

# **Longitudinal, Contactless, Mobile Sleep Monitoring Reveals Night-to-Night Sleep Variability as a Hallmark of Chronic Insomnia: Prospective Cohort Study**

Devon A Hansen, Mary E Peterson, Myles G Finlay, Elie Gottlieb, Sharon Danoff-Burg, Roy JEM Raymann, Dedra Buchwald, Nathaniel F Watson

Submitted to: JMIR mHealth and uHealth  
on: March 14, 2025

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# Longitudinal, Contactless, Mobile Sleep Monitoring Reveals Night-to-Night Sleep Variability as a Hallmark of Chronic Insomnia: Prospective Cohort Study

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## Abstract

**Background:** Current longitudinal insomnia assessments are subjective. Accurate insomnia assessment requires objective, longitudinal, naturalistic measures. Objective, ecologically-valid, longitudinal sleep measurements are needed to help identify and manage insomnia at a clinical and population level. A potential solution is consumer sleep technologies which are growing in popularity but rarely used clinically.

**Objective:** We sought to prove the clinical utility of a contactless, radiofrequency-based device by demonstrating the ability to differentiate individuals with insomnia from healthy good sleepers.

**Methods:** Individuals with chronic insomnia (n=83) and healthy, good sleeper controls (n=29) underwent 8 consecutive weeks of sleep monitoring using an objective, contactless, radiofrequency-based sleep monitoring device in the naturalistic home environment. Objective sleep variables were quantified as daily means and standard deviations.

**Results:** On average, individuals with chronic insomnia had reduced sleep efficiency, increased sleep latency, and increased intermittent wakefulness as compared to healthy, good sleeper controls. Similarly for standard deviations, those with chronic insomnia demonstrated greater night-to-night variability in sleep efficiency, sleep latency, and intermittent wakefulness as compared to good sleeper controls (all  $p < 0.01$ ).

**Conclusions:** We show a radiofrequency-based, contactless sleep monitoring device deployed longitudinally in the subjects' typical sleep environment accurately distinguished healthy good sleepers from those with insomnia. Importantly, we show that night-to-night variability in objective sleep measures is a hallmark of the chronic insomnia phenotype. Clinical Trial: Naturalistic Monitoring and Treatment of Chronic Insomnia, <https://www.clinicaltrials.gov>, NCT04013321

(JMIR Preprints 14/03/2025:73969)

DOI: <https://doi.org/10.2196/preprints.73969>

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## Original Manuscript

## Original Paper

# Longitudinal, Contactless, Mobile Sleep Monitoring Reveals Night-to-Night Sleep Variability as a Hallmark of Chronic Insomnia: Prospective Cohort Study

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## Abstract

**Background:** Current longitudinal insomnia assessments are subjective. Accurate insomnia assessment requires objective, longitudinal, naturalistic measures. Objective, ecologically-valid, longitudinal sleep measurements are needed to help identify and manage insomnia at a clinical and population level. A potential solution is consumer sleep technologies which are growing in popularity but rarely used clinically.

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variability in sleep efficiency, sleep latency, and intermittent wakefulness as compared to good sleeper controls (all  $p < 0.01$ ).

**Conclusions:** We show a radiofrequency-based, contactless sleep monitoring device deployed longitudinally in the subjects' typical sleep environment accurately distinguished healthy good sleepers from those with insomnia. Importantly, we show that night-to-night variability in objective sleep measures is a hallmark of the chronic insomnia phenotype.

**Trial Registration:** Naturalistic Monitoring and Treatment of Chronic Insomnia, <https://www.clinicaltrials.gov>, NCT04013321

**Keywords:** insomnia; consumer sleep technology; non-contact sleep monitoring; insomnia phenotype; night-to-night sleep variability; sleep efficiency; sleep latency; intermittent wakefulness

## INTRODUCTION

Chronic insomnia is a significant public health concern affecting upwards of 30% of U.S. adults [1] with similar rates of persistence at 1-year [2]. Insomnia is more prevalent in women, middle- to older-aged adults, and is strongly associated with poor mental and physical health [2]. Insomnia involves difficulty initiating or maintaining sleep or early morning awakenings occurring at least 3 nights per week for at least 3 months. According to the International Classification of Sleep Disorders, impairment in daytime functioning must also be present [3]. Poor sleep quality and intra-individual variability of sleep over time are considered key characteristics of chronic insomnia [4-7]. Specific sleep complaints and comorbidities vary among individuals with chronic insomnia making evaluation and management challenging [8]. Presently, longitudinal assessment of sleep in people with insomnia is largely subjective. Objective, ecologically-valid, longitudinal sleep measurements are needed to help identify and manage insomnia at a clinical and population level.

