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ORIGINAL RESEARCH

Real-World Evaluation of Clinical Response and Long-Term Healthcare Resource Utilization Patterns Following Treatment with a Digital Therapeutic for Chronic Insomnia

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Background and Objectives: This analysis evaluated insomnia severity and long-term impact on healthcare resource utilization (HCRU) and costs after treatment with Somryst® (previously called SHUTi), a digital therapeutic delivering cognitive behavioral therapy for insomnia (CBT-I).

Methods: Change from baseline in insomnia severity index (ISI) score was assessed using last observed ISI score. A pre/post analysis of claims data was conducted, comparing HCRU in patients with self-identified sleep problems who successfully initiated the therapeutic (index date) between June 1, 2016 and December 31, 2018.

Results: A total of 248 patients were analyzed (median age 56.5 years, 57.3% female, mean ISI score 19.13, 52.4% treated with sleep aid medications pre-index). After 9 weeks, mean ISI score declined by 37.2% from baseline (19.1 vs 12.0), 58.8% of patients achieved ISI responder status (ISI score improved by =>7; NNT: 1.7), and 26.6% of patients achieved insomnia remission (ISI score <8; NNT for remission: 3.8). After two-year follow-up, post-index events were reduced (compared to 2 years pre-index) for emergency department visits (−53%; IRR: 0.47; 95% CI 0.27, 0.82; *P*=0.008), hospiatizations (-21%; IRR: 0.79; 95% CI 0.46, 1.35; *P*=0.389) and hospital outpatient visits (−13%; IRR: 0.87; 95% CI 0.66, 1.14; *P*=0.315). Slightly increased rates were observed for ambulatory surgical center visits (2%; IRR: 1.02; 95% CI 0.73, 1.44; *P*=0.903) and office visits (2%; IRR: 1.02; 95% CI 0.92, 1.14; *P*=0.672). The number of patients treated with sleep aid medications dropped 18.5% (52.4% pre-index vs 42.7% post-index). Average number of prescriptions decreased from 3.98 pre-index to 3.73 post-index (*P*= 0.552). Total two-year cost reduction post-index vs pre-index was $510,678, or -$2059 per patient.

Conclusion: In a real-world cohort of patients with chronic insomnia, treatment with a digital therapeutic delivering CBT-I was associated with reductions in insomnia severity, emergency department visits, and net costs.

Keywords: CBT-I, cognitive behavioral therapy for insomnia, chronic insomnia, prescription digital therapeutic, SHUTi, Somryst

Plain Language Summary

Many people have insomnia, which is difficulty falling asleep or staying asleep. The recommended treatment for insomnia is a type of therapy called cognitive behavioral therapy for insomnia, or CBT-I. CBT-I is very effective, but few people actually use it. Prescription digital therapeutics (PDTs) are FDA-authorized treatments that people use on mobile devices. This study looked at whether the use of a PDT for insomnia by 248 adults led to reduced symptoms at the end of treatment, and whether use of the PDT led to lower health care costs two years after treatment.

At the end of treatment, average scores on a measure of insomnia symptoms declined by 37.2% compared to the start of the study, and 26.6% of the group reported that their insomnia was no longer a problem. Compared to the two years before treatment with the

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PDT, emergency department visits were 53% lower two years after treatment, hospitalizations were 21% lower, and hospital outpatient visits were 13% lower. The number of patients treated with sleep aid medications dropped 18.5%. The reduced use of health care facilities led to a savings, after two years, of $2059 per patient treated with the PDT.

The reductions in insomnia symptoms and long-term health care costs observed in this study suggest that use of a PDT for insomnia is both clinically and economically effective, which may lead to wider use of this non-drug form of insomnia treatment.

Introduction

Insomnia is defined as trouble initiating or maintaining sleep with daytime symptoms of impaired decision making, work performance, and quality of life.[1] About one-third of adults in the United States (US) report that they have difficulty with sleep initiation or sleep maintenance at least weekly[2,3] and it is estimated that between 6% and 15% meet the criteria of insomnia (sleep disturbance and significant daytime dysfunction).[2,4] The COVID-19 pandemic has exacerbated insomnia, due to disrupted circadian rhythms,[5] and increases in psychological stress.[6]

