

Clinical Evaluation of *Yashtimadhu Taila Shirodhara* and *Yoga Nidra* in Chronic Insomnia: A Research Protocol for Randomised Crossover Trial

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ABSTRACT

Introduction: Chronic insomnia, caused by factors such as stress, anxiety, depression, poor sleep habits, environmental influences, or underlying health conditions, significantly impairs quality of life and may lead to headaches, body heaviness, mental disturbances, and reduced *agni*. Ayurveda uses diet, lifestyle changes, and *Panchakarma* treatments, such as *Nasya*, *Shirodhara*, and *Shirolepa*, to restore balance of mind and body. *Shirodhara* involves dripping oil or liquid on the forehead, *Yashtimadhu Taila*, which improves sleep quality. *Yoga Nidra* reduces stress and enhances relaxation, promoting better sleep duration and quality.

Need of the study: Both *Shirodhara* and *Yoga Nidra* have demonstrated benefits in improving sleep; however, a comparative evaluation is lacking. *Yashtimadhu Taila Shirodhara* is described in Ayurveda for calming the mind and inducing sleep, while *Yoga Nidra* enhances relaxation and mental balance. This study seeks to provide scientific validation of these therapies as holistic, patient-friendly approaches for managing chronic insomnia.

Aim: To evaluate and compare the effects of *Yashtimadhu Taila Shirodhara* with *Yoga Nidra* in the management of chronic insomnia through a randomised crossover study.

Materials and Methods: A randomised crossover study will be performed on patients from Dr. D. Y. Patil College of Ayurved and Research Centre, Pimpri, Pune, Maharashtra, India from March 2025 to March 2026. A total of 40 patients, aged 25 to 60 years, suffering from chronic insomnia, will be randomly divided into Group A or Group B in a 1:1 ratio. A sleep diary will be provided. Twenty patients will receive *Yashtimadhu Taila Shirodhara*, and the other 20 will receive *Yoga Nidra* for seven days. After a washout period of 10 days, crossover will occur, and the same patients will receive alternate therapy for seven days. Subjective and objective parameters will be assessed on the 8th, 18th and 25th day. Repeated measures Analysis of Variance (ANOVA) test, Friedman test, Mann-Whitney U test will be used, and a significance level of p-value <0.05 will be taken.

Keywords: *Panchakarma*, *Shirolepa*, Quality of sleep

INTRODUCTION

Insomnia refers to poor sleep quality, difficulty in initiating sleep, frequent awakenings during the night, and waking up earlier than desired or planned [1]. The International Classification of Sleep Disorders states chronic insomnia as the inability to fall or stay asleep at least three times per week for three months, even when sleep opportunities are available [2]. Global studies show that 10-30% of people experience chronic insomnia [3]. Now-a-days, stress, anger, smoking, eating late in the evening, and poor sleep habits are common causes of Insomnia. Chronic sleep disturbance may lead to symptoms such as headaches, body heaviness, mental disturbances, and reduced *agni* [4]. Ayurveda uses diet, lifestyle, along with *Panchakarma* techniques and medicines to balance *doshas* and restore harmony to the mind and body. The body and mind are exhausted from day-long activity, resulting in spontaneous detachment or dissociation of sense organs from their respective objects, which induces a state called sleep [5]. *Panchakarma* techniques, such as *Nasya*, *Shirodhara*, *Shirolepa*, etc., for the treatment of insomnia.

Shirodhara is a therapeutic technique in which oil or other liquids are gently poured onto the forehead, and it has shown effective results in treating sleep disorders, anxiety, stress, headaches, and hypertension [6]. An article shows that *Glycyrrhiza glabra* (*Yashtimadhu*) induces sleep, and its constituents enhance inhibitory neurotransmission through GABA receptor modulation, leading to reduced sleep onset time and improved sleep continuity

[7]. *Yashtimadhu*, described as a *rasayana*, helps regulate *Vata* and *Pitta*; *Vata* aggravation disturbs sleep continuity, while *Pitta* excess causes restlessness, and their pacification promotes sound sleep [8]. *Taila* pacifies the vitiated *doshas*, so *Yashtimadhu taila* has been taken for research. *Yashtimadhu Taila* is well tolerated for external use, with rare mild local reactions and negligible risk of systemic effects.

