

Digital Cognitive-Behavioral Therapy for Insomnia: Positive Results Maintained at 18- and 24-months After Treatment

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Introduction

Insomnia is one of the most prevalent sleep disorders (10-15% of adults), but few receive first-line therapy (Cognitive-Behavioral-Therapy for Insomnia, CBT-I). Although it is an effective treatment for insomnia and can improve co-occurring chronic conditions, barriers limit access to CBT-I care.

FDA-cleared digital therapeutics represent one innovative approach to overcoming limitations of traditional care models and increasing access to evidence-based care. Even so, the durability of long-term effectiveness of digital CBT-I (dCBT-I) in real-world settings remains unclear.

Objective: The purpose of this study was to assess the durability of the real-world impact of an FDA-cleared dCBT-I therapeutic (Somryst®)^{1,2} on insomnia severity, depression, and anxiety symptoms at 18- and 24-months follow-up. Six and 12-month outcomes were previously published.³

Methods

This prospective, single-arm pragmatic clinical trial investigated real-world outcomes among adults aged 22-75 with chronic insomnia. Patients engaged in a 6 to 9-week digital cognitive behavioral therapy for insomnia (dCBT-I) intervention administered via the Somryst® mobile application. The therapeutic consists of 6 treatment lessons or Cores that deliver the key mechanisms of CBT-I (e.g., sleep restriction and consolidation; stimulus control; cognitive restructuring).

Of the 1891 patients screened for participation, 1752 satisfied inclusion criteria and completed the Insomnia Severity Index (ISI) at baseline, thereby constituting the full study cohort (Table 1). Demographic data on the sample who completed the 18-month and 24-month assessments are included in Table 1 for increased context. Insomnia severity was assessed using the Insomnia Severity Index (ISI) at baseline, at the beginning of Cores 1-6 of treatment, end of treatment (EOT), and 6, 12, 18, and 24 months post-treatment.

Depression and anxiety symptoms were measured at Cores 1, 3, and 5 of treatment and at each assessment period using established measures: the 8-item Patient Health Questionnaire (PHQ-8) and the 7-item Generalized Anxiety Disorder scale (GAD-7). Longitudinal changes were analyzed using MMRM with time as a fixed effect and patients as a random intercept.

Table 1: Patient characteristics

Category	Full Cohort (N=1752)	18-Month Cohort (N=918)	24-Month Cohort (N=266)
Age (Yrs); Mean (SD)	48.2 (13.86)	50.1 (12.81)	48.5 (13.50)
Sex, % (n)			
Female	77.1% (1317/1708)	78.3% (711/908)	67.3% (177/263)
Male	22.9% (391/1708)	21.7% (197/908)	32.7% (86/263)
Number of States (+DC)	51	51	40
Baseline ISI Score; Mean (SD)	19.3 (4.16)	19.1 (3.98)	19.0 (4.09)
Baseline PHQ-8 Score; Mean (SD)	12.3 (5.22)	11.7 (5.00)	11.1 (4.76)
Baseline GAD-7 Score; Mean (SD)	10.0 (5.58)	9.5 (5.51)	9.5 (5.24)

**Baseline ISI collected at screening or Core 1 (higher value used). Baseline GAD-7 and PHQ-8 were collected at Core 1. Age, gender, and state data were collected after eligibility was confirmed and before accessing the digital therapeutic.*

Insomnia Severity. The mean (sd) baseline ISI was 19.3 (4.17), 31.1% (545/1752), indicating severe insomnia. This decreased to 11.0 (6.17) at the end of treatment assessment (9 weeks after treatment initiation). Of these, only 5.5% (73/1331) continued to report severe insomnia. At the end of 18 months, 437 out of 918 who reached the assessment completed it, scoring 12.4 (5.57) on the ISI. At the end of 24 months, 103 out of 266 who reached the assessment completed it, scoring 12.0 (6.26). Changes from baseline became significant by Core 2. Largest improvements were seen among patients who completed Core 6 (p<0.001). Improvements were maintained for the full two years (Figure 1a).