Insomnia is considered chronic when it persists at least three times per week for at least three consecutive months.[7] Chronic insomnia is associated with a range of comorbidities and negative sequelae, including increased risk for depression,[8] Alzheimer's disease,[9] heart disease, chronic pain, and hypertension.[10] Untreated insomnia has clinical consequences that impact systemic inflammatory,[11] and cardiometabolic pathways,[12] and it has also been shown to increase health care use and costs,[13] and be associated with an increased risk of falls and injuries[14] as well as reduced work productivity.[15]

Cognitive behavioral therapy for insomnia (CBT-I) is recognized as first-line treatment for patients with chronic insomnia as recommended in guidelines from professional organizations in Europe,[16,17] Australasia,[18] and the United States.[19,20] CBT-I has been shown to produce durable effects by helping patients address the maladaptive behaviors and cognitions that perpetuate chronic insomnia, and is characterized by a favorable benefit-to-risk profile compared to pharmacologic alternatives.[21,22] In contrast, sleep aid medications carry boxed warnings related to increased risk of serious injury or death from abnormal sleep behaviors, which are activities performed unconsciously, leading to serious injury through falls, burns, exposure to extreme cold temperatures, self-inflicted gunshot wounds, drowning, and fatal motor vehicle accidents.[23] Sleep aid medications are also contraindicated in older adults,[24] an age group where chronic insomnia has the highest prevalence.[23]

A major factor hampering the delivery of CBT-I to patients in need is the shortage of mental health providers[25] and board-certified behavioral sleep medicine specialists. With one behavioral sleep specialist per 43,000 patients, and a concentration mainly around urban areas, rural communities in particular are left facing disproportionately low levels of access.[26–29] Additionally, many patients are unable to access traditional CBT-I due to logistical complications related to dependent care, work schedules, limited transportation, and other issues.[27]

Prescription digital therapeutics (PDTs) can overcome these barriers by delivering evidence-based disease treatments asynchronously. Somryst is the first commercially available FDA-authorized prescription digital therapeutic (PDT) for chronic insomnia in adults. Somryst was previously called Sleep Healthy Using the Internet (SHUTi) and delivers equivalent therapeutic content. One of the most extensively studied digital therapeutics, Somryst/SHUTi has been evaluated in over 40 randomized clinical trials and studies.[30–35] The Somryst therapeutic delivers digital CBT-I and also allows for periodic assessment of key clinical variables such as insomnia severity index (ISI) score, sleep onset latency, and wake after sleep onset as well as symptoms of depression and anxiety.[36]

Meta-analyses of randomized controlled trials (RCTs) have found that digitally delivered CBT-I is effective and can reduce insomnia severity.[37] RCTs of the digital treatment used in this study specifically demonstrate consistent and long-lasting improvements in insomnia symptoms across diverse patient populations when compared to active or attention-matched controls.[30–34] This evaluation of the software treatment using chronic insomnia patient-reported outcomes recorded through the PDT, in addition to real-world health care resource utilization (HCRU) changes via claims data, serves as a valuable complement to RCTs because it provides potentially valuable evidence in a broad, generalizable population treated in the context of an uncontrolled routine clinical practice.[38]

This study evaluated HCRU outcomes, associated healthcare costs, and insomnia severity in a real-world population of adults with chronic insomnia two years before and after SHUTi treatment initiation.

Methods

Population and Study Design

A retrospective observational pre-post analysis of HCRU and insomnia severity index was conducted in patients with chronic insomnia across the US who successfully initiated SHUTi (index) between June 1, 2016 and October 31, 2018. Patients were required to have medical insurance coverage for a minimum of 16 months pre- and post-index.

Intervention

Somryst (previously called SHUTi) is an interactive digital CBT-I intervention delivering 3 primary mechanisms of action: sleep consolidation and restriction, cognitive restructuring, and stimulus control. The software-therapeutic is structured as 6 sequential treatment modules (called Cores) based on the key elements of CBT-I, which include an overview of insomnia, sleep restriction, stimulus control, cognitive restructuring, sleep hygiene, and relapse prevention.[39,40] A detailed description has been previously published.[36,41]

Patients were either referred to the digital therapeutic by their healthcare provider or accessed the intervention on their own. Upon registration, patients were provided with a username and password and the automated sequence of the therapeutic was initiated. Patients completed a self-assessment in Core 1 to provide information about their sleep history. After Core 1, patients were required to complete a minimum of five daily online sleep diaries over a 7-day period to unlock Core 2, where they receive their first recommended sleep restriction window (assigned bedtime to arising time). Thereafter, each Core was unlocked seven days after completion of the previous Core and patients were encouraged to submit daily sleep diaries following standardized recommendations from the Consensus Sleep Diary panel.[42]

If a patient did not complete five diaries in a seven-day window between each Core, the patient could continue completing Cores but did not receive an updated sleep window (because sleep windows are determined, in part, by sleep diary data).

