Effectiveness of a Prescription Digital Therapeutic of Cognitive-Behavioral Therapy for Insomnia In 2 Clinical Trials and in Real-World Clinical Settings: A Number Needed to Treat Analysis

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SCAN ME

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INTRODUCTION

Chronic insomnia is a significant public health problem that is highly prevalent and associated with significant functional impairment and reduced quality of life.[1] First-line treatment of chronic insomnia is cognitive-behavioral therapy for insomnia (CBT-I), but there is a widespread lack of CBT-I providers across the United States.[2] Consequently, most patients with chronic insomnia do not receive CBT-I.[2] Although use of sleep-inducing medication for insomnia is common, multiple studies suggest many of these medications have an undesirable number needed to treat (NNT), often ranging from 10-13.[3,4]

Prescription digital therapeutics (PDTs) are a new class of FDA-authorized, software-based disease treatments that deliver evidence-based therapeutic interventions on smartphones or tablets. A PDT was developed to provide digital CBT-I (dCBTi) for adults with chronic insomnia.

This secondary analysis evaluated the effectiveness of insomnia treatment response and remission (including NNT) of dCBTi (including this specific PDT) across multiple randomized clinical trials and real-world populations.

OBJECTIVE

To compare NNTs among studies of dCBT-I from clinical trials and real-world samples of adults with chronic insomnia

METHODS

DESIGN

- Adults with chronic insomnia had access to dCBTi for 9 weeks in:
  - 2 pivotal randomized controlled trials (GoodNight, ACTRN12611000121965 [n=1,149] and UVA Study, NCT01438697 [n=303]);[5,6]
  - A real-world ongoing study (DREAM, NCT04325464; n=777 at end of treatment [EOT]);[7] and
  - A real-world population whose claims were followed for 24 months (n=248).[8]
- Treatment response was measured via Insomnia Severity Index (ISI) score improvement of >7 points.
- ISI ranges are
  - 0-7: absent
  - 8-14 sub-threshold
  - 15-21 moderate; and
  - 22-28 severe
- Remission was measured via an ISI score <8 at EOT.
- Effect sizes (pre-post treatment) were estimated at EOT.
- NNTs were calculated vs control data or vs baseline data if no controls available.

INTERVENTION

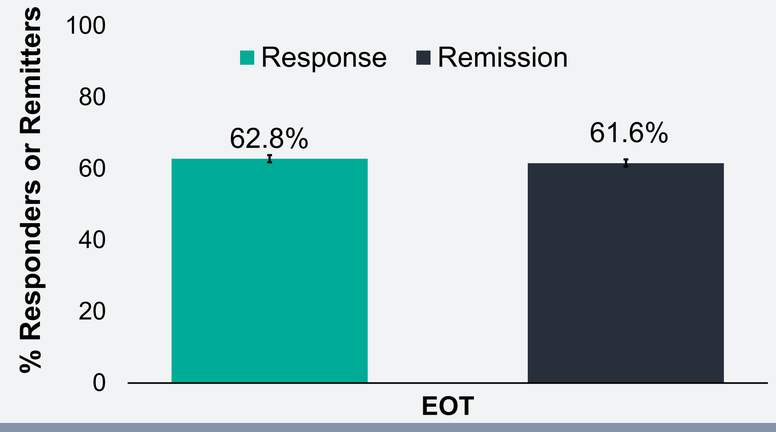
- The PDT provides a digital version of CBT-I to clinician-supervised patients in outpatient settings.
- Content is delivered via 6 interactive treatment modules (Cores), designed to parallel the traditional face-to-face delivery and structure of CBT-I sessions during a 6- to 9-week treatment period.

RESULTS

Insomnia Treatment Response and Insomnia Remission: GoodNight Pivotal Trial[5]

Baseline Characteristics of PDT Recipients

- 574 patients
- 42.9 Median age (years)
- 74% female
- 20% Not in labor force
- 19% Rural
- 15.9 Baseline ISI



Response NNT: 2.0

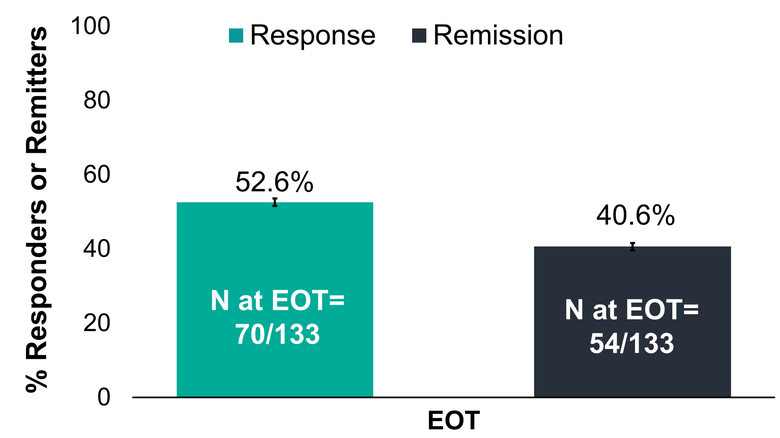
Remission NNT: 2.1

Effect size ISI change: Cohen's d= 2.00

Insomnia Treatment Response and Insomnia Remission: UVA Pivotal Trial[6]

