Contents lists available at UGC-CARE

International Journal of Pharmaceutical Sciences and Drug Research

[ISSN: 0975-248X; CODEN (USA): IJPSPP]

journal home page : https://ijpsdronline.com/index.php/journal

Research Article

A Focused Group Human Volunteer Study on the Efficacy of a Novel Candyceutical Sleep Aid: "Restore Your Sleep"

Shefali Thakkar[1*], Nikita Naterwalla[1], Kirti Laddha[2]

[1]*Department of Research and Product Development, Arelang Naturals Private Limited, Mumbai, Maharashtra, India.*
[2]*Department of Medicinal and Natural Products, Institute of Chemical Technology, Mumbai, Maharashtra, India*

ARTICLE INFO

Article history:
Received: 26 June, 2024
Revised: 19 August, 2024
Accepted: 23 August, 2024
Published: 30 September, 2024

Keywords:
Candyceutical, Non-melatonin, Restore your sleep, Dark chocolates, Melatonin supplements.

DOI:
10.25004/IJPSDR.2024.160506

ABSTRACT

Sleep disorders affect a significant portion of the population and often lead to detrimental health outcomes. Traditional sleep aids, such as melatonin supplements, though widely used, come with potential side effects and risks of dependency. Caim by Arelang Naturals Private Limited developed "Restore Your Sleep" - a non-melatonin dark chocolate enriched with herbal extracts including nutmeg, walnut, St. John's wort, passionflower, and valerian for promoting restorative sleep and overall vitality. The Leeds sleep evaluation questionnaire (LSEQ) was used to evaluate the effectiveness of the chocolates in inducing restorative sleep throughout 15-day focused group observational research with 75 individuals. Significant increases in sleep quality were observed in the trial. Total sleep time (TST) increased from 6.4 to 8.2 hours (t-value: -43.20, *p-value*: 0.0000273), and sleep onset latency (SOL) decreased from 48 minutes to 18 minutes (t-value: 19.61, *p-value*: 0.00029). The results indicate that restore your sleep dark chocolates are effective in improving both sleep quality and duration.

INTRODUCTION

Sleep disorders are pervasive, affecting approximately 30% of adults worldwide and leading to significant health and societal consequences. Improper or poor-quality sleep is associated with a range of detrimental health outcomes, including metabolic disorders, cardiovascular disorders, cognitive impairments, and impaired overall quality of life. In India alone, an estimated 34.7% of healthy college students suffer from insomnia, underscoring the urgent need for effective and safe treatment options.[1]

Traditional sleep aids, such as benzodiazepines and melatonin supplements, are commonly used to manage sleep disorders.[2,3] However, these solutions come with various drawbacks. Benzodiazepines can cause dependency and adverse side effects, while melatonin supplements may not be suitable for all individuals and can have inconsistent effects.[4-7] The search for alternative sleep-promoting solutions that are both effective and safe is, therefore crucial.

Herbs like passionflower, nutmeg, walnut, St. John's wort, and valerian have been used in the Ayurvedic system of medicine for a very long time. 'Charaka Samhita' and 'Sushrutha Samhita'- the ancient Indian texts from 1500 BC have also mentioned the use of these medicinal plants.

Walnut (*Juglans regia*)[8-10]

J. regia are abundant sources of omega-3 fatty acids, melatonin, and antioxidants. Research suggests that walnuts can help improve sleep quality by increasing melatonin levels in the body, thus regulating sleep-wake cycles. A study found that consuming walnuts significantly increased melatonin levels and improved sleep quality among participants.

***Corresponding Author:** Dr. Shefali Thakkar

Address: Department of Research and Product Development, Arelang Naturals Private Limited, Mumbai, Maharashtra, India.

Email ✉**:** pajwanis@gmail.com

Tel.: +91-8879350005

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Valerian (*Valeriana officinalis*)[11-16]

One well-known herbal treatment for anxiety and insomnia is valerian root. It is researched to increase the brain's production of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA), which aids in bodily relaxation and sleep promotion. Clinical studies have shown that valerian can enhance sleep quality and reduce sleep onset latency, or the time it takes to fall asleep, without producing hangover symptoms or morning lethargy.

