



An exploratory single-arm open-label clinical study to evaluate the combined effect of *Vamana* and *Sarasvata Churna* in reducing excessive daytime sleepiness

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ARTICLE INFO

Keywords:

Excessive daytime sleepiness

Nidradhikya

Vamana

Sarasvata churna

ABSTRACT

Background: Excessive Daytime Sleepiness (EDS) is inferred as persistent sleepiness and often a general lack of energy during the day even after apparently adequate or even prolonged nighttime sleep. The subjects may not be identifying excessive daytime sleepiness but may present as feeling tired, lack of energy etc. They may seem apparently healthy and without any other systemic illness. The prevalence was found to be as high as 18 % in 2012 in United Kingdom. Also, it is a risk factor for diseases like Alzheimer's disease, Parkinson's disease and other neurodegenerative diseases. Conventional management (Modafinil, Sodium Oxybate and Stimulants) addresses only the subjective condition in EDS and is associated with adverse effects compromising the quality of life. In the current health scenario there is a need for alternative interventions to manage this disease. On analyzing this condition through *Ayurveda*, we could understand it as *Nidradhikya* (Excessive daytime sleepiness) which is caused due to vitiated *Kapha Dosha* along with *Vridhdha Tamoguna* (increased *Tamoguna*) that can be managed by *Shodhana* (biopurification) followed *Shamana* (pacification) therapies.

Objective: This study was aimed to assess the combined effect of *Vamana* (therapeutic vomiting) and *Sarasvata Churna* in reducing Excessive Daytime Sleepiness.

Materials and methods: This was a single-arm exploratory open-label clinical trial. 10 subjects having EDS diagnosed using Modified Epworth Sleepiness Scale (MESS) with a score of 10–24 with proper exclusion were recruited from OPD and IPD, Department of *Kāyachikitsa*, Amrita School of Ayurveda. All the participants were clinically examined, sought for medical history and further checked biochemically to exclude any other systemic illness that may lead to this condition. Only healthy subjects with quality night sleep (assessed by PSQI) and without any other systemic illness were selected. The treatment protocol adopted was *Vamana Karma* followed by 30 days of *Sarasvata Churna* as *Shamana Aushadha* (medicine for pacification). Assessment was done using MESS on 0th day and after 30 days of *Shamana Aushadha Sevana*. After completion of treatment, the results were statistically analysed using Wilcoxon Signed Rank Test and final conclusion was drawn.

Results: On analysis of the symptoms using Modified Epworth Sleepiness Scale, the mean total score reduced from 14.8 to 2.8 with 81.08 % relief in these 10 subjects and a significant p value < 0.05 after *Vamana* followed by 30 days of *Shamana Aushadha Sevana*.

Discussion: *Vamana* helps in *Kapha Nirharana* (expelling) which removes the *Avarana* (occlusion) of *Manas* seen in *Nidradhikya*. This results in *Hrit Shuddhi* (purity of heart) that helps in bringing the equilibrium of *Mano Gunas* (qualities of mind) (*Satvoudaryam Tamojayaha*) which forms the line of management. *Sarasvata Churna* which was administered as *Shamana Aushadha* possesses *Medhya* (Nootropic), *Buddhi Smriti Dhriti Vardhaka* (intellect, memory and patience promoting) attributes and is being indicated in *Vicetas*. Most of the drugs in *Sarasvata*

Peer review under responsibility of Transdisciplinary University, Bangalore.

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<https://doi.org/10.1016/j.jaim.2024.100960>

Received 13 January 2022; Received in revised form 16 June 2023; Accepted 2 May 2024

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Churna are *Rasayana* (rejuvenation) that imparts *Indriya Bala* (strengthening of senses) and *Priti* (contentment) to *Manas* by *Prinana* (nourishing) of *Rasa Dhatu*.

Conclusion: From this study, we could conclude that the combination of *Vamana Karma* followed by *Sarasvata Churna* administration is effective in reducing EDS.

1. Introduction

Adequate alertness is essential for proper daytime functioning. Any impairment in alertness or increase in sleepiness results in suboptimal performance which adversely affects the quality of life of an individual. Excessive Daytime Sleepiness (EDS) is understood as persistent sleepiness and often a general lack of energy during the day even after apparently adequate or even prolonged night-time sleep with a prevalence rate found to be as high as 18% in 2012 [1]. In Excessive Daytime Sleepiness, people fall asleep in inappropriate situations like during classes, meetings and travelling which impairs their work productivity, quality of life and other domains of life. Moreover, EDS is one of the diseases of major concern and is a risk factor for diseases like Alzheimer's disease, Parkinson's disease and other neurodegenerative diseases [2,3].

Currently available medications insufficiently control symptoms in a substantial proportion. The commonly used medications include Modafinil, Amphetamines, Sodium Oxybate, Pitolisant, Flumazenil, and Clarithromycin. Their use is limited due to the adverse effects like nausea, tremor, hypertension, headache, gastro esophageal reflux, personality changes, hepatic toxicity in susceptible patients and drug abuse [4]. Regardless of its incidence, effect on quality of life and economic costs to the society, there are only finite evidence based options available for the management of EDS. So in the current health scenario there is a need for alternative interventions to manage this disease entity.

