

# Night-to-night sleep variability in menopausal women: smartwatch-derived sleep metrics vs. patient-reported outcomes from the ESTeeM study

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## INTRODUCTION

- » Sleep disturbance affects around two-thirds of menopausal women, impacting quality of life and productivity.<sup>1,2</sup>
- » The 28-day US based ESTeeM real-world observational study characterized night-to-night variability in smartwatch sleep metrics in women experiencing sleep disturbance associated with menopause (SDM) and their correlations with patient-reported outcomes.

## OBJECTIVE

- » To describe smartwatch-derived and patient-reported sleep measurements in women experiencing SDM.
- » To explore the clinical utility of smartwatch in describing SDM.

## METHODS

- » Among 737 postmenopausal women included in the ESTeeM study, a subset consented to wearing a Samsung Galaxy Watch 6 or Watch 6 Classic.
  - » 175 watches sent out
  - » 77 Activated
  - » 75 Completed (Smartwatch analysis set)
  - » 34 With ≥ 11 nights for monthly mean
- » Smartwatch metrics measured: total sleep time (TST, hours), sleep efficiency (SE, %), wakefulness after sleep onset (WASO, minutes), and number of awakenings (NAW).
- » SE was derived by TST/TSPD (total sleep period duration), where TSPD was the time between watch-designated sleep onset and final wake-up time.
- » Participants completed a Daily Morning Diary (DMD), capturing patient-reported (s)TST, sSE, sWASO and Patient-Reported Outcomes Measurement Information System Sleep Disturbance Short Form 8b (PROMIS SD SF 8b) at baseline, day 14, and day 28.
- » Night-to-night variability in smartwatch metrics was quantified using within-women coefficients of variation (CVs; standard deviation/mean).
- » Spearman rank correlations assessed associations between person-level mean smartwatch metrics & corresponding DMD sleep measures.

