Validation of Waveband for evaluation of sleep in hypersomnia disorders

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Introduction

- Narcolepsy type 1 (NT1) is rare neurological disorder linked to orexin deficiency and characterized by excessive daytime sleepiness (EDS), cataplexy, hallucinations, sleep paralysis, and disrupted nighttime sleep.[1-3]
- NT1 diagnosis and clinical trials evaluating NT1 therapies currently rely on in-clinic polysomnography (PSG) and multiple sleep latency test (MSLT), which are time consuming, burdensome, uncomfortable for patients, and require trained personnel.[4]
- However, PSG is not suitable for capturing sleep variability across nights and may not reflect a natural sleep environment.[5]
- We present results from a prospective clinical validation study to evaluate Waveband (formerly Dreem 3S), a US Food and Drug Administration 510(k)–cleared at-home dry-electrode encephalography device, in individuals with suspected hypersomnia disorders and those with confirmed NT1 (NCT06531876).

Objectives

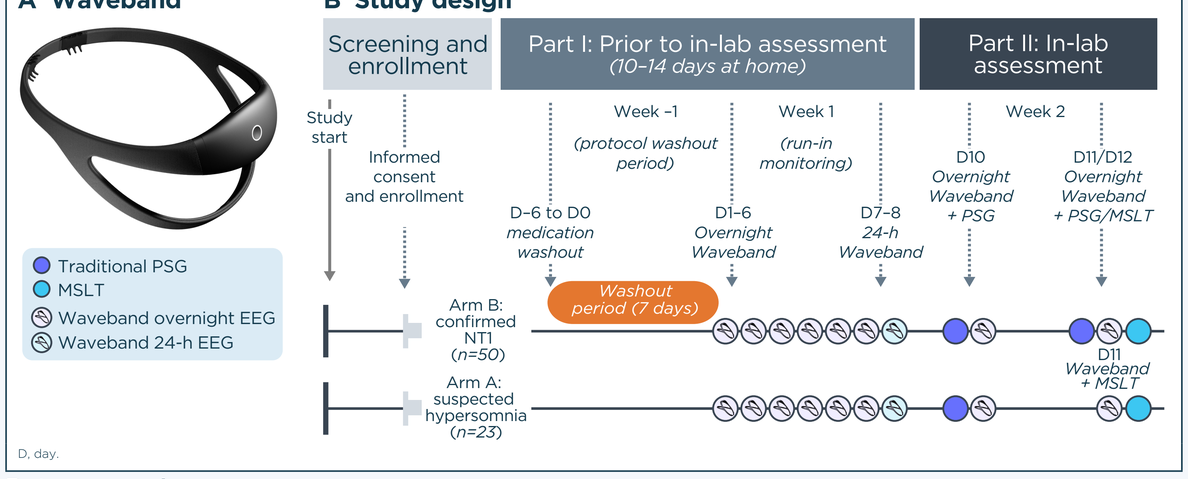
- To evaluate Waveband in participants with suspected hypersomnia or NT1 for:
  - Compliance with multi-night at-home recording protocol
  - Data quality in recordings made at home without technical intervention
  - Concordance of sleep staging accuracy with gold-standard in-clinic testing
  - Perceived usability versus traditional PSG.

Methods

Study design and population

- Data from 73 participants aged ≥18 years were analyzed.
- Arm A included 23 participants with suspected disorders of primary hypersomnia (reported EDS, fatigue, or hypersomnia, with daily or almost daily symptoms for ≥1 month prior to consult, and whose symptoms were not related to insufficient sleep), and who were referred for nocturnal PSG and MSLT as part of their clinical diagnostic workup.
- Arm B included 50 participants with investigator-confirmed NT1 diagnoses (based on clinical symptoms and PSG/MSLT) who were deemed safe by their treating physician to temporarily withdraw from medication including stimulants, wake-promoting agents, antidepressants, oxybates, and pitolisant (participants could maintain ≤50% of their antidepressant and oxybate doses 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 used the Waveband electroencephalogram (EEG) headband[6] at home to record 6 consecutive nights of sleep followed by a 24-h continuous recording period, then recorded 1 (arm A) or 2 (arm B) nights of in-clinic PSG concurrently with Waveband (**Figure 1**).
- The System Usability Scale (SUS), a broadly used standardized assessment of the perceived usability of a system/product, was collected after at-home night 6 (Waveband SUS) and after in-clinic night 1 (PSG SUS).