Assessment of sleep by means of polysomnography (PSG) is not indicated for insomnia, due to reverse first night effects, where paradoxically sleep improves in the sleep laboratory [9]. Wrist

actigraphy has been used to assess sleep naturalistically [10-16]. These data, typically averaged within individuals over time, generally conclude limited differences between insomnia patients and healthy controls, which leads researchers and practitioners to conclude that objective sleep differences between individuals with insomnia and healthy, good sleeper controls are generally limited and minor [6,7,17,18]. However, this overlooks the marked intra-individual variability observed in some individuals with chronic insomnia [8,19]. Intra-individual variability in sleep parameters correlates with self-reported ratings of sleep quality, suggesting the most challenging aspect of insomnia may not be continual exposure to poor sleep but rather night-to-night inconsistency of sleep [17].

For the benefit of both research and clinical practice, more extensive, objective, longitudinal, ecologically valid research is needed regarding the naturalistic sleep of individuals with chronic insomnia. This is modestly achievable with wrist actigraphy [20-22], with measurement duration substantially limited by battery life to roughly two weeks of monitoring. Furthermore, users must remember to wear the actigraph during sleep periods, and depending on the actigraph model, user or researcher/practitioner interaction may be required to download the data. Wearing the actigraph during sleep can be intrusive and thus negatively influence the very sleep it is measuring. Actigraphic data also requires further processing [23] and scoring to reliably assess sleep parameters day by day. Finally, recent performance evaluations of traditional actigraphy highlight its poor specificity (i.e., wake detection) relative to more novel and emerging consumer sleep technology (CST) devices, such as the radiofrequency-based device used in this research [22]. The underestimation of wake after sleep onset – commonly observed with actigraphy measurement – is particularly problematic in sleep-disordered populations such as insomnia where sleep fragmentation is a typical sequela.

New CSTs involving contactless sleep measurement from the bedside overcomes these limitations. One such bedside sleep monitoring device is the SleepScore Max (SSM; SleepScore Labs, Carlsbad, CA). This non-contact device uses ultra-low energy radar to track bodily movements



and respiration patterns through measurement of chest cavity motion. The SSM also measures light levels and ambient room temperature. The device is energized by a wall-powered AC-DC adapter and communicates with a compatible smartphone through Bluetooth technology. If the Bluetooth connection is lost or interrupted, the SSM continues to track sleep as long as power is maintained [24]. Recorded data are transferred from the SSM to the smartphone for processing to identify the presence of a sleeper and when periods of sleep and different stages of sleep occur. Requiring no user activation or interaction, the processed results are uploaded from the smartphone to the cloud. Unlike actigraphy, duration of SSM use or data storage are not limited, sleep can be monitored indefinitely in an ecologically valid manner in the person's typical sleep environment. The contactless nature of the SSM ensures the measurement itself does not impact sleep. Researchers affiliated with academic or clinical institutions can access the data stored in the cloud through a download portal (SleepScore Labs).

The SSM is validated against PSG and wrist actigraphy in healthy sleepers [22,25,26], as well as patients with obstructive sleep apnea (OSA) [27,28]. Relative to PSG, in healthy sleepers, the SSM's sensitivity to detect sleep is above 90%, with its specificity in the 50–75% range [22,26]. For comparison, the sensitivity of wrist actigraphy is as high as 97%, but the specificity is lower at 39% [22]. In OSA, the SSM's sensitivity to detect sleep is 86%, with a specificity of 52%. In a head-to-head comparison with SSM in patients with OSA, actigraphy showed slightly better sensitivity at 94%, but substantially lower specificity at 34% [28]. Importantly, SSM can estimate sleep stages, distinguishing between light, deep, and rapid eye movement sleep [29]. Wrist actigraphy cannot estimate sleep stages. Relative to PSG, in healthy sleepers the SSM's accuracy for sleep staging was found to range from 52% to 67% regardless of sleep stage [26]. Thus, the SSM's ability to monitor sleep naturalistically is comparable to wrist actigraphy, with the additional benefits of sleep staging, long-term sleep monitoring, contactlessness, and higher specificity. This makes it particularly suitable for long-duration studies of the naturalistic sleep of individuals with chronic insomnia.

