6–9 weeks. In this interim analysis, participants completed the Insomnia Severity Index (ISI), 8-item Patient Health Questionnaire (PHQ-8), and Generalized Anxiety Disorder-7 scale (GAD-7) and other self-reported outcomes—at screening (baseline/prior to Core 1), end of treatment (Day 63), and 6-month follow-up (Day 243).

Results. Mean ISI scores decreased ($p<0.0001$) from baseline (n=991) to post-treatment (n=777;18.8 vs 11.3) and to Day 243 (n=193; 18.8 vs 12.1). Mean GAD-7 scores improved from baseline to Day 63 (n=744; $p<0.0001$, Cohen's $d = 0.48$) and to Day 243 (n=186; $p<0.0001$, $d = 0.45$). Similarly, PHQ-8 scores improved from baseline to Day 63 (n=747; $p<0.001$, $d = 0.76$) and to Day 243 (n=186; $p<0.0001$, $d = 0.60$). These patterns persisted across baseline anxiety and depressive severity levels among people with any baseline depressive or anxiety symptoms (all $p<0.05$ for depression, all $p<0.0001$ for anxiety), with large effect sizes observed for severe anxiety (d=1.43 Day 63, d=1.55 Day 243) and for moderate to severe depression (d range = 0.96-1.51).

Conclusion. In this study, treatment with digital CBT-I was associated with significant reductions in ISI, anxiety, and depression at posttreatment and at 6 months. The largest observed decreases in GAD-7 and PHQ-8 scores were among people with more severe baseline mood symptoms.

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Rates of Inpatient Hospitalizations Across a 2-Year Time Horizon Between reSET-O and Control Patients: A Difference in Differences Approach

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Abstract

Introduction. reSET-O® is an FDA-authorized prescription digital therapeutic (PDT) for opioid use disorder (OUD) providing cognitive behavioral therapy as an adjunct to buprenorphine therapy. This analysis describes differences in inpatient hospitalization rates over a 2-year period between patients treated with the PDT and those who were not.

Methods. A real-world claims analysis using the HealthVerity Private Source 20 database compared inpatient hospitalization rates (including intensive care unit stays and rehospitalizations) in patients who filled a reSET-O prescription ("cases") to patients not filling their prescription ("controls"). Index date was date of reSET-O initiation for cases, and prescription date for controls, from January 1, 2019 to June 30, 2020. Pre- and post-index incidence rates of HCRU were compared with the incidence rate ratio (IRR) using a repeated-measures negative binomial model, adjusted for age, sex, region, payer type, Charlson comorbidity index (CCI) score, and number of similar services in the 12 months pre-index with an offset for number of days in the 12-month post-index period. Adjusted differences in inpatient hospitalizations in cases vs. controls were evaluated at 3-month intervals beginning at 12 months pre-index through 12 months post-index, using a difference in differences (DID) approach.

Results. In this analysis, 901 cases (median age 36 years, 62.4% female, 73.9% Medicaid recipients, 95% treated with buprenorphine in the post-index period) were compared with 978 controls (median age 38 years, 55.1% female, 65.4% Medicaid recipients, 95% treated with buprenorphine in the post-index period). Incidence rate ratios of inpatient stays trended lower in later pre-post comparison periods among cases (IRRs 0.80, 0.95, 0.87, and 0.75 at 3-, 6-, 9-, and 12 months pre-post, respectively), and trended higher in later pre-post periods in controls (IRRs 0.93, 0.83, 0.86, 0.88 at 3-, 6-, 9-, and 12-month intervals respectively). The DID for controls vs. cases during the 12-month post interval compared to the 12-month pre-index rates, represented a 44% lower incidence of inpatient hospitalizations vs. controls between the first and last quarters of observation.

Conclusions. This difference in difference analysis showed a lower 12-month pre-post incidence rate ratio of inpatient hospitalizations for patients using reSET-O vs. controls, and a 24-month change in quarterly inpatient hospitalizations in reSET-O patients that was almost half that of controls.

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Reduced Healthcare Resource Utilization in Patients With Chronic Insomnia 24 Months After Treatment With Digital CBT-I: A Matched-Control Study

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Abstract

Introduction. This analysis examined the impact of a digital therapeutic for treating chronic insomnia (currently marketed as Somryst®, at the time called Sleep Healthy Using The internet [SHUTi]) on healthcare resource use (HCRU) by comparing patients treated with the digital cognitive behavioral therapy for insomnia (dCBTi) to patients not treated with dCBTi, but with insomnia medications.

Methods. A retrospective observational study using health claims data was conducted in two cohorts across the United States: patients who registered for dCBTi (cases) between June 1, 2016

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