Passionflower (*Passiflora incarnata*)[17,18]

The passion flower has anciently been used to manage anxiety and insomnia. It contains compounds that act on the central nervous system to produce a calming effect. A randomized controlled trial demonstrated that passion flower extract significantly improved sleep quality in patients with mild sleep disturbances.

Nutmeg (*Myristica fragrans*)[19-22]

Nutmeg is used in various traditional medicines as a remedy for sleep disorders. It contains myristicin and elemicin, which have sedative properties that may help induce sleep. Although scientific research on nutmeg's sleep-inducing effects is limited, anecdotal evidence and traditional use support its possible advantages.

St. John's Wort (*Hypericum perforatum*)[23-27]

Hypericum, with its active constituent hypericin and hyperforin, is commonly used for managing anxiety and depression conditions, which are often associated with sleep turbulences. It acts by stimulating the levels of feel-good hormones like serotonin, dopamine, and other neurotransmitters in the brain. According to a research study by Sharpley *et al*., (1998),[23] hypericum can improve sleep quality, particularly in those who suffer from depressive symptoms.

Previous studies as mentioned above in individual ingredients have shown promising results for non-melatonin sleep aids. For instance, Anghel *et al*.'s research from 2022[5] examined the effects of a valerian root and passionflower combination on the quality of sleep for persons with mild to moderate insomnia. The study included 150 participants and showed significant improvements in sleep onset, duration, and overall sleep quality without any notable side effects. This research highlights the potential of plant-based sleep aids in providing a natural alternative to traditional medications. In the current pharmaceutical landscape, there is a significant demand for natural, non-addictive, and effective sleep aids due to the growing awareness of the side effects associated with conventional medications. "Restore Your Sleep" dark chocolates provide a novel solution by leveraging the therapeutic properties of traditional herbal extracts in a palatable form. This product addresses a critical gap by offering a melatonin-free alternative that minimizes the risk of dependency and adverse effects. As a candyceutical, it integrates wellness into everyday indulgence, aligning with the modern trend toward functional foods that support health and well-being. Given the prevalence of sleep disorders and the increasing preference for natural remedies, "Restore Your Sleep" dark chocolates have the potential to make a significant impact in improving sleep quality and overall health outcomes. This study's main goal was to evaluate how well "Restore Your Sleep" from Caim by Arelang can enhance the quality of sleep. The Leeds sleep evaluation questionnaire (LSEQ) was used to assess this in volunteer subjects. A t-test was employed for statistical analysis to compare sleep parameters before and after consuming "Restore Your Sleep" dark chocolates.

Materials And Methods

Research Design and Participants

To determine how "Restore Your Sleep" dark chocolates affected the quality of sleep, a focused group observational research was conducted. The trial, which ran for 15 days, included 75 people, ages 18 to 55 years. Participants ate the dark chocolates at this time to assess their efficacy. The study was approved by the Institutional Review Board (IRB) and conducted following the Declaration of Helsinki. Informed consent was obtained from all participants before enrolment.

Inclusion Criteria

- Age: 18 to 55 years
- Self-reported sleep disturbances for at least one month before the study
- Willingness to comply with the study protocol and attend all scheduled visits
- No history of sleep disorders requiring pharmacological intervention

Exclusion Criteria

- Use of any sleep aids or medications within four weeks before the study
- History of chronic illnesses that could affect sleep, such as severe depression, anxiety, or sleep apnea
- Pregnant or breastfeeding women
- Consumption of more than two alcoholic drinks per day
- Shift workers or individuals with irregular sleep schedules

Intervention

Participants were given 7 chocolates, each weighing 10 g, to be consumed nightly for 15 days. The dark chocolates, developed by Arelang Naturals Private Limited, contain herbal extracts, including Nutmeg, Walnut, St. John's Wort, passionflower, and valerian, formulated to promote restorative sleep without melatonin.