ISI Responders and Remitters. At the end of treatment, 50.9% (677/1331; 95%CI:48.2-53.5%) of patients met responder criteria, defined as a ≥7-point reduction in ISI. Responder rates were 41.2% (180/437; 95%CI:36.7-45.9%) at 18 months and 45.6% (47/103; 95%CI:36.3-55.2%) at 24 months (Table 2).. Remission, defined as ISI <8, was achieved by 32.2% (428/1331; 95%CI:29.7-34.7%) at the end of treatment, 21.3% (93/437; 95%CI:17.7-25.4%) at 18 months, and 32.0% (33/103; 95%CI:23.8-41.6%) at 24 months (Table 2).

Among individuals completing all six treatment cores, outcomes were superior: 64.1% (467/729; 95%CI:60.5-67.5%) were responders at end of treatment. Remission rates reached 45.0% (328/729; 95%CI:41.4-48.6%), 28.3% (73/258; 95%CI:23.1-34.1%), and 38.8% (26/67; 95%CI:28.0-50.8%) at EOT, 18-month, and 24-month follow-up, respectively.

In this real-world study, dCBT-I (Somryst) was associated with sustained improvements in insomnia severity, depressive symptoms, and anxiety symptoms out to 24 months post-treatment. These findings are consistent with RCTs of dCBT-I and demonstrate durability in real-world settings. While funding prohibited the full cohort from being assessed at the 2-year assessment, the study was well-powered to detect treatment effects at 24-months. Future research should examine how sleep improvements relate to additional health outcomes and potential changes in healthcare utilization and economic impact.

