

ASSESSING THE EFFECT OF COFFEA CRUDA IN INSOMNIACS OF ADULT POPULATION USING INSOMNIA SEVERITY INDEX : A TWO ARMED RANDOMIZED CONTROL TRIAL

¹Dr. Nidhi Wankhede., ²Dr. Sabreen Khan., ³Dr. Vaibhav Mahajan., ⁴., and
⁵Dr. Gulfisha Mirza

Intern., HOD., ^{4,5,6}Asst. Professor

^{1,2}Intern, Dhanvantari Homoeopathic Medical College & Hospital

³Department of Community Medicine, Dhanvantari Homoeopathic Medical College & Hospital.

⁴Department of Repertory, Dhanvantari Homoeopathic Medical College & Hospital.

⁵Department of Surgery, Dhanvantari Homoeopathic Medical College & Hospital.

⁶Department of Pharmacy, Dhanvantari Homoeopathic Medical College & Hospital.

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ABSTRACT

Background: Insomnia is a widespread sleep disorder where individuals experience difficulty in initiating sleep, maintaining it, or achieving restful sleep, even when the environment is conducive. This condition can significantly disrupt personal, social, and occupational well-being. It may present as short-term, temporary, or chronic, and is frequently associated with other health issues such as anxiety, depression, cardiovascular disorders, and persistent pain. Common symptoms involve fatigue, poor concentration, mood fluctuations, and reduced efficiency in daily activities. While standard treatments often include medications like Melatonin, Escitalopram, and Lopez, their outcomes and side effects can vary. **Objective:** The aim of this study was to evaluate the effectiveness of Coffea Cruda, a homeopathic remedy, in comparison to conventional pharmacological treatments for improving sleep quality, as measured by the Insomnia Severity Index (ISI), in adult patients. **Methods:** A randomized controlled trial was conducted with 30 adult participants diagnosed with insomnia. They were evenly divided into two groups: one group received Coffea Cruda, while the other was treated with standard conventional medications. **Conclusion:** The findings indicate that Coffea Cruda was more effective in enhancing ISI scores compared to conventional medications, suggesting it may be a promising homeopathic treatment for insomnia. Additional comprehensive studies are encouraged to support these initial outcomes.

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INTRODUCTION

Insomnia is a prevalent sleep disorder characterized by difficulty in initiating or maintaining sleep, or experiencing non-restorative sleep despite adequate opportunity and circumstances for sleep. It affects the quality of life by impairing cognitive functions, mood, performance, and overall health. Chronic insomnia is associated with increased risks of psychiatric disorders such as depression and anxiety, as well as physical illnesses including cardiovascular diseases and

diabetes (1). According to the DSM-5, insomnia disorder is diagnosed when sleep disturbances occur at least three nights per week for at least three months, causing significant distress or impairment in daily functioning (2).

The etiology of insomnia is multifactorial, involving physiological, psychological, and behavioral components. Hyperarousal-both cognitive and somatic-plays a central role in the pathophysiology of insomnia (3). Additionally, maladaptive sleep habits and dysfunctional beliefs about sleep often perpetuate the disorder. Insomnia is also categorized into primary (independent) and secondary (related to medical or psychiatric conditions) forms.

Epidemiological studies estimate that about 10–30% of the global population suffers from insomnia symptoms, with higher prevalence in women, older adults, and individuals

*Corresponding author: **Dr. Nidhi Wankhede**

with comorbid conditions (4). Due to its widespread impact, insomnia remains a significant public health issue, and understanding its mechanisms is crucial for effective management.

Recent advancements in neuroimaging and psychophysiological research have provided deeper insight into the neural correlates of insomnia. Functional MRI studies have revealed heightened activity in the brain's default mode network and limbic regions during resting states in individuals with insomnia, indicating persistent hyperarousal even outside of sleep periods. These findings support the cognitive model of insomnia, which posits that worry and rumination contribute to the difficulty in initiating and maintaining sleep(5).

Moreover, insomnia has been identified not only as a symptom but also as a potential precursor or risk factor for various psychiatric and medical disorders. Longitudinal studies have demonstrated that untreated chronic insomnia significantly increases the risk of developing major depressive disorder, generalized anxiety disorder, and even neurodegenerative diseases such as Alzheimer's (6). These associations highlight the need for early diagnosis and comprehensive management strategies to prevent long-term complications.

Conventional treatments for insomnia primarily include pharmacological agents such as benzodiazepines, non-benzodiazepine hypnotics, melatonin receptor agonists, antidepressants, and antihistamines (7). Though effective in the short term, these drugs often lead to adverse effects including tolerance, dependency, residual sedation, cognitive impairment, and increased risk of falls in older adults (8,9). As a result, there is growing interest in non-pharmacologic therapies, such as cognitive behavioral therapy for insomnia (CBT-I), relaxation techniques, mindfulness-based interventions, and complementary and alternative medicine (10,11).

Homeopathy, a system of alternative medicine, provides individualized treatment options aimed at stimulating the body's natural healing responses. Among various homeopathic remedies, Coffea Cruda is traditionally recommended for insomnia characterized by mental overactivity, heightened sensitivity, racing thoughts, and sleeplessness due to excessive joy, excitement, or grief (12). It is derived from unroasted coffee beans and has been noted in classical materia medica texts as a remedy particularly suitable for sleeplessness arising from nervous excitement (13).

Preliminary studies have indicated that homeopathic interventions may have a role in improving sleep patterns, reducing anxiety, and enhancing overall well-being with minimal side effects(14). While the scientific community remains divided over homeopathy's mechanism of action, the demand for safer, non-sedative, and holistic alternatives to conventional drugs is on the rise(15).

This study was designed to evaluate the effectiveness of Coffea Cruda in improving sleep quality using the Insomnia Severity Index (ISI) in adult patients diagnosed with insomnia, compared to conventional allopathic pharmacotherapy.

METHOD

This study explored the effectiveness of the homeopathic remedy Coffea Cruda by conducting a randomized controlled

trial. It compared 15 patients prescribed Coffea Cruda to 15 patients given conventional medications, measuring outcomes through changes in insomnia severity.

Study Design: Two-group randomized controlled trial.

Study Setting: College OPD and peripheral OPD, Nashik.

Sample Size: 30 patients.

Sampling Technique: Simple random sampling.

Selection of Study Subjects: Thirty individuals diagnosed with insomnia were selected randomly from the college and peripheral OPDs. Coffea Cruda was prescribed to the experimental group after a comprehensive case assessment based on symptom patterns. Regular follow-ups monitored symptom changes over time.

Inclusion Criteria

- Adults experiencing difficulty in falling or staying asleep.
- Dissatisfaction with their sleep.
- Sleep issues affecting daytime functioning.
- Anxiety about sleep quality.

Exclusion Criteria:

- Individuals under 18 years of age.
- Cancer patients.
- Immunocompromised patients.
- Individuals with alcohol dependency.

Operational Definition: Insomnia is characterized by difficulty initiating sleep despite appropriate conditions and dissatisfaction with sleep quality, leading to fatigue, poor memory, emotional disturbances, and other daily impairments.

RESULTS

[The group administered Coffea Cruda demonstrated a total ISI score improvement of 112 points, averaging 7.47 points per patient. Conversely, the conventional medicine group improved by a total of 97 points, with an average