Comparing adherence for a prescription digital therapeutic for insomnia across controlled and real-world settings

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Introduction

Digital Cognitive Behavioral Therapy for Insomnia (dCBT-I) offers scalable first-line treatment versus face-to-face care, but a potential trade-off is lower treatment adherence. In clinical trials, adherence rates to dCBT-I have been variable, and there is no defined standard for acceptable adherence to dCBT-I. Further, the generalizability of adherence data from clinical trials to real-world settings is unclear.

Objective

This study compared adoption and adherence data from two randomized controlled trials submitted to the FDA with real-world adherence data from the FDA-authorized digital therapeutic delivering CBT-I (Somryst).[1]

Methods

The full study protocol was previously published.[2] Adoption and adherence data were derived from a prospective, single-arm, pragmatic clinical study (DREAM [USA; N=1565, age ≥18 years]). These data were compared to clinical trial adherence data derived from two RCTs[3,4] previously submitted to FDA as part of its authorization (RCT-1 [USA; N=151, age 21-65 years] and RCT-2 [Australia; N=574, age 18-64 years]).

Adherence was defined as the percentage of participants with dCBT-I access who completed each treatment Core. In order to improve adherence, the therapeutic automatically reminded users to complete treatment via push notifications. Study team members also sent manual emails to remind participants of **procedures to collect outcome data** during the study.

Treatment Cores

The dCBT-I intervention includes 6 treatment Cores to be completed over a 9-week period. Each Core is made available seven days after the completion of the previous Core. Sleep Diaries are encouraged throughout program use but must be completed between Cores 1 and 2 in order to establish sleep restriction parameters.

Demographics

		RCT-1 (N = 151)	RCT-2 (N = 574)	DREAM (N = 1565)
AGE	mean (SD)	44 (11.3)	43 (12.2)	46 (13.3)
GENDER	Female	68.2%	73.5%	76.6%
	Male	31.8%	26.5%	22.1%
	Unknown	-	-	1.2%
ISI SCORE	mean (SD)	17.0 (4.0)	15.9 (4.2)	19.3 (4.1)

Results

FIGURE 1: Treatment initiation:

Of the 1668 adults with chronic insomnia who entered the screening process and received access to the digitally delivered treatment, **1565 (93.8%) initiated treatment (started Core 1).**

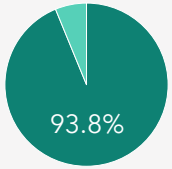


FIGURE 2: Treatment adoption:

Adoption was also high, with nearly **90% of participants** (1404/1565) **completing the first treatment Core**, in line with the results from the previous RCTs.

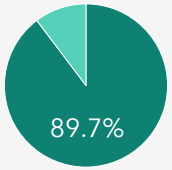
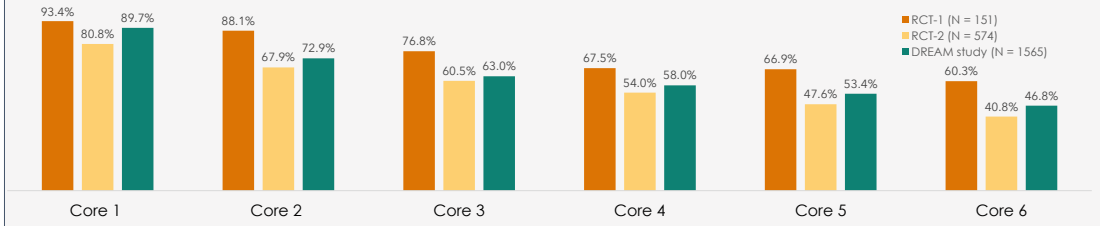


FIGURE 3: Treatment adherence and completion:

- Just over half of patients (58%) adhered and were exposed to all the key cognitive and behavioral components of treatment, **defined as completing at least through Core 4**. This rate is again in line with that observed in the two RCTs submitted to the FDA.
- When defined as **completing all six treatment Cores**, the completion rate is nearly 50%, again falling between the values observed in the two RCTs reviewed by the FDA.



Key Takeaways

- Adherence to a digital CBT-I solution outside of the controls of an RCT remains consistent with numbers observed in the RCTs submitted to the FDA for authorization supporting the generalizability of adherence data from RCTs and potential opportunities to increase adherence early in treatment.
- Digital therapeutics provide an opportunity to understand the patient journey in more detail, noting when and where patients may discontinue treatment.

Next Steps

- Determining when and how to intervene with patients who fail to continue in order to determine how to best utilize clinicians and care managers.
- Examining the clinical outcomes observed with adherent and non-adherent patients.
- Defining acceptable standards for adherence to dCBT-I in the real world.
- Showing changes in insomnia severity and related sleep metrics from baseline to months following intervention completion.

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