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A RANDOMIZED CONTROL TRIAL TO EVALUATE THE EFFICACY BETWEEN *JATAMANSI TAILA SHIRODHARA* AND *BALA–SHATAVARI SIDDHA KSHEERA SHIRODHARA* IN INSOMNIA (*ANIDRA*)

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Background: *Anidra* (~insomnia), is described in *Ayurveda* as the inability to initiate or maintain sleep, often linked to an imbalance in the *Doshas*—particularly *Vata* and *Pitta*. It affects both mental and physical well-being, leading to fatigue, irritability, and impaired cognitive function. *Shirodhara*, a classical *Ayurvedic* therapy is proposed as an effective treatment in *Anidra*, offering both symptomatic relief and improved quality of life. **Aim**: To evaluate the effect of *Jatamansi Siddha Taila Shirodhara* in the management of *Anidra* in comparison to *Bala Shatavari Siddha Ksheera Shirodhara.* **Materials and methods:** Study was conducted at the Panchakarma Department, Ch. Brahm Prakash Ayurved Charak Sansthan, Khera Dabar, New Delhi, under Guru Gobind Singh Indraprastha University, Delhi. Designed as a randomized controlled trial with 90 participants equally divided into two groups 45 patients each (Group A – Jatamansi Taila *Shirodhara* and Group B – Bala–Shatavari Siddha Ksheera *Shirodhara*), the study involved a 14-day intervention followed by a 28-day follow-up, with assessments at baseline, post-treatment, and follow-up). **Results**: The findings indicated a

statistically significant decrease in Insomnia Severity Index (ISI) scores, enhancements in sleep start latency, sleep duration, and sleep efficiency in both groups, with noticeable variations in sustained effects throughout follow-up *Jatamansi Taila Shirodhara* exhibited more durable benefits **Conclusion:** The clinical trial shows an overall improvement in symptoms of *Anidra* in both the groups and *Jatamansi Taila* demonstrated sustained efficacy, favouring its use for prolonged symptom remission.

Keywords: *Anidra*, *Ayurveda, Bala–Shatavari Siddha Ksheera,* Insomnia, *Jatamansi Taila, Shirodhara*.

Introduction: Numerous global researches have revealed that 10%–30% of people suffer with insomnia, with some reports indicating that the percentage is as high as 50%–60%.[1] The term *Anidra* is composed of two parts: "A" meaning absence and "Nidra" meaning sleep. Thus, *Anidra* denotes the absence or disturbance of normal sleep, a condition widely recognized both in classical Ayurvedic texts and modern clinical practice.[2] Ayurveda considers *Health depends upon the three important sub pillars of life known as tryaupasthambha, which include Ahara (*food*), Nidra (*sleep*), and Bramhacharaya (*~celibacy*).* Amidst one of the main sub pillars is *Nidra.*[3] According to *Acharya Charka*, who explains the physiology of *Nidra*, when a person's mind becomes tired due to physical or mental exertion, they fall asleep.[4] The quality of sleep affects various aspects of life, including happiness, sorrow, strength, weakness, virility, impotence, knowledge, ignorance, and even the existence or cessation of life.[5]

Anidra is primarily attributed to the vitiation of *Vata* and *Pitta Doshas*, often triggered by stress, irregular lifestyle, mental strain, and improper diet.[6] Symptoms may include difficulty falling asleep, frequent night awakenings, irritability, lack of concentration, and exhaustion. Ayurvedic classics such as *Charaka Samhita*, *Ashtanga Hridya* and *Sushruta Samhita* describe various modalities for treating Anidra, *including Abhyanga*,*Padabhyanga*,*Shiro Abhyanga* and most notably *Shirodhara.*[7] *Shirodhara*, a form of *Murdhni Taila*, involves the continuous pouring of warm, medicated oil on the forehead (Shira), specifically at the *Ajna Marma* (third eye region), which is associated with calming the mind and balancing doshas. This therapy stimulates the hypothalamus, regulates hormonal activity, and promotes deep relaxation. Both classical texts and clinical studies support its efficacy in treating *anidra* by reducing anxiety, stabilizing the nervous system, and improving sleep quality and duration.