Data Sources and Management

Treated patients who were identified in the Komodo Health claims database (Healthcare Map™) registration data were identified for analysis. The database includes medical and pharmacy claims for more than 325 million commercially insured, Medicare, and Medicaid patients. This study received a waiver of authorization for the use and disclosure of protected health information and a determination of exempt status under 45 CFR § 46.104(d)(4) from Western Institutional Review Board on October 15, 2021. (WIRB is a fully accredited independent institutional review board not affiliated with any specific authors or institutions.) None of our institutions/authors are affiliated with an IRB, therefore we used an independent IRB review for protocol review.

Clinical Outcomes Categories

At the beginning of each Core, patients were required to complete the ISI survey to assess the severity of both nighttime and daytime insomnia symptoms. An ISI score of 22–28 corresponds to severe insomnia, 15–21 to moderate insomnia, 8–14 to subthreshold insomnia, and 0–7 no insomnia. ISI baseline data were compared to last-observed ISI score within the 9-week period to calculate change from baseline. A decrease in ISI score of equal to or greater than 7 indicates a clinical response, and achievement of a score less than 8 indicates remission of chronic insomnia. Number needed to treat to achieve a remission was calculated by dividing 1 by the absolute risk difference between baseline and last ISI reported ($NNT = 1/ARR^{[\text{last ISI} - \text{baseline ISI}]}$).

HCRU Categories

All-cause HCRU was compared between the pre-index and post-index periods (ie, across 24 months). Inpatient stays identified from the Komodo Health inpatient admissions file, and outpatient visits were identified from Centers for Medicare & Medicaid Services (CMS) place of service codes. Outpatient visits included the following:

- Emergency department visits
- Hospitalizations (inpatient stays)
- Ambulatory surgical center (ASC) visits
- Hospital outpatient department (HOPD) visits
- Office visits (includes physician office visits, walk-in retail health clinic visits, and urgent care facility visits)

Prescribed insomnia-related medications were assessed using National Drug Codes (NDCs).

Statistical Analyses

The analysis examined mean and categorical ISI changes from baseline and differences in the incidence rate of HCRU encounters between the pre-index and post-index periods. The incidence rate for each HCRU encounter type was calculated using a repeated measures (pre/post) negative binomial model. The model included a parameter for period (ie, pre/post) and an offset for the observation time in each period. The model was fit using generalized estimating equations.

An incidence rate ratio (IRR) was calculated as the incidence in the post-index period relative to the incidence in the pre-index period, and was used to compare the pre-index and post-index incidence (eg, an IRR < 1 indicates lower HCRU in the post-index period compared to the pre-index period). The 95% confidence interval (CI) for the incidence rate and IRR, along with the IRR *P*-value, was assessed in the repeated measure negative binomial model.

The adjusted number of events (and associated 95% CIs) was evaluated by multiplying the HCRU incidence rate (and associated 95% CI), from the negative binomial model outlined above, by the number of patients in the cohort.

All analyses were performed using SAS version 9.4 or higher statistical software (SAS Institute, Cary, North Carolina) via the Komodo Health platform user interface. Cost calculations were performed by multiplying number of events by published costs for each HCRU category.

Results

A total of 1003 patients treated with the digital therapeutic between June 1, 2016 and October 31, 2018 (index date) were identified, and 755 (75.3%) of these patients were excluded for not meeting study eligibility (Figure 1). A total of 248 patients initiating the PDT were analyzed (median age 56.5 years, 57.3% female, mean ISI score 19.13, 52.4% treated with sleep aid medications pre-index) (Table 1).

Mean ISI score was 37.2% lower post-index compared to baseline (12.0 vs 19.1). Almost six out of 10 (58.8%) of patients achieved criteria for ISI response, and more than one in four (26.6%) achieved insomnia remission (ISI score <8). There was a 76.9% reduction in patients experiencing severe insomnia, from 31.5% of patients at baseline, to 7.3% after 9 weeks (Table 2). NNT to achieve responder status was 1.7; NNT for remission status was 3.8.

