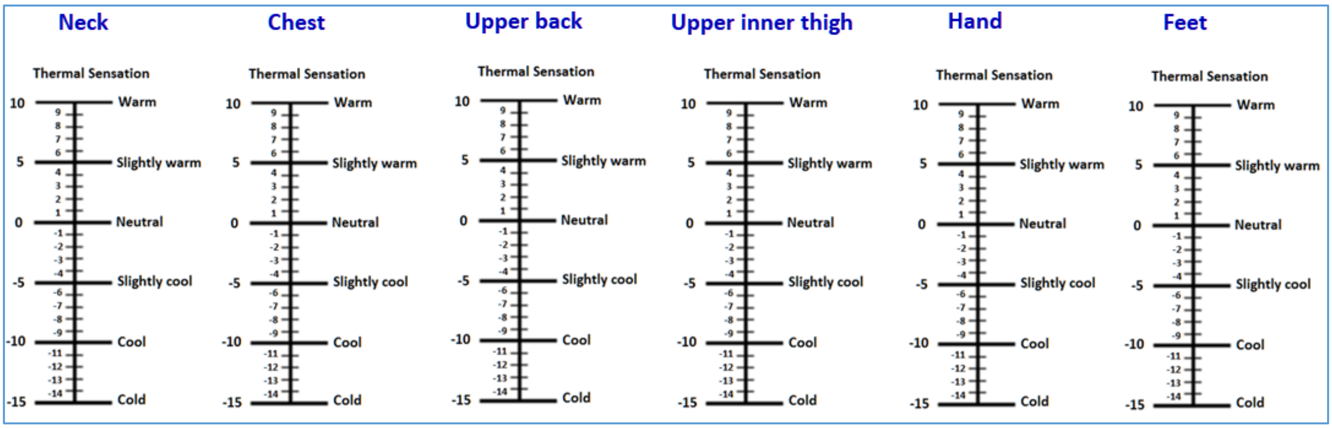
Clothing comfort Scale

Please mark on each of the scales below how you feel about the wetness perception, warm/cool sensation, and thermal comfort of the sleepwear fabric:



Interval scales for wetness perception, thermal sensation and thermal comfort (Raccuglia et al 2017)

Please mark on each of the scales below how you feel about the warm/cool sensation of the sleepwear fabric at different skin sites:



Page 5 of 6 pages

On waking

Mood Scale

Please mark on the scales below a point between 0 - 10, which best describes HOW YOU HAVE BEEN FEELING RIGHT NOW.

Motivation	Bored		Interested
Arousal state	Sleepy		Alert
Fatigue level	Weary		Energetic
Ease of concentration	Very low		Very high
Psychological tension	Tense		Relaxed
Elation	Sad		Happy
Physical discomfort	Very high		Very low
Contentedness	Unpleasant		Pleasant
Trouble falling asleep	Much worse		Much better
		0 10	

How many times did you wake up last night? (0-6)? Amount ___________

Did you experience any hot flashes last night?

No ☐

Yes ☐

How many times? (0-10)? Amount ________

Not sure ☐

THE UNIVERSITY OF SYDNEY

ABN 15 211 513 464

CONCORD REPATRIATION GENERAL HOSPITAL

Your 4-digital Study Code:

AWI(40xx)

What's your current visit?

Timing of this questionnaire:

Please mark on each of the scales below how you feel about the wetness perception, warm/cool sensation, and thermal comfort of the sleepwear fabric:

- A. Wetness Perception
  - 30 Extremely wet (soaked)
  - 25 Very wet
  - 20 Wet
  - 15 Slightly wet (damp)
  - 10 Barely wet
  - 5 Dry
  - 0 Extremely dry

30 Extremely wet (soaked)

30 25 20 15 10 5 0

0 Extremely dry

15 is your choice

Please mark on each of the scales below how you feel about the wetness perception, warm/cool sensation, and thermal comfort of the sleepwear fabric:

- B. Thermal Sensation
  - 10 Warm
  - 5 Slightly warm
  - 0 Neutral
  - -5 Slightly cool
  - -10 Cool
  - -15 Cold

10 Warm

10 5 0 -5 -10 -15

-15 Cold

0 is your choice

Please mark on each of the scales below how you feel about the wetness perception, warm/cool sensation, and thermal comfort of the sleepwear fabric:

- C. Thermal Comfort
  - 7 Very uncomfortable
  - 5 Uncomfortable
  - 3 Slightly uncomfortable
  - 1 Comfortable

7 Very uncomfortable

7 6 5 4 3 2 1

1 Comfortable

1 is your choice

→

ABN 15 211 513 464

Please mark on each of the scales below how you feel about the warm/cool sensation of the sleepwear fabric at different skin sites:

- Neck
  - 10 Warm
  - 5 Slightly warm
  - 0 Neutral
  - -5 Slightly cool
  - -10 Cool
  - -15 Cold

10 Warm
10 · 5 · 0 · -5 · -10 · -15
-15 Cold

0 is your choice

- Chest
  - 10 Warm
  - 5 Slightly warm
  - 0 Neutral
  - -5 Slightly cool
  - -10 Cool
  - -15 Cold

10 Warm
10 · 5 · 0 · -5 · -10 · -15
-15 Cold

0 is your choice

- Upper back
  - 10 Warm
  - 5 Slightly warm
  - 0 Neutral
  - -5 Slightly cool
  - -10 Cool
  - -15 Cold

10 Warm
10 · 5 · 0 · -5 · -10 · -15
-15 Cold

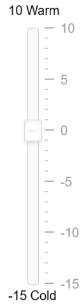
0 is your choice

- Upper inner thigh
  - 10 Warm
  - 5 Slightly warm
  - 0 Neutral
  - -5 Slightly cool
  - -10 Cool
  - -15 Cold

10 Warm
10 · 5 · 0 · -5 · -10 · -15
-15 Cold

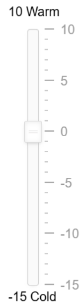
0 is your choice

- Hand
  - 10 Warm
  - 5 Slightly warm
  - 0 Neutral
  - -5 Slightly cool
  - -10 Cool
  - -15 Cold



0 is your choice

- Feet
  - 10 Warm
  - 5 Slightly warm
  - 0 Neutral
  - -5 Slightly cool
  - -10 Cool
  - -15 Cold



0 is your choice

→

ABN 15 211 513 464

Mood Scale

Please mark on the scales below a point between 0 - 10, which best describes HOW YOU HAVE BEEN FEELING RIGHT NOW.

	Bored									Interested		
	0	1	2	3	4	5	6	7	8	9	10	
Motivation						●						5
	Sleepy									Alert		
	0	1	2	3	4	5	6	7	8	9	10	
Arousal state						●						5
	Weary									Energetic		
	0	1	2	3	4	5	6	7	8	9	10	
Fatigue level						●						5
	Very low									Very high		
	0	1	2	3	4	5	6	7	8	9	10	
Ease of concentration						●						5
	Tense									Relaxed		
	0	1	2	3	4	5	6	7	8	9	10	
Psychological tension						●						5
	Sad									Happy		
	0	1	2	3	4	5	6	7	8	9	10	
Elation						●						5
	Very high									Very low		
	0	1	2	3	4	5	6	7	8	9	10	
Physical discomfort						●						5
	Unpleasant									Pleasant		
	0	1	2	3	4	5	6	7	8	9	10	
Contentedness						●						5
	Much worse									Much better		
	0	1	2	3	4	5	6	7	8	9	10	
Trouble falling asleep						●						5

→

ABN 15 211 513 464

We thank you for your time spent taking this survey.
Your response has been recorded.

Sleep Quality and Menopause
Modified Greene Climacteric Scale

Your Study Code: | | | | | | | | |

Please indicate the extent to which you are bothered **at the moment** by any of these symptoms by placing a tick in the appropriate box.

SYMPTOMS	Not at all	A little	Quite a bit	Extremely
1. Heart beating quickly or strongly				
2. Feeling tense or nervous				
3. Difficulty in sleeping				
4. Excitable				
5. Attacks of panic				
6. Difficulty in concentrating				
7. Feeling tired or lacking in energy				
8. Loss of interest in most things				
9. Feeling unhappy or depressed				
10. Crying spells				
11. Irritability				
12. Feeling dizzy or faint				
13. Pressure or tightness in head or body				
14. Parts of body feel numb or tingling				
15. Headaches				
16. Muscle and joint pains				
17. Loss of feeling in hands and feet				
18. Breathing difficulties				
19. Hot flushes				
20. Sweating at night				
21. Loss of interest in sex				

Tools Saved Dec 30, 2024 at 12:06 AM Draft Preview Publish

Modified Greene Climacteric Scale

ExpertReview score Fair

Block 1

Q4

Current Visit

Initial Review

Visit 1 (screening in laboratory)

Visit 2 (sleep study)

Visit 3 (sleep study)

Visit 4 (sleep study)

Visit 5 (sleep study)

Visit 6 (sleep study)

Back to preview mode

+ Add page break

Q3

Display this question

If Current Visit Initial Review Is Not Selected

And Current Visit Visit 1 (screening in laboratory) Is Not Selected

Your 4-digits Study Code

AWI(40xx)

Q5

Display this question

If Current Visit Initial Review Is Selected

Or Current Visit Visit 1 (screening in laboratory) Is Selected

Please enter your email address

Import from library + Add new question

Add Block

Default Question Block

Q1

Please indicate the extent to which you are bothered **at the moment** by any of these symptoms by placing a tick in the appropriate box.

	Not at all	A little	Quite a bit	Extremely
1. Heart beating quickly or strongly	○	○	○	○
2. Feeling tense or nervous	○	○	○	○
3. Difficulty in sleeping	○	○	○	○
4. Excitable	○	○	○	○
5. Attacks of panic	○	○	○	○
6. Difficulty in concentrating	○	○	○	○
	Not at all	A little	Quite a bit	Extremely
7. Feeling tired or lacking in energy	○	○	○	○
8. Loss of interest in most things	○	○	○	○
9. Feeling unhappy or depressed	○	○	○	○
10. Crying spells	○	○	○	○
11. Irritability	○	○	○	○
12. Feeling Dizzy or faint	○	○	○	○
	Not at all	A little	Quite a bit	Extremely
13. Pressure or tightness in head or body	○	○	○	○
14. Parts of body feel numb or tingling	○	○	○	○
15. Headaches	○	○	○	○
16. Muscle and joint pains	○	○	○	○
17. Loss of feeling in hands and feet	○	○	○	○
18. Breathing difficulties	○	○	○	○
	Not at all	A little	Quite a bit	Extremely
19. Hot flashes	○	○	○	○
20. Sweating at night	○	○	○	○
21. Loss of interest in sex	○	○	○	○

Import from library   Add new question

Add Block

End of Survey

We thank you for your time spent taking this survey.

Your response has been recorded.

Sleep Quality and Menopause
Insomnia Severity Index

1. Please rate the current (i.e., last 2 weeks) **SEVERITY** of your insomnia problem(s).

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

2. How **SATISFIED**/dissatisfied are you with your current sleep pattern?

Very Satisfied				Very Dissatisfied
0	1	2	3	4

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

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

4. How **NOTICEABLE** to others do you think your sleeping problem is in terms of impairing the quality of your life?

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

5. How **WORRIED**/distressed are you about your current sleep problem?

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

Célyne H. Bastien, Annie Vallières and Charles M. Morin. Sleep Medicine Volume 2, Issue 4, July 2001, Pages 297-307

Sleep Quality and Menopause
Participant Screening Questionnaire

Your Study Code: | | | | | | | | |

Demographics

Your Age:

Height:

Weight:

Are you experiencing cyclic irregularity in menstrual periods (menopause transition)? □ Yes □ No

Have you ceased menses? □ Yes □ No

If Yes, how long have you been in this menopausal stage?

□ For at least 1 year □ < 2 years □ > 2 years

Have you had surgery to remove both ovaries? □ Yes □ No

If Yes, when did the surgery occur? □ 1 year ago □ < 2 years ago □ > 2 years ago

On average, how many hot flashes do you have per day? ________

Are you on shift work or have crossed several time zones in the past fortnight? □ Yes □ No

Are you willing to refrain from moderate-intense exercise of greater than 30 minutes or mild exercise of greater than 1h on each sleep study night? □ Yes □ No

Your Health Status

Do you have any health issues? □ Yes □ No

If Yes, please specify ____

Please indicate if it is (they are) well under control/managed? □ Yes □ No

Any Comments: ……………………………………………………………

Do you have any sleep disorders? □ Yes □ No

If Yes, please specify ____

Do you have any psychiatric conditions (e.g, insomnia, restless leg syndrome, depression, schizophrenia)? □ Yes □ No

Are you on any medications containing estrogen, progestins, or androgens? □ Yes □ No

If Yes, please list the medications……………………………………………………………………………………

CASE REPORT FORM (CRF)

Full Study Title:

An Investigation of the Impact of Sleepwear Fibre Type on Menopausal Sleep Quality

Short Title:

Sleepwear fibre and sleep quality

Protocol No. 2019/151

Discipline of Exercise and Sport Science,
Sydney School of Health Sciences,
Faculty of Medicine and Health,
Room K222, Building C42,
The University of Sydney,
NSW 2006 AUSTRALIA

FDA's CDASH (Clinical Data Acquisition Standards Harmonization) standards
Case Report Form (CRF)

The following pages are included in each clinical trial CRF:

- Front page
- CRF Completion Instructions
- Demographics (including informed consent details, but the ethnicity is not compulsory)
- Inclusion and Exclusion Criteria
- Eligibility Review and sign off
- Trial Medication Administration (choose the appropriate method of administration, or add your own)
- Trial Assessments
- Study completion
- Adverse events page
- Concomitant Medications table
- Principal Investigator's sign off

Instructions

Complete the CRF using a black / blue ballpoint pen and ensure that all entries are complete and legible.

Avoid the use of abbreviations and acronyms.

The CRF should be completed as soon as possible after the scheduled visit.

Do not use participant identifiers anywhere on the CRF, such as name, hospital number etc., in order to maintain the confidentiality of the participant. Ensure that the header information (i.e. participant's initials and ID number) is completed consistently throughout the CRF. Missing initials should be recorded with a dash (i.e. D-L).

Each CRF page should be signed and dated by the person completing the form.
The 'completed by' Name in the footer of each page must be legible and CRFs should only be completed by individuals delegated to complete CRFs on the Site Delegation log (and signed by the PI).

Ensure that all fields are completed on each page:

- If a test was Not Done record ND in the relevant box(es)
- Where information is Not Known write NK in relevant box(es)
- Where information is not applicable write NA in the relevant box(es)

Medications taken by the participant during the trial should be recorded on the "Concomitant Medications Log" using the generic name whenever possible, except combination products which will be recorded using the established trade name. All non-IMPs mentioned in the protocol should also be recorded on the "Concomitant medication Log" for the duration of the trial.

Verbatim Adverse Event terms (initial medical term) should be recorded as the final diagnosis whenever possible.

Complete all dates as day, month, year i.e. 13/NOV/2008. Partial dates should be recorded as NK/NOV/2008.

All times are to be recorded in 24 hour format without punctuation and always use 4-digits; i.e. 0200 or 2130. Midnight is recorded as 0000.

Weights should be recorded to the nearest 0.1 kg.

Source documents such as lab reports, ECG reports etc. should be filed separately from the CRF (if not in the medical notes) for each participant and be signed and dated by a delegated Investigator as proof of review of the assessment during the trial. Questionnaire should be considered as the CRF appendices (except standard approved questionnaire e.g. EQ-5D)

If a participant prematurely withdraws from the trial a single line must be drawn across each uncompleted page to correspond with the last visit of the participant as mentioned on the "Trial Completion" page.

The protocol deviation/violation/serious breach log should be used to record comments relating to each CRF visit that cannot be captured on the page itself. This includes reason for delayed or missed protocol visits or trial assessments, unscheduled visits etc.

The Chief Investigator (for lead site)/Principal Investigator is responsible for the accuracy of the data reported on the CRF. The CI/PI must sign and date the Principal Investigator's Sign Off page to certify accuracy, completeness and legibility of the data reported in the CRF.

Serious Adverse Events (SAEs)
SAEs should be faxed within 24 hours of the site being aware of the event using the trial specific SAE report form to the local site HREC and relevant governance office as required by the NHMRC registered HREC.

Storage
CRF documents should be stored in the Research Data Store, University of Sydney where confidentiality can be maintained. Ensure that they are stored separately to any other documents that might reveal the identity of the participant.

Monitoring Plan
Ensure all visits are referenced/aligned to the clinical trial monitoring plan for the study.

All the date in the format of DD/MON/YYYY e.g. 01/JAN/2020
All the time in the format of HHMM e.g. 5:00pm = 1700

Demographics

Age:

Ethnicity:

☐ **Asian**
☐ **Caucasian**
☐ **Mixed Background**
☐ **Other** (specify)______________

Informed Consent Process

Participant Information Statement and related study documents were thoroughly reviewed with the subject. ***Date:*** ***Time:***

☐ **Yes** ☐ **No**

Subject had sufficient time to review the documents and ask questions.

☐ **Yes** ☐ **No**

Informed consent was signed by the participant. ***Date:*** ***Time:***

☐ **Yes** ☐ **No**

A copy of the signed documents has been given to the subject.

☐ **Yes** ☐ **No**

If no, please explain: ____

The signed consent form has been filed in the study folder.

☐ **Yes** ☐ **No**

If no, please explain: ____

Name of person who obtained consent: Cynthia Li

Questionnaires completed	**Yes**	**No**	**Version Date**
Participant Screening Questionnaire			
Insomnia Severity Index			
Modified Greene Climacteric Scale			

Reasons for not consenting to study:

____

____

All the date in the format of DD/MON/YYYY e.g. 01/JAN/2020
All the time in the format of HHMM e.g. 5:00pm = 1700

Eligibility Criteria

Inclusion Criteria

Patients who meet ***all*** of the following criteria are eligible for enrollment as study participants:

		YES	NO	N/A
1.	Aged 45-65 years			
2.	BMI ≤ 30 $kg \cdot m^{-2}$			
3.	peri-menopausal (experience cyclic irregularity over the preceding 12 months and up to 11 months of amenorrhea – menopause transition), or post-menopausal (have ceased menses for at least 1 year and not more than 2 years), or had bilateral oophorectomy at least six weeks before screening			
4.	Vasomotor scale of 2 or greater (Greene Climacteric Scale)			
5.	Insomnia Severity Index score ≤ 14			
6.	Willing to undergo five nights of sleep studies.			
Restrictions				
1.	refrain from caffeinated beverages (tea/coffee/cola drinks etc), alcohol or strenuous exercise eight hours prior to their usual bedtime.			

Exclusion Criteria

Patients who meet ***any*** of these criteria are ***not*** eligible for enrollment as study participants:

		YES	NO
1.	Currently use medication containing estrogen, progestins, or androgens within 8 weeks from the start of the study.		
2.	Have (or a history of) disorders that might affect sleep and/or thermoregulation (e.g., diabetes, cancer, heart disease, lung diseases, Raynaud's syndrome).		
3.	Have (or a history of) moderate to severe sleep breathing disorders, sleep disorders and psychiatric conditions (e.g., insomnia, restless leg syndrome, depression, schizophrenia).		
4.	Are on shift work or have crossed several time zones in the past fortnight.		
5.	Are unwilling to refrain from moderate-intense exercise of greater than 30 minutes or mild exercise of greater than 1h on each sleep study night.		
6.			

All the date in the format of DD/MON/YYYY e.g. 01/JAN/2020
All the time in the format of HHMM e.g. 5:00pm = 1700

Medical and Smoking History

Does the participant have any relevant medical history?

☐ **Yes** ☐ **No**

If yes, please list medical conditions: ____

Does the participant take any medications?

☐ **Yes** ☐ **No**

If yes, please list medications: ________________________________

Has the participant ever smoked?

☐ **Yes** ☐ **No**

If yes,

For ☐ **Current Smoker,** the average daily use (number per day): ________

For ☐ **Former Smoker,** smoked for ____years and _____months,

date when smoking ceased (DD/MMM/YYYY): ________

Physical Measurement

Item	**Record**	**Time** (HHMM)
Height		
Body Weight		
Neck Circumference		
Waist Circumference		
Blood Pressure		
Dominant Hand		

Participant Eligibility Review		YES	NO
1.	Does the Participant satisfy the inclusion/exclusion criteria?		
2.	Have the medical history and concomitant medication question been completed?		
3.	Is the Participant still willing to proceed in the trial?		

Participant Enrolment:

Study Number Allocated:

Date of Enrolment:

Participant's eligibility Investigator sign-off
Is the Participant eligible to take part in the Clinical Trial? ☐ **Yes** ☐ **No** (If no, please give reasons below) Principal Investigator's (or delegated individual*) Signature: Chin Moi Chow Date (DD/MMM/YYYY): Investigator's Name: Cynthia Li *Must be reflected in the Delegation of Authority Log
Reason(s) for screen failure
1.
2.
3.

PI: Chin Moi Chow, Study No. 2019/151, Sleepwear fibre and sleep quality
Participant Study ID: AWI40 Visit 2-6 sleep study

All the date in the format of DD/MON/YYYY e.g. 01/JAN/2020
All the time in the format of HHMM e.g. 5:00pm = 1700
1 or √ stands for **YES** 0 or X stands for **NO**

Items		Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
Date (DD/MON/YYYY)						
Sleepwear allocated		Green				
Telephone contact	Attempt(s) Time (Contact occurred)					
	How's your sleep last night? (1.normal 0.very good/poor)					
	Don't do strenuous exercise today.					
	Don't drink caffeine beverage after noon.					
	Any questions?					
Notification email send time						
Participant arrived time						
Physical activity record completion time						
Blood pressure & time (mmHg)						
Body weight &time (kg)						
Neck circumference (cm), time						
Waist circumference (cm), time						
Mealtime						
Sleepwear weight (kg)						
Changing sleepwear time						
Clothing comfort and mood scales time 1						
Last fluid intake						
Sensors	PSG					
	Thor					
	Therm					
	Leg					
Time to enter bedroom						
Body weight at bedtime (to the nearest 0.01 kg)						
Clothing comfort and mood scales time 2						
Light out time						
Wake up time						
Clothing comfort and mood scales time 3						
Body weight on waking (to the nearest 0.01 kg)						
Greene Climacteric Scale time						
Sleepwear weight						
Amount of urine (kg) (to the nearest 0.01 kg)						
Participant left laboratory time						

Date subject went off study:
DD/MMM/YYYY

Subject Off Study

Visit(s) Completed:

☐ **Visit 1** ☐ **Visit 2** ☐ **Visit 3** ☐ **Visit 4** ☐ **Visit 5** ☐ **Visit 6**

Indicate off study reason:

☐ **Person reasons**

☐ **Lost to follow-up**

☐ **Non-compliance**

Comments:

____

____

____

Form Completed By:

Cynthia Li

Principle Investigator's Signature:

Chin Moi Chow

Faculty of Health Sciences
College of Health Sciences
Cumberland Campus
East Street (PO Box 170)
Lidcombe NSW 2141 (1825)

RESEARCH STUDY INTO

Sleep Quality and Menopause

This study is conducted by *A/Prof Chin Moi Chow (Associate Professor, Discipline of Exercise and Sport Science).*

STATEMENT OF CONSENT

Re: MotionWatch8

I, …………………………………………………………………………….[name]

……………………………………………………………………………….[address1]

……………………………………………………………………………….[address2]

……………………………………………………………………………….[phone number]

will wear the MotionWatch8 [Asset tag # ……………………] for a period of _______ from

_______________ to _________________.

I am aware that this wrist-watch is a property of the University of Sydney, and I hereby agree to take responsibility for its care and will return it at the end of my involvement with the study.

Signature:..

Name:...

Date:...

ABN 15 211 513 464

Discipline of Exercise and Sport Science
Faculty of Medicine and Health
The University of Sydney
NSW 2006 AUSTRALIA
Telephone: +61 2 9351 9332
Email: chin-moi.chow@sydney.edu.au

Study Title: An Investigation of the Impact of Sleepwear Fibre Type on Menopausal Sleep Quality

Short Title: Sleep Quality and Menopause

PARTICIPANT INFORMATION STATEMENT

1. What is this study about?

You are invited to take part in a research study looking at how well you sleep and your menopausal symptoms overnight comparing different sleepwear material. We are interested to find out which sleepwear material promotes a better night's sleep. This is a 3-4 week study. We are recruiting healthy menopausal women aged 45-65 years, who are going through a menopause transition and experiencing hot flashes, night sweats, and sleeping difficulties, and who are in the first two years of menopause.

Knowing what is involved will help you decide if you participate in this research. This Information Statement provides certain details about the research. Please read these details carefully and ask questions about anything that you do not understand or want to know more about.