Aim:

To evaluate the effect of *Jatamansi Siddha Taila Shirodhara* in the management of *Anidra* in comparison to *Bala Shatavari Siddha Ksheera Shirodhara.*

Materials and Methods:

Trial design:

The study design was a single-centred, open-label, randomized controlled study, with one group of active control, without any crossover.

Participants:

For this clinical study, 90 patients were enrolled, clinically diagnosed patients of *Anidra* (~Insomnia) after approval from the Institutional Ethical Committee (IEC) of Ch. Brahm Prakash Ayurveda Charak Sansthan with letter no. F2(605)/19-20/CBPACS/Princ. /IEC/5699-5700, dated 28/11/2023. The trial was prospectively registered with the Clinical Trials Registry-India (CTRI) on 29/01/2024 (Registration No. **CTRI/2024/05/067566**).

Well-diagnosed 90 cases of *Anidra* (~Insomnia) were selected from the OPD of the *Panchakarma* Department of Ch. Brahm Prakash Ayurveda Charak Sansthan. The case selection was random regardless of age, sex, occupation, and socioeconomic status. Patients were taken after a complete evaluation of the clinical features of *Anidra* (~Insomnia)*)* for the study. A regular record of assessment of all patients was maintained according to the proforma prepared for the purpose. 90 clinically diagnosed and confirmed patients of *Anidra* (~Insomnia) were randomly divided into the following two groups:

Table 1: Study Groups and Intervention Details

Group	**No. of patients**	**Intervention**	**Duration(days)**
Control Group A	45	*Shirodhara with Bala and Shatavari siddha ksheera*	14
Trial Group B	45	*Shirodhara with Jatamansi Siddha Taila*	14

Plan of Study

For the present randomized clinical trial, patients were diagnosed prior to enrollment. A total of 90 patients presenting with symptoms suggestive of *Anidra* (Insomnia) were diagnosed from the OPD and IPD of Chaudhary Brahm Prakash Ayurved Charak Sansthan, New Delhi. Out of these, 60 patients fulfilling the inclusion criteria were registered for the study. The registered patients were randomly allocated into two groups using a simple random sampling method. Both groups underwent baseline assessment on the 1st day before intervention. Assessment was carried out based on subjective parameters of *Anidra*, including difficulty in sleep initiation, sleep maintenance, early morning awakening, associated symptoms such as headache, fatigue, irritability, and heaviness, along with evaluation using the Insomnia Severity Index (ISI). These parameters were assessed before treatment (BT), after completion of therapy on the 14th day (AT), and during follow-up on the 28th day. The intervention in both groups consisted of Shirodhara administered for 14 consecutive days—Group A received *Bala* and *Shatavari Siddha Ksheera Shirodhara*, while Group B received *Jatamansi Siddha Taila Shirodhara*. Weekly monitoring was done to observe improvement in the signs and symptoms of *Anidra*. The collected data were subjected to appropriate statistical analysis to evaluate intra-group and inter-group efficacy of the interventions

Inclusion Criteria:

Patients diagnosed with Insomnia according to DSM-5-TR[8] . Age group 16 to 50 years. Patients of insomnia with hypertension and anxiety disorders without complicationsof any other systemic diseases.

Exclusion Criteria

Having major psychiatric illness like schizophrenia, Alzheimer's, Brain tumor and uncontrolled hypertension. With alcohol dependency. Patients of asthma, malignancies, liver cirrhosis, chronic renal failure. Patients of any acute illness.

Withdrawal Criteria

Patients willing to quit in between study will be allowed to quit and will be replaced and if any co morbidities develop than patient will be excluded.