Compared to the pre-index period, post-index events were reduced for ED visits (−53%; IRR: 0.47; 95% CI 0.27, 0.82; *P*=0.008), hospitalizations (-21%; IRR: 0.79; 95% CI 0.46, 1.35; *P*=0.3887), and HOPD visits (−13%; IRR: 0.87; 95% CI 0.66, 1.14; *P*=0.315) (Table 3). Slightly increased rates were observed for ASC visits (2%; IRR: 1.02; 95% CI 0.73, 1.44; *P*=0.903) and office visits (2%; IRR: 1.02; 95% CI 0.92, 1.14; *P*=0.672).

Overall, there was an 18.5% reduction in the number of patients treated with sleep aid medications (52.4% pre-index vs 42.7% post-index). The average number of prescriptions declined from 3.98 pre-index to 3.73 post-index (*P*=0.552). Total estimated two-year cost savings associated with changes in HCRU was $510,678, or $2059 per patient, driven primarily by reductions in hospitalizations and ED visits (Table 4).

Discussion

Numerous RCTs, studies, and real-world evaluations[35] have convincingly demonstrated the effectiveness of digitally-delivered, CBT-I, but an evaluation of Somryst/SHUTi on HCRU outcomes has not previously been reported. The analyses presented in this paper demonstrate that use of the digital therapeutic was associated with long-term reductions in HCRU as well as reductions in per-patient health care costs. Key drivers of the reduced HCRU were emergency department visits (statistically significant 53% reduction) and non-significant reductions in hospitalizations (21%

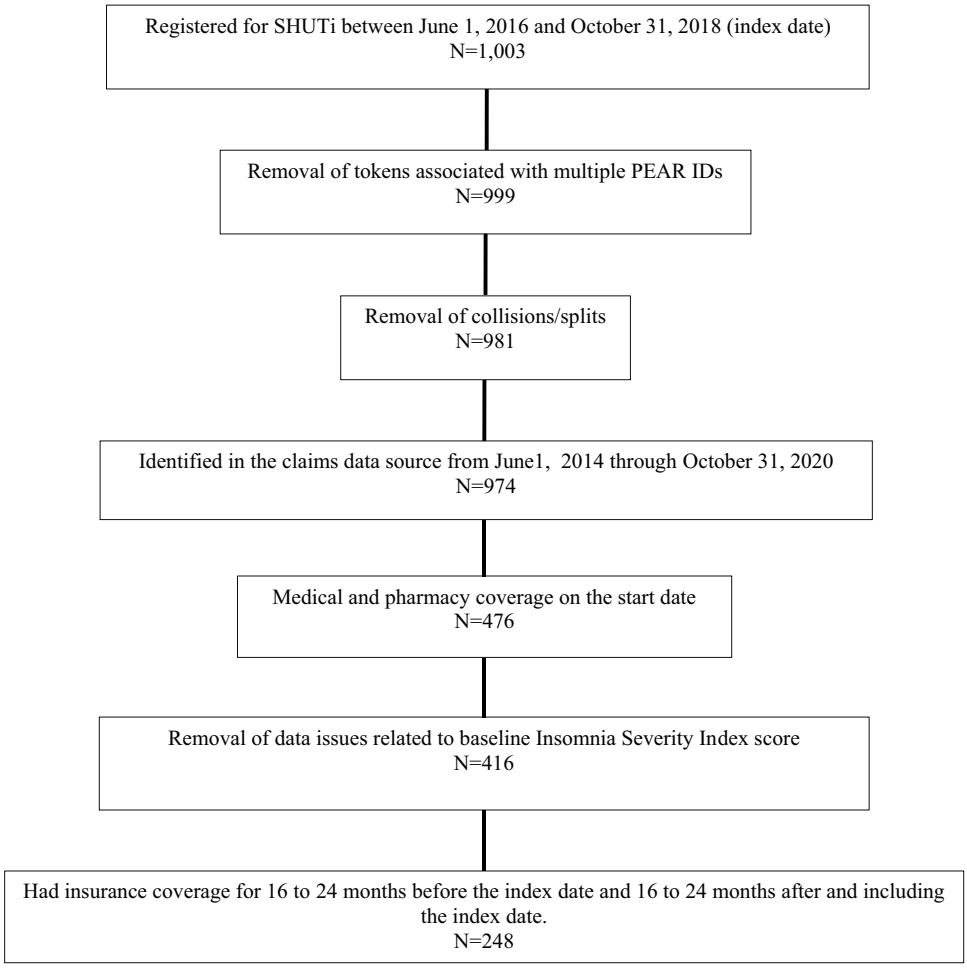

Figure 1 CONSORT diagram.
Note: Patient attrition from initial population sample to N=248 patient population analyzed.

reduction), and hospital outpatient department visits (13% reduction), which offset the marginal increases in office visits and ambulatory care center visits (2% increase in each), resulting in a net decrease in total cost of care in the two years after the initiation of the therapeutic, compared to the two-year baseline period.

