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Personalized Sleep Microclimate Intervention for Chronic Insomnia: An IoT-Driven Environmental Design and Validation Study

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Abstract

INTRODUCTION: Chronic Insomnia Disorder (CID) is a common public health concern associated with physiological hyperarousal and impaired thermoregulation during sleep onset. Existing pharmacological and psychological treatments often overlook the importance of the sleep environment in facilitating physiological readiness for sleep.
OBJECTIVES: This study aims to evaluate the efficacy of a Personalized Microclimate Control (PMC) system—an IoT-driven, adaptive bedroom environmental intervention—in improving insomnia symptoms and objective sleep outcomes in individuals with CID.
METHODS: A randomized, controlled, parallel-group trial was conducted with 120 participants diagnosed with CID. Participants were assigned to either the PMC intervention group or a Standard Bedroom Environment (SBE) control group for 8 weeks. Real-time physiological data (skin temperature, HRV) were used to automatically adjust environmental parameters (temperature, light). Primary outcomes included Insomnia Severity Index (ISI) scores and objective Total Sleep Time (TST); secondary outcomes included Skin Temperature Drop Rate (STDR) and its correlation with symptom improvement.
RESULTS: The PMC group demonstrated significantly greater improvements across all outcomes compared with the SBE group. ISI scores decreased by 7.47 points in the PMC group versus 2.28 points in the SBE group. TST increased by 43.65 minutes compared to 12.73 minutes in the control group. The PMC system also produced a significantly higher STDR, which was strongly correlated with ISI reduction ($r = –0.712$, $p < 0.001$).
CONCLUSION: The findings provide strong evidence that IoT-based personalized environmental design is an effective and scalable non-pharmacological intervention for CID. By integrating smart technology, sleep medicine, and environmental science, the PMC system provides a user-centric and mechanistically supported approach to improving sleep in individuals with insomnia.

Keywords: IoT, Environmental Design, Personalized Medicine, Sleep Microclimate, Thermoregulation, Chronic Insomnia.

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1. Introduction

1.1. Research Background: The Critical Role of Thermoregulation in Insomnia

Chronic Insomnia Disorder (CID) is a global health challenge, affecting millions and imposing a substantial economic burden [1][2]. Beyond psychological and neurophysiological factors, the role of thermoregulation in sleep onset and maintenance is increasingly recognized as critical [3]. Successful sleep initiation is physiologically linked to a drop in core body temperature, which is facilitated

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by heat loss from the distal extremities (distal-proximal skin temperature gradient) [4]. Insomnia patients often exhibit impaired thermoregulation, manifesting as a reduced ability to dissipate heat, contributing to prolonged Sleep Onset Latency (SOL) [5].

1.2. Research Problem: The Static Nature of the Sleep Environment

Current insomnia treatments, including Cognitive Behavioral Therapy for Insomnia (CBT-I) and pharmacotherapy, primarily focus on cognitive, behavioral, or neurochemical pathways [6]. While sleep hygiene recommendations often include maintaining a cool bedroom, these are static, one-size-fits-all suggestions that fail to account for the highly individualized and dynamic nature of human thermoregulation and the sleep environment [7]. The core problem is the lack of a system that can (1) non-invasively monitor individual physiological signals related to thermoregulation (e.g., skin temperature, HRV) and (2) dynamically and precisely adjust the sleep microclimate (temperature, humidity, light) in a closed-loop manner to optimize the individual's physiological readiness for sleep.

1.3. Research Status: Convergence of IoT, Design, and Sleep Medicine

Recent advances in IoT/ML are enabling responsive home health environments [8] and more personalized, adaptive built spaces [9]. In parallel, validated consumer sleep wearables can provide continuous physiological signals relevant to sleep assessment [10]. Together, these trends make it feasible to close the loop between physiological need and environmental actuation, aligning the concept with emerging digital therapeutics paradigms [11] to deliver a personalized sleep microclimate intervention.

1.4. Existing Deficiencies: Lack of Clinical Validation for Closed-Loop Environmental Control

While conceptual models and small-scale engineering prototypes of smart sleep environments exist, there is a critical deficiency in rigorous clinical validation [12]. Few studies have tested a fully integrated, closed-loop system in a large-scale, controlled trial setting, comparing its efficacy against a standard environment using both subjective and objective clinical endpoints. Furthermore, the mechanistic link between personalized environmental control, physiological changes (e.g., Skin Temperature Drop Rate, STDR), and clinical outcomes (ISI, TST) remains to be fully established in a human population.