Participation in this research study is voluntary.
By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

2. Who is running the study?

This study is being conducted by Cynthia Li (Research student) and will form the basis for the degree of Doctor of Philosophy - Research at The University of Sydney under the supervision of A/Prof Chin Moi Chow and A/Prof Mark Halaki of the University of Sydney.
This study is funded by an organisation that represents the interests of a sector of the clothing industry, which receives a report from the Principal Investigator at each milestone that is met with funding payment. The organisation receives a final report and a manuscript for journal submission and does not receive raw or processed data. The organisation may potentially benefit from the study results via journal publications or newsletters. All publications are subject to funding organisation's prior written approval.

3. What will the study involve for me?

This study will require you to make a total of six visits to the Concord Sleep Study Unit at Concord Hospital, five of which are overnight sleep studies. The sleep studies will be conducted at warm conditions of ~30°C. The Sleep Study Unit is located at Level 6 East Multi-Building (Building 5) Hospital Rd, Concord.

Visit 1: This visit involves health screening and answering a number of questionnaires (the Modified Greene Climacteric scale and Clothing comfort & mood scale will be completed online on the Qualtrics platform, and the Insomnia Severity Index questionnaire is paper-based). If you satisfy the screening requirements, you will be supplied with a wristwatch (MotionWatch8) to wear for the duration of the study. Your height, weight, neck circumference, and waist circumference will be measured, and blood pressure taken.

MotionWatch8:
This is a wristwatch that you wear for the entire study period. The MotionWatch8 records your physical activity level and sleep patterns. Data logged by this device are downloaded and stored in Research Data Store (DashR) and backed up regularly by University. These are de-identified data.
The MotionWatch 8 can be worn 24/7. We suggest that you remove it while in the shower/swimming. We supply a re-charged MotionWatch8 every 7-14 days.

Visit 2: This visit requires an overnight sleep study after Visit 1. This night serves as a familiarisation night for getting used to sleeping in the lab and with the equipment setup.

Overnight Sleep Study:
On the study night, skin sensors will be applied to your scalp, face and chest, and effort bands will be applied over your chest and abdomen to record signals for sleep patterns. A Bahr Monitor (a small gadget taped to the chest) is for recording the number of hot flashes. Sweat output is measured via urine collection.

A bedroom of your own is provided in the Sleep laboratory during an overnight sleep study. Sleepwear will be provided and that the sleepwear will be a long sleeved top and long pants. For purpose of communication and safety, the bedroom has an infrared camera so that the researcher monitoring you can see what's happening in the room after lights out. The researcher can talk to you and hear you from the monitoring room outside the bedroom.

Visits 3-6: Each of these four visits requires an overnight sleep study as arranged with the researcher. Each visit must be separated by at least one night.

You will arrive at the Sleep laboratory at a time arranged for you (usually at 5-7pm). A standardised evening meal is provided. This is eaten 4 hours before your usual bedtime.

- Eight hours prior to your usual bedtime, please refrain from caffeinated beverages (tea/coffee/cola drinks etc), alcohol or strenuous exercise.
- You will be asked to complete a Clothing comfort scale and a mood scale both at bedtime and on waking. In addition, you will be asked to complete the Modified Greene Climacteric scale (regarding your menopausal symptoms).
- You will be retained for ~10 minutes after waking following each sleep study to allow for adequate time to remove testing equipment.

4. How much of my time will the study take?

The study will require you to attend the laboratory: Visit 1 for screening for roughly 3-4 hours for physiological measurements, and to complete questionnaires. Visits 2-6 are five overnight sleep studies. Each sleep study will take 11 to 13 hours from arriving to leaving the laboratory, depending on your usual sleep duration.

Mainly at your Home: Wear the MotionWatch8.

5. Who can take part in the study?

Any women 45-65 years of age, who are in menopause transition or have ceased menstruation for no more than two years, are welcome to join the study.

Exclusion:

- Currently use medications used for menopausal symptom relief within 8 weeks of the study start
- Have (or a history of) disorders that might affect sleep (e.g., diabetes, cancer, heart disease, conditions that affect your temperature regulation)
- Have (or a history of) moderate to severe sleep breathing disorders, sleep disorders and psychiatric conditions (e.g., insomnia, restless leg syndrome, depression, schizophrenia)
- Are on shift work or have crossed several time zones in the past fortnight
- Are unwilling to refrain from moderate-intense exercise of greater than 30 minutes or mild exercise of greater than 1h on each sleep study night

6. Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney or Concord Hospital.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by letting the researcher, Chin Moi Chow or Cynthia Li, know via email at chin-moi.chow@sydney.edu.au or cynthia.li@sydney.edu.au that you no longer wish to participate.

If you decide to withdraw from the study, we will not collect any more information from you. Please let us know at the time when you withdraw what you would like us to do with the information we have collected about you up to that point. If you wish your information will be removed from our study records and will not be included in the study results, up to the point that we have analysed and published the results.

7. Are there any risks or costs associated with being in the study?

No intentional risk involves in this study because the study design and screening has been designed taking considerations into possible risks involved. Anyone allergic to sleepwear fabric (e.g., cotton, polyester, wool) should avoid participating in this study. In the event that you have any medical problem or fabric allergy, please contact your GP.

Cynthia Li, Research student, will attend your sleep study. Please contact Security/support if you have any concerns about your safety at any time – Phone: 9767 6223.

Apart from giving up your time and cost for travelling to the Sleep laboratory, we do not expect that there will be any risks or costs associated with taking part in this study.

8. Are there any benefits associated with being in the study?

We cannot guarantee that you will receive any direct benefits from being in the study.
You will receive $1000 for your participation when you complete the study (a familiarisation night + 4 test nights). Payment of $600 will be made for completion of the familiarisation night and at least 3 of the 4

nights required. If you do not participate at least 3 nights, the data become unusable. There is no payment provision for participation if it is less than these number of nights specified.

9. What will happen to information about me that is collected during the study?

All the information collected about you for the study will be treated confidentially. The data (hard copies) are de-identified, scanned and securely stored on The University of Sydney approved software license for Research Data Store (RDS). The online questionnaire data are stored on the Qualtrics Experience Management Platform™, which is security compliant (see https://www.qualtrics.com/platform/security/). The data will be retained for 20 years before it is destroyed. The hard copies are destroyed by shredding or placed in secure locked bins for disposal by the University.

Only the researchers named above will have access to your data. If you consent to take part in this study your study records may be inspected by regulatory authorities or by the Human Research Ethics Committee to check that the research has been carried out appropriately. By signing the consent form you are giving permission for this to be done. All details obtained by those named will remain confidential.

If you give us your permission by signing the consent document, we plan to publish the results in peer-reviewed journals, presentation at conferences or other professional forums. Some journals request that data be shared. In any publication, information will be provided in such a way that you cannot be identified. A copy of the manuscript for journal submission will also be sent to the clothing industry funding body, as it is interested to collect evidence on how the different sleepwear affects sleep outcomes. The clothing industry will not influence the decision to submit the manuscript or alter the manuscript.

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

10. **Can I tell other people about the study?**

Yes, you are welcome to tell other women if they would like to take part in the study.

11. What if I would like further information about the study?

When you have read this information, at the time of consent, A/Prof Chin Moi Chow will be available to discuss the project with you further and answer any questions you may have.

12. **Will I be told the results of the study?**

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box in the Consent form. This feedback will be in the form of a one-page lay summary. You will receive this feedback after the study is completed.

13. What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the Sydney Local Health District – Concord Repatriation General Hospital. If you have any concerns or complaints about the conduct of the research study, you may contact the Executive Officer of the Ethics Committee, on (02) 9767 5622 and quote study number 2020/ETH03028. As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007) updated 2018.* This statement has been developed to protect people who agree to take part in research studies.

The conduct of this study at the Concord Sleep Study Unit has been authorised by Concord Hospital Research Office. Any person with concerns or complaints about the conduct of this study may contact the Research Governance Officer on (02) 9767 5622 and quote protocol number 2020/ETH03028.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

Supplementary Information

The Australian Federal and State Governments have implemented social distancing requirements to manage the COVID-19 pandemic that may affect your willingness to continue in this research.

The researchers have implemented the following steps to comply with social distancing requirements and ensure participant and researcher safety

For the overnight sleep study, the following procedures will be observed and followed:

- A $4m^2$ space per individual will be provided for each person. You have own bedroom.
- You and the researcher will don face masks. You remove the mask only during electrode (sensor) placements on the scalp, behind the ears and skin surfaces.
- Social distancing of 1.5 metres minimum will be kept, except during electrode placements. Aseptic techniques are applied with electrode placement as per standard procedure. The researcher will wear a disposable plastic gown/ lab coat and gloves during this procedure.
- Hand hygiene (alcohol-based hand rub and/or hand washing) before and after all contact.
- Following the study, all reusable gold-cup electrodes are soaked in detergent, rinsed, and followed by soaking in a disinfectant solution and rinsing as per standard procedure.
- All surfaces of work benches are wiped down before and after each overnight study.
- All wastes are plastic wrapped for disposal by the cleaners.
- Bed linen are washed in hot water after each overnight study. Gloves are worn during handling of linen.

This information sheet is for you to keep

ABN 15 211 513 464

CONCORD REPATRIATION GENERAL HOSPITAL

Discipline of Exercise and Sport Science
Faculty of Medicine and Health
The University of Sydney
NSW 2006 AUSTRALIA
Telephone: +61 2 9351 9332
Email: chin-moi.chow@sydney.edu.au

Study Title: An investigation of the Impact of Sleepwear Fibre Type on Menopausal Sleep Quality

Short Title: Sleep Quality and Menopause

PARTICIPANT CONSENT FORM

I, ... [PRINT NAME], agree to take part in this research study.

In giving my consent I state that:

- I understand the purpose of the study, what I will be asked to do, and any risks/benefits involved.
- I have read the Participant Information Statement and have been able to discuss my involvement in the study with the researchers if I wished to do so.
- The researchers have answered any questions that I had about the study and I am happy with the answers.
- I understand that being in this study is completely voluntary and I do not have to take part. My decision whether to be in the study will not affect my relationship with the researchers or anyone else at the University of Sydney now or in the future.
- I understand that I can withdraw from the study at any time.
- I understand that personal information about me that is collected over the course of this project will be stored securely and will only be used for purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.
- I understand that the results of this study may be published, and that publications will not contain my name or any identifiable information about me.
- I understand that the University of Sydney software license for DashR, a platform for data storage system, will be used to manage the collection and storage of my research data.

- The funding body will receive a report of the study findings and a manuscript for submission to a journal for publication.
- Any stored samples/data that is used for related or future research, will first be reviewed and approved by an appropriately constituted Ethics Committee.

The tick boxes are for procedures that are in addition to the main study.

I consent to:

Being contacted about future studies	YES	☐	NO	☐
Anonymised data being shared beyond the project	YES	☐	NO	☐
I would like to receive feedback about the overall results of this study	YES	☐	NO	☐

If you answered **YES**, please indicate your preferred form of feedback and address:

☐ Postal: ____

____

☐ Email: ____

Signature of participant	**Please PRINT name**	**Date**	**At (place)**
______________________	________________________	________________	__________________
Signature of investigator	**Please PRINT name**	**Date**	**At (place)**
______________________	________________________	________________	__________________

THE UNIVERSITY OF SYDNEY

Discipline of Exercise and Sport Science
School of Health Sciences
Faculty of Medicine and Health

ABN 15 211 513 464

Chin Moi Chow
Associate Professor

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Building C42
The University of Sydney
NSW 2006 AUSTRALIA
Telephone: +61 2 9351 9332
Facsimile: +61 2 9351 9204
Email: chin-moi.chow@sydney.edu.au
Web: http://www.sydney.edu.au/

Sleep Quality and Menopause

PARTICPANT INFORMATION – COVID-19 SUPPLEMENT

Dear participant.

You have previously consented to participate in the clinical trial

Sleep Quality and Menopause

Being conducted by Cynthia Li, A/Prof Chin Moi Chow, A/Prof Mark Halaki

The Australian Federal and State Governments have implemented social distancing requirements to manage the COVID-19 pandemic that may affect your willingness to continue in this research.

The researchers have implemented the following steps to comply with social distancing requirements and ensure participant and researcher safety

For the overnight sleep study, the following procedures will be observed and followed:

- A 4m^2 space per individual will be provided for each person. You have own bedroom.
- You and the researcher will don face masks. You remove the mask only during electrode (sensor) placements on the scalp, behind the ears and skin surfaces.
- Social distancing of 1.5 metres minimum will be kept, except during electrode placements. Aseptic techniques are applied with electrode placement as per standard procedure. The researcher will wear a disposable plastic gown/ lab coat and gloves during this procedure.
- Hand hygiene (alcohol-based hand rub and/or hand washing) before and after all contact.
- Following the study, all reusable gold-cup electrodes are soaked in detergent, rinsed, and followed by soaking in a disinfectant solution and rinsing as per standard procedure.
- All surfaces of work benches are wiped down before and after each overnight study.
- All wastes are plastic wrapped for disposal by the cleaners.
- Bed linen are washed in hot water after each overnight study. Gloves are worn during handling of linen.

THE UNIVERSITY OF SYDNEY

ABN 15 211 513 464

Discipline of Exercise and Sport Science
School of Health Sciences
Faculty of Medicine and Health

PARTICIPANT CONSENT FORM - COVID-19 SUPPLEMENT

I have reviewed the supplemental information provided

- I understand the purpose of the research, what I will be asked to do, and any risks/benefits involved.
- I have read the Participant Information Statement and have been able to discuss my continuing involvement in the clinical trial with the researchers if I wished to do so.
- The researchers have answered any questions that I had, and I am happy with the answers.
- I understand that continuing in this clinical trial is completely voluntary and I do not have to take part. My decision whether to continue to participate will not affect my relationship with the researchers or anyone else at the University of Sydney [INSERT, if applicable to your study, any other individuals or institutions relating to your research] now or in the future.
- I understand that I can withdraw from the clinical trial at any time.

I wish to (check one of the options below)

☐	continue participation in the trial**, OR**
☐	temporarily discontinue participation in the trial during the COVID-19 social distancing restrictions, **OR**
☐	withdraw from all further participation in the trial

Participant's Study Identifier / Enrolment ID …………………………………………………

Participant's name (printed) ……………………………………………………………………….

Participant's signature: …………………………………………… Date of Signature: ………………….

THE UNIVERSITY OF SYDNEY – CLINICAL TRIALS SUPPORT OFFICE (CTSO)

COVID-19 SYMPTOMS PRE-SCREEN FOR FACE-TO-FACE VISITS

Participant ID:

This tool may be used to document participant pre-screening for COVID-19 symptoms prior to a trial face-to-face visit
Researchers should also monitor themselves and all research staff for the same symptoms.

Clinical Trial Title: Menopause and sleep quality study								
Site & Site Principal Investigator:	**Timepoint**							
	When Scheduling Appointment	**Day Before Visit**	**Visit 1**	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**
Date and Time of contact with participant								
In the past 14-days has the participant:								
1. Returned from overseas travel (or a cruise ship) or visited / resided in an Australian COVID-19 "hot-spot"?	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No
2. Been in contact with a possible or positive case of COVID-19?	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No
3. Been suspected of, or confirmed with, having COVID-19?	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No
4. Had a fever of 37.5°C or more or symptoms suggestive of fever (eg, night sweats, chills)?	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No
5. Had a respiratory infection (eg, cough, shortness of breath, sore throat)?	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No
6. Been unwell in any way? If Yes, describe.	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No	☐ Yes / ☐ No
Interviewer Name, Signature & Date:								

If the participant has answered Yes to:

- *Question 1, ensure 14-day quarantine is completed;*
- *Any of Questions 2-5, reschedule the face-to-face visit*
- *Question 6, assess on a case-by-case basis*

Adverse event, including COVID-19 infection, reporting requirements must be adhered to!

APPENDIX B

ETHICS DOCUMENTS

Ethics Approval Letter- The University of Sydney 2019/151

Ethics Approval Letter- SLHD-CRGH 2020/ETH03028

Advertisement

Bulletin Advertisement

Trialfacts Promotional Material

ATRG entry CamNtech MotionWatch Actigraphy

THE UNIVERSITY OF SYDNEY

Prof Duncan Ivison
Deputy Vice-Chancellor (Research)

Clinical Trials Support
The University of Sydney
Research Portfolio, Level 3
Administration Building (F23)
The University of Sydney | NSW | 2006

07/05/2019

Associate Professor Chin-Moi Chow
Room K222, Building C43,
Faculty of Health Sciences,
The University of Sydney, NSW 2006

Attention: chin-moi.chow@sydney.edu.au

Dear A/Prof Chin-Moi Chow

Project Title: An investigation of the Impact of Sleepwear Fibre Type on Menopausal Sleep Quality

APPROVING HREC: USYD **HREC No:** 2019/151

HREC APPROVAL DATE: 17/04/2019

INITIAL SITE-SPECIFIC ASSESSMENT APPROVAL LETTER

Thank you for submitting your site-specific assessment application for the abovementioned new clinical trial.

I am pleased to inform you that Site Authorisation has been granted **for Health Sciences Lidcombe Campus at the University of Sydney.**

The following research personnel are permitted to begin study related activities:
A/Prof Chin-Moi Chow

A summary of the documentation submitted includes:

Document Type	**Version**	**Version or Execution Date**	**Acknowledged** *(receipt for USYD Site)*	**Document Approved** *(for use at USYD Site)*
Clinical Trials Risk and Site-Specific Assessment Initial Application Form		03/01/2019	X	
HREC approval letter		17/04/2019	X	
Protocol	01	03/01/2019	X	X
Participant Information Sheet	02	27/03/2019	X	X

ABN 15 211 513 464
CRICOS 00026A

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Document Type	**Version**	**Version or Execution Date**	**Acknowledged** *(receipt for USYD Site)*	**Document Approved** *(for use at USYD Site)*
Participant Consent Form	03	09/04/2019	X	X
CVs for all the above-mentioned personnel			X	
Clothing comfort Mood	02	27/03/2019	X	X
Participant payment form	02	27/03/2019	X	
Advertisement	01	03/01/2019	X	X
Bulletin Advertisement	01	03/01/2019	X	X
Insomnia severity index	01	03/01/2019	X	X
Letter to place advertisement	01	03/01/2019	X	X
Modified greene climacteric scale	01	03/01/2019	X	X
Newspaper advertisement	01	03/01/2019	X	X
Participant screening questionnaires	01	03/01/2019	X	X
Power calculations	01	08/02/2019	X	
Email to participants – initial contact	01	03/01/2019	X	X
Bahr Monitor User Guide	01	11/04/2019	X	
Clinical Trial Budget	01	03/01/2019	X	
Clinical Trial Data Management Plan	01	03/01/2019	X	
Clinical Trial Monitoring Plan	01	03/01/2019	X	
SOP	01	03/01/2019	X	

The following conditions apply to this research study. These are additional to those Conditions imposed by the Human Research Ethics Committee (HREC) that granted Ethical approval:

1. This Clinical trial will be conducted under the TGA CTN Scheme. Your study **cannot** commence until it has been notified to the Therapeutic Goods

THE UNIVERSITY OF SYDNEY

Administration (TGA) and a copy of the TGA acknowledgement email has been received by the Principal Investigator.

   a. Please contact the Clinical Trial Governance Office and complete the CTN Form. Once Governance has created the record and you have processed payment via your credit card, you must submit a copy of the TGA Receipt.to the Clinical Trial Governance mailbox (clinical-trials.research@sydney.edu.au) to finalise your submission.

2. A copy of the annual report, and any other reports provided to the approving HREC (including any SAEs/SUSARs/SSIs or serious breaches originating from the authorised site) accompanied by a copy of the approving HREC's acknowledgement letter, must be sent to the Clinical Trial Governance mailbox for review. (clinical-trials.research@sydney.edu.au)
3. Proposed amendments to the research protocol or conduct of the research, which may affect the **ethical acceptability** of the study and are submitted to the lead HREC for review must be sent to the Clinical Trial Governance mailbox. (clinical-trials.research@sydney.edu.au)
4. Proposed amendments to the research protocol or conduct of the research, which may affect the ongoing **site acceptability** of the study, must be submitted to Clinical Trial Governance mailbox. (clinical-trials.research@sydney.edu.au)
5. The Principal Investigator is responsible to ensure all study staff are trained according to the Protocol, ICH GCP and institutional policies and procedures.
6. Site authorisation will cease on the date of HREC expiry.

Yours sincerely,

Professor Duncan Ivison
Deputy Vice-Chancellor (Research)

Prepared by: MC

Contact: Sydney Local Health District Human Research Ethics Committee
Concord Repatriation General Hospital
Concord NSW 2139
Telephone: (02) 9767 5622
Email: SLHD-ConcordEthics@health.nsw.gov.au
Local Ref: *CH62/6/2020-209*

CONCORD
REPATRIATION GENERAL
HOSPITAL

22 January 2021

A/Professor Chin Moi Chow
The University of Sydney

Dear A/Professor Chow,

Re: **Local reference number:** CH62/6/2020-209
REGIS ethics application number: 2020/ETH03028
REGIS project ID number: 2020/PID03408
Project title: An Investigation of the Impact of Sleepwear Fibre Type on Menopausal Sleep Quality

Thank you for submitting the above research proposal for single ethical and scientific review. This project was first considered by the Sydney Local Health District Human Research Ethics Committee – CRGH at its meeting held on 26 November 2021. This Human Research Ethics Committee (HREC) has been accredited by the NSW Ministry of Health as a lead HREC under the model for single ethical and scientific review.

This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice.*

I am pleased to advise that final ethical approval has been granted on the basis of the following:

- The research project meets the requirements of the *National Statement on Ethical Conduct in Human Research*.

The documents reviewed and approved include:

	VERSION	**DATE**
Human Research Ethics Application (HREA)	2	03 December 2020
Protocol	2	11 December 2020
Participant Information Sheet	2	11 December 2020
Participant Consent Form	2	11 December 2020
Research Data Management Plan	1	15 December 2020
Master Code Sheet	2	11 December 2020
Email to potential participants	2	11 December 2020
Advertisement	2	11 December 2020
Bulletin Advertisement	2	11 December 2020
Letter to place advertisement flyers on notice boards and bulletin	2	11 December 2020
Randomization Plan	No version	No date
Clothing comfort scale	1	08 November 2020
Participant Information – COVID-19 supplement	1	08 November 2020
COVID-19 pre screening	1.1	08 November 2020
Insomnia Severity Index	1	08 November 2020

Modified Greene Climacteric Scale	1	08 November 2020
MotionWatch8 Loan Letter	1	08 November 2020
Participant Screening Questionnaire	1	08 November 2020
PSG Study Timeline Checklist	No version	No Date
Trail Facts Promotional Material	No version	No Date
Case Report Form (CRF) Cover Page	No version	No Date
Case Report Form (CRF)	No version	No Date
Combined Participant Records	No version	No Date
ICH-GCP training – Cynthia Li	No version	31 January 2020
ICH-GCP training – Chin Moi Chow	No version	04 June 2019
The University of Sydney HREC Approval letter (noted)	No version	17 April 2019
Clinical Trial Notification (noted)	No version	20 August 2019

The HREC has provided ethical and scientific approval for the following sites:

1. Concord Repatriation General Hospital

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until you have submitted a Site Specific Assessment (SSA) Form to the Research Governance Officer (RGO) and received separate authorisation from the Chief Executive or delegate at that site.

Please note the following conditions of approval:

1. HREC approval is valid for five (5) years subject to the supply of an annual progress report. The first report should be sent to the HREC by **22/01/2022.** You must also provide an annual report to the HREC upon completion of the study.

2. You will adhere to the study protocol at all times as failure to do so will invalidate the Indemnity agreement.

3. Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review.

4. You will notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.

5. You will immediately report anything which might warrant review of ethical approval of the project, including unforeseen events that might affect continued ethical acceptability of the project, (including Significant Safety Issues).

6. It is noted that REDCap will be utilised for the study. Once the REDCap project has been set-up please provide a copy of the REDCap Project Code Sheets with a version number and date to the Ethics Committee for review and approval prior to study commencement. Please note, the SLHD Research Data Manager and REDCap Administrator can be contacted for assistance and bookings via email or online for consultation if necessary.

7. If you are a University of Sydney Staff/Student or hold an affiliation and you are conducting a Clinical Trial on site at the University of Sydney or The University of Sydney will be the sponsor for your project, please contact the Clinical Trial Risk and Governance Officers via email before you commence your study (clinical-trials.research@sydney.edu.au).

8. HREC approval is granted on the assumption that all students and early career researchers are adequately supervised by the principal and senior investigators on a project. This supervision would ensure that all privacy concerns are met (including the

completion of confidentiality agreements by participating students) and that both students and participants are supported in the conduct of the study in line with the approved research protocol.