Figure 1. Study design



D, day.

Data processing

- At-home wear compliance was assessed based on algorithmically detected "on-head" device wear time.
- Data quality was assessed using the previously developed Waveband "scorability" algorithm, which was developed and trained on an independent dataset of Waveband EEG signals, labeled as either good or bad quality by sleep experts trained in scoring Waveband EEG.
- In-clinic PSG was scored by 3 registered PSG technologists (RPSGTs). The manually scored consensus sleep staging was compared with the machine learning–based sleep stages that Waveband automatically generates. Algorithmic results were further adjudicated by 3 RPSGTs and compared with manual consensus PSG-based sleep stages.

Data analysis

- Compliance and quality assessments: primary endpoint (overnight): ≥4 of 6 nights of data containing ≥4 h of wear time with ≥85% of sufficient quality to be scored. Secondary endpoint (24-h period): ≥17 h of wear time with ≥85% of sufficient quality to be scored.
- Sleep staging assessments: primary endpoint: positive percent agreement (PPA) for wake between PSG and adjudicated Waveband sleep staging methods, defined as percentage of PSG epochs identified as wake by RPSGTs that the adjudicated Waveband sleep staging also identified as wake.
  - This metric is the same as that used for the primary endpoint of the Waveband 510(k) validation study.

Results

Participants

- Demographics for 73 participants are shown in **Table 1**.

At-home compliance and data quality

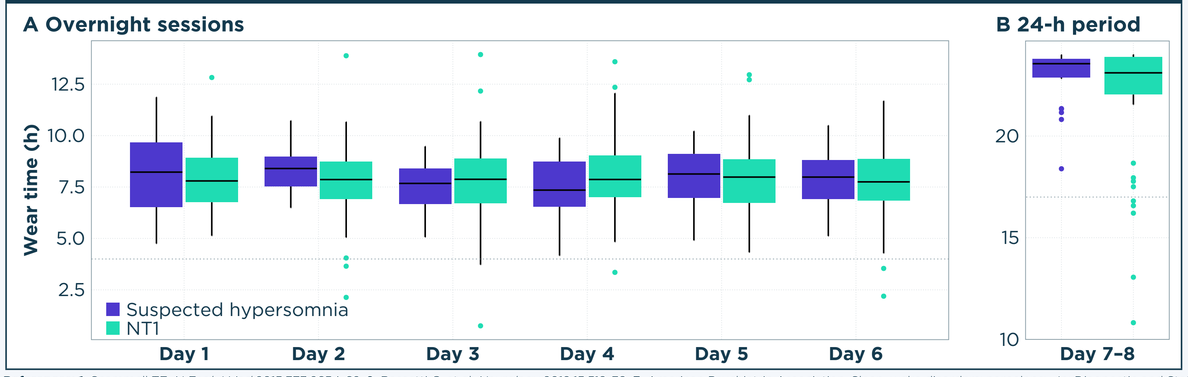
- 22/23 (96%) participants with suspected hypersomnia and 50/50 (100%) with NT1 met the compliance and data quality primary endpoint; mean (SD) passing nights per participant were 5.9 (0.2) and 5.5 (0.7), respectively.
- 22/23 (96%) participants with suspected hypersomnia and 45/50 (90%) with NT1 met the 24-h continuous recording secondary endpoint; mean (SD) wear times were 22.1 (3.0) and 22.8 (1.6) h, respectively (**Figure 2**).

