

# Head-to-head comparison of a contactless home sleep monitor with polysomnography in women with sleep disturbance associated with menopause

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## INTRODUCTION

- ▶ **Sleep disturbance** is common among women during menopause owing to hormonal and behavioral changes,<sup>1,2</sup> affecting up to 69% of midlife women globally and causing a substantial impact on women's health and quality of life.<sup>3-7</sup>
- ▶ While **polysomnography (PSG)** is the gold standard for objective sleep assessments, it is costly, resource-intensive, and relies on an artificial sleep environment that is uncomfortable for patients.<sup>8,9</sup> **Patient-reported outcomes**, though informative for subjective experience, have inherent inter-individual variability.
- ▶ Sleepiz One+ is a **touchless home-based sleep monitor** based on radar technology developed to address the unmet need of objective, patient-friendly, and continuous monitoring of sleep disturbance in the most natural environment at home (Figure 1).
- ▶ The exploratory Phase II **NIRVANA** trial (NCT06112756)<sup>10</sup> evaluated the effect of elinzanetant – a dual neurokinin (NK)1 and NK3 receptor antagonist for vasomotor symptoms (VMS) and sleep disturbance – on wakefulness after sleep onset (WASO) using both objective (PSG, Sleepiz One+) and subjective (Sleep Diary) measures in postmenopausal women with moderate-to-severe VMS (Figure 2).
- ▶ This study evaluated the **agreement** in a head-to-head comparison between the reference standard **PSG** and **Sleepiz One+** to assess sleep/wake status on the 30-second epoch level and to measure sleep quality parameters (WASO, number of awakenings, sleep efficiency, total sleep time, and latency to persistent sleep) in women with sleep disturbance associated with menopause from the NIRVANA trial.

Figure 1. Sleep monitoring using PSG vs. touchless remote technologies (Sleepiz One+)

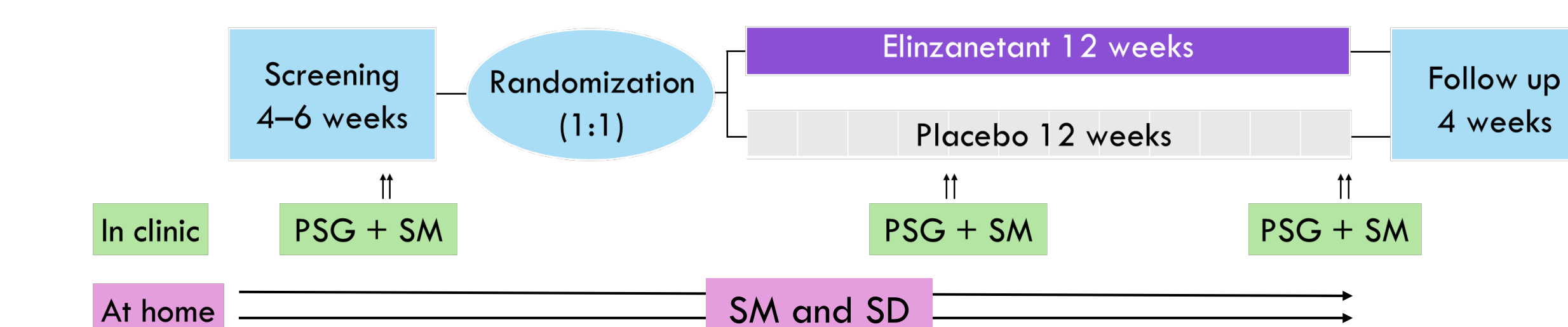


PSG, polysomnography; SM, sleep monitor (Sleepiz One+).