Yoga Nidra is recognised as a structured approach that promotes holistic relaxation - physical, psychological, and emotional - by shifting focus inward. It shifts autonomic balance toward parasympathetic dominance, reduces stress hormone levels such as cortisol, thereby improving subjective sleep quality [9]. *Yoga Nidra* is an effective form of psychic rest and has been shown to improve sleep habits.

Shirodhara and *Yoga Nidra* influence sleep by reducing psychophysiological arousal and enhancing parasympathetic activity [10]. Both help in stress, EEG alpha-theta dominance, and improved sleep continuity [11,12]. *Shirodhara* acts through sustained tactile-thermal stimulation, while *Yoga Nidra* works via guided cognitive relaxation. Both mechanisms may produce different therapeutic responses, so a randomised crossover design is appropriate to compare effects within the same individuals while limiting inter-subject variability. Therefore, the study is planned to evaluate the comparative effects of *Yashtimadhu Taila Shirodhara* and *Yoga Nidra* in chronic insomnia.

REVIEW OF LITERATURE

Sleep regulation depends on coordinated neurophysiological, psychological, and autonomic processes. Therapeutic interventions such as *Shirodhara* and *Yoga Nidra* aim to reduce heightened arousal and restore autonomic balance. Both therapies are widely used in integrative and Ayurvedic treatments. Datta K et al., conducted an RCT with 41 chronic insomnia patients in which 21 patients were given *Yoga Nidra*, and 20 were given Cognitive Behavioural Therapy (CBT). It showed that *Yoga Nidra* is a useful complementary approach for improving sleep and sleep onset, sleep duration, and daytime functioning [9]. Soldatos CR et al., conducted an instrument-validated study with 299 participants, consisting of 105 insomniacs, 144 psychiatric patients, and 50 healthy controls, and it showed that the Athens Insomnia Scale (AIS) scale effectively measures insomnia severity based on International Classification of Diseases, 10th Revision (ICD-10) criteria and is suitable for clinical trials [13].

Dhuri KD et al., study showed that *Shirodhara* procedure influences the hypothalamic-pituitary-adrenal axis, lowers stress hormone levels, enhances parasympathetic activity and produces electroencephalographic changes characterised by alpha-wave dominance, reflecting a calm yet alert mental state [14].

Sharma V et al., in their case study, showed that *Shirodhara* is an effective approach for promoting restful sleep and managing stress, and has a calming effect on the central nervous system [15]. Kuldeep SL et al., in their review article, mentioned that *Tailadhara* has shown a significant effect in insomnia and reduces fatigue and anxiety by pacifying aggravated *doshas* [16]. Vinjamury SP et al., conducted a case series on *Shirodhara with Brahmi oil* in 10 volunteers with chronic insomnia, and it showed that participants who received *Shirodhara* for five days showed an effect even at 7-day follow-up. The study concludes that *Shirodhara with Brahmi oil* is beneficial for moderate to severe insomnia [17]. Vyas T and Patwardhan RP conducted a trial in the geriatric population, and it showed that *Yoga Nidra* had a more significant result for the management of chronic insomnia compared to *Bhramari Pranayama* due to its deeper relaxation effect [18].

As both therapies, *Shirodhara* and *Yoga Nidra*, are effective, this study helps to make a direct comparison of interventions through a crossover design, limiting inter-subject variation through within-group comparison. Although both therapies have shown independent efficacy, comparative evidence remains limited. Therefore, the present study was designed for a clearer evaluation and comparison of the therapeutic potential of *Yashtimadhu Taila Shirodhara with Yoga Nidra* in the management of chronic insomnia through a randomised crossover study.