Table 1: LSEQ score for evaluating sleep quality parameters

Age group (in years)	*No. of participants*	*Ease of initiating sleep*	*Quality of sleep*	*Ease of waking*	*Behaviour following wakefulness*
18–30	24	4.21	4.04	4.63	4.83
30–50	34	4.15	4.38	4.82	4.82
50 +	17	4.18	4.24	4.88	4.88
All	75	4.17	4.24	4.77	4.84

Evaluation of Sleep Quality

The LSEQ, an approved measure that gauges subjective variations in sleep quality, was used to evaluate the quality of sleep. The LSEQ assesses four dimensions: Behavior after wakefulness, ease of waking, quality of sleep, and ease of commencing sleep. Every domain is assigned a value ranging from 0 to 5, where higher scores correspond to higher quality sleep.

Study Procedure

Participants maintained a sleep diary, recording their sleep patterns before the commencement of the study, during the trial period, and on washout days when chocolates were not consumed. The study incorporated gaps (washout days) to assess the retention of improved sleep patterns and circadian rhythm without the intervention.

Data Collection

The information gathered included sleep efficiency, sleep onset latency (SOL), total sleep time (TST), ease of waking, quality of sleep, and ease of starting sleep.

Statistical Analysis

GraphPad Prism (version 10.0, trial version) was used to analyze the data. To compare sleep metrics before, during, and on washout days, a paired t-test was employed, with a significance level set at $p < 0.05$. The efficacy of dark chocolate in enhancing sleep quality was evaluated by t-test results, which evaluated the statistical significance of changes in SOL, TST, and LSEQ scores.

Results

The objective of the research was to evaluate the impact of "Restore Your Sleep" dark chocolates on many aspects of sleep, including the ease of falling asleep, the quality of the sleep, the ease of waking up, the behavior after waking up, the SOL, the TST, and the efficiency of the sleep. Over 15 days, 75 volunteers, ages 18 to 55 years, were observed. Table 1 provides a full account of the LSEQ score observations.

Sleep Onset Latency

Table 2 displays the sleep onset latency values. Throughout the study period, the average SOL for the group dropped dramatically from 48 to 18 minutes. In comparison to the pre-trial SOL, the SOL was lowered by an average of 12 minutes on the washout days. A highly significant reduction was indicated by the paired t-test findings for sleep onset latency from the pre-trial to the trial period, which produced a t-value of 19.61 and a *p-value* of 0.00029. The t-value was 7.72, with a *p-value* of 0.00452 from the pre-trial to the washout days, showing a significant decrease.

Total Sleep Time

Table 3 displays the results for the overall amount of sleep time. Throughout the trial period, there was an hour and 48-minute increase in the average TST for the entire group. In comparison to the pre-trial TST, the TST increased by an average of 50 minutes on the washout days. A highly significant increase was shown by the paired t-test findings for total sleep time from the pre-trial to the trial period, which produced a t-value of -43.20 and a *p-value*

Table 2: Sleep onset latency observations

Age group (in years)	*No. of participants*	*Pre-trial*	*During trial*	*Washout days*
18–30	24	6:30	8:25	7:17
30–50	34	6:34	8:17	7:26
50 +	17	5:54	7:45	6:47
ALL	75	6:24	8:12	7:14

Table 3: Total sleep time observations

Age group (in years)	*No. of participants*	*Pre-trial (in mins)*	*During trial (in mins)*	*Washout days (in mins)*
18–30	24	53	19	36
30–50	34	43	16	34
50 +	17	51	18	38
ALL	75	48	18	36

Table 4: Sleep efficiency observations

Age group (in years)	*No. of participants*	*Pre-trial (%)*	*During trial (%)*	*Washout days (%)*
18–30	24	87.93	94.03	90.25
30–50	34	90.03	95.06	91.90
50 +	17	87.39	93.01	89.88
ALL	75	88.78	94.27	90.94

of 0.0000273. The t-value was -38.17 with a *p-value* of 0.0000395 from the pre-trial period to the washout days, further suggesting a substantial rise.

