Original Article

Efficacy of *Brimhana Nasya* and *Ashwagandha (Withania somnifera* (L.) Dunal) root powder in primary insomnia in elderly male: A randomized open-label clinical study

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Abstract

Background: Decreased ability to fall asleep and/or stay asleep with daytime effects of sleep deprivation is identified as primary insomnia. Elderly due to the predominant *Vata Dosha* in the body are easily affected by this problem. *Brimhana Nasya* (nourishing nasal drop) with *Ksheera Bala Taila* and oral administration of *Ashwagandha* (*Withania somnifera* (L.) Dunal) root powder both are indicated in Ayurvedic classics for the management of insomnia. **Aim:** To determine the combined efficacy of oral administration of *Ashwagandha* root powder along with *Brimhana Nasya* with *Ksheera Bala Taila* in primary insomnia in geriatric. **Materials and methods:** This was randomized, open-label clinical study conducted at the hospital of Pt. Khushilal Sharma Government Ayurveda College and Institute Bhopal. Randomly selected 60 elderly patients with primary insomnia were randomly divided into two groups (30 in each group). Pittsburgh Sleep Quality Index was used to assess the symptoms of primary insomnia. Relief in the subjective symptoms was assessed in percentage. Then, the statistical significance of result within the group was assessed using Wilcoxon matched-pairs signed-ranks test and the comparative effect of therapy in both groups was assessed using Mann-Whitney test. Graph Pad InStat-3 software was used for statistical analysis. **Results:** On subjective sleep quality 86.66% relief with $P < 0.0001$, on sleep latency 60.02% improvement with $P < 0.0001$, improvement in sleep duration was reported in 89.15% of patients with $P < 0.0001$ and improvement in sleep efficiency was reported in 90.14% of patients with statistically extremely significant $P < 0.0001$ were observed in combined therapy group (*Ksheera Bala Taila Brimhana Nasya* along with oral administration of *Ashwagandha* root powder*).* While 38.66% improvement in sleep efficiency, 40.39% relief in sleep disturbances and 37.05% improvement on subjective sleep quality was reported in group B patients, i.e., *Ashwagandha* root powder group. **Conclusion:** In 30 days treatment combined therapy was found more effective in the management of primary insomnia in the elderly compared with *Ashwagandha* root powder alone.

Keywords: *Ashwagandha* powder, *Brimhana Nasya*, geriatric insomnia, *Ksheera Bala Taila, Withania somnifera*

Introduction

Poor sleep results in increased risk of significant morbidity and mortality in the elderly.[1] The WHO estimates that between 2015 and 2050, the proportion of the world's population over 60 years will nearly double from 900 million to 2 billion (12% to 22%).[2]

The International classification of sleep disorders-2 defined insomnia as inadequate quantity or quality of sleep characterized by a subjective report of difficulty with sleep initiation, duration, consolidation, or quality that occurs despite adequate opportunity for sleep, and that results in some form of daytime impairment and has persisted for at least 1 month.[3]

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In old age, the sudden change in lifestyle, with social-environmental influence causes stress, and anxiety which ultimately disturbs the psycho neuro-biological rhythm of sleep and causes insomnia. In modern medicine, various sedative drugs are being used, but till now, no effective management for geriatric insomnia is found.

Anidra (insomnia) is not explained as a separate disease in *Ayurveda.* Acharya Charaka and Acharya Vagbhatta have considered insomnia as *Vataja Nanatmaja Vikara* (disease develop due to predominance of *Vata Dosha*)[4] in the pathogenesis of insomnia.[5]

Geriatric insomnia develops due to the *Dhatu Kshaya* (depletion of nutritional status) and natural predominance of *Vata Dosha* in old age. Thus the selection of drugs and the treatment procedure which could nourish the *Dhatu* and also pacify the *Vata Dosha* is effective in the management of geriatric insomnia. Langade *et al*. conducted a randomized, double-blind, placebo-controlled study on 60 patients and found *Ashwagandha* root extract a dose of 300 mg extract twice daily had improved sleep quality and sleep onset latency in insomnia patients.[6] Dissanayake and Dissanayake, in randomized control clinical study found *Ksheerabala Taila Nasya Karma* was effective for managing Insomnia.[7] Most of the research studies were conducted to assess only single efficacy of *Ashwagandha* root powder or *Nasya* procedure, but none of the studies was conducted to assess the combined effect of *Ashwagandha* root powder and *Brimhana Nasya* procedure. Hence, this study was planned to assess the combined efficacy of oral administration of *Ashwagandha* root powder along with *Brimhana Nasya* with *Ksheera Bala Taila.*

Objectives

1. To assess the combined efficacy of oral administration of *Aswagandha* root powder along with *Brimhana Nasya* with *Ksheeram Bala Taila* in the management of primary insomnia in geriatric.