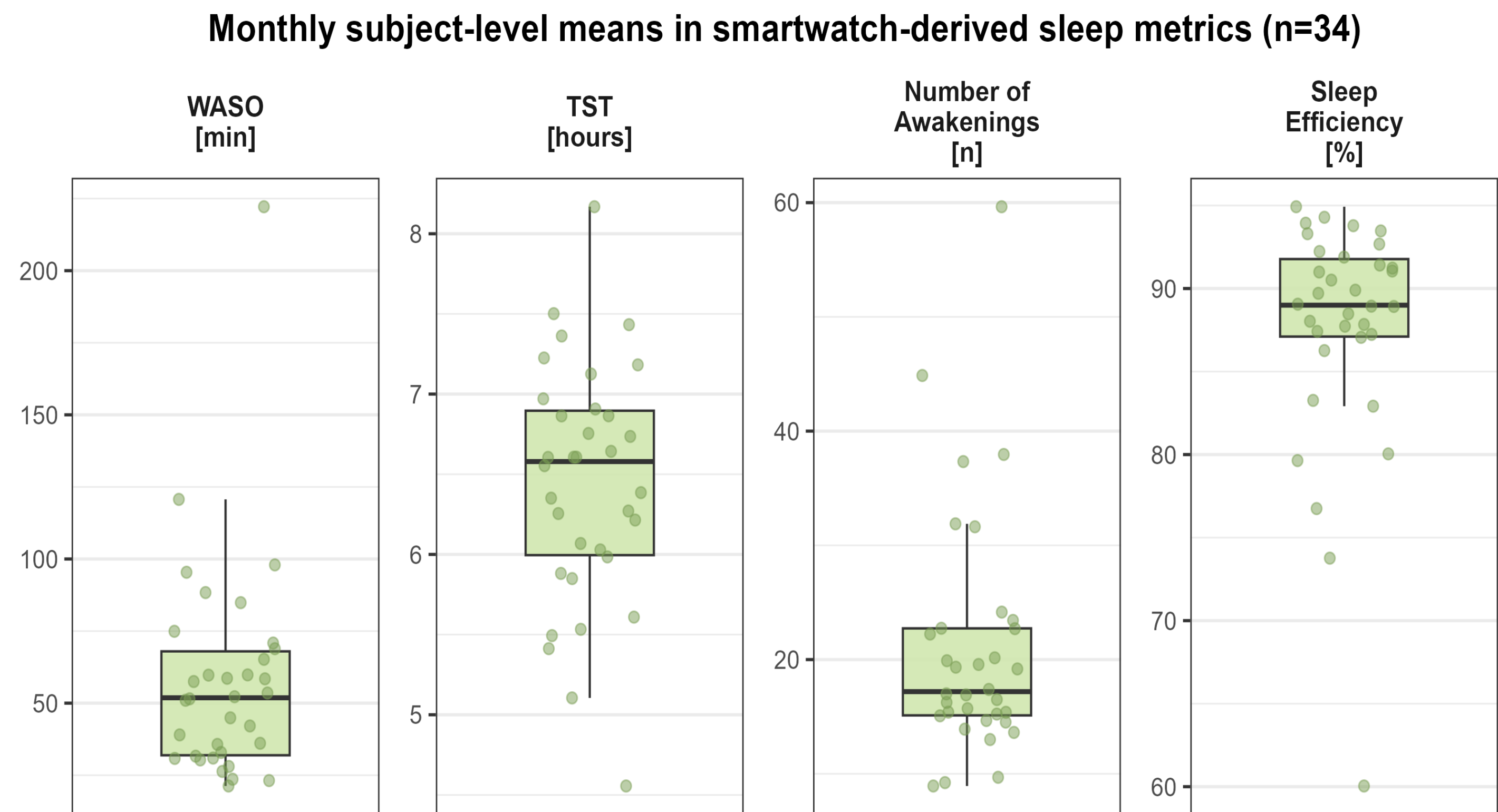
## BASELINE CHARACTERISTICS

	Wearable subgroup (n=34)
<b>Age at enrollment</b>	
Mean (SD)	54.6 (6.0)
<b>BMI category, n (%)</b>	
Normal weight	4 (11.8)
Overweight	9 (26.5)
Obese	11 (32.4)
Missing	10 (29.4)
<b>Depression score, n (%)*</b>	
Normal / mild / moderate	26 (76.5) / 7 (20.6) / 1 (2.9)
<b>Anxiety score, n (%)*</b>	
Normal / mild / moderate / severe	16 (47.1) / 11 (32.4) / 5 (14.7) / 2 (5.9)
<b>ISI total score, n (%)</b>	
No clinical sign of insomnia	1 (2.9)
Subthreshold insomnia	17 (50.0)
Moderate insomnia	11 (32.4)
Severe insomnia	5 (14.7)
<b>PROMIS SD SF 8b total T-score on day 1, n (%)</b>	
Within normal limits	10 (29.4)
Mild	11 (32.4)
Moderate	9 (26.5)
Severe	3 (8.8)
Missing	1 (2.9)
<b>Nighttime VMS frequency at enrollment, n (%)**</b>	
None	16 (47.1)
Low (≤3/day)	11 (32.4)
High (>3/day)	7 (20.6)

\*Based on Hospital Anxiety and Depression Scale (normal: 0–7, mild: 8–10, moderate: 11–14, severe: 15–21). \*\*Low/high split based on median of baseline VMS count among subjects with >0 episodes. BMI, body mass index; ISI, Insomnia Severity Index; PROMIS SD SF 8b, Patient-Reported Outcomes Measurement Information System Sleep Disturbance Short Form 8b; SD, standard deviation; VMS, vasomotor symptoms.

