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Validation of Waveband for capturing sleep in hypersomnia disorders

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*At the time of the study

Background

- Narcolepsy type 1 (NT1) is a rare neurological disorder caused by orexin deficiency and characterized by excessive daytime sleepiness, cataplexy, hallucinations, sleep paralysis, disrupted nighttime sleep, and cognitive symptoms.[1-4]
- NT1 is diagnosed using in-clinic nocturnal polysomnography (PSG) and multiple sleep latency testing (MSLT) plus documented cataplexy (or cerebrospinal fluid orexin deficiency), making the process resource-intensive and burdensome for patients.[2]
- Waveband, a US Food and Drug Administration–cleared at-home dry-electrode electroencephalogram (EEG), enables multi-night and daytime recording in a natural home setting.[5,6]
- Here, we discuss its performance evaluation in a prospective clinical validation study (NCT06531876) in individuals with NT1 and suspected central disorders of hypersomnolence (CDHs).

Objective

- To evaluate the Waveband device and the updated* sleep staging algorithm for:
  - **Adherence** with multi-night at-home recording protocol.
  - **Data quality** in recordings made at home without technical intervention.
  - Perceived **usability** versus traditional PSG.
  - Concordance of **sleep staging accuracy** with gold-standard in-clinic testing.

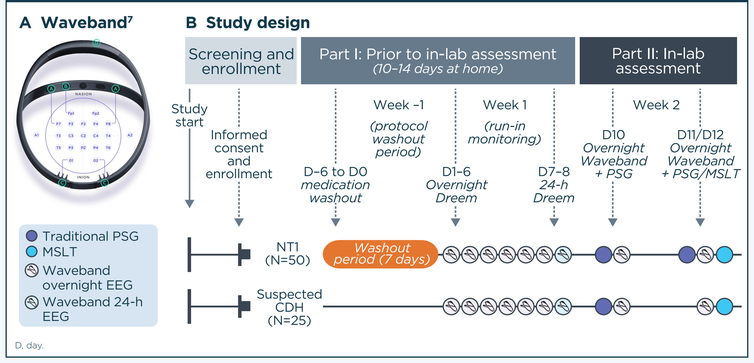
*Updated under the Predetermined Change Control Plan relative to the original study algorithm.

Methods

Study design and population

- Data from 75 participants aged ≥18 years were analyzed; 3 additional enrolled participants withdrew prior to phase 1 completion for reasons unrelated to the protocol or device.
- Arm A (n=25): participants with suspected CDHs, defined by excessive daytime sleepiness, fatigue, or hypersomnia with daily or near-daily symptoms for ≥1 month not attributable to insufficient sleep, referred for nocturnal PSG and MSLT as part of their clinical diagnostic workup.
- Arm B (n=50): participants with investigator-confirmed NT1 (based on clinical symptoms and PSG/MSLT) who were deemed safe to temporarily withdraw from stimulants, wake-promoting agents, antidepressants, oxybates, and pitolisant (≤50% of antidepressant and oxybate doses could be maintained at investigator discretion).
- Participants were recruited from Kaiser Permanente (CA), Sleep Insights (NY), Florida Pediatric Research Institute (FL), Sleep Therapy and Research Center (TX), Stanford University (CA), and Intrepid Research (OH).
- Participants wore the Waveband EEG headband at home for 6 consecutive nights followed by a 24-h continuous recording, then completed 1 (arm A) or 2 (arm B) in-clinic PSG nights concurrent with Waveband (**Figure 1**).
- The System Usability Scale (SUS) was administered after at-home night 6 (Waveband SUS) and in-clinic night 1 (PSG SUS).

Figure 1. Study design



D, day.

Data processing

- At-home wear compliance was assessed using algorithmically detected on-head device wear time.
- Data quality was assessed using the Waveband scorability algorithm, developed and trained on an independent dataset of Waveband EEG signals labeled as good or bad quality by trained sleep experts.
- In-clinic PSG was scored by 3 Registered PSG Technologists; Waveband sleep stages were generated using the automated sleep staging algorithm updated per a predetermined change control plan.

Data analysis

- Compliance and quality endpoints — primary (overnight): ≥4 of 6 nights with ≥4 h of wear time and ≥85% scorable data; secondary (24 h): ≥17 h of wear time with ≥85% scorable data.
- Sleep staging primary endpoint: positive percent agreement (PPA) for wake, defined as the percentage of PSG wake epochs also identified as wake by adjudicated Waveband staging, consistent with the metric used in the Waveband 510(k) validation study.

