Effect of a prescription digital therapeutic for chronic insomnia on daytime sleepiness: Results from the real-world DREAM study

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Introduction

The real-world DREAM study assessed the benefits of a tailored prescription digital therapeutic for chronic insomnia. An exploratory aim was to evaluate changes in sleepiness across treatment, as well as at post-treatment follow-up periods.

Digital Cognitive Behavioral Therapy for Insomnia (dCBT-I) delivers gold-standard treatment for chronic insomnia. However, concerns about increased sleepiness during the sleep restriction phase may limit its use, especially in safety-sensitive occupations like those regulated by the Department of Transportation (DOT). Despite its clinical effectiveness[1,2] and demonstrated positive primary outcomes in real-world settings[3], further investigation of exploratory outcomes is needed to identify which individuals are most suitable for these therapeutics.

This study examined the impact of dCBT-I on subjective daytime sleepiness, as measured by the Epworth Sleepiness Scale (ESS)[4], across the 9-week treatment, as well as at post-assessments at Day 63, 6, 12, and 18-months.

Methods

This prospective, single-arm, pragmatic clinical study (DREAM; USA; N=1565; ages 22-75; ClinicalTrials.gov: NCT04325464) evaluated real-world data from participants with chronic insomnia. The intervention was a digital CBT-I (dCBT-I) program delivered over 9 weeks via the Somryst® [1,2] mobile application.

This FDA-cleared therapeutic included six interactive treatment Cores based on CBT-I principles, with sleep restriction implemented between Cores 2 and 3. The Epworth Sleepiness Scale (ESS) was administered at the start of each Core, and daily sleep diaries completed over the previous seven days were used to personalize sleep restriction and consolidation recommendations. Validated patient-reported outcomes were collected at baseline, before each treatment Core, immediately post- intervention, and at 6, 12, and 18-month follow-up assessments.

1,565 adults with chronic insomnia met inclusion criteria and were granted access to treatment. The cohort included adults from all 50 US states and Washington, DC, with a mean age of 46 (SD = 13.28) and were predominantly female (74.7%). Descriptive characteristics of this cohort in addition to additional characteristics of the pre-screening respondents of interest are presented in **Table 1.**

Table 1*: Participant characteristics throughout screening process

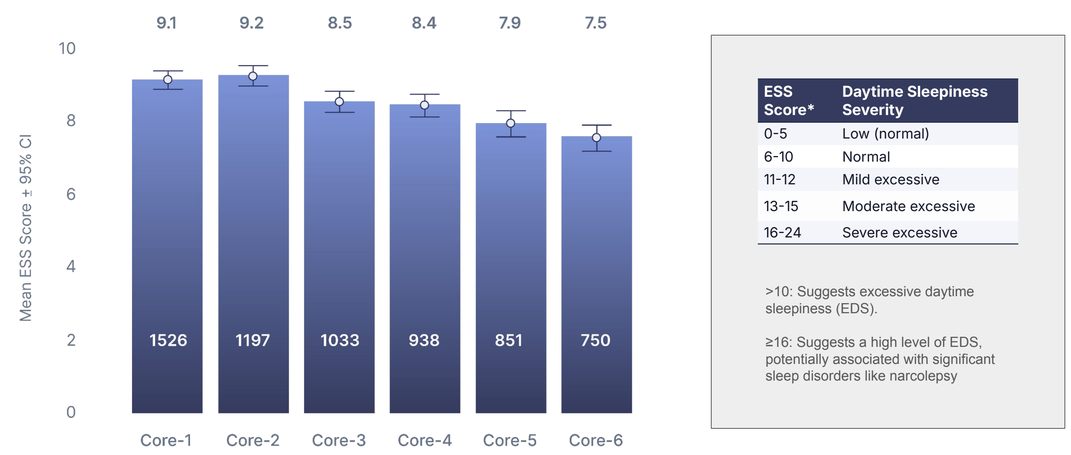
Category	N	Mean	SD
Length of sleep difficulties (months)	8521	161.1	137.05
Est. sleep duration (hours/night)	8540	4.9	1.44
Past month sleep problems (nights/week)	8540	5.9	1.31
Baseline ISI	1668	19.3	4.07
Age	1565	46	13.28
Gender	N	%	-
Female	1129	76.6%	-
Male	326	22.1%	-
Unknown	10	0.7%	-
Missing	8	0.5%	-
States Represented	**50 States + DC**		

**Sleep characteristics collected at pre-screening. Baseline ISI collected at screening. Age, gender, and states represented collected after screening, before accessing the digital therapeutic.*

Results

As shown in the figure below, mean ESS scores remained stable or declined following the initiation of sleep restriction after Core 2 (measured at the start of Core 3): Core 1 [9.1], Core 2 [9.2], Core 3 [8.5], Core 4 [8.4], Core 5 [7.9] and Core 6 [7.5]. These results suggest that, contrary to concerns, sleepiness did not increase with sleep restriction and instead showed a downward trend throughout the intervention.