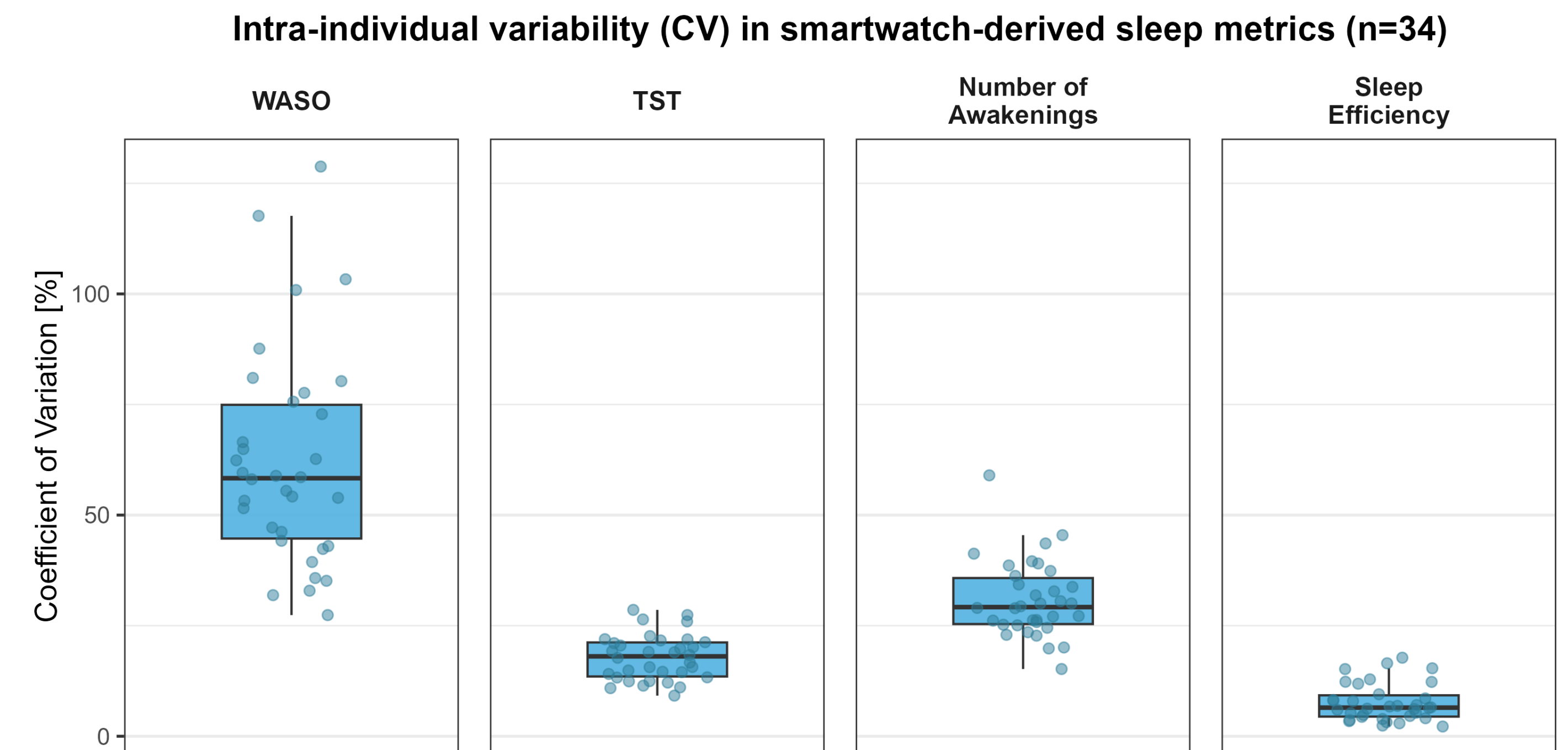
## RESULTS

Figure 1. Monthly subject-level means in smartwatch-derived sleep metrics<sup>†</sup>: WASO (min), TST (hours), number of awakenings/night, sleep efficiency (%)



<sup>†</sup>Median of 16 valid nights of sleep data per participant. TST, total sleep time; WASO, wakefulness after sleep onset.

Figure 2. Median subject-level variability (CV) in smartwatch-derived sleep metrics<sup>††</sup>: WASO (min), TST (hours), number of awakenings/night, sleep efficiency (%)



<sup>††</sup>CV=SD/mean, with higher values indicating greater intraindividual variability across nights. CV, coefficient of variation; SD, standard deviation; TST, total sleep time; WASO, wakefulness after sleep onset.

- » Median CVs showed **highest variability for WASO (58%) & NAW (29%), with lower variability for TST (18%) & SE (6%) (Figure 2).**
- » Spearman correlations between smartwatches & DMD sleep measures were **weak or moderate (Table 1).**
- » Test-retest reliability was good to excellent: average-measures **ICC(A,k) ranged from 0.798–0.957** across instruments.
- » Subgroup analysis by pooled ISI showed higher WASO and NAW with lower TST in women with moderate or severe insomnia compared with women with subthreshold or no insomnia (data not shown).
- » However, these findings should be interpreted cautiously given the small sample size.

Table 1. Correlations between sleep measures from smartwatches & DMD<sup>‡</sup>

N=34 (100%)	Spearman Rank Correlation
<b>NAW per night</b>	
Coefficient	<b>0.26</b>
95% CI	<b>(-0.0855 - 0.5499)</b>
<b>WASO (minutes) per night</b>	
Coefficient	<b>0.39</b>
95% CI	<b>(0.0493 - 0.6372)</b>
<b>TST (hours) per night</b>	
Coefficient	<b>0.52</b>
95% CI	<b>(0.2165 - 0.7278)</b>
<b>SE (%) per night</b>	
Coefficient	<b>0.46</b>
95% CI	<b>(0.1356 - 0.6861)</b>

<sup>‡</sup>Correlations were calculated between person-level mean smartwatch sleep measures and DMD sleep measures. Because participants contributed to different numbers of valid nights, the DMD mean could be based on up to 28 nights, whereas the wearable mean could be based on fewer nights (median 16 valid nights in this subgroup). CI, confidence interval; DMD, Daily Morning Diary; NAW, number of awakenings; SE, sleep efficiency; TST, total sleep time; WASO, wakefulness after sleep onset.

## LIMITATIONS

- » Small exploratory sample size.
- » Wearable and diary data were not night-matched.
- » Correlations were based on aggregated monthly means.
- » Diary entries may be influenced by watch displays.
- » For wearable data, SE was approximated as TST/TSPD since time in bed (TIB) was not available, whereas DMD-based SE calculation used TST/TIB.

## CONCLUSIONS

Smartwatch-derived sleep measures showed distinct variability profiles: TST varied more between women than within women; WASO showed the opposite pattern; NAW and SE showed low variability both between and within women.

Wearable-derived sleep metrics may complement patient-reported outcomes by capturing night-to-night variability in real-world menopausal sleep assessment.

## REFERENCES

1. Maki PM, et al. Menopause 2024;31:724–33; 2. DePree B, et al. Menopause 2023;30(9):887–97.

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