Aim

To evaluate and compare the effects of *Yashtimadhu Taila Shirodhara* with *Yoga Nidra* in the management of chronic insomnia through a randomised crossover study.

Primary objectives:

- To evaluate the effects of *Yashtimadhu Taila Shirodhara* in the management of chronic insomnia.
- To evaluate the effects of *Yoga Nidra* in the management of chronic insomnia.

Secondary objectives:

- To compare the effects of *Yashtimadhu Taila Shirodhara* and *Yoga Nidra* in the management of chronic insomnia.

Null hypothesis (H₀): There is no significant difference between the efficacy of *Yashtimadhu Taila Shirodhara* and *Yoga Nidra* in chronic insomnia.

Alternate hypothesis (H₁): There is a significant difference between the efficacy of *Yashtimadhu Taila Shirodhara* and *Yoga Nidra* in chronic insomnia.

MATERIALS AND METHODS

An open-label, randomised crossover clinical trial will be conducted at Dr. D. Y. Patil College of Ayurved and Research Centre, Pimpri, Pune, Maharashtra, India from March 2025 to March 2026. Ethical approval is obtained from the Ethics Committee (IEC/886/2024), and the trial is registered with the Clinical Trials Registry of India (CTRI/2025/02/080214). Informed consent will be obtained from participants before the study.

Inclusion criteria: Participants aged 25-60 years following a regular sleep-wake schedule, diagnosed with chronic insomnia as per Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR) criteria [19], and presenting with symptoms such as *Angamarda* (Malaise), *Jrumbha* (Yawning), *Shirogaurav* (Heaviness of head), *Ghani* (Drowsiness), and *Klama* (Fatigue) will be included in the study.

Exclusion criteria: Individuals with bipolar disorder or schizophrenia, medical conditions significantly affecting sleep such as sleep apnoea, restless leg syndrome, or chronic pain disorders, those using prescribed or over-the-counter sleep medications, having a history of substance abuse, shift workers, and pregnant or lactating women will be excluded from the study.

Sample size calculation:

Sample size (n) = $n = (Z_{\alpha/2} + Z_{\beta})^2 \cdot \sigma^2 d / \delta^2$

$Z_{\alpha/2} = 1.96$, $Z_{\beta} = 0.84$, $\sigma d = 4.2$, $\delta = 3$ [20]