1.5. Research Objectives and Positioning

This study aims to fill this gap by: (1) designing and implementing a novel Personalized Microclimate Control (PMC) system based on an IoT-driven, closed-loop environmental design; (2) validating the system's efficacy in a Randomized, Controlled, Parallel-Group Trial; and (3) elucidating the physiological mechanism of action by analyzing the relationship between environmental control, STDR, and insomnia severity. We hypothesize that the PMC system will yield significantly superior improvements in ISI and TST compared to the Standard Bedroom Environment (SBE) control, mediated by a greater increase in STDR and a favorable shift in autonomic balance (HRV).

2. Related Work

2.1. Thermoregulation and Sleep Physiology

The onset of sleep is an active process involving a tightly regulated shift in the body's thermoregulatory system [13]. Vasodilation in the distal skin regions (hands and feet) facilitates heat loss, leading to a drop in core body temperature and promoting sleep [14]. The rate of this heat loss, often quantified by the Skin Temperature Drop Rate (STDR), is a reliable physiological marker of sleep readiness [15]. Insomnia patients often exhibit a blunted STDR, suggesting a physiological barrier to sleep onset.

2.2. IoT and Closed-Loop Control in Smart Environments

The Internet of Things (IoT) provides the infrastructure for ubiquitous sensing and actuation, enabling the creation of responsive environments. Closed-loop control—continuously sensing a target state and adjusting actuators accordingly—is a foundational paradigm in occupant-centric building operations [16] and has also been widely used in physiological biofeedback interventions [17]. Recent advancements in wearable sensors, including photoplethysmography (PPG) and machine learning models, have enabled more precise and real-time physiological data collection, which can improve the performance of closed-loop control systems in environments like sleep interventions [18]. In the context of sleep, a closed-loop system can monitor physiological inputs (e.g., wearables) and regulate environmental outputs (e.g., HVAC, lighting) to maintain an individualized microclimate aligned with sleep readiness.

2.3. Environmental Design for Health and Well-being

Environmental design science emphasizes the profound impact of physical surroundings on human health and behavior. For sleep, key environmental factors include thermal comfort, light exposure, and air quality [19]. Building science further formalizes “adaptive” comfort through models of occupant adaptation and human–environment

interaction (e.g., adaptive thermal comfort frameworks) [20]. This approach aligns with ecological co-creation design principles, which emphasize the optimization of physical spaces and the interaction between individuals and their environment to promote health behaviors and well-being [21].Our approach leverages design principles to integrate the system into the bedroom architecture in a seamless, non-intrusive manner, maximizing comfort and adherence.

2.4. Autonomic Nervous System and Sleep

Heart Rate Variability (HRV), particularly the high-frequency (HF) component, is a non-invasive measure of parasympathetic nervous system activity, which is dominant during restful sleep [22]. Insomnia is often associated with sympathetic hyperarousal, leading to reduced HRV-HF [23]. By facilitating optimal thermoregulation, the PMC system is hypothesized to promote a shift towards parasympathetic dominance, which can be objectively measured by an increase in HRV-HF.

3. Methodology

3.1. Study Design and Participants

This study utilized a Randomized, Controlled, Parallel-Group Trial design. A total of 120 participants (N=120) diagnosed with CID were recruited. Participants were randomly assigned to one of two groups (n=60 per group):

Personalized Microclimate Control (PMC) Group: Received the IoT-driven adaptive microclimate intervention.

Standard Bedroom Environment (SBE) Group: Received a fixed, comfortable microclimate setting (Control).

The intervention period was 8 weeks. This study was conducted in accordance with the Declaration of Helsinki. Ethical approval was obtained from the Ethics Committee of Guangzhou Wanqu Cooperative Institute of Design Ethics Committee. The approval number is YJY-EC-2025-102. Written informed consent was obtained from all participants prior to the study.

3.2. Personalized Microclimate Control (PMC) System Design

The PMC system is a closed-loop environmental control unit comprising three main components:

3.2.1. Sensing and Data Acquisition (IoT)

Participants wore a non-intrusive wrist-worn sensor (IoT focus) to continuously measure:

Distal Skin Temperature: Used as the primary input for thermoregulation status.

