P532

Evaluation of Dreem 3S for sleep monitoring and diagnosis in narcolepsy type 1

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Introduction

- Narcolepsy type 1 (NT1) is a chronic, rare, neurological disease, characterized by excessive daytime sleepiness, sudden muscle weakness (cataplexy), disrupted nighttime sleep, sleep paralysis, hallucinations, and cognitive difficulties.[1-3]
- NT1 diagnosis and clinical trials currently rely on in-clinic measurements of sleep using polysomnography (PSG), requiring substantial patient time and trained personnel costs.[4]
- Furthermore, in-clinic PSG is unable to capture sleep variability across nights and may not reflect a natural sleep environment.[5]
- We present results from a prospective clinical validation study investigating Dreem 3S, a US FDA–cleared at-home dry-electrode electroencephalogram (EEG) device, in participants with NT1 (NCT06531876).

Objective

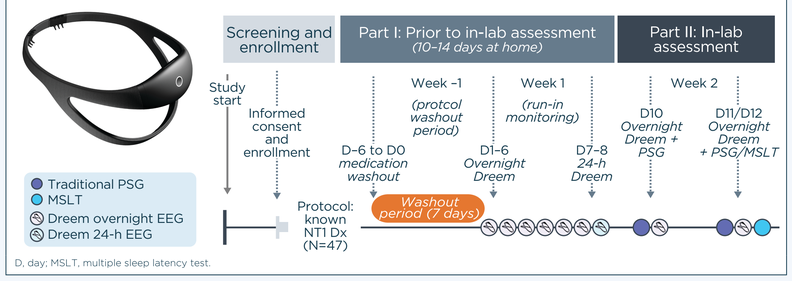
- To evaluate Dreem 3S in participants with NT1 for:
  - Compliance with multi-night at-home recording
  - Data quality in recordings made without technical intervention
  - Concordance with gold-standard in-clinic testing
  - Perceived usability versus traditional PSG.

Methods

Study design and population

- Data from 47 participants with NT1 were included in this analysis.
- Participants aged ≥18 years with a confirmed NT1 diagnosis (based on clinical symptoms and PSG/multiple sleep latency test) who were deemed safe by their treating physician to temporarily withdraw from medication 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).
- Withdrawn medications included stimulants, wake-promoting agents, antidepressants, oxybates, and pitolisant (participants could maintain ≤50% of their antidepressant and oxybate doses at investigator discretion based on comorbid mood disorders and narcolepsy symptoms).
- At home with the US FDA 510(k)-cleared Dreem 3S dry-electrode EEG headband[6] (now called Waveband), participants recorded 6 nights of sleep followed by a 24-h continuous recording period. Participants then recorded 2 nights of in-clinic PSG concurrently with Dreem 3S (**Figure 1**).
- The system usability scale (SUS), a broadly used standardized assessment of the perceived usability of a system, was collected after at-home night 6 (Dreem SUS) and after in-clinic night 1 (PSG SUS).

Figure 1. Study design



D, day; MSLT, multiple sleep latency test.

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 Dreem 3S "scorability" algorithm, which was developed and trained using Dreem EEG signals labeled as either good or bad quality by sleep experts trained in scoring Dreem EEG.
- In-clinic PSG was scored by 3 registered PSG technologists (RPSGTs). The manually scored consensus sleep staging was compared to the machine-learning–based sleep stages that Dreem 3S automatically generates. For a subset of the analysis, algorithmic results were further adjudicated by 3 RPSGTs and compared to 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 Dreem 3S sleep staging methods, defined as percentage of PSG epochs identified as wake by RPSGTs that the adjudicated Dreem 3S sleep staging also correctly identified as wake.

Results

Participants

- Demographics for 47 participants with NT1 are shown in the **Table**.