Assessment Criteria

Assessment was done using the Insomnia Severity Index (ISI)[9], a standardized and validated tool for evaluating the severity of Insomnia. The ISI consists of seven items, each scored on a five-point

scale ranging from 0 to 4. These items include difficulty in falling asleep, difficulty in staying asleep, and problems with early morning awakening, which were graded from none (score 0) to very severe (score 4). Patient satisfaction with the current sleep pattern was assessed from very satisfied (score 0) to very dissatisfied (score 4). The extent to which the sleep problem was noticeable to others in terms of impairment in quality of life was graded from not at all noticeable (score 0) to very much noticeable (score 4). The degree of worry or distress caused by the sleep problem was assessed from not at all noticeable (score 0) to very much noticeable (score 4). Lastly, the extent to which the sleep problem interfered with daily functioning, including daytime fatigue, mood, work performance, concentration, and memory, was graded from not interfering at all (score 0) to very much interfering (score 4). The cumulative scores were used to assess the severity of insomnia and to evaluate therapeutic response in both treatment groups.

Allocation concealment:

The allocation of participants to their respective groups was not concealed.

Blinding

This study was open-label.

Result:

A schematic CONSORT flow chart of the trial is presented in Figure 1, and baseline patient characteristic are summarized in table 2.

Figure 1:CONSORT flow chart

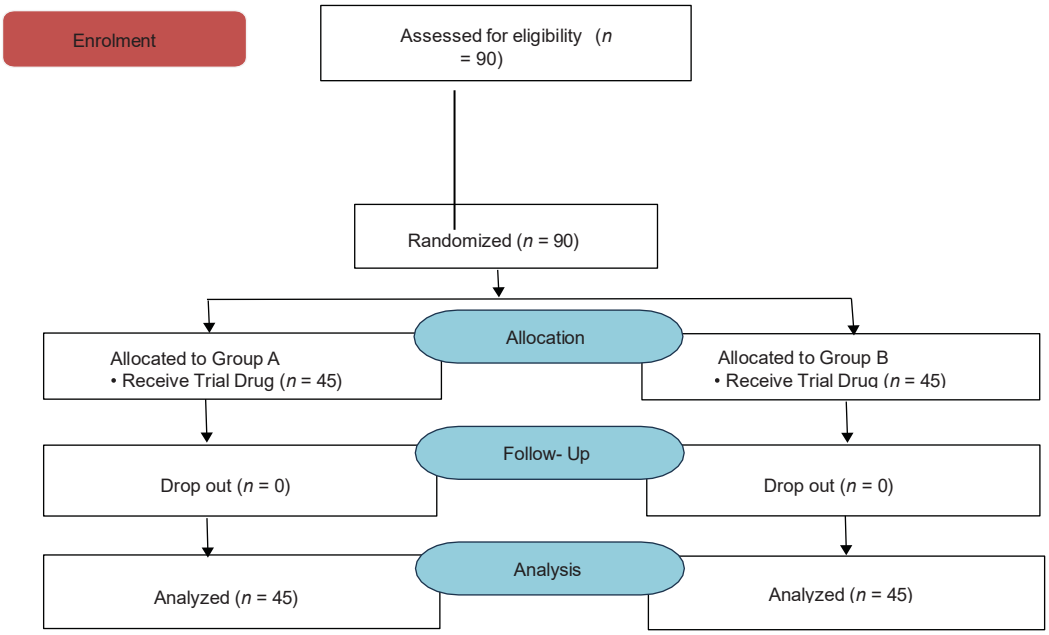
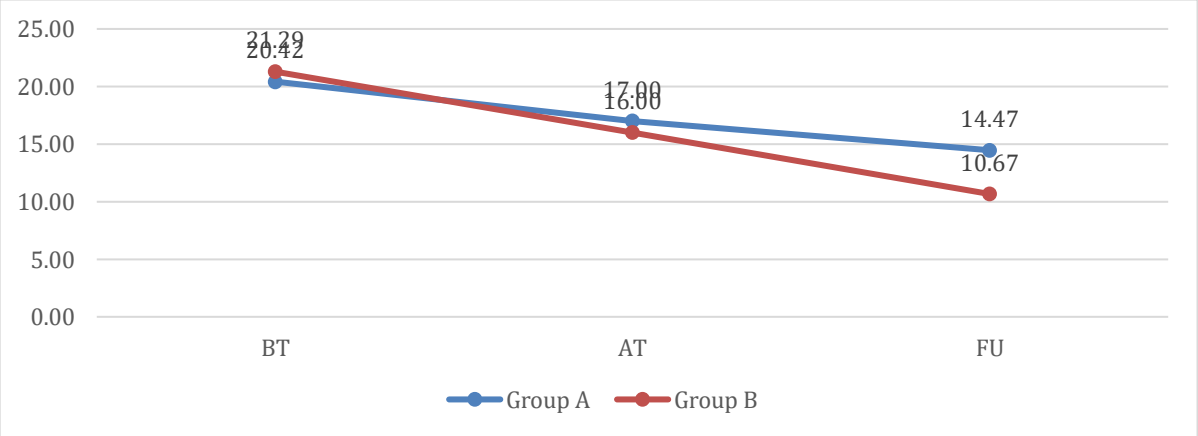