Sleep Efficiency

Table 4 presents the sleep efficiency observations. During the study period, the group's average sleep efficiency increased by 5.49%, with an additional TST of one hour and 48 minutes.

Discussion

The results of this study show that "Restore Your Sleep" dark chocolates may be effective in helping participants' sleep quality across a range of metrics. The study used the LSEQ and comprehensive assessments of SOL, TST, and sleep efficiency. It was conducted over 15 days with a diverse age group of 75 volunteers.

Sleep Quality and LSEQ Scores

The assessed domains—easiness of awakening, quality of sleep, ease of starting sleep, and behaviour after wakefulness—showed significant improvements in the LSEQ scores. The total LSEQ score improved significantly in all age groups, indicating a continuous improvement in sleep quality, according to the aggregate values (Table 1). Interestingly, those over 50 years and those between the ages of 30 and 50 years had marginally higher ratings, indicating that dark chocolates may have a more noticeable impact on older people who frequently have more severe sleep problems.

Sleep Onset Latency

The results of the study showed that during the trial time, SOL significantly decreased. On the days when the chocolates were consumed, the average SOL for the entire group dropped by thirty minutes, from 48 to 18 minutes (Table 2). The SOL was lowered from the pre-trial baseline by an average of 12 minutes, even on washout days. A significant reduction in sleep onset latency is shown by the high t-value of 19.61 and the low *p-value* of 0.00029, suggesting that the chocolates helped assist participants in falling asleep more quickly. The decrease in SOL on washout days adds more evidence that dark chocolates have long-lasting positive effects.

Total Sleep Time

Significant gains were also observed in TST. Throughout the study, TST rose by an average of one hour and 48 minutes, with a significant increase of 50 minutes on washout days (Table 3). The efficiency of dark chocolate in encouraging longer and maybe more restorative sleep cycles is demonstrated by this continuous rise in sleep length. The very low *p-value* of 0.0000273 and the extremely high negative t-value of -43.20 show a statistically significant increase in total sleep time during the trial period compared to the pre-trial period. The extended impact seen on washout days indicates that the chocolates may have had a longer-lasting impact in addition to enhancing sleep duration when consumed.

Sleep Efficiency

Another benefit of the study was the increase in sleep efficiency. Throughout the trial period, there was an average 5.49% improvement in sleep efficiency (Table 4). This measure, which shows the proportion of time in bed to time asleep, shows that individuals were not only getting longer sleep but also more restful sleep. Higher quality sleep is suggested by improved sleep efficiency, and this improves general health and well-being.

Conclusion

The statistically significant improvements in SOL and TST, coupled with enhanced LSEQ scores, provide strong evidence of the efficacy of "Restore Your Sleep" dark chocolates. These findings are promising for those seeking natural alternatives to traditional sleep aids. The combination of nutmeg, walnut, St. John's wort, passionflower, and valerian appears to offer a synergistic effect in promoting better sleep without the drawbacks associated with melatonin supplements.

Future research could expand on these findings by exploring longer-term use and the potential cumulative benefits of these dark chocolates. Additionally, studies involving a larger and more diverse sample size could further validate the generalizability of these results. Overall, "Restore Your Sleep" dark chocolates present a valuable, natural option for enhancing sleep quality and overall health.

Acknowledgment

We would like to express our gratitude to "The Institute of Chemical Technology", Matunga, Mumbai for the invaluable support and guidance throughout this research.