At-home compliance and data quality

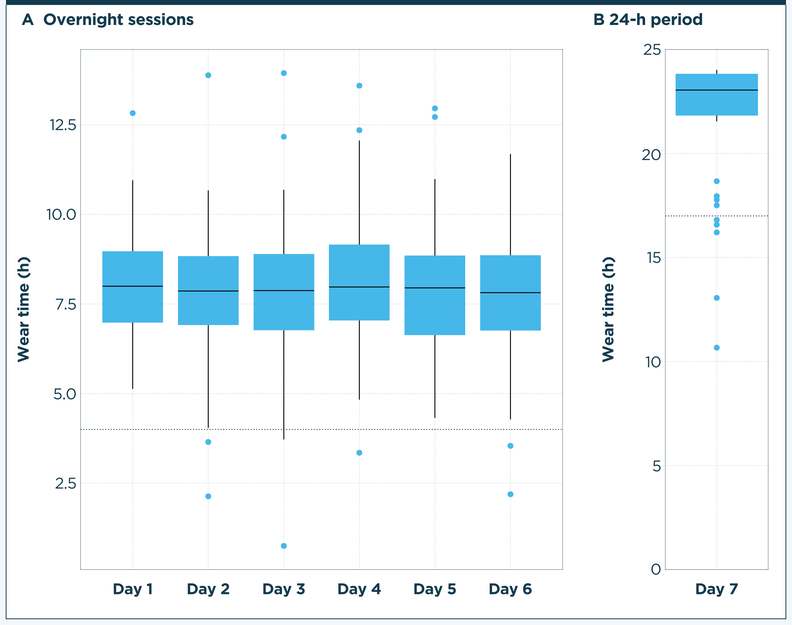
- All participants met the primary endpoint for compliance and data quality. Mean (SD) and median (range) passing nights per participant were 5.6 (0.6) and 6 (4–6), respectively.
- 89.4% of participants met the 24-h continuous recording secondary endpoint.
- Mean (SD) overnight night wear time was 7.9 (1.9) h, with an average scorable proportion of 0.99 (0.02), followed by 21.8 (3.1) h and 0.99 (0.01) during the 24-h continuous recording period (**Figure 2**).

Table. Participant demographics

	Study participants
NT1 diagnosis, n (%)*	47 (100)
with cataplexy	47 (100)
Median age (range), years	32 (19–61)
Female, n (%)	30 (64)
Race, n (%)	
Asian	1 (2)
Black/African American	12 (26)
White	31 (66)
Hispanic/Latino ethnicity, n (%)	13 (28)
Mean (SD) SOREMPs on MSLT†	2.5 (1.5)
Mean (SD) sleep latency on MSLT, min†	3.7 (2.7)

*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, HLA testing was not included but will be offered to participants in a follow-up study. †Includes n=28 participants who had primary PSG/MSLT reports or clinical summaries with all values listed.

Figure 2. At-home Dreem 3S wear time



In-clinic sleep staging

- Mean PPA for wake between the adjudicated Dreem 3S sleep staging and PSG was 84.2% (90% CI, 81.6–86.8), meeting the primary endpoint of 90% CI lower bound above 65%.
- Sleep staging agreement between adjudicated Dreem 3S and PSG was high across sleep stages (**Figure 3**; mean Cohen's kappa 0.78 [90% CI, 0.76–0.80]).
- Performance was similarly high between the unadjudicated Dreem 3S sleep staging and PSG (**Figure 4**; mean Cohen's kappa 0.76 [90% CI, 0.74–0.79]).
- The strong performance is notable, given human- and machine-based staging are challenging in people with NT1, due to unusual sleep stage transitions characteristic of NT1.[7]

Figure 3. Adjudicated algorithmic sleep staging

Expert-adjudicated stage – Dreem 3S	Expert consensus assigned stage – PSG: Wake	N1	N2	N3	REM	No consensus	PPA, % mean (90% CI)
Wake	**12,422 (86.7%)**	612 (10.4%)	542 (1.5%)	1 (0.0%)	760 (4.6%)	141 (10.3%)	84.2 (81.6–86.8)
N1	604 (4.2%)	**2,623 (44.5%)**	396 (1.0%)	0 (0.0%)	231 (1.4%)	133 (9.7%)	44.4 (41.8–47.1)
N2	488 (3.4%)	1,577 (26.8%)	**30,009 (84.7%)**	957 (7.1%)	718 (4.4%)	364 (26.5%)	84.7 (82.5–86.9)
N3	63 (0.4%)	11 (0.2%)	2,464 (7.0%)	**12,561 (92.8%)**	2 (0.0%)	62 (4.5%)	88.8 (85.4–92.2)
REM	430 (3.0%)	800 (13.6%)	1,827 (5.2%)	2 (0.0%)	**14,395 (88.0%)**	577 (42.1%)	86.6 (82.9–90.4)
No consensus	320 (2.2%)	265 (4.5%)	177 (0.5%)	14 (0.1%)	247 (1.5%)	95 (6.9%)	–
Total epochs	14,327	5,888	35,388	13,535	16,353	1,372	–

