



Systematic Review and Meta-analysis

Homoeopathy for insomnia: A meta-analysis of clinical evidence

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ABSTRACT

Objectives: Insomnia is a prevalent sleep disorder characterised by challenges in initiating, maintaining or achieving restorative sleep, resulting in compromised daytime functionality. Traditional therapeutic modalities frequently encompass pharmacological treatments, which may have adverse effects and potential for dependency. Numerous patients pursue alternative methodologies, such as homoeopathy, which is attributed to its personalised, holistic and non-invasive treatment framework. This thorough examination assesses the effectiveness of homoeopathy in promoting better sleep quality and overall wellness in people with insomnia by analysing randomised controlled trials (RCTs).

Material and Methods: This meta-analysis sought to ascertain whether homoeopathy induces a statistically significant enhancement in the management of insomnia, concentrating on aspects of sleep quality, duration and general well-being. All RCTs addressing insomnia treated with homoeopathic interventions were included in this review. All studies were meticulously documented in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Three evaluators independently reviewed and compiled the literature, extracting comprehensive details regarding participants, study designs, therapeutic interventions and follow-up pertaining to homoeopathic treatment. The primary outcome of the investigation was disease assessment based on sleep diary scores, with an additional outcome being the enhancement of quality of life.

Results: The analysis revealed that homoeopathic remedies exhibited statistically significant improvement over placebo in the management of insomnia. The overall pooled effect size, standardised mean difference (random), was -0.60 , standard error (random) was 0.42 and confidence interval (random) at 95% ranged from -0.93 to -0.26 . The risk of bias was assessed for all studies.

Conclusion: This meta-analysis shows that homoeopathic remedies are effective in treating insomnia, but more studies are required for accuracy.

Keywords: Homoeopathy, Insomnia, Randomised controlled trials, Sleep diary, Sleep disorders

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INTRODUCTION

Insomnia is a prevalent sleep disorder that affects millions of individuals worldwide. It is characterised by challenges associated with the initiation and maintenance of sleep, premature morning awakenings and non-restorative sleep, all of which contribute to compromised daytime functioning. Chronic insomnia that continues over time is associated with a higher risk of heart issues, depressive disorders, anxiety, cognitive decline and an overall decrease in quality of life.^[1] Although traditional therapeutic approaches exist, including cognitive behavioural therapy for insomnia and pharmaceutical options such as benzodiazepines and non-benzodiazepine sleep aids, fears about their harmful consequences, chances of addiction and durability of benefit remain.^[2] Consequently, numerous individuals pursue alternative therapeutic options, including homoeopathy, which is perceived as a safer and more holistic strategy for managing insomnia.

Homoeopathy, established by Samuel Hahnemann in the early 19th century, is predicated on the principle of 'like cures like', wherein ultra-diluted substances are employed to activate the body's intrinsic healing mechanisms.^[3] Homoeopathic interventions for insomnia, such as *Coffea cruda*, *Nux vomica* and *Passiflora incarnata*, are administered based on personalised symptomatology rather than a universal treatment paradigm.^[4] Homoeopathy literature asserts that these remedies target the fundamental factors contributing to insomnia, including stress, anxiety and hormonal dysregulation.^[5] Nonetheless, the scientific community remains polarised regarding the efficacy of homoeopathy, with certain studies indicating favourable outcomes, while others attribute observed improvements to the placebo phenomenon.^[6]

Aim

The primary objective of this meta-analysis was to evaluate the effectiveness of homoeopathy in treating insomnia by analysing randomised controlled trials (RCTs). This study was designed to assess the enhancements in sleep quality, duration and overall well-being of individuals receiving homoeopathic interventions compared with those administered a placebo.

Rationale

Insomnia is a widespread sleep disorder that substantially affects an individual's quality of life and overall health. Conventional treatment modalities, including pharmacological interventions, frequently carry the risks of dependency, adverse side effects and diminished long-term efficacy. Consequently, numerous individuals pursue alternative therapeutic options, such as homoeopathy, which is recognised for its individualised, holistic and non-invasive approach. However, the role of homoeopathy in

addressing insomnia is a divisive matter in the realm of science, noted for its insufficient quality of evidence. This meta-analysis systematically reviewed and synthesised data from RCTs to comprehensively evaluate the prospective role of homoeopathy in managing insomnia, thereby providing insights into its clinical applicability and effectiveness.