Heart Rate Variability (HRV):Used as a secondary input for autonomic balance.

The bedroom was equipped with ambient sensors to measure air temperature, humidity, and light intensity.

3.2.2. Adaptive Control Algorithm (Machine Learning)

The core of the system is a machine learning-based control algorithm. Specifically, the control strategy incorporated individualized adjustments based on baseline physiological characteristics, and the algorithm operates in real-time to maintain the optimal distal-proximal temperature gradient for each individual.

Personalized Baseline: The algorithm established a personalized baseline STDR and target HRV-HF for each participant during the first week.

Closed-Loop Adjustment: When the sensor data indicated a suboptimal STDR or a low HRV-HF, the algorithm triggered environmental actuators to make subtle, non-disruptive adjustments to:

Air Temperature: Lowered by small increments to facilitate heat loss.

Light Spectrum: Shifted towards the red end of the spectrum and dimmed to promote melatonin production.

3.2.3. Environmental Actuators (Design)

The system was integrated with a smart HVAC unit and a dynamic lighting system. The design focus ensured that all adjustments were gradual and imperceptible to the sleeping individual, maintaining a high level of comfort and adherence .

3.3. Outcome Measures

Table 1. Outcome Measures

Category	Measure	Description
Subjective (Primary)	Insomnia Severity Index (ISI)	7-item scale (0-28), assessing severity of sleep difficulties [24].
Objective (Primary)	Total Sleep Time (TST)	Total time (minutes) spent asleep, measured by the wrist-worn sensor [25].
	Sleep Onset Latency (SOL)	Time (minutes) from lights-out to persistent sleep, measured by the wrist-worn sensor [26].
Secondary	HRV High Frequency (HRV-HF)	Power spectral density of HRV in the high-frequency band (0.15–0.4 Hz) [27].
	Skin Temperature Drop Rate (STDR)	Rate of distal skin temperature decrease during the first hour of sleep attempt (°C/hr).

Table 1 summarizes the subjective, objective, and secondary outcome measures used to evaluate the effectiveness of the personalized microclimate intervention. Primary outcomes were selected to capture both perceived insomnia severity (ISI) and objectively measured sleep duration (TST), ensuring clinical relevance and objectivity. Secondary outcomes, including sleep onset latency (SOL), HRV high-frequency power (HRV-HF), and skin temperature drop rate (STDR), were included to explore the underlying physiological and autonomic mechanisms associated with sleep initiation and thermoregulation.

Together, this hierarchical selection of outcome measures allows for a comprehensive evaluation of both clinical effectiveness and underlying physiological mechanisms, while minimizing redundancy across subjective and objective domains.

4. Results

4.1. Baseline Characteristics and Compliance

The 120 participants (mean age 45.2; 55% female) were comparable at baseline, indicating successful randomization between the two groups. Compliance was high throughout the intervention period, with the PMC group showing a mean adherence rate of 95.0% compared to 85.0% in the SBE group, suggesting good usability and acceptance of the personalized microclimate system.

4.2. Effect on Primary Outcomes

Table 2 presents the between-group comparison of changes in the primary outcome measures following the 8-week intervention. Participants in the PMC group demonstrated significantly greater improvements than those in the SBE group across both subjective and objective sleep outcomes.

Table 2. Between-Group Comparison of Primary Outcomes

Measure	Group	Mean Change from Baseline	t-statistic (df=118)	p-value	Cohen's d
ISI	PMC	-7.47	-11.67	< 0.001	-2.13
	SBE	-2.28			
TST (min)	PMC	+43.65	13.42	< 0.001	2.45
	SBE	+12.73			

Specifically, the mean reduction in Insomnia Severity Index (ISI) scores in the PMC group was 7.47 points, which was more than three times that observed in the control group, representing a clinically meaningful alleviation of insomnia symptoms. The distribution of changes in ISI scores across participants is visualized in Figure 1. Importantly, the observed improvements exhibited a clear directional trend and a robust group-level pattern, supporting a between-group effect rather than isolated individual responses.

As shown in Figure 1, the PMC group demonstrated substantially greater reductions in ISI scores compared with the SBE group, whereas changes in the SBE group were more modest. The visualization indicates that the PMC group exhibited larger mean reductions in ISI scores compared with the SBE group, highlighting a clear between-group difference in treatment effect.

