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Randomized Controlled Trial [J Ethnopharmacol.](#) 2021 Jan 10:264:113276.

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Clinical evaluation of the pharmacological impact of ashwagandha root extract on sleep in healthy volunteers and insomnia patients: A double-blind, randomized, parallel-group, placebo-controlled study

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Abstract

Ethnopharmacological relevance: Ashwagandha (*Withania somnifera* (L.) Dunal.) is long known for its sleep-inducing effects. Ashwagandha can be proposed as an alternative to the recommended present treatments for insomnia. This study aimed to evaluate the pharmacological effect of Ashwagandha root extract on sleep in healthy subjects and also in the subjects having insomnia.

Material and methods: We performed a randomized, parallel-group, stratified design, placebo-controlled study. A total of 80 eligible participants, 40 in Arm-A (healthy) and 40 in Arm-B (insomnia) were assigned to two groups, either Ashwagandha or placebo and studied for 8-weeks. The assessment was done based on the sleep parameters (Sleep Onset Latency, Total Sleep Time, Wake After Sleep Onset, Total time in bed, and Sleep Efficiency), Pittsburgh Sleep Quality Index and Hamilton Anxiety scale-A questionnaire, mental alertness on rising assessment, and sleep quality questionnaire. Safety and adverse events along with the concomitant medication were also assessed.

Results: In both healthy and insomnia subjects, there was a significant improvement in the sleep parameters in the Ashwagandha root extract supplemented group. The improvement was found more significant in insomnia subjects than healthy subjects. Repeat measure Analysis of variance (ANOVA) confirmed the significant improvement in SOL ($p < 0.013$), HAM-A outcomes ($p < 0.05$), mental alertness ($p < 0.01$), and sleep quality ($p < 0.05$) of the insomnia patients. A two-way ANOVA was used to confirm the outcomes that denoted sleep onset latency ($p < 0.0001$) and sleep efficiency ($p < 0.0001$) as the most improved parameters, followed by TST ($p < 0.002$) and WASO ($p < 0.040$). All these parameters (SOL, TST, WASO, TIB, SE, PSQI, HAM-A, Mental Alertness, and Sleep quality) were also statistically assessed for the significant improvement within the group both for the treatment, and the placebo groups in the healthy and the insomnia datasets. Obtained results suggest statistically significant ($p < 0.0001$) changes between the baseline values and the end of the study results except for the HAM-A and the mental alertness scores in the healthy subject group.

Conclusion: The present study confirms that Ashwagandha root extract can improve sleep quality and can help in managing insomnia. Ashwagandha root extract was well tolerated by all the

participants irrespective of their health condition and age. Additional clinical trials are required to generalize the outcome.

Keywords: Actigraphy; Anxiety; Ashwagandha; Herbal medicine; Insomnia; Sleep onset latency.

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