Results

Figure 1: Insomnia, depression, and anxiety symptom severity over 24 months

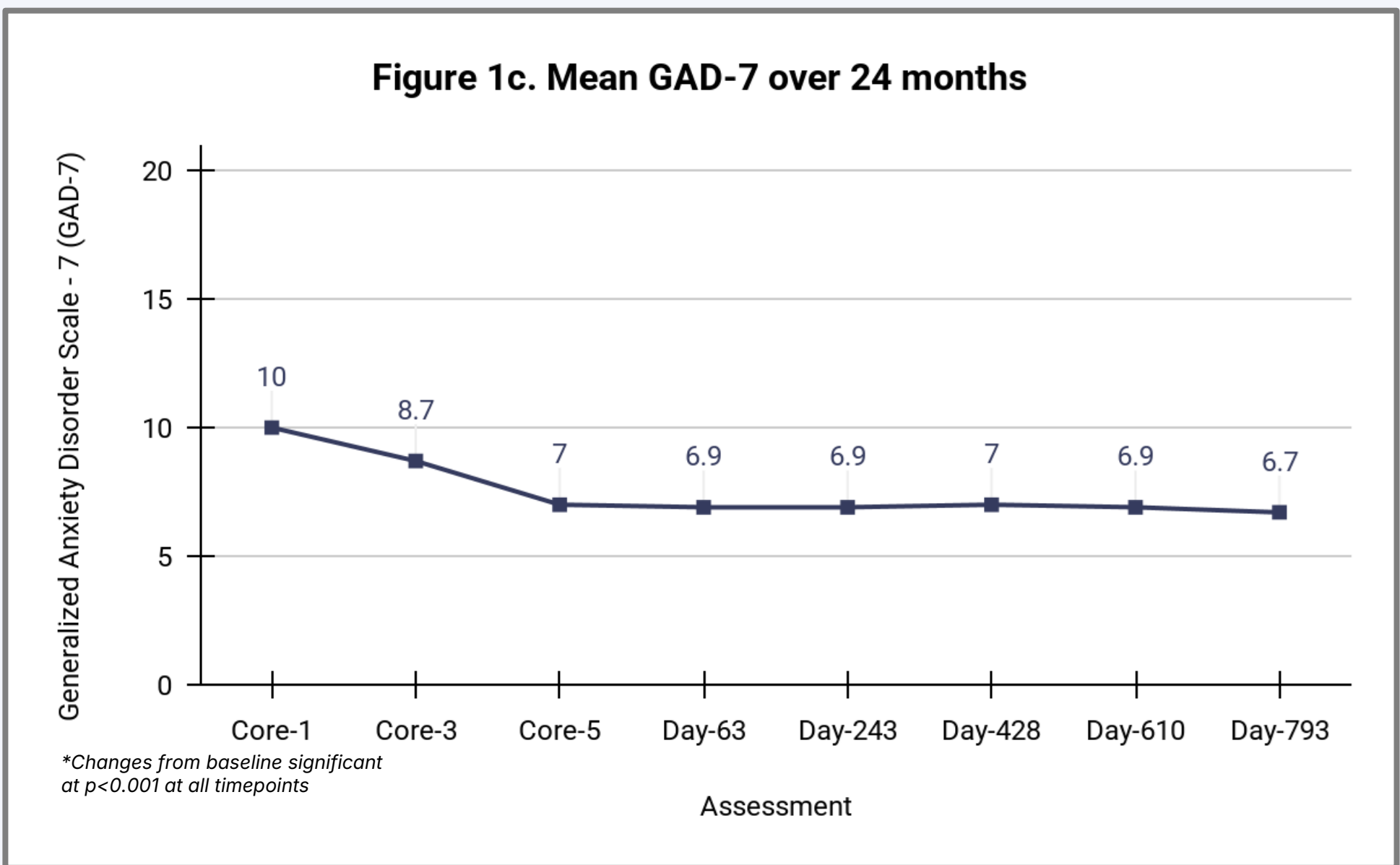
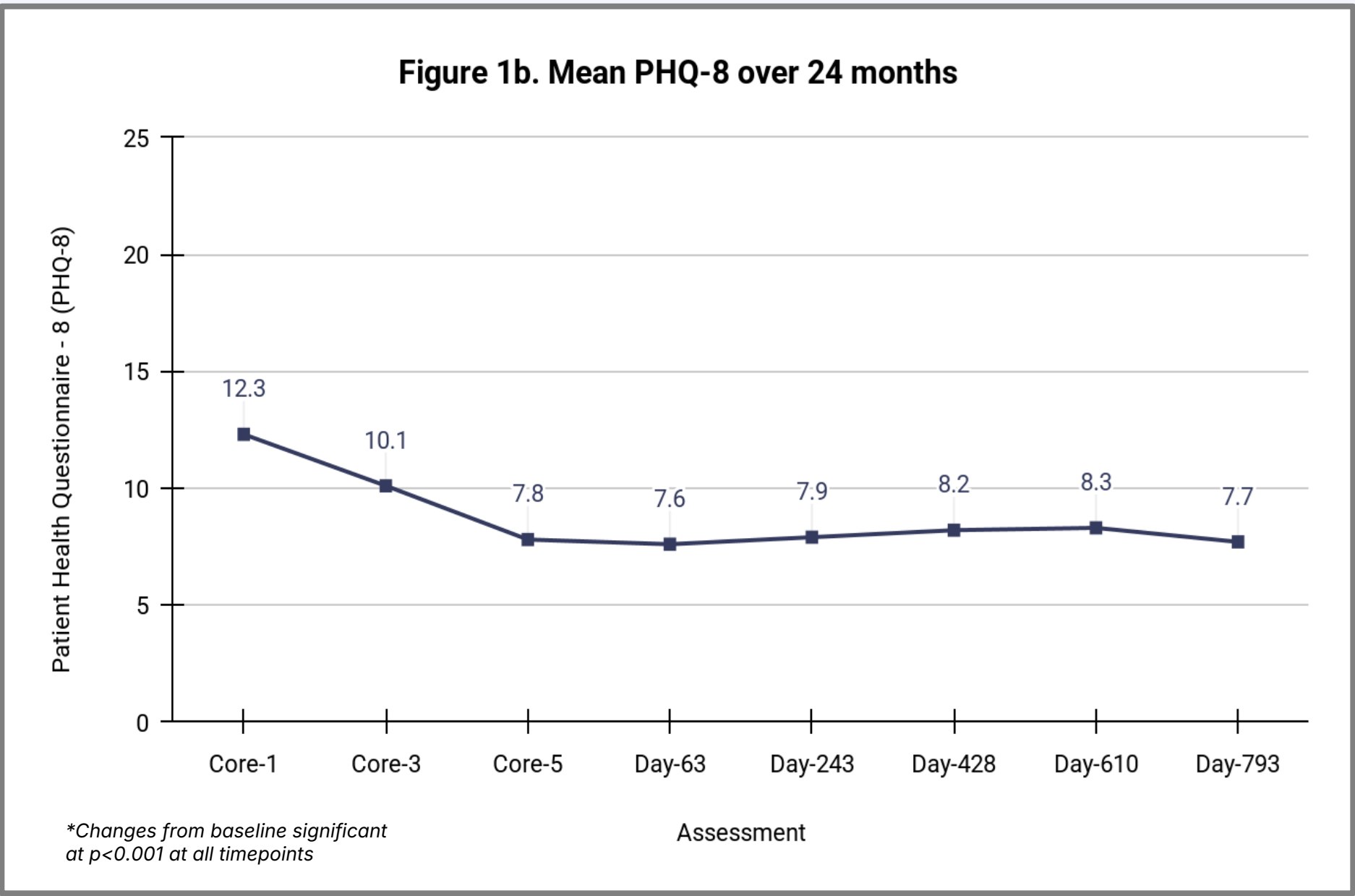
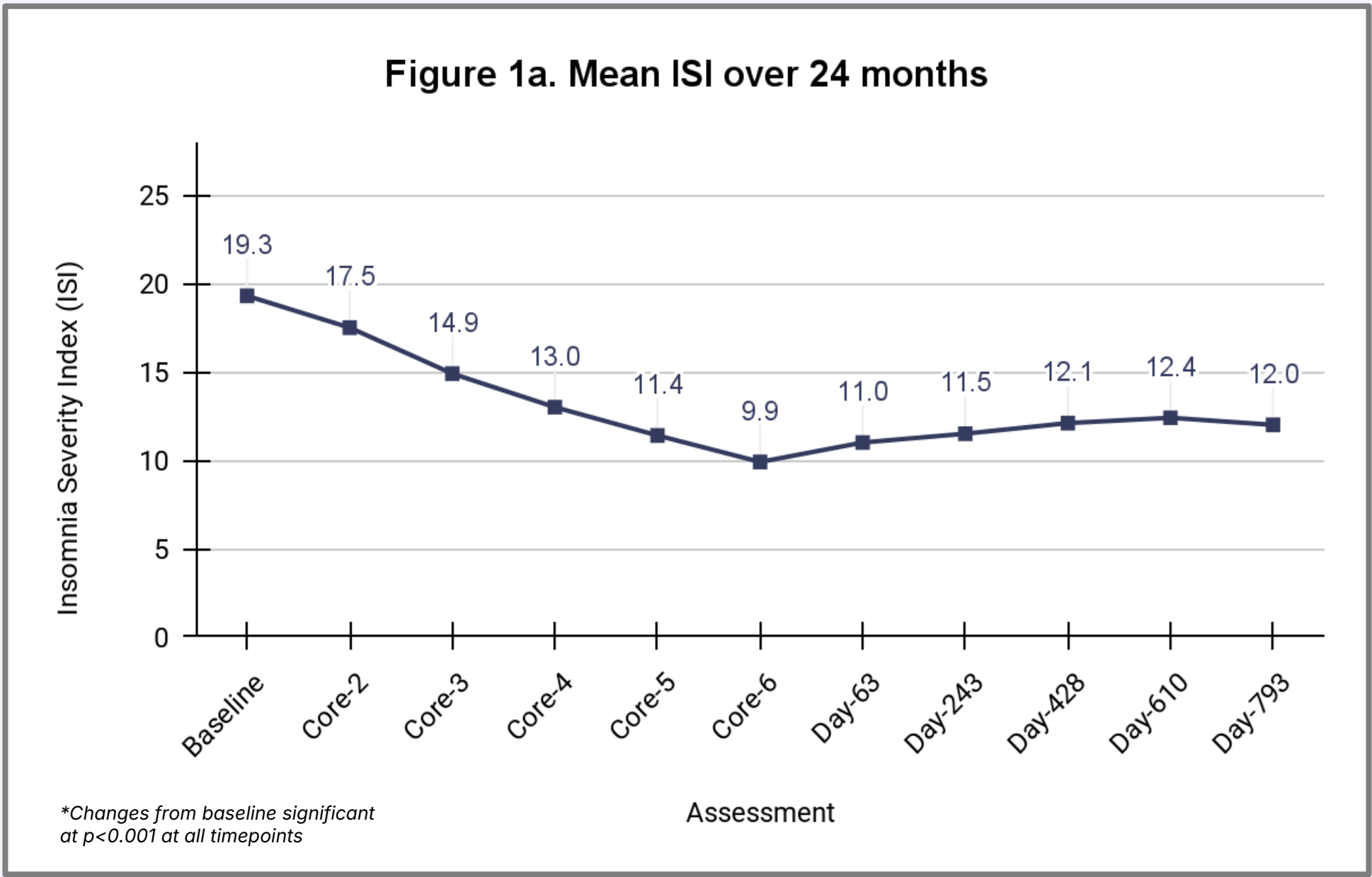