These long-term improvements in HCRU were preceded by improvements in ISI after 9 weeks, which showed that one in six patients achieved treatment response, and one in four patients achieved insomnia remission status. Furthermore, the reduction in mean score from baseline across the population was 7.1 points in the nine weeks after initiation of treatment, which exceeds the clinically meaningful threshold for response. In addition, there was an overall movement from more severe ISI categories to less severe ISI categories. For example, the percentage of patients in the ISI severe category decreased 77%, from 31.5% to 7.3%, while the remission category went from 0% of patients at baseline to 26.6% after nine weeks, with two-thirds of the population reporting ISI scores in the subthreshold insomnia or remission categories, compared to just 14% of the population at baseline. NNTs for remission and for remission/ subthreshold insomnia were low, with both values being less than 4. Notably, these changes in ISI are consistent with previous clinical trials as well as real-world data where the persistent durability of the ISI response was observed at eighteen months after a single treatment with the digital therapeutic.[30,31,35]

Given the heavy financial burden that chronic insomnia places on payers, employers, and state and federal healthcare programs, the clinical improvements and cost reductions demonstrated in these analyses are highly relevant and encouraging. Mental Health inequity is a major issue[43] and chronic insomnia patients have high rates of co-occurring depressive symptoms and anxiety symptoms. These results suggest that Somryst/ SHUTi provides an effective, non-

Table 1 Patient Characteristics and Demographics

	24-Month Cohort N=248
Age on index date (median)	56.5 years
Age group on index date, n (%)	
18–24	5 (2.0%)
25–34	16 (6.5)
35–44	41 (16.5)
45–54	53 (21.4)
55–64	83 (33.5)
65+	50 (20.2)
Female Sex, n (%)	142 (57.3%)
Payer type (%)	
Commercial	53.2%
Medicaid	1.2%
Medicare	8.1%
Other	2.0%
Self insured	27.8%
Unknown	7.7%
Geographic region (%)	
Northeast	25.0%
South	33.5%
Midwest	19.4%
West	22.2%
Charlson co-morbidity index (mean)	0.7
Any insomnia-related medication in pre-index period (%)	52.4%
Any insomnia diagnosis, pre-index (%)	56.5%
Baseline mean ISI score	19.1

Table 2 Insomnia Severity Index Scores as Assessed at Baseline and at the Last Core Learning Modules Completed (Last Core) (N=248)

ISI Category	Baseline		Last Core	
	Count	Percent	Count	Percent
Absence of insomnia (ISI 0–7)	0	0.0%	66	26.6%
Sub-threshold insomnia (ISI 8–14)	35	14.1%	99	39.9%
Moderate insomnia (ISI 15–21)	135	54.4%	65	26.2%
Severe insomnia (ISI 22–28)	78	31.5%	18	7.3%

pharmacological first-line treatment for chronic insomnia, with highly durable positive impacts on the use of healthcare resources 24 months after treatment initiation. This complements earlier data that demonstrated improvements in work productivity[44] and reductions in insomnia symptoms in various subpopulations after treatment with the therapeutic.[33]

With the significant shortage in licensed clinicians who can deliver CBT-I, delayed access to evidence-based treatment may increase morbidity as patients wait to receive needed care.[27] During these waiting periods, which