Table 1. Participant demographics

	Participants with suspected hypersomnia (n=23)	Participants with NT1 (n=50)
NT1 diagnosis (with cataplexy), n (%)*	0 (0)	50 (100)
Age, median (range), years	25 (18–73)	32 (19–61)
Female, n (%)	18 (78.3)	32 (61.5)
Race, n (%)		
Asian	4 (17.4)	2 (3.9)
Black/African American	1 (4.4)	13 (25.0)
White	13 (56.5)	33 (63.5)
Hispanic/Latino ethnicity, n (%)	9 (39.1)	13 (25.0)
SOREMPs on MSLT, mean (SD)	N/A	2.7 (1.4)
Sleep latency on MSLT, mean (SD), min	N/A	3.2 (2.6)

N/A, not available; SOREMP, sleep-onset REM period.
*Participants were included based on a clinical diagnosis of NT1, as determined by the sleep-treating physician and site PR, and who withdrew from their therapy for the study period. In most cases, human leukocyte antigen testing was not included but will be offered to participants in a follow-up study.

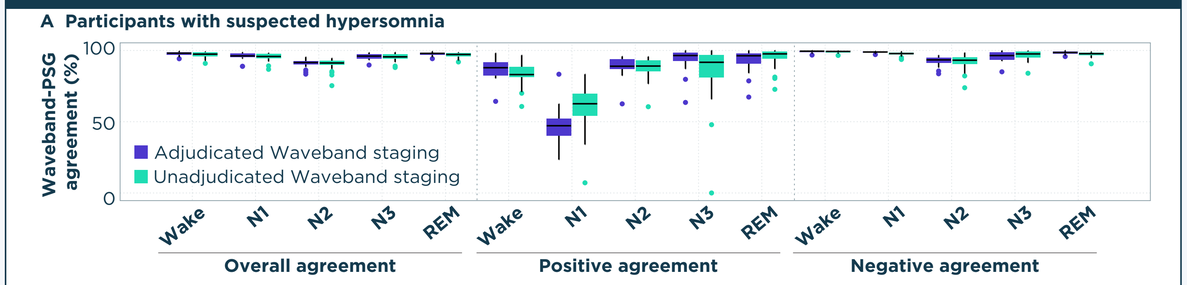
Figure 2. At-home Waveband wear time



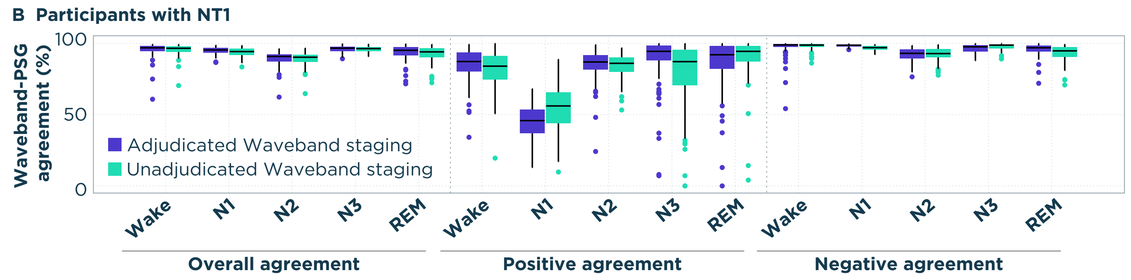
In-clinic sleep staging

- Mean PPA for wake between adjudicated Waveband and PSG was 85% (90% CI, 83–87) in participants with NT1, meeting the primary endpoint of 90% CI lower bound >65%.
- Sleep staging agreement between adjudicated Waveband and PSG was high across sleep stages; mean Cohen's Kappa (90% CI) was 0.84 (0.82–0.86) for suspected hypersomnia and 0.78 (0.76–0.80) for NT1 (**Figure 3**).
- Performance was similarly high between unadjudicated Waveband sleep staging and PSG; mean Cohen's Kappa (90% CI) was 0.82 (0.79–0.84) for suspected hypersomnia and 0.76 (0.74–0.79) for NT1 (**Figure 3**).
- Agreement between adjudicated/unadjudicated Waveband sleep staging and PSG was high across several standard sleep macrofeatures (**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.[7]