Table 2 : Analysis of the participants according to Insomnia severity index

Insomnia severity index	Group A			Group B			Group A vs B*	
	Mean	S.D	S.E	Mean	S.D	S.E	t value	p value
BT	20.42	0.50	3.33	21.29	0.39	2.63		
AT	17.00	0.55	3.66	16.00	0.34	2.30	-3.806	<0.001
FU	14.47	0.60	4.04	10.67	0.49	3.30	-6.998	<0.001
BT,AT,FU**	F = 155.132, p < .001			F = 294.520, p < .001				
Effect size***	η^2 = .779			η^2 = .870				
Post hoc pairwise comparison with Bonferroni correction								
	Group A			Group B				
	M.diff	% diff	p value	M.diff	% diff	p value		
BT-AT	3.42	17%	<0.001	5.29	25%	0.002		
BT-FU	5.96	29%	<0.001	10.62	50%	<0.001		
* Independent t test ** Repeated measure of anova ***Partial eta squared								



Baseline demographics:

A total of 90 patients were registered in this trial. Most patients belonged to the 18–30 years age group, with a predominance of males and individuals of *Vata-Pittaja Prakruti*. The majority had *Madhyama Kostha*, with normal stool consistency and *Sama Agni*.

Outcomes and estimation

Table 3 : Analysis of the participants according to overall improvement in all parameters

	Group A	Group B
Sleeplessness	17%	27%
Headache	23%	28%
Heaviness	18%	27%
Difficulty falling asleep	17%	26%
Difficulty staying asleep	16%	27%
Problem waking up too early	16%	21%
Satisfied/dissatisfied with current sleep	14%	24%
How noticeable do you think your sleep problem is in terms of impairing the quality of your life	20%	29%
How worried/distressed are you about your current sleep	15%	27%
How much does your sleep problem interfere with your daily functioning	14%	23%
Insomnia severity index	17%	25%