Table 3 Incidence of Inpatient and Outpatient Stays Over 24 Months Post-Index

Resource	Pre-Index Period			Post-Index Period					
	n (%)	Incidence	95% CI	n (%)	Incidence	95% CI	IRR	95% CI	P-value
Hospitalizations	43 (17.3)	0.464	0.297, 0.726	38 (15.3)	0.366	0.232, 0.579	0.789	0.460, 1.352	0.3887
ED visits, no admission	51 (20.6)	0.572	0.343, 0.953	43 (17.3)	0.268	0.194, 0.371	0.470	0.268, 0.821	0.0080
ASC visits	53 (21.4)	0.332	0.251, 0.439	62 (25.0)	0.339	0.259, 0.444	1.022	0.726, 1.437	0.9027
HOPD visits	159 (64.1)	3.764	2.955, 4.794	143 (57.7)	3.271	2.527, 4.234	0.869	0.661, 1.143	0.3151
Office visits	241 (97.2)	25.432	22.265, 29.051	242 (97.6)	26.021	22.968, 29.478	1.023	0.920, 1.137	0.6720
Medication	**n (%)**	**LS Mean (SE)**	**95% CI**	**n (%)**	**LS Mean (SE)**	**95% CI**	**LS Mean Difference**	**95% CI**	**P-value**
Any insomnia-related medication	130 (52.4)	3.980 (0.454)	3.087–4.874	106 (42.7)	3.732 (0.441)	2.863–4.600	−0.249 (0.418)	−1.072, 0.574	0.5522

Abbreviations: ASC, ambulatory surgical center; CI, confidence interval; ED, emergency department; HOPD, hospital outpatient department; IRR, incidence rate ratio; n, number of patients.

Table 4 HCRU by Services and Associated Healthcare Costs Across 24 Months

Events	Pre-Index HCRU	Post-Index HCRU	Difference	Per HCRU Cost	Total Pre-Post Cost Difference
Hospitalizations[46]	115	91	−24	$11,700.00	($284,427)
ED visits, no admission[47]	142	67	−75	$1389.00	($104,453)
Ambulatory Surgical Center[48]	82	84	2	$3160.00	$5593
Hospital outpatient department[49]	934	811	−123	$1275.00	($155,958)
Office Visits[49]	6307	6453	146	$199.00	$29,022
Sleep Medications[50]*	987	926	−62	$7.40	($455)
Total					($510,678)
Cost Difference/Patient (n=248)					($2059)

Notes: *Sleep medications evaluated: zolpidem, eszopiclone, temazepam, zaleplon, suvorexant, ramelteon, estazolam, triazolam, trazodone, amitriptyline, doxepin.
Abbreviations: ED, emergency department; HCRU, healthcare resource utilization.

can extend for months, insomnia-related comorbidities (eg, depression, anxiety, cardiovascular diseases) may worsen, with subsequent impacts on overall healthcare costs. Digital therapeutics (such as the one evaluated in this study), which patients can access as soon as they are identified as needing treatment, can more rapidly reduce morbidity and costly HCRU.

Prescription digital therapeutics such as Somryst are changing the paradigm for the treatment of chronic insomnia. The COVID-19 pandemic has accelerated this trend[45] by increasing the demand for contact-less treatment options for therapy, creating a demand for technologies, such as PDTs, which deliver high-quality, evidence-based therapeutic content remotely. The shortage of qualified specialty providers for treating chronic insomnia will continue to be a barrier for the foreseeable future, and one that PDTs are an emerging treatment to help overcome, as they allow for more asynchronous and flexible patient engagement with evidence-based, clinical guideline-recommended, first-line CBT for insomnia.

Limitations

Claims databases were created for administrative purposes, and therefore do not contain comprehensive clinical data, such as severity or duration of insomnia, limiting the conclusions that can be drawn about the digital therapeutic intervention. However, claims data do report on important patient encounters within the health care system, which makes them an attractive source for real-world analyses. Secondly, the results reported here should not be interpreted as indicating a causal relationship, but rather an association between exposure to the digital therapeutic and outcomes. Prior RCTs have evaluated causality and internal validity and are referenced in this manuscript. Although our sample size is relatively small, the results may be generalizable given the inclusion of a broad population who engaged with the therapeutic in real-world conditions.

Conclusions

In a large real-world cohort of patients with chronic insomnia, treatment with a digital therapeutic delivering CBT-I was associated with improvements in insomnia symptoms after 9 weeks, and a net reduction in the number of health care services rendered to these patients over a 24-month period, with an associated net cost-savings of $2059 per patient.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

FF, FPT, XX, FFV, and YAM are employees of Pear Therapeutics (US), Inc. FPT also reports equity and employment from BeHealth Solutions, during the conduct of the study; and was a previous faculty member at institution (University of Virginia) that developed precursor (SHUTi) to this work. TGK and RB are employees of Market Access Consulting, Labcorp Drug Development, which participated in this study under contract with Pear Therapeutics (US), Inc. DCM is a consultant of Strategic Therapeutics, LLC, which participated in this study under contract with Pear Therapeutics (US), Inc. The authors report no other conflicts of interest in this work.

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