On analyzing this condition through *Ayurveda*, we could understand it as *Nidradhikya* [5]. We can differentiate this condition from *Tandra* and *Klama* as *Tandra* is understood by the feeling of heaviness of body, more of yawning, exhaustion and activities of a person similar to that of a sleeping person [6]. Ashtanga Sangraha explains *Tandra* as a condition in which *Kapha* gets slightly increased and moves upwards into the head by *Vata* causing obstruction to the *Dhamanis* resulting in loss of sensation and consciousness and produce delusions. The eyes will be wide open, eye ball gone in, pupil dilated, tears flowing out and eyelashes disarranged. It is also said to have a poor prognosis unlike *Nidradhikya* [7]. *Klama* is fatigue without doing any work, not accompanied with dyspnea and it disturbs the sense perception greatly [8]. Also, this cannot be considered as *Bahudoshavasta* as the subjects suffering from this condition lack the other symptoms mentioned in *Bahudoshavasta* like *Panduta*, *Pitaka*, *Kota*, *Kandu* etc [9].

According to *Acharya Charaka*, an individual falls asleep when his mind, sensory and motor organs get exhausted and they dissociate themselves from their objects [10]. *Susruta* described that sleep occurs when *Hridaya* - the seat of *Cetana* is covered by *Tamas*. He also states that *Tamoguna* is the cause for physiological sleep and *Satva guna* is the cause for awakening [11]. *Sharangadhara* mentions that *Nidra* is a state where there is predominance of *Kapha* and *Tamas* [12]. *Bhela* explains that *Kapha* situated in *Hridaya* is augmented during the process of digestion of food during day time and when this covers the *Cakṣuvāha* and *Śrotravāha Srotas*, it leads to sleep [13]. *Ashtanga Sangraha* quotes that due to *Avarana* of *Kapha* in *Manovaha Srotas* and due to *Srama*, *Indriya* withdraws from their *Karma* and *Nidra* occurs [14].

Further, *Sangraha* states that, the *Kapha* not undergoing regular processing because of its increased quantity obstructs the *Srotas*. This *Srotorodha* causes *Gātra Gaurava* (heaviness of the body) and from this *Gātra Gaurava* occurs *Alasya* (Idleness), which in turn causes *Atinidrata* or *Nidradhikya* [15]. *Acharya Sushruta* quotes that increase in *Tamoguna* is the cause for sleep during both day and night [11]. *Chakrapani* comments that the *Nidra* that occurs during the daytime is caused due to *Tamoguna* [16]. Considering these, we can devise the *Samprapti* of *Nidradhikya* as - due to *Nidana* the vitiated *Kapha Doṣa* along with *Vridha Tamoguna* afflicts *Hṛdaya* which is the *Sthana* of *Manas*. This in turn results in the *Sanga* of *Manovaha Srotas* rooting to dissociation of *Indriyavisayas* and *Manas* culminating to *Nidradhikya*. So, when there is vitiated *Kapha Doṣa* along with *Vṛddha Tamoguna*, there occurs *Nidradhikya* that can be managed by *Shodhana* followed *Shamana* therapies.

On literary search, it was found that no studies have been done to address Excessive Daytime Sleepiness through *Ayurveda* till now. Therefore, this clinical trial was conducted with an objective to assess the effectiveness of *Ayurvedic* treatment protocol containing *Vamana Karma* followed by *Sarasvata Churna* (Table 2) in terms of Modified Epworth Sleepiness Scale Score.

2. Methodology

This was a single-arm exploratory open-label clinical trial conducted in ten subjects to assess the combined effect of *Vamana* and *Sarasvata Churna* in reducing excessive daytime sleepiness. Diagnosis was done based on Modified Epworth Sleepiness Scale. Epworth Sleepiness Scale

Table. 1
Details of therapeutic intervention.

Interventional Schedule	Duration	Drug	Dose
Pachana Deepana (appetizing and digesting)	3–7 days (till <i>Samyak Langhana Lakshanas</i> (features of proper deprivation) proper are seen)	<i>Trikatu Churna</i>	12 g in divided dosage before food with warm water
Snehapana	3–7 days (till <i>Samyak Snigdha Lakshanas</i> (features of proper oleation) are seen)	<i>Panchagavya Ghrita</i>	25 ml starting dose, then increased according to digestive capacity of patient
Sarvanga Abhyanga & Bashpa Sveda	2 days	<i>Tila Taila</i>	Q.S
Kaphotklesakara Ahara (foods that increase a Ahara) (foods that increase Kapha)	1 day	Idli, Milk, Sugar, Rice, Curd, <i>Tila</i> balls, <i>Māsa Pāyasa</i>	Q.S
Vamana	1 day	<i>Madanaphala yoga</i> (<i>Vacha</i> , <i>Madanaphala</i> , <i>Saindhava</i> , <i>Madhu</i> , <i>Yaṣṭimadhu</i>)	<i>Madanaphala</i> (12g), <i>Vaca</i> (4g), <i>Saindhava</i> (5g), <i>Yaṣṭimadhu</i> (5g), <i>Madhu</i> (Q.S)
Samsarjana Krama	According to <i>Shuddhi</i> ^a (symptoms of appropriate purification)	<i>Peyayi Samsarjana</i>	Q.S
Shamana Aushadha	30 days	<i>Sarasvata Churna</i>	12 g in divided dosage after food with honey and Ghee

^a *Pravara Shuddhi* – 5 days, *Madhyama Shuddhi* – 3 days, *Avara Shuddhi* – 2 days].