N1/2/3, sleep stage 1/2/3. Confusion matrix showing sleep staging results pooled over all participants/recordings and 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.

Figure 4. Algorithmic sleep staging

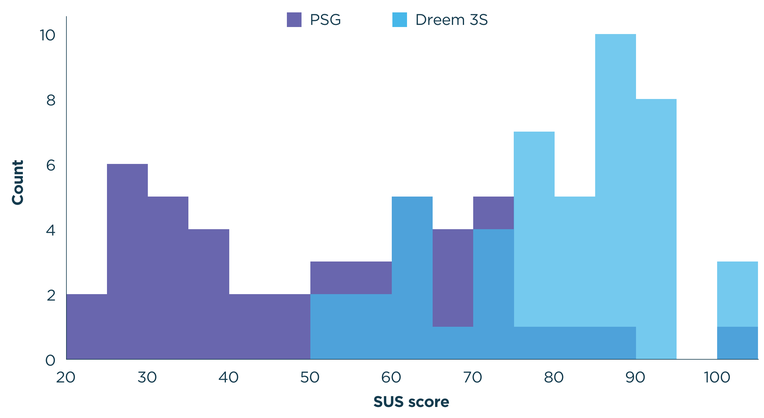
Algorithm-assigned stage – Dreem 3S	Expert consensus assigned stage – PSG: Wake	N1	N2	N3	REM	No consensus	PPA, % mean (90% CI)
Wake	**11,779 (82.2%)**	547 (9.3%)	292 (0.8%)	8 (0.1%)	472 (2.9%)	133 (9.7%)	80.3 (77.3–83.3)
N1	1,046 (7.3%)	**3,108 (52.8%)**	1,077 (3.0%)	1 (0.0%)	510 (3.1%)	237 (17.3%)	53.9 (50.1–57.8)
N2	403 (2.8%)	1,114 (18.9%)	**29,879 (84.4%)**	1,938 (14.3%)	446 (2.7%)	277 (20.2%)	84.2 (82.3–86.0)
N3	42 (0.3%)	8 (0.14%)	1,560 (4.4%)	**11,586 (85.6%)**	12 (0.1%)	46 (3.4%)	80.1 (75.6–84.6)
REM	1,057 (7.4%)	1,111 (18.9%)	2,580 (7.3%)	2 (0.0%)	**14,913 (91.2%)**	679 (49.5%)	90.4 (87.2–93.5)
Total	14,327	5,888	35,388	13,535	16,353	1,372	–

N1/2/3, sleep stage N1/2/3. Confusion matrix showing sleep staging results pooled over all participants/recordings and 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.

Dreem 3S versus PSG usability

- Dreem 3S mean SUS score of 78.5 surpassed the secondary endpoint target of 68.
- SUS scores were consistently higher for Dreem 3S than PSG, and the respective 90% CIs were nonoverlapping (**Figure 5**).

Figure 5. Dreem 3S versus PSG SUS scores



	PSG (n=45)	Dreem 3S (n=47)
Mean (SD)	50.6 (19.9)	78.5 (13.0)
90% CI	45.6–55.5	75.3–81.6
Median (range)	53 (20–80)	80 (50–100)

90% CIs were calculated using a t-distribution.

Conclusions

These results support the use of Dreem 3S to collect high-quality sleep data and quantify sleep stages in participants with NT1 in both at-home and in-clinic settings.

Participants prefer at-home Dreem 3S versus in-clinic PSG recording.

Dreem 3S has potential to be used for monitoring sleep longitudinally in a patient's home, thereby improving data quality and collection with multiple measurements at a lower burden and cost.

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