References

1. Suri TM, Ghosh T, Mittal S, Hadda V, Madan K, Mohan A. Systematic review and meta-analysis of the prevalence of obstructive sleep apnea in Indian adults. Sleep Medicine Review. 2023 Oct;71:101829. Available from: doi.org/10.1016/j.smrv.2023.101829.
2. Lie JD, Tu KN, Shen DD, Wong BM. Pharmacological Treatment of Insomnia. Pharmacy and Therapeutics. 2015 Nov;40(11):759-71. PMID: 26609210; PMCID: PMC4634348.
3. Pagel JF, Parnes BL. Medications for the Treatment of Sleep Disorders: An Overview. The Primary Care Companion To The Journal of Clinical Psychiatry. 2001 Jun;3(3):118-125. Available from: doi.org/10.4088/pcc.v03n0303.
4. Wright A, Diebold J, Otal J, *et al*. The effect of melatonin on benzodiazepine discontinuation and sleep quality in adults attempting to discontinue benzodiazepines: a systematic review and meta-analysis. Drugs Aging. 2015;32:1009–18.
5. Anghel L, Baroiu L, Popazu CR, Pătraș D, Fotea S, Nechifor A, Ciubara A, Nechita L, Mușat CL, Stefanopol IA, Tatu AL, Ciubara AB. Benefits and adverse events of melatonin use in the elderly (Review). Experimental and Therapeutic Medicine. 2022 Mar;23(3):219. Available from: doi.org/10.3892/etm.2022.11142.

