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Short Communication

Treating Insomnia in Primary Care: A Pilot Trial of Cognitive Behavioral Therapy for Insomnia with Sleep Medication Taper

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ABSTRACT

Insomnia is prevalent, with approximately 30% of individuals reporting difficulty sleeping and 10% of individuals meeting diagnostic criteria for insomnia [1]. Insomnia is associated with functional impairment, increased healthcare costs, and economic burden [2].

Medications are often the initial treatment provided to individuals complaining of insomnia [3], and yet many individuals continue to experience poor sleep despite taking sleep medications. Moreover, sleep medications are associated with cognitive impairment and increased risk for falls [4]. Many health care systems now employ models of integrated care in which behavioral health providers are incorporated into primary care settings. Integrated care settings offer the opportunity to implement behavioral treatments more readily and allows for multidisciplinary treatment protocols. The present study examines a new clinical process for the management of insomnia in primary care in which pharmacy and psychology work collaboratively to improve patients' sleep quality and reduce their reliance on sleep medications. This treatment program was offered to patients in primary care taking sleep medications. Patients who participated in the treatment reported increased sleep quantity and improved sleep quality and reduced their use of sleep medications. Clinical and research implications are discussed.

Keywords: Insomnia, Integrated care, Primary care, Interdisciplinary treatment.

Treating Insomnia in Primary Care

A Pilot Trial of Cognitive Behavioral Therapy for Insomnia with Sleep Medication Taper Insomnia consists of a subjective dissatisfaction with sleep quality or quantity, with adequate opportunity for sleep. Patients generally have difficulty falling asleep, maintaining sleep, or with waking too early in the morning. The condition leads to a significant impairment in daytime functioning, such as fatigue, daytime somnolence, or impaired cognitive functioning. Insomnia is associated with functional impairment, increased healthcare costs, and economic burden [2,3]. Insomnia is prevalent, with approximately 30% of individuals reporting difficulty sleeping and 10% of individuals meeting diagnostic criteria for insomnia [1]. Insomnia is even more prevalent in veterans, with more than half of newly enrolling veterans endorsing clinically significant insomnia symptoms at one VA center [5].

Many patients seek treatment for insomnia in primary care, and medications or education on sleep hygiene are often the initial treatment provided [6]. For example, in a study of primary care patients with insomnia, Simon, et al. [3] found that patients were more likely to be prescribed a benzodiazepine or antidepressant than to be referred for mental health services. Head to head comparisons of CBT-I and medication consistently show that CBT-I is superior to medication in both efficacy and reduced adverse effects [2,7,8]. A recent systematic review of CBT-I versus pharmacologic therapy concluded that CBT-I is more effective than medication treatment for long term treatment of insomnia [9].

Following this empirical data, recent recommendations from ACP suggest CBT should be used preferentially before pharmacotherapy, for improved safety and effectiveness. The American College of Physicians (ACP) recently published evidence reports regarding psychological and behavioral interventions for insomnia [10] and pharmacological treatments for insomnia [11]. The ACP concluded that CBT-I should be the initial treatment for insomnia, and that if CBT-I is ineffective, medication could be prescribed but should be time limited (a few weeks).

These recommendations lie in stark contrast to how insomnia is currently being treated in primary care. Available medications for insomnia, including benzodiazepines (BZD) and benzodiazepine-receptor agonists ("Z-drugs") are effective for treatment of acute insomnia where symptoms persist for less than 3 months. However, these drugs are often used for chronic insomnia lasting longer than 3 months [12], despite a lack of safety and efficacy data. Concerns about long term use include dependence, addiction, rebound insomnia, withdrawal and cognitive impairment. These symptoms are especially concerning in the elderly where they are associated with falls and their associated sequelae, and with cognitive impairment, including exacerbation of neurodegenerative disorders [13].

Given the empirical evidence and guidelines from national bodies about the benefits of CBT-I and risks of medications in

treatment of insomnia, there is a need to develop and implement methods to help people sleep better with fewer medications. The present study sought to help patients sleep better by tapering from sleep medications and using behavioral strategies (CBT-I) to improve sleep. A clinical pharmacist and psychologist working in primary care offered these services to patients who had been on medications for sleep long-term.