9. You agree that you will not commence the trial named above until the Clinical Trial Notification (CTN) has been submitted to the Therapeutic Goods Administration (TGA) using the online form. This HREC approval letter fulfils the documentation required to indicate the approval of the Human Research Ethics Committee responsible for monitoring the trial. A copy of the TGA acknowledgment of receipt of a CTN must be submitted to the CRGH Research Office as soon as it is available.

10. It is a requirement of ethics approval that before its commencement this clinical trial is registered on a publicly accessible register, such as the Australian New Zealand Clinical Trials Registry or another appropriate international register. You are asked to provide details of the Register in which the study has been included and its registration number.

11. Where appropriate, the Committee recommends that you consult with your Medical Defence Organisation or relevant governing body to ensure that you are adequately covered for the purposes of conducting this study.

12. It is a condition of approval that the investigators follow the relevant jurisdictional public health guidelines in relation to COVID-19 site requirements.

Should you have any queries about the HREC's consideration of your project please contact the Executive Officer - (02) 9767-5622. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the website: https://www.slhd.nsw.gov.au/concord/Ethics/Ethics.html

We wish you every success in your research.

Please quote the local reference number at the top of this letter in all correspondence.

Yours sincerely,

Professor David Le Couteur
Chair
Sydney Local Health District Human Research Ethics Committee – CRGH

- ***Are you in menopause transition or have ceased menses for not more than two years?***
- ***Are you experiencing hot flashes, night sweats, sleeping difficulties?***
- ***Are you 45-65 years old?***

Does different sleepwear material promote a better night's sleep under warm conditions? Find out more … join the study

You will receive research study payment for your participation (6 visits, 5 of which are overnight sleep studies)

Need more information?

Please contact Study Coordinator
A/Prof Chin Moi Chow
Phone: 9351 9332
Email: chin-moi.chow@sydney.edu.au
or Research Assistant Cynthia Li
Phone: 9351 9332
Email: cynthia.li@sydney.edu.au

V2 11.12.2020

Sleep quality and menopause
Email: chin-moi.chow@sydney.edu.au
Phone: 9351 9332

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Email: chin-moi.chow@sydney.edu.au
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Phone: 9351 9332

Sleep quality and menopause
Email: chin-moi.chow@sydney.edu.au

Sleep Quality and Menopause

You are invited to participate in a research study that evaluates how well you sleep and your menopausal symptoms. The study involves five sleep studies over 3-4 weeks.

If you are in menopause transition or have ceased menses for not more than two years with symptoms of hot flashes, night sweats, sleeping difficulties, and are 45-65 years old, you can participate. You will be paid for study participation (6 visits, 5 of which are overnight sleep studies). Should you need more information, or would like to participate please call, or email us. Your participation is greatly appreciated.

Contact: Asso Prof Chin Moi Chow
Phone: 9351 9332
Email: chin-moi.chow@sydney.edu.au OR

Contact: Cynthia Li
Email: Cynthia.li@sydney.edu.au

Table of Contents

1. Web Ad

A Study That May Help Improve Sleep Quality in Women Experiencing Menopause

Research Centre: Faculty of Health Sciences Sleep Laboratory
Location: Level 6 East Multi-Building (Building 5) Hospital Rd, Concord, NSW, Australia
Lead Doctor: Associate Professor Chin Moi Chow
Ethics Committee: This study has been reviewed and approved by University of Sydney Human Research Ethics Committee and HREC of
the Sydney Local Health District – Concord Repatriation General Hospital

Background

When a woman experiences the absence of menstrual periods for 12 months, she might be going through menopause. Menopause can cause various changes to a woman's physical, emotional and mental well-being. However, this does not happen overnight. It is a gradual process and symptoms vary from woman to woman.

The usual complaints of most women are hot flashes, mood disorders, insomnia, sleep apnoea, snoring, and other sleep disorders. This study seeks to investigate the potential benefit of a new approach to improving sleep quality in women who are experiencing menopause.

This study seeks adults aged 45 to 65 years old who are in their first 2 years of experiencing menopause. Participants are required to attend 5 non-consecutive overnight stays at the research site over approximately 4 weeks and will be compensated for their time and travel expenses. Meals will also be provided during overnight stays at the research site. Through participation in this study, participants may help researchers understand how this new approach can potentially improve sleep quality and help manage menopause symptoms in menopausal women.

Why Participate?

- You may experience improvements in menopause symptoms.
- You may be taught how to better manage menopausal symptoms.
- You may experience improvements in quality of sleep.
- You will be compensated for your time and travel.
- You will be provided meals during your overnight stay.
- You will be helping to advance medical research.

Your Rights

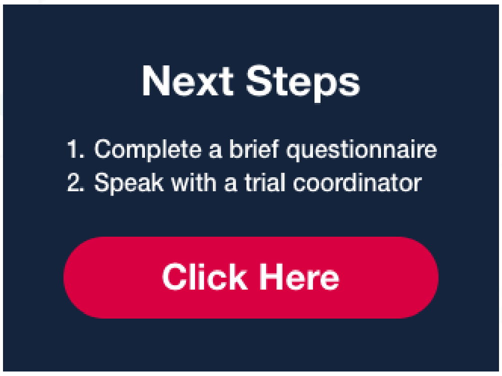
- If you decide to participate in the study and later feel that you no longer wish to be part of it, you may withdraw at any time.

- Your records relating to this study and any other information received will be kept strictly confidential, except as required by the law.
- Qualified health professionals will monitor your health as it relates to the study.

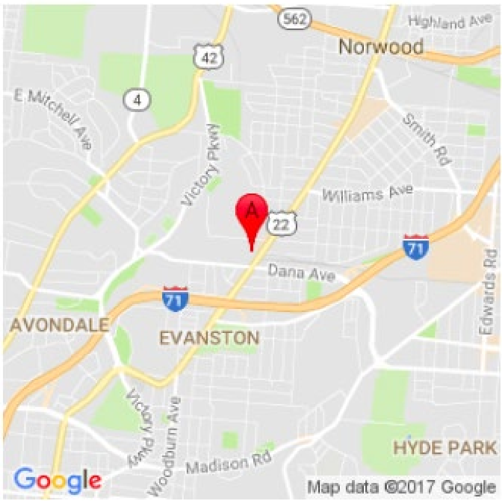
Who Can Participate?

- Women aged 45 to 65 years old who are experiencing menopause
- Must be in their first two years of menopause
- Able to attend 5 non-consecutive overnight visits at the research site over approximately 4 weeks.

Standard side widgets (shown alongside the web ad)



Trial Location



Click the above for a larger map

Please note:

The trial location is updated as per the location of the study.

Standard footer widgets (shown at the bottom of the web ad)

What Next?

1. Click the link below to enter your contact details and answer some eligibility questions.
2. The research centre will then contact you by phone to discuss the trial and answer your questions.

Click Here to Enter Your Contact Details and Be Contacted by Phone About the Trial

2. Recruitment Questionnaire

Please note:
The text in red after the pre screening questions will not be shown to patients, they are for internal use only, and indicate eligibility.

Consent to continue

After completing this brief questionnaire more detailed information will be given to you before you decide whether or not to take part in the research, and you will have the opportunity to speak with and ask questions of a study coordinator. You can stop this interview at any time.
Please note that by completing this questionnaire, you consent to us collecting your answers to the questions, including your contact information. All information you provide in this questionnaire will be held in strict confidence, and shared only with the research centre conducting the study. Trialfacts will delete your information from our records upon your request. While completing the questionnaire you will have the option to join our mailing list to be contacted via email about future clinical trials for which you may be eligible. You will not be contacted about future trials if you choose not to sign up to our mailing list.
For your reference, please find a link to the Trialfacts Privacy Policy.

Are you willing to continue? (must select Yes)

( ) Yes
( ) No

[For Australia] State* [must select NSW]

( ) ACT
( ) NSW
( ) NT
( ) QLD
( ) SA
( ) TAS
( ) VIC
( ) WA

This question is to check that you have read our information. (/This question is to make sure that you understand what you are required to participate in the research study.)

How many times are you required to attend the study site?

[correct answer is 6]

[the note appears after answering]

You are expected to attend 1 clinical visit + 5 non-consecutive overnight sleep study at Concord Hospital. You are free to withdraw at any time.

Are you available to attend the study? (must select Yes)

( ) Yes

( ) No

Gender* (Must be Female)
( ) Male
( ) Female

Contact Details
First Name*: ____
Last Name*: ____
Email Address*: ____
Primary Contact Number*: ____
Type*:
Mobile
Home
Work
Mobile Number: ____
What is the best time to contact you?: ____
Post code*: ____

Would you like to be contacted via email about future clinical trials for which you may be eligible?*

( ) Yes
( ) No

How did you hear about this trial?*

( ) Trialfacts Email
( ) Google
( ) Facebook or Twitter
( ) Another website
( ) Another Email
( ) Family member or friend
( ) Radio
( ) Newspaper
( ) TV

Please provide **height***____
Please provide **weight*** ____
(BMI automatically generated. Must be $\leq$30 kg/m²)

Age (years) * **(Must be 45-65 years old)**

____

This is the last page of the questionnaire to determine your eligibility. Please fill out the questions on this page and then click the "Next" button at the bottom of the page. Thanks for your patience.

1. **Please select the statement(s) that best describe you**. **(Must select a,b and/or c)**
   (a) I have had an irregular period for the previous year while not being pregnant (transition in menopause)
   (b) I have not had my period (menstrual cycle) for at least 1 year
   (c) I have had a surgical bilateral oophorectomy (removal of both ovaries), with or without a hysterectomy, more than 6 weeks ago
   (d) None of these statements describe me

2. **[If b] How many years have you been postmenopausal? (Must select a or c)**

   (a) Less than 2 years

   (b) More than 2 years

   (c) Unsure

3. **Will you be willing to attend all the necessary site visits which includes 5 non-consecutive overnight stays over 4 weeks? (Must select Yes)**

   ( ) Yes

   ( ) No

   ( ) Unsure

4. **(If Yes) Specifically, will you be willing to attend 5 separate overnight stays at the** Sleep study unit of Concord Repatriation General Hospital (Hospital Rd, Concord, NSW, 2139) arriving at 6pm and leaving within 30 minutes upon waking (typically before 7am)? Appointments are available normally on (Sunday and) Monday nights. (Must Select Yes)

   ( ) Yes

   ( ) No

   ( ) Unsure

5. W**ill you be willing** to sleep under warm conditions of 30 degrees Celsius? (Must select Yes/Unsure)

   ( ) Yes

( ) No

( ) Unsure

6. Will you be willing to consume an evening meal consisting of sundried tomatoes, chicken with rice, paired with a hearty chicken and vegetable soup during your overnight visits at the Sleep Laboratory? (Must select Yes/Unsure)

( ) Yes

( ) No

( ) Unsure

7. **Do you have any known allergies towards textile fabrics of cotton, linen, polyester,silk or wool? (Must select No/Unsure)**

( ) Yes

( ) No

( ) Unsure

8. **Have you been diagnosed with insomnia? (Must select No/Unsure)**

( ) Yes

( ) No

( ) Unsure

9. **Have you used hormonal products such as estrogen, progestins or androgens within the last 8 weeks? (Must select No/Unsure)**

( ) Yes

( ) No

( ) Unsure

10. **Do you have any of the following conditions? (Must select No/Unsure)**
    - **Diabetes**
    - **Cancer**
    - **Heart disease**
    - **Raynaud's syndrome**
    - **Lung conditions such as COPD**

( ) Yes

( ) No

( ) Unsure

11. **Do you have any psychiatric conditions such as bipolar disorder, depression or schizophrenia?(Must select No/Unsure)**

( ) Yes

( ) No

( ) Unsure

12. **Are you committed to answering your phone when the research team reaches out to you at the appointed date and time that you choose? (Must select Yes)**

( ) Yes

( ) No

13. **If you are unable to attend an appointment at the research site, are you willing to inform the study staff? (Must select Yes)**

( ) Yes, I will definitely let the study staff know if I can no longer attend or change my mind about attending

( ) No, I can not be sure that I will let the study staff know if I can not or no longer wish to attend

Please tell us why you decided to sign up for this trial. Your insight is greatly appreciated. (Thank you!)

CONFIRMATION TEXT (displayed on passing the questionnaire):

Congratulations, based on your answers it looks like you are a good candidate for this study, the final step is to pick a time for a short phone call below:

[question("value"), id="137"] will then call you at this time for a 5-20 minute phone call where we will (a) introduce this study (b) answer any questions you have, and (c) if you would like to move forward, check your information, confirm your eligibility and find a time for you to come into the research centre.

Questions you can ask the study staff during your phone appointment:

- What is the purpose of this study?
- What have been the outcomes of the previous study groups? What previous testing/ethics approval have been completed prior to this trial?
- What can I expect during the study visits?
- What will happen during the screening appointment?
- When can I book a screening appointment?

Note: If you can not find a suitable time available on the calendar, please click here to submit your questionnaire and provide a time most suitable to contact you.

CONFIRMATION TEXT (received on passing the questionnaire - Without an appointment booked:

Thanks very much for taking the time to fill out the **University of Sydney Sleep and Menopause** Research Study screening questionnaire, it looks like you are a good candidate for this study. [question("value"), id="137"] will have a quick phone call with you to confirm your eligibility, provide you with further details of the study and answer any questions you have.

Questions you can ask the study staff during your phone appointment:

- What is the purpose of this study?
- What have been the outcomes of the previous study groups? What previous testing/ethics approval have been completed prior to this trial?
- What can I expect during the study visits?
- What will happen during the screening appointment?
- When can I book a screening appointment?

CONFIRMATION EMAIL TEXT (received on passing the questionnaire - Booked an appointment:

Hi [Name]

Thanks very much for taking the time to fill out the **University of Sydney Sleep and Menopause** Research Study screening questionnaire. [question("value"), id="137"] will have a quick phone call with you to confirm your eligibility, provide you with further details of the study and answer any questions you have.

Details of your phone call below:

- Your call time: [question("value"), id="134"]
- Calendar event: Add the phone call appointment to your calendar using this link
- Rescheduling: To reschedule your appointment, please use the link provided to you in the confirmation email that was sent when you booked a phone appointment
- Questions: Please reply to this email, cc'ing all contacts with your query or call [question("value"), id="137"] on [question("value"), id="138"]

Meet the Lead Researcher:

Associate Professor Chin Moi Chow

Dr. Chow is an associate professor of sleep and wellbeing at the University of Sydney, Australia. Dr. Chow has had a long standing interest in sleep health research with a focus on the impact of lifestyle factors (thermal comfort, exercise, daytime napping, dietary, altitude) on sleep quality and patterns. Dr Chow has mentored many research higher degree students, who are making important contributions to knowledge and will go on to make broader contributions to society.

Questions you can ask the study staff during your phone appointment:

- What is the purpose of this study?
- What have been the outcomes of the previous study groups? What previous testing/ethics approval have been completed prior to this trial?
- What can I expect during the study visits?
- What will happen during the screening appointment?
- When can I book a screening appointment?

Kind Regards,
The Trialfacts Team

CONFIRMATION EMAIL TEXT (received on passing the questionnaire - Did not book an appointment):

Hi [Name]

Thanks very much for taking the time to fill out the **University of Sydney Sleep and Menopause** Research Study screening questionnaire. Based on your answers it looks like you are a good candidate for this study.
The next step is to do a quick phone call with a member of the research team (CC'd) who will confirm your eligibility, provide you with further details of the study and answer any questions you have. Study staff will contact you, or you can contact them if you would prefer. Relevant details are below:

Site Contact Name: [question("value"), id="137"]
Site Contact Phone Number: [question("value"), id="138"]

Meet the Lead Researcher:

Associate Professor Chin Moi Chow

Dr. Chow is an associate professor of sleep and wellbeing at the University of Sydney, Australia. Dr. Chow has had a long standing interest in sleep health research with a focus on the impact of lifestyle factors (thermal comfort, exercise, daytime napping, dietary, altitude) on sleep quality and patterns. Dr Chow has mentored many research higher degree students, who are making important contributions to knowledge and will go on to make broader contributions to society.

Questions you can ask the study staff during your phone appointment:

- What is the purpose of this study?
- What have been the outcomes of the previous study groups? What previous testing/ethics approval have been completed prior to this trial?
- What can I expect during the study visits?
- What will happen during the screening appointment?
- When can I book a screening appointment?

Kind Regards,
The Trialfacts Team

DISPLAYED UPON FAILING QUESTIONNAIRE:

Thanks very much for taking the time to fill out the **University of Sydney Sleep and Menopause** Research Study screening questionnaire. Based on your answers we have unfortunately determined that you are ineligible for this particular clinical trial.

If you chose the answer "Yes" to be contacted about other trials in the future, we will inform you of other upcoming trials for which you may be eligible.

Please note, If you answered "no" but would now like to join the New Trial Mailing List, you can do so here.

Frequently Asked Questions

Why am I ineligible?

In order to collect the data required from clinical trials, only patients that meet certain criteria can participate. The criteria are different for every trial, including trials involving the same medical condition.

Unfortunately you are not eligible for this particular trial because you do not meet one (or more) of these criteria. However, that does not mean you will be ineligible for other similar trials, and sometimes trials do alter the eligibility criteria if they cannot find enough people to participate.

How will I know if the eligibility criteria change?
If this happens, and it appears you may now be eligible, we will email you. You can unsubscribe from our mailing list if you do not want to be contacted.

How can I know before filling out the questionnaire whether I'll be eligible?
For all trials listed on Trialfacts there is a section titled "Who Can Participate?" We require that all research centres list as much information here as possible about the eligibility criteria.

Click here to return to the Trialfacts website.

SENT UPON BEING MARKED AS UNREACHABLE AFTER 5 ATTEMPTS:

Hi [referral name],

Thank you again for your interest in the University of Sydney Sleep and Menopause Research Study and taking our online questionnaire. We are looking forward to moving on to the next step towards your participation in the study, however, the study staff have been unable to get in touch with you to discuss further details and next steps for the study.

Are you still interested in participating in this study? If so, please pick a time for a short phone call by clicking HERE.

[question("value"), id="137"] will then call you at this time for a 5-20 minute phone call where we will **(a) introduce this study (b) answer any questions you have, and (c) if you would like to move forward, check your information, confirm your eligibility and find a time for you to come into the research centre.**

Study staff will contact you, or you can contact them if you would prefer. Relevant details are below:

Site Contact Name: [question("value"), id="137"]
Site Contact Phone Number: [question("value"), id="138"]
Site Contact Email: [ENTER]

The research team is looking forward to hearing from you soon.

Regards,

SENT UPON BEING MARKED AS CLINIC SCREEN-NO SHOW:

Hi [Referral name],

Thank you again for your interest in the University of Sydney Sleep and Menopause Research Study. We are reaching out as the research team as alerted us that you did not attend the research site on the day of the scheduled visit.

Would you still like to participate in this study? Are there questions/concerns the research team could answer for you?

If you are still interested in participating, you can contact the research site to schedule a new time to visit the research site.

Site Contact Name: [question("value"), id="137"]
Site Contact Phone Number: [question("value"), id="138"]

The research team is looking forward to hearing from you soon.

Regards,

3. Promotional Ads

Please note

- *The headline and ad text can be used interchangeably and in various combinations. More than one ad text can be combined to form a new ad text. It is important to have as many as possible approved.*
- *The ads will be linked to the landing page, which in turn is linked to the questionnaire.*
- *Ads may run on a combination of platforms, including: Facebook, Google, Google Display Network, Yahoo, Bing, Instagram*
- *The logo images can be used in the promotional ads*
- *Logos of sponsor, the research site and the ethics committee may be used in the promotional ads*

Headlines options:

1. Menopause Sleep Quality Research Study
2. Join a Sleep Quality Improvement During Menopause Research Study
3. New Potential Approach to Help Manage Menopause Symptoms
4. Poor Sleep Quality Due to Menopause?
5. Menopause + Sleep Quality Research Study
6. Potential Sleep Quality Improvement Research Study
7. Menopause Study Seeks Participants
8. Participants Needed for Menopause Research Study
9. Can New Approach Potentially Manage Menopause Symptoms?
10. Want to Join a Study That May Potentially Improve Sleep Quality?
11. Women Experiencing Menopause Invited!

Ad text options:

1. This study seeks to investigate the potential benefit of a new approach to improving sleep quality in women who are experiencing menopause.
2. This study seeks women aged 45 to 65 years old who are in their first 2 years of experiencing menopause.
3. Participants are required to attend 1 clinical visit and 5 non-consecutive overnight stays at the research site over approximately 4 weeks.
4. Participants will be compensated for their time, travel expenses and will be provided meals during their overnight stay at the research site.
5. This study seeks to find out how a new approach may potentially help improve sleep quality in women who are experiencing menopause.
6. Having trouble sleeping because of menopause? This study seeks to improve sleep quality by helping manage symptoms due to menopause.
7. The study seeks women aged 45 to 65 years old who are in their first two years of menopause.
8. Participants must be in their first 2 years of menopause.
9. Participants may be taught on how to better manage menopausal symptoms.
10. Can a new approach potentially improve the quality of sleep in menopause?

Short Ad text options (for Google Ads):

1. Experiencing menopause symptoms?
2. Help women struggling with menopause!
3. Calling women aged 45 to 65 years old!
4. In your first 2 years of menopause?
5. Treatment may help improve sleep quality
6. Overnight stays at the research site!
7. Experience potential improvements to sleep!
8. Women aged 45 to 65 years old are invited!
9. Participation will be compensated!
10. Help women struggling with menopause!

Emojis: 😪 💤 ☝️ 👍 🤲 ✋ 😷 ❤️ 🐦 🔎 📋 🤗 😍 😀 😉 🤩 🥰 😌 👌 👏

Sign up button options:

1. Learn more
2. Sign up
3. Apply now

Facebook ad mockup:

Trialfacts

Sponsored ·

This study seeks adults aged 45 to 65 years old who are in their first 2 years of experiencing menopause.

SIGNUP.TRIALFACTS.COM

Menopause Research Study

Learn more.

Like Comment Share

4. Landing Pages

Please note

- *Multiple landing page 'layouts' will be utilized throughout recruitment but all layouts will only utilize the approved text options and images.*
- *Logos of the sponsor, the research site and ethics committee may be used in the landing pages.*
- *All landing pages will include the following sections:*
    - *Headline*
    - *What is this study about?*
    - *Sign up form with Sign up Call to Action & Sign up button*
    - *Key benefits box*
- *The following is optional:*
    - *Sub-headline*
    - *Images*
    - *Why Participate?*
    - *Who Can Participate?*
    - *Meet the Research Team*
    - *Research centre & ethics committee details*

Headline and sub-headline options:

1. Menopause Sleep Quality Research Study
2. Join a Sleep Quality Improvement During Menopause Research Study
3. New Potential Approach to Help Manage Menopause Symptoms
4. Menopause + Sleep Quality Research Study
5. Potential Sleep Quality Improvement Research Study
6. Menopause Study Seeks Participants
7. Participants Needed for Menopause Research Study
8. Want to Join a Study That May Potentially Improve Sleep Quality?
9. Women Experiencing Menopause Invited!

Sign up button options:

1. Learn more
2. Sign up
3. Apply now
4. Take me to the prescreen questionnaire to see if I am eligible
5. Take the questionnaire
6. Take the questionnaire and find out more
7. Find out more and take the questionnaire
8. Find out more and take the questionnaire to see if I am eligible
9. Start the questionnaire
10. Join Now

Sign up call to action options:

1. LEARN MORE ABOUT CONTRIBUTING TO **MENOPAUSE + SLEEP QUALITY** RESEARCH
2. SEE IF YOU QUALIFY FOR THIS RESEARCH STUDY
3. FIND OUT IF YOU ARE ELIGIBLE FOR THIS RESEARCH STUDY
4. LEARN MORE ABOUT THIS **MENOPAUSE + SLEEP QUALITY** RESEARCH STUDY
5. Fill in your details
6. Take the questionnaire to apply
7. Apply now by filling out the questionnaire on the next page
8. Sign up to take the questionnaire
9. Apply now by taking the questionnaire
10. All applicants need to pass a short eligibility questionnaire. Please fill in your details below to start.
11. To join this research study applicants need to pass a short eligibility questionnaire. Please fill in your details below to start.
12. Join This Research Study
13. Interested?
14. Join Now

'What is the study about?' options (may be combined, as well as used individually)**:**

1. This study seeks to investigate the potential benefit of a new approach to improving sleep quality in women who are experiencing menopause.
2. This study seeks adults aged 45 to 65 years old who are in their first 2 years of experiencing menopause.
3. Participants are required to attend 5 non-consecutive overnight stays at the research site over approximately 4 weeks.
4. Participants will be compensated for their time, travel expenses and will be provided meals during their overnight stay at the research site.
5. This study seeks to find out how a new approach may potentially help improve sleep quality in women who are experiencing menopause.
6. Having trouble sleeping because of menopause? This study seeks to improve sleep quality by helping manage symptoms due to menopause.
7. The study seeks women aged 45 to 65 years old who are in their first two years of menopause.
8. Participants must be in their first 2 years of menopause.
9. Participants may be taught on how to better manage menopausal symptoms.
10. Can a new approach potentially improve the quality of sleep in menopause?