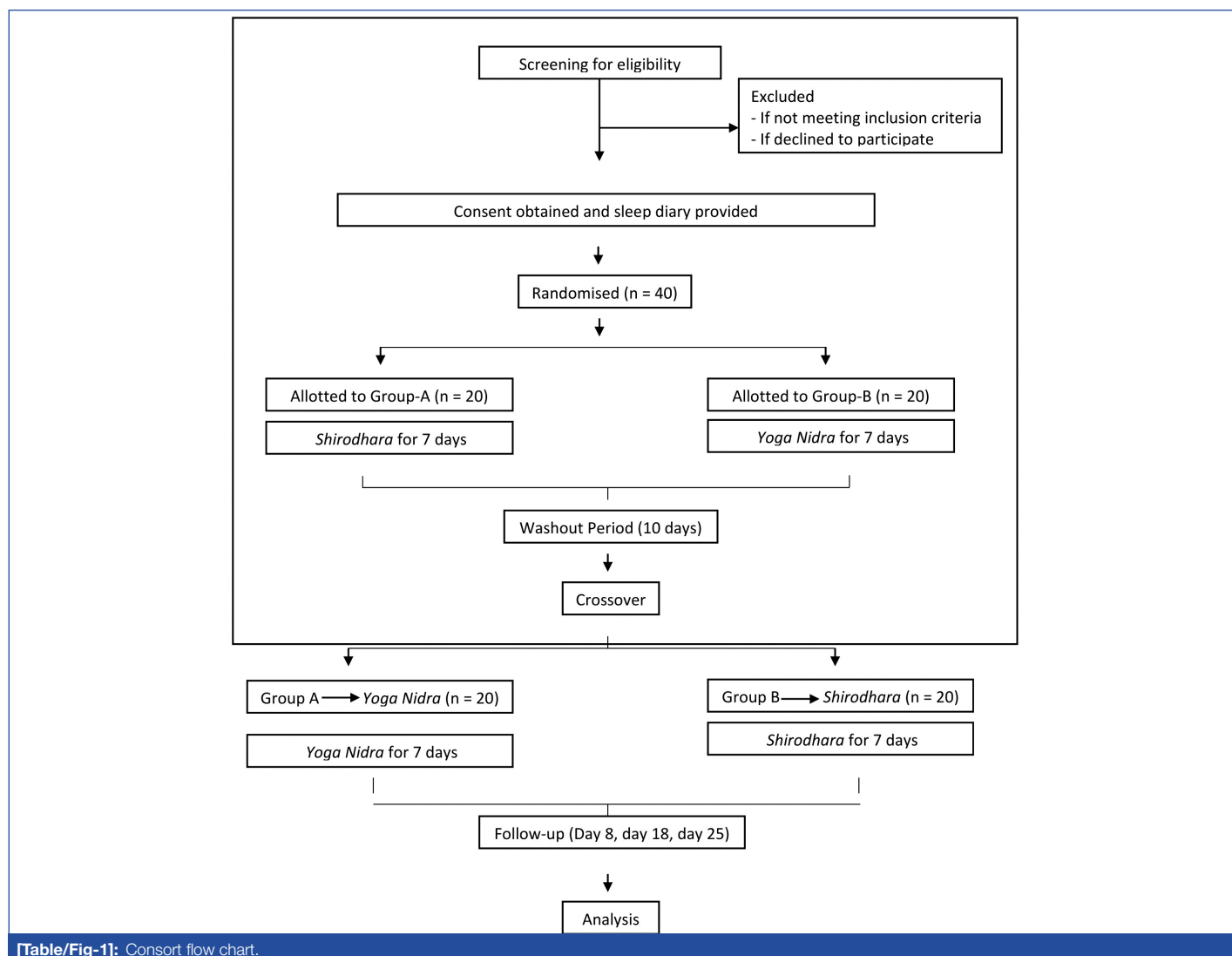
$n = (1.96 + 0.84)^2 \cdot (4.2)^2 / 3^2 = 7.84 \times 17.64 / 9 = 138.30 / 9 = 15.37$

Thus, approximately 16 patients are required in each group. Considering a possible 20% dropout, 38 per group will be considered, but, 40 patients will be included and divided into Group A and Group B, 20 participants each. Group A will receive *Yashtimadhu Taila Shirodhara*, and Group B will receive *Yoga Nidra* therapy. After a 10-day washout period, a crossover will take place, and the same patients will receive the alternate therapy for seven days. Follow-up on the 8th, 18th and 25th day of the patient will be done. Carryover effects are minimised by taking an adequate washout period of 10 days between intervention phases [Table/Fig-1]. Each patient will receive a sleep diary that includes a daily log for both therapies and a daily scoring chart for the AIS [13].

Randomisation will be carried out using a computer-generated simple random sampling technique with an allocation ratio of 1:1. Allocation concealment will be ensured through Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE). Participants will be recruited by the principal investigator. The two interventions differ procedurally, and blinding of participants is not feasible. The washout period between two therapies will be 10 days. Crossover will be done (Group A → Group B and Group B → Group A). Drugs will be purchased from authentic sources, and drug preparation, authentication and standardisation will be done in the college lab pharmacy.