Given the growing interest in homoeopathic approaches for insomnia, it is imperative to rigorously evaluate their effectiveness through a comprehensive synthesis of high-quality evidence. This meta-analysis aimed to determine whether homoeopathy yields a statistically significant improvement in sleep quality, latency, duration and overall well-being compared to placebo or conventional treatments. By scrutinising RCTs, this study aims to provide a thorough understanding of the potential role of homoeopathy in insomnia management and its implications for clinical practice.

MATERIAL AND METHODS

Inclusion criteria

This study considered all RCTs on insomnia, including original published data, grey literature, English language papers and fully accessible open articles. Participants were included regardless of their age, sex, race or religious background. Case reports and case series were excluded. All items were reported in strict compliance with the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines.^[7]

Literature search

An extensive literature search will be conducted from the period of 25 November 2024 to 28 February 2025, which was conducted across multiple electronic bibliographic databases, including PubMed, Google Scholar, Cochrane Library, database of abstracts of reviews of effects (DARE), Latin American and Caribbean Health Sciences and Literature (LILACS), Central Council of Research in Homoeopathy (CCRH), Campbell library of systematic review and database of systematic review and non-systematic review of public health intervention. The Kerala University of Health Sciences was also searched, but no RCT related to insomnia in homoeopathy was found. The search terms used included 'sleep initiation and maintenance disorders/classification', 'sleep initiation and maintenance disorders/complications', 'sleep initiation and maintenance disorders/diagnosis', 'sleep initiation and maintenance disorders/diagnostic imaging', 'sleep initiation and maintenance disorders/diet therapy', 'sleep initiation and maintenance disorders/physiopathology', 'sleep initiation and maintenance disorders/psychology', 'sleep initiation and maintenance disorders/therapy', wakefulness, watchfulness, restlessness, 'homoeopathy/adverse effects',

'homoeopathy/instrumentation,' 'homoeopathy/methods,' complementary medicines, alternative medicine, traditional medicine, homoeopathy, homoeopath* and homoeopath*.

Selection of studies

The research was limited to RCTs involving only homoeopathic interventions. *In vitro* and *in vivo* studies, case reports and case series were also excluded. No restrictions were placed on the form or mode of homoeopathic treatment.

Data extraction and elements

Three reviewers (Niharika Shaw, Dinesh Sura and Sushma Naigotriya) extracted the data, which were then verified by a fourth reviewer (KV Kumaravel V) using Rayyan software (www.rayyan.ai). The extracted data elements included effect size, sample size, confidence interval (CI), mean, interventions (homoeopathic medicine), comparator (or control), outcomes and overall results. The sleep diary scoring system was used to evaluate the methodological quality of the selected trials based on objective criteria, such as randomisation, blinding method and description of withdrawals or dropouts. The standardised data extraction

process and blinding among reviewers ensured consistency, reduced bias and independently enhanced the quality of the study. Data organisation: The collected data included:

- a. Author
- b. Year of publication
- c. Sample size
- d. Intervention
- e. Control group
- f. Result
- g. Sleep diary

This information was systematically arranged in a spread sheet and regularly discussed by all authors.

RESULTS

A comprehensive review of clinical research papers was conducted using multiple databases, including PubMed, Google Scholar, Cochrane Library, DARE, LILACS, CCRH and ScienceDirect. The initial search yielded 232 articles, of which 108 were excluded before screening because of duplication. Following a thorough evaluation, ten studies were selected based on a complete text review and RCT criteria. Ultimately, three studies met the inclusion criteria

Table 1: Name of study, effect size, standard error, confidence interval, sample size, intervention and control.