Table. 2
Ingredients of *Sarasvata Churna*.

S.No	Drug	Botanical Name
1	<i>Kustha</i>	Saussurea lappa
2	<i>Ashvagandha</i>	Withania somnifera
3	<i>Saindhava Lavana</i>	Rock Salt
4	<i>Ajamoda</i>	Trachyspermum ammi
5	<i>Sveta Jiraka</i>	Cuminum cyminum
6	<i>Krisna Jiraka</i>	Nigella sativa
7	<i>Pippali</i>	Piper longum
8	<i>Marica</i>	Piper nigrum
9	<i>Śunthi</i>	Zingiber officinalis
10	<i>Patha</i>	Cyclea peltata
11	<i>Mangalyapuṣpi (Sankhapuṣpi)</i>	Clitorea ternatea
12	<i>Vacha</i>	Acorus Calamus
13	<i>Brahmi Rasa</i>	Bacopa monnieri

(ESS) is intended to measure the daytime sleepiness by use of a self-administered questionnaire. Modified Epworth Sleepiness Scale was developed by conducting a cross-sectional study at the National Institute of Mental Health And Neurosciences (NIMHANS), Bangalore, jointly by the departments of Neurology and Epidemiology over a one-year period. Some of the questions in ESS were felt to be difficult to be directly applied in the Indian context and hence those were modified and one question was completely recasted [17].

Pittsburg Sleep Quality Index was used for assessing the night sleep quality as the persons with sleep deprivation or sleep disturbance have more chances of Excessive Daytime Sleepiness and are excluded in this study. So, the subjects with a PSQI Score of ≤ 5 were selected for the study. Further they were tested for routine blood and urine in order to rule out any other illness. After this biochemical test, only subjects with normal report were selected so as to avoid any other systemic disorders. The selected subjects were explained the purpose, duration, details of the procedure, nature of the study, the common difficulties that they may experience during the treatment (Diet restrictions, avoidance of day sleep, cold water, mandatory night sleep, accurate diet pattern etc.) in detail. Consent form was read thoroughly in mother tongue of the subject and then asked for his/her willingness to participate in the study.

2.1. Recruitment of patient and data collection

Persons attending the O.P.D of Amrita Ayurveda Hospital, Vallickavu, Kollam, Kerala under the postgraduate department of *Kayachikitsa* with complaints of excessive sleepiness, tiredness and lack of energy were first screened by Modified Epworth Sleepiness Scale (MESS)

Table. 3
Effect of therapy on individual components of Modified Epworth Sleepiness Scale with percentage of relief

Parameters		Mean	SD	Mean Difference	z value ^a	p value	% of Relief
Sitting and observing children/grandchildren do homework/play	BT	2.500	0.527	1.900	-2.913 ^{b,c}	0.004	76%
	AT	0.600	0.516				
Watching TV/Listening to radio/Music	BT	1.300	0.675	1.300	-2.739 ^{b,c}	0.006	100%
	AT	0.000	0.000				
Sitting inactive in a public place (Movies/Park/Panchayath kata/Temple)	BT	2.300	0.675	1.900	-3.051 ^{b,c}	0.002	82.608%
	AT	0.400	0.516				
As a passenger in a vehicle for an hour without a break	BT	2.300	0.823	1.900	-2.913 ^{b,c}	0.004	82.608%
	AT	0.400	0.516				
Lying down to rest in the afternoon when circumstances permit	BT	2.900	0.316	2.000	-3.162 ^{b,c}	0.002	68.965%
	AT	0.900	0.316				
Sitting and talking to someone	BT	0.300	0.483	0.300	-1.732 ^b	0.083	100%
	AT	0.000	0.000				
Sitting quietly after a lunch without alcohol	BT	2.300	0.483	1.800	-2.842 ^{b,c}	0.004	78.260%
	AT	0.500	0.527				
During work, when taking a short break	BT	0.900	1.101	0.900	-2.041 ^{b,c}	0.041	100%
	AT	0.000	0.000				

[BT-Before Treatment; AT-After Treatment].

^a Wilcoxon Signed Ranks Test.

^b Significant at 0.05 level.

^c Based on positive ranks].

questionnaire. Those with a score of 10–24 were evaluated for nighttime sleep using Pittsburgh Sleep Quality Index (PSQI). Subjects with a PSQI score of ≤ 5 were selected and further evaluated biochemically (Routine Blood – HB, Total WBC count, Differential count, ESR and Routine Urine – Urine Albumin, Urine RBC, Urine Glucose and microscopic examination). Subjects fulfilling the eligibility criteria were selected for the study. The study period was from January 10, 2020 to May 17, 2021 comprising a total duration of 16 months. Total 10 subjects were recruited and there were no dropouts.