Results

Participants

- Demographics for 75 participants are shown in **Table 1**.

At-home compliance and data quality

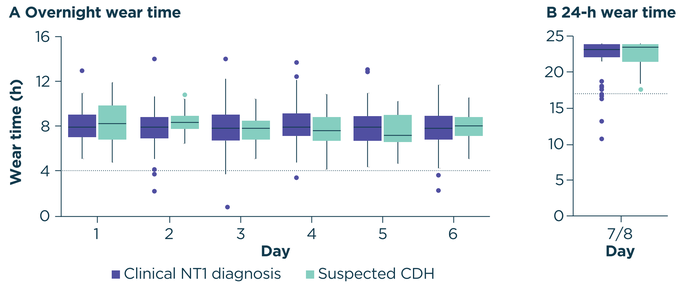
- 75/75 (100%) participants met the compliance and data quality primary endpoint; mean (SD) passing nights per participant were 5.6 (0.6) for NT1 and 5.9 (0.2) for CDH.
- 45/50 (90%) with NT1 and 24/25 (96%) with CDH met the 24-h continuous recording secondary endpoint; mean (SD) wear times were 22.0 (3.0) and 22.6 (1.8) h, respectively (**Figure 2**).

Table 1. Participant characteristics

Characteristics	NT1* (n=50)	Suspected CDH† (n=25)
NT1 diagnosis, n (%)	50 (100)	0 (0)
Median (range) age, years	32 (19–61)	23 (18–73)
Female, n (%)	32 (64)	19 (76)
Race, n (%)		
Asian	2 (4)	3 (12)
Black/African American	12 (24)	1 (4)
White	33 (66)	15 (60)
Declined to respond	3 (6)	6 (24)
Hispanic/Latino ethnicity, n (%)	13 (26)	10 (40)
Site, n (%)		
Kaiser Permanente	18 (36)	25 (100)
Sleep Insights	13 (26)	-
Stanford	9 (18)	-
Sleep Therapy and Research Center	5 (10)	-
Intrepid Research	3 (6)	-
Florida Pediatric Research Institute	2 (4)	-
SOREMP present on PSG, n (%)	6 (16)	0 (0)
Mean (SD) SOREMPs on MSLT	2.7 (1.4)	0.75 (1.2)
Mean (SD) sleep latency on MSLT, min	3.2 (2.6)	10.0 (4.4)

SOREMP, sleep-onset rapid eye movement period. *Diagnostic data: PSG, n=36; MSLT, n=39. †Diagnostic data: PSG, n=10; MSLT, n=24.

Figure 2. At-home Waveband wear time

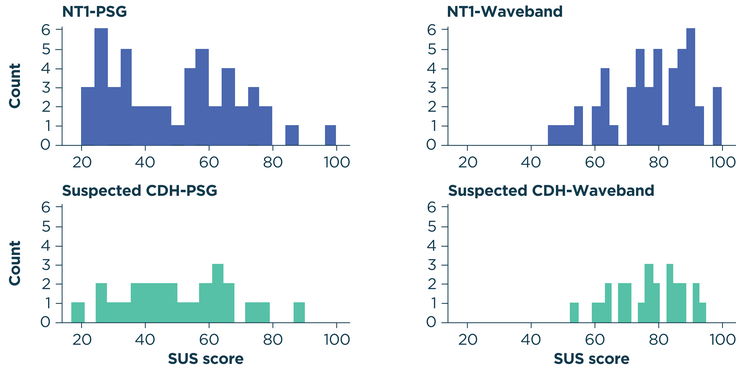


The dotted lines indicate the endpoint thresholds (4 h of wear time for overnight recordings, and 17 h of wear time for 24-h recordings).

Waveband versus PSG usability

- Waveband mean SUS score of 77.4 in participants with NT1 surpassed the secondary endpoint target of >68.
- Waveband SUS scores were significantly higher than PSG scores (paired *t* test for difference in means, P<0.001 for CDH and NT1) (**Figure 3**).
- Waveband SUS scores were comparable with common at-home health care devices including an inhaler (66.7), blood pressure cuff (73.6), pregnancy test kit (66.7), and blood glucose meter (69.6).[8]