Why Participate? (optional text):

- You may experience improvements in menopause symptoms.
- You may be taught how to better manage menopausal symptoms.
- You may experience improvements in quality of sleep.
- You will be compensated for your time and travel.
- You will be provided meals during your overnight stay.
- You will be helping to advance medical research.

Who Can Participate? (optional text):

- Women aged 45 to 65 years old who are experiencing menopause
- Must be in their first two years of menopause
- Able to attend 5 non-consecutive overnight visits at the research site over approximately 4 weeks.

Your Rights (optional text):

- If you decide to participate in the study and later feel that you no longer wish to be part of it, you may withdraw at any time.
- Your records relating to this study and any other information received will be kept strictly confidential, except as required by the law.
- Qualified health professionals will monitor your health as it relates to the study.

Meet the Lead Researcher (optional text):

Associate Professor Chin Moi Chow

Dr. Chow is an associate professor of sleep and wellbeing at the University of Sydney, Australia. Dr. Chow has had a long standing interest in sleep health research with a focus on the impact of lifestyle factors (thermal comfort, exercise, daytime napping, dietary, altitude) on sleep quality and patterns. Dr Chow has mentored many research higher degree students, who are making important contributions to knowledge and will go on to make broader contributions to society.

Research centre & ethics committee details with map of location (optional text/map):

Research Centre: Faculty of Health Sciences Sleep Laboratory
Location: 75 East Street, Lidcombe, NSW, Australia
Lead Doctor: Associate Professor Chin Moi Chow
Ethics Committee: This study has been reviewed and approved by University of Sydney Human Research Ethics Committee

Landing page mockup:

5. Alternative Images for Promotional Material


Adobe Stock
#182426937

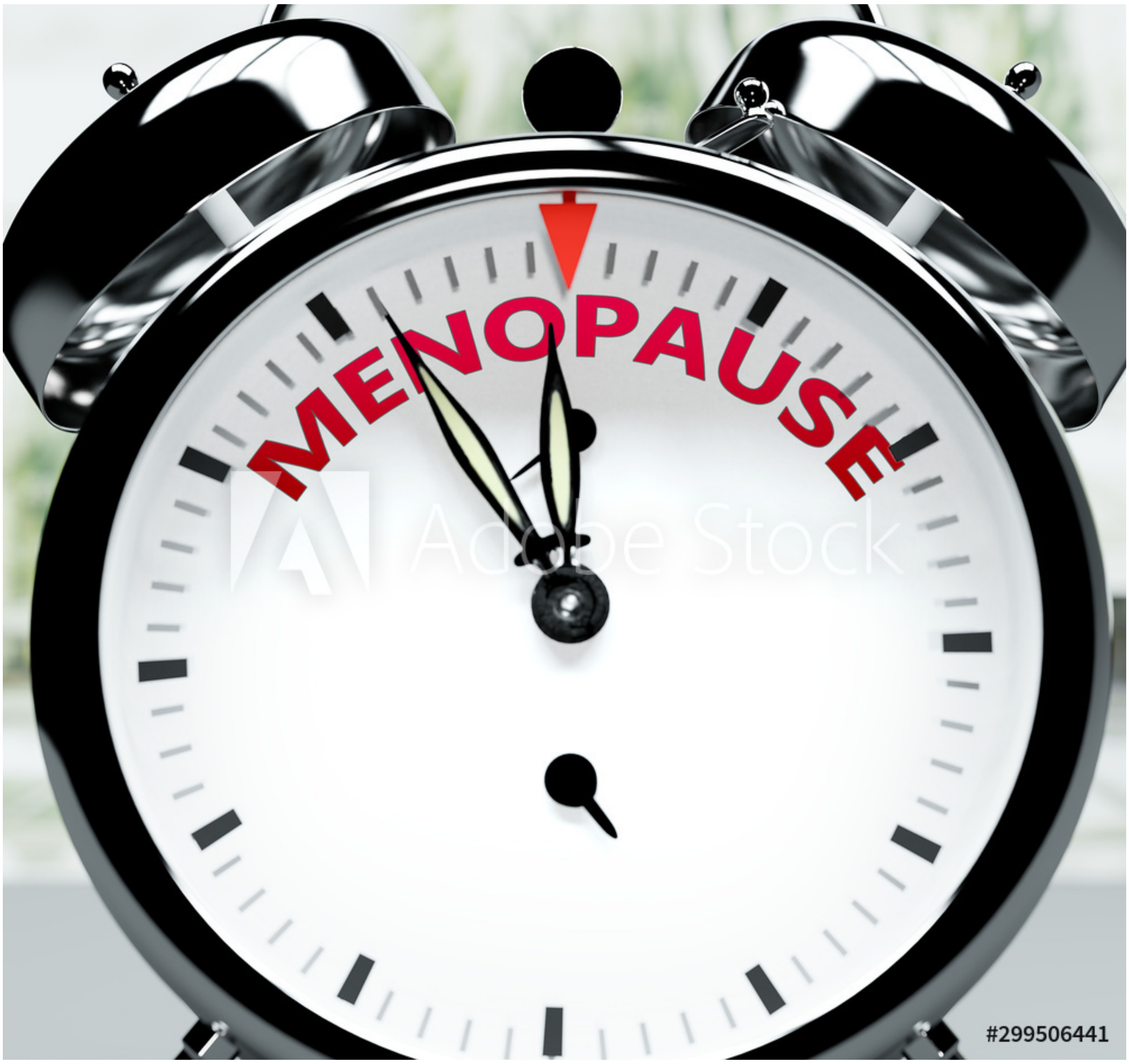

Adobe Stock
#200568525


Adobe Stock
#204069263


Adobe Stock
#235146902


Adobe Stock
#249548193


Adobe Stock
#297087759


MENOPAUSE
Adobe Stock
#299506441

THE UNIVERSITY OF SYDNEY

Video Links:

https://stock.adobe.com/ph/video/gorgeous-mature-female-sitting-on-couch-and-looking-into-camera-advertisement/188760405?prev_url=detail

https://stock.adobe.com/ph/video/senior-female-sitting-on-sofa-and-dreaming-about-summer-vacation-retirement/176897559?prev_url=detail

https://stock.adobe.com/ph/video/woman-with-severe-neck-pain-in-loft-apartment-selective-focus/307418096?prev_url=detail https://stock.adobe.com/ph/video/stressed-woman-waking-up-early-in-morning-do-not-want-to-get-up-go-to-bad-work/217238547?prev_url=detail

https://stock.adobe.com/ph/video/sorrowful-dowager-touching-pillow-remembers-close-relative-person-sleeping-near/217240390?prev_url=detail

https://stock.adobe.com/ph/video/a-older-woman-cools-herself-off-with-a-portable-fan-in-the-summer/159721562?prev_url=detail

https://stock.adobe.com/ph/video/middle-aged-whimsical-female-wake-up-want-not-to-get-up-from-comfortable-bed/217241708?prev_url=detail

https://stock.adobe.com/ph/video/two-mature-women-friends-talking-and-smiling-about-hot-flashes/182715595?prev_url=detail

https://stock.adobe.com/ph/video/female-retiree-sitting-on-edge-of-bed-rubbing-temples-health-problems-climax/177318262?prev_url=detail

Australian Government

Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	219452	Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Patient data recorder, long-term, physical activity

ARTG entry for	Medical Device Included Class 1
Sponsor	Emergo Asia Pacific Pty Ltd T/a Emergo Australia
Postal Address	Level 20 Tower II Darling Park 201 Sussex Street, SYDNEY, NSW, 2000 Australia
ARTG Start Date	22/01/2014
Product category	Medical Device Class 1
Status	Active
Approval area	Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
CamNtech Ltd	Upper Pendrill Court Ermine Street North Papworth Everard, Cambridge, CB23 3UY United Kingdom

Products

1. Patient data recorder, long-term, physical activity

Product Type	Medical device system	**Effective date**	22/01/2014

GMDN	36252 Patient data recorder, long-term, physical activity
Intended purpose	The system consists of a wrist-worn electronic patient diary and associated PC program which can record the user's answers to questions during daily living in a very flexible and easy to use way. The system also incorporates a tri-axial accelerometer to allow objective actigraphy data to be collected while the device is worn. Actigraphy data may be saved and loaded into the program for analysis of sleep, Circadian rhythm, and activity levels. The system can be used to monitor a wearer's condition and symptoms before treatment, or detect a change in the wearer's symptoms during or after intervention. It can also be used to remind the wearer to take treatment at regular or irregular intervals or to record events when marked by the wearer. The system is very flexible to different recording requirements for various areas of research.

Specific Conditions

No Specific Conditions included on Record

Email to potential participants

Dear xxx,

Thank you for your interest in our study. We appreciate your participation. Please find attached the screening questionnaire and Participant Information Sheet (PIS). **You need to complete and send the screening questionnaire to me so that we screen that with our eligibility criteria.** Those who may be eligible and agree to participate will be requested to attend the Sleep laboratory on a day suitable to both parties.

On that day, can you please come to Concord Hospital Sleep Study Unit located at Level 7 West Multi-Building (Building 5) Hospital Rd, Concord. We will go over the study procedure, obtain your signed consent form, and will provide you with a wristwatch (MotionWatch8) to wear for the period of the study. The MotionWatch8 records your physical activity level and sleep patterns. The study instructions are clearly given on the PIS. After reading the PIS, if you are doubtful about anything you can always reach me on my mobile or e-mail.

Please see the attached a map for transportation and parking.

Thanking you in anticipation,

Sincerely,

Asso Prof Chin Moi Chow and Cynthia Li

Phone: 9351 9332

Appendix C

Publications and Presentations

How do sleepwear and bedding fibre types affect sleep quality: A systematic review

Validation of MotionWatch8 Actigraphy Against Polysomnography in Menopausal Women Under Warm Conditions

Agreement between MotionWatch8 and Polysomnography sleep outcomes in Menopausal Women

Effect of sleepwear fibre type on menopausal sleep quality-Study protocol and preliminary data

Actigraphic Assessment of Sleep Patterns in Women with Menopausal Symptoms

The Conversation: Why can't I sleep? It could be your sheets or doona

ISPRM poster presentation certificate

Received: 21 December 2023 | Revised: 6 February 2024 | Accepted: 3 April 2024
DOI: 10.1111/jsr.14217

REVIEW ARTICLE

Journal of Sleep Research ESRS

How do sleepwear and bedding fibre types affect sleep quality: A systematic review

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[2]Charles Perkins Centre, University of Sydney, Camperdown, New South Wales, Australia

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Email: cynthia.li@sydney.edu.au

Funding information
Australian Wool Innovation

Summary

Sleepwear and bedding materials can affect sleep quality by influencing the skin and body temperature and thermal comfort. This review systematically evaluates the impact of sleepwear or bedding of different fibre types on sleep quality. A systematic search was conducted in six data bases plus Google Scholar and manual searches. Original articles that compared human sleep quality between at least two fibre types of bedding or sleepwear were included, resulting in nine eligible articles included in the review. The fibre types included cotton, polyester, wool, and blended materials for sleepwear; cotton, duck down, goose down, polyester and wool for duvet; and linen and a combination of cotton and polyester for bedding. The interplay between fibre materials and sleep quality is complex. Blended sleepwear demonstrated potential benefits for specific populations. Wool sleepwear showed benefits for sleep onset in adults (cool conditions) and in older adults (warm conditions). Linen bedsheets improved sleep quality under warm conditions in young adults. Goose down-filled duvets increased slow-wave sleep under cool conditions in young adults. However, a systematic comparison of fibre types is challenging due to the diverse nature of the studies evaluating sleep quality. Further research employing standardised methodologies with standard fibre samples in different populations and in different temperature conditions is imperative to elucidate comprehensively the effects of fibre choices on sleep quality. Despite the limitations and heterogeneity of the included studies, this analysis offers valuable insights for individuals seeking to optimise their sleep experiences and for manufacturers developing sleep-related products.

KEYWORDS
bedding, fibre, sleep, sleepwear

1 | INTRODUCTION

Sleep, accounting for approximately one-third of an individual's lifespan, plays a fundamental role in maintaining human health and overall well-being (Lee, 1997). Inadequate or poor sleep has been associated with detrimental effects on both cognitive and motor performance, mood regulation, as well as disruptions in metabolic, hormonal, and immunological systems (Ferrara & De Gennaro, 2001; Kecklund & Axelsson, 2016). The body temperature rhythms have a stable internal relationship with the sleep–wake cycle, as the timing of sleep is highly correlated with the phase of the body temperature rhythm (Monk, 1987). Sleep duration is extended when bedtime occurs on the falling limb of the core body temperature curve, whereas sleep duration is short when bedtime occurs on the rising limb of the curve. There is a strong tendency for sleep termination when sleep occurs at the temperature peak (acrophase) (Monk, 1987). Hence, sleep timing and duration are closely associated with changes in the circadian core body temperature.

Sleep quality can be affected by many factors such as health behaviours, physical health, psychological health (Xu et al., 2014), as well as environmental factors such as light, noise, temperature, air pollution, social neighbourhood safety, etc. (Johnson et al., 2018; Troynikov et al., 2018). Among the environmental factors, the thermal environment is very important for sleep maintenance (Lan et al., 2014; Lan et al., 2017; Troynikov et al., 2018). Previous studies have shown that an excessively high, low, or fluctuating air temperature can compromise sleep quality (Fletcher et al., 1999; Lan et al., 2014; Yao et al., 2007; Yao et al., 2011).

Sleepwear and bedding types can have an impact on sleep quality by affecting thermal comfort. Skin temperature plays an essential role in thermoregulation, as receptors for warmth and cold detection found in the skin help adjust peripheral blood flow and control heat loss (Krauchi et al., 2000; Xu & Lian, 2023). The skin's sensitivity to temperature fluctuations and the pervasive effect of ambient temperature on skin temperature have been well documented (Lan et al., 2014).

Sleep onset coincides with decreases in core body temperature, which is supported by selective vasodilation of distal skin regions to contribute to the decrease of core body temperature and promote sleep onset (Krauchi et al., 2000). During the sleep period, the skin temperature remains relatively stable, with a slight increase during rapid eye movement (REM) sleep (Okamoto-Mizuno & Mizuno, 2012). Clothing provides thermal resistance and insulation for the human body, which is important for maintaining the thermal balance of the body during sleep.

Achieving thermal comfort plays a vital role in maintaining good sleep quality (Lan et al., 2017; Macpherson, 1973; Xu & Lian, 2023). Thermal comfort is a condition of mind that expresses satisfaction with the thermal environment (Auliciems & Szokolay, 1997) with a need to maintain a stable core body temperature (Nicol et al., 2012), in this way, it varies from person to person (Djongyang et al., 2010). The thermal exchange between a human body and the environment includes sensible heat loss from the skin, evaporative heat loss from the skin, and respiratory losses (Djongyang et al., 2010). A recent review by Xu and Lian (2023) highlighted the importance of designing a bedroom environment that promotes thermal comfort to improve sleep quality (Xu & Lian, 2023). The paper suggested that bedding conditions, such as the type of mattress and clothing, can impact thermal comfort and sleep quality. Sleepwear and bedding insulate the body and influence the skin and body temperature, and therefore can significantly affect sleep. Notably, the thermal properties of fabric fibres, including insulation and water vapour resistance, influenced by factors such as fibre type, thickness, and yarn structure, play a pivotal role. Specifically, natural fibres such as cotton and wool exhibit lower thermal conductivity when dry, but this can increase significantly after moisture absorption (Kothari, 2006). To optimise thermal comfort under normal or warm conditions, a fibre's water vapour permeability should be high to allow sweat to evaporate from the skin and to keep the skin dry (Kothari, 2006), for example, wool has a higher water vapour permeability than cotton and polyester, which allows efficient sweat evaporation, keeping the skin dry and enhancing thermal comfort (Bhatia & Malhotra, 2016).

Although there have been numerous studies investigating the effects of various fibre types of sleepwear and bedding on sleep quality, to the best of our knowledge, no systematic reviews have been conducted on this topic. Therefore, this review aims to systematically evaluate the impact of sleepwear or bedding of different fibre types on sleep quality by summarising the existing evidence. By analysing the effects of fibre types and thermal properties of sleepwear and bedding on sleep outcomes, this review aims to provide insights into selecting appropriate materials for better sleep quality.

2 | METHOD

This systematic review was conducted in accordance with the recommendations outlined in the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement (Page et al., 2021). The study protocol was registered with PROSPERO under the registration number CRD42021204652.

2.1 | Study search

Systematic literature searches were conducted using six electronic databases (MEDLINE, Embase, CINAHL, Web of Science, Scopus, Proquest) and additional searches were conducted in Google Scholar with the first 17 pages and via citation searches. These data were added to the search results. An initial search was conducted on 18 August 2021 and updated every month by search alerts until November 2023. The search strategy contained four concepts with their combinations (bedding OR sleepwear) AND fibre AND sleep quality. For each concept, both text words and MeSH terms (controlled vocabulary) were searched where applicable.

The detailed keywords for each concept were as follows:

- bedding – "bedding and linen*" OR bed?sheet* OR "bed linen*" OR bedding* OR "quilt cover*" OR bedspread* OR "fitted sheet*" OR "top sheet*" OR "bed cover*" OR coverlet* OR comforter* OR quilt* OR duvet* OR blanket* OR underlay;
- sleepwear – pyjama* OR pyjama* OR cloth* OR night?dress* OR nighti* OR nightshirt* OR nightcloth* OR night?gown* OR Sleep?wear* OR "night garment*" OR lounge?wear;
- fibre – cotton* OR wool* OR "Merino wool*" OR flannelette* OR hemp OR viscose* OR modal* OR lycra* OR lyocell* OR polyester* OR polycotton* OR rayon* OR synthetic* OR silk* OR linen* OR bamboo OR textile* OR fibre* OR fibre* OR fabric* OR flax*;

- sleep quality – "sleep polysom*" OR "quality of sleep*" OR "sleep efficienc*" OR sleep* OR polysomnography* OR "Pittsburgh Sleep Quality Index" OR "PSQI" OR "Insomnia severity index" OR "ISI" OR "Insomnia index" OR Actigraph* OR "sleep assessment*" OR Polygraph* OR "Sleep Stage*" OR "sleep diar*" OR "sleep quality scale*" OR "sleep monitoring".

The search included all studies that had an English title and abstract without other limitation. All results were exported into EndNote X9 for selection.

2.2 | Study selection

After removing duplicates, all titles and abstracts were screened independently by two reviewers (XL and CMC or MH) for inclusion. Disagreements between individual judgements were resolved via discussion within the team. Studies were included in the review if they satisfied the following criteria: the study was conducted on humans of any age, reported sleep quality outcome measures (objective or subjective), investigated fibre type of the bedding or sleepwear, compared at least two fibre types (e.g., cotton vs wool). Studies were excluded if they only investigated one fibre type (e.g. cotton only), investigated the effect of chemical or medicinal fibre coatings, pillows, mattresses, or other supporting systems such as weighted blankets or clothes with different tightness. If an article potentially matched the inclusion criteria, the full text was reviewed using the same process and criteria. References where a full text could not be accessed were excluded (Lu et al., 2010). If separate references were examining the same study, the most updated data were included (He et al., 2019; Utkun, 2013). Articles written in languages other than English were translated via Google translate, and the accuracy of the translated information was corroborated by individuals proficient in the respective language.

2.3 | Quality assessment

The methodological quality of each study was assessed using Joanna Briggs Institute (JBI) Critical Appraisal Tools (quasi experiments and randomised controlled trials). Two reviewers (CMC and XL) independently evaluated the quality of included articles. Disagreements in scoring were discussed until consensus was reached.

2.4 | Data extraction and analysis

The following information was extracted from each study: (1) publication information: title, author(s), publish year, doi or url; (2) participants: number, age, sex, health conditions; (3) study design; (4) sleepwear, bedding, and fibre types; (5) sleep outcomes: measurement method (subjective or objective), parameters and data. Data presented in figures were extracted using GetData Graph Digitizer 2.26 software. XL extracted data and CMC or MH checked all extracted data. Disagreements between individual judgements were resolved via discussion within the team. For missing data, the corresponding author was contacted for unreported data. If unreachable, the data was recorded as missing (not reported, NR).

The data were analysed in Microsoft Excel. Computation of Hedges' g effect sizes of differences in sleep parameters between fibre types was made to facilitate data interpretation, where Hedges' g values of 0.20, 0.50, and 0.80 are considered to be indicative of small, medium, and large effect sizes (Cohen, 1992). A *p*-value less than 0.05 is considered to indicate a statistically significant difference.

$$\text{Hedges}'\text{g} = \frac{\text{M1} - \text{M2}}{\sqrt{\frac{(\text{SD}_1^2 + \text{SD}_2^2)}{2}}}$$

M1 and M2 refer to the mean value of fibre 1 and fibre 2 respectively; SD1 and SD2 refer to the standard deviation of fibre 1 and fibre 2 respectively.

3 | RESULTS

3.1 | Study selection

The literature search across databases yielded 2362 references. After duplicates were removed, abstract and full text screening, nine studies (Araujo et al., 2013; Chow et al., 2019; He et al., 2019; Lee et al., 2004; Nejedlá & Minařík, 2016; Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015; Shin et al., 2016; Utkun et al., 2015) were included for the systematic review. A total of 25 studies were excluded by full text for: no quantitative sleep outcomes reported for nine records, no control fibre for nine records, no clear fibre details for three records, with more updated results in another publication for one record, no bedding or sleepwear for one record, or review articles for two records. Figure 1 represents the detailed PRISMA flow chart of the study screening and selection process. All the nine included articles were experimental studies. A detailed description of the included studies is given in Table 1.

3.2 | Risk of bias of included studies

In adherence to the CONSORT statement (Dwan et al., 2019), crossover studies of randomised design are an extension of RCT, therefore the risk-of-bias of three studies (Araujo et al., 2013; Chow et al., 2019; Shin et al., 2016) was evaluated using the JBI-RCT tool. The rest of the studies (He et al., 2019; Lee et al., 2004; Nejedlá & Minařík, 2016; Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015; Utkun et al., 2015) were assessed using the JBI quasi-experimental tool. The ranking results are presented in Tables 2 and 3.

Nejedlá's (Nejedlá & Minařík, 2016) study only included one participant and statistical analysis could not be performed. Four studies (He et al., 2019; Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015; Utkun et al., 2015) did not apply multiple measurements on the outcomes. The rest of the studies (Araujo et al., 2013; Chow

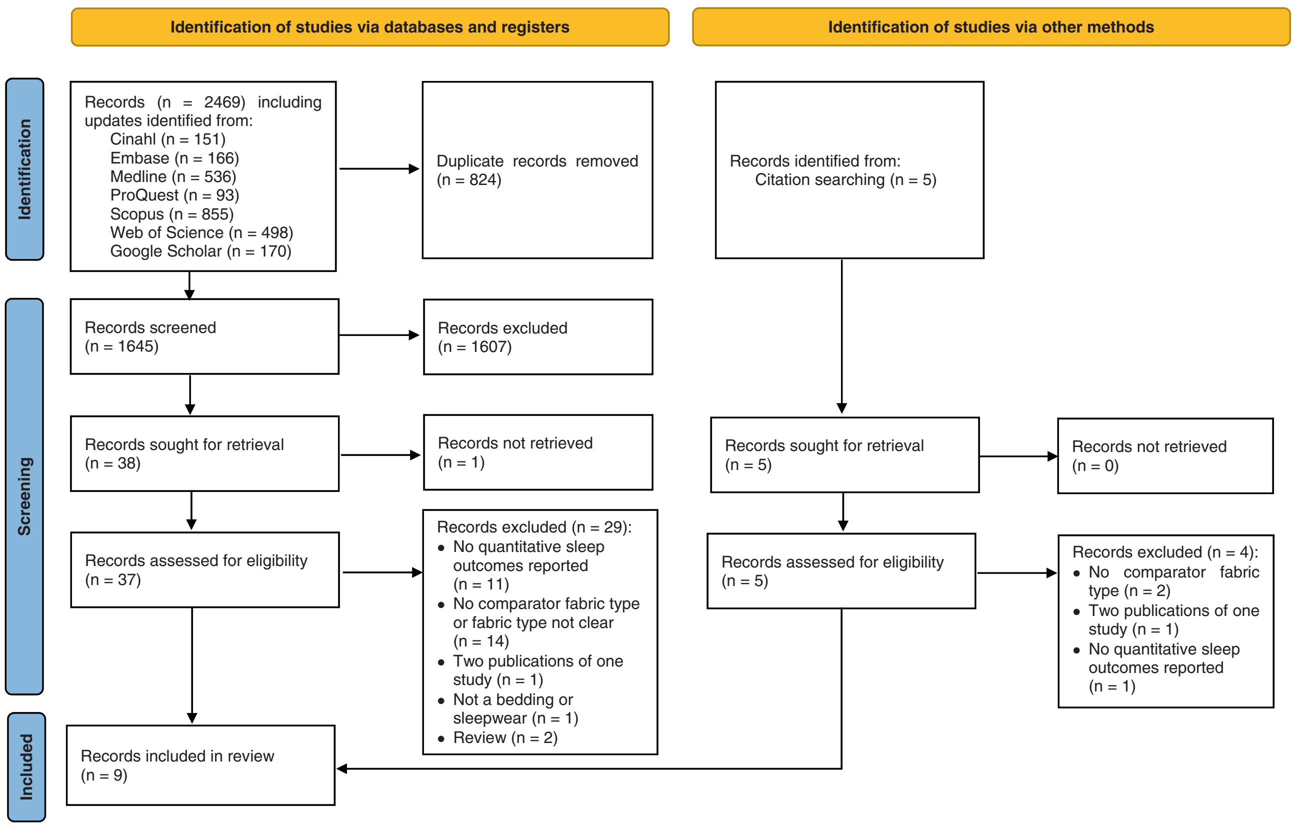

FIGURE 1 PRISMA flow chart of study selection in the systematic review.

et al., 2019; Lee et al., 2004; Shin et al., 2016) were considered to have "good" methodological quality. These studies were characterised by robust controls, meticulous experimental design, and comprehensive statistical analyses, collectively underscoring their methodological rigour and capacity to yield reliable insights.

