

A Randomized Trial of Ayurvedic Herbal Remedies for Sleep Quality: An App-Based Assessment

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Abstract

Introduction: The quest for treatment of insomnia without side effects has been elusive and thus has led to herbal therapies. Two such supplements are Ayurvedic-based herbs, Ashwagandha and valerian. Even though the anti-inflammatory and antioxidant properties of Ashwagandha have been investigated, its sleep enhancing properties have not been studied. It was hypothesized that Ashwagandha would have sleep quality enhancing effects similar to those of valerian and would be more beneficial than the placebo. Further, a smart phone app based sleep assessment technology was utilized to monitor the participants in this study.

Methods: Thirty-three participants were given either Ashwagandha, valerian, or placebo for 4 weeks (single blinded and randomized) and their sleep quality was monitored using a smart phone app or with questionnaires. After this study period and a brief washout period, the same procedure was repeated except the participants did not take any supplement, serving as a comparison measurement.

Results: Sleep quality improved significantly in participants who took Ashwagandha ($P < 0.0001$) when compared to valerian and placebo. They also appeared to have a higher percentage of deep sleep than the other groups. A much greater sleep quality increase was observed during the study period than during the later

comparison period in both of the herbal groups ($p = 0.02$) but not in the placebo group. In addition, the app-based sleep monitoring system appeared feasible in this study.

Conclusions: The results suggest that Ashwagandha may be an effective sleep-enhancing supplement. Its exact clinical relevance is not known and further investigation would be required to elucidate these findings.

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Introduction

While studies indicate that 7 to 8 hours of sleep per night is optimal [1], sleep deprivation, insomnia, and sleep disorders are present in as many as 30% of adults [2,3]. Sleep disorders, in turn, result in adverse health consequences, such as high blood pressure, depression, heart rhythm disorders, and motor vehicle accidents [1,2,4-6]. Currently, treatment includes pharmacological as well as behavioral treatment. The most commonly prescribed medications for sleep are sedative hypnotics such as benzodiazepine [7]. These agents act via

GABA (Gamma Amino Butyric Acid) receptors [8,9]. Almost all of these current therapies have adverse side effects, including withdrawal, dependency, and rebound insomnia [10-12]. Herbal and dietary supplements, which do not have these effects, are being considered as alternative therapies [13].

Ayurveda (Sanskrit for “the scripture for longevity”), an ancient Indian healing science that approaches health holistically [14-16], offers two possible herbal supplements purported to improve sleep: Ashwagandha (*Withania Somnifera*) and valerian [16]. Ashwagandha has been studied for its powerful antioxidant, anti-inflammatory, and anti-cancer benefits [17-19]. It is believed to be a mild sedative that will promote sleep by reducing stress, believed to be an imbalance, which when balanced would relieve other imbalances such as lack of sleep quality. Ashwagandha is believed to have no apparent side effects, although few studies have been conducted previously to test the safety and efficacy of this herb in improving sleep quality [17,20,21]. Valerian, another root, is reported to have similar beneficial effects, but this agent has been relatively extensively studied and its effects widely documented [11,22-25].

Traditionally, to conduct a sleep study to determine the efficacy of such therapies, researchers have used either a sleep laboratory or self-reporting. The first is an unnatural, unfamiliar setting which may affect the results of the study, and the second is highly unreliable. However, new mobile device, app-based technologies have emerged to provide ways of monitoring sleep using the device’s accelerometer to analyze movement and assess sleep quality allowing subjects to be studied in their real-life environment. Whether these newer technologies can be effectively used to assess the safety and efficacy of natural sleep-enhancing supplements is unknown.

This study aims to test the hypothesis that the Ayurvedic herb Ashwagandha promotes sleep quality at a similar level as that of valerian but is superior to a placebo. It also aims to determine whether or not new app-based sleep assessment technologies are an effective tool in evaluating sleep quality.

Methods

This study was approved by the Scientific Review Committee of Rochester, Minnesota. Thirty-three adult participants were recruited to the study and their informed consent was obtained. Twenty-two females and 11 males with an average age of 47 participated regardless of a preexisting sleep disorder. There was no specific targeted population outside of this; anyone above the age of eighteen, who was not pregnant, and who did not have a disrupting factor such as a newborn child to wake them up during the night, was allowed to participate. Before beginning the experiment, the subjects were asked to complete a Pittsburgh Sleep Quality Index questionnaire to assess whether they had any severe sleep conditions (with which it was determined that none did) or experienced high stress before starting on the supplements. They were separated randomly into 3 groups by alternation, or for the sake of simplicity, participants who lived in the same household were placed into the same group. One group (Group A) was selected to take Ashwagandha supplements (13 of 28 participants), the second group (Group B) another valerian supplement (8 of 28 participants), and the third group (Group C) a placebo (7 of 28 participants). Each was told to take one supplement every evening for a period of four weeks. The valerian and Ashwagandha supplements had equal dosages of 100 mg each, and rice powder (which closely resembled the herbal powders used in the other supplements) was used as a placebo.

