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Protocol

Scope of Ayurvedic interventions for insomnia: a systematic review protocol

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ABSTRACT

Background: Anidra (Insomnia), corresponding to the ICD-11 TM2 code SK02 and ICD-10/ICD-11 codes G47.00, F51.01, and 7A00, is a highly prevalent global disorder affecting 10–30% of the population, with significant impacts on mental health and quality of life. Current pharmacological treatments are limited by side effects and tolerance, and although Ayurveda offers a comprehensive range of pharmacological and non-pharmacological therapies for insomnia, the existing evidence remains scattered and inadequately synthesized.
Methods: This systematic review will evaluate and synthesize the methodological quality, safety, and effectiveness of Ayurvedic interventions for insomnia. Randomized controlled trials, comparative clinical trials, non-randomized controlled trials, and quasi-experimental studies involving adolescents and adults with insomnia (Anidra/Nidranasha), assessed using validated scales (ISI, PSQI) or objective sleep parameters (SOL, TST, SE%), will be included. Comparators will include standard care (hypnotics, CBT-I), placebo, or other conventional approaches. Searches will be conducted in trial registries and databases including PubMed/MEDLINE, PubMed Central, AYUSH Research Portal, Ayushdhara, Shodhganga, and Google Scholar. Two independent reviewers will screen studies and extract data as per PRISMA guidelines, and risk of bias will be assessed using the Cochrane RoB 2 tool. Findings will be synthesized narratively (SWiM), and the certainty of evidence will be assessed using GRADE.
Conclusions: This review will consolidate the existing evidence on Ayurvedic interventions for insomnia, identify critical research gaps, and provide a scientific foundation for future high-quality clinical trials and evidence-based Ayurvedic practice.
Trial Registration: Trial registration isCRD420251180334 (PROSPERO).

Keywords: Insomnia, *Anidra*, *Nidranasha*, Ayurveda, Sleep disorders, Systematic review, Integrative medicine, Sleep quality

INTRODUCTION

Insomnia is a highly prevalent sleep disorder globally, affecting 10–30% of the population, with significant impacts on mental health and quality of life. Despite their effectiveness, modern pharmaceutical treatments are constrained by tolerance, reliance, and side effects, while non-pharmacological alternatives have accessibility problems. By using herbal formulations, Panchakarma treatments, and mind-body therapies that address both physiological and psychological causes, Ayurveda provides a comprehensive approach to managing Anidra. Ashwagandha, Mamsyadi Kwatha, and Shirodhara have all showed encouraging results in a number of clinical trials; nevertheless, the evidence is still fragmented, small-scale, and inadequately synthesized. Therefore, a systematic review is necessary to compile the available data, evaluate the quality of the methodology, highlight research gaps, and encourage the use of evidence-based Ayurvedic methods in the treatment of insomnia. This

review will provide a scientific foundation for future large-scale and high-quality clinical trials.

Objectives

Primary objective

To systematically evaluate and synthesize the available evidence on the effectiveness and safety of Ayurvedic interventions in the management of insomnia (*Anidra*/ *Nidranasha*) among adolescents and adults using validated subjective sleep scales and objective sleep parameters.

Secondary objectives

The secondary objectives of this systematic review are to compare the effectiveness and safety outcomes of Ayurvedic interventions with standard care, placebo, or other conventional approaches for insomnia; to critically assess the methodological quality and risk of bias of the included studies; to evaluate the certainty of the available evidence; and to identify current evidence gaps and provide directions for future research in Ayurvedic management of insomnia.

METHODS

Population

The review will include studies involving adolescents and adults diagnosed with insomnia using established diagnostic criteria, including DSM, ICD, ICSD, or validated sleep assessment instruments. Studies describing insomnia using Ayurvedic terminology such as *Anidra* or *Nidranasha* will also be considered, provided that insomnia or sleep-related outcomes are clearly reported. Participants with either primary or secondary insomnia will be eligible for inclusion.

Intervention

Ayurvedic interventions encompassing both pharmacological and non-pharmacological modalities will be included.

Pharmacological: Single herbs or compound formulations such as *Mamsyadi Kwatha*, *Ashwagandha*, *Tagara, Jatamansi*, *Saraswatarishta*, *Churna*, *Arishta*, or *Ghana Vati*.

Non-pharmacological: Panchakarma procedures like *Shirodhara*, *Shirobasti*, *Abhyanga*, *Nasya*, and mind–body therapies such as *Sattvavajaya Chikitsa* (meditation, counseling, relaxation techniques).