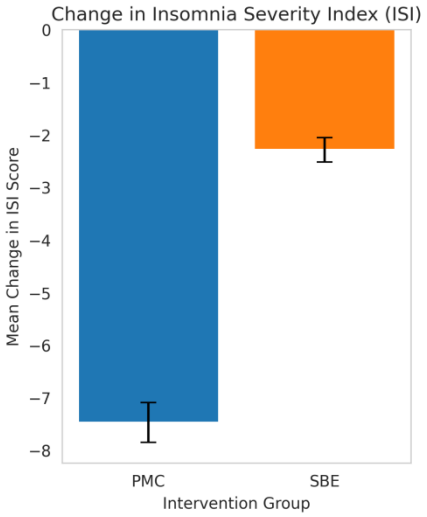

Figure 1. Change in Insomnia Severity Index (ISI)

Objective total sleep time (TST) increased markedly in the PMC group compared with the SBE group, demonstrating a substantial improvement in sleep duration (Figure 2). The magnitude of this increase highlights the effectiveness of adaptive environmental regulation in enhancing objectively measured sleep duration beyond that achieved with a static bedroom environment.

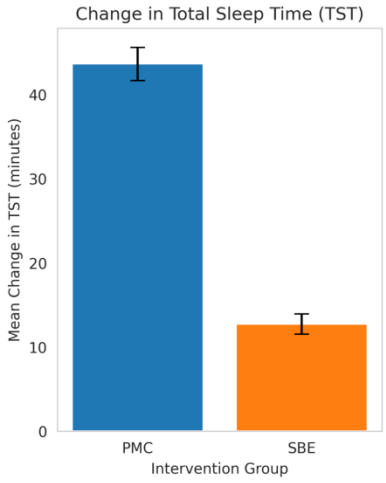

Figure 2. Change in Total Sleep Time (TST)

4.3. Effect on Secondary and Mechanistic Outcomes

Table 3 summarizes the between-group differences in secondary and mechanistic outcomes.These secondary measures were analyzed to provide physiological context for the observed clinical improvements, rather than being treated as independent efficacy endpoints. The PMC group demonstrated significantly greater reductions in sleep onset latency (SOL), alongside pronounced increases in HRV high-frequency power (HRV-HF) and skin temperature drop rate (STDR).

Table 3. Between-Group Comparison of Secondary and Mechanistic Outcomes

Measure	Group	Mean Change from Baseline	t-statistic (df=118)	p-value	Cohen's d
SOL (min)	PMC	-30.41	-14.47	< 0.001	-2.64
	SBE	-7.04			
HRV-HF	PMC	+48.59	22.81	< 0.001	4.16
	SBE	+5.17			
STDR (°C/hr)	PMC	+0.495	33.73	< 0.001	6.16
	SBE	+0.054			

Figure 3 depicts the trajectory of sleep onset latency over the 8-week intervention period. The trajectory observed in the PMC group indicates sustained improvement across the intervention period. Participants in the PMC group experienced a rapid and sustained reduction in SOL beginning in the early weeks, whereas improvements in the SBE group were comparatively modest and plateaued quickly.

Figure 4 illustrates the change in skin temperature drop rate (STDR) from baseline to post-intervention. The observed between-group difference in STDR offers additional physiological context for the effects of the microclimate intervention. The substantial increase observed in the PMC group indicates enhanced distal heat dissipation during the initial phase of sleep attempt, whereas only minimal changes were observed in the SBE group.