***Figure 1*: Mean Epworth Sleepiness Scores During Treatment**



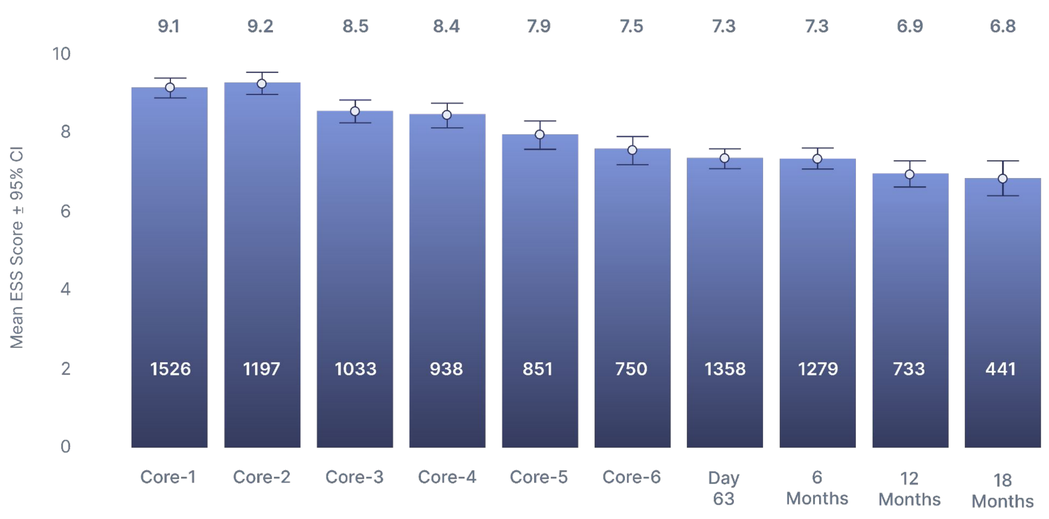
ESS Score*	Daytime Sleepiness Severity
0-5	Low (normal)
6-10	Normal
11-12	Mild excessive
13-15	Moderate excessive
16-24	Severe excessive

>10: Suggests excessive daytime sleepiness (EDS).

≥16: Suggests a high level of EDS, potentially associated with significant sleep disorders like narcolepsy

Relative to Core 1, the mean ESS score differences at subsequent Cores were: Core 3 (-0.66, $p < 0.001$), Core 4 (-0.81, $p < 0.001$), Core 5 (-1.37, $p < 0.001$), and Core 6 (-1.84, $p < 0.001$).

***Figure 2*: Mean Epworth Sleepiness Scores Over Time**



Daytime sleepiness was also assessed at follow-up. Compared to the Core 1 baseline mean of 9.14, ESS scores continued to decline to 7.3 at Day 63, 7.3 at 6-Months, 6.9 at 12-Months, and 6.8 at 18-Months ($p<0.0001$ for all). These results indicate a sustained reduction in subjective sleepiness over time, even following the active dCBT-I treatment period.

Limitations: Despite positive outcomes, limitations include a lack of a comparator group and limited data due to early study termination.

Conclusions

Evaluation of Epworth Sleepiness Scale (ESS) scores throughout the dCBT-I intervention revealed a significant decrease in subjective daytime sleepiness, including during the sleep restriction phase—often considered a barrier for some patients, especially in safety-sensitive settings. Instead, participants experienced progressive reductions in ESS scores across treatment Cores and continued improvements over time. These findings support dCBT-I as a viable and effective treatment option, warranting further exploration of its applicability in broader patient populations.

Future directions: Examine subsets of participants with more extreme ESS scores and changes in ESS scores over time.

References: **1)** Morin, C. M. (2020). Profile of Somryst prescription digital therapeutic for chronic insomnia: Overview of safety and efficacy. Expert Review of Medical Devices, 17(12), 1239–1248. **2)** US Food and Drug Administration. Somryst 510(k) Decision Summary. March 23, 2020. **3)** Thorndike, F. P., et al. (2024). Effect of a prescription digital therapeutic for chronic insomnia on post-treatment insomnia severity, depression, and anxiety symptoms: Results from the real-world DREAM study. Frontiers in Psychiatry, 15, 1450615. **4) J**ohns, M. W. (1991). A new method for measuring daytime sleepiness: The Epworth Sleepiness Scale. Sleep, 14(6), 540–545.

Conflict of Interest Disclosures: C.H., R.H., S.E., F.T., and H.R. are employees of Nox Health, Inc., which now distributes the therapeutic as part of its comprehensive care program. R.G. and L.R. serve as research consultants for Nox Health. L.R. and F.T. also hold equity in a company that originally licensed the therapeutic from the University of Virginia.

Clinical Trial #: NCT04325464 (clinicaltrials.gov). Primary outcomes have been published in reference 3 (Thorndike FP et al).