Shirodhara: It will be performed for seven days, in the evening, for 30 minutes, at a temperature of 39.0±0.2 °C [21]. Oil used for *Shirodhara* therapy will be *Yashtimadhu Taila*. *Yashtimadhu Taila* will be prepared according to the *Sharangdhar Samhita* [22]. *Yashtimadhu* as *Kalka Dravya*, *Tila Taila* as *Sneha Dravya* and *Yashtimadhu Kashaya* as *Drava Dravya* will be taken in 1:4:16 parts and purchased from authentic sources. The sesame oil will be heated gently, and then the decoction prepared with *Yashtimadhu bharad* and *Yashtimadhu kalka* (paste) will be added, and the mixture will be cooked on mild heat. The heating process will continue until the classical signs of proper *Sneha* preparation are observed. The oil will then be filtered while still warm and stored in an airtight container until it cools completely. Trained ayurveda therapists will do the therapy.

Yoga Nidra: It is an effective form of psychic rest, and includes steps such as preparation of the patient, relaxation, resolve,



[Table/Fig-1]: Consort flow chart.

rotation of consciousness, breathing, image visualisations, resolve and end procedure. It will be done for seven days in the evening for 30 minutes. Patients will be instructed in *Yoga Nidra* guided by *Paramahansa Swami Satyananda Saraswati* using a provided recording. Initial training will be given, after which they will practice it at home.

Primary outcomes: AIS- It comprises eight points, each rated from 0 to 3, where higher scores indicate greater sleep disturbance. The total AIS score ranges from 0 to 24 [23].

1. Total sleep duration- adequacy of total sleep time.
2. Sleep induction- difficulty in falling asleep.
3. Awakenings during the night- frequency of nocturnal awakenings.
4. Final awakening earlier than desired- waking earlier than desired.
5. Vitality after morning awakening- energy level on waking.
6. Performance of daily activities- effect on daily activities.
7. Sleep quality evaluation- overall sleep satisfaction.
8. Sleepiness during day- severity of sleepiness during the day.

Secondary outcomes: It includes *Angamarda* (Malaise), *Shirogaurava* (Heaviness of head), *Jrumbha* (Yawning), *Klama* (Fatigue), and *Ghani* (Drowsiness). [Table/Fig-2] shows grading of subjective parameters [24].

Outcomes assessment will be conducted at the baseline and on the 8th, 18th and 25th day.

Information regarding patients will be collected during the screening process. A case record form will be used to document relevant details of patients. A sleep diary will be provided to all

Grade	Lakshanas
Zero	No complaints
One	Occasionally present
Two	Very often present
Three	Always present

[Table/Fig-2]: Gradation of subjective parameter [24].

patients, which includes a day-to-day record form of both the therapies and a daily score chart for the AIS. Data for assessing outcome will be gathered using a sleep diary, both before, during and after treatment. Participant timeline is shown in [Table/Fig-3].

STATISTICAL ANALYSIS

Data will be arranged in MS Excel and IBM Statistical Package for the Social Sciences (SPSS) Version 26.0 will be used for statistical analysis. All observed data will be collected, and the repeated measures ANOVA test, the Friedman test, Mann-Whitney U test will be used for objective and subjective parameters. Missing data will be handled using a suitable method. A p-value <0.05 is considered statistically significant.

Data management: Information will be collected in folders and maintained. Access to these folders will be limited to the investigator and supervisors only. Data collected will be exported to Microsoft Excel for organisation.

Funding information: The study is self-funded.

Supplementary material: Sleep diary will be used as supplementary data.

Study event	Baseline	1 st day	1 st day - 7 th day	8 th day	8 th day - 17 th day	18 th day	18 th day - 24 th day	25 th day
Baseline assessment (Athens Insomnia Scale Score, Subjective Parameters)	✓							
Informed consent	✓							
Recruitment	✓							
Demographic profile	✓							
Intervention (<i>Shirodhara</i> and <i>Yoga Nidra</i> - 7 days each with crossover of treatment)			✓				✓	
Follow-up				✓		✓		✓
Washout period					✓			
Assessment by clinical evaluation	✓	✓		✓		✓		✓
Evaluation using the assessment (Athens Insomnia Scale Score, Subjective Parameters)		✓		✓				✓

[Table/Fig-3]: Study schedule.

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