Method

Setting

The Minneapolis Veterans Affairs Health Care System (Minneapolis VAHCS) is a large Joint Commission accredited medical center that provides primary, tertiary, and long-term care to approximately 100,000 veterans. Veterans receive primary care services in several primary care clinics throughout the hospital. Primary care clinic staff includes physicians, nurses, psychologists, pharmacists, dieticians, and administrative assistants.

Patient Identification and Recruitment

A SQL database was used to identify upcoming PCP appts for the clinic, and patients who were taking benzodiazepines or zolpidem, eszopiclone, or zaleplon, and with "bedtime" or "sleep" in the directions field. To ensure that short term prescriptions were excluded, patients had to have been receiving the medications for 90 days or more. On the day of their PCP clinic visit, these patients were provided with a letter that briefly described challenges of treatment of insomnia and risks of certain medications. The letter offered a patient the option of specific clinic services including CBT-I and a pharmacist information on sleep medications, including a supervised sleep medication taper for interested patients. The letter also provided contact information for the psychologist and pharmacist, along with the patient's clinic visit materials for the day. The patient could then discuss with provider and walk in or be referred to the PC Insomnia Treatment Program if interested. If the patient and provider agreed, either the pharmacist or the psychologist contacted the patient by phone or saw in person to engage in CBT-I and to discuss medication therapy. Unless patients were experiencing adverse effects or expressed desire to decrease urgently, medications were not decreased or withdrawn until an improvement in sleep was noted.

Cognitive Behavior Therapy for Insomnia

CBT-I included two to five 30-minute treatment sessions with a psychologist trained in providing CBT-I. CBT-I sessions focused predominantly on sleep restriction and stimulus control. The psychologist provided education on sleep/wake regulation, sleep drive, the circadian clock, and sleep hygiene. Considerable time was spent discussing the process of sleep restriction with patients. Patients were given sleep diaries and instructed on how to track periods of sleep and insomnia. The psychologist also provided information on relaxation strategies (deep breathing, autogenic training) and on cognitive techniques (distraction, category tasks) to use during periods of insomnia. In each treatment session, the psychologist reviewed patients' sleep diaries and provided recommendations about altering the sleep schedule. The psychologist also reviewed sleep restriction, stimulus control, and sleep hygiene practices as needed.

Supervised Tapering and Withdrawal Monitoring

Overall, medication tapering was individualized based on the patient's readiness to quit, current amount of hypnotic use, and absence or presence of withdrawal symptoms. Patient specific goals were established, and patients were encouraged to increase the number of drug free nights and use hypnotics on a decreasing scheduled basis rather than an as needed basis.

Participants

During the 12-month period studied, 189 patients were given letters describing the treatment options for CBT-I and sleep medication taper. As the service developed, providers began to refer patients with insomnia to the treatment team outside of the letter system. Twenty of these patients (10.58%) were willing to meet to discuss the services. Patients were all men, with an average age of 69.60 years (range 52 – 86, SD = 7.52). Of patients who were willing to meet with a provider to discuss the services, four patients (20%) were not interested in participating in either CBT-I or the medication taper. Several patients were interested in CBT-I (13/20) or medication taper (13/20); ten patients were interested in both CBT-I and a sleep medication taper. In terms of medication use, 11/20 (55%) patients were on zolpidem, 4 of 20 (20%) were on temazepam, 1 of 20 (5%) were on trazodone, 1 of 20 (5%) on lorazepam, and 3 of 20 (15%) were on OTC sleep medications containing diphenhydramine, 2 of which were as an add-on sleep medication. Two patients were currently not on any medications.

Measures

Insomnia Severity Index [14] is a brief 7-item self-report measure of insomnia symptoms. Patients rate the severity of their insomnia problem (falling asleep, staying asleep, waking too early) on a scale from 0 (none) to 4 (severe). Patients also rate their satisfaction with sleep, their worry about sleep, and the extent to which their sleep problem is noticeable and affects daily functioning. Total scores on the ISI range from 0 to 28, with higher scores indicating greater difficulty. The ISI has demonstrated good internal consistency and reliability and is sensitive in detecting changes in insomnia symptoms [15]. Patients completed the ISI at pretreatment and posttreatment.