## METHODS

- ▶ In the NIRVANA study, postmenopausal women with sleep disturbance underwent simultaneous Sleepiz One+ and PSG recordings (Figure 1) for six nights (two consecutive nights each at baseline, week 4, and week 12 [Figure 2]).
- ▶ PSG was conducted in qualified sleep laboratories and scored manually by two independent scorers blinded to treatment, following American Academy of Sleep Medicine guidelines.
- ▶ Sleepiz One+ data were analyzed automatically using proprietary algorithms. Time synchronization between modalities was achieved using PSG's "lights-off"/"lights-on" markers and respiratory signal alignment. Only high-quality, synchronized datasets were included, resulting in 237,258 epochs (standard 30-second intervals used in sleep scoring) from 66 subjects for analyses, which were compared one by one to assess sleep/wake classification.
- ▶ Agreement between modalities was assessed using **epoch-level analyses** and **parameter-level analyses**. For **epoch-level analysis**, sleep/wake status was compared in **30-second intervals (epochs)** across devices to calculate sensitivity, specificity, accuracy, and prevalence-adjusted bias-adjusted kappa (PABAK) presented as the mean across participants with 95% confidence intervals (CIs). For **parameter-level analysis**, **nightly metrics** – such as WASO, sleep onset latency, total sleep time, number and duration of awakenings, and sleep efficiency – were calculated per night by each method and compared between devices.