If the participant had a capable smartphone, they were asked to use a sleep assessment app (developed by MaciekDrejek labs) and send in results each day; if they did not, they were asked to fill out subjective assessment questions each morning. With the use of a built-in accelerometer, smartphone assessment apps measured not only duration of sleep but the amount of time spent in deep sleep or light sleep, which then gave a sleep quality percentage based primarily off of these two factors (duration and depth of sleep) and allowed subtle differences and improvements to be detected and analyzed. This occurred through the accelerometer’s analysis of the user’s movement throughout the night. In this study, the app was activated and

then ended by the participant each night, and the participant also had to send a stored collection of the data in desired intervals to the researcher. All of the participants giving objective assessment used the same method of assessment. Although the name of the app varied between Android and iOS users, the processes used to determine a sleep quality percentage were determined to be identical. Participants without capable smartphones used subjective assessment questionnaires.

In order to get a comparison measurement, after the four weeks were completed and data collected, the participants continued the same reporting process for another two weeks, but without taking the supplements. In this way we were able to analyze the data in an analog fashion by comparing sleep quality from the beginning of the study period, when the supplement had not been taken, to the end of the study period, when the supplement had been taken for four weeks, and again during a time when the participant was not taking the supplement. In this way, each participant essentially served as his or her own control.

At the end of the study period, the subjects took a post-study questionnaire to report any negative or positive effects observed during the experiment. Sleep quality percentages were monitored and analyzed over the full duration of the four-week study period. This was separated into data from the beginning of the study period and data from the end of the study period. The overall improvement between these two sets of data was observed as the overall change over the study period. The data was then analyzed for statistical significance using the Analysis of Variance test (ANOVA).

Results

The total number of participants in the study was 33, all of whom submitted data. Of these, 28 gave complete sets of data. Twenty-two subjects were smartphone users and 6 used subjective assessment questions instead. Overall, the number of sleep days measured from all participants totaled 804. Of these, 511 sleep days were with Ashwagandha as a supplement, 199 with valerian, and 94 with a placebo.

For Group A, the average increase in sleep quality percentage between the beginning of the study period and the end was 10.99%. This was compared with a 0.037% increase in Group B ($p=0.002$) and -1.37% difference in Group C ($p=0.003$), demonstrating that Ashwagandha, even when compared to an already effectively used supplement, significantly increased sleep quality (ANOVA < 0.0001). (Figure 1)

Figure: 1

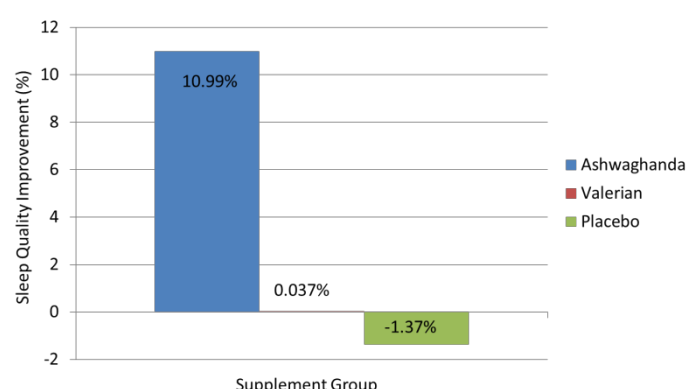


Figure 1: Comparative sleep quality improvement percentages between the three supplement groups, with the Ashwagandha group showing the greatest increase in sleep quality over the study period.

Because the initial baseline sleep quality percentages between both the participants and the three groups were different, this was adjusted for by separating a fourth group from all participants. This group had initially high sleep quality percentages without supplement use. When assessing the data from these participants, sleep quality percentage in Group A members increased (10.8%), there was virtually no change in Group B members, and sleep quality in Group C members decreased (-4%) (Figure 2).

