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Original Article

A randomized, double blind, placebo controlled study to evaluate the effects of ashwagandha (*Withania somnifera*) extract on sleep quality in healthy adults

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Highlights

- Ashwagandha improved the quality of sleep, and reduced non-restorative sleep measures in healthy subjects with frequent non-restorative sleep.
- Ashwagandha decreased the SOL.
- Ashwagandha increased SE.
- Ashwagandha improved QOL.

Abstract

Objective

Non-restorative sleep (NRS) affects 10% people worldwide, leading to poor sleep quality, as well as physical and cognitive fatigue. This is the first human study in which an extract of ashwagandha (*Withania somnifera* Dunal L.) was evaluated for effects in improving overall sleep quality in subjects with NRS.

Methods

In this randomized, double-blind, placebo-controlled trial, 150 healthy subjects scoring high on non-restorative sleep measures were given 120mg of standardized ashwagandha extract (Shoden®) once daily for six weeks. Subjects were evaluated using the Restorative Sleep Questionnaire-weekly version and World Health Organization Quality of Life-Bref (WHOQOL) scale. Sleep actigraphy was used to measure the onset of sleep latency, sleep efficiency, total sleep time and wake after sleep onset. Safety of the treatment was determined by testing of vitals, hematology, biochemistry and urinalysis.

Results

A total of 144 subjects completed the study, with no dropouts due to adverse events. A 72% increase in self-reported sleep quality was found for the treatment group, compared with 29% in the placebo group ($p<0.001$). Based on activity monitoring data, the treatment group showed significant improvement in sleep efficiency (SE) ($p<0.01$), total sleep time ($p<0.001$) and sleep latency ($p<0.01$) and wake after sleep onset (WASO) ($p<0.05$) versus placebo after six weeks. In the ashwagandha group quality of life (QOL) scores showed significant improvement in physical ($p<0.001$), psychological ($p<0.001$), and environment domains ($p<0.01$).

Conclusions

Supplementation with the standardized ashwagandha extract for six weeks improved the overall quality of sleep by significantly improving the NRS condition in healthy subjects. No treatment related adverse events were reported in the study.

Trial registration

Clinical Trials Registry-India (www.ctri.nic.in). Registration number: CTRI/2017/02/007801.

Introduction

Nonrestorative sleep (NRS) has been recently developed identified and validated as a clinical endpoint for inadequate sleep [1]. NRS is commonly associated with insomnia and lack of restful sleep, and is often a feature of medical conditions like fibromyalgia and chronic fatigue syndrome [2]. NRS increases fatigue, lowers cognitive function and reduces quality of life (QOL), making the recognition and treatment of NRS a priority for physicians in the field of sleep medicine [3].

Recently, NRS has been investigated in the absence of other disorders in healthy people, and also accompanying comorbid conditions [4,5]. Other studies have indicated a high degree of psychiatric comorbidity, with NRS occurring more frequently in individuals with mood disorder, anxiety, and substance abuse disorder [6].

Previous versions of International Classification of Sleep Disorders (ICSD) allowed for NRS as a sole complaint in absence of sleep onset or sleep maintenance issues to qualify for diagnosis of Insomnia. However, currently available treatments for insomnia, including psychological therapy and pharmacologic treatments are designed for difficulty in initiating or maintaining sleep. The current version (ICSD-3) has removed NRS as a sole criterion for diagnosis of Insomnia, however it does admit to the fact that further research is needed to explore the clinical significance in the context of Insomnia. Pharmaceutical treatments have shown efficacy for improving sleep, however many adverse effects are associated with these medicines. Despite recent advances in the development of newer sleeping aids and hypnotics in modern medical science, a significant number of patients with sleep disturbances, consume supplements regularly to support sleep [7]. Hence there is a need for medicines which are shown to be effective in addressing the issue of "NRS".

Many chronic Insomnia patients have thoughts about ongoing sleep difficulties through the day and may be amplified near bedtime. Often performance anxiety about "sleep" itself is present. A learned pattern of physiological arousal at bedtime is often seen. All this leads to perceived stress furthering Insomnia [8].

Ashwagandha (*Withania somnifera*), also known as Indian ginseng, is a shrub plant belonging to the Solanaceae family. Ashwagandha has been used by traditional Indian Ayurvedic medicine for thousands of years to help with sleep, inflammation, sexual issues, nerve tissue damage, stress, anxiety, insomnia and other ailments [9]. The efficacy of ashwagandha against anxiety and depression has been previously reported in clinical trials [[9], [10], [11], [12], [13]]. Ashwagandha has since long been well recognized to be a sleep inducing plant and in a recent study, efficacy and safety of ashwagandha root extract has been reported in subjects diagnosed with insomnia and anxiety [14]. While NRS is associated with stress, anxiety, depression and daytime fatigue [15], ashwagandha is shown to be effective in relieving stress and depression [12,16]. It is also effective in reducing fatigue [17] and inflammation [18]. Thus, it was proposed that ashwagandha may have beneficial effects in reducing NRS.

The primary objective of the present trial was to evaluate effect of daily supplementation of a standardized ashwagandha extract compared to placebo in healthy subjects with NRS after six weeks. The secondary objectives were to compare ashwagandha and placebo groups on change from baseline up to six weeks by activity monitoring during sleep, and quality of life scores using World Health Organization Quality of Life-Bref (WHOQOL-Bref) scale.

Section snippets

Study design

This was a prospective, randomized, double blind, parallel, placebo controlled, clinical study. The study was conducted at International Institute of Sleep Sciences, NEST Hospital, Thane, Maharashtra, India. The study was conducted in accordance with the Declaration of Helsinki, the ICH-GCP E6 (R1, R2), and ICMR-National Ethical Guidelines for Biomedical and Health Research, 2006. The study protocol was approved by the institutional ethics committee and registered with Clinical Trials …

Results

A total of 751 subjects were assessed during Mar 2017 to Sep 2018 for eligibility, from which 154 subjects met the study criteria and were randomized into two groups (77 subjects in each group) (Fig. 1). Four subjects (two from each group) withdrew before treatment exposure, thus, 150 subjects (75 in each study group) received the intervention. Study duration per subject was six weeks. Out of 75 subjects in each group, 73 subjects completed the study in placebo group and two subjects were lost …

Discussion

Many people find it hard to get restful sleep. Low sleep quality leads to chronic fatigue, daytime sleepiness, and may result in other sleep disorders [25]. Restorative sleep is considered to be an important aspect of the overall sleep experience for healthy individuals. Non-restorative sleep, as measured in this study, is one indicator of poor sleep quality that results in day time fatigue and lethargy [26]. In Ayurvedic literature and traditional practice, "*Nidrajanan*" (sleep induction) is …

Conclusion

Supplementation with 120mg of ashwagandha extract improved the overall quality of sleep in healthy individuals by significantly improving NRS condition, by reducing the SOL, WASO, average awakening time and significantly improving TST, SE, and QOL. The ashwagandha extract used in this study can be considered as a useful supplement to promote healthy sleep patterns, and restful sleep. …

CRediT authorship contribution statement

Abhijit Deshpande: Conceptualization, Data curation, Formal analysis, Writing - original draft, Writing - review & editing. **Nushafreen Irani:** Investigation, Methodology, Project administration, Writing - review & editing. **Ratna Balkrishnan:** Resources, Software, Supervision, Writing - review & editing. **Irin Rosanna Benny:** Validation, Visualization, Writing - review & editing. …

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