3.3 | Study characteristics

The geographical distribution of the included studies reflects a diverse global perspective. Notably, two studies (Chow et al., 2019; Shin et al., 2016) were conducted in Australia, three studies (Araujo et al., 2013; Nejedlá & Minařík, 2016; Utkun et al., 2015) were conducted within the European region, while four studies (He et al., 2019; Lee et al., 2004; Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015) were conducted in East and Southeast Asia. As we included human studies covering the lifespan, the participants' age ranged from 6 months to 66 years: three studies investigated infants (Utkun et al., 2015) and children (Araujo et al., 2013; Lee et al., 2004) (age < 18 years); five studies investigated adults (age: 18–50 years) (He et al., 2019; Nejedlá & Minařík, 2016; Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015; Shin et al., 2016); and one study investigated older adults (age: 50–70 years) (Chow et al., 2019). There were 115 participants (66 males and 49 females) included in total; one study included all female participants (Lee et al., 2004), three studies included all male participants (Nejedlá & Minařík, 2016; Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015) and five studies included both genders (Araujo et al., 2013; Chow et al., 2019; He et al., 2019; Shin et al., 2016; Utkun et al., 2015). In addition, one study investigated participants with a skin condition (atopic dermatitis) (Araujo et al., 2013), others were all healthy participants. Of all the product types, seven were sleepwear (Araujo et al., 2013; Chow et al., 2019; Lee et al., 2004; Nejedlá & Minařík, 2016; Okamoto-Mizuno et al., 2015; Shin et al., 2016; Utkun et al., 2015), two included quilt filler (He et al., 2019; Shin et al., 2016), and one included bedsheets (Okamoto-Mizuno et al., 2013).

Cotton emerged as the fibre type commonly used either as a control or an investigated fibre. The fibre types of sleepwear include cotton, wool, polyester, and five different types of blended materials (Araujo et al., 2013; Lee et al., 2004; Nejedlá & Minařík, 2016; Okamoto-Mizuno et al., 2015; Utkun et al., 2015) (three studies with cellulose-based fibres made from natural sources (Araujo et al., 2013; Nejedlá & Minařík, 2016; Utkun et al., 2015), one with synthetic materials of polyester Healtha and polyolefin (Lee et al., 2004), and one with natural and synthetic materials (Okamoto-Mizuno et al., 2015)). Two studies (He et al., 2019; Shin et al., 2016) compared duvet fibre type between wool and polyester and between cotton and down fibres separately. One study compared bedsheets (Okamoto-Mizuno et al., 2013) fibre type between linen and a combination of cotton bed sheet and polyester bed pad. Detailed material properties are displayed in Table 4.

Of the included studies, seven reported the bedroom ambient conditions. For the room temperature, two studies (He et al., 2019;

273

TABLE 1 Summary of included studies.

Authors year country	Participants	Method: Design	Method: Ambient condition	Method: Study procedures	Method: Comparators	Outcomes (only statistically significant data are reported)
(Lee et al., 2004) Republic of Korea	$N = 9$ 0 male Age: 12 ± 2 years BMI: 24.3 ± 0.8 Healthy	Cross-over, counter-balanced	NR	3 consecutive days in sleep laboratory, 2 consecutive nights in cotton and 2 consecutive nights with experimental wear. (5 control, 4 MFF) 2-week wash out then switch	Sleepwear control fibre: 100% cotton; MFF: super-absorptive and fast-drying capacities, anti-bacterial, sun-blocking, and far-infrared radiation	**S1 (%)** Blended: 9.4 ± 3.1, Cotton: 15.2 ± 2.5, $p < 0.05$, Hedges' $g = -1.96$ **S2 (%)** Blended: 36.1 ± 4.5, Cotton: 44.1 ± 9.3, $p < 0.01$, Hedges' $g = -1.02$ **SWS (%)** Blended: 35.0 ± 2.9, Cotton: 18.4 ± 6.5, $p < 0.01$, Hedges' $g = 3.14$ **subjective sleep quality on a VAS** (with 0 representing "feel very bad after sleep" and 100 representing "feel very good after sleep") Blended: 83.2 ± 7.3, Cotton: 73.2 ± 8.2, $p < 0.01$, Hedges' $g = 1.22$
(Araujo et al., 2013) Portugal	$N = 18$ 61.1% male Age: 7 years BMI: NR All with atopic dermatitis (AD), 33.3% with personal history of atopy (Allergic rhinoconjunctivitis & asthma)	RCT	NR	From D0 the clothes were used continuously (24 h/day) for 7 days. After D7, the clothes were only used overnight, until D90. Clinical assessments taken at D0, D7, and D90. Participants slept in their own home	Babygrows (long sleeve no pants) for babies around 1-year-old and pyjamas (short top long pants) and sockets for older patients Trial group: 70% cotton fibres, 20% cellulose fibres with algae extracts and 10% silver activated algal cellulose fibres; control group: 100% cotton	**VAS of sleep disturbances** from 0 (lowest) to 10 (highest) points no significant differences were recorded
(Okamoto-Mizuno et al., 2013) Japan	$N = 8$ 100% male Age: 22.5 ± 3.5 years BMI: 20.3 ± 1.28 Healthy	Cross-over, counter-balanced	29 ± 0.5°C 70 ± 3%RH	The interval between the two conditions was between 2 and 6 days. Nap sleep study between 13:00 and 15:00	Sheet, bed pad and pillowcase: Cotton: cotton sheets, polyester bed pads and cotton pillowcases; Linen: linen (hemp) sheets, bed pads and pillowcases	**Wakefulness** (*N*) Linen: 7.9 ± 1.7, Cotton: 11.1 ± 2.5, $p < 0.05$, Hedges' $g = -1.42$ **S1** (min) Linen: 17.8 ± 3.1, Cotton: 23.7 ± 3.9, $p < 0.05$, Hedges' $g = -1.58$

(Continues)

TABLE 1 (Continued)

Authors year country	Participants	Method: Design	Method: Ambient condition	Method: Study procedures	Method: Comparators	Outcomes (only statistically significant data are reported)
(Okamoto-Mizuno et al., 2015) Japan	$N = 10$ 100% male Age: 23 ± 4 years BMI: 21.5 ± 2.1 Healthy	Cross-over, counter-balanced	29 ± 0.5°C RH: 70 ± 3%	Study conducted during August and September, before wearing, the sleepwears were conditioned at 5°C for at least 24 h. Crossover design for the two sleepwear types. The interval between the two conditions was between 2 and 6 days. Nap sleep study between 13:00 and 15:00	Sleepwears: short sleeve and long pants type C: 100% cotton; type L: polyamide-based elastomer fibre 45%, rayon 55%	**S3 (min)** Cotton: 16.5 ± 3.3, Blended: 9.1 ± 3.1, $p < 0.05$, Hedges' g = −2.21
(Utkun et al., 2015) Turkey	$N = 8$ 50% male Age: 6–12 months BMI: NR HS: NR	Cross-over, counter-balanced	22–24°C RH: 40%–65%	1st, 3rd, 5th, 7th night: own underwear; 2nd, 4th, 6th, 8th night: test two-piece pyjama set over own underwear: 2nd night D6; 4th night D6-6, 6th night D2-3; 8th night Ö4. Infant's sleep time, wakeup times during the night, duration of being awake, and wakeup time were followed by the mother	Two-piece pyjama set: top and bottom, long sleeve D6, D6-6, Ö4: 100% cotton with different weaves D2-3: Blended (50% cotton +25% Tencel LF® + 25% Bamboo)	**Average sleep duration (min):** Cotton (D6): 659 ± 60.822, Cotton (D6-6): 715 ± 46.664, Cotton (Ö4): 665 ± 82.412 Blended (D2-3): 700 ± 77.068, ANOVA main effect $p = 0.037$ Hedges' g: Blended (D2-3) vs Cotton (D6): 0.56 Blended (D2-3) vs Cotton (D6-6): −0.22 Blended (D2-3) vs Cotton (Ö4): 0.41
(Nejedlá & Minařík, 2016) Czech Republic	$N = 1$ male Age: young BMI: NR Healthy	single case	NR	The test was carried out on two defined days during 3 weeks, in total six measurements. Time in bed: 10 pm - 6 am	Sleepwear: 100% cotton vs 60% TencelC +40% Tencel +PADh	**PSG** no significant differences were recorded
(Shin et al., 2016) Australia	$N = 17$ 58.8% male Age: 24.6 ± 6.9 years BMI: 23.7 ± 2.2 Healthy (all females were on contraceptives)	Randomised, cross-over, counter-balanced	17.4°C ± 0.3°C and 22.4°C ± 0.5°C RH: 60.3% ± 2.0%	1 familiarisation night +8 nonconsecutive test nights no more than a week apart	Sleepwear (long sleeve and long pants): 100% cotton vs 100% Merino wool Duvet: wool vs polyester	**SOL (min)** wool sleepwear: 11.0 ± 8.2, cotton sleepwear: 15.0 ± 18.0, $p = 0.043$, Hedges' g = −0.28 **SOL (at the ambient condition of 17°C)** wool sleepwear: 9.9 ± 6.6 min, cotton sleepwear: 18.1 ± 0.9 minutes, $p = 0.006$, Hedges' g = −1.70 **%N3 at 22°C** wool sleepwear: 18.0 ± 1.2, cotton sleepwear: 19.6 ± 1.2, $p < 0.05$, Hedges' g = −1.30

TABLE 1 (Continued)

Authors year country	Participants	Method: Design	Method: Ambient condition	Method: Study procedures	Method: Comparators	Outcomes (only statistically significant data are reported)
(Chow et al., 2019) Australia	$N = 36$ 50% male Age: 60.0 ± 6.2 years BMI: 25.6 ± 4.1 Healthy (female participants were tested on the follicular phase)	Randomised, cross-over, counter-balanced	30.1 ± 0.5°C RH: 50.2 ± 2.9%	Study process: 1 adaptation night +3 testing nights randomly slept in cotton, polyester or wool sleepwear	Sleepwear: long sleeve and pants, loose-fitting: cotton vs wool vs polyester	**SOL (min)** Cotton: 18.5 ± 23.5; Polyester: 18.2 ± 15.5; Wool: 16.0 ± 15.5, ANOVA main effect $p = 0.04$ Hedges' g: Polyester vs Cotton: −0.01 Wool vs Cotton: −0.12 Wool vs Polyester: −0.14 SOL (min) in Old age subgroup (≥65 years, $n = 13$) Cotton: 26.7 ± 36.1 Polyester: 21.6 ± 21.0 Wool: 12.4 ± 13.4, ANOVA main effect $p = 0.001$ ($p = 0.011$ for difference between wool and cotton, $p = 0.011$ for difference between wool and polyester) Hedges' g: Polyester vs Cotton: −0.17 Wool vs Cotton: −0.51 Wool vs Polyester: −0.51 **SFI (number. hour^{-1})**, sleep fragmentation index Cotton: 13.3 ± 5.8; Polyester: 13.7 ± 4.4*; Wool: 12.1 ± 4.2*, ANOVA main effect $p = 0.01$, (*$p < 0.05$ for difference between polyester and wool) Hedges' g: Polyester vs Cotton: 0.08 Wool vs Cotton: −0.23 Wool vs Polyester: −0.37
(He et al., 2019) China	$N = 8$ 50% male Age: 23 ± 3 years BMI: 21.8 ± 2.1 Healthy	Cross-over, counter-balanced	11.52 ± 0.85°C RH: 58.91 ± 7.52%	Every day, 2 subjects (1 male and 1 female) participated in the experiment. For each subject, three kinds of quilts were applied respectively to three-night sleeping test in a fixed sleep chamber. The experimental conditions were presented in Latin-square design. Time in bed: 23:30 pm – 7:30 am	Quilts (150 *210 cm^2) with cotton cover: 90% white duck down, 90% white goose down or 100% cotton	**Subjective sleep quality** (5-point scale, −2 very uncomfortable to +2 very comfortable) duck down: −0.03 ± 0.35, goose down: 0.48 ± 0.25, cotton: −0.25 ± 0.44, ANOVA main effect $p < 0.05$ ($p = 0.077$ for difference between duck down and goose down, $p < 0.05$ for difference between cotton and goose down) Hedges' g: Duck down vs Cotton: 0.52 Goose down vs Cotton: 1.93 Goose down vs Duck down: 1.59

(Continues)

275

TABLE 1 (Continued)

Authors year country	Participants	Method: Design	Method: Ambient condition	Method: Study procedures	Comparators	Outcomes (only statistically significant data are reported)
						PSG: N3% duck down: 28.35 ± 1.07, goose down: 29.58 ± 0.91, cotton: 26.05 ± 1.23 ($p = 0.083$ for difference between duck down and cotton, $p < 0.01$ for difference between cotton and goose down) Hedges' g: Duck down vs Cotton: 1.89 Goose down vs Cotton: 3.08 Goose down vs Duck down: 1.17

Abbreviations: HS, health status; NR, not reported; RH, relative humidity; SE, sleep efficiency; SFI, sleep fragmentation index; SOL, sleep onset latency; SWS, slow wave sleep; TST, total sleep time; VAS, Visual Analogue Scale; W, awake.

Note: N1/S1, sleep stage NREM stage 1; N2/S2, sleep stage NREM stage 2; N3, sleep stage NREM Stage 3; the merging of stage S3 and S4. N1/N2/N3 are standard from AASM from 2005 (AASM, 2005), S1/S2/S3/S4 are standard from Rechtschaffen and Kales (R&K) from 1968 (Rechtschaffen & Kales, 1968).

Shin et al., 2016) were conducted below 20°C, two studies (Shin et al., 2016; Utkun et al., 2015) were between 21 and 25°C, and three studies (Chow et al., 2019; Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015) at 29–30°C. Most studies that reported relative humidity (RH) were conducted at a RH between 40% and 65%, except for two studies (Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015) which were conducted at a RH of 70%.

Two studies (Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015) were daytime nap sleep studies of a fixed time of 2 h while all others were overnight sleep studies, of which, three studies (He et al., 2019; Lee et al., 2004; Nejedlá & Minařík, 2016) had a fixed sleep time of 8 hours, with the others being sleep ad libitum. Of the nine studies, one study (Araujo et al., 2013) was conducted at the participants' own home, whereas all other studies were conducted in a sleep laboratory.

Eight studies used objective measurements (actigraphy and/or polysomnography) while one study (Utkun et al., 2015) only used a sleep diary to assess sleep quality. The main sleep outcomes reported included sleep efficiency (SE) in six studies (Chow et al., 2019; Lee et al., 2004; Nejedlá & Minařík, 2016; Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015; Shin et al., 2016), total sleep time (TST) in five studies (Chow et al., 2019; Lee et al., 2004; Okamoto-Mizuno et al., 2015; Shin et al., 2016; Utkun et al., 2015), proportion of sleep stages in six studies (Chow et al., 2019; He et al., 2019; Lee et al., 2004; Nejedlá & Minařík, 2016; Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015), sleep onset latency (SOL) and REM sleep and latency in five studies (Chow et al., 2019; Nejedlá & Minařík, 2016; Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015; Shin et al., 2016), wake after sleep onset (WASO) in four studies (Chow et al., 2019; Nejedlá & Minařík, 2016; Okamoto-Mizuno et al., 2013; Shin et al., 2016) and Pittsburgh Sleep Quality Index (PSQI) score in two studies (He et al., 2019; Shin et al., 2016). Other sleep outcomes reported include the sleep fragmentation index (Chow et al., 2019), arousal index, subjective rated sleep quality (Lee et al., 2004), sleep disturbance (Araujo et al., 2013), and sleep comfort (He et al., 2019), each with one report.

3.4 | Fibre properties

Seven articles (Chow et al., 2019; He et al., 2019; Lee et al., 2004; Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015; Shin et al., 2016; Utkun et al., 2015) provided the texture properties of the sleepwear, bedding, or duvet used in the study. A summary of the material properties is provided in Table 4.

3.5 | Sleep outcomes using different fibres

3.5.1 | Sleepwear

Cotton vs blended materials

Five studies (Araujo et al., 2013; Lee et al., 2004; Nejedlá & Minařík, 2016; Okamoto-Mizuno et al., 2015; Utkun et al., 2015)

TABLE 2 Joanna Briggs Institute (JBI) Critical Appraisal Tools for RCT studies.

JBI-RCT	(Araujo et al., 2013)	(Shin et al., 2016)	(Chow et al., 2019)
1. Was true randomisation used for assignment of participants to treatment groups?	Yes	Yes	Yes
2. Was allocation to groups concealed?	Yes	Yes	Yes
3. Were treatment groups similar at the baseline?	Yes	Yes	Yes
4. Were participants blind to treatment assignment?	Yes	Not clear	Not clear
5. Were those delivering treatment blind to treatment assignment?	Yes	Not clear	Not clear
6. Were outcomes assessors blind to treatment assignment?	Not clear	Yes	Yes
7. Were treatment groups treated identically other than the intervention of interest?	Yes	Yes	Yes
8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analysed?	Not clear	Not applicable	Not applicable
9. Were participants analysed in the groups to which they were randomised?	Yes	Yes	Yes
10. Were outcomes measured in the same way for treatment groups?	Yes	Yes	Yes
11. Were outcomes measured in a reliable way?	Yes	Yes	Yes
12. Was appropriate statistical analysis used?	yes	Yes	Yes
13. Was the trial design appropriate for the topic, and any deviations from the standard RCT design accounted for in the conduct and analysis?	Yes	Yes	Yes

compared the sleep outcome between blended sleepwear and cotton sleepwear, and only Lee's study (Lee et al., 2004) reported that the blended sleepwear (Polyester Healtha & Polyolefin) promoted significantly shorter N1% and N2%, longer SWS% and a higher subjective sleep quality on VAS compared with cotton sleepwear. Although Okamoto-Mizuno's study (Okamoto-Mizuno et al., 2015) reported a significant difference in Stage 3, there were no significant differences in the combined stage 3 + stage 4, or other sleep variables. None of the other studies did reported any significant differences in sleep outcomes between cotton and blended sleepwear (Araujo et al., 2013; Nejedlá & Minařík, 2016; Utkun et al., 2015).

Utkun et al. (2015) compared infant sleep quality when wearing underwear made of cotton fibres with three different weave structures and those of blended materials (50% cotton +25% Tencel LF® + 25% Bamboo). No consistent finding was found for sleep outcome between cotton and blended sleepwear. It was found that the D2-3 showed a medium positive effect on TST compared with D6 and a small positive effect compared with Ö4, which indicated that D2-3 promoted a longer total sleep time than D6 and O4.

Nejedlá and Minařík (2016) reported non-significant differences in sleep quality between 100% cotton sleepwear and blended sleepwear (60% TencelC /40% Tencel+PADh) across three nights each in one healthy young man, although participants reported the blended sleepwear was nicer and finer for sensation. Of the six sleep study nights, the participant's sleep was disrupted by a siren on one night. Statistical analysis was not conducted.

Araujo et al. (2013) reported non-significant differences in sleep outcomes between biofunctional textile (consisting of 70% cotton fibres, 20% cellulose fibres with algae extracts, and 10% silver activated algal cellulose fibres) and all-cotton sleepwear.

A nap study investigated the effects of pyjamas made of cotton and blended material (45% polyamide-based elastomer fibre and 55% rayon) on sleep under mild humid heat exposure (Okamoto-Mizuno et al., 2015) and reported a significant reduction with a large effect in Stage 3 when sleeping in the blended pyjama compared with sleeping in cotton ($p < 0.05$), while there were no significant differences in SWS (stage 3 + stage 4) and other sleep variables between the blended pyjamas and cotton pyjamas.

Cotton vs polyester

Chow et al. (2019) conducted a study to determine the influences of sleepwear made of cotton, wool and polyester on sleep quality for adults aged 50–70 years old, with different BMI (>25 vs. ≤25 kg·m^{-2}), and PSQI (poor sleepers vs. good sleepers whose PSQI score ≤5). When comparing cotton and polyester, there were no significant differences reported for all the sleep parameters. However, with the interaction between sleepwear and PSQI group, poor sleepers had a significantly longer REM sleep latency when sleeping in polyester than in cotton ($p = 0.037$).

Cotton vs wool

Two studies compared Merino wool sleepwear (Chow et al., 2019; Shin et al., 2016) with cotton sleepwear with both showing that wool sleepwear promoted shorter SOL than cotton sleepwear.

Shin et al. (2016) conducted a study among young adults which evaluated sleepwear, bedding at two temperature conditions (Shin

TABLE 3 Joanna Briggs Institute (JBI) Critical Appraisal Tools for quasi experimental studies.

JBI-quasi-experiment	(Lee et al., 2004)	(Okamoto-Mizuno et al., 2013)	(Okamoto-Mizuno et al., 2015)	(Utkun et al., 2015)	(Nejedlá & Minařík, 2016)	(He et al., 2019)
1. Is it clear in the study what is the "cause" and what is the "effect" (i.e. there is no confusion about which variable comes first)?	Yes	Yes	Yes	Yes	Yes	Yes
2. Were the participants included in any comparisons similar?	Yes	Yes	Yes	Yes	Yes	Yes
3. Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	Yes	Yes	Yes	Yes	Yes	Yes
4. Was there a control group (control treatment)?	Yes	Yes	Yes	Yes	Yes	Yes
5. Were there multiple measurements of the outcome both pre and post the intervention/exposure?	Yes	No	No	No	Yes	No
6. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analysed?	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
7. Were the outcomes of participants included in any comparisons measured in the same way?	Yes	Yes	Yes	Yes	Yes	Yes
8. Were outcomes measured in a reliable way?	Yes	Yes	Yes	Yes	Yes	Yes
9. Was appropriate statistical analysis used?	Yes	Yes	Yes	Yes	No	Yes

et al., 2016). The results showed that wool sleepwear produced a significantly shorter SOL than cotton sleepwear with a small effect overall, with a large effect at 17°C. However, a marginal significant interaction was observed under 22°C that sleeping in cotton produced more N3% than wool with a large effect. All the rest of the sleep parameters were not significantly different between cotton and wool sleepwear.

A study conducted among older adults (Chow et al., 2019) also showed a similar result that sleepwear significantly reduced the SOL compared with cotton ($p = 0.044$) with no effect. Subgroup analysis showed significant differences in the following parameters: for age > 65 years old, SOL was significantly reduced when sleeping in wool compared with sleeping in cotton ($p = 0.011$) with a medium effect; poor sleepers (PSQI>5) had a significantly reduced WASO when sleeping in wool than in cotton ($p = 0.047$).

Wool vs polyester

In the same study (Chow et al., 2019) that showed a significant effect of sleepwear on SOL ($p = 0.044$), sleeping in wool sleepwear contributed to a lower SOL than sleeping in polyester sleepwear with no effect. Moreover, the sleep fragmentation index (SFI) was significantly lower when sleeping in wool (12.1 ± 4.2) than polyester (13.7 ± 4.4*) with a small effect ($p = 0.005$). When considering interaction effects with subgroups, for older adults (age > 65 years old), sleeping in wool significantly reduced SOL than sleeping in polyester ($p = 0.011$); for poor sleepers (PSQI > 5), sleeping in polyester significantly prolonged REM sleep latency compared with sleeping in wool ($p = 0.036$).