The Smartphone application technology set a threshold for when the participant entered a deeper sleep stage. It was then able to analyze the amount of overall sleep time spent beyond this threshold to give a deep sleep percentage. Using this feature, data regarding the amount of time subjects in Groups A

and C spent in deep sleep or light sleep was recorded and compared between the two groups. Participants in Group A had a larger percentage of deep sleep by 15% ($p < 0.001$) (Figure 3).

Figure: 2

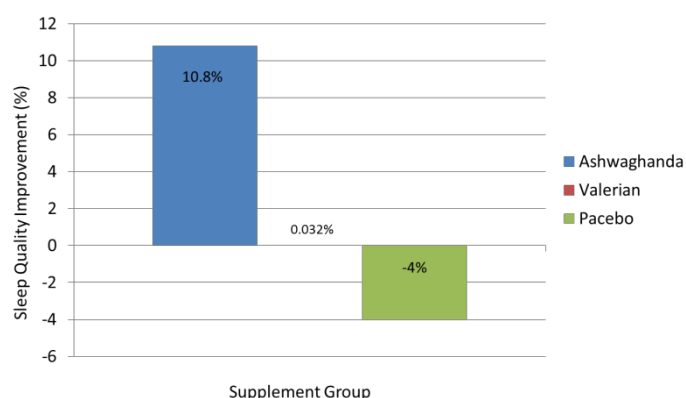


Figure 2: Comparative sleep quality improvement percentages between the three supplement groups, taken from a subset of the population who had demonstrated initially high sleep quality percentages at the beginning of the study period.

Figure: 3

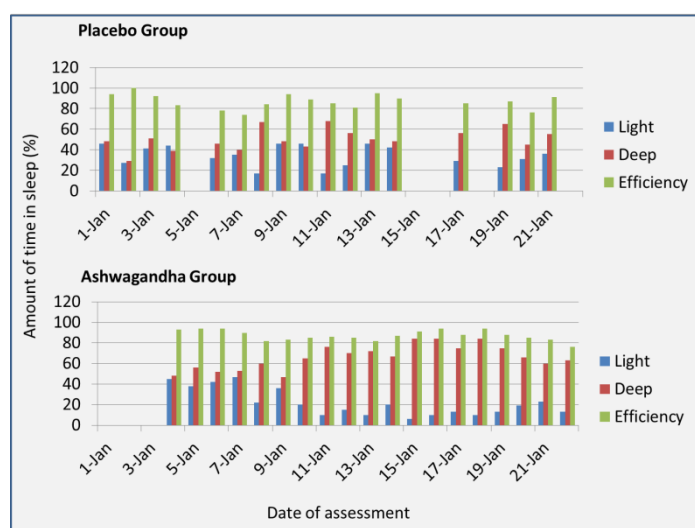


Figure 3: Comparative amount of time spent in deep sleep or light sleep between the placebo group and the Ashwagandha supplement group, as well as the relative sleep efficacies.

Because Ashwagandha and valerian are purported to carry out these sleep-enhancing effects through stress relief, participants who initially reported high stress the stress questionnaire taken at the beginning of the study period were analyzed for sleep quality percentage increase or decrease. The results were similar to those of the overall average; Group A increased sleep quality by 13.4%, Group B by 1.7%, and Group C by -2.3%.

Each participant submitted four weeks of data with supplement use and two weeks of comparison data without supplement use, and the results were compared. Sleep quality percentages in Group A were 8% higher with the use of the supplement than during the comparison period ($p = 0.02$). For Group B, this difference was 3%, which was statistically insignificant, and for participants in Group C, there was no significant difference.

In addition, sleep latency, or the amount of time it takes to fall asleep, was compared between the study period using Ashwagandha and the comparison measurements. This sleep latency was separated into two measurements: light sleep latency and deep sleep latency. While participants in Group A tended to take the same amount of time to enter light sleep as those in the placebo group, the time to enter deep sleep was greatly reduced (Figure 4).

