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NIH INSOMNIA ABSTRACT

Systematic Review of the Efficacy and Safety of Nondrug and Sequential Treatments in the Management of Chronic Insomnia in Adults

Manisha Witmans, M.D.

University of Alberta and Pediatric Sleep Program and Pediatric Sleep Medicine, Stollery Children's Hospital and University of Alberta Hospital, Edmonton, Alberta, Canada

The role of psychological factors in insomnia has resulted in the development of alternative, nonpharmacological interventions for the management of insomnia. Cognitive/ behavioral therapy has been recognized as a valid and successful treatment approach for insomnia.[1] Components of treatment may include sleep restriction, sleep hygiene, stimulus control, and cognitive restructuring. Various forms of relaxation therapy are used to alleviate somatized tension and cognitive arousal and may be used for management of insomnia. Many of these commonly used clinical tools have not undergone rigorous testing to determine their efficacy and long-term safety. The efficacy of these treatments has been evaluated in some studies,[1–3] but differences in the definition of insomnia and outcome measures makes it difficult to compare study results. Although complementary and alternative substances have been increasingly used in the management of insomnia, their efficacy remains unclear. Similarly, the efficacy of sequential treatments in the management of chronic insomnia is unclear. The Evidence-based Practice Center's objective was to conduct a systematic review of the efficacy and safety of psychological and sequential treatments in the management of chronic insomnia in adults. A systematic search of 21 electronic databases was conducted. The following databases were searched: MEDLINE®, EMBASE, CINAHL®, Ovid MEDLINE® in-process and other nonindexed citations, Ovid OLDMEDLINE®, PsycINFO®, EBM Reviews–Cochrane Central Register of Controlled Trials, International Pharmaceutical Abstracts, AMED (Allied and Complementary Medicine Database), HealthSTAR/Ovid HealthSTAR, EBM Reviews–Cochrane Database of Systematic Reviews, ACP Journal Club, Database of Abstracts of Reviews of Effects, Science Citation Index Expanded™, Biological Abstracts, Cochrane Complementary Medicine Field Registry, CAB Abstracts, SIGLE, OCLC Proceedings First, Dissertation Abstracts, Alt HealthWatch, NLM Gateway, and PubMed®.

A study was considered to be relevant to the review if it involved a psychological intervention (relaxation and cognitive/behavioral therapy) and met the following criteria: (1) the report was written in English; (2) the majority of participants were at least 18 years old; (3) participants suffered from chronic insomnia defined as a sleep disturbance of at least 1 month in duration; (4) participants were randomized to intervention or placebo; and (5) it assessed at least one of the following outcomes: sleep onset latency (SOL), wakefulness after sleep onset (WASO), sleep efficiency, total sleep time, sleep quality, or quality of life. Sleep onset latency was the primary outcome. The placebo treatment for relaxation therapy and cognitive/behavioral therapy was minimal treatment, such as sleep hygiene recommendations or minimal instruction. For sequential treatment involving combination therapy, the study was not required to have a placebo arm for inclusion in the review.

If the majority of participants met one of the following criteria, the study population was considered to suffer from chronic insomnia: (1) participants suffered from a sleep disturbance of 4 weeks or more; (2) participants were described as having a chronic sleep disturbance; or (3) participants were selected from a sleep disorders clinic. The Jadad Scale was used to assess study quality. The concealment of treatment allocation was also assessed. Data were analyzed quantitatively using the Random Effects Model.

The nondrug interventions were classified as complementary and alternative care, relaxation therapy, and cognitive/behavioral therapy. The complementary and alternative substances reviewed included L-tryptophan, melatonin, and valerian. SOL was significantly decreased by melatonin (mean difference [MD]: -8.3; 95 percent confidence interval [CI]: [-14.5, -2.0]). SOL was not significantly reduced by either L-tryptophan (MD: -11.0; 95 percent CI: [-33.0, 11.1]) or valerian (MD: -1.3; 95 percent CI: [-21.4, 18.9]), compared to placebo; however, there were only two and three studies in each category, respectively. Melatonin did not have a significantly higher risk of harm compared to placebo (risk difference: 0.09; 95 percent CI: [-0.11, 0.29]). WASO was not significantly reduced by melatonin (MD: -9.7; 95 percent CI: [-33.6, 14.3]). There were no studies for L-tryptophan and only one study for valerian that provided data on this outcome, precluding a meta-analysis for these substances. SOL was significantly decreased by relaxation therapy with short-term treatment (less than 4 weeks) (MD: -22.0; 95 percent CI: [-41.0, -2.9]); however, WASO was not significantly reduced by relaxation therapy (MD: -1.6; 95 percent CI: [-14.1, 10.8]). WASO was significantly decreased by cognitive/behavioral therapy (MD: -18.2; 95 percent CI: [-30.4, -6.0]); however, SOL was not significantly reduced by cognitive/behavioral therapy (MD: -4.6; 95 percent CI: [-9.8, 0.6]). Only one study was identified that analyzed the efficacy of

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combined versus sequential treatment. The study examined the efficacy of a nonbenzodiazepine and cognitive/behavioral therapy administered in combination versus these interventions administered sequentially. The combined treatment did not significantly increase sleep efficiency (MD: 4.0; 95 percent CI: [-23.4, 31.4]) or total sleep time (MD: -25.8; 95 percent CI: [-169.9, 118.3]) compared to the sequential treatment.

There is some evidence that melatonin is effective in the management of chronic insomnia in subsets of the chronic insomnia population, and there is no evidence that melatonin poses a risk of harm. However, more research is required in this area, given that the results are based on a small number of studies. There is evidence that relaxation and cognitive/behavioral therapy are effective in the management of chronic insomnia in subsets of the chronic insomnia population. Additional studies are needed to determine the efficacy of sequential treatments in the management of chronic insomnia.

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