Table 2: ISI response and remission rates by assessment

Assessment	Day 63	Day 243	Day 428	Day 610	Day 793
% ISI Responders	50.9%	48.8%	42.2%	41.2%	45.6%
% ISI Remitters	32.2%	29.0%	25.1%	21.3%	32.0%

Table 3. ISI, PHQ_8, and GAD-7 scoring

ISI Severity Scoring	PHQ-8 Severity Scoring	GAD-7 Severity Scoring
22-28 Clinical insomnia (severe)	20-24 Severe	15-21 Severe Anxiety
15-21 Clinical insomnia (moderate severity)	15-19 Moderately severe	10-14 Moderate Anxiety
8-14 Sub-threshold insomnia	10-14 Moderate	5-9 Mild Anxiety
0-7 No clinically significant insomnia	5-9 Mild	0-4 Minimal Anxiety
	0-4 None/Minimal	

Depression and Anxiety Severity. Depressive symptoms, measured by PHQ-8, declined from a mean of 12.3 (5.24) (moderate depression) at baseline to 7.6 (5.50) at EOT, with values maintained at 8.3 (5.34) and 7.7 (5.06) at 18 and 24 months, mild severity, respectively (Figure 1b). Anxiety symptoms, assessed by GAD-7, decreased from 10.0 (5.59) (moderate anxiety) at baseline to 6.9 (5.33) , 6.9 (5.24), and 6.7 (5.34) at EOT, 18, and 24 months post treatment, mild severity, respectively (Figure 1c).

Adherence and Effect Sizes. To place changes in context, effect size reduction in insomnia severity was large from baseline to EOT (d = 1.5 (1.4-1.6)), to 18 months (d = 1.3 (1.1-1.4)), and to 24 months (d = 1.1 (0.9-1.4)). For patients who completed all 6 cores, the effect sizes were larger (d = 1.9, 1.3, and 1.4, respectively).

Conclusions

References: 1. Morin CM. Profile of Somryst prescription digital therapeutic for chronic insomnia: Overview of safety and efficacy. *Expert Rev Med Devices*. 2020;17(12):1239-1248. 2. US Food and Drug Administration. *Somryst 510(k) Decision Summary*. March 23, 2020. 3. Thorndike FP, et al. 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. *Front Psychiatry*. 2024;15:1450615. **Conflict of Interest Disclosures:** F.P.T., J.C.O., S.M.E., A.M.S., H.P.R. are all employees of Nox Health, which makes Somryst available commercially. J.M.O. was PI of the trial. L.M.R., F.P.T., and C.M.M. report having equity ownership in BeHealth Solutions, L.L.C., the company that was originally established to make available digital health products, including Somryst. L.M.R., C.M.M., R.W.G., E.M.W. are paid consultants of Nox Health. C.M.M. has also served on advisory boards for Eisai, Merck, & Phillips; served as consultant for Eisai, Merck, Sunovion, & Weight Watchers; received research support from Eisai, Idorsia, Canopy Health, & Lallemand Health. E.M.W.'s institution has received research funding from the AASM Foundation, Dept. of Defense, Merck, NIH/NIA, ResMed, the ResMed Foundation, and the Sleep Research Society Foundation. E.M.W. has served as a scientific consultant to Axsome Therapeutics, DayZz, Eisai, EnsoData, Idorsia, Merck, Primasun, Purdue, and ResMed and is an equity shareholder in WellTap. These companies had no role in the preparation of this poster. **Support:** Study was initially funded by Pear Therapeutics and later funded by Nox Health who supported this analysis. **Clinical Trial #:** NCT04325464 (clinicaltrials.gov). Primary outcomes have been published in reference 3 (Thorndike FP et al).