2.1.1. Inclusion criteria

Individuals of either gender in the age group of 20–60 years, irrespective of socioeconomic status, having Modified Epworth Sleepiness Scale Score 10 to 24, Pittsburgh Sleep Quality Index Score less than or equal to 5, willing to give written consent and those who are eligible for *Vamana Karma* (Fig. 1).

2.1.2. Exclusion criteria

Diagnosed cases of systemic, metabolic and psychiatric disorders, Body Mass Index of ≥ 25 kg/m² and < 18 kg/m², pregnant women, lactating mothers, children, those who are taking over the counter medications, smokers, alcoholic persons, those taking antidepressants or hormone replacement therapy or having a current diagnosis of post-traumatic stress disorder and those who are taking illicit drugs.

2.1.3. Diagnostic criteria

Diagnosis was done based on Modified Epworth Sleepiness Scale Score (10–24) for Excessive Daytime Sleepiness and Pittsburg Sleep Quality Index (less than or equal to 5) for night sleep quality.

2.1.4. Assessment criteria

Assessment was done before treatment and after treatment i.e. on 0th day and after 30 days of *Shamana Aushadha Sevana* using Modified Epworth Sleepiness Scale.

2.1.5. Intervention

The treatment protocol adopted was *Pachana Deepana* with *Trikatu Churna* [18], *Snehapana* (internal oleation) with *Panchagavya Ghrita* [19], *Sarvanga Abhyanga* (external oleation) with *Tila Taila*, *Bashpa Sveda* (sudation), *Vamana Karma* with *Madanaphala yoga* [20], *Samsarjana Karma* (post purification dietary regimen) [21] and *Shamana Aushadha Sevana* with *Sarasvata Churna* [22].

The details of therapeutic intervention is detailed in Table 1.

2.2. Statistical analysis

The results were statistically analysed using Wilcoxon signed rank test and final conclusions were drawn.

2.3. Patient inflow chart

The persons visiting O.P.D of Amrita Ayurveda Hospital, Vallickavu, Kollam, Kerala with complaints regarding sleepiness, tiredness, lack of energy were screened. They were enrolled, allocated and analysed based on exclusion and inclusion criteria related to age, Modified Epworth Sleepiness Scale Score and Pittsburgh Sleep Quality Index Score. This patient inflow is depicted in Fig 1.

3. Results

Demographic details: Among the 10 subjects, majority (6 subjects) were in the age group of 26–30 years followed by 20–25 years (3 subjects). 8 subjects were following non-vegetarian diet with intake of bakery items, maida preparations, fast foods and pastries in excess. 8 subjects had reduced appetite and 6 subjects had regular dietary pattern. 5 subjects does not spent any time for fitness activities, 4 subjects were doing exercises irregularly and 1 subject was doing regularly. 7 subjects were having moderate stress. Predominance of *Kapha Prakriti* (constitution) was seen in majority (6 subjects) of the persons.

The symptoms in these 10 subjects were analysed both before and after treatment using Modified Epworth Sleepiness Scale. It was found that there was significant reduction in all the symptoms [Table 3].

The effect of therapy on Modified Epworth Sleepiness Scale is depicted in Tables 3 and 4.

After the statistical assessment of individual variables, a graph has been provided for better understanding of the effect after the study.

4. Discussion

4.1. Discussion on need for the study

Many individuals were approaching the OPD with complaints of feeling sleepy during daytime, general fatigue and lack of energy. On a detailed history taking, examination and ruling out other clinical conditions, it was found that they were suffering from idiopathic hypersomnia which comes under central disorders of hypersomnolence of ICSD-3 and is characterized by excessive daytime sleepiness [23]. This clinical condition disturbs the work productivity, quality of life and other domains of life of the affected people with the prevalence rate found to be as high as 18% in 2012 [1]. The present day management includes medications like Modafinil, Sodium Oxybate and stimulants which are prescribed for the management of the subjective symptoms in EDS. Their use is limited to severe conditions owing to their detrimental effects over the quality of life thereby denying the standard of care to mild and moderate cases [4]. Regardless of its incidence, effect on quality of life and economic costs to the society, there are only finite evidence based options available for the treatment of EDS. Moreover, EDS can be an early indicator of decline in cognitive functioning and onset of dementia as studies have found its association in the

pathogenesis of Alzheimer disease [24–26]. The same scenario is seen among Parkinson's disease population as well [27]. In this situation, there is a need for the efficient management of EDS without leading to any further adverse effects. On analyzing this condition through Ayurveda, we could understand it as *Nidradhikya* [5]. On literary search, it was found that no studies have been done to address Excessive Daytime Sleepiness till now. Hence this topic was selected to discern the effectiveness of Ayurvedic protocol for EDS.

4.2. Discussion on disease

Excessive Daytime Sleepiness is identified as persistent sleepiness and often a general lack of energy during the day even after apparently adequate or even prolonged nighttime sleep. Unlike fatigue, excessive sleepiness makes the person feel so tired that it interferes with their social, professional and personal domains by falling asleep in inappropriate situations. Due to this bewilderment the individuals do not identify excessive daytime sleepiness but instead report it as fatigue, feeling run down and having low energy. American Academy of Family Physician reports that persons with excessive daytime sleepiness are at risk of motor vehicle as well as work-related incidents, and have poorer health than comparable adults [28]. ICSD-3 categorizes this as idiopathic hypersomnia. As the name idiopathic implies, the pathophysiology remains unclear regardless of the ongoing researches. Although various ailments can cause sleepiness, a careful history taking and methodical investigations can rule out the other causes.

