Digital CBT-I is Associated with Meaningful, Sustained Reductions in Depression and Anxiety Among those with Clinically Significant Baseline Symptoms

Frances P. Thorndike[1], Charles M. Morin[2], Joseph M. Ojile[3], Lee M. Ritterband[4], Robert W. Gerwein[5], Jason C. Ong[1], Aleena M. Sange[1], Samantha M. Edington[1], Rebecca M. Hankla[1], Emerson M. Wickwire[6], Heidi D. Riney[1]

[1] Nox Research, Nox Health llc., Alpharetta, GA, United States. [2] Laval University, Quebec, CA; [3] Clayton Sleep Institute, St. Louis, MO, USA; [4] University of Virginia School of Medicine, Charlottesville, VA, USA; [5] Independent Biostatistician, Newington, CT, USA; [6] University of Maryland School of Medicine, Baltimore, MD, US

Presented at SLEEP 2026, Baltimore, Maryland, USA

Introduction

Previous studies found that Cognitive-Behavioral-Therapy for Insomnia (CBT-I) can improve psychological functioning among people with insomnia and comorbid depression/anxiety.[1,2] However, the following knowledge gaps remain:

- It is unclear if these findings can generalize to real-world delivery of digital CBT-I.
- It is unknown if these effects are sustainable in the real world.

Study Aims

To examine whether real-world delivery of dCBT-I can improve psychological functioning with regards to mood and anxiety symptoms for individuals who enter treatment with clinically significant distress.

Methods

Study Design and Participants

A prospective, single-arm pragmatic clinical trial among adults aged 22-75 years old with chronic insomnia.

The present study analyzed data from participants (N=266) who completed the PHQ-8 and GAD-7 questionnaires from a large-scale, real-world deployment of the dCBT-I program (Somryst).[3] See Table 1 for participant characteristics.

Digital CBT-I Program

Patients engaged in a 6 to 9-week digital CBT-I intervention administered via the Somryst® mobile application. The program 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).

Data analysis

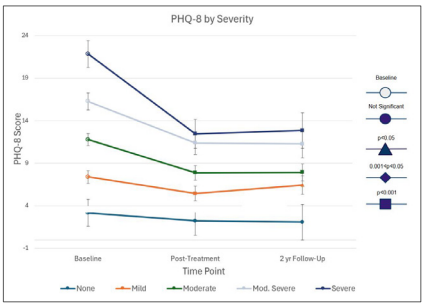
All available endpoints were evaluated using a mixed-model repeated measures analysis with study visit (baseline, post-treatment, two-year follow-up) as a fixed effect and subject as a random intercept. Participants were stratified based on baseline symptom severity.

Results

Table 1. Participant Characteristics

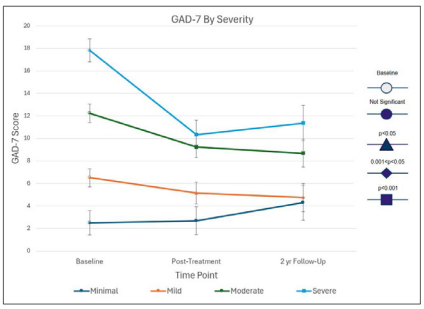
Category	N=266
Age (Yrs); Mean (SD)	48.5 (13.50)
Sex, % (n)	
Female	67.3% (177/263)
Male	32.7% (86/263)
Baseline ISI Score; Mean (SD)	19.0 (4.09)
Baseline PHQ-8 Score; Mean (SD)	11.1 (4.76)
Baseline GAD-7 Score; Mean (SD)	9.5 (5.24)

Figure 1. PHQ-8 Outcomes



Depression: PHQ-8 Participants with severe depression at baseline (mean PHQ-8 score=21.6; SE=0.31) experienced similarly large improvements at post-treatment (mean=13.0; SE=0.33; d=1.93) and 2-year follow-up (mean=12.5; SE=1.43, d=1.53); p< 0.0001. Improvements were less pronounced for participants with mild depression (baseline mean PHQ-8 score=7.1, SE=0.20; post-treatment mean=5.1, SE=0.21; d=0.82.