Comparator

Eligible comparator groups will include placebo, no treatment, usual care, active control interventions such as pharmacological treatment or cognitive behavioral therapy for insomnia (CBT-I), and other clearly defined conventional management approaches. Comparative studies involving Ayurvedic and conventional interventions will be included where treatment effects can be independently evaluated.

Outcomes

Primary outcomes

Primary outcomes will include changes in insomnia severity and sleep quality measured using validated subjective assessment tools such as the Insomnia Severity Index (ISI), Athens Insomnia Scale (AIS), and Pittsburgh Sleep Quality Index (PSQI), along with objective sleep parameters including Sleep Onset Latency (SOL), Total Sleep Time (TST), and Sleep Efficiency (SE%).

Secondary outcomes

Secondary outcomes will include safety-related outcomes such as adverse events, treatment tolerability, and study withdrawals; measures of daytime functioning and quality of life where reported; and sustainability of treatment effects based on follow-up assessments. Additional outcome measures reported across included studies will be narratively synthesized where appropriate.

Eligibility criteria

Studies will be included if they are clinical human studies evaluating Ayurvedic interventions for insomnia, including randomized controlled trials (RCTs), comparative clinical trials, non-randomized controlled trials, and quasi-experimental studies. The review will include adolescents and adults diagnosed with insomnia (primary or secondary) based on established diagnostic criteria such as DSM, ICD, or ICSD, as well as studies referring to insomnia using Ayurvedic terminology such as *Anidra* or *Nidranasha*, provided that sleep-related outcomes are reported. Studies assessing Ayurveda-based interventions, including pharmacological and non-pharmacological approaches, either as standalone or integrative interventions, will be included where the Ayurvedic component can be separately evaluated. Only studies published between 1 January 2015 and 31 December 2025 will be considered.

Studies will be excluded if they are animal or in-vitro studies, review articles, systematic reviews, meta-analyses, study protocols, editorials, commentaries, conference abstracts, or opinion papers. Studies involving populations without insomnia, studies lacking relevant sleep-related outcome measures, duplicate publications, overlapping datasets, and studies with unavailable full text or insufficient extractable data will also be excluded.

Language restriction and publication bias

Only studies published in English and Hindi will be included due to feasibility considerations and availability of translation resources. This restriction will be acknowledged as a potential source of language bias. To minimize publication bias and improve comprehensiveness, grey literature sources including trial registries, reference list screening, and relevant institutional repositories will also be searched. Where sufficient studies are available and methodological assessment permits, reporting bias and publication trends will be considered during evidence synthesis and interpretation.

Information sources

A comprehensive literature search will be conducted across multiple electronic databases, including PubMed/MEDLINE, PubMed Central, AYUSH Research Portal, Ayushdhara, Shodhganga, and Google Scholar (limited to the first 200 relevant filtered results). To identify ongoing and unpublished studies, trial registries including the Clinical Trials Registry–India (CTRI), ClinicalTrials.gov, and the WHO International Clinical Trials Registry Platform (ICTRP) will also be searched. Additionally, manual searching of key Ayurveda journals and the reference lists of included studies will be performed to identify potentially relevant records not captured through electronic searches. The search will include studies published between 1 January 2015 and 31 December 2025.

Search strategy

A comprehensive and systematic literature search will be conducted across multiple electronic databases, including PubMed/MEDLINE, PubMed Central, AYUSH Research Portal, *Ayushdhara*, *Shodhganga*, and Google Scholar (limited to the first 200 relevant filtered records), to identify studies evaluating Ayurvedic interventions for insomnia. Additional searches will be performed in trial registries including Clinical Trials Registry–India (CTRI), ClinicalTrials.gov, and the WHO International Clinical Trials Registry Platform (ICTRP), along with manual screening of reference lists and selected Ayurveda journals to identify potentially eligible studies not retrieved electronically. Search terms will be developed using a combination of controlled vocabulary (where applicable) and free-text keywords related to insomnia and Ayurveda. The search strategy will combine three conceptual domains: (1) insomnia-related terms ("insomnia", "sleep disorder*", "sleep quality", "*Anidra*", "*Nidranasha*"); (2) intervention-related terms ("*Ayurveda*", "*Shirodhara*", "*Nasya*", "*Ashwagandha*", "*Jatamansi*", "*Tagara*"); and (3) study design-related terms ("randomized", "clinical trial", "controlled trial", "comparative study", "double-blind"). Boolean operators (AND/OR) will be applied to combine search terms appropriately. Searches will be limited to human studies published in English or Hindi during the predefined study period.

Study records, screening, and data extraction

All search records retrieved from electronic databases and other sources will be exported in RIS/CSV format and managed using reference management software (Zotero and/or EndNote), where duplicate records will be identified and removed. Study selection will be conducted independently by two reviewers in two stages: initial screening of titles and abstracts followed by full-text assessment of potentially eligible studies. Any disagreements between reviewers will be resolved through discussion and consensus, and where required, consultation with a third reviewer. The study selection process will be documented and reported in accordance with the PRISMA guidelines.

Data extraction will be performed independently by two reviewers using a standardized and pilot-tested data extraction form. Extracted information will include study identification details (author, year, country, and setting), study design, sample size, participant characteristics, diagnostic criteria used for insomnia, details of interventions and comparators, outcome measures, results, reported adverse events, and information relevant to methodological quality assessment.

Risk of bias assessment

The methodological quality and risk of bias of included studies will be assessed independently by two reviewers. Randomized controlled trials will be evaluated using the Cochrane Risk of Bias 2 (RoB 2) tool across domains including the randomization process, deviations from intended interventions, missing outcome data, outcome measurement, and selection of reported results. For non-randomized studies, appropriate JBI critical appraisal tools will be applied according to study design. Any disagreements during the assessment process will be resolved through discussion and consensus, with consultation from a third reviewer where necessary.

Data synthesis

Data will be synthesized using a narrative synthesis approach in accordance with the SWiM (Synthesis Without Meta-analysis) reporting framework. Included studies will be grouped based on intervention characteristics, outcome domains, and study design to facilitate structured interpretation of findings. Results will be summarized descriptively using tables and narrative reporting, with emphasis on effectiveness outcomes, safety findings, methodological quality, and consistency across studies. Due to anticipated heterogeneity in interventions and outcome measures, statistical pooling will not be performed.

Missing data

Where data are missing, unclear, or insufficiently reported, attempts will be made to contact corresponding authors up to two times for clarification. If additional information is not obtained, the available data will be synthesized narratively and the limitations arising from incomplete reporting will be documented.

Certainty of evidence

The certainty of evidence across major outcomes will be evaluated using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach. Evidence quality will be categorized as high, moderate, low, or very low based on factors including risk of bias, inconsistency, indirectness, imprecision, and publication bias. A Summary of Findings table will be prepared for key outcomes.

Ethics and dissemination

As this review involves analysis of previously published data and does not involve direct human participation or collection of primary data, ethical approval is not required. The findings of this systematic review will be disseminated through publication in a peer-reviewed journal and presentation at academic or scientific forums related to Ayurveda, sleep medicine, or integrative health.

Timeline and resources

The systematic review is expected to be completed within an estimated duration of 10–12 weeks. Reference management and de-duplication will be performed using Zotero and/or EndNote, while screening and study selection will be conducted using Rayyan. Data extraction and synthesis will be managed using Microsoft Excel or Google Sheets. The review team will consist of a lead reviewer, two independent reviewers for screening and extraction, and one Ayurveda domain expert.

RESULT

As this manuscript represents a systematic review protocol, results are not currently available. Upon completion of the review process, relevant evidence regarding Ayurvedic interventions for insomnia will be identified, extracted, critically appraised, and synthesized. The final review is expected to provide a structured overview of intervention characteristics, effectiveness, safety outcomes, methodological quality, and existing evidence gaps in accordance with PRISMA and SWiM recommendations.

DISCUSSION

Insomnia is increasingly recognized as a complex disorder influenced by interacting neurophysiological, behavioral, psychological, and circadian mechanisms rather than a single disturbed process. Although conventional approaches, including pharmacotherapy and cognitive behavioral interventions, remain standard treatment options, concerns related to long-term adherence, adverse effects, and variability in treatment response have contributed to increasing interest in complementary and integrative approaches for sleep management.[1]

In Ayurveda, *Nidra* is considered one of the fundamental determinants of health and physiological balance, and disturbances of sleep (*Anidra* or *Nidranasha*) are interpreted in relation to broader alterations in bodily and mental functioning. Ayurvedic management therefore extends beyond symptomatic treatment and may include herbal formulations, Panchakarma procedures, and mind–body interventions individualized according to patient characteristics. Emerging clinical studies evaluating interventions such as *Ashwagandha*, *Mamsyadi*, formulations, *Shirodhara* and *Nasya* have reported improvement in sleep quality and insomnia-related outcomes; however, the available evidence remains methodologically diverse and difficult to interpret collectively.[2-12]

Despite growing scientific interest, the current evidence base remains fragmented. Existing literature frequently evaluates individual interventions in isolation, and broader evidence syntheses often report substantial heterogeneity in study design, intervention protocols, outcome measures, and methodological quality, limiting conclusions regarding comparative effectiveness and long-term applicability.

This protocol has therefore been developed to provide a transparent and reproducible framework for systematically identifying, evaluating, and synthesizing available evidence on Ayurvedic interventions for insomnia. Through predefined eligibility criteria, structured risk of bias assessment, and standardized synthesis methods, the completed review is expected to identify current evidence patterns, methodological limitations, and areas requiring stronger clinical investigation. Such findings may contribute to strengthening the evidence base for integrative approaches to insomnia management and support future high-quality clinical research.

CONCLUSION

This review will evaluate single-herb formulations (*Ashwagandha*), compound preparations (*Mamsyadi Kwatha* and its Ghana capsule and *Saraswatarishta*-based variants), single procedures (*Shirodhara*, alone or with Insomrid Tablet), a combined herb-procedure regimen (*Brimhana Nasya* with *Ashwagandha* in elderly patients), mind-body approaches (*Sattvavajaya Chikitsa* with *Guda Pippalimula Churna*), yoga-based practice alone and in combination with Ayurveda, and *Parsikayavanyadi* capsule, drawn from twelve identified trials. Since none of these trials directly compares one intervention against another, this review will determine, through GRADE-

graded synthesis, which single interventions and which combined regimens (herb-with-procedure or Ayurveda-with-yoga) show the most consistent improvement in sleep onset, sleep quality, and insomnia severity, and whether combined approaches outperform single interventions, and for which patient groups (e.g., elderly versus general adult populations, primary versus secondary insomnia) providing the first comparative, evidence-graded answer to this question in Ayurvedic insomnia research.

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REFERENCES

1. Sarris J, Byrne GJ. A systematic review of insomnia and complementary medicine approaches. Sleep Med Rev. 2011;15(2):99–106.
2. Upadhyay A, Bansal C, Shukla U. Efficacy of Brimhana Nasya and Ashwagandha (Withania somnifera) root powder in primary insomnia in elderly male: a randomized open-label clinical study. Ayu. 2020;41(3):159-65.
3. Langade D, Kanchi S, Salve J, Debnath K, Ambegaokar D. Efficacy and safety of Ashwagandha (Withania somnifera) root extract in insomnia and anxiety: a double-blind, randomized, placebo-controlled study. Cureus. 2019;11(9):e5797.
4. Lad A, Tubaki BR, Kavya Shree S. Effects of Mamsyadi Kwatha in primary insomnia: a randomized controlled trial. J Ayurveda Integr Med. 2023;14(6):100830.
5. Kedar NA, Tubaki BR, Krishna Priya G, Manasa M. Efficacy of Mamsyadi Ghana capsule in Insomnia Disorder: a randomized controlled trial. J Ayurveda Integr Med. 2024;15(6):100970.
6. Manasa M, Padmashali A, Tubaki BR, Manisha. Efficacy of Mamsyadi Ghana capsule and Saraswatarista in the management of Insomnia Disorder: a randomized controlled clinical trial. J Ayurveda Integr Med. 2025;16(4):101160.
7. Pokharel S, Sharma AK. Evaluation of Insomrid Tablet and Shirodhara in the management of Anidra (Insomnia). Ayu. 2010;31(1):40-7.
8. Vinjamury SP, Vinjamury M, der Martirosian C, Miller J. Ayurvedic therapy (Shirodhara) for insomnia: a case series. Glob Adv Health Med. 2014;3(1):75-80.
9. Rawal P, Vyas M, Baghel AS, Kamble S. Efficacy of Sattvavajaya Chikitsa in the form of relaxation techniques and Guda Pippalimula Churna in the management of Anidra (insomnia): an open-labelled randomized comparative clinical trial. Ayu. 2019;40(2):89-96.
10. Verma K, Singh D, Srivastava A. Comparative impact of yoga and ayurveda practice in insomnia: a randomized controlled trial. J Educ Health Promot. 2023;12:160.
11. Verma K, Srivastava A, Singh D. Effects of yoga on psychological health and sleep quality of patients with acute insomnia: a preliminary study. Adv Mind Body Med. 2022;36(4):11-4.
12. Muthugala MPSKR, Goyal M, Chandola HM, Dave AR. Evaluation of Parsikayavanyadi capsule in the management of Anidra with special reference to insomnia. Anc Sci Life. 2012;32(Suppl 1):S29.

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