

Delivering Digital Cognitive Behavioral Therapy for Insomnia within a Real-World, Comprehensive Telehealth Sleep Care Management Program: Initial Findings

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Introduction

Insomnia is the most common adult sleep disorder and cognitive behavioral therapy for insomnia (CBT-I) is considered the first-line treatment.^{1,2} Digital delivery of CBT-I (dCBT-I) is supported by evidence from randomized clinical trials, but real-world clinical effectiveness remains less established.

Study Objective: The purpose of this study was to determine the effects of dCBT-I delivered within a US-based comprehensive telehealth sleep care management program. We hypothesized that dCBT-I would be associated with reductions in insomnia severity in real-world patients, with greater improvements among those who completed the intervention.

Methods

Study Design and Participants

This study was a retrospective analysis of real-world clinical data from patients who received ongoing clinical care in a comprehensive, value-based sleep telehealth service between January 2025 and February 2026. All patients were diagnosed with insomnia by a board-certified sleep physician during an initial telehealth visit and were offered 12-month access (i.e., eligible for renewals) to an FDA-cleared prescription digital therapeutic dCBT-I program (Somryst® [K191716]). Patient support was provided remotely (phone or secure messaging) by a physician-led care team trained to address both technical and clinical issues.

Digital CBT-I Program

Patients engaged in the digital CBT-I intervention administered via the Somryst® mobile application over 9 weeks. The program is automated and consists of 6 treatment sessions (“Cores”) that deliver the key components of CBT-I (see Table 1).

Table 1. dCBT-I Treatment Components by Core

	Core 1	Core 2	Core 3	Core 4	Core 5	Core 6
Treatment Components	Sleep Education	Sleep Restriction	Stimulus Control	Cognitive Restructuring	Sleep Hygiene and Education	Relapse Prevention

Measures

Insomnia Severity Index (ISI): Primary outcome measure administered at the beginning of each Core with Core 1 serving as baseline. The ISI was also used to determine remission (ISI < 8) and response (ISI reduction from baseline to treatment ≥ 7).

Sleep Diary Data: Sleep Efficiency (SE), Sleep Onset Latency (SOL), and Wake After Sleep Onset (WASO) were collected daily and averaged across the week.

Patient Health Questionnaire-8 (PHQ-8): Measure of depressive symptoms administered at Core 1 (baseline), Core 3, and Core 5.

Data Analysis

Paired samples t-tests evaluated changes in outcomes from baseline to each Core completed (including contents and questionnaires). Additional t-tests compared completers (all 6 cores) vs non-completers (< 6 cores), and chi-square tests compared treatment response and remission rates between groups.

Table 2. Sample Characteristics

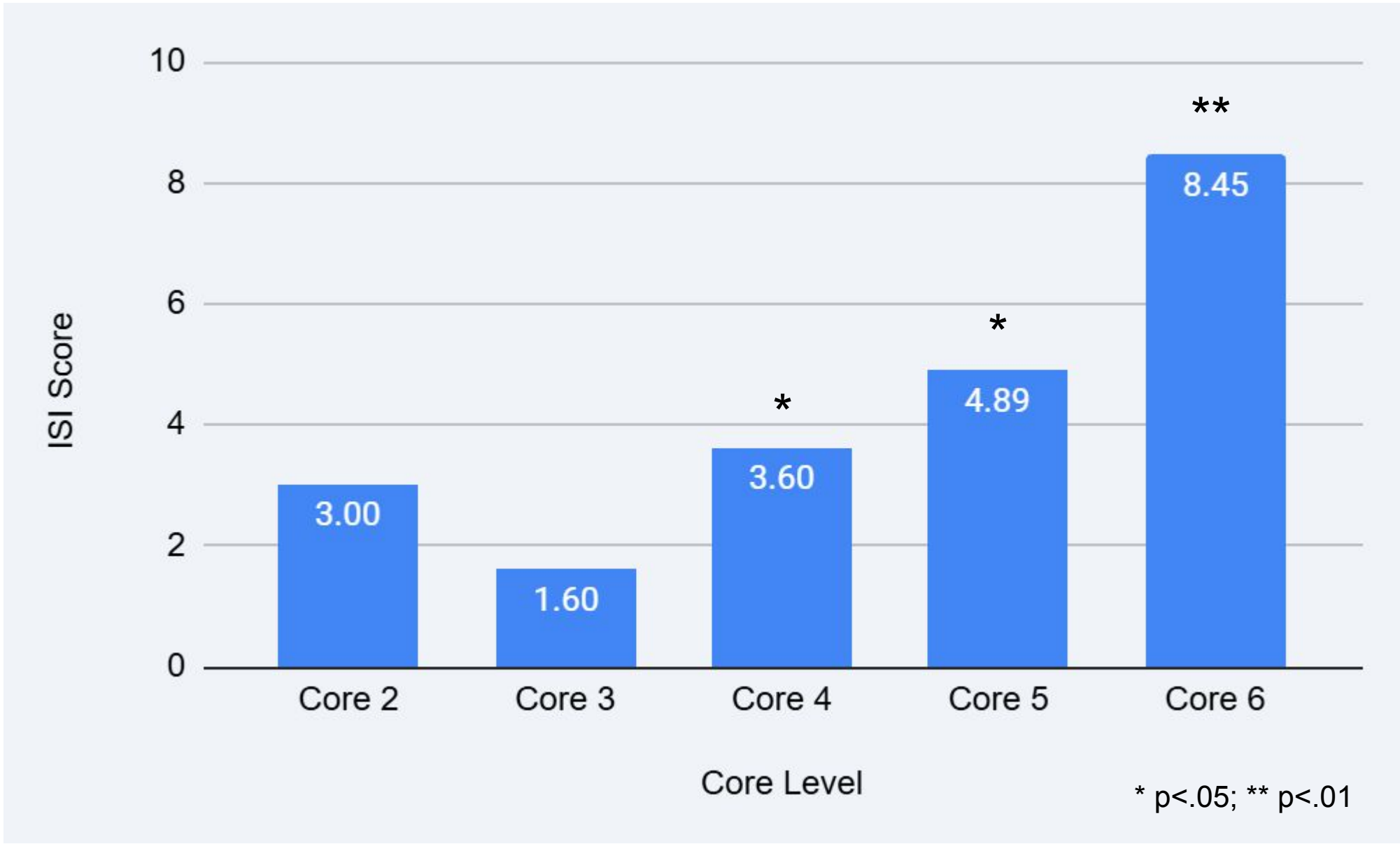
Characteristic	Total (n=74)
Age (Mean, range)	51.85 years (22 – 69 years)
Race (n, %)	
African American	8 (10.81%)
Asian	3 (4.05%)
Caucasian	31 (41.89%)
Hispanic	5 (6.76%)
Not provided	27 (36.49%)
Gender (n, %)	
Male	22 (29.73%)
Female	48 (64.86%)
Unknown / Unspecified	4 (5.41%)