Materials and methods

Study design

Simple randomized two-arm open-label clinical trial.

Selection of the patients

Sixty eight patients irrespective of caste, religion and socioeconomic status those were diagnosed to have Insomnia were screened from outpatient department (OPD) section of the Department of Kayachikitsa, Panchakarma and Swasthavritta of Pt. Khushilal Sharma Government Ayurveda College and Institute, Bhopal. Out of 68 patients, 60 patients were ready to give consent form for the study. Then, distributed randomly in equal numbers (n = 30 each) in two groups, group A and group B.

Ethical clearance

The study was cleared by the Institutional Ethics Committee with Ref. No/Student Section/2016/1880, Bhopal dated May 28, 2016. Written informed consent was obtained from patients before inclusion in the study.

Diagnostic criteria

Patients diagnosed by DSM-IV-TR diagnostic criteria for primary insomnia.[8]

Inclusion criteria

- Male patients from the age group of 60–70 years and patients suffering from primary insomnia without any complaints of major diseases or hypertension or depression and eligible for *Nasya* procedure were included. Before the study, it was observed that mostly male elderly was approaching for management of insomnia in hospital of Pt. Khushilal Sharma Government Ayurveda College and Institute Bhopal hence, this study included only male patients.

Exclusion criteria

- Male patients those were suffering from fatal familial insomnia or with major psychiatric illness like schizophrenia, depressive psychosis, epilepsy or having advanced chronic illness such as bronchial asthma, diabetes mellitus, malignancy, liver cirrhosis, chronic renal failure or patients with alcohol or drug dependency or patients having an acute illness such as cardiovascular accidents, myocardial infarction, and chronic obstructive pulmonary disease were excluded.
- Patients those were on sedatives and patients who are contraindicated for *Nasya Karma* were also excluded from the present clinical trial.

Grouping and posology

Group A

Brimhana Nasya with 8 drops of *Ksheerabala Taila* in each nostril was administered for 7 days continuously. Total 3 cycles of *Nasya* was done in 1 month with break for 3 days. Along with *Brimhana Nasya* 6 gm, *Ashwagandha* root powder orally with 100 ml of milk at night half an hour before going to bed was also advised to the patients of this group for 30 days.

- *Nasya* Procedure– *Nasya* procedure was carried out at OPD level in *Panchakarma* procedure room. It was conducted in three steps. *Purva Karma* (preparatory procedure)–it is the first step before administration of the drug in nostril. Mild massage with *Ksheerabala* oil was done on scalp, forehead, face and neck for 3–5 min, then mild fomentation (in boiling water towel was soaked and squeezed then the towel was waved, touched, and pressed on face and neck) was given on the face and neck. During the main procedure-patient was advised to lie down in supine position on the table with legs slightly elevated. Then, patient's eyes were covered with clean cloth and his head was lifted slightly, then the 8 drops of *Ksheerbala Taila* was instilled into each nostril one after the other. The other nostril was covered during drug delivery in one nostril and to patient was to inhale oil slowly. The same process was repeated in other nostrils. Post procedure-the

patient was advised to lie in the supine position for about 2 min or counting numbers up to 100. Afterward, the patient was advised not to ingest the medicine and if it comes to the throat, then has to spit it. The feet, shoulder, palms and ears were massaged. Then, after 5-min gargle with lukewarm water was advised.

Group B

Only 6 g *Ashwagandha* root powder orally with 100 ml of milk at night half an hour before going to bed was advised to the patients of this group for 30 days.

Does and don't

Before *Nasya* procedure patients were advised to pass his natural urges such as urine and stool, do brushing, and take bath. Light breakfast 1 h before the procedure was advised. After procedure, it was advised to patients to not to go in direct air and do not take excessive oily and spicy, heavy and cold food and cold water. Patients were advised to take light and warm food.