Sleep Log Patients were provided with sleep logs to track their sleep patterns. Patients tracked bedtime, wake time, the number and length of wakeups, and the use of sleep medication. Patients were instructed to complete the sleep log each morning and to bring the sleep logs to CBT-I sessions.

Results

CBT-I Outcomes

Paired samples t-tests were used to analyze change in patient's ISI scores and total number of sleep hours from pre-

treatment to post-treatment. ISI scores changed significantly from pre-treatment to post-treatment, $t(12) = 4.64$, $p < 0.005$. ISI scores decreased from pre- treatment ($M = 16.33$, $SD = 4.44$) to post-treatment ($M = 8.67$, $SD = 3.52$). Based on symptom classification of ISI scores, this suggests patients' scores moved from the moderate clinical insomnia range to the subthreshold insomnia range.

A paired samples t-test was also used to evaluate change in total sleep time from pre- treatment to post-treatment. Analyses showed that patient's total hours of sleep time changed significantly $t(12) = 3.98$, $p < .005$. Participants reported greater sleep at post-treatment ($M = 6.21$, $SD = 0.96$) than at pre-treatment ($M = 4.69$, $SD = 1.17$).

Sleep Medication Taper Outcomes

Sleep medication dose data was gathered from prescription files, before and after the intervention. Six of 11 patients (55%) who entered the program on zolpidem had no change in zolpidem use. Five of 11 (45%) stopped using zolpidem completely. Three of 4 patients on temazepam (75%) stopped the medication completely. The remaining patient taking temazepam decreased his temazepam use. All 3 patients on diphenhydramine-containing OTC medications reported stopping them. The trazodone patient had no change in trazodone dose.

Discussion

The present investigation examined the effects of a collaborative care model of CBT-I delivery in which CBT-I clinician and clinical pharmacist worked with patients to improve sleep outcomes while reducing/discontinuing sedative-hypnotics. The results of the study suggest that this intervention was successful in reducing symptoms of insomnia and reducing reliance on sleep medications. Increased quality of life associated with better objective sleep metrics, and harm reduction by minimizing exposure to sleep medications are encouraging outcomes of this program. Patients completing CBT-I demonstrated improvement in insomnia symptoms (as measured by the ISI) and also demonstrated a significant increase in the total number of hours of sleep per night. Many patients who participated in the sleep medication taper were able to reduce their medication use. Further, many were also were able to reduce or discontinue their hypnotic medication by the end of the study. Most primary care providers are aware of the substantial risks and limited benefits of long-term hypnotic use, but may be less aware of the benefits of CBT-I. It would likely be advantageous to educate PCPs about the value of CBT-I, the availability of pharmacotherapy consults for a hypnotic taper, and the combination of these two services.

Limitations and Future Directions

This was a preliminary examination of a same-day, voluntary referral for CBT-I and sleep medication taper for patients with insomnia in a primary care clinic. While patients benefited from the program, some limitations should be noted. In this study patients were allowed to select which services they engaged in (e.g., CBT-I vs. sleep medication taper vs. CBT-I with sleep medication taper). While this method of service referral is patient-centric and can allow some statistical analysis of results, it does not allow for comparison of different groups (e.g., those who completed CBT-I versus those who completed CBT-I with sleep medication taper).

Additionally, this model of sleep treatment relies on having a prescriber and behavioral health provider that have a working relationship with providers, available and accessible. Finally, this study utilized a small sample and thus results may not generalize to the larger population.

The present study evaluated a pilot treatment for insomnia involving a pharmacist led medication taper and CBT-I. Initial findings suggest the treatment was successful in improving sleep and reducing medication use. Due to the increasing availability of psychology and pharmacy services in primary care, more clinics can start to offer these types of programs in order to improve effectiveness and safety of treatment of insomnia in veterans. Further research is needed to demonstrate the generalizability of these findings and to determine how best to deliver this service within the VA.

Declaration

This information was previously presented at the national conference for the American Psychological Association: Possis E, Geurkink E, Westanmo A, Olson D. Treating Insomnia in Primary Care: A Pilot Trial of Cognitive Behavioral Therapy for Insomnia with Sleep Medication Taper. 2019. Poster session presented at the 127th annual meeting of the American Psychological Association, Chicago, IL.

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