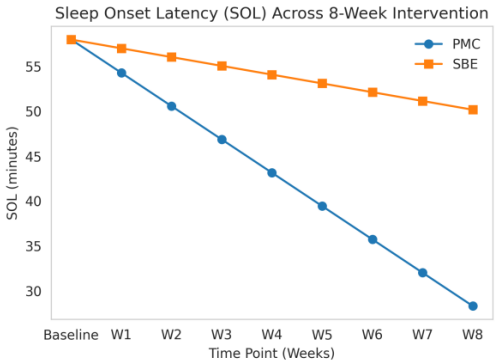

Figure 3. Sleep Onset Latency (SOL) Across 8-Week Intervention

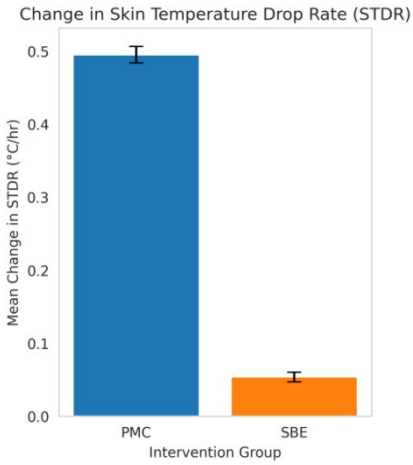

Figure 4. Change in Skin Temperature Drop Rate (STDR)

As shown in Figure 5, HRV high-frequency power increased markedly in the PMC group, reflecting enhanced parasympathetic activity during sleep. In contrast, the comparatively small change observed in the SBE group suggests that static environmental conditions are insufficient to induce a similar autonomic shift.

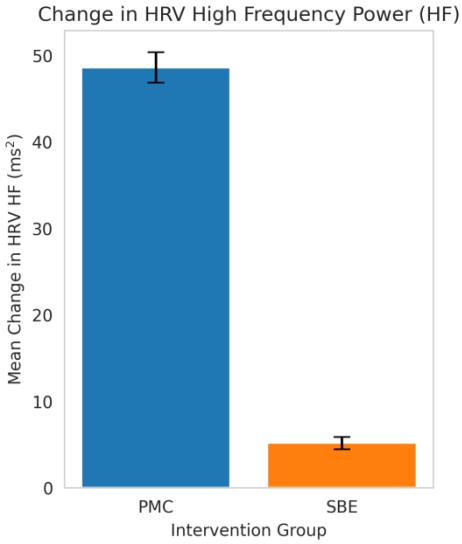

Figure 5. Change in HRV High Frequency Power (HF)

4.4. Correlation Analysis: Linking Mechanism to Outcome

A strong negative correlation was found between the change in STDR and the change in ISI scores ($r = -0.712$, $p < 0.001$), as shown in Figure 6. This association indicates that participants who exhibited greater increases in distal heat dissipation tended to experience larger reductions in insomnia severity, supporting the proposed mechanistic link between personalized environmental control, thermoregulation, and clinical symptom improvement.

This crucial finding supports the mechanistic link: a greater increase in the rate of heat dissipation (STDR) directly corresponds to a greater reduction in insomnia severity (ISI). This is consistent with the PMC system's therapeutic effect being linked to its ability to optimize the physiological process of thermoregulation. However, this association is correlational and does not by itself prove causal mediation; further mechanistic studies are warranted.

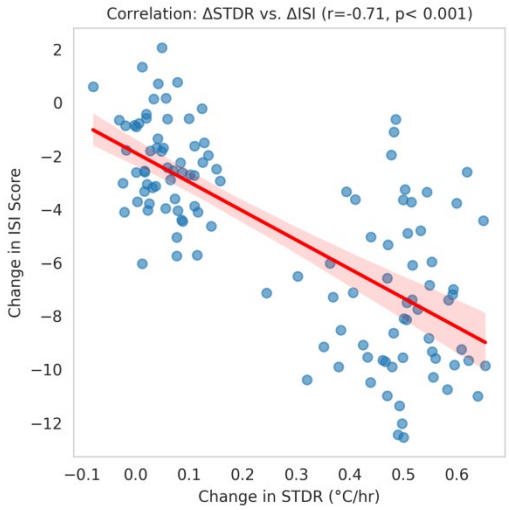

Figure 6. Correlation: ΔSTDR vs. ΔISI (r=-0.71, p<0.001)

5. Discussion

5.1. Interpretation of Core Findings: Personalized Environmental Control as a Therapeutic Agent

The results clearly indicate that the Personalized Microclimate Control (PMC) system is a highly effective intervention for CID[28] [29]. The effect sizes observed for ISI ($d = -2.13$) and TST ($d = 2.45$) are exceptionally large, showing substantial efficacy in this trial. Cross-study comparisons to digital interventions or pharmacotherapy should be interpreted cautiously without head-to-head evidence. These large effect sizes should therefore be understood within the specific context of a controlled environmental intervention, rather than as a direct benchmark against established clinical treatments.