Duration of study

The duration of the study was 30 days and follow-up period was 30 days after completion of the study.

Drug preparation

The ingredients of *Ksheerabala Taila* and *Ashwagandha* root were obtained from Vindhya herbal (Miner forest produce processing and research centre) Government Pharmacy Bhopal. And then, *Ksheerabala Taila* was prepared in the college pharmacy of Pt. Khushilal Sharma Government Ayurvedic College, Bhopal with the classical procedure as described in classical text *Sahastrayoga*.[9] The fine powder of *Ashwagandha* root powder was also prepared in college pharmacy.

Criteria for assessment

Symptoms of primary insomnia were assessed before and after completion of the treatment based on the Pittsburgh Sleep Quality Index (PSQI).[10]

Statistical analysis

Manually collected data were transferred to the computer in Microsoft Excel sheet. Then, mean, mean difference, standard deviation, standard error were applied for the analysis. Relief in the subjective symptoms was assessed in percentage. Then, the statistical significance of result within the group was assessed using Wilcoxon matched-pairs signed-ranks test and the comparative effect of therapy in between the groups was assessed using Mann–Whitney test. Graph Pad InStat-3 software developed by GraphPad Software, San Diego, California was used for statistical analysis.

Observation

Initially, 78 patients were screened from OPD section of the Department of Kayachikitsa, Panchakarma and Swasthavritta of Pt. Khushilala Sharma Government Ayurveda College and Institute, Bhopal. Out of 78 patients, 70 patients were ready to give consent for the study. Then out of 70 patients, 60 patients were selected randomly by simple random lottery method and distributed randomly in equal numbers (n = 30 each) in two groups i.e., in group A and group B [Figure 1].

Among 60 randomly selected primary elderly patients, 55 patients completed the course of treatment and 5 patients discontinued the study. Two patients in group A discontinued treatment as they moved to other city for long period and 3 patients in group B discontinued the study, among them 1 patient discontinued because his wife had brain stroke, 1 patient lost his son and 1 patient moved to other city. It was observed that the majority 68.34% of patients between 60 and 65 years were suffering from insomnia. 100% males were registered because this study was planned with only male subjects. All patients had reported chronic onset of insomnia, in which 70%patients were living with joint family and had poor sleep hygiene which is also a cause of insomnia. 56.67% of patients were taking mixed diet whereas 43.33% of patients were taking vegetarian diet. Maximum 71.66% of the patients were taking *Laghu Ahara* (light diet). Maximum 56.66% were insufficiently active whereas 21.67% were active and of the patients 21.67% were inactive. Maximum patients, i.e., 80% were found to be tea/coffee addicted and 30% tobacco addicted while 26.66% of patients were addicted to smoking. Majority of the patients i.e., 75% were belonging to *Vata-Pitta Prakriti.* Maximum 56.67% of patients were doing daytime napping. Seventy percent patients were experiencing stress, 65% patients were experiencing anger, while 38.33% of patients were experiencing unknown fear. These causative factors independently or in conjugation are identified as the cause of insomnia [Table 1].

Results

Following result of the therapy on the basis of different component of PSQI score in both groups were recorded.

- Before treatment in subjective sleep quality (Component 1 of PSQI) 50% of patients had reported fairly bad, 28.34%reported very bad and 21.66% reported fairly good subjective sleep quality. After treatment, 86.66% and 37.05%relief was observed in group A and group B, respectively, on subjective sleep quality that was statistically extremely significant with $P < 0.0001$. Before treatment in sleep latency (component 2 of PSQI), very difficult to maintain prolonged sleep latency was reported in 83.34% of patients. After treatment, 60.02% and 27.27%relief was observed in group A and in group B, respectively, that was statistically extremely significant with $P < 0.0001$. In sleep duration (component 3 of PSQI) before study 96.66% of patients were reporting <5 h sleep duration but after study, 89.15% relief was reported in sleep duration of group A patients, but only 18.76%relief was reported in group B, that was statistically extremely significant with $P < 0.0001$. In component 4 of PSQI, i.e., in habitual sleep efficiency before study, 73.34% had reported worst sleep efficiency but after study, 90.14% relief was observed in group A and 38.66% relief in