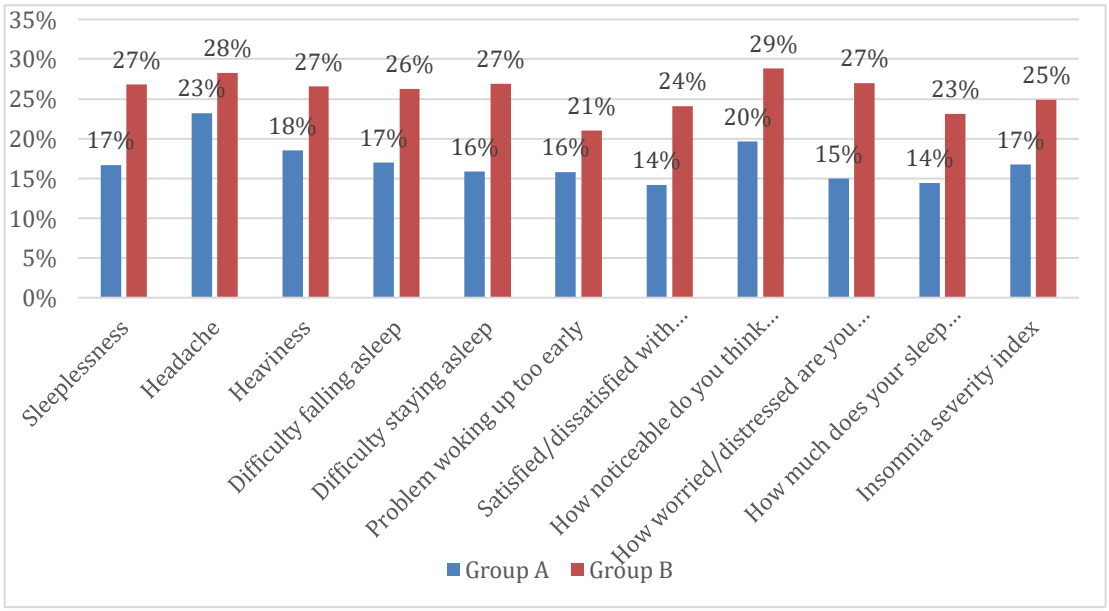


Table 4: Treatment Outcome Distribution in Group A and Group B

	Group A		Group B		Total	
	N	%	N	%	N	%
Cured	3	6.7%	8	17.8%	11	12.2%
.Marked Improvement	11	24.4%	30	66.7%	41	45.6%
Mild Improvement	20	44.4%	6	13.3%	26	28.9%
Unchanged	11	24.4%	1	2.2%	12	13.3%
	45	100.0%	45	100.0%	90	100.0%

Adverse event:

There was no incidence of any notable adverse clinical events observed during this study.

Discussion:

The present randomized controlled trial provides important insights into the demographic profile and clinical response of patients with *Anidra* (~insomnia) to *Ayurveda* interventions. The predominance of *Vata-Pitta* and *Vata-Kapha Prakruti* among participants supports the classical *Ayurveda* concept that *Vata* aggravation plays a central role in the pathogenesis of insomnia. As *Nidra* is considered one of the three pillars of life (*Trayopasthambha*), its disturbance leads to both physical and mental imbalance. The clinical improvements observed in this study can be attributed to the pacification of aggravated *Vata* and *Pitta* along with restoration of *Kapha*, which is essential for normal sleep induction and maintenance.