Figure 3. Waveband usability exceeds PSG

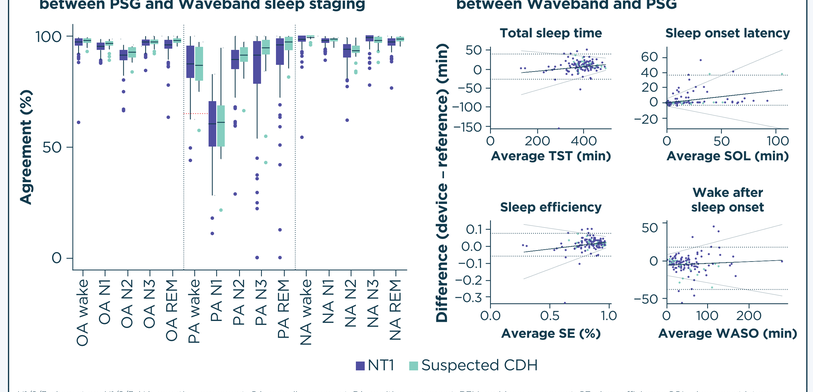


SUS questionnaire administered before the 24-h recording period begins (Waveband) and after the first night PSG (PSG).

In-clinic sleep staging

- Mean PPA for wake between Waveband and PSG was 86.8% (90% CI, 84.8–88.8) in participants with NT1, exceeding the primary endpoint of 90% CI lower bound >65%.
- Sleep staging agreement between Waveband and PSG was high across sleep stages; mean Cohen's kappa (90% CI) was 0.81 (0.79–0.82) for NT1 and 0.85 (0.84–0.87) for CDH (**Figure 4**).
- Intraclass correlation coefficient (ICC) between Waveband- and PSG-derived sleep features was excellent (ICC range: 0.89–0.95 for NT1; 0.89–0.95 for CDH) (**Table 2**).
- The strong performance is notable, given that human- and machine-based staging are challenging in people with NT1 because of unusual sleep stage transitions characteristic of NT1.[9]

Figure 4. Sleep staging



N1/2/3, sleep stage N1/2/3; NA, negative agreement; OA, overall agreement; PA, positive agreement; REM, rapid eye movement; SE, sleep efficiency; SOL, sleep onset latency; TST, total sleep time; WASO, wake after sleep onset.. The dotted red line indicates the threshold for the primary endpoint. Mean agreement metrics were estimated using a pooling approach via fitting a linear mixed-effect model.

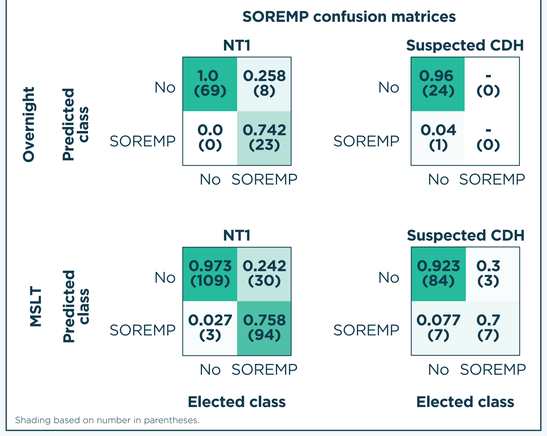
Table 2. ICC between Waveband and PSG

Sleep feature	ICC (90% CI) NT1	ICC (90% CI) Suspected CDH
Total sleep time	0.94 (0.91–0.95)	0.93 (0.70–0.98)
Sleep onset latency	0.89 (0.84–0.93)	0.89 (0.80–0.94)
Wake after sleep onset	0.95 (0.93–0.96)	0.94 (0.80–0.98)
Sleep efficiency	0.92 (0.89–0.94)	0.95 (0.76–0.98)

Sleep-onset REM period (SOREMP) detection

- Waveband demonstrated near-perfect specificity for overnight SOREMP detection in NT1 (100%) and CDH (96%), with moderate sensitivity in NT1 (74%) (**Figure 5**).
- On the MSLT, SOREMP specificity remained high (97% for NT1; 92% for CDH) with moderate sensitivity (76% for NT1; 70% for CDH) (**Figure 5**).

Figure 5. Waveband showed high specificity in SOREMP detection



Shading based on number in parentheses.

Conclusions

- **Waveband enables accurate, scalable, at-home sleep evaluation of hypersomnia with high compliance and data quality, and usability on par with commonly used home health care devices.**
- **SOREMPs were accurately identified during PSG/MSLT with 74/76% sensitivity and 100/97% specificity.**
- **The updated Waveband sleep staging algorithm reliably detects EEG features of narcolepsy.**
- **These results support the use of Waveband use in NT1 clinical trials and are encouraging for its potential application in real-world evaluations of suspected hypersomnolence disorders.**

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