

Treatment for insomnia in women with hot flashes found to be safe, efficacious

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Hot flashes and night sweats are a common cause of insomnia among peri- and postmenopausal women. Hot flashes, night sweats and insomnia are all linked to reduced quality of life and distress. Despite



how common insomnia disorder associated with night sweats is, treatment options are limited. Through a randomized, double-blind, placebo-controlled clinical trial, investigators at Brigham and Women's Hospital found that the insomnia medication suvorexant, made by Merck & Co., was safe and efficacious, improving insomnia and night sweats among peri- and postmenopausal women. Results of the study are published in *Sleep*.

"Our study shows that there is a well-tolerated treatment that's now available to treat chronic insomnia in peri- and postmenopausal women that may also help reduce night sweats," said Shadab Rahman, Ph.D., MPH, of the Division of Sleep and Circadian Disorders and Mary Horrigan Connors Center for Women's Health and Gender Biology. "Our results are promising in the population we studied and there's a strong biological explanation for why we may be seeing improvements in reported insomnia as well as night sweats."

Current <u>treatment options</u> for insomnia include cognitive behavioral therapy (CBT) and medications such as nonbenzodiazepine GABA-A receptor modulators (these include commonly prescribed 'Z drugs' such as zolpidem/Ambien). Hormone therapy may also improve sleep in midlife <u>women</u> with insomnia related to night sweats. But each treatment has its drawbacks, including constrained access and adherence to CBT recommendations as well as concerns about side effects of sedative drugs and hormone therapy.

The researchers designed their study to test suvorexant because of its promising mechanism of action. The drug blocks the receptors for orexin, a neuropeptide involved in arousal and wakefulness and may also contribute to the occurrence of <a href="https://linear.com/https://lin



The research team conducted a four-week trial in which 60 women between the ages of 40 and 65 were randomized to receive either suvorexant or a placebo. Participants were assessed at in-person visits for insomnia severity and kept a diary recording their hot flashes and night sweats.

Insomnia symptom severity was scored using the Insomnia Severity Index (ISI). The decline in symptom severity at the end of the four-week trial, compared to baseline, was greater in the group that received suvorexant than in the group that received placebo (a decrease of 8.1 versus 5.6 points on the ISI), a meaningful and significant difference. The number of night sweats also decreased significantly for the suvorexant group compared to the control group. Daytime hot flashes and other related symptoms did not differ between the groups.

The authors note that their sample size for the study was small, limiting their ability to detect changes in other secondary sleep outcomes after adjusting for multiple testing. In the future, Rahman hopes to validate the findings by conducting a study in a larger population and seeing if improvements in insomnia severity and night sweats lead to improvements in health problems for women that are closely related, such as metabolism and cardiovascular disease.

"This study sends an important message to midlife women that there is an expanded repertoire of treatments available to help with their insomnia. So many women suffer with <u>insomnia</u> because of their night sweats and they don't seek treatment or know that safe and effective options are available to them," said Hadine Joffe, MD, MSc, senior author on the study and executive director of the Connors Center, Paula A. Johnson Professor of Psychiatry in the Field of Women's Health and executive vice chair for academic and faculty affairs in the Department of Psychiatry.



More information: Shadab A Rahman et al, A double-blind, randomized, placebo-controlled trial of suvorexant for the treatment of vasomotor symptom-associated insomnia disorder in midlife women, *Sleep* (2022). DOI: 10.1093/sleep/zsac007

Provided by Brigham and Women's Hospital

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