Ayurveda considered *Nidra* as one among the thirteen *Adāraṇīya Vega* (non-suppressible urges). The suppression of this urge leads to many complications like *Jrimbha* (yawning), *Angamarda* (squeezing type of pain), *Tandra* (fatigue), *Śirogaaurava* (heaviness of head), *Akṣigaaurava* (heaviness of eyes), *Moha* (loss of consciousness), and *Alasya* (laziness) [29]. Excessive daytime sleepiness would not come under the purview of *Nidra Vega Dharana* as daytime is not the preferred time for *Nidra*. As per Ayurveda, proper time mentioned for *Nidra* is night [30].

References for excessive daytime sleepiness are available in Ayurvedic treatises as *Nidradhikya* [5]. Ayurveda considers this condition as an abundance of *Kapha Dosha* along with predominance of *Tamoguṇa* which can be managed by *Shodhana* (purification therapies) and *Shamana* therapies (palliative therapies). *Chakrapani* comments that the *Nidra* that occurs during the daytime is caused due to *Tamoguṇa* [31]. Due to *Nidana* the vitiated *Kapha Doṣa* along with *Vruddha Tamoguṇa* afflicts *Hridaya* which is the *Sthana* of *Manas*. This in turn results in the *Sanga* of *Manovāha Srotas* rooting to dissociation of *Indriyavishayas* and *Manas* culminating to *Nidradhikya*. The aim of the treatment was to eliminate the accumulated *Kapha Dosha* as well as *Tamoguṇa* by *Shodhana* procedure and to improve alertness by administering *Shamana Auśadha*.

4.3. Discussion on probable mode of action of study drugs and therapies

Excessive Daytime Sleepiness which is identified as *Nidradhikya* in Ayurveda is understood as the abundance of *Kapha Dosha* and *Tamoguṇa*. Hence the treatment approach demands the removal of *Kapha Dosha* and *Tamoguṇa* which can be attained by *Shodhana* procedure followed by *Shamana Auśadha Sevana* for *Mana Prasadana* (alertness to mind).

Table 4
Effect of therapy on total score of Modified Epworth Sleepiness Scale.

Parameters		Mean	Std. Deviation	Mean Difference	z value ^a	p-value	% of Relief
Modified Epworth Sleepiness Scale Total Score	BT	14.800	2.150	12.000	−2.810 ^{b,c}	0.005	81.08 %
	AT	2.800	1.398				

[BT-Before Treatment; AT-After Treatment].

^a Wilcoxon Signed Ranks Test.

^b Significant at 0.05 level.

^c Based on positive ranks].

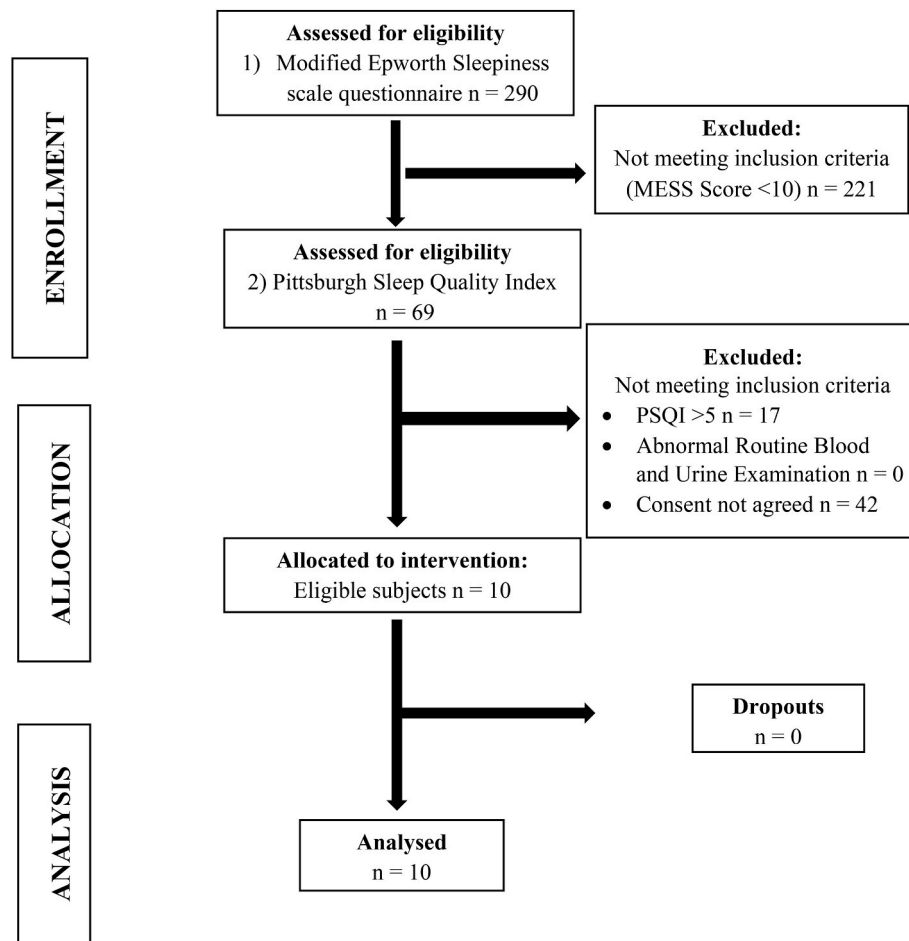


Fig. 1. Patient inflow chart.