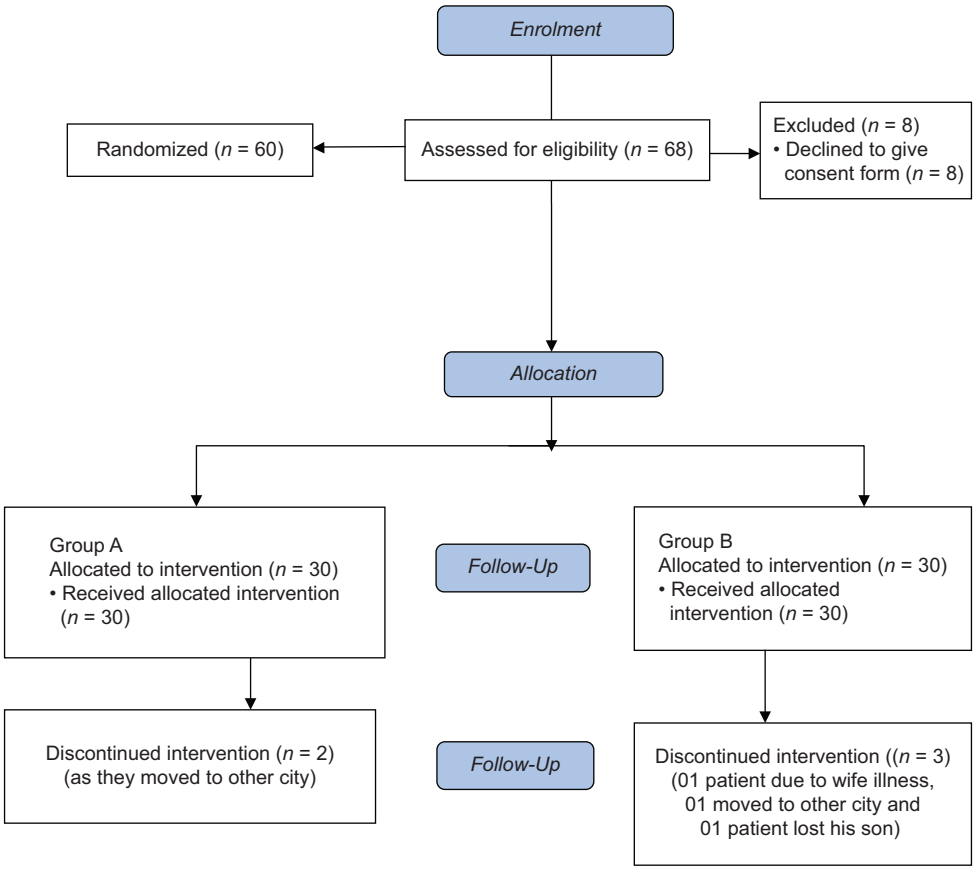

Figure 1: CONSORT flow diagram

Table 1: Result of observation of baseline data (*n*=60) primary insomnia geriatric patients

Total observation of (*n*=60) patients in percentage	Observation
Total 68.34% (*n*=21 and *n*=20 in group A and B respectively)	Elderly between the age group of 60-65 elderly were suffering from primary insomnia
Total 70% (*n*=22 and *n*=20 in group A and B respectively)	Had reported poor sleep hygiene
Total 56.67% (*n*=16 and *n*=18 in group A and B respectively)	Patients were taking mixed diet
Total 56.66% (*n*=19 and *n*=15 in group A and B respectively)	Were insufficiently active
Total 80% (*n*=23 and *n*=25 in group A and B respectively)	Patients addicted with tea/coffee
Total 30% (*n*=8 and *n*=10 in group A and B respectively)	Patients addicted with tobacco chewing
Total 26.66% (*n*=9 and *n*=7 in group A and B respectively)	Patients addicted with smoking
Total 75% (*n*=23 and *n*=22 in group A and B respectively)	Patients belonged to *Vata-Pitta Prakriti*
Total 56.67% (*n*=23 and *n*=11 in group A and B respectively)	Patients were doing daytime napping
Total 70% (*n*=20 and *n*=22 in group A and B respectively)	Patients were experiencing stress
Total 65% (*n*=21 and *n*=18 in group A and B respectively)	Patients were experiencing anger
Total 38.33% (*n*=13 and *n*=10 in group A and B respectively)	Patients were experiencing unknown fear