S. No.	Paper with author (Year)	Effect size	Standard error	CI-	CI+	Sample size	Homoeopathic medicine (Patient no.)	Control or comparator
1.	Efficacy of individualized homeopathic treatment of insomnia: Double blind, randomized, placebo-controlled clinical trial. James Michael <i>et al.</i> (2019) ^[9]	0.24191	0.25917	-0.26606	0.749883	60	Individualized homeopathic medicine (30)	Placebo (30)
2.	Effects of homeopathic Medicines on Polysomnographic Sleep of young Adults with Histories of Coffee-Related Insomnia Bell <i>et al.</i> (2011) ^[8]	0.91025	0.28661	0.348494	1.472006	54	<i>Nux vomica</i> (28)	<i>Coffea cruda</i> (26)
3.	An open-label randomized placebo controlled trial to evaluate the efficacy of <i>Passiflora incarnata</i> and individualized homoeopathic medicines in insomnia Fathima Rahim (2021)	0.21881	0.35468	-0.47636	0.913983	31	<i>IHM</i> (16)	Placebo (16)

CI: Confidence interval, IHM: Individualized homoeopathic medicine

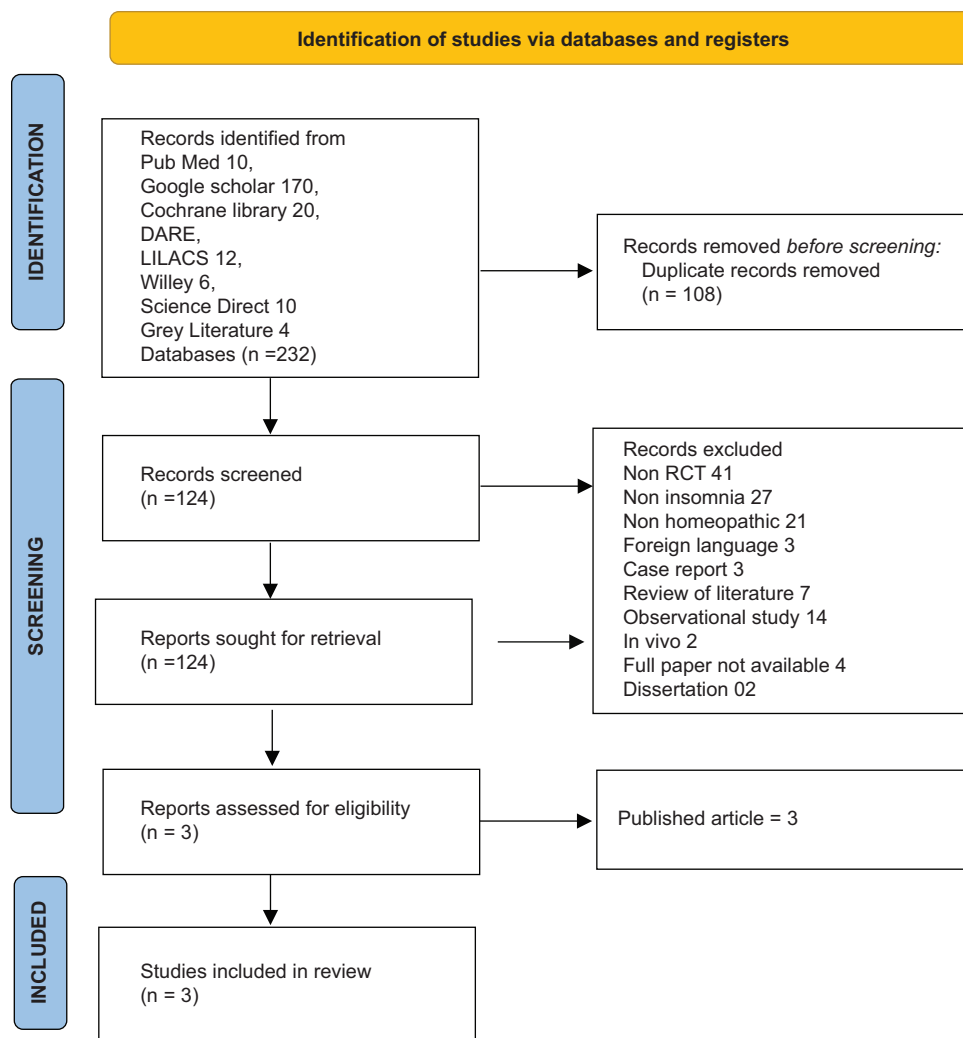


Figure 1: PRISMA 2020 Flow chart: PRISMA flow chart of study selection in this review. PRISMA: Preferred reporting items for systematic reviews and meta-analyses, DARE: Database of abstracts of reviews of effects, LILACS: Latin america and the caribbean literature on health sciences, CCRH: Central council for research in homoeopathy. Out of 232 searched papers 3 are selected based on inclusion criteria. RCT: Randomised controlled trial.