Vamana being the ideal therapy for the elimination of *Kapha Dosha* was adopted here for *Shodhana* as the condition is caused by *Kapha Dosha Vridhi*. *Sarasvata Churna* which helps in improving alertness by its *Medhya Rasayana* drugs and which is being indicated in *Vicetas* was selected for *Shamana Aushadha Sevana*.

On analyzing the results, there was significant reduction in all the symptoms in all the study subjects. This improvement was observed due to the combined effect of *Vamana Karma* and *Shamana Aushadha – Sarasvata Churna*.

Trikatu Churna used for *Pachana Deepana* is *Katu Rasa*, *Ruksha Guna* and *Ushna Virya* which aids to its *Deepana*, *Ama Pachana*, *Sroto Shodhana* and *Kapha Dosha Nirharana* properties [18]. *Shodhananga Snehapana* was done using *Panchagavya Ghrita* which is *Srotoshodhaka*, *Agniideepaka* and has disease affinity by its *Kaphahara*, *Hridya* and *Medhya* action. *Vamana* is considered as the best therapy for the elimination of *Kapha Dosha*. *Madanaphala* which was used for *Vamana Karma* is *Kapha Vatahara* by nature. *Laghu Rooksha Guna*, *Ushna Virya*, and *Lekhaniya Karma* of *Madanaphala* helps in *Kapha Nirharana*. The *Kapha Nirharana* attained by *Vamana* helps in removal of *Avarana* of *Manas* seen in *Nidradhikya*. This will result in *Hrit Shuddhi* that helps in bringing the equilibrium of *Mano Gunas* (*Satvoudaryam Tamojayaha*) which forms the line of management of *Nidradhikya*. Thus *Vamana* imparts *Mana Prasadana*, *Laghutva* to the body, *Hrit Shuddhi* and *Indriya Shuddhi* [32]. Being a *Shodhana Karma*, it also endows *Buddhi Prasadana*, *Bala* to *Indriyas*, *Sthiratva* to *Dhatu* and *Agni Deepana* [33].

Sarasvata Churna is having qualities like *Medhya*, *Buddhi Smriti Dhriti Vardhaka* and is being indicated in *Vicetas* [22]. Most of the drugs in *Sarasvata Churna* are *Katu Tikta rasa* which aids to its *Kaphaghna Karma*. The drugs like *Ashvagandha*, *Kushta*, *Ajamoda*, *Pippali*, *Marica*, *Shunti*,

Saindhava and both *Jeerak* are *Deepana*, *Pachana* which helps in *Sroto Shodhana*. *Ashvagandha*, *Ajamoda*, *Brahmi*, *Saindhava*, *Shunti*, both *Jeeraka* are *Hridya* which in turn have influence over mind. *Kushta* is indicated in *Manoroga* which shows its effect over *Manas* and *Vaca* is *Mano Doshahara* which helps in curbing the *Tamoguna*. The drugs like *Kushta*, *Ashvagandha*, *Pippali*, *Shankhapushpi*, *Vacha*, *Brahmi* are *Rasayana* and *Medhya*. *Rasayana Dravyas* by nature impart *Indriya Bala* which also adds to its efficacy. The mechanism of action of *Rasayana Dravyas* are by nourishing *Rasadi Dhatus*. *Rasa Dhatu* does *Prinanam* and commentator *Indu* quotes '*Prinanam Chitta Priti*'. *Arunadatta* clarifies that *Rasa Dhatu* brings about *Prasadana* of *Indriyas* which in turn impart *Mana Priti*. These drugs having *Rasayana* property helps in achieving *Mana Prasadana*. Here *Brahmi Svarasa* is used for *Bhavana* which is *Sheeta Virya*, *Madhura Vipaka* and *Medhya* in *Prabhava* that potentiates the effect of drug.

Thus, administration of *Sarasvata Churna* as *Shamana Yoga* following *Vamana Karma* helps in reducing Excessive Daytime Sleepiness.

5. Conclusion

Excessive Daytime Sleepiness (EDS) is the inability to stay alert and awake during the major waking episodes of the day, resulting in unintended lapses of sleep with a prevalence of 18% in 2012. The present day management is limited due to the adverse effects, drug abuse and dependence. EDS is one of the diseases of major concern and is a risk factor for diseases like Alzheimer's disease, Parkinson's disease and other neurodegenerative diseases. In Ayurveda, it can be understood as *Nidradhikya* caused by abundance of *Kapha Dosha* and *Tamoguna*. This study was aimed to evaluate the efficacy of Ayurvedic Protocol in

reducing EDS assessed using Modified Epworth Sleepiness Scale. On analysis of the symptoms using Epworth Sleepiness Scale, the mean total score reduced from 14.8 to 2.8 with a significant p value < 0.05. Hence, based on observations and results in this clinical study, the combined action of Vamana followed by Sarasvata *Churna* is found to be effective in reducing Excessive Daytime Sleepiness with relief rate of 81.08 %.