3.5.2 | Bedsheets

One study (Okamoto-Mizuno et al., 2013) investigated the effect of bedsheets on sleep quality under warm conditions (29–30°C). The fibres included 100% linen and 100% cotton. The results showed that linen bedsheets promoted better sleep than cotton bedsheets (see below).

Linen bed sheet and pad vs cotton sheet + polyester bed pad

In the nap study (Okamoto-Mizuno et al., 2013), conducted under mild humid heat conditions, compared 100% cotton sheet and pillowcases with 100% polyester bed pad and with 100% linen sheet, pillowcases,

TABLE 4 Summary of fibre material properties used in the included articles

Product	Author, year	Fibre component	Weight (g·m^{-2})	Thickness (mm)	Water vapour permeability/ moisture transmission (g·m^{-2}·24 h^{-1})	Vapour resistance (m^2·Pa·W^{-1})	Water spreading transport capacity	Air permeability/air transmission (l m^{-2}·s^{-1})
Sleepwear	(Lee et al., 2004)	Standard	NP	NP	-	-	NP	-
		100% cotton	165	0.7	-	-	0.5	-
		Polyester Healtha & Polyolefin	168	0.71	-	-	1.5	-
	(Araujo et al., 2013)	-	-	-	-	-	-	-
	(Okamoto-Mizuno et al., 2015)	Standard	NP	NP	JIS L 1099 A	-	-	JIS L 1096 A
		100% cotton	100	0.42	10675.2$^{\Delta}$	-	-	1148$^{\Delta}$
		polyamide-based elastomer fibre 45%, rayon 55%	160	0.18	10560$^{\Delta}$	-	-	104$^{\Delta}$
	(Utkun et al., 2015)	Standard	SFS 3192:1974 standard	SFS-EN ISO 5084:1997 standard	Gore cup method	-	-	SFS-EN ISO 9237:1996
		D2-3: 50% cotton, 25% Tencel LF®,25% Bamboo	142	0.61	4975	-	-	1345
		D6: 100% cotton, structure: Plain weave	69.9	0.30	5643	-	-	1610
		D6-6: 100% cotton, first-type modified twill weave	79.4	0.49	4961	-	-	2780
		Ö4: 100% cotton, interlock knitted	216	0.80	4663	-	-	390
	(Nejedlá & Minařík, 2016)	-	-	-	-	-	-	-
	(Shin et al., 2016)	Standard	NP	NP	-	NP	-	NP
		Cotton sleepwear: 100% cotton	153.80 ± 0.45	0.51 ± 0.00	-	3.532 ± 0.07	-	181.70 ± 7.32
		Wool sleepwear: 100% wool	161.40 ± 0.89	0.41 ± 0.00	-	2.820 ± 0.06	-	347.74 ± 7.32
	(Chow et al., 2019)	Standard	NP	NP	-	-	-	-
		100% Cotton	140.0 ± 0.0	0.57 ± 0.03	-	-	-	-
		100% Wool	143.5 ± 2.1	0.52 ± 0.01	-	-	-	-
		100% polyester	150.5 ± 0.7	0.49 ± 0.04	-	-	-	-
Bedsheets	(Okamoto-Mizuno et al., 2013)	Standard	NP	NP	JIS L 1099	-	-	-

(Continues)

TABLE 4 (Continued)

Product	Author, year	Fibre component	Weight ($g{\cdot}m^{-2}$)	Thickness (mm)	Water vapour permeability/ moisture transmission ($g{\cdot}m^{-2}{\cdot}24\,h^{-1}$)	Vapour resistance ($m^2{\cdot}Pa{\cdot}W^{-1}$)	Water spreading transport capacity	Air permeability/air transmission ($l\,m^{-2}{\cdot}s^{-1}$)
		sheet linen 100%	234.6	0.44	480^{Δ}	-	-	-
		bed pad 100% linen	1345.1	14.8	302.4^{Δ}	-	-	-
		sheet 100% cotton	123.5	0.2	528^{Δ}	-	-	-
		bed pad 100% polyester	1245	24	307.2^{Δ}	-	-	-
Duvets and quilts	(Shin et al., 2016)	Standard	NP	NP	-	NP	-	-
		Wool	694	15.7 ± 1.0	-	60.09	-	-
		Polyester	933	17.3 ± 7.6	-	20.51	-	-
	(He et al., 2019)	Standard	NP	NP	-	-	-	-
		100% cotton	133.2	4.18	-	-	-	-
		90% white duck down	200	8.7	-	-	-	-
		90% white goose down	Air density 200	8.7	-	-	-	-

Product	Author, year	Thermal resistance ($m^2{\cdot}K{\cdot}W^{-1}$)	Thermal conductivity ($W{\cdot}m^{-1}{\cdot}K^{-1}$)	Thermal insulation value (%)	Clo value cloth insulation (clo)	Thermal character q-max ($W{\cdot}cm^{-2}$)	Moisture regain (%)
Sleepwear	(Lee et al., 2004)	-	NP	-	-	-	-
		-	19.76^{Δ}	-	-	-	-
		-	6.97^{Δ}	-	-	-	-
	(Araujo et al., 2013)	-	-	-	-	-	-
	(Okamoto-Mizuno et al., 2015)	-	-	ThermoLaboll	-	NP	gravimetric method under 27°C RH90%
		-	-	23.1	-	0.15	12.5
		-	-	13.1	-	0.27	15.8
	(Utkun et al., 2015)	Alambeta (manufactured by Czech SENSORA Company	Alambeta (manufactured by Czech SENSORA Company	-	-	-	-
		0.019	0.047	-	-	-	-
		0.01	0.04	-	-	-	-
		0.01	0.04	-	-	-	-
		0.02	0.07	-	-	-	-
	(Nejedlá & Minařík, 2016)	-	-	-	-	-	-
	(Shin et al., 2016)	NP	-	-	-	-	-

280

TABLE 4 (Continued)

Product	Author, year	Thermal resistance ($m^2{\cdot}K{\cdot}W^{-1}$)	Thermal conductivity ($W{\cdot}m^{-1}{\cdot}K^{-1}$)	Thermal insulation value (%)	Clo value cloth insulation (clo)	Thermal character q-max ($W{\cdot}cm^{-2}$)	Moisture regain (%)
		0.021 ± 0.0001	-	-	-	-	-
		0.023 ± 0.0032	-	-	-	-	-
	(Chow et al., 2019)	NP	-	-	-	-	-
		0.030	-	-	-	-	-
		0.025	-	-	-	-	-
		0.030	-	-	-	-	-
Bedsheets	(Okamoto-Mizuno et al., 2013)	-	-	ThermoLaboII	-	KES	-
		-	-	36.4	-	0.12	-
		-	-	80.7	-	0.09	-
		-	-	29.0	-	0.12	-
		-	-	85.9	-	0.12	-
Duvets and quilts	(Shin et al., 2016)	NP	-	-	-	-	-
		0.54	-	-	-	-	-
		0.38	-	-	-	-	-
	(He et al., 2019)	-	NP	-	NP	-	-
		-	4.5	-	1.433	-	-
		-	1.102	-	7.583	-	-
		-	1.102	-	7.583	-	-

Note: Entries marked with $^{\Delta}$ have been converted from their original units. NP: standard used to obtain the measure was not provided.

and bed pad on sleep quality. The condition with cotton sheets had a significantly increased number of awakenings and N1% compared with linen sheets and pillowcases with a large effect ($p < 0.05$). There were no significant differences for any other sleep variables.

3.5.3 | Duvets and quilts

Two studies investigated quilt materials and sleep quality (He et al., 2019; Shin et al., 2016). The materials as a filler included duck down, goose down, cotton, polyester, and wool. The studies were conducted under the ambient conditions of 11, 17, and 22°C. Goose down promoted longer SWS compared with cotton, and no significant differences were found between other materials.

Cotton vs duck down vs goose down

A study (He et al., 2019) showed quilt materials had a significant and large effect on sleep quality. Goose down promoted significantly longer SWS (N3%) compared with cotton with a large effect ($p < 0.01$), with no difference between duck down and cotton, or duck down and goose. No significant differences were shown for other PSG outcomes.

Wool vs polyester

From Shin's study (Shin et al., 2016), non-significant differences were observed between wool and polyester quilts.

4 | DISCUSSION

Six of the nine included studies reported that different fibre types that make up sleepwear or bedding significantly ($p \leq 0.05$) affected sleep quality measured using various sleep outcomes with a medium to large effect (Chow et al., 2019; He et al., 2019; Lee et al., 2004; Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015; Shin et al., 2016). However, the relationship between sleep quality and the type of fibre used in sleepwear and bedding is intricate. Blended fibre sleepwear has shown potential advantages for certain groups. In cool environments, wool sleepwear has been found to aid sleep onset in adults, while in warm environments, it benefits older adults. Young adults experienced better sleep quality with linen sheets in hot conditions. Goose down duvets, under cool conditions, enhanced slow-wave sleep in young adults. However, comparing different fibre types systematically is difficult due to the varied nature of the studies on sleep quality.

4.1 | The performance of different sleepwear fibres on sleep quality

4.1.1 | Cotton vs blended materials

Despite five studies employing blended materials, comparisons between studies to derive a systematic sleep outcome is challenging for a diversity of methodological issues, namely (1) the blended fibre type differs, for example, Lee's study (Lee et al., 2004) used synthetic sources of polyester Healtha and polyolefin, while the other studies employed natural cellulose-based fibres (Araujo et al., 2013; Nejedlá & Minařík, 2016; Utkun et al., 2015) or natural and synthetic materials (Okamoto-Mizuno et al., 2015), (2) the target populations and study environment differed in that Lee et al. (Lee et al., 2004) studied healthy girls aged 12 ± 2 years in a sleep laboratory, while two studies conducted home studies in young children (7 years) with AD (Araujo et al., 2013), and or in infants (aged between 6 months to 12 months) (Utkun et al., 2015). A further two studies performed studies in young male adults (age < 30 - years) in a sleep laboratory (Nejedlá & Minařík, 2016; Okamoto-Mizuno et al., 2015). One study was conducted in warm conditions (Okamoto-Mizuno et al., 2015), one in cool conditions (Nejedlá & Minařík, 2016), and three studies (Araujo et al., 2013; Lee et al., 2004; Utkun et al., 2015) did not report the ambient conditions.

It can only be concluded that for adolescent girls, sleepwear made of materials blended from synthetic sources (Lee et al., 2004) with the merits of super-absorptive and fast-drying capacities was effective in inducing more deep sleep and improving sleep quality compared with cotton sleepwear. This study (Lee et al., 2004) along with (Araujo et al., 2013; Utkun et al., 2015) were considered to have "good" methodological quality, although only study (Lee et al., 2004) yielded significant sleep changes with blended materials. The study suggests that blended fibres, with superior absorption, quick-drying properties, and lower thermal conductivity than cotton, enhance sleep quality, particularly SWS when the body temperature was usually lower than other sleep stages (Szymusiak, 2018), in girls aged 12 ± 2 years, possibly by better maintaining body temperature. However, the ambient temperature during the study was not reported. No differences in sleep outcomes were observed between cotton and other blended sleepwear in infants, children, and young men.

In sum, these diverse studies underscore the intricate interplay between fibre composition, weave structure, and their combined influence on sleep outcomes. The findings highlight both similarities and disparities in sleep quality between cotton and blended materials, contextualising the multifaceted factors influencing sleep experiences within varying populations.

4.1.2 | Pure materials

Two studies (Chow et al., 2019; Shin et al., 2016), both considered to have "good" methodological quality, investigated the sleep effect among sleepwear made of cotton, polyester, and Merino wool, with significant differences reported. Shin's study (Shin et al., 2016) was conducted among young (25 ± 7 years) healthy adults at 17 and 22°C, while Chow's study (Chow et al., 2019) was conducted among relatively older adults (60 ± 6 years) at 30°C. The comparisons between materials are discussed below.

4.1.3 | Cotton vs wool

Significant sleep benefits were observed with wool compared with cotton, including a shortened sleep onset in young adults in cooler conditions (17°C) (Shin et al., 2016) and in older adults in warmer conditions (30°C) (Chow et al., 2019). Wool also led to decreased N2% and increased N3% sleep stages in young adults at 17°C but not at 22°C (Shin et al., 2016). Interestingly, cotton sleepwear showed a greater N3% at 22°C (Shin et al., 2016). These findings indicated that wool sleepwear performed better under cooler conditions, while cotton sleepwear would be more suitable for warmer thermal conditions in young adults. In Chow's study (Chow et al., 2019) that compared cotton sleepwear with wool sleepwear, older adults and poor sleepers (with a PSQI >5) benefitted more from wool, showing a shorter SOL, lower WASO, and shorter REM latency. This suggests that these individuals may prefer sleeping at a higher ambient temperature for more favourable thermal comfort (Giamalaki & Kolokotsa, 2019; Wong et al., 2009) which wool sleepwear can provide due to its superior insulation and moisture transport properties (Ukponmwan, 1993). Additionally, wool sleepwear can help to regulate the body temperature and prevent overheating or getting too cold by trapping air and moisture, creating a favourable microclimate between the skin and garment (Iqbal, 2021).

In summary, wool sleepwear is favourable for cooler conditions, older populations, and poorer sleepers for a faster sleep onset and more consolidated sleep. For healthy young adults under normal ambient temperatures, cotton sleepwear would be better for a deeper sleep.

4.1.4 | Cotton vs polyester

Sleepwear made of cotton and polyester was compared in one study (Chow et al., 2019) in older adults under warm conditions but no significant differences in sleep outcomes were reported.

4.1.5 | Wool vs polyester

In this comparison, one study (Chow et al., 2019) found that older adults who slept in wool under warmer conditions experienced significant improvements in their sleep. Specifically, they had a shortened SOL and a decrease in SFI, indicating fewer disruptions during sleep compared with polyester. Furthermore, among older adults with poor sleep quality, those who slept in wool had decreased REM latency, meaning they entered the REM sleep stage quicker compared with those who slept in polyester. However, in young adults, non-significant differences were observed between wool and polyester quilts under cool and comfortable conditions (Utkun et al., 2015). These findings suggested that wool sleepwear performed better than polyester sleepwear by contributing to a shorter sleep onset and maintaining a less fragmented sleep, especially for older adults in warmer conditions.

Taken together, material properties such as weight and thermal resistance can determine the thermo-physiological wear comfort and skin sensation wear comfort (Rechtschaffen & Kales, 1968; Zaki et al., 2021) and can in turn affect sleep quality. In Chow's study (Nejedlá & Minařík, 2016), the weight and thickness of the wool sleepwear lies between cotton and polyester sleepwear, while the thermal resistance values were similar. The higher moisture buffering of wool sleepwear (9.9 $KJ \cdot m^{-2}$) compared with polyester (0.6 $KJ \cdot m^{-2}$) or cotton (6.9 $KJ \cdot m^{-2}$) (Pan et al., 2012) potentially contributed to a faster sleep onset, which was associated with a fall in core body temperature and a rise in distal skin temperature (Fanger, 1970; Gagge et al., 1967; Lan et al., 2017). Sleeping in wool also showed the lowest SFI compared with cotton and polyester sleepwear. A lower SFI reflected fewer stage shifts and less thermal stress under hot humid conditions (Hosseini Ravandi & Valizadeh, 2011), which may be linked to the beneficial moisture transfer and the wicking properties of wool. While in Shin's study (Utkun et al., 2015), the wool sleepwear was a little heavier and thinner than the cotton sleepwear, with a higher air permeability, lower vapour resistance, and similar thermal resistance value compared with cotton sleepwear. A previous study (Lan et al., 2017) showed that slight warming of proximal skin in the comfortable range would decrease SOL and enhance SWS. The wool sleepwear might perform better in keeping the proximal skin warm.

4.2 | The performance of different bedsheet materials on sleep quality

Only one study (Okamoto-Mizuno et al., 2013) investigated the effect of bedsheets on sleep quality under a warm/hot condition, which compared a composite of linen (hemp) bedsheets, bed pads, and pillowcases with a composite of cotton sheets, polyester bed pads, and cotton pillowcases. The results indicated that the linen composite promoted a better sleep through a significantly shorter W%, N1%, and fewer awakenings compared with cotton composite. Given the bed pads were different between conditions, it is difficult to establish whether the bedsheet fibre type or bed pad played a more important role in this situation.

4.3 | The performance of different duvets and quilts materials on sleep quality

Based on the studies reviewed, only He's study (He et al., 2019) reported a significant impact of duvet material on sleep quality. Duvets filled with goose down promoted the longest N3% compared with duvets filled with cotton when sleeping under a cool condition (11°C). Duvets filled with duck down also showed a longer N3% compared with that with cotton but non-significant differences reported. This difference may be explained by the higher insulation value and lower thermal conductivity of feather down compared with cotton, which would have created a thermal comfort bed micro-climate for people under a cool condition. Conversely, an uncomfortable cool condition would increase muscle activity, stimulate wakefulness, and improve the frequency of the arousals or stage transition from SWS to shallow sleep (Pan et al., 2012). Meanwhile, there were no significant differences found between wool and polyester quilts under normal ambient condition (17 and 22°C) (Shin et al., 2016).

4.4 | Limitations of the included studies

Although the studies included in this review shed light on the potential impact of sleepwear and bedding materials on sleep quality, there are some limitations that should be noted. Firstly, the sample sizes in some studies were relatively small, like Nejedlá's study (Nejedlá & Minařík, 2016) that included one participant. Four studies (He et al., 2019; Lee et al., 2004; Okamoto-Mizuno et al., 2013; Utkun et al., 2015) had sample sizes of <10 participants, which may limit the generalisability of the findings. However, by comparison, the studies by Shin et al. (Shin et al., 2016) and Chow et al. (Chow et al., 2019) reported a sample size of $N = 17$ and $N = 36$, respectively. Secondly, the studies employed different materials under different ambient conditions. Indeed, Xu and Lian highlighted the importance of the relationship between thermal environment, body temperature, human's thermal comfort and sleep quality (Xu & Lian, 2023). Since humans are sensitive to temperature differences (Fanger, 1970) which influence thermal comfort and sleep propensity and quality (Gagge et al., 1967; Lan et al., 2017), sleep outcomes from different studies are not directly comparable. Some studies did not report the temperature conditions (Araujo et al., 2013; Lee et al., 2004; Nejedlá & Minařík, 2016) or fibre material properties (Araujo et al., 2013; Nejedlá & Minařík, 2016; Zaki et al., 2021), making it difficult to draw definitive conclusions about the effects of specific materials or conditions on sleep. However, other studies (Chow et al., 2019; He et al., 2019; Lee et al., 2004; Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015; Shin et al., 2016; Utkun et al., 2015) clearly presented the properties of the fibres. Finally, some studies had limitations in their methodology.

Specifically, Utkun's study (Utkun et al., 2015) used fibres with different structures and yarns, thus making it difficult to determine the specific characteristics of the fibres and to compare the fibre properties. Sleep duration was reported by the mother, which may introduce biased reporting and errors.

Araujo's study (Araujo et al., 2013) did not report the material properties of the sleepwear and did not conduct objective sleep measurement in the experiment. Furthermore, it is worth noting that there was a difference in sleep disturbances between the blended and cotton sleepwear groups at baseline (day 0), with values of 5.2 ± 2.3 and 4.7 ± 2.4, respectively. This finding raises the possibility of introducing bias and reducing the accuracy and reliability of the study's results.

Okamoto-Mizuno's studies (Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015) investigated the effects of different sleepwear and beddings under hot and humid conditions during daytime naps, which may not be representative of night-time sleep, as a human's body temperature would change according to the thermoregulatory system.

Nejedlá's study (Nejedlá & Minařík, 2016), as mentioned earlier, is considered to have a high risk of bias due to the small sample size and lack of proper statistical analysis. This paper did not report any material properties or the bedroom environment conditions.

4.5 | Limitation of this review and implications for future research

This review has several limitations that should be considered when interpreting the findings. Firstly, the inclusion criteria only considered papers with English abstracts, which may have resulted in the exclusion of relevant studies published in other languages. Additionally, two of the included papers (Okamoto-Mizuno et al., 2013; Okamoto-Mizuno et al., 2015) were translated using Google Translate, which may have led to some misinterpretation or omission of key information. Furthermore, publication bias may have influenced the results, as studies with statistically significant results are more likely to be published.

Moreover, due to the heterogeneity of the studies included in this review, such as varying designs, materials, and outcome measures, it was not possible to conduct a meta-analysis, thus limiting the generalisability of the findings. Most studies were conducted in laboratory settings, which may not reflect real-world sleeping conditions.

Sleep quality can be affected by the performance of different fibre types (along with their material properties, fibre weave types, and blending) in different ambient conditions. Material properties such as weight and thermal resistance can determine the thermo-physiological wear comfort and skin sensation wear comfort (Hosseini Ravandi & Valizadeh, 2011; Saville, 1999) and can in turn affect sleep quality. Other physiological factors such as sex, age, and metabolic rates can also impact the interaction with microclimate and sleep quality (Kayabekir, 2019; Okamoto-Mizuno & Tsuzuki, 2010). The human metabolic processes generate heat and moisture, which interact with the clothing with respect to its dissipation and affect comfort (Bhatia & Malhotra, 2016). These factors were not considered in this review.

Future research should include larger and more diverse samples, standardised study designs with specific types of fibres for sleepwear/bedding, and objective outcome measures of sleep (using polysomnography and actigraphy) to provide a more comprehensive understanding of the effects of sleepwear and bedding materials on sleep quality. The authors recommend testing the difference between two ensembles (for example): one with cotton sleepwear, bedding, and pillowcases, and another with wool sleepwear, bedding, and pillowcases.

5 | CONCLUSION

Overall, the reviewed studies suggest that different types of sleepwear, bedsheets, and duvet materials can affect sleep outcomes, and selecting appropriate materials for sleepwear, bedsheets, and duvets can have a positive impact on sleep quality. However, based on the limited evidence from this review, it is hard to draw an overall conclusion. Some points can be drawn from the comparison of subgroups. For sleepwear, wool sleepwear appears to be the most beneficial for promoting sleep quality compared with cotton or polyester sleepwear, while sleepwear made of materials blended from synthetic sources was effective in inducing more deep sleep and improving sleep quality compared with cotton sleepwear for adolescent girls. There were no significant differences reported or no evidence for other fibre or condition. For bedding, as only one study was included in this review, which showed under hot conditions, linen promoted less W%, N1%, and awakening in healthy young men compared with a combination of cotton and polyester bedding, no conclusion can be drawn for this section for the lack of evidence. For the duvets, under cool conditions, duvets filled with goose down were preferable to cotton-filled duvets, while there was no significant difference between cotton and duck down. Meanwhile, under normal temperatures, there was no significant difference found between wool and polyester quilts either. However, the heterogeneity of the studies included, and the limitations of this review indicate a need for more standardised research with larger and more diverse samples to fully understand the effects of sleepwear and bedding fibre materials on sleep quality. Nonetheless, the findings of this review provide valuable insights for individuals seeking to improve their sleep quality and for companies designing sleep products.

AUTHOR CONTRIBUTIONS

Xinzhu Li: Writing – original draft. **Mark Halaki:** Writing – review and editing. **Chin Moi Chow:** Writing – review and editing.

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DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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Validation of MotionWatch8 Actigraphy Against Polysomnography in Menopausal Women Under Warm Conditions

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Highlights

What are the main findings?

- MotionWatch8 overestimated TST and SE while it underestimated SOL and WASO.
- MotionWatch8 showed high sensitivity for sleep detection (94.8%) but low specificity for wake detection (33.1%), with an overall accuracy of 87.3%.

What is the implication of the main finding?

- MotionWatch8 may be less reliable for individuals with more extreme sleep characteristics (SOL > 30 min and WASO > 80 min (criteria that fall under insomnia in DSM-5), and SE < 77%).
- Caution is needed when using this device in clinical populations with sleep disturbances.