Here, we conducted a study comprised of people with chronic insomnia and healthy, good sleeper controls. Both groups underwent 8 consecutive weeks of contactless, naturalistic sleep monitoring using the SSM. Based on this study design, we compared daily means and daily variabilities of sleep between individuals with chronic insomnia and good sleeper controls.

## METHODS

### Participants

A total of 112 individuals living in the U.S. participated in the at-home sleep monitoring study. The sample included 83 adults with chronic insomnia, aged  $29.7 \pm 8.8$  (average  $\pm$  SD), of which 58 were female (69.9%). The controls were 29 healthy adults with self-reported good sleep, aged  $38.3 \pm 12.0$ , of which 21 were female (72.4%). The composition of our sample is consistent with higher prevalence rates of insomnia observed in women [30,31].

Prior to the start of the at-home sleep monitoring study, participants were screened to meet eligibility criteria. Eligibility criteria included being 18–65 years of age. Individuals within the chronic insomnia group met International Classification of Sleep Disorders -3 criteria for chronic insomnia with no other clinically relevant condition contributing to their reported sleep disturbance [3]. Individuals in the healthy good sleeper control group reported no current, clinically relevant history of medical disorders or other illnesses and were free of suspected sleep disorders as determined by the STOP BANG [32] (score no greater than low-risk for OSA) and the Pittsburgh Sleep Quality Index (score  $<5$ ) [33]. Participants were required to have daily access to an iPhone to run the smartphone application associated with the SSM.

Six participants were screened in the laboratory and completed data collection prior to the COVID-19 pandemic. All other participants were screened remotely – through videoconference meetings and secure administration of online questionnaires –to adhere to COVID-19 social distancing requirements. Participants gave written, informed consent, and the study was approved by

the Institutional Review Board of Washington State University. Upon completion of the study, participants were compensated with a gift card and allowed to keep their SSM device.

## Procedure

For data collection, participants were instructed to place the SSM within arm's length on their bedside table or nightstand and to collect 8 consecutive weeks of nightly sleep recordings. Participants manually initiated and ended each nightly recording through the smartphone application associated with the SSM.

SSM data capture was generally high throughout, with an initial 97.3% participation rate, an 91.7% average weekly participation rate, and 83.0% of participants using their device at least 2 nights per week through each of the 8 weeks of data collection.

## Instrument

### Non-contact sleep monitoring device

The SSM recorded sleep data in 30 second epochs. Data were measured by the SSM and processed by the associated smartphone application. Time in bed and sleep parameters were estimated based on the ultra-low energy radar measurements and automatically uploaded to the cloud, and later downloaded by the researchers. These data were linked to and coded for each participant using a unique study ID.

The following SSM sleep parameters were assessed for each of the recorded nights. Sleep efficiency was defined as the ratio of sleep duration to time in bed; time in bed, defined as the amount of time spent in bed after the sleep recording was initiated; sleep duration, defined as the total amount of sleep obtained. Sleep latency was defined as the interval from bedtime to the onset of any stage of sleep and intermittent wakefulness was defined as the total amount of time spent awake after sleep onset.

## Statistical Analyses

Data from the SSM was tabulated day by day. Sleep variables were analyzed using linear random-effects regression [34] to establish group means and within-subject standard deviations (as an index of night-to-night variability), controlling for age and sex. Results compared the chronic insomnia group to the good sleeper controls by means of planned contrasts and plotted for females (as they predominate the sample) and the grand average age (36.1 years).