6. Limitations and recommendations

- Long term follow-up was not done as it was a time bound study.
- The sample size was not adequate to draw solid conclusions.
- Including sleep studies will help to recognize in depth knowledge of samples.
- More in-vivo studies can be done to understand the pharmacodynamics and pharmacokinetic action of the drug

Confidentiality

The data collected were coded to maintain the confidentiality of the study subjects. The study was approved by the Institutional Ethics Committee with number IEC-AIMS-2019-AYUR-142 and CTRI registration number CTRI/2020/01/022704.

Author contributions

All the authors contributed in acquiring data and drafting the manuscript.

Arathy Menon: Investigation, Formal analysis, Writing - Original Draft, **Maresh C Kundagol:** Conceptualization, Methodology, Investigation, Resources, Data Curation, Supervision, Project administration, **James Chacko:** Investigation, Resources, Supervision, Project administration, **Anandaraman P V:** Investigation, Resources, Supervision, Project administration, **Sreejith K:** Investigation, Resources, Supervision, Project administration, **Devipriya Soman:** Conceptualization, Methodology, Investigation, Resources, Supervision, Formal analysis, Project administration, Writing - Original Draft, Writing - Review & Editing.

Source(s) of funding

None.

Declaration of generative AI in scientific writing

We have not taken any assistance from AI in preparing the manuscript.

Declaration of competing interest

Nil.