Figure 2. NIRVANA trial design

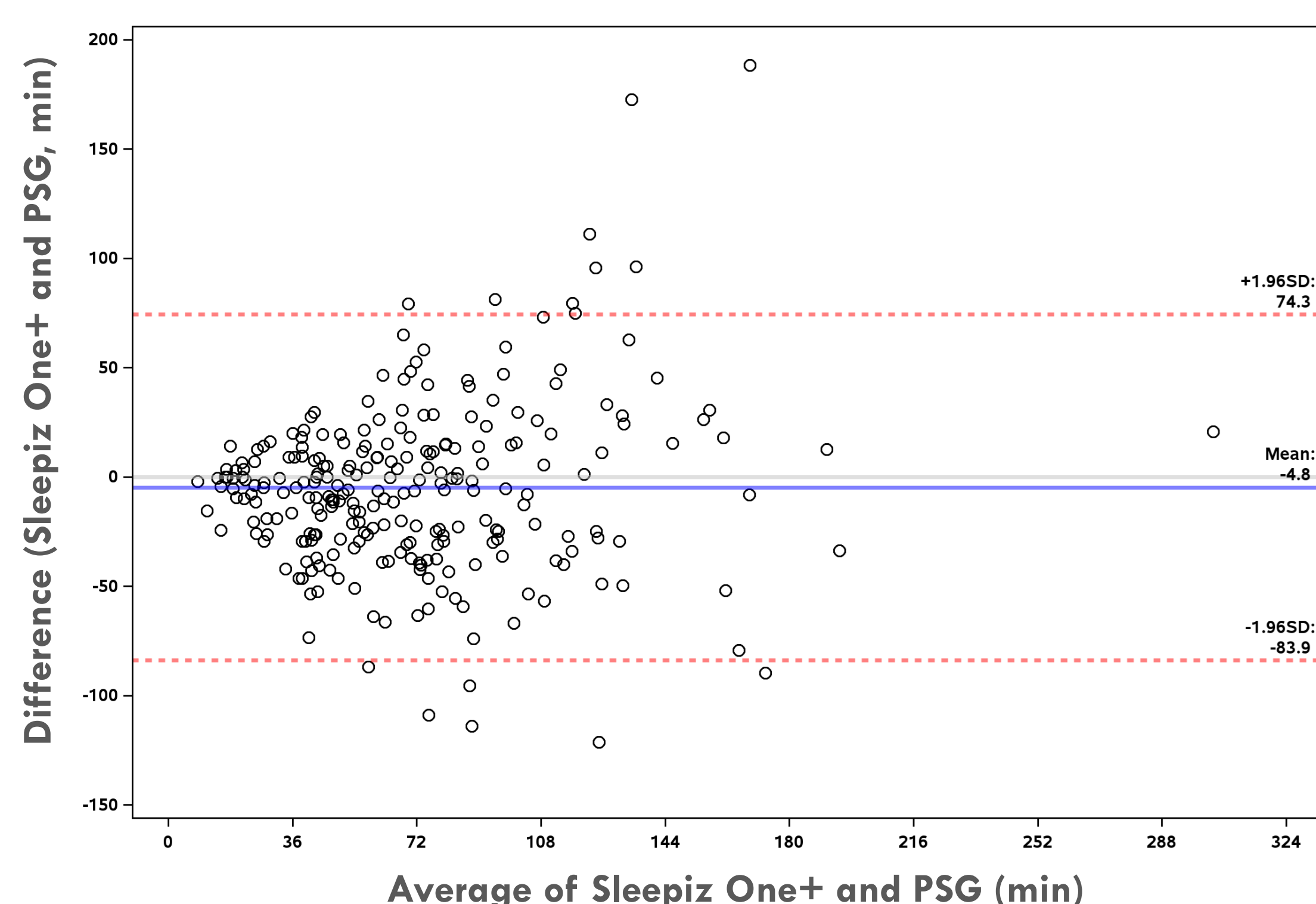


PSG, polysomnography; SD, sleep diary; SM, sleep monitor (Sleepiz One+).

## RESULTS

- ▶ **Epoch-level comparisons** between Sleepiz One+ and PSG indicated good agreement: PABAK mean (95% CI) value, 0.72 (0.68–0.76) (Table 1).
- ▶ **Parameter-level comparisons** showed that Sleepiz One+ underestimated WASO by 4.8 minutes, latency to persistent sleep by 9.6 minutes, total sleep time by 7.1 minutes, number of awakenings by 0.4, and duration of awakenings by 1.0 minute. Sleep efficiency was overestimated by 2.1%.
- ▶ The Bland-Altman plot for WASO showed overall good agreement between PSG and Sleepiz One+ (Figure 3).
- ▶ Overall, **improvements** in nightly WASO assessed with Sleepiz One+ from individual participants in the NIRVANA study were visually observed in the elinzanetant arm compared with placebo (Figure 4).

Figure 3. Bland-Altman plot showing level of agreement between Sleepiz One+ and PSG to assess WASO