Abstract: This study evaluated the agreement between MotionWatch8 actigraphy and polysomnography (PSG) in measuring sleep parameters among menopausal women under controlled 30 °C laboratory conditions. Sixteen peri- and post-menopausal women (age: 51.4 ± 4.2 years, BMI: 26.0 ± 3.1 kg/m^2) contributed 59 nights of simultaneous recordings, with parameters analyzed using Bland–Altman plots, linear mixed model analysis, and epoch-by-epoch comparisons. Results showed MotionWatch8 significantly overestimated total sleep time by 18.6 min and sleep efficiency by 3.5%, while underestimating sleep onset latency by 11.2 min and wake after sleep onset by 9.1 min compared to PSG. Significant proportional errors were observed, particularly for participants with prolonged sleep onset latency, high wake after sleep onset, and lower sleep efficiency. Epoch-by-epoch analysis revealed high sensitivity for sleep detection (94.8%) but low specificity for wake detection (33.1%), with 87.3% overall accuracy. These findings demonstrate that MotionWatch8 may be less reliable for individuals with more extreme sleep characteristics, such as insomnia, as measurement accuracy declines with increasing severity of sleep disturbances, highlighting the need for caution when using this device for detailed sleep assessments in clinical populations with sleep disturbances.

Keywords: validation; PSG; polysomnography; actigraphy; sleep; menopause; MotionWatch8

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1. Introduction

Menopause is a significant life transition that can drastically affect a woman's health, with sleep disturbances being one of the most reported issues [1,2]. Sleep disturbances affect around 40–60% of menopausal women [3,4]. Vasomotor symptoms, such as hot flashes and night sweats, reported by 75% of menopausal women, contribute to sleep disturbances [3,5,6]. Despite their high prevalence and considerable impact, sleep disturbances in menopausal women are often overlooked or trivialised. Accurately capturing sleep disturbances in menopausal women is critical to understanding their extent and developing effective approaches to address their impact.

While polysomnography (PSG), the gold standard for sleep measurement, captures important data on sleep architecture and patterns [7], it is impractical for tracking sleep over extended periods. Nevertheless, the SWAN sleep study demonstrated the feasibility of conducting three-night PSG recordings, albeit in-home studies [8]. Actigraphy, a non-invasive method that tracks movement, offers an accessible alternative in the home and field setting for long-term monitoring [9–11]. Since its introduction in the 1970s, actigraphy has been widely used and validated in diverse populations [9,12], consistently demonstrating high concordance with PSG results across different conditions, such as insomnia, circadian rhythm disorders, and chronic health conditions, as well as across age groups ranging from children, adolescents, to older adults [13–19]. A recent validation study by Waki et al. [20] compared the MotionWatch8 with a commercial wearable (Fitbit Inspire HR) in healthy adults.

However, despite its widespread application, few studies have specifically validated actigraphy in menopausal women, a population uniquely affected by sleep disturbances due to hormonal fluctuations. This gap is especially relevant given that warm environmental conditions are known to trigger vasomotor symptoms such as hot flashes and night sweats [21–23], which in turn exacerbate sleep disturbances in this population. Although the MotionWatch© has been validated against PSG in some conditions, including in non-shift-working adult population [15,19,24–30], its performance under warm environmental conditions and in hormonally sensitive populations such as menopausal women remains unclear. This issue is particularly important in regions regularly experiencing summer temperatures exceeding 30 °C, such as Sydney and Melbourne (Australia) [31,32], Cancun (Mexico) with an average temperature of 30.5 °C in January [33], many coastal cities in China [34], and the eastern United States [35]. Countries like Qatar and Kenya experience such temperatures all year round [36,37]. Previous research by Shin et al. [38] demonstrated that ambient temperature can influence the behaviour and accuracy of actigraphy devices in sleep measurements, underscoring the need for validation in controlled warm conditions. This study therefore aims to address this gap by validating the effectiveness of the MotionWatch8© (CamNtech Ltd., Cambridgeshire, UK) against PSG in measuring sleep parameters among menopausal women under controlled warm laboratory conditions.

2. Method

2.1. Participants

A total of 16 peri- or post-menopausal women from the Greater Sydney Area, NSW, Australia, participated in this study. Participant characteristics are summarised in Table 1.

Inclusion criteria: Participants were required to be experiencing vasomotor menopausal symptoms, defined as a vasomotor scale score ≥ 2 on the Modified Greene Climacteric Scale [39] or with self-reported daily hot flashes or night sweats. Additional criteria included irregular menstruation period due to menopause transition over the past 12 months (perimenopausal), cessation of menstruation for at least one year (postmenopausal), or bilateral oophorectomy (surgically induced menopause) at least six weeks prior to screening.

Exclusion criteria: Individuals were excluded if they were shift workers, had sleep difficulties or sleep disorders, chronic health conditions affecting sleep (e.g., cardiovascular diseases, pulmonary diseases, diabetes, or metabolic syndrome), were on hormone replacement therapy (HRT) or were taking medications that could impact sleep.

Recruitment strategy: Participants were mainly recruited via advertisements through flyers, local newspapers, social media, and referrals from a recruiting agency, Trialfacts (Available online: https://trialfacts.com (accessed on 6 February 2020)).

Actigraphy and PSG data were collected simultaneously during overnight sleep studies.

Table 1. Participant characteristics.

Variable	n (%)	Mean± SD	Range
Age		51.4 ± 4.2 years	45–63 years
BMI		26.0 ± 3.1 kg/m^2	20.7–30.0 kg/m^2
Menopause type			
Natural	15 (93.8%)		
Surgical	1 (6.3%)		
Menopause stage			
Last menses < 1 year	8 (50.0%)		
1 year < last menses < 2 years	6 (37.5%)		
last menses > 2 years	2 (12.5%)		
Dominant Hand			
Right	13 (81.3%)		
Left	3 (18.8%)		
Ethnicity			
Asian	4 (25.0%)		
Caucasian	12 (75.0%)		

2.2. Study Procedures

During the laboratory visits, participants underwent screening by completing several questionnaires about health history, sleep-related scales, menopausal status, and menopause symptoms. Demographic information was collected. Physical measurements, including height, weight, waist and neck circumference, and blood pressure were recorded.

Eligible participants completed four overnight sleep studies inconsecutively with at least one night interval between studies in a controlled laboratory environment. The bedroom was maintained at a temperature of 30 °C (30.1 ± 0.5 °C) and relative humidity of 50% (46.4 ± 2.7%) as part of a broader investigation into the effects of sleepwear fibre type on sleep quality.

On each study night, participants arrived approximately 4.5–5 h before their usual bedtime. A standardised dinner was served at 4 h before their usual bedtime, following a physical examination. Participants were encouraged to maintain adequate fluid intake during the day but to restrict water consumption within two hours before bedtime to minimize nocturnal awakenings. PSG setup, including electrode and sensor placement, began 1.5–2 h before bedtime. Participants remained in the waiting area before transitioning to the sleeping room 20 min prior to lights-off. The lights-off and lights-on times corresponded to participants' usual bedtimes and wake-up times, ensuring adherence to their typical sleep routines. During the PSG study, participants wore the MotionWatch8© on their non-dominant wrist for the entire sleep period to capture actigraphy data concurrently.

2.3. PSG Recording

Overnight PSG sleep data were collected using a Compumedics E-series or W-series Sleep system (Compumedics Australia Pty Ltd., Abbotsford, VIC, Australia). A standardised procedure for the placement of 10–20 electrodes was followed according to the American Academy of Sleep Medicine (AASM) guidelines [40].

Electrode placement included the following:

Electroencephalogram (EEG): Five scalp electrodes referenced to mastoid processes (C3-M2, C4-M1, O1-M2, O2-M1, F3-M2), Cz on the scalp as reference, and one ground electrode Fpz on forehead.

Electrooculogram (EOG): Bilateral electrodes placed near the outer canthus of each eye.
Electromyogram (EMG): Submental electrodes placed under the chin to record muscle activity.
Electrocardiogram (ECG): Electrodes placed on the chest to monitor heart activity.

All signals were sampled at a frequency of 256 Hz.

2.4. PSG Data Scoring

The PSG recordings were scored by an external independent experienced scorer according to the AASM manual [40]. A report was generated using the Compumedics Profusion PSG4 software Version 4 (Compumedics Australia Pty Ltd., Abbotsford, VIC, Australia) including the following items: report start and end time/duration, lights-off and lights-on time, time available for sleep, sleep latency, REM latency, sleep period start and end time/duration, wake after sleep onset, total sleep time (minutes), NREM sleep, sleep stages (N1/N2/N3/REM) time and proportion, and sleep efficiency. The stage of each epoch was also exported.

2.5. MotionWatch8 Recording and Scoring

The MotionWatch8 was selected for this study due to its widespread clinical and research use, compatibility with legacy actigraphy scoring protocols, and manufacturer-supported algorithms validated for 30 s epochs. It has been previously validated in the general adult population [41], enabling comparisons with earlier work while allowing us to explore its applicability in a thermally challenging setting. Recordings were taken in 30 s epochs using MotionWatch Mode 1, which is an epoch-based recording mode using a single axis algorithm and peak detection. Participants wore it on the non-dominant wrist.

The actigraphy recordings were processed using the software's algorithm (MotionWare 1.2.28, CamNtech Ltd., Cologne, Germany). This algorithm, which is not publicly disclosed in detail, is designed by the manufacturer to mimic legacy actigraphy devices (e.g., Actiwatch). The movement thresholds used for sleep/wake classification are proprietary and cannot be adjusted by the user. Lights-off and lights-on times for each sleep interval were manually checked and marked by reviewing the light level, and activity counts and were cross-checked and adjusted based on the participant's documented sleep log to improve the accuracy of the marked rest interval. The software algorithm then automatically calculated the sleep statistical data.

2.6. Data Analysis

To assess the agreement between PSG and actigraphy, both sleep summary statistics and epoch-by-epoch analyses were performed using data across the sleep period. Nights with incomplete actigraphy or PSG recordings were excluded from the analysis.

Bland–Altman plots were used to assess the agreements between MotionWatch8 and PSG for the sleep outcome variables of total sleep time (TST), sleep efficiency (SE), sleep onset latency (SOL) and wake after sleep onset (WASO). Each night's data was treated as an independent observation in the analysis, meaning that data from different nights for the same participant were analysed separately, rather than averaged or combined. In the Bland–Altman plots, each data point represents the sleep parameters recorded for a single night, regardless of whether the nights belonged to the same or different participants. The differences for each sleep variable (displayed on the y-axis) were calculated as actigraphy outcome minus PSG outcome, and the mean of the two measures was displayed on the x-axis. The limits of agreements (LOA) were calculated as the mean difference $\pm 1.96 \times$ standard deviation, which indicated the range of values expected for 95% of individuals. To further evaluate the systematic bias and potential dependency of measurement differences on the size of the measurement, statistical significance tests were performed using SPSS. A one-sample *t*-test was used to examine whether the mean difference (offset) for each sleep variable significantly deviated from zero. Linear regression analyses were conducted to assess whether the differences (dependent variable) were significantly associated with the mean values (independent variable). The regression slope was tested for significance to determine if the measurement bias varied across the range of measurement values.

To assess the agreement between PSG and MotionWatch8, sleep parameters, including SOL, TST, SE, and WASO were compared using a linear mixed model (LMM) in SPSS. The LMM approach was chosen to account for the repeated measures design as each participant contributed up to four nights of data, and to incorporate both fixed and random effects. The model included device (PSG vs. MotionWatch8) as a fixed factor to evaluate the main effects of measurement method and visit number (night-to-night variability) as a repeated fixed factor. Study ID was included as a random intercept to account for within-subject correlation across repeated measures, with a first-order autoregressive covariance structure (AR1) specified. Estimated Marginal Means (EM Means) were generated for device to compare main effects. The model employed restricted maximum likelihood estimation (REML) for parameter estimation and used the Satterthwaite approximation for calculating degrees of freedom.

Epoch-by-epoch comparison was made to calculate sensitivity, specificity, and accuracy. Only the epochs where both the actigraphy and PSG have stages were analysed. Sleep epochs were coded as 1 and awake epochs were coded as 0. Sensitivity reflects sleep agreement and was calculated as the number of true sleep (TP)/(TP+ number of false wake epoch (FN)). Specificity measures wake agreement was calculated as the number of true wake epochs (TN)/(TN + number of false sleep epoch (FP)). Accuracy shows the overall performance of sleep and wake detection for the actigraphy against PSG, which was calculated as (TP + TN)/(TP + TN + FP + FN).

All analysis was conducted using SPSS v.29.0.1.0 and Microsoft Excel. The level of significance was set at $p < 0.05$.

3. Result

After excluding nights with technical issues, a total of 59 nights of valid recordings from 16 participants were included for analysis. Participants' ages ranged from 45 to 63 years old (51.4 ± 4.2 years).

3.1. Bland–Altman Plots

The Bland–Altman plots for SOL, TST, SE, and WASO are displayed in Figure 1. The MotionWatch8 tended to overestimate TST by an average of 18.6 min, with LOA ranging from −56.8 min to 94.0 min. No proportional bias was found for TST ($p = 0.819$, $R^2 = 0.0009$). It overestimated SE by 3.5%, with LOA between −11.7% and 18.7% and a significant proportional bias. On the other hand, the MotionWatch8 underestimated SOL by an average of 11.2 min, with LOA from −53.6 to 31.3 min. The proportional error was significant, particularly for participants with sleep onset latency greater than 30 min. Similarly, WASO was underestimated by 9.06 min, with LOA ranging from −74.80 min to 56.68 min, with a significant dispersion from the mean where WASO was greater than 55 min. Table A1 provides the mean differences, lower and upper limits of agreement (LOA), ranges, the *p* value for offset, and regression line for SOL, TST, SE, and WASO.

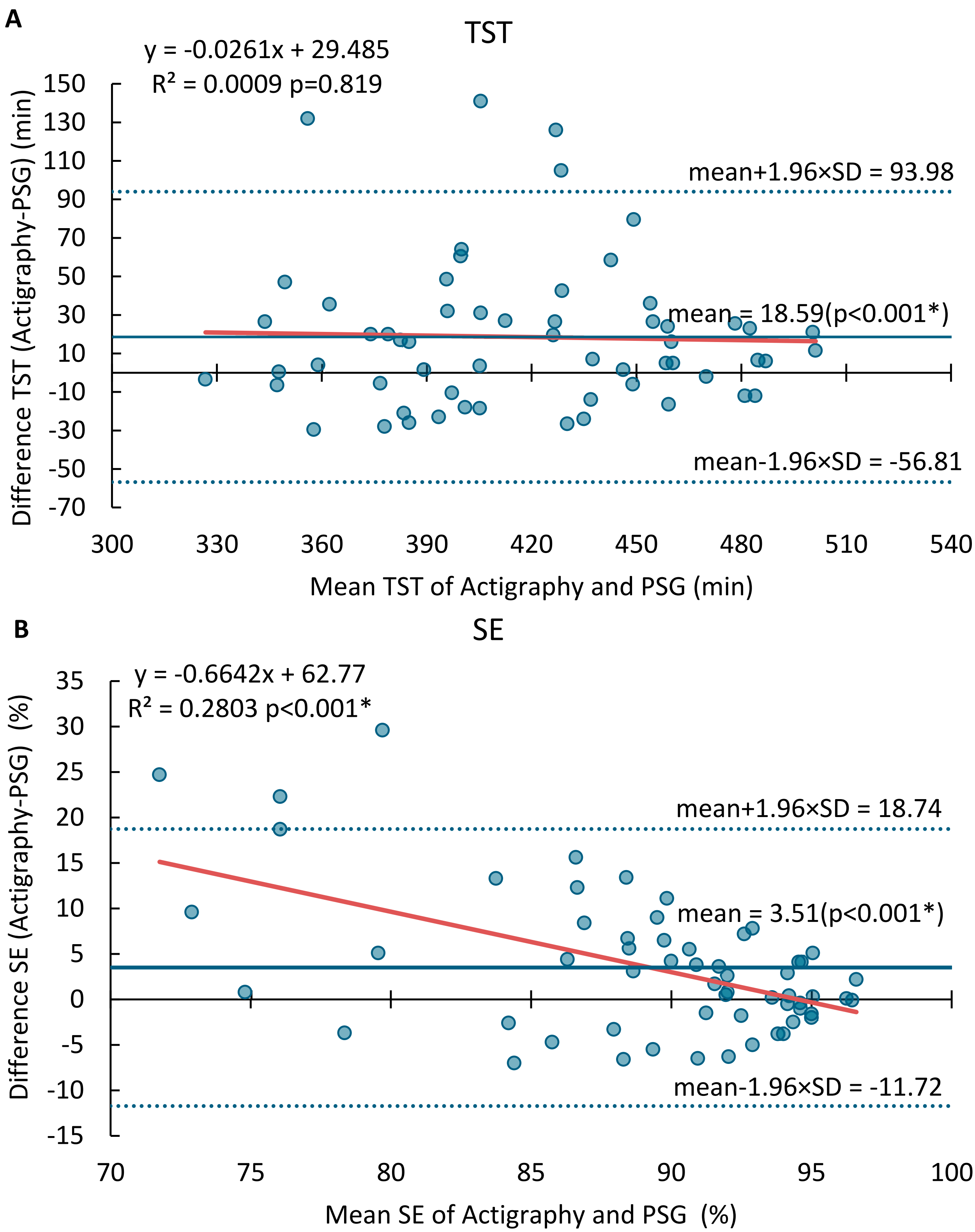

Figure 1. *Cont.*

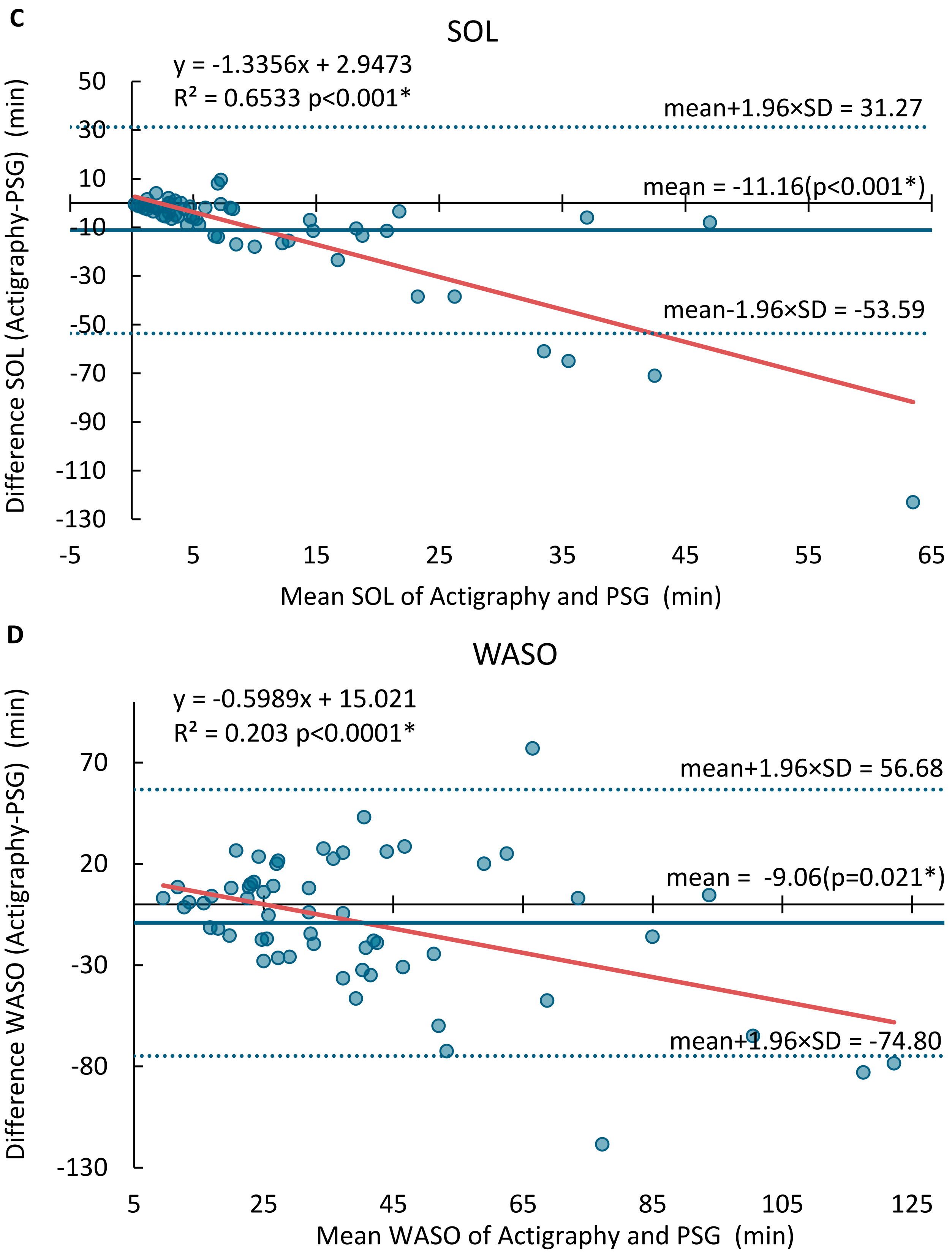

Figure 1. Bland–Altman analysis of agreement between MotionWatch8 and PSG for (**A**) Total sleep time (TST), (**B**) Sleep Efficiency (SE), (**C**) Sleep Onset Latency (SOL) and (**D**) Wake After Sleep Onset (WASO). Significant results ($p < 0.05$) are marked with *. The blue dots represent the differences between paired measurements (MotionWatch8—PSG) for each night, plotted against the mean of the two methods. The solid red line indicates the regression line showing proportional bias. The solid blue line indicates the mean differences. The dash blue lines indicate ±1.96 standard deviations.

3.2. Linear Mixed Model

Table 2 summarises the linear mixed model (LMM) analysis results for sleep onset latency (SOL), wake after sleep onset (WASO), total sleep time (TST), and sleep efficiency (SE). The table displays the estimated marginal means (mean ± std. error) for each device (PSG and MotionWatch8), along with the F-values and p-values for the main effect of device.

Table 2. Result of linear mixed model analysis.

Sleep Parameter	Device (Mean ± Std. Error)		F-Value	Devices
	PSG	MotionWatch8		
SOL (minutes)	16.0 ± 3.2	5.1 ± 3.2	9.835	0.004 *
WASO (minutes)	45.9 ± 6.6	36.2 ± 6.6	3.729	0.063 *
TST (minutes)	408.1 ± 11.0	426.8 ± 11.0	11.677	0.002 *
SE (%)	87.3 ± 1.6	90.9 ± 1.6	10.458	0.003 *

Significant results ($p < 0.05$) are marked with *.

Significant differences were observed between PSG and MotionWatch8 for SOL, TST, SE, and as indicated by *p*-values below 0.05. Additionally, a marginally significant difference was observed for WASO between the two devices ($p = 0.063$).

3.3. Epoch-by-Epoch Comparison

Table 3 displays the comparison results for sensitivity for sleep, specificity for wake, and accuracy between the classifications of sleep and wake.

Table 3. Sensitivity, specificity, and accuracy of MotionWatch8 compared to PSG.

	Mean ± SD	Range	95% CI
Sensitivity	94.8 ± 3.2%	85.8–100%	94.0%, 95.6%
Specificity	33.1 ± 19.5%	0.0–82.2%	28.1%, 38.1%
Accuracy	87.3 ± 6.6%	65.8–96.8%	85.6%, 88.9%

4. Discussion

The present study highlights the utility and limitations of MotionWatch8 for sleep assessment in menopausal women under controlled warm laboratory conditions. Our study validated the MotionWatch8 against PSG, revealing that MotionWatch8 systematically overestimates sleep duration and underestimates wakefulness-related metrics, particularly in participants with higher SOL, WASO, and lower SE values.

Specifically, Bland–Altman plots revealed that MotionWatch8 overestimated total sleep time (TST) and sleep efficiency (SE), while underestimating sleep latency (SOL) and wake after sleep onset (WASO), with significant proportional errors observed for SE, SOL, and WASO. The linear mixed model (LMM) analysis results indicated significant differences between PSG and MotionWatch8 for TST, SE, and SL, with MotionWatch8 tending to overestimate TST and SE while underestimating SOL compared to PSG. Additionally, a trend toward significance was observed for WASO between the two devices ($p = 0.063$), with MotionWatch8 tending to underestimating WASO compared to PSG.

Significant proportional biases were observed for SOL, SE, and WASO as indicated by their regression slopes, while no proportional bias was found for TST ($p = 0.819$, $R^2 = 0.0009$). This indicates that while MotionWatch8 performs satisfactorily for objective measurement of sleep parameters in individuals with regular sleep patterns, it may not be suitable for populations with disrupted sleep, e.g., insomnia. Specifically, the proportional bias for SOL (R^2 = 0.65) and WASO (R^2 = 0.20) suggests that device inaccuracy worsens with higher disturbance severity. These biases have clinical implications as sleep onset of >30 min and high WASO approach diagnostic thresholds for insomnia (DSM-5) [42,43]. Furthermore, an underestimation of SOL by an average of 11.2 min and WASO by 9.1 min, as observed in our study, may result in failure to meet clinical diagnostic thresholds, potentially leading to false negatives in insomnia screening or underestimation of symptom severity. These limitations stem from MotionWatch8's tendency to misclassify periods of quiet wakefulness as sleep and its difficulty in detecting fragmented or disrupted sleep patterns.