References

- [1] Slater G, Steier J. Review Article Excessive daytime sleepiness in sleep disorders. *J Thorac Dis* 2012;4(6):608–16. <https://doi.org/10.3978/j.issn.2072-1439.2012.10.07>. PMID: 23205286; PMCID: PMC3506799.
- [2] Smagula SF, Jia Y, Chang CH, Cohen A, Ganguli M. Trajectories of daytime sleepiness and their associations with dementia incidence. *J Sleep Res* 2020 Dec;29(6):e12952. <https://doi.org/10.1111/jsr.12952>. Epub 2019 Nov 28. PMID: 31782578; PMCID: PMC7253318.
- [3] Abbott RD, Ross GW, White LR, Tanner CM, Masaki KH, Nelson JS, Curb JD, Petrovitch H. Excessive daytime sleepiness and subsequent development of Parkinson disease. *Neurology* 2005;65(9):1442–6. <https://doi.org/10.1212/01.wnl.0000183056.89590.0d>. PMID: 16275833.
- [4] Bollu PC, Manjmalai S, Thakkar M, Sahota P Hypersomnia. *Mo Med* 2018;115(1): 85–91. PMID: 30228690; PMCID: PMC6139790.
- [5] Yadavji T. Charaka Samhita of Agnivesa, Sutra sthana; sutrasthana: chapter 20, verse 17. Varanasi: Choukambha Sanskrit Sansthan; 2017;. p. 115.
- [6] Jadvji T, Narayan RK. Susruta samhita of susruta, Sareerasthana, Garbhavyakarana Sharira, Chapter 4, 360. Varanasi: Chaukhambha Sanskrit Sansthan 2017;49.
- [7] Sharma S Ashtanga sangraha of vridha vagbhata, sutrasthana; Virudhanna Vijnaniyam, chapter 9. Varanasi: Chaukhambha Sanskrit Series Office. p. 93. v44.
- [8] Jadvji T, Narayan RK. Susruta samhita of susruta, Sareerasthana, Garbhavyakarana Sharira, Chapter 4. Chaukhambha Sanskrit Sansthan; 2017. p. 360. v51.
- [9] Yadavji T. In: Charaka samhita of agnivesa, sutrasthana; sutrasthana, Sutrasthana, Chikitsaprabhritiya Adhyaya. Varanasi: Chaukhambha Sanskrit Series Office; 2017. Chapter 16, 13-16.
- [10] Yadavji T. In: Charak Sanhita of Agnivesh Sutrasthana, Sutrasthana, Adhyaya Ashtouninditiya. Varanasi: Choukambha Sanskrit Sansthan; 2017. p. 118. Chapter 21 35.
- [11] Jadvji T, Narayan RK. Editors. Susruta samhita of susruta, sareerasthana, Chapter 4. In: Varanasi: Chaukhambha Sanskrit Sansthan; 2017. p. 358. 34.
- [12] Srikantha Murthy KR. In: Sharangadhara samhita of sharangadhara, pradhama khanda. 30. Varanasi: Chaukhambha Orientalia; 2010. Chapter 6, 24.
- [13] Sharma PV. In: Bhela samhita of acharya bhela, chikitsasthana:Chapter 23. 1st ed. Varanasi: Chaukhambha Visvabharati Publications; 2000. p. 445.
- [14] Sharma S. In: sangraha of vridha vagbhata, sutrasthana; Virudhanna Vijnaniyam, Chapter 9. Varanasi: Chaukhambha Sanskrit Series Office; 2006. p. 91–2. 28-30.
- [15] Sharma S Ashtanga sangraha of vridha vagbhata, sutrasthana, Virudhanna Vijnaniyam, Chapter 9. first ed. Varanasi: Chaukhambha Sanskrit Series Office. p. 93. v40.
- [16] Yadavji T. In: Commentary Ayurveda dipika of chakrapanidatta on charaka samhita of agnivesa, sutrasthana: Ashtouninditiya Adhyaya, Chapter 21. 119. Varanasi: Choukambha Sanskrit Sansthan; 2017;. 58.
- [17] Panda S, Taly AB, Sinha S, Gururaj G, Girish N, Nagaraja D. Sleep-related disorders among a healthy population in South India. *Neurol India* 2012;60(1):68–74. <https://doi.org/10.4103/0028-3886.93601>.
- [18] Srikantha Murthy KR. Sharangadhara samhita of sharangadhara, Madhyama khanda, Choorna Kalpana: Chapter 6. Varanasi: Chaukhambha Orientalia; 2010;. p. 86. 12.
- [19] Yadavji T. Charaka samhita of agnivesa, sutrasthana; Chikitsasthana, Apasmara Chikitsa, Chikitsasthana: Chapter 10. 17. Varanasi: Choukambha Sanskrit Sansthan; 2017. v17.
- [20] Yadavji T. Charaka samhita of agnivesa, sutrasthana; Kalpasthana, Madanakalpa, Chapter 1. Varanasi: Choukambha Sanskrit Sansthan; 2017;. 13.
- [21] Paradakara HS. In: Ashtangahridaya of vagbhata, sutrasthana, Vamana Virechana Vidhiradhyaya, Chapter 18. Varanasi: Chaukhambha Sanskrit Sansthan; 2018. p. 265. 28-30.
- [22] Bhava. In: prakasha of bhavamisra Madhyama Khanda Unmada Adhikara, Chapter 22. Varanasi: Chaukhambha Orientalia; 2014. p. 255. 46-49.
- [23] American Academy of Sleep. MedicineInternational classification of sleep disorders: diagnostic and coding manual. Third ed. Westchester, IL: American Academy of Sleep Medicine; 2014.
- [24] Carvalho DZ, St Louis EK, Knopman DS, Boeve BF, Lowe VJ, Roberts RO, et al. Association of excessive daytime sleepiness with longitudinal β -amyloid accumulation in elderly persons without dementia. *JAMA Neurol* 2018;75(6): 672–80. <https://doi.org/10.1001/jamaneurol.2018.0049>.
- [25] Smagula SF, Jia Y, Chang CH, Cohen A, Ganguli M. Trajectories of daytime sleepiness and their associations with dementia incidence. *J Sleep Res* 2020;29(6): e12952. <https://doi.org/10.1111/jsr.12952>. Epub 2019 . PMID: 31782578; PMCID: PMC7253318.
- [26] Foley D, Monjan A, Masaki K, Ross W, Havlik R, White L, Launer L. Daytime sleepiness is associated with 3-year incident dementia and cognitive decline in older Japanese-American men. *J Am Geriatr Soc* 2001;49(12):1628–32. <https://doi.org/10.1046/j.1532-5415.2001.t01-1-49271.x>. PMID: 11843995.].
- [27] Abbott RD, Ross GW, White LR, Tanner CM, Masaki KH, Nelson JS, Curb JD, Petrovitch H. Excessive daytime sleepiness and subsequent development of Parkinson disease. *Neurology* 2005;65(9):1442–6. <https://doi.org/10.1212/01.wnl.0000183056.89590.0d>. PMID: 16275833.
- [28] Pagel JF. American Academy of Family Physician 2009;79(5):391–6. <https://www.aafp.org/afp/2009/0301/p391.html>.
- [29] Paradakara HS. In: Ashtangahridaya of vagbhata, sutrasthana. Roganutpadaneeya Adhyaya, Chapter 4. Varanasi: Chaukhambha Sanskrit Sansthan; 2018. p. 52. 12,13.
- [30] Paradakara HS. In: Ashtangahridaya of vagbhata, sutrasthana. Ashtouninditiya Adhyaya, Chapter 21. Varanasi: Chaukhambha Sanskrit Sansthan; 2018;. 58-59.
- [31] Yadavji T. In: Commentary Ayurveda dipika of chakrapanidatta on Charaka samhita of agnivesa, sutrasthana; Ashtouninditiya Adhyaya, Chapter 21. Varanasi: Choukambha Sanskrit Sansthan; 2017. p. 119. 58.
- [32] Yadavji T. In: Charaka samhita of agnivesa; Sidhisthana; Kalpanasidhi, Chapter 1. Varanasi: Choukambha Sanskrit Sansthan; 2017;. 16.
- [33] Paradakara HS Ashtangahridaya of vagbhata, Sutrasthana. Vamana Virechana Vidhiradhyaya, Chapter 18. Varanasi: Chaukhambha Sanskrit Sansthan. v16.