Figure 3. Sleep staging



Expert-adjudicated stage Waveband	Expert consensus–assigned stage – PSG (%)						PPA, % mean (90% CI)
	Wake	N1	N2	N3	REM	No consensus	
Wake	**88.9**	6.2	0.6	0.1	0.5	6.6	87.2 (84.6–89.7)
N1	4.7	**45.3**	0.8	0.0	0.5	7.7	47.2 (42.9–51.5)
N2	3.5	39.1	**89.2**	4.8	4.1	**44.4**	88.7 (86.2–91.2)
N3	0.8	0.5	7.2	**95.2**	0.0	12.2	93.9 (91.2–96.8)
REM	1.0	5.0	1.9	0.0	**93.9**	21.9	93.5 (98.1–97.3)
No consensus	1.1	3.9	0.3	0.0	1.0	7.1	–



Expert-adjudicated stage Waveband	Expert consensus–assigned stage – PSG (%)						PPA, % mean (90% CI)
	Wake	N1	N2	N3	REM	No consensus	
Wake	**87.0**	10.7	1.5	0.0	4.8	10.5	85.0 (82.7–87.2)
N1	4.1	**44.9**	1.1	0.0	1.5	9.9	44.9 (42.4–47.3)
N2	3.3	26.7	**85.3**	7.2	5.2	27.6	85.2 (83.1–87.3)
N3	0.4	0.2	6.7	**92.7**	0.0	4.4	88.4 (85.2–91.6)
REM	3.0	12.9	4.9	0.0	**87.0**	**40.4**	86.4 (82.8–89.9)
No consensus	2.2	4.6	0.6	0.1	1.6	7.3	

N1/2/3, sleep stage N1/2/3.
Participants with (**A**) suspected hypersomnia and (**B**) NT1, where the top panels show overall, positive, and negative agreement metrics for each stage between the adjudicated/unadjudicated Waveband stage and expert consensus–assigned stage from PSG. The bottom panels show confusion matrices of average participant-level PPA for each sleep stage and 90% CIs of the mean. Estimates obtained using linear mixed-effects models, pooling participant- and night-specific PPA values.

Table 2. Sleep macrofeature agreement

Diagnosis		NT1		Suspected hypersomnia	
Waveband sleep staging method		Adjudicated	Unadjudicated	Adjudicated	Unadjudicated
Sleep feature ICC (90% CI)	TST	0.92 (0.89–0.94)	0.92 (0.83–0.95)	0.97 (0.92–0.97)	0.94 (0.88–0.97)
	WASO	0.75 (0.67–0.82)	0.77 (0.69–0.83)	0.97 (0.89–0.99)	0.94 (0.81–0.97)
	Sleep efficiency	0.90 (0.86–0.92)	0.89 (0.78–0.94)	0.98 (0.94–0.99)	0.94 (0.71–0.98)
	REM, %TST	0.75 (0.66–0.82)	0.64 (0.36–0.78)	0.94 (0.88–0.97)	0.84 (0.66–0.92)
	N1, %TST	0.67 (0.23–0.83)	0.76 (0.68–0.82)	0.69 (0.28–0.86)	0.93 (0.86–0.97)
	N2, %TST	0.73 (0.65–0.80)	0.74 (0.56–0.84)	0.87 (0.74–0.93)	0.79 (0.61–0.89)
	N3, %TST	0.86 (0.79–0.91)	0.88 (0.83–0.91)	0.85 (0.59–0.93)	0.90 (0.79–0.95)

ICC, intraclass correlation; N1/2/3, sleep stage N1/2/3; TST, total sleep time; WASO, wake after sleep onset.
Sleep features measured via ICC, calculated assuming 2-way mixed-effects model.