Epoch-by-epoch comparisons demonstrated high sensitivity (94.8%) and overall moderate accuracy (87.3%), but low specificity (33.1%) for wake detection. These findings align with previous validation studies of actigraphy devices [19]. Marino et al. [15] and Lichstein et al. [28] both reported similar trends in Actiwatch devices, attributing these overestimations to the reliance on movement-based algorithms that often misclassify quiet wakefulness as sleep. Likewise, studies [27,44] highlighted actigraphy's inherent limitations in distinguishing wake epochs during periods of minimal movement. Our study extended these findings by observing more pronounced proportional errors for SOL and WASO compared to prior research, potentially due to the controlled laboratory environment and population characteristics. For instance, Full et al. [27] found that SOL errors were less severe in healthy adult populations, potentially due to their shorter sleep latency ranges. While MotionWatch8 demonstrated high sensitivity (94.8%) for sleep detection, its low specificity (33.1%) for wake detection highlights its limitations in distinguishing wake epochs during periods of minimal movement [45]. These findings align with Kosmadopoulos et al. [44], who observed similar challenges in shift workers with irregular schedules. The lack of significant differences in WASO observed in our study differs from some previous findings, potentially due to differences in laboratory conditions or sample characteristics. Moreover, our findings suggest that MotionWatch8's accuracy diminishes significantly in participants with extended SOL or fragmented sleep patterns, which may be a result of its algorithmic limitations under fixed laboratory conditions. These discrepancies highlight the importance of considering device-specific calibration and population-specific factors when interpreting actigraphy data.

It is worth noting that the study sample comprised predominantly Caucasian women (75%) whose menopause occurred naturally (94%). Previous research has demonstrated that both menopausal type and ethnicity can significantly affect sleep characteristics. Extreme sleep characteristics may reduce the level of concordance by actigraphy devices. For example, the sleep characteristics of our participants may show fewer extreme parameters, contrasting with women who displayed more severe sleep disturbances who had surgical menopause due to abrupt hormonal changes [4,22]. The SWAN sleep study also indicated that African-American women exhibited longer sleep onset latency and lower sleep efficiency compared to Caucasian women [8]. Notably, there is no evidence to suggest that these factors alter the validation process relative to PSG. However, the narrow participant group limits applicability to diverse populations. Future validation studies involving more ethnically and clinically diverse populations are warranted to enhance generalisability and to investigate these potential moderating effects.

Although we collected data from only 16 participants, each participant contributed up to four nights of recordings, resulting in 59 independent paired nights of data. We used linear mixed models to account for the repeated-measures design, thereby enhancing statistical power. A key strength of this study is the use of simultaneous PSG and actigraphy recordings over multiple nights, providing robust data for analysis. Furthermore, this study uniquely employs multiple statistical methods, including Bland–Altman plots, linear mixed models, and epoch-by-epoch comparisons, offering a comprehensive evaluation of the MotionWatch8's performance. These statistical approaches are particularly well-suited to the experimental design and study population in this study, enhancing the validity of the findings. However, the controlled laboratory environment may limit generalisability, as natural sleep patterns could be influenced by fixed bedtimes. Additionally, MotionWatch8's reliance on movement-based algorithms poses challenges in detecting wake epochs during periods of quiet rest, which remains a limitation of this device.

5. Conclusions

MotionWatch8 demonstrated overestimations for total sleep time (TST) and sleep efficiency (SE) and underestimations for sleep onset latency (SOL) and wake after sleep onset (WASO) compared to PSG. Bland–Altman plot analysis revealed significant proportional biases for SE, SOL, and WASO, while no proportional bias was observed for TST. Linear mixed model (LMM) analysis confirmed significant differences between the two devices for SOL, TST, and SE, and a marginally significant difference for WASO, indicating that MotionWatch8 and PSG do not produce interchangeable measurements for these parameters. Epoch-by-epoch comparisons revealed high sensitivity for sleep (94.8%) but low specificity (33.1%) for wake detection, underscoring the device's challenges in accurately identifying wake epochs during periods of minimal movement. These findings suggest that while MotionWatch8 has potential for monitoring overall sleep patterns under warm laboratory conditions, it may be less reliable for individuals with more extreme sleep characteristics (e.g., insomnia), highlighting the need for caution in its use for detailed sleep assessments. Future studies should consider validating the MotionWatch8 in larger, more diverse populations, including real-world home settings and in individuals with diagnosed insomnia or thermoregulatory dysfunctions. Software improvements in scoring algorithms or device-specific calibration targeting extreme sleep characteristics may enhance accuracy in theses populations.

These findings contribute to the limited literature on actigraphy validation in thermally and hormonally sensitive populations and offer practical insights into its limitations under real-world clinical conditions.

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Data Availability Statement: Data are contained within the article.

Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

PSG	polysomnography
SOL	sleep onset latency
TST	total sleep time
SE	sleep efficiency
WASO	wake after sleep onset
LMM	linear mixed model
SD	standard deviation
AASM	American Academy of Sleep Medicine
EEG	electroencephalogram
EOG	electrooculogram
EMG	electromyogram
ECG	electrocardiogram
LOA	limits of agreements

Appendix A

Table A1. Bland–Altman Analysis Summary for Sleep Variables.

Variable	Mean Difference	Lower LOA	Upper LOA	Range	*p* (Offset)	*p* (Regression Slope)
SOL (min)	−11.2	−53.6	31.3	84.9	<0.001 *	<0.001 *
WASO (min)	−9.1	−74.8	56.7	131.5	0.021	<0.001 *
TST (min)	18.6	−56.8	94.0	150.8	<0.001 *	0.819
SE (%)	3.6	−11.7	18.7	30.5	<0.001 *	<0.001 *

Significant results ($p < 0.05$) are marked with *.

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O039

AGREEMENT BETWEEN MOTIONWATCH8 AND POLYSOMNOGRAPHY SLEEP OUTCOMES IN MENOPAUSAL WOMEN

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Introduction: Polysomnography (PSG) is the gold standard for sleep measurement but is costly and can disrupt sleep. Actigraphy offers a non-invasive alternative for longer-term monitoring. This study aims to validate the MotionWatch8 device against PSG for sleep outcomes among menopausal women.

Methods: Sixteen healthy women aged 45-65 years with menopausal symptoms underwent four in-lab overnight PSG studies while wearing the MotionWatch8. Sleep parameters including time in bed (TIB), total sleep time (TST), sleep efficiency (SE), sleep onset latency (SOL), and wake after sleep onset (WASO) were measured. Agreements between MotionWatch8 and PSG was assessed using Bland-Altman plots.

Results: MotionWatch8 tended to overestimate: TIB by 1.2 minutes with limits of agreement (LOA): 6.7 to 9.2 minutes; SE by 3.5%, LOA: -11.7% and 18.7%, and significant proportional error especially for nights with SE<92%; and TST by 18.6 minutes, LOA: -56.8 to 94.0 minutes. MotionWatch8 underestimated: SOL by 11.2 minutes, LOA: -53.6 to 31.3 minutes, and a significant proportional error especially for a longer sleep latency (SOL>20minutes); and WASO by 7.4 minutes, LOA: 40.5 to 25.7 minutes.

Discussion: The results indicate that the MotionWatch8 provides acceptable agreement and LOA with PSG for TIB, TST and WASO; and for SOL and SE for people without significant sleep problem. The device is not recommended to be used for people with longer sleep latency and poorer sleep efficiency. While the MotionWatch is a feasible tool for large-scale sleep studies in menopausal women, it should be used with caution for these specific situations.

P077

RELIABILITY OF THE CLINICAL CHARACTERIZATION OF ISOLATED REM SLEEP BEHAVIOR DISORDER

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Purpose: Compare agreements between polysomnography-based (PSG) diagnosis of isolated REM-sleep-behavior-disorder (iRBD) and Non-REM-Hypertonia (NRH), a novel biomarker independently associated with synucleinopathy-related neurodegenerative diseases.

Methods: Sixteen patients with histories of dream-enactment-behavior (DEB)(women=38%; age:64.6±13.0) underwent PSG with simultaneously-recorded Sleep Profiler (SP).

Two boarded sleep neurologists independently characterized iRBD. Physician1 combined abnormal qualitative REM-sleep-without-atonia (RSWA) by submental electromyography, with video-confirmation of probably DEB. Physician2 relied solely on qualitative RSWA. SP was auto-staged, technically reviewed, and reprocessed for automated abnormal NRH detection. Kappa scores measured physician and NRH agreements.

Results: In the 14 records with REM sleep, iRBD was characterized in: Physician1=64%, Physician2=79%, NRH=71% of the records. Across the three methods, unanimous iRBD agreement occurred in 57% of the records (positive=7, negative=1).

The between-physician agreement in iRBD classifications was fair (kappa=0.32). The agreement between NRH and Physician1 was moderate (kappa=0.52) versus slight with Physician2 (kappa=0.05). NRH comparisons to consensus physician agreement yielded one false-positive and one false-negative iRBD finding. Physician2 classified: a) iRBD in two cases that were negative by Physician1 and NRH, and b) one negative case that Physician1 and NRH characterized as iRBD. Physician1 identified one negative case that was classified iRBD by Physician2 and NRH. Additionally, NRH was abnormal in one of the two records with no REM sleep.

Discussion: NRH may assist in iRBD risk assessment, given it agreed with at least one physician in 86% of the cases and the between-physician iRBD agreement was only fair. NRH also characterized iRBD-risk in patients with insufficient REM sleep for RSWA assessment.

P078

ORAL APPLIANCE FABRICATION SETTINGS IMPACT TREATMENT EFFICACY

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Purpose: Assess the impact of custom oral appliance (CA) fabrication settings on treatment outcomes.

Methods: CPAP-intolerant patients completed a two-night home-sleep-apnea study (HSAT); Night1=baseline, Night2=Apnea Guard® trial appliance (AG). The AG vertical-dimension-of-occlusion (VDO) selection was based on tongue-scallop (women=5.5/6.5 mm, men= 6.5/8.0 mm), with a target protrusion of 70% from neutral-maximum while in situ.

Study1 CA VDO was dependent on sex (women=2.5 mm, men=5 mm), with protrusion set using a George-Gauge measured 70% from maximum retrusion-protrusion with dentist-directed titration. Study2 CA was fabricated to the AG VDO and target protrusion bite-registration.

Efficacy HSATs were conducted after completion of Study1 CA titration with vertical-elastics optional, and at the AG target protrusion with vertical-elastics mandatory in Study2. Statistics included Mann-Whitney, Chi-squared, and Bland-Altman analyses.

Results: The Study1 (n=84) and Study2 (n=46) distributions were equivalent for tongue-scallop (64/63%) and sex (women=45/41%), however, noted differences in age (53.8±11.9 vs. 58.4±12.2; P=0.052), body-mass-index (29.4±5.7 vs. 27.8±4.0; P=0.128) and pre-treatment AHI severities (24.6±14.4 vs. 29.2±17.4 events/h; P=0.155) were observed.

The Bland-Altman biases were significant different (Study1=4.2±7.8 vs. Study2=1.3±7.0 events/h, P=0.035). The significant Study1 differences between the CA vs. AG AHIs (12.3±9.2 vs. 8.2±5.9 events/h, P<0.0002) were not apparent in Study2 (11.7±8.0 vs. 10.4±6.7 events/h, P=0.362), however, the Study2 AG AHI values were higher (P=0.055).

Discussion: Despite the trend toward greater Study2 pre-treatment and AG AHI severities, CA treatment efficacy was equivalent to the AG once VMO was controlled and fabricated using the AG VDO and protrusion bite-registration. These findings confirmed CA fabrication settings impact treatment outcomes.

P079

EFFECT OF SLEEPWEAR FIBRE TYPE ON MENOPAUSAL SLEEP QUALITY – STUDY PROTOCOL AND PRELIMINARY DATA

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Introduction: Vasomotor symptoms and sleep disturbances are common in menopausal women. Different fabric types affect thermal comfort through moisture absorption and thermal insulation. This study examined the impact of cotton and wool sleepwear on menopausal women's sleep quality.

Methods: This is a randomized, crossover, repeated-measures and triple-blinded trial comparing the sleep quality and vasomotor symptoms of healthy menopausal women between cotton and wool sleepwear at 30°C, 50% relative humidity. Participants undergo 6 laboratory visits. After a screening visit and a familiarization night, participants are randomized to 4 nights (2 nights in cotton and 2 nights in wool sleepwear) during which polysomnography and actigraphy recordings are taken including objective hot flush events, room temperature and relative humidity measurements, as well as subjective questionnaires on clothing comfort, mood and vasomotor symptoms.

Results: Eleven participants (age 51.2±4.7 years, BMI 26.8±2.9 kg.m-2, Insomnia Severity Index 11.1±5.5) completed all six visits so far. Reasons for exclusion: 3 didn't have vasomotor symptoms; 1 on HRT, 5 had severe sleep disturbances, 3 on medications, 4 had diabetes, 1 asthma, and 1 had BMI>30. All sleep-related outcomes are pending analysis (blinding).

Discussion: Recruitment is a major study challenge. Many participants found it hard to arrange a time to attend overnight studies due to family/work commitments. The COVID-19 pandemic changed people's attitude as some were hesitant to attend the laboratory. Menopause transition status is an important time during women's lifespan. Effective management, e.g., through appropriate sleepwear, would be helpful to improve menopausal women's symptom and quality of life.

P080

AN EMBEDDED PATHWAY TO MANDIBULAR ADVANCEMENT SPLINT (MAS) CONSTRUCTION IN A TERTIARY HOSPITAL REDUCES BARRIERS TO CARE FOR LOW-INCOME INDIVIDUALS

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Introduction: The aim of this study was to report the outcomes of patients referred within and to a tertiary hospital dental unit for subsidised construction of a MAS over a 5-year period.
Methods: Medical records of patients referred from 2015–2020 were examined for reason for referral, details of diagnosis, pathway to diagnosis, treatment, compliance, clinician-reported and lab-based outcomes and follow-up reviews.
Results: One hundred patients referred from: The Hospital Sleep Unit 40, other Tertiary Hospitals 27, Private Sleep Clinics 13, Medical GPs 10. 76 patients were confirmed health care card holders. 30 patients did not proceed for reasons of cost or poor oral health. 59 patients were newly fitted with a MAS (27F,32M), 17 severe, 21 moderate, 17 mild OSA, mean age 52.9(+13.9) years, BMI 30.2(+6.3) kg/m2, ESS 11.4(+5.3). 22 of 36 patients with serial ESS scores had excessive daytime sleepiness upon initial presentation. 15/22(68%)(p<0.005) of patients had resolution of their excessive daytime sleepiness following MAS wear. 8/15(53%) of patients had a subsequent AHI <50%. 33 patients (56%) continued MAS wear, mean follow-up time 13.8(±14.6) months with an average of 5.8(+3.0) visits. 6 were lost to follow up, 20 patients (33%) ceased MAS wear with 10(50%) of these stopping because routine dental treatment affected the device fit or discomfort later developed.
Conclusion: Subsidised expert construction of MAS embedded in a tertiary hospital is a well-utilised and effective service which reduces barriers for patients. The referrals to this service appear to be appropriate, with most patients proceeding to MAS construction.

P081

ASSESSMENT OF CHANGE IN PALATOGLOSSUS LENGTH WITH MANDIBULAR ADVANCEMENT AND RELATIONSHIP TO RESPONSE TO MANDIBULAR ADVANCEMENT SPLINT THERAPY IN OBSTRUCTIVE SLEEP APNOEA

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Background: The palatoglossus is a muscle of the soft palate extending from the palatine aponeurosis inferolaterally along the pharyngeal wall inserting at the posterolateral surface of the tongue. Palatoglossal stimulation dilates the retropalatal space in subjects with obstructive sleep apnoea (OSA). Whether there is alteration in palatoglossus length during mandibular advancement and how this relates to Mandibular Advancement Splint (MAS) outcomes is unknown.
Methods: Participants with OSA referred for MAS underwent upper airway MRI with and without mandibular advancement. The linear distance between the origin of the palatoglossus muscle at the palatine aponeurosis and its insertion at the tongue was measured to approximate palatoglossus length. The difference in measured lengths with and without mandibular advancement was calculated. Change in palatoglossus with advancement was compared to treatment outcomes.
Progress to date: 71 participants with mean±SD AHI 26.0±16.1 events/hr were included in our study. Mean±SD palatoglossus length was 49.58±5.74mm. With mandibular advancement, mean±SD palatoglossus length was 51.21±5.46mm this was a significant change in length of mean±SD 1.63±4.3mm. This was a mean±SD 4.79±9.08% alteration in length with mandibular advancement. Treatment response was not significantly related to change in palatoglossus length (p> 0.05).
Intended outcome and Impact: Our intention was to demonstrate significant length alteration in palatoglossus with mandibular advancement and correlate this to treatment outcome. This may highlight palatoglossus as a target for MAS or other OSA therapies for future clinicians.

P082

GENDER MODERATES THE EFFECTS OF TOTAL SLEEP DEPRIVATION AND SLEEP RESTRICTION ON RISK PREFERENCE

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Introduction: Total sleep deprivation (TSD) affects risk preference in decision-making. However, little work has examined the effects of sleep restriction (SR), or the potentially moderating role of gender, on risk preference. Here, we investigate the effects of TSD, SR, and gender on risky decision-making.
Methods: 47 healthy adults (age=24.57±5.26 years, 24F) were randomly assigned to either of 2 counterbalanced protocols: 1) well-rested (WR: 9-hours time-in-bed for 6 nights) and 30hours TSD; or 2) WR and SR (4-hours time-in-bed for 4 nights). Participants performed the Lottery Choice Task (LCT) on the last day of each week. LCT requires a series of choices between two risky gambles with different risk levels. In one block, participants sought to maximise monetary gain (GAINS), and in another block, they sought to minimise losses (LOSSES). A trial-level analysis evaluated participants' likelihood of choosing the "safer" gamble under influence of each sleep condition.
Results: The version*condition*gender interaction was significant. GAINS: everyone became more risk averse during TSD. Females also became more risk averse during SR, but males did not. LOSSES: everyone became more risk seeking during SR. During TSD, females became relatively more risk averse, while males became relatively more risk seeking.
Conclusion: TSD and SR had similar impacts on risk preference. However, gender moderated some effects. Women generally became more risk averse during sleep loss for both GAINS and LOSSES. Men were more risk averse for GAINS and risk seeking for LOSSES. This has implications for real-world situations where individuals are required to make risky decisions.

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P082

ACTIGRAPHIC ASSESSMENT OF SLEEP PATTERNS IN WOMEN WITH MENOPAUSAL SYMPTOMS

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Introduction: Approximately 40%-60% of menopausal women suffer from sleep disturbances, commonly linked to vasomotor symptoms of hot flashes and night sweats. This study aims to evaluate sleep patterns and quality in peri- and post-menopausal women using actigraphy.

Methods: Thirty-nine participants (45 to 65y, BMI 25.62±3.02 kg/m², Insomnia Severity Index (ISI) score 10.98±4.10) experiencing menopausal symptoms underwent actigraphy recordings of sleep onset/offset, duration, and mid-sleep times over at least three consecutive nights with 357 nights of data analysed.

Results: The vasomotor subscales (hot flash and night sweat, Greene Climacterics questionnaire) yielded a score of 2.43±1.15 (compared to general population: 1.79±1.12 and menopause clinic: 4.41±1.70). Sleep onset times ranged from 19:06-03:16 with the most common time at 22:00-22:59 (31.1%) followed by 23:00-23:59 (27.5%). Sleep offset times ranged from 03:39-11:28 with the most common time at 06:00-06:59 (34.5%). The average sleep duration ranged from 231 to 819 minutes with the most common duration 470-529 min (33.6%) with 43.1% of nights with <8h of sleep. The mid-sleep times ranged from 23:50-05:19 with the most common mid-sleep time at 02:30-02:59(19%), followed by 02:00-02:29 (17.9%) and 03:00-03:29 (17.4%).

Discussion: In consideration of demographic factors, moderate vasomotor symptoms and some irregularities in sleep-wake timing, the menopausal women in this study largely have adequate sleep duration of around eight or more hours. It is likely that their symptoms were not as severe as the clinic sample. However, it is not clear if better sleep in this group is linked to increased awareness of sleep as a health behaviour.

303

THE CONVERSATION
Academic rigour, journalistic flair

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Why can't I sleep? It could be your sheets or doona

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It's winter, so many of us will be bringing out, or buying, winter bedding.

But how much of a difference does your bedding make to your thermal comfort? Can a particular textile help you sleep?

Is it wool, or other natural fibres, such as cotton? How about polyester? With so much choice, it's easy to be confused.

Here's what we found when we reviewed the evidence – not just for winter, but also for the summer ahead.

The importance of bedding

We rely on our bedding to maintain a comfortable temperature to help us sleep. And the right textiles can help regulate our body temperature and wick away moisture from sweat, promoting better sleep.

In the cooler months, we're mainly concerned about a textile's insulation properties – keeping body heat in and the cold out. As the temperature climbs, we're less concerned about insulation and more concerned about wicking away moisture from sweat.

Another factor to consider is a textile's breathability – how well it allows air to pass through it. A breathable textile helps keep you cool, by allowing warmth from your body to escape. It also helps keep you comfortable by preventing build-up of moisture. By releasing excess heat and moisture, a breathable textile makes it feel cooler and more comfortable against the skin.

Different textiles have different properties

Some textiles are better than others when it comes to insulation, wicking away moisture or breathability.

For instance, cotton and wool have tiny air pockets that act as insulation to provide warmth in cold weather. Thicker fabrics with more air pockets tend to be warmer, softer and more breathable. But these factors are also affected by the type of fibre, the weave of the fabric and the manufacturing process.

Cotton and wool are also breathable fabrics, meaning they help regulate temperature.

Bedding textiles and their properties

Textile	Insulation	Wicking	Breathability
Wool	✓	✓	✓
Cotton	✓	✗	✓
Linen	✗	✓	✓
Polyester[1]	✓/✗	✓/✗	✓/✗

1: Polyester can be manufactured or treated to alter its properties

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While cotton absorbs moisture (sweat) from your skin, it doesn't wick it away efficiently. This retained moisture can make cotton feel clingy and uncomfortable, potentially leading to chills in warm weather.

But wool is highly absorbent and wicks moisture effectively. In warmer weather, when we sweat, wool fibres allow for airflow and moisture transfer, promoting efficient sweat evaporation and cooling, and preventing overheating. So wool (in different thicknesses) can be a good option in both summer and winter.

Linen, although breathable and having moisture-wicking properties, provides less insulation than wool and cotton due to its hollow fibres. This makes linen less effective for keeping warm in winter but is effective for keeping cool in summer.

Polyester is a synthetic fibre that can be made to trap air for insulation, but it is not naturally breathable. Usually, it absorbs moisture poorly. So it can trap sweat next to the skin, causing discomfort. However, polyester can be specially treated to help control moisture from sweat.

Which sheets help you sleep?

As part of our review, we couldn't find any studies that directly compared sheets made from different textiles (for instance, regular cotton and flannelette) and their impact on sleep when it's cold.

However, linen sheets are particularly effective in warmer conditions. In one study, conducted at 29°C and high humidity, linen sheets promoted less wakefulness and fewer stages of light sleep than cotton sheets.

Which is best in summer, linen or cotton sheets? Gabriele Maltinti/Shutterstock

How about doonas?

If you don't heat your bedroom at night in winter, a goose down doona (one made from fine, goose feathers) might be an option.

These promoted the longest, deep-sleep, followed by duck down, then cotton when sleeping at 11°C. This may be because down offers better insulation (by trapping more air) than cotton. Down also has lower thermal conductivity than cotton, meaning it's better at keeping warmth in.

Choosing between a wool or polyester doona? In a wool-industry funded study two of us (Chow and Halaki) co-authored, there wasn't much difference. The study in young adults found no significant difference on sleep at 17°C or 22°C.

So how do I choose?

The choice of bedding is highly individual. What feels comfortable to one person is not the same for the next. That's because of variations in body size and metabolic rate, local climate, bedroom temperature and building insulation. These can also affect sleep.

This variability, and a wide range of study designs, also makes it hard to compare different studies about the impact of different textiles on sleep. So you might need to experiment with different textiles to discover what works for you.

Many factors can affect your sleep, not just your bedding. So if you're having trouble sleeping, you can find more information from the Sleep Health Foundation. If symptoms continue, see your GP.

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Ms Xinzhu Li

was a poster presenter during the official program at the
18th World Congress of the International Society of Physical and
Rehabilitation Medicine (ISPRM) in Sydney, Australia.