U.S. Department of Veterans Affairs

Veterans Health Administration
VA Pittsburgh Healthcare System

SEDATIVE: A Virtual Insomnia Study

Call 412-360-2394 to validate this research study.

What is the SEDATIVE study?

We are recruiting Veterans over the age of 18 who are interested in reducing or stopping their usage of sleep medications. The purpose of this research study is to assess the usability and effectiveness of a mobile app to help reduce insomnia symptoms and medication use. The study will involve working with a Clinical Pharmacist and Sleep Psychologist through the mobile app to develop an individualized plan to reduce your medication use, while improving your sleep.

What is insomnia?

Insomnia is difficulty falling asleep, staying asleep, or waking up too early and struggling to fall back asleep.[1] Insomnia causes daytime impairment, such as making it harder to accomplish tasks or enjoy life. If this happens more than three nights a week for more than three months, you may have insomnia disorder.

Insomnia impacts over 50% of Veterans.[2,3]

Insomnia is often treated with sleep medications called sedative-hypnotics. This study is focused on helping Veterans reduce their use of these sleep medications: zolpidem (Ambien), eszopiclone (Lunesta), zaleplon (Sonata), trazodone (Desyrel), or temazepam (Restoril).

Why would someone want to reduce their use of sleep medications?

Sleep medications are designed to be used for several weeks or months, however many individuals stay on them for years.[3, 4] This elevates the risk of developing tolerance (need more medication to get same effect), dependence (struggle to stop using without experiencing negative withdrawal effects) and increases the medication's abuse potential (increased risk for tolerance, dependence, and negative side effects).[5] Side effects can include daytime drowsiness, decreased mental and physical functioning, and

an increased risk of falls and injuries [6, 7]. Also, sleep medications are not the recommended treatment—the VA and DoD recommend behavioral interventions, like Cognitive Behavioral Therapy for Insomnia, as they have equal or better outcomes with less risk than medications.

WHO CAN PARTICIPATE?

You may be eligible to participate if you:

- Have a desire to reduce or stop using sleep medications—zolpidem (Ambien), eszopiclone (Lunesta), zaleplon (Sonata), trazodone (Desyrel), or temazepam (Restoril).
- Have access to a mobile device with Wi-Fi or Internet connection.
- Willing to participate in a remote study—no in-person visits—and interact with your study clinicians through the mobile app.

WHAT IS INVOLVED?

1. Call 412-360-2364 to determine if you are eligible.
2. Download the free mobile app and complete sleep and health questionnaires.
3. Record your sleep behaviors every day to receive personalized treatment recommendations.
4. Work with a Clinical Pharmacist and Sleep Psychologist, through the mobile app, for up to 12 weeks on a personalized plan to reduce or eliminate your use of sleep medication.
5. Complete a post-treatment assessment and 3-month follow-up assessment.

If eligible and you choose to enroll in this study, after the consent process, you will begin by downloading the COAST mobile app and complete questionnaires and self-report measures about your sleep and health. A licensed Clinical Pharmacist will then work with you, through COAST, for up to 12 weeks on a personalized plan to reduce or eliminate your use of sleep medication. After the 12 weeks, if necessary and desired, you can continue your withdrawal plan with the provider who first prescribed your medication.

During the 12-week study period, the COAST app will also lead you through Cognitive Behavioral Treatment for Insomnia (CBT-I), an evidence-based treatment. Each day, you will use the COAST app to record your sleep behaviors (e.g., bedtime, how long to fall asleep, number of awakenings, wake time). This information will be reviewed by a study Sleep Psychologist who will make recommendations to change and improve your sleep quality. You can use the COAST app to talk with you study Sleep Psychologist if you have any questions or need to make changes to your sleep behaviors.

RISKS AND BENEFITS

Risks

Participating in this study has similar risk to receiving typical care for insomnia and sleep medication reduction. Risks may include increased sleepiness, anxiety, restlessness, irritability, and fatigue—all common when reducing sleep medications. The study team will work with you to minimize these symptoms (if present).

Benefits

You may directly benefit from participating in this study by learning how to sleep well without sleep medications while having your insomnia symptoms reduced. This may include falling asleep faster, staying asleep longer, and/or feeling more rested when you wake up. However, we cannot guarantee these results. Indirect benefits may include learning more about improving sleep quality through a mobile app and reduction of medications that may benefit Veterans like you with sleep problems in the future.

Privacy

As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you.

FUNDING AND MORE INFORMATION

- This research is sponsored by VA Rehabilitation Research and Development Service (VA RR&D).
- A description of this clinical trial is available on http://www.ClinicalTrials.gov (search: NCT05027438), as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

FREQUENTLY ASKED QUESTIONS

Will I be compensated for my participation?

If you choose to participate in this research study, you may receive up to $175 in compensation. $50 will be awarded upon completion of baseline measures, $50 for completing post-treatment measures, and $50 for information collected 3 months after completion of the study. Additionally, you may be selected to participate in an interview about your experience with the app. If so, you will receive an additional $25. Payments will be issued through Electronic Funds Transfer (EFT)—direct deposits to your bank account.

Are there alternatives to participation?

If you do not participate in this study, you may still seek treatment for insomnia, including Cognitive Behavioral Therapy for Insomnia. You may also talk with a provider about starting a step-by-step process to reduce your sleep medication. You can also choose not to seek treatment for insomnia or reduction of sleep medication if you are satisfied with your current care. Finally, there may be other studies that you qualify for. Talk to your provider about such options or contact the VA Pittsburgh Research Office.

CONTACT US

Interested in Participating? Please Call **412-360-2364**

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References

1. American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). https://doi-org.ezproxy.frederick.edu/10.1176/appi.books.9780890425596
2. Troxel WM, Shih RA, Pedersen E, et al. *Sleep in the Military: Promoting Healthy Sleep Among U.S. Servicemembers*. RAND Corporation; 2015:1-282. http://www.rand.org/pubs/research_reports/RR739.html
3. Mysliwiec V, McGraw L, Pierce R, Smith P, Trapp B, Roth BJ. Sleep disorders and associated medical comorbidities in active duty military personnel. *Sleep*. 2013;36:167-174. doi:10.5665/sleep.23
4. Hooft C, Jong G, Dieleman J, et al. Inappropriate drug prescribing in older adults: the updated 2002 Beers criteria--a population-based cohort study. *Br J Clin Pharmacol*. 2005;60:137-144.
5. Siriwardena AN, Apekey T, Tilling M, et al. Effectiveness and cost-effectiveness of an educational intervention for practice teams to deliver problem focused therapy for insomnia: rationale and design of a pilot cluster randomised trial. *BMC Fam Pract*. 2009;10:9. doi:10.1186/1471-2296-10-9.
6. Carson S, McDonagh M, Thakurta S, Yen P-Y. *Drug Class Review: Newer Drugs for Insomnia*. Oregon Health & Sciences University; 2008:1-395.
7. Riemann D, Perlis ML. The treatments of chronic insomnia: A review of benzodiazepine receptor agonists and psychological and behavioral therapies. *Sleep Med Rev*. 2009;13:205-214. doi:10.1016/j.smrv.2008.0