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 both suspected hypersomnia and NT1) (**Table 3**).
- Waveband SUS scores were comparable or higher than those reported in the literature for 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]

Table 3. System Usability Scale (SUS) scores for Waveband versus PSG

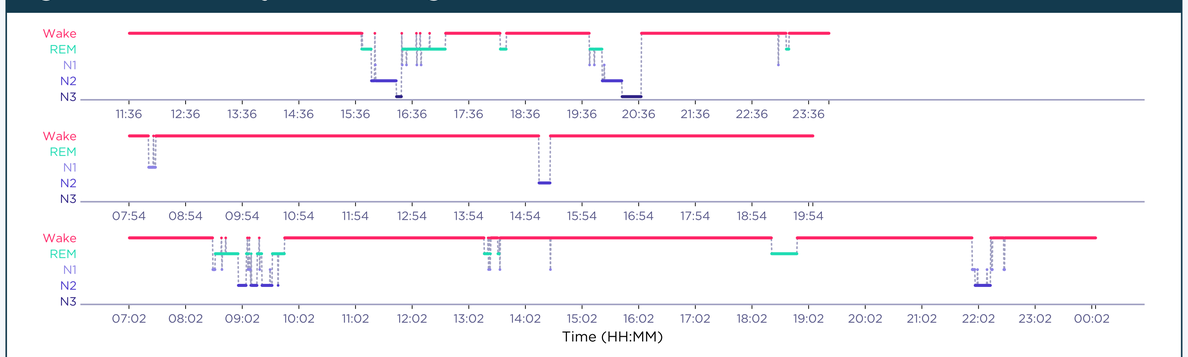
	SUS score			
	Suspected hypersomnia		NT1	
SUS	**Waveband**	**PSG**	**Waveband**	**PSG**
n	22	22	49	48
Mean (SD)	76.4 (11.2)	51.8 (16.9)	77.4 (13.7)	49.6 (19.8)
Median (min–max)	52.5–95.0	27.5–90.0	45.0–100.0	20.0–100.0
90% CI	72.3–80.5	45.6–58.0	74.1–80.7	44.8–54.4

90% CIs were calculated using a t-distribution.

At-home daytime recordings

- Example hypnograms computed from the daytime portion of the 24 hour recordings are shown in **Figure 4**, demonstrating the ability to capture sleep and nap-like events with the Waveband.

Figure 4. At-home daytime recordings



Conclusions

- **These results provide validation and feasibility data that support using Waveband to collect high-quality sleep data and quantify sleep stages in a hypersomnia population.**
- **Waveband could provide insight into diagnosis, treatment response, and disease progression.**
- **Waveband has the potential to be used at home to assess sleep and treatment response longitudinally, thereby improving data quality and collection with multiple measurements at a**

References: 1. Scammell TE. *N Engl J Med* 2015;373:2654-62. **2.** Bassetti C, et al. *Neurology* 2019;15:519-39. **3.** American Psychiatric Association. Sleep–wake disorders; narcolepsy. In: Diagnostic and Statistical Manual of Mental Disorders, 5th ed. Washington, DC: American Psychiatric Association; 2013:372-82. **4.** Sateia M, American Academy of Sleep Medicine. International Classification of Sleep Disorders, 3rd Ed. Darien, IL: AASM; 2014. **5.** Kingshott RN, Douglas NJ. *Sleep* 2000;23:1109-13. **6.** US Food and Drug Administration. 510(k) Summary for Dreem 3S [510(k) Number: K223539]. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K223539. Accessed May 2, 2025. **7.** Stephansen JB, et al. *Nat Commun* 2018;9:5229. **8.** Kortum P, Peres SC. *JMIR Hum Factors* 2015;2:e10.

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