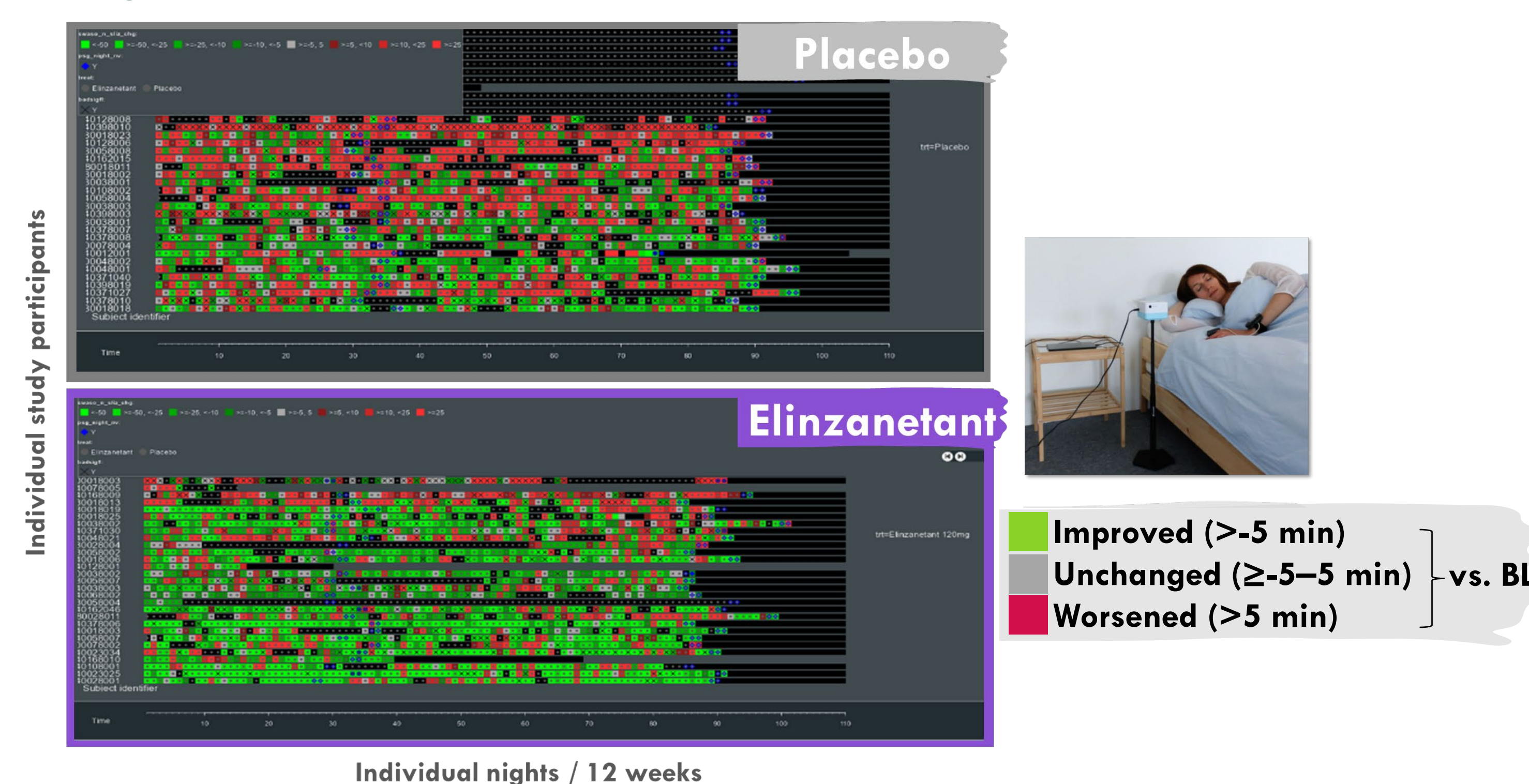
PSG, polysomnography; SD, standard deviation; WASO, wakefulness after sleep onset.

Table 1. Epoch-level comparisons between Sleepiz One+ and PSG

| Classification | Sleepiz One+ vs. PSG (N=66) |            |
|----------------|-----------------------------|------------|
|                | Mean (SD)                   | 95% CI     |
| Sensitivity    | 0.91 (0.09)                 | 0.89, 0.94 |
| Specificity    | 0.64 (0.17)                 | 0.60, 0.68 |
| Accuracy       | 0.86 (0.08)                 | 0.84, 0.88 |
| PABAK          | 0.72 (0.16)                 | 0.68, 0.76 |

CI, confidence interval; PABAK, prevalence-adjusted bias-adjusted kappa; PSG, polysomnography; SD, standard deviation.

Figure 4. Nightly WASO assessment with Sleepiz One+ for all participants (one per row) during the NIRVANA study in the natural sleep environment at home



This figure was produced in an unvalidated setting. BL, baseline; WASO, wakefulness after sleep onset.

## CONCLUSIONS

This study extended previous validations of the Sleepiz tool in healthy and sleep-disordered populations, supporting the use of Sleepiz One+ as a contactless device for sleep assessment at home in clinical trials, and confirming the device's fitness for purpose in menopause-related sleep research.

Epoch-level and parameter-level analyses showed good agreement between Sleepiz One+ and PSG in menopausal women with sleep disturbance.

The Sleepiz One+ device enables continuous home recordings over extended periods and broader data collection than PSG in a natural setting.

The Sleepiz One+ device offers a promising path to objective, user-friendly, easy-to-use, and scalable sleep monitoring.

## REFERENCES

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## DISCLOSURES

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