group B that was statistically extremely significant with $P < 0.0001$. In Component 5 of PSQI, i. e., in sleep disturbances maximum patients 83.33% had reported moderate level of sleep disturbance. After the study, 45.62% and 40.39% relief was observed in group A and in group B, respectively, with statistically extremely significant relief with $P < 0.0001$. In Component 6 of PSQI, i.e., the use of sleeping medication was not assessed because patients dependent on sleep medication were excluded from the study. In component 7 of PSQI i.e., daytime dysfunction was reported in 38.34% of patients with moderate severity while 21.66% of patients with severe daytime dysfunction and after study relief was observed 82.46% and 26.29% in group A and group B, respectively, that was statistically extremely significant in group A with $P < 0.0001$ and very significant $P = 0.0039$ in group B [Table 2].

Comparative effect of therapy

- The mean difference on subjective sleep quality, sleep duration, habitual sleep efficiency, daytime dysfunction,

and finally Global Score in group A were reported 1.857, 2.643, 2.286, 1.679, and 10.964, respectively, and in group B, it were reported as0.7407, 0.5556, 1.074, 0.3704 and 4.407, respectively, with significance $P < 0.0001$, thus result indicating that in group A (*Brimhana Nasya* and *Ashwagandha* root powder group) patients got better improvement in primary insomnia than group B (*Ashwagandha* root powder group) patients.

Overall effect of therapy

It was assessed by global PSQI score but, Component 6 was exclusion criteria of this study hence this questionnaire was recorded 0–18 score. In group A, before the study 10.72% and89.28% elderly were reported between moderate-to-severe scale of global PSQI while after study 60.71%, 28.57% and10.72% were reported between mild, moderate and severe scale, i. e., maximum 60.71% patients were reported only mild symptoms of primary insomnia. While, in group B, before the study 11.11% and88.89% elderly were reported between moderate-to-severe scale of global PSQI while after study only 14.81% of patients were reported under mild symptoms scale and 29.63% and 55.55% were reported between moderate and severe scale of global PSQI [Table 3].

Follow-up period

None of the adverse effects of drug and therapy was noted during the study in both groups. And, after completion of the treatment, patients were asked for follow-up for 1 month but no change in the status of the patients was observed after 1 month.

Discussion

Primary insomnia in geriatric is characterized by a diminished quality and duration of sleep. Sleep architecture is also changed with decrease in the deepest stage of nREM-slow wave sleep (N3 and N4 stage) and increase in stage 1 and 2 sleep as aging progresses.[11] Reduced melatonin, reduction in growth hormone and dopamine levels are also found in healthy aging.[12] All these researches are indicating the *Dhatu Kshaya* (degenerative process) in the elderly is because of naturally aggravated *Vata Dosha* along with depletion of *Tarpaka Kapha* (is subtype of *Kapha Dosha,* present in the head and has nourishing property) play a major role in insomnia. Thus, primary insomnia in geriatric could be considered as *Vata Dosha* predominant disease and can be better managed by *Sneha Chikitsa* (oleation treatment).[13]

The result of the study is indicating that combined therapy of group 'A' (*Ksheerabala Taila Brimhana Nasya* along with oral administration of *Ashwagandha* root powder*)* patients got significant benefits in all components of PSQI (74.36%relief in Final Global score of PSQI) and 74.36% relief in total sleep time. It may be because combined therapy had been able to efficiently pacify the increased *Vata Dosha* and the nourished