## RESULTS

### Characteristics of Chronic Insomnia

Figure 1 shows the daily measurements made with the SSM averaged over the duration of the study (weeks 1–8) for participants with chronic insomnia as compared to the good sleeper controls for means (left panels), and SDs (right panels). Table 1 shows the comparisons between study conditions for means (top) and SDs (bottom). Compared to the good sleeper controls, the insomnia group had lower mean sleep efficiency ( $p=0.001$ ) with higher night-to-night variability ( $p<0.001$ ) in SDs. For sleep latency, participants with insomnia had a higher mean sleep latency ( $p=0.001$ ) and greater night-to-night variability in SDs ( $p<0.001$ ) compared to good sleeper controls. Also, participants with insomnia exhibited more intermittent wakefulness both in terms of daily means ( $p=0.001$ ) and SDs ( $p<0.001$ ) as compared to the good sleeper controls. Across groups, no significant differences were observed in mean time in bed, which averaged 7.65 h ( $\pm 0.30$  h) per night ( $p=0.105$ ), or in night-to-night variability for SDs ( $p=0.343$ ). The groups did not differ on means in sleep duration, which averaged 6.59 h ( $\pm 0.16$  h) per night ( $p=0.907$ ), or in night-to-night variability for SDs ( $p=0.115$ ).

Table 1. Comparison of daily means and standard deviations between individuals with insomnia vs.

	Sleep Efficiency		Time in Bed		Sleep Duration		Sleep Latency		Intermittent Wakefulness	
<b>Means</b>	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>
Insomnia vs. Controls	11.45	<b>0.001</b>	2.68	0.105	0.01	0.907	12.27	<b>0.001</b>	11.54	<b>0.001</b>
<b>Standard Deviations</b>										
Insomnia vs. Controls	117.91	<b>&lt;0.001</b>	0.91	0.343	2.52	0.115	398.08	<b>&lt;0.001</b>	204.46	<b>&lt;0.001</b>

healthy sleeper controls.

Table 1. Group comparison of daily Means (top) and daily standard deviations (bottom) as measured with the contactless sleep monitoring device (SSM) between individuals with chronic insomnia and good sleeper controls.

Table 2 further supports our findings. As observed with the SSM, on average, sleep efficiency was 5.34% lower, sleep latency was 10.15 minutes longer, and intermittent wakefulness was higher by 18.45 minutes in individuals with chronic insomnia as compared to the good sleeper controls. Night-to-night variability was greater for sleep efficiency by 1.77%, for sleep latency by 8.80 minutes, and for intermittent wakefulness by 8.60 minutes among individuals with insomnia.

Table 2. Comparison of group differences for means and standard deviations between individuals with insomnia vs. healthy sleeper controls.

<b>Group Differences for Non-Contact Device</b>	<b>Insomnia Compared to Controls</b>	
<b>Daily Means</b>	<i>M</i>	<i>SE</i>
<i>Sleep Efficiency (%)**</i>	-5.34	0.05
<i>Time in Bed (h)</i>	0.42	0.06
<i>Sleep Duration (h)</i>	-0.03	0.06
<i>Sleep Latency (min)**</i>	10.15	0.02
<i>Intermittent Wake (min)**</i>	18.45	0.34
<b>Daily SDs</b>	<i>M</i>	<i>SE</i>
<i>Sleep Efficiency (%)***</i>	1.77	0.03
<i>Time in Bed (h)</i>	0.03	0.02
<i>Sleep Duration (h)</i>	0.05	0.01
<i>Sleep Latency (min)***</i>	8.80	0.00
<i>Intermittent Wake (min)***</i>	8.60	0.10

**\*\* $p < 0.01$ , \*\*\* $p < 0.001$**

Table 2. Group differences, with standard errors (SE), comparing individuals with chronic insomnia to healthy, good sleeper controls, for the daily Means (top half) and daily standard deviations (bottom half) – as measured with the contactless sleep monitoring device (SSM).

## DISCUSSION

### Principal Results

## Chronic Insomnia Sleep Phenotype

In this longitudinal naturalistic study, we observed that the SSM detected clear objective differences in the sleep of individuals with primary chronic insomnia compared to healthy, good sleeper controls. Even though average time in bed and sleep duration were similar, individuals with chronic insomnia demonstrated significantly less sleep efficiency, longer sleep latency, and more intermittent wakefulness than the good sleeper controls. Importantly, we report a novel longitudinal objective finding of significantly greater night-to-night variability in sleep efficiency, sleep latency, and intermittent wakefulness in participants with chronic insomnia as compared to good sleeper controls. An increased focus on night-to-night variability in studies of insomnia have become prevalent in the recent literature [5,13,17,19,35,36], but technological and methodological challenges have hampered efforts to demonstrate night-to-night variability. While work by Buysse et al., 2010 [5] has shown greater variability in intermittent wakefulness and sleep efficiency using 2-weeks of actigraphy in older adults with insomnia as compared to non-insomnia controls, they did not find significant differences in variability in sleep latency or in mean values of any sleep measure as found in the current study.