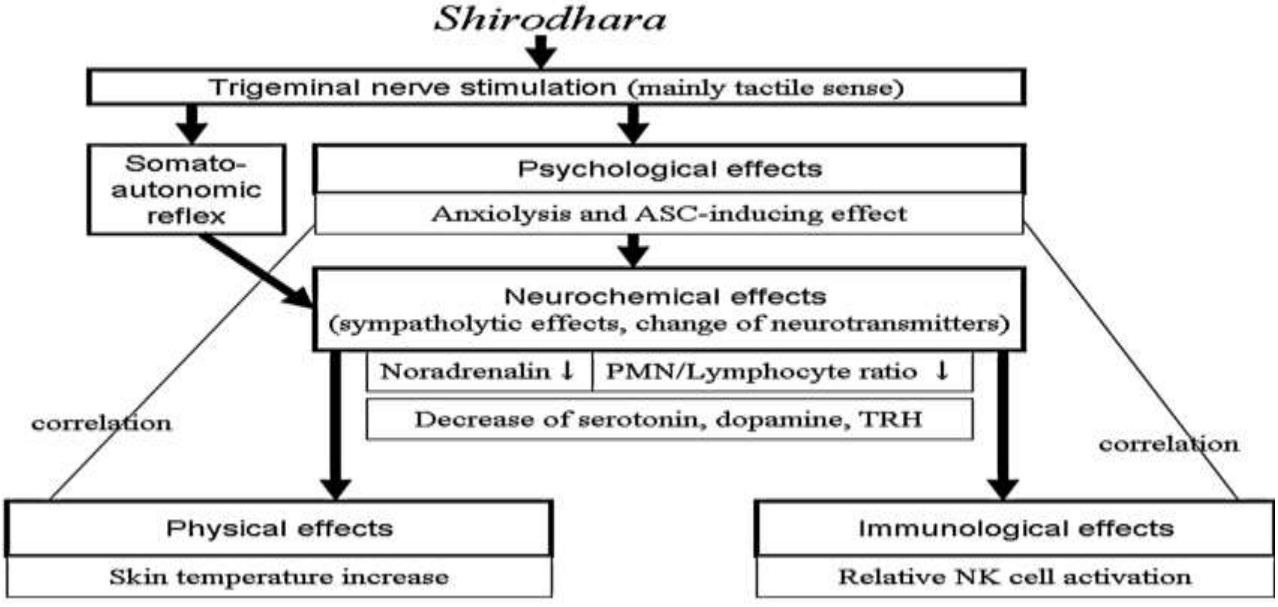
Both interventions—*Jatamansi Taila Shirodhara* and *Bala–Shatavari Siddha Ksheera Shirodhara*—demonstrated highly significant intra-group improvements ($p < 0.001$) across major parameters, including sleeplessness, difficulty in sleep initiation and maintenance, early morning awakening, headache, heaviness, and overall sleep satisfaction. The *Insomnia Severity Index (ISI)* scores also showed a consistent decline in both groups, confirming the effectiveness of *Shirodhara* as a therapeutic modality. Additionally, both therapies effectively reduced associated symptoms such as fatigue, mental restlessness, and heaviness, indicating a holistic impact on both *Sharirika* and *Manasika* aspects of the disease.

From an inter-group perspective, both groups showed comparable improvement immediately after treatment; however, differences became more evident during follow-up. *Bala–Shatavari Siddha Ksheera Shirodhara* demonstrated superior long-term benefits, particularly in

maintaining sleep, reducing early awakening, alleviating heaviness, and improving overall sleep satisfaction. This sustained effect can be attributed to the *Rasayana* and *Brimhana* properties described in *Ayurveda*, along with the nourishing and *Kapha*-promoting qualities of *Ksheera*, which contribute to *Dhatu poshana*and long-term stabilization of the nervous system.

In contrast, *Jatamansi Taila Shirodhara* showed relatively better outcomes in parameters related to sleep initiation and mental calmness *Jatamansi,* being a *Medhya Rasayana* with *Nidrajanana* properties exerts a direct effect on *Manovaha Srotas*, reducing mental hyperactivity and facilitating sleep onset. Its *Sheeta Virya* and *Vata–Kapha shamaka* properties, combined with the *Sukshma* and *Vyavayi* qualities of *Tila Taila*, enable deeper penetration and quicker therapeutic action, thereby effectively reducing sleep latency and mental restlessness.

The mode of action of Shirodhara can be explained through both Ayurveda and modern perspectives. According to ancient textbook, it is manas *Prashamana* bt stabilizing *Rajas* and *Tamas* and enhancing *Kapha*. From a modern viewpoint, the continuous rhythmic stimulation over the forehead may modulate the autonomic nervous system by reducing sympathetic activity and enhancing parasympathetic dominance, thereby promoting relaxation and sleep. Furthermore, pharmacological evidence suggests that *Jatamansi* may act on GABAergic pathways, producing sedative and anxiolytic effects, while *Bala* and *Shatavari* exhibit adaptogenic, neuroprotective, and restorative properties that support sustained improvement.



Flowchart 2: A schematic presentation of the hypothesized neurophysiological mechanism of Shirodhara

The findings of this study are consistent with previous *Ayurveda* and institutional research that highlights the efficacy of *Shirodhara* in insomnia and stress-related disorders. Compared to conventional pharmacological treatments, which are often associated with dependency, tolerance, and adverse effects, *Shirodhara* offers a safe and non-pharmacological alternative. The sustained improvements observed, particularly in the *Bala–Shatavari* group, also parallel the long-term benefits seen with non-pharmacological approaches such as cognitive behavioral therapy for insomnia (*CBT-I*).

