Carlo simulation. Potential drug-drug, gene-drug, or gene-drug-drug interaction risk was characterized as minor, moderate, or major.
**Results.** Based on prescription data only, the probability of a DDI of any impact (mild, moderate, or major) was 26% [95% CI: 0.248-0.272] in the population. This probability increased to 49.6% [95% CI: 0.484-0.507] when simulated genetic polymorphisms were additionally assessed. When assessing only major impact interactions, there was a 7.8% [95% CI: 0.070-0.085] probability of drug-drug interactions and 10.1% [95% CI: 0.095-0.108] probability with the addition of genetic contributions. The probability of drug-drug-gene interactions of any impact was correlated with the number of prescribed medications, with an approximate probability of 77%, 85%, and 94% in patients prescribed 5, 6, or 7+ medications, respectively. When stratified by specific drug class, antidepressants (19.5%), antiemetics (21.4%), analgesics (16%), antipsychotics (15.6%), and antiparasitics (49.7%) had the highest probability of major drug-drug-gene interaction.
**Conclusions.** In a community-based population of outpatients, the probability of drug-drug interaction risk increases when genetic polymorphisms are attributed to the population. These data suggest that pharmacogenetic testing may be useful in predicting drug interactions, drug-gene interactions, and severity of interactions when proactively evaluating patient medication profiles.
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# Comparative Effectiveness of an FDA-Authorized Digital Therapeutic to Medications and Cognitive Behavioral Therapy Treating Chronic Insomnia in Adults

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**Abstract**

**Introduction.** Chronic insomnia affects the physical and mental health, quality of life, and productivity of 6 to 10% of the adult population (15-25 million U.S. adults). Available treatments include guideline-recommended first-line cognitive behavioral therapy for insomnia (CBT-I) and medications. However, limitations such as patient access to CBT-I and limited efficacy, the presence of significant side effects, as well as safety concerns about medications limit favorable outcomes. Somryst is an FDA-authorized prescription digital therapeutic for the treatment of chronic insomnia in adults. The purpose of this analysis is to compare the effectiveness of the digital therapeutic vs CBT-I and medications for primary insomnia.
**Methods.** Chronic insomnia trials focused on digital therapeutic, CBT-I, or medication were identified in a systematic literature review. Studies using a comparator arm that cannot be considered clinically equivalent to other treatments in the network were excluded (eg, meaningfully different definition of placebo arm). A Bayesian network meta-analysis was performed in R on the mean change from baseline and the proportion of remitters using the insomnia severity index (ISI) endpoint with follow-up time-points between 6 and 12 weeks. Mean change in ISI score from baseline was analyzed as a continuous endpoint while comparisons of the proportion of remitters were performed using odds ratios. The analysis used a random-effects model for the base case analysis. A surface under the cumulative ranking curve (SUCRA) analysis was performed to rank the treatments on each endpoint.
**Results.** In total, 13 studies reported ISI mean change from baseline data. Only the digital therapeutic and CBT-I were significantly different than placebo. The digital therapeutic had the greatest mean change from baseline in ISI from placebo (−5.77 points, 95% Credible Interval (CrI) [−8.53, −3.07]), followed by CBT-I (−4.3 points, 95% CrI [−6.32, −2.39]). In the SUCRA analysis, the digital therapeutic had the highest probability (56%) of being the most effective treatment based on ISI mean change from baseline. Only 8 studies reported the proportion of ISI remitters. Only the digital therapeutic showed a statistically significant difference in remission vs placebo and had the highest odds ratio for remission vs placebo (12.33 95% CrI [2.28, 155.91]). The odds ratio for remission vs placebo in CBT-I was not statistically significant (4.08 95% CrI [0.45, 45.58]). The digital therapeutic had the highest probability (64%) of being the most efficacious for inducing remission per ISI.
**Conclusions.** Somryst was projected to be the most effective therapy on both mean change in ISI and ISI remission within 6 to 12 weeks of treatment start vs either CBT-I or medications. Further investigation should be performed to demonstrate the long-term effectiveness of all chronic insomnia treatments.
**Funding.** Pear Therapeutics

# Outcomes from Engagement and Use of a Prescription Digital Therapeutic to Treat Opioid Use Disorder: A Real-World Pilot Study

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**Abstract**

**Introduction.** The opioid epidemic in the United States is getting worse: in 2020 opioid overdose deaths hit an all-time high of 92,183. This underscored the need for more effective and readily available treatments for patients with opioid use disorder (OUD).

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