Baseline Characteristics of PDT Recipients

- 151 patients
- 43.7 Median age (years)
- 68% female
- 10.0 Years of sleep problems
- 6% Black, 4.6% Asian, 4.6% Other
- 6.0 Median nights/ week w/ sleep problems
- 17.0 Baseline ISI



Response NNT: 1.9

Remission NNT: 2.5

Effect size ISI change: Cohen's d= 1.62

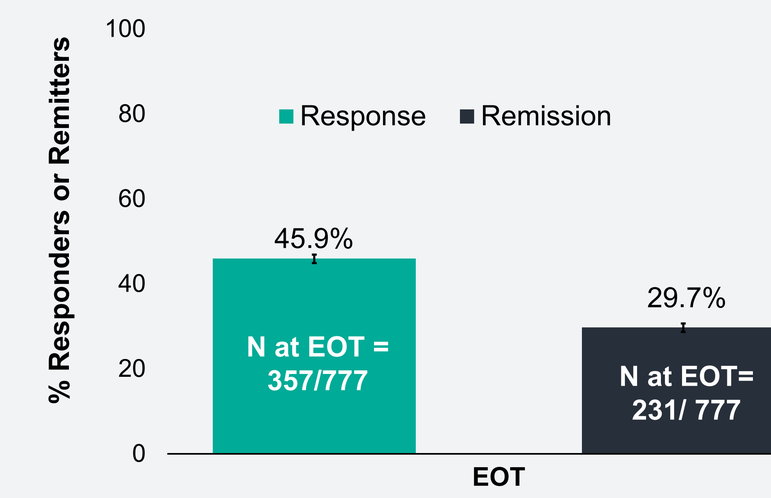
CONCLUSIONS

- ✓ Nine-week treatment with digitally delivered CBT-I was **effective in reducing insomnia severity and helping adults with chronic insomnia achieve response and remission**, regardless of study setting.
- ✓ Patients in real-world cohorts demonstrated similarly **high treatment response, high treatment remission, both with large effect sizes, and correspondingly low NNTs,** comparable to those in pivotal trial cohorts.
- ✓ NNTs with the PDT were dramatically lower than those with many sleep medications reported in the literature (e.g., NNT = 10-13).[3,4]

Insomnia Treatment Response and Insomnia Remission: DREAM Real-World Trial[7]

Baseline Characteristics of PDT Recipients

- 933 patients
- 47.3 Median age (years)
- 78% female
- 13.0 Years of sleep problems
- 4.7 Mean hours slept/night
- 6.0 Mean nights/week w/ sleep problems
- 18.8 Baseline ISI



Response NNT: 2.2

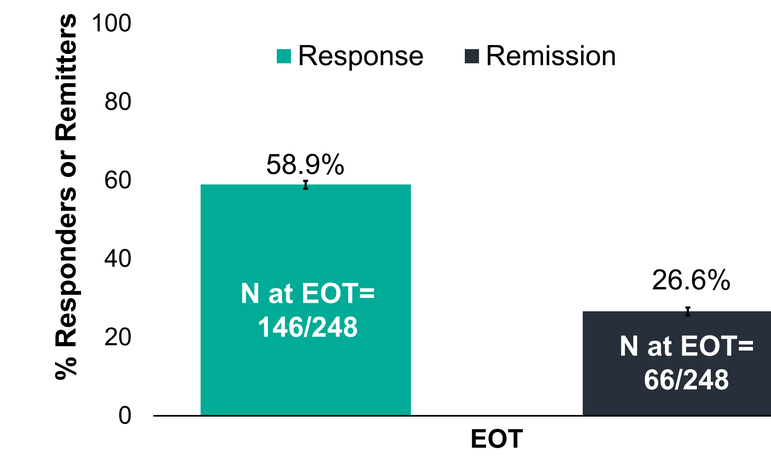
Remission NNT: 3.4

Effect size ISI change: Cohen's d= 1.41

Insomnia Treatment Response and Insomnia Remission: 24-Month Real-World Analysis[8]

Baseline Characteristics of PDT Recipients

- 248 patients
- 56.5 Median age (years)
- 57% female
- 53.2% Commercial, 8.1% Medicare, 1.2% Medicaid
- 0.7 Charlson Comorbidity Index (mean)
- 19.1 Baseline ISI



Response NNT: 1.7

Remission NNT: 3.8

Effect size ISI change: Cohen's d= 1.75

KEY TAKEAWAYS

Delivery of dCBT-I over 9 weeks was associated with posttreatment reductions in insomnia:

- ✓ Regardless of the study setting.
- ✓ With effect sizes that were both large and comparable among clinical trial and real-world patients.
- ✓ With NNTs that were substantially lower than published NNTs of many sleep medications.

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