In conclusion, the present study validates the effectiveness of *Shirodhara* in the management of *Anidra* and emphasizes the importance of selecting appropriate medicaments based on therapeutic needs. While *Jatamansi Taila Shirodhara* is more effective for rapid mental calming and sleep initiation, *Bala–Shatavari Siddha Ksheera Shirodhara* provides more sustained and nourishing benefits. These findings reinforce the holistic and individualized principles of *Ayurveda* and support their integration into modern insomnia management strategies.

Mode of action of interventions:

The therapeutic effects observed in this study can be understood through an integration of *Ayurveda* principles and modern neurophysiological concepts. Both interventions—*Jatamansi Taila Shirodhara* and *Bala–Shatavari Siddha Ksheera Shirodhara*—share the common procedural component of *Shirodhara*, which plays a pivotal role in inducing mental relaxation and regulating sleep.

From an *Ayurveda* perspective, *Shirodhara* exerts its effect through *Vata-shamana* and *Manas-prashamana*, while its inherent *Snigdha*, *Guru*, and *Sheeta* qualities promote *Kapha*, thereby facilitating the initiation and maintenance of *Nidra*. In modern terms, the continuous rhythmic stimulation over the forehead is believed to modulate the autonomic nervous system, resulting in decreased sympathetic activity and enhanced parasympathetic tone, which contributes to reduced stress and improved sleep quality.

Jatamansi, classified as a *Medhya Rasayana*, primarily acts on *Manovaha Srotas* by reducing mental hyperactivity and promoting calmness, thereby aiding in sleep initiation. Its probable influence on *GABAergic* neurotransmission explains its sedative and anxiolytic properties. In contrast, *Bala–Shatavari Siddha Ksheera* demonstrates sustained therapeutic effects due to

its *Rasayana* and nourishing actions, which help in strengthening the nervous system, replenishing *Dhatus*, and maintaining long-term sleep stability.

Thus, while *Jatamansi Taila Shirodhara* is more effective in facilitating sleep onset, *Bala–Shatavari Siddha Ksheera Shirodhara* contributes to the maintenance and continuity of sleep. This integrative interpretation supports the clinical efficacy of these interventions in the management of *Anidra*.

Conclusion:

This study sought to assess and compare the effectiveness of *Bala Shatavari Siddha Ksheera Shirodhara* and *Jatamansi Taila Shirodhara* in the treatment of Anidra (~insomnia) using a randomized controlled experiment with 90 participants. Both therapies shown substantial enhancement in perceived sleep quality and insomnia-related symptoms. The findings indicated a statistically significant decrease in Insomnia Severity Index (ISI) scores, enhancements in sleep start latency, sleep duration, and sleep efficiency in both groups, with noticeable variations in sustained effects throughout follow-up *Jatamansi Taila Shirodhara* exhibited more durable benefits, *while Bala Shatavari Siddha Ksheera Shirodhara* showed earlier improvements in certain sleep parameters. These findings support the hypothesis that both Panchakarma modalities are effective and safe alternatives in insomnia management with distinct therapeutic advantages.

Limitation of study: The present study has certain limitations that should be considered while interpreting the results. The absence of blinding and allocation concealment may introduce bias in assessment and outcomes. Additionally, the lack of a placebo or standard control group makes it difficult to precisely evaluate the true efficacy of the interventions. Although the sample size was adequate, it remains relatively small, which may limit the generalizability of the findings. The follow-up duration was short and may not adequately reflect long-term effects. Furthermore, the study relied mainly on subjective clinical parameters, without incorporating objective measures such as EEG or polysomnography. Lastly, as a procedure-based therapy, minor variations in the application of Shirodhara could also influence the results.

Financial support and sponsorship:

Nil

Conflicts of interest

There are no conflicts of interest.

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