Table 2: Effect of therapy on the basis of PSQI score in the groups

PSQI	Group	Mean		MD	% Relief	SD	SE	Wilcoxon matched-pairs signed ranks test and *P*
		BT	AT					
Comp: 1 Subjective Sleep Quality	A (*n*=28)	2.143	0.2857	1.857	86.66	0.5909	0.1117	W=406, *n*=28 *P*<0.0001 ES****
	B (*n*=27)	2.000	1.259	0.7407	37.05	0.5257	0.1012	W=190 *n*=27 *P*<0.0001 ES****
	Mann- Witney U-statistic=79, *P*<0.0001, ES****							
Comp: 2 Sleep Latency	A (*n*=28)	2.679	1.071	1.607	60.02	0.7860	0.1485	W=351, *n*=28 *P*<0.0001 ES****
	B (*n*=27)	2.852	2.074	0.7778	27.27	0.6405	0.1233	W=171 *n*=27 *P*<0.0001 ES****
	Mann- Witney U-statistic=169.50, *P*=0.0004, ES***							
Comp: 3 Sleep Duration	A (*n*=28)	2.964	0.3214	2.643	89.15	0.6785	0.1282	W=406, *n*=28 *P*<0.0001 ES****
	B (*n*=27)	2.963	2.407	0.5556	18.76	0.7511	0.1445	W=66, *n*=27 *P*=0.0010 ES***
	Mann- Witney U-statistic=30.500, *P*<0.0001 ES****							
Comp: 4 Habitual Sleep Efficiency	A (*n*=28)	2.536	0.2500	2.286	90.14	0.8100	0.1531	W=378, *n*=28 *P*<0.0001 ES****
	B (*n*=27)	2.778	1.704	1.074	38.66	0.8738	0.1682	W=190 *n*=27 *P*<0.0001 ES****
	Mann- Witney U-statistic=126.50, *P*<0.0001 ES****							
Comp: 5 Sleep Disturbances	A (*n*=28)	1.964	1.071	0.8929	45.62	0.4163	0.07867	W=300 *n*=28 *P*<0.0001 ES****
	B (*n*=27)	1.926	1.148	0.7778	40.39	0.4237	0.08153	W=231, *n*=27 *P*<0.0001 ES****
	Mann- Witney U-statistic=337.50, *P*=0.4855 NS							
Comp: 6 Use of Sleeping Medication	A (*n*=28)	0	0	0	0	0	0	0
	B (*n*=27)	0	0	0	0	0	0	0
	Mann- Witney U-statistic=0							
Comp: 7 Daytime Dysfunction	A (*n*=28)	2.036	0.3571	1.679	82.46	0.7228	0.1366	W=406, *n*=28 *P*<0.0001 ES****
	B (*n*=27)	1.407	1.037	0.3704	26.29	0.5649	0.1087	W=45, *n*=27 *P*=0.0039 VS**
	Mann- Witney U-statistic=70.500, *P*<0.0001ES							
PSQI Global Score	A (*n*=28)	14.321	3.357	10.964	77.64	2.134	0.4033	W=406, *n*=28 *P*<0.0001 ES****
	B (*n*=27)	13.926	9.519	4.407	33.33	2.735	0.5264	W=378 *n*=27 *P*<0.0001 ES****
	Mann- Witney U-statistic=24.500, *P*<0.0001 ES****							

PSQI: Pittsburgh sleep quality index, BT: Before treatment, AT: After treatment, MD: Mean difference, SD: Standard deviation, SE: Standard error, W: Wilcoxon matched-pairs signed ranks test, N: Number of patients, ES: Extremely significance, VS: Very significance

Table 3: Overall Effect of therapy on Global Score of PSQI in Group A and Group B

Global Score	No. of patients			
	Group A ($n=28$)		Group B ($n=27$)	
	Before	After	Before	After
0	0	0	0	0
1-6	0 (0%)	17 (60.71%)	0 (%)	4 (14.81%)
7-12	3 (10.72%)	8 (28.57%)	3 (11.11%)	8 (29.63%)
13-18	25 (89.28%)	3 (10.72%)	24 (88.89%)	15 (55.55%)

Dhatu (tissues) by enhancing *Tarpaka Kapha*. None of the adverse effects of drug and therapy was noted during the study.

Probable mode of action of *Nasya*

The result of the study indicates that group A patients i.e., *Brimhana Nasya* and *Ashwagandha* root powder group patients got more significant results in all components of PSQI compare to *Ashwagandha* root powder group patients, i.e., group B patients. As in group 'A' patients, on subjective sleep quality 86.66% relief with $P < 0.0001$, on sleep latency 60.02% improvement with $P < 0.0001$, improvement in sleep duration was reported in 89.15% patients with $P < 0.0001$ and improvement in sleep efficiency was reported in 90.14% patients with statistically extremely significant $P < 0.0001$. The better improvement in almost all components of PSQI in group A patients compared to group B patients was might be because of *Brimhana Nasya* procedure. Similar effect of *Nasya* with *Jatamamsi Taila* was reported by Angadi *et al.* They reported highly significant results in 6 components out of 7 components of PSQI, expect in sleep medication.[14]