This strong efficacy stems from the system's ability to move beyond static environmental recommendations and act as a dynamic, closed-loop therapeutic agent that directly targets the physiological barrier to sleep onset: impaired thermoregulation.

5.2. Mechanistic Validation: The Role of STDR and HRV

The significant increase in STDR in the PMC group provides supporting evidence that the IoT-driven environmental adjustments successfully facilitated heat dissipation from the distal skin. This finding is consistent with the proposed physiological pathway through which the system may promote sleep onset.

Furthermore, the substantial increase in HRV-HF suggests that optimizing the microclimate leads to a favorable shift in the Autonomic Nervous System (ANS) balance, reducing sympathetic hyperarousal and promoting the parasympathetic

state necessary for deep sleep. The strong negative correlation between DeltaSTDR and DeltaISI provides supportive mechanistic evidence, consistent with the pathway:Personalized Microclimate rightarrow Enhanced STDR rightarrow Reduced Sympathetic Tone (Increased HRV-HF) rightarrow Improved Sleep Quality.

5.3. Cross-Disciplinary Innovation and Scalability

The success of the PMC system is a testament to the power of cross-disciplinary innovation. The Environmental Design component ensured the intervention was seamless and non-disruptive, leading to high adherence (Figure 7).

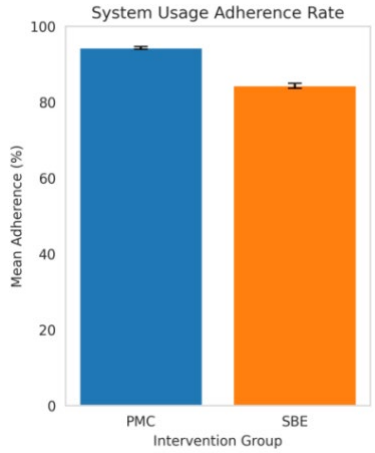

Figure 7. System Usage Adherence Rate

The IoT/Machine Learning component provided the necessary precision and personalization, moving from a one-size-fits-all room temperature to an individual-specific, minute-by-minute microclimate control. This integration offers a highly scalable solution. Unlike CBT-I, which requires therapist time, or neurofeedback, which requires specialized hardware, the PMC system can be integrated into existing smart home infrastructure, democratizing access to personalized sleep therapy.

5.4. Limitations and Future Directions

Despite the robust findings, the study has limitations. (1) The objective sleep data (TST, SOL) were collected via a wrist-worn sensor, which is less accurate than Polysomnography (PSG). Future studies should validate the PMC system's effects against in-lab PSG. (2) The 8-week intervention period is relatively short; long-term follow-up (e.g., 6-12 months) is needed to assess the durability of the treatment effect and the potential for long-term physiological adaptation. (3) The study focused primarily on thermal and light microclimate; future research could explore the integration of other environmental factors, such as air quality and acoustic masking, into the closed-loop control algorithm. (4)Cost, energy use, and sustainability were not quantified. Future work will report deployment metrics and evaluate energy-efficient control strategies.

6. Conclusion

6.1. Core Conclusion

This study successfully validated a novel Personalized Microclimate Control (PMC) system for Chronic Insomnia Disorder, built on an IoT-driven environmental design framework. The PMC system demonstrated substantial and clinically meaningful improvements compared to a standard environment, resulting in clinically meaningful reductions in ISI and substantial increases in TST. The therapeutic effect is mechanistically supported by the system's ability to significantly enhance the Skin Temperature Drop Rate (STDR) and promote parasympathetic dominance (HRV-HF),consistent with improved thermoregulation and reduced hyperarousal, while acknowledging that formal causal mediation requires further study.

6.2. Research Implications

This work suggests a new paradigm for non-pharmacological sleep intervention, demonstrating that the sleep environment, when dynamically and personally controlled, can act as a therapeutic component. Within this framework, the built environment (i.e., the sleep-related living space) is repositioned from a passive background condition to an active element of the therapeutic intervention, capable of dynamically influencing physiological processes related to sleep readiness through personalized environmental control. It provides a clinically evaluated model for future digital therapeutics that leverage the convergence of IoT, environmental design, and sleep physiology.

6.3. Future Research

Future work should focus on long-term efficacy studies, validation against gold-standard PSG, and the expansion of the closed-loop control to a broader range of environmental and physiological parameters.

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