We show that a validated, contactless, longitudinal consumer sleep technology (SSM) can differentiate individuals with insomnia from healthy good sleeper controls. Thus, the SSM can be considered a valid method to accurately assess the sleep of those with insomnia and as such, has clinical utility in the screening and potential diagnosis of this condition and may be considered for use in insomnia medication clinical trials.

Using a SSM enabling automated, unobtrusive recording of sleep over extended periods (8 consecutive weeks), we found unequivocal evidence of substantially increased night-to-night variability in measures of sleep onset and sleep continuity. The heightened variability from day to day in these sleep characteristics and the uncertainty in the sleep experience of people with chronic insomnia may contribute to the characteristic complaints and burden of this disorder. We posit that

night-to-night variability is a hallmark of the chronic insomnia phenotype, and that objectively and longitudinally capturing this variability in an ecologically valid manner is key to investigating and understanding the disorder.

### **Sleep Monitoring Technology**

The SSM we used in this study derived participants' sleep/wake patterns based on ultra-low energy radar tracking of gross body motion and thoracoabdominal respiratory pattern measurements from the bedside table or nightstand. Other than user interaction to start and stop a recording each night, after initial setup the SSM required no intervention from users or investigators to function, and data were automatically uploaded to cloud storage. Further, SSM did not require a sleep diary to record bedtimes and rising times or "off wrist" periods, and battery life or memory storage capacity were not constrained as is typical of wearable devices like actigraphy. In this way, use of the SSM constituted a major step forward in enabling objective longitudinal home recordings and exposed night-to-night variability as a hallmark of chronic insomnia. As such, SSM technology appears to be a promising tool for long-duration, naturalistic studies of sleep and hold promise for remote patient monitoring to objectively determine successful treatment of insomnia.

### **Limitations**

Six of the 112 study participants completed data collection prior to the COVID-19 pandemic and 106 were studied during the pandemic. We do not know to what degree the pandemic may have contributed to symptomology in our sample of individuals with chronic insomnia, and whether and how the pandemic may have shaped the observations in this study. Although the differences we found between individuals with chronic insomnia and good sleeper controls are likely to be robust qualitatively, they may not generalize to post-pandemic circumstances quantitatively. It is worth

noting sleep duration for our study participants averaged about 30 minutes less than the consensus recommendation of 7 or more hours per night on a regular basis [37], regardless of group or condition. However, the average sleep duration of our predominantly female sample of our study was consistent with wearable-based findings for average sleep duration in U.S. adults before the COVID-19 pandemic [38].

Our sample included 83 individuals with chronic insomnia and 29 healthy good sleepers whose average age was nearly 9 years older than those with chronic insomnia. Insofar the disparity in group size and the difference in age might have biased our results, it is more likely that it would have tempered, as opposed to enhanced, the observed differences between chronic insomnia and good sleeper controls.

## Conclusions

Capturing objective, longitudinal, contactless within-person variability of sleep and mean differences in common measures of insomnia in the home setting adds an important dimension to our understanding of poor sleep and provides a more comprehensive, ecologically valid characterization of sleep problems as experienced in daily life. This study demonstrates the potential clinical and research utility of the SSM in the diagnosis and management of insomnia and our understanding of the disease. In the present 2 month, naturalistic sleep monitoring study, we documented the novel finding of elevated night-to-night variability in measures of sleep onset and sleep continuity in individuals with chronic insomnia as compared to healthy, good sleeper controls. This important finding was due to use of an unobtrusive SSM, which enabled long-term, objective, naturalistic sleep recordings in a large sample at a relatively low financial and logistical cost. Night-to-night variability may be a critical aspect of the chronic insomnia phenotype, and long-term naturalistic sleep monitoring is essential to reliably document this phenomenon.

It remains to be determined whether recognition of night-to-night sleep variability as a hallmark



of chronic insomnia can shed new light on some enigmatic features of the disorder, such as the discrepancy between subjective and objective daytime impairments [11,39], the heightened sensitivity to performance impairment during sleep deprivation [40], or the dampened responsiveness to stressors [41,42]. In this context, use of a SSM for long-term naturalistic sleep monitoring may constitute an important methodological advancement in both research and clinical settings. Indeed, with no real limit to the duration of monitoring, the SSM allows an understanding of sleep in insomnia heretofore unavailable to the sleep medicine community.