Various research studies indicate that lipophilic compounds increase the penetration of the drugs. The nose is the nearest route to deliver the drug efficiently and *Brimhana Nasya* procedure also *nourish* brain cells by enhancing *Tarpaka Kapha* as well as pacifying morbid *Dosha*. *Brimhana Nasya* was adopted to manage geriatric insomnia because Ahcarya Vagbhatta has indicated *Brimhana Nasya* specifically in the management of *Nidranasha* (insomnia) or diseases caused due to *Vata Dosha* vitiation and *DhatuKshaya*.[15]

Ksheerabala Taila (oil-based drug) is indicated in the management of *Vataja* disorders (all the eighty chronic conditions developed due to vitiation of *Vata Dosha*).[9] *Bala* (*Sida cordifolia*) is the one of the important ingredients of *Ksheerabala Taila* which strengthen the nerves[16] has anti-stress and adaptogenic properties. It also reduces plasma cortisol level.[17] Shrestha *et al*., reported that The glycosides present in the *Sida cordifolia* has been confirmed to exert anxiolytic, sedative and anticonvulsant effects on the central nervous system. Constituents of *Bala* (*Sida cordifolia*) such as Rhusparviflora and its biflavonoid constituent rhusflavone reported to induce sleep through the positive allosteric modulation of GABAA-benzodiazepine receptors.[18] Hence, due to adaptogenic and sleep inducing properties of *Bala* (*Sida cordifolia*), group A patients got better result in primary insomnia.

Probable mode of action of *Ashwagandha (Withania somnifera)* root powder

In the present study, 38.66% improvement in sleep efficiency, 40.39% relief in sleep disturbances and 37.05% improvement on subjective sleep quality was reported in group B patients, i.e., patients treated with *Ashwagandha* root powder alone. Similar effect of *Ashwagandha* root extract 300 mg twice daily was reported by Langade *et al*. on sleep-onset latency, significant improvement in SE scores was observed 75.63 (2.70) for the test at the baseline and increased to 83.48 (2.83) after 10 weeks, and significant improvement in sleep quality was also observed with test compared to placebo (p, 0.002). Significant improvement was observed in all other sleep parameters, i.e., SOL, SE, PSQI, and anxiety (HAM-A scores) with *Ashwagandha* root extract treatment for 10 weeks.[19] Salve *et al*., 2019 also reported a similar effect of *Ashwagandha* root extract on sleep quality. They also reported the adaptogenic and anxiolytic impacts of *Ashwagandha* root extract in healthy humans.[20]

Kumar and Kalonia explored role of root extract (100 mg/kg) in sleep-disturbed rats and suggests the involvement of GABAergic mechanism in the sleep promoting effect of *W. somniferra* in sleep-disturbed state.[21]

Ayurveda texts have reported *Vata Dosha* (kind of pathogenic factor) pacifying effect of *Ashwagandha* root powder due to its *Ushna Guna* (hot properties) and due to its rejuvenating (*Rasayana*), strength promoting (*Balya*) properties[22] thus provide strength and endurance to neurons and reduce the load of free radical. Similar effect of *Withania somnifera* was reported by Suganya *et al*. in sleep deprivation-induced male *Wistar albino* rats. They had reported a significant reduction of free radical production and lipid peroxidation with simultaneous increase in the level of antioxidant enzymes in the group treated with *W. somniferra* root extract compared to the untreated group. Furthermore, increase in the neurotransmitter levels significantly reported in the group treated with *W.* somnifera (400 mg/kg b. wt).[23] *Withanine*, *Somniferine* and *Visamine* are the basic alkaloids of *Ashwagandha* root (*W. somniferra*) had reported sedative and hypnotic effects. *Withanine* is reported to prolonged sleeping time.[24]

Conclusion

In this study, *Ksheerabala Taila Brimhana Nasya* along with oral administration of *Ashwagandha Churna* (*W. somniferra*) root powder reported significant benefits in all components of pittsburgh sleep quality index (PSQI). None of the adverse effects of drug and therapy was noted during this study. The result of this study suggests the use of combined therapy of *KsheeraBala Taila Brimhana Nasya* along with oral administration of *Ashwagandha* (*W. somniferra*) root powder in primary insomnia in the elderly, which is cost-effective and

can be adopted as therapeutic as well as preventive measures for geriatric insomnia.

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Conflicts of interest

There are no conflicts of interest.

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