6. De Crescenzo F, D'Alò GL, Ostinelli EG, Ciabattini M, Di Franco V, Watanabe N, *et al*. Comparative effects of pharmacological interventions for the acute and long-term management of insomnia disorder in adults: a systematic review and network meta-analysis. Lancet. 2022 Jul 16;400(10347):170-184. Available from: doi.org/10.1016/S0140-6736(22)00878-9.
7. Garcia L. Melatonin and its Effects: The Truth Behind this Popular Supplement. California State University Stanislaus. 2020.
8. Chauhan A, Chauhan V. Beneficial Effects of Walnuts on Cognition and Brain Health. Nutrients. 2020 Feb 20;12(2):550. Available from: doi.org/10.3390/nu12020550.
9. Tapia MI, Sánchez-Morgado JR, García-Parra J, Ramírez R, Hernández T, González-Gómez D. Comparative study of the nutritional and bioactive compounds content of four walnut (Juglans regia L.) cultivars. Journal of Food Composition and Analysis. 2013;31(2):232-7. Available from: doi.org/10.1016/j.jfca.2013.06.004.
10. Verde A, Míguez JM, Leao-Martins JM, Gago-Martínez A, Gallardo M. Melatonin content in walnuts and other commercial nuts: influence of cultivar, ripening and processing (roasting). Journal of Food Composition and Analysis. 2022;105:104180. Available from: doi.org/10.1016/j.jfca.2021.104180.
11. Müller D, Pfeil T, von den Driesch V. Treating depression comorbid with anxiety--results of an open, practice-oriented study with St John's wort WS 5572 and valerian extract in high doses. Phytomedicine. 2003;10 Supplement 4:25-30. Available from: doi.org/10.1078/1433-187x-00305.
12. Dominguez RA, Bravo-Valverde RL, Kaplowitz BR, Cott JM. Valerian as a hypnotic for Hispanic patients. Cultural Diversity and Ethnic Minority Psychology. 2000 Feb;6(1):84-92. Available from: doi.org/10.1037/1099-9809.6.1.84.
13. Zare Elmi HK, Gholami M, Saki M, Ebrahimzadeh F. Efficacy of Valerian Extract on Sleep Quality after Coronary Artery bypass Graft Surgery: A Triple-Blind Randomized Controlled Trial. Chinese Journal of Integrated Medicine. 2021 Jan;27(1):7-15. Available from: doi.org/10.1007/s11655-020-2727-1.
14. Tammadon MR, Nobahar M, Hydarinia-Naieni Z, Ebrahimian A, Ghorbani R, Vafaei AA. The Effects of Valerian on Sleep Quality, Depression, and State Anxiety in Hemodialysis Patients: A Randomized, Double-blind, Crossover Clinical Trial. Oman Medical Journal. 2021 Mar 31;36(2). Available from: doi.org/10.5001/omj.2021.56.
15. Bent S, Padula A, Moore D, Patterson M, Mehling W. Valerian for sleep: a systematic review and meta-analysis. The American Journal of Medicine. 2006 Dec;119(12):1005-12. Available from: doi.org/10.1016/j.amjmed.2006.02.026.
16. Pakseresht S, Boostani H, Sayyah M. Extract of valerian root (Valeriana officinalis L.) vs. placebo in treatment of obsessive-compulsive disorder: a randomized double-blind study. Journal of Complementary and Integrated Medicine. 2011 Oct 11;8:/j/jcim.2011.8.issue-1/1553-3840.1465/1553-3840.1465.xml. Available from: doi.org/10.2202/1553-3840.1465.
17. Ngan A, Conduit R. A double-blind, placebo-controlled investigation of the effects of Passiflora incarnata (passionflower) herbal tea on subjective sleep quality. Phytotherapy Research. 2011 Aug;25(8):1153-9. Available from: doi.org/10.1002/ptr.3400.
18. Janda K, Wojtkowska K, Jakubczyk K, Antoniewicz J, Skonieczna-Żydecka K. Passiflora incarnata in Neuropsychiatric Disorders-A Systematic Review. Nutrients. 2020 Dec 19;12(12):3894. Available from: doi.org/10.3390/nu12123894.
19. Shafiei Z, Shuhairi NN, Md Fazly Shah Yap N, Harry Sibungkil CA, Latip J. Antibacterial Activity of Myristica fragrans against Oral Pathogens. Evidence Based Complementary and Alternative Medicine. 2012;2012:825362. Available from: doi.org/10.1155/2012/825362.
20. Gupta AD, Rajpurohit D. Antioxidant and antimicrobial activity of nutmeg (Myristica fragrans). In: Preedy VR, Watson RR, Patel VB, editors. Nuts and seeds in health and disease prevention. Academic Press; 2011. p. 831-9. Available from: doi.org/10.1016/B978-0-12-375688-6.10098-2.
21. Sultan MT, Saeed F, Raza H, Ilyas A, Sadiq F, Musarrat A, *et al*. Nutritional and therapeutic potential of nutmeg (Myristica fragrans): a concurrent review. Cogent Food and Agriculture. 2023;9(2). Available from: doi.org/10.1080/23311932.2023.2279701.
22. Prathibha CK, Anandaraman PV, Nanda GG. Managing insomnia with Jathiphala (Myristica fragrans) powder: a pilot study. International Ayurvedic Medical Journal. 2018;6(1).
23. Sharpley AL, McGavin CL, Whale R, Cowen PJ. Antidepressant-like effect of Hypericum perforatum (St John's wort) on the sleep polysomnogram. Psychopharmacology (Berl). 1998 Oct;139(3):286-7. Available from: doi.org/10.1007/s002130050718.
24. Eatemadnia A, Ansari S, Abedi P, Najar S. The effect of Hypericum perforatum on postmenopausal symptoms and depression: a randomized controlled trial. Complementary Therapies in Medicine. 2019 May;45.
25. Hübner WD, Lande S, Podzuweit H. Hypericum treatment of mild depressions with somatic symptoms. Journal of Geriatric Psychiatry and Neurology. 1994 Oct;7 Suppl 1. Available from: doi.org/10.1177/089198879400700105.
26. Di Pierro F, Risso P, Settembre R. Role in depression of a multi-fractionated versus a conventional Hypericum perforatum extract. Panminerva Medica. 2018 Dec;60(4):156-160. Available from: doi.org/10.23736/S0031-0808.18.03518-8.
27. Schrader E. Equivalence of St John's wort extract (Ze 117) and fluoxetine: a randomized, controlled study in mild-moderate depression. International Clinical Psychopharmacology. 2000 Mar;15(2):61-8. Available from: doi.org/10.1097/00004850-200015020-00001.

HOW TO CITE THIS ARTICLE: Thakkar S, Naterwalla N, Laddha K. A Focused Group Human Volunteer Study on the Efficacy of a Novel Candyceutical Sleep Aid: "Restore Your Sleep". Int. J. Pharm. Sci. Drug Res. 2024;16(5):788-792. **DOI:** 10.25004/IJPSDR.2024.160506