## **Acknowledgments**

We thank the study volunteers for their participation. This study was supported by NIH grant KL2TR002317. D. Hansen designed the study, collected the data, performed the analysis, wrote the paper. M. Peterson collected the data and prepared data for analysis. M. Finlay collected the data. E. Gottlieb provided sleep monitoring devices and edited the paper. S. Danoff-Burg provided sleep monitoring devices and edited the paper. R. Raymann provided sleep monitoring devices and edited the paper. D. Buchwald assisted in study design and edited the paper. N. Watson designed the study and wrote the paper.

## **Conflicts of Interest**

Non-contact sleep monitoring devices were provided by SleepScore Labs. SleepScore Labs was not involved in experimental design, study implementation, or data analyses. Dr. Watson serves on the scientific advisory board to SleepScore Labs. All other authors have no conflicts of interest to report.

## **Abbreviations**

COVID-19: coronavirus disease of 2019

SSM: SleepScore Max  
PSG: polysomnography  
SDs: standard deviations



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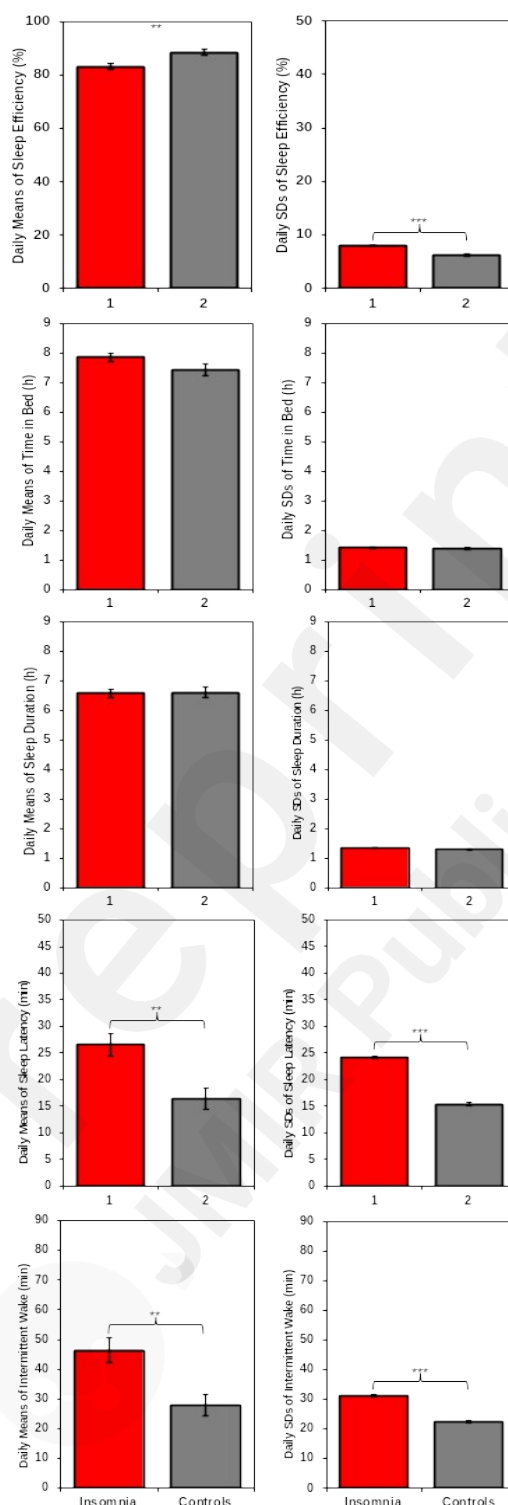
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**FIGURE 1. Comparison of sleep variables in individuals with chronic insomnia vs. healthy sleeper controls.**



**Figure 1.** Head-to-head comparisons of sleep variables in individuals with chronic insomnia (red) versus healthy, good sleeper controls (gray) for the daily Means (left side) and for the daily SDs (right side) as measured with the contactless sleep monitoring device (SSM), collapsed over days. Error bars denote standard error. \*\* $p < 0.01$ , \*\*\* $p < 0.001$