Figure: 4

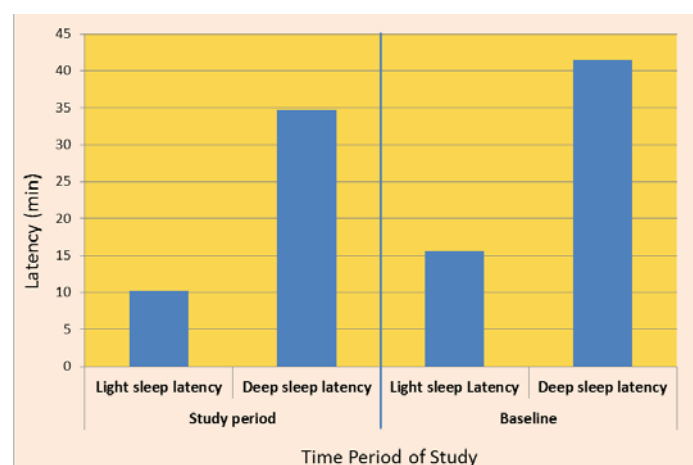


Figure 4: Sleep latency, or the time required to fall asleep, was compared between the Ashwagandha group study period and the same group's baseline (comparison) period. It was observed,

though not statistically significant, that both light and deep sleep latency were decreased during the study period.

The differences in the range of data from smartphone apps and from subjective assessments indicate that data from smartphone apps was more reliable than from subjective assessments since in subjective assessments, almost all participants tended to give a single answer in the middle of the spectrum, which was not specific nor encompassed a broad range of sleep quality, whereas when examining smartphone app data, the reality was very different and reflected the wide range of quality one actually experiences during sleep.

No adverse side effects were mentioned in the post-study questionnaire, although two participants in Group A noted an increase in the vividness and the frequency of dreams.

Discussion

These results show that the use of Ashwagandha results in statistically significant improvement in sleep quality and concur with the few studies that have been made both with Ashwagandha [19,21] and with an herbal preparation that included Ashwagandha [26].

Speculations have been made about the mechanism of action of the herb Ashwagandha [27]. As shown by the study data, this supplement increased deep sleep and gradually increased sleep quality rather than having an effect right away. These characteristics are not typical of sedative hypnotics or other sleep aids that work via GABA receptors, which generally do not increase deep sleep or enhance overall sleep quality [7,9]. However, a possible mechanism of action for Ashwagandha could be via melatonin receptors, which would explain the gradual adapting of circadian rhythms and the increased quality of sleep. Melatonin analogues, which are currently being developed, have been observed to have similar effects [28].

Both Ashwagandha and valerian appeared to be safe, as no side effects were reported after the study, but with a marked difference in effectiveness. Because no clinical sleep studies

have been done up to this point using app-based technology or sleep quality percentages which this technology provides, and although the increase in sleep quality percentage is statistically significant, the exact clinical significance of this increase could not be determined in this study.

Despite this, the use of the smartphone app was reported by participants to be easy and intuitive, and it proved to be feasible and effective in this pilot study and may be considered for larger clinical trial use.

Implications

Making use of Ayurvedic herbs could be a way to improve sleep quality without the negative side effects associated with current sedative hypnotics [6,10]. Furthermore, combining these supplements with app-based assessment to allow real-time titration of herbal supplement type and dosage could provide holistic improvement in sleep quality. With further study, this could be implemented for more widespread use.

A concomitant app-based sleep assessment and formal study with an EEG could be conducted for absolute validation of the technology. The effects of Ashwagandha on melatonin and GABA receptors to find the mechanism of action could be determined using ex-vivo assessment. Also, repeat studies with varying doses of Ashwagandha and valerian could reduce the possibility of under-dosing valerian, leading to reduced effectiveness. The addition of EKG and other sensors could assess physiological effects concurrent to sleep pattern data.

Limitations

This study used a small sample size, although almost all data was still statistically significant. Also, due to inconsistencies in participant compliance, there was an unequal distribution between the supplement groups despite efforts to randomize the placement of participants in each group.

Compliance of participants could not be directly monitored. While many subjects were consistent in reporting, a percentage did not send complete sets of data. Also, the supplement may

not have been taken or the app may not have been set up correctly on a given day.

In addition, a longer study duration is necessary to determine whether tachyphylaxis develops or side effects are noted. As the results showed, Ashwagandha works gradually, so the full extent of these benefits may not have been adequately measured in this time period.

Comparison measurements occurred after the study period. This may have affected the results if the supplement had continuing residual effects. Whether or not the effects of the herb are lingering could not be determined by this study and has not been tested before, so it is unknown.

Also, the efficacy of the sleep app could not be conclusively determined because the technology in this study was not directly tested against current gold standards in sleep studies, such as polysomnography and actigraphy.

Conclusion

Ashwagandha appears to be an effective sleep-enhancing supplement that improves sleep quality without negative side effects. App-based sleep assessment technologies are feasible and effective. Both of these in combination could have implications to promote enhanced sleep and conduct more comprehensive sleep studies. Questions concerning mechanism and duration of action of these supplements require further investigation.

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