Results

Core Completion

Within-subjects and relative to baseline, insomnia severity was reduced with each Core completed in a general dose-response pattern. Statistically significant changes (p<.05) emerged at Core 4 and persisted through Core 6 (Figure 1).

Figure 1. ISI Change Score by Core Completed



Significant improvements in sleep parameters were observed by Core 6 for SE, SOL, and WASO; SE and WASO also showed significant improvement by Core 5. PHQ-8 scores showed significant improvement at Core 4 and Core 6 (Table 3).

Table 3. Clinical Outcomes by Completion Status

Outcome Measure	Parameter	Core 3 n = 11	Core 4 n = 10	Core 5 n = 9	Core 6 n = 42
Sleep Efficiency (%)	Mean Change	+1.19%	+4.60%	+11.78%	+12.95%
	p-value	0.812	0.22	0.041*	<.001*
Sleep Onset Latency (SOL, min)	Mean Change	-4.54	-13	-28.89	-26.14
	p-value	0.655	0.147	0.054	<.001*
Wake After Sleep Onset (WASO, min)	Mean Change	-1.37	-7	-31.11	-27.33
	p-value	0.902	0.38	0.038*	<.001*
PHQ-8 Score	Mean Change	+0.73	-2.7	-0.22	-3.76
	p-value	0.618	0.048*	0.925	<.001*

* p<.05

Completers vs Non-Completers

Compared to non-completers, patients who completed all 6 Cores reported significantly greater improvements on all outcome variables (Table 4). Furthermore, completers demonstrated significantly greater rates of response (69.0% vs 31.3%, p<.01) and remission (52.4% vs 18.8%, p<.01).

Table 4. Clinical Outcomes by Completers vs Non-Completers

Variable	Completers (N=42)	Non-Completers (N=32)	p-value	Cohen's d
ISI Change	8.45	3.25	<.001*	1.13
SE % Change	12.95%	5.34%	0.003*	0.73
SOL Change	26.14	10.37	0.032*	0.51
WASO Change	27.33	9.28	0.010*	0.62
PHQ-8 Change	3.76	1.16	0.013*	0.60
ISI Response	69.00%	31.30%	0.0028*	
ISI Remission	52.40%	18.80%	0.0067*	

Note: ISI Response = Change from Baseline ISI ≥ 7; ISI Remission = ISI < 8 at last core completed. * p<.05

Conclusions

This study adds preliminary real-world evidence that dCBT-I delivered within a fully-connected value-based sleep service is associated with improvements in insomnia severity, sleep parameters, and depressive symptoms.

Statistically significant benefits were observed in Cores 4 and 5 and were greatest among patients who completed all 6 Cores.

Limitations: The naturalistic design lacked randomization and a control condition, limiting causal inference. Concurrent treatments may also contribute to observed improvements. The limited sample could also allow for selection/attrition bias.

References:

1. Edinger JD, Arnedt JT, Bertisch SM, et al. Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2021;17(2):255-262. doi:10.5664/jcsm.8986
2. Qaseem A, Kansagara D, Forciea MA, Cooke M, Denberg TD. Management of chronic insomnia disorder in adults: a clinical practice guideline from the American College of Physicians. *Ann Intern Med.* 2016;165(2):125-133. doi:10.7326/M15-2175

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