Figure 2. GAD-7 Outcomes



Anxiety: GAD-7 Participants with severe anxiety at baseline (mean GAD-7 score=17.5; SE=0.20) experienced large, clinically meaningful improvements in anxiety at post-treatment (mean score=10.6; SE=0.22; Cohen's d=1.68) and 2-year follow-up (mean=10.8; SE=0.82; d=1.35); p< 0.0001. Improvements were less pronounced for participants with mild anxiety (baseline mean GAD-7 score=6.8 [SE=0.18]; post-treatment mean=5.2 [SE=0.19]; d=0.59).

Conclusions

Digital CBT-I significantly improved psychological functioning as measured by the PHQ-8 and GAD-7 among individuals with comorbid insomnia and clinically significant depression and anxiety at baseline.

The largest improvements were observed among individuals with severe depression and/or anxiety at baseline.

- These findings demonstrate that individuals with clinically significant psychological distress can engage in and benefit from dCBT-I.
- The reduction in PHQ-8 and GAD-7 scores appear sustainable for up to two years after receiving dCBT-I.

Limtations: This was a single-arm trial with no control group; 24-month follow-up was impacted by a change in funding

These findings support the use of dCBT-I as an effective, sustainable tool for managing comorbid insomnia and improving psychological functioning in real-world practice.

References:

1. Lee S, Oh JW, Park KM, Lee S, Lee E. Digital cognitive behavioral therapy for insomnia on depression and anxiety: a systematic review and meta-analysis. NPJ Digit Med. 2023 Mar 25;6(1):52.
2. Wu JQ, Appleman ER, Salazar RD, Ong JC. Cognitive Behavioral Therapy for Insomnia Comorbid With Psychiatric and Medical Conditions: A Meta-analysis. JAMA Intern Med. 2015 Sep;175(9):1461-72.
3. Morin C, Thorndike FP, Ojile JM, Gerwien R, Wendorf A, Maricich YA. Digital CBT-I Treatment Improves Sleep and Reduces Anxiety and Depression Symptoms in Adults With Chronic Insomnia: Interim Analysis of DREAM Study. CNS Spectrums. 2023;28(2):227-228.

Funding and Disclosures: Funded by Pear Therapeutics and Nox Health (ClinicalTrials.gov: NCT04325464; primary outcomes in ref 3). **Disclosures: Nox Health (Somryst):** F.P.T, J.C.O., S.M.E., A.M.S., and H.P.R. are employees. L.M.R., C.M.M., R.W.G., and E.M.W. are consultants. L.M.R.'s arrangement is UVA COI-approved. **BeHealth Solutions:** L.M.R., F.P.T., and C.M.M. hold equity. BeHealth and UVA hold royalty agreements with Nox Health for Somryst (originally SHUTi/Pear Therapeutics). **Other:** J.M.O. was trial PI. **C.M.M.:** Advisory/consulting for Eisai, Merck, Phillips, Sunovion, Weight Watchers; research support from Eisai, Idorsia, Canopy, Lallemand. **E.M.W.:** Equity in WellTap; consulting for Axsome, DayZz, Eisai, EnsoData, Idorsia, Merck, Primasun, Purdue, ResMed; institutional research funding from AASM, DoD, Merck, NIH, ResMed, SRSF. *External companies had no role in this work. The depression and anxiety symptom outcomes presented in this poster were secondary, exploratory endpoints of a study conducted in patients seeking treatment for chronic insomnia. Two-year follow-up findings presented here have not been published or peer reviewed. These findings do not establish that Somryst® is safe or effective for the treatment of depression, anxiety, or psychological distress and should not be interpreted as such.*