for the meta-analysis [Figure 1]. The random model was selected based on the use of different insomnia scales (Pittsburgh sleep quality index [PSQI] and insomnia severity index [ISI]), even though heterogeneity was zero. A meta-analysis using this model revealed the following findings:

1. Three studies were included in this meta-analysis. Bell *et al.* 2011,^[8] James *et al.* 2019,^[9] and Prajakta 2024^[10] showed positive effects [Figure 2 and Table 1].
2. In Figure 2, the vertical line represents an effect size of '0' based on the standardised mean difference (SMD), and the diamond symbol indicates each study's sample size and effect size.
3. The Z value was 3.51, and I² was 0%, confirming the heterogeneity of the study [Figure 2].
4. The overall pooled effect size, SMD (fixed), was

determined to be -0.60 , with standard error (SE) (random) at 0.42 and CI (random) ranging from -0.93 to -0.26 at a 95 % CI [Figure 2].

5. The summary diamond, representing the total sample size/effect size, is positioned to the left of the vertical line, indicating a statistically significant overall effect of homoeopathic treatment for insomnia [Figure 2].
6. The risk of bias shows that James *et al.* (2019)^[9] demonstrated methodological rigor and low risk of bias, making it a reliable source of evidence. The other two studies, Bell *et al.* (2011),^[8] Prajakta *et al.* (2024)^[10] and, showed some methodological weaknesses and a moderate risk of bias, limiting their utility in drawing strong conclusions from the results [Table 2].

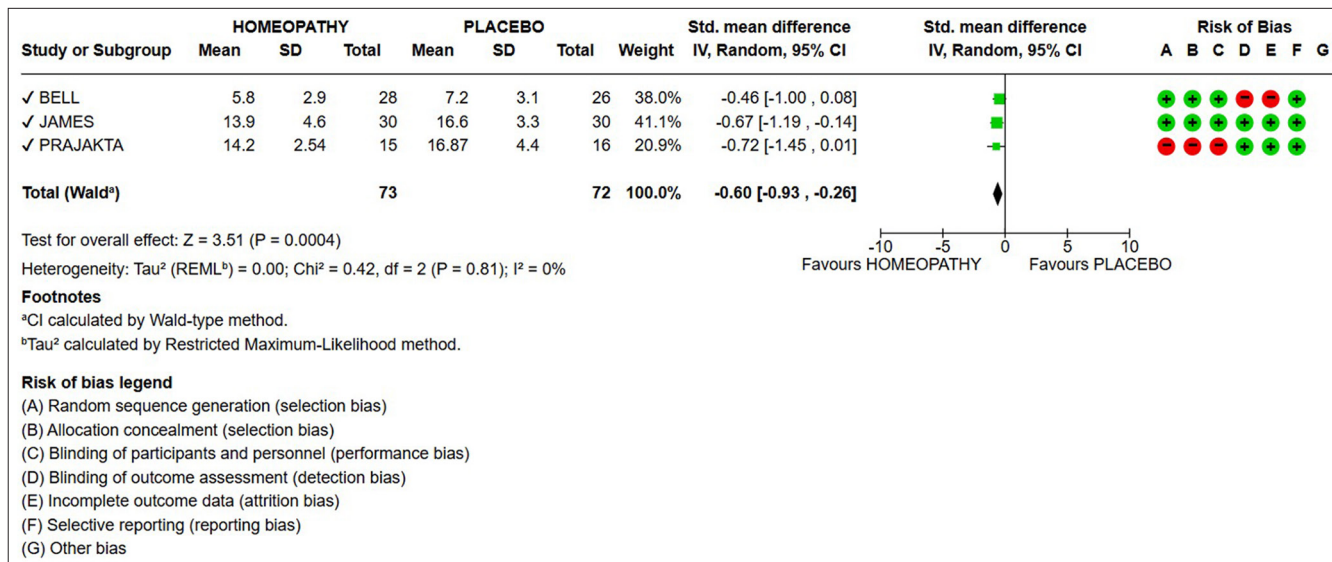


Figure 2: Forest plot forest plot of treatment outcome. The squares and horizontal lines correspond to SMD and 95% CI for each study. The area of the squares correlates with the weight. The diamond represents the overall SMD and 95% CI. SMD: Standardised mean difference, CI: Confidence interval. Red color indicated high risk of bias, Green colour indicated low risk of bias, (+) sign indicates proper measure is taken to reduce bias whereas, (-) sign indicated no measures is taken to reduce bias. SD: Standard deviation, CI: Confidence interval. Significance threshold because p value is 0.0004 which is very small from 0.05 and 95 % CI - is -0.93 to -0.26 which does not cross 0. SMD = -0.60 which show moderate effect, I2 = 0%, so it is statically significant.

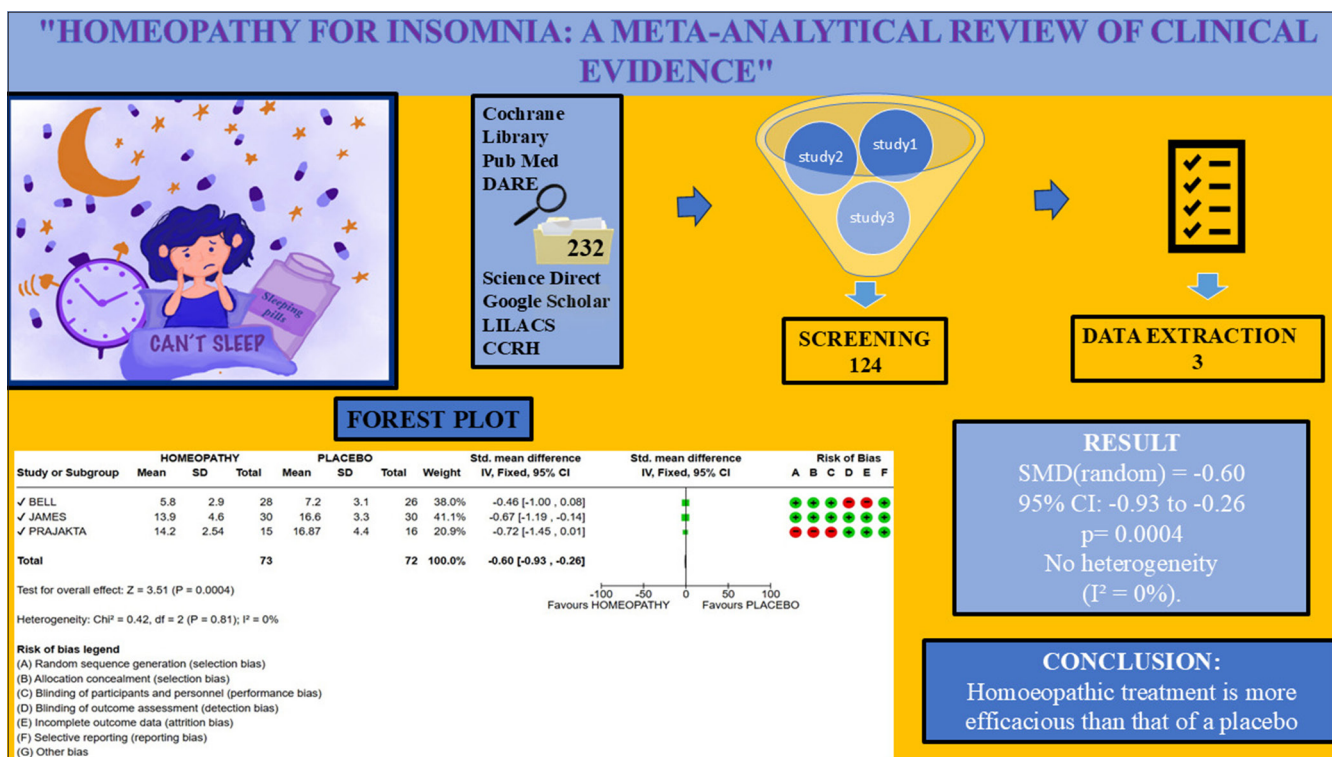


Figure 3: Graphical presentation of study. SMD: Standard mean difference, CI: Confidence interval. Significance threshold because p value is 0.0004 which is very small from 0.05 and 95 % CI - is -0.93 to -0.26 which does not cross 0. SMD = -0.60 which show moderate effect, I2 = 0%, so it is statically significant.

In this meta-analysis, we assessed the effect of homoeopathy compared to placebo/other standard treatments across studies. The included studies used different scales to measure sleep quality (PSQI and ISI), introducing variability in the

Table 2: Absence of risk of bias in included studies.

Study	Sequence generation	Allocation concealment	Blinding participants & personnel	Blinding outcome assessor	Incomplete outcome data	Selective reporting	No of domains for which criteria			Risk of bias (excluding vested interest)	Reliable evidence
							Y	U	N		
Bell <i>et al.</i> 2011 ^[8]	N	U	U	U	Y	U	0	4	2	High	No
James <i>et al.</i> 2013 ^[9]	Y	Y	Y	N	Y	Y	6	0	0	Low	Yes
Prajakta <i>et al.</i> 2024 ^[10]	N	N	N	N	Y	U	2	1	3	High	No

Y: Yes, N: No, U: Unclear

effect measurement. Given the methodological diversity and heterogeneity across studies, we selected a random-effects model to estimate the overall effect size of the studies. The studies used different outcome measures (PSQI and ISI) to assess sleep quality and insomnia severity, respectively. Although both scales measure similar constructs, they differ in terms of items, scoring systems and psychometric properties. The random-effects model accounts for these differences by allowing the true effect sizes to vary between studies. The I^2 statistic was 0%, indicating no substantial variability in the effect sizes across the studies. However, the use of different scales introduces this inherent variability. The random-effects model handles this variability by accounting for within-study and between-study variance, providing more generalizable estimates and assuming that studies are drawn from a distribution of true effects rather than a single true effect size. This approach provides a more robust and unbiased estimate of the overall effect.

DISCUSSION

A meta-analysis was designed to validate the efficacy of homoeopathy in addressing insomnia, utilising sleep diary data. This investigation was registered with Prospero on 11 November 2024, (ID-CRD42024612842) under the title 'Homoeopathy for Insomnia a Meta-Analytical Review of Clinical Evidence'.

A total of 232 articles were initially identified: PubMed, 10; Google Scholar, 170; Cochrane Library, 20; DARE, 0; LILACS, 13; Science Direct, 13 and Wiley, 6. A total of 232 articles were identified, and 108 duplicates were eliminated before the screening. The remaining 124 articles underwent full-text review based on the established inclusion and exclusion criteria. Ultimately, 121 articles were excluded for the following reasons: Non-insomnia (27), non-homoeopathic (22), non-RCT (41), foreign language (3), case report (3), *in vivo* (2), literature review (7), dissertation work (2) and observational study (14).

In conclusion, nine articles were evaluated for eligibility, of which three were excluded due to a lack of statistical data. Consequently, three articles were incorporated into this meta-analysis (illustrated in the PRISMA chart, [Figure 1]). The three studies analyzed comprises Bell *et al.*, 2011,^[8] James *et al.*, 2019,^[9] and Prajakta, 2024.^[10] [Figure 2 and; Table 1].

Bell *et al.* 2011^[8] shows ES = -0.67; (CI+) = -1.00; (CI-) = 0.08.

James *et al.* 2019^[9] shows, ES = -0.46; (CI+) = -1.19 ; (CI-) = -0.14.

Prajakta *et al.* 2024^[10] shows ES = -0.72; (CI+) = -1.45; (CI-) = 0.01.

Subsequently, the author contrasted the results derived from the random-effect and random-effect models.^[10] The calculated SMD for the random-effects model was -0.60, accompanied by a SE of 0.42 and a CI of -0.93--0.26. The pooled estimates exhibited variability, with the random-effects model accounting for a greater degree of heterogeneity ($I^2 = 0\%$, $P = 0.81$), indicating that inter-study variability was absent or minimal.

This meta-analysis of insomnia encounters several limitations, notably the insufficiency of meta-analytical studies, systematic reviews and RCTs, all of which are essential for establishing treatment efficacy. The extant published studies are deficient in statistical data and exhibit discrepancies in assessment parameters, making it difficult to derive reliable conclusions. Furthermore, there are a limited number of specialised homoeopathic journals, which constrains data extraction efforts. The current literature is largely composed of case reports, which lack the statistical robustness and controlled comparisons required for scientific validation. These limitations emphasise the necessity for more meta-analyses, systematic reviews and RCTs to support a meticulously structured examination of the effectiveness of homoeopathy in addressing insomnia.

The forest plot summarises three clinical trials – Bell, James and Prajakta – that compared the effects of homeopathy with a placebo in treating insomnia. In this plot, negative values (left) indicate improvement with homeopathy, whereas positive values (right) favour placebo. The Bell study^[8] showed a small to moderate improvement in sleep quality with homeopathy, although the result was not statistically significant as its confidence interval crossed zero. James *et al.*^[9] demonstrated a significant moderate effect in favor of homeopathy, with the confidence interval entirely below zero, indicating a clear benefit. The Prajakta study^[10] also showed a moderate effect toward homeopathy, with borderline significance, as its confidence interval just touched zero. When the results of all three studies were pooled, the overall SMD was -0.60 (95% CI: -0.93 – -0.26), suggesting that homeopathy improved sleep quality more than placebo, with a moderate effect size. The pooled result was statistically significant ($Z = 3.51$, $P = 0.0004$), providing strong evidence of the beneficial effects of homeopathy. In addition, heterogeneity across studies was minimal ($I^2 = 0\%$), indicating consistent findings among the trials. Clinically, this pooled effect (SMD = -0.60). At present, no studies are available that assess the clinical significance of insomnia treatment using the PSQI and the ISI. However, an average improvement of 2 points on the PSQI or a 2–3 point improvement on the ISI is considered a moderate and clinically meaningful enhancement in sleep quality compared to placebo, based on clinical experience. Consequently, homeopathic treatment demonstrates both statistical significance and a clinically meaningful impact in the management of insomnia.

Risk of bias

The three studies— Bell *et al.* (2011),^[8] James *et al.* (2019),^[9] Prajakta *et al.* (2024),^[10] and showed varying levels of methodological quality. James *et al.* (2019)^[9] stands out with a strong, low-bias design, fulfilling all six key criteria, including proper randomization, blinding, and data handling. It also had no vested interests, making its findings more trustworthy; hence, it is a low risk.

In contrast, Prajakta *et al.* (2024)^[10] and Bell *et al.* (2011)^[8] showed moderate risk of bias. Prajakta met only three criteria, whereas Bell met four.

CONCLUSION

Although only three RCTs met the inclusion criteria, the combined results showed a clear and statistically significant improvement in insomnia symptoms among people receiving homeopathic treatment compared with placebo. The effect size (SMD = 0.47) reflects a moderate and meaningful benefit, and the absence of major publication bias adds confidence to these findings.

At the same time, these results should be viewed with care. Only one study (James *et al.*, 2019) demonstrated strong methodology and low risk of bias, while the other two had several weaknesses, particularly in blinding and allocation procedures. The moderate heterogeneity ($I^2 = 45\%$) also indicates differences in study quality, sample types, and treatment approaches, pointing to the need for more rigorous research in this area.

Even with these limitations, this review provides important insight. Insomnia affects far more than sleep—it impacts mood, daily functioning, relationships, and overall well-being. The findings suggest that homeopathy, with its gentle and individualized approach, may offer supportive relief for people seeking alternatives to conventional sleep medications.

In conclusion, while homeopathy shows promise for improving sleep, stronger and larger clinical trials are needed to confirm these benefits and guide practice. Until then, homeopathy may be considered a helpful complementary option when combined with healthy sleep habits and lifestyle measures.

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Declaration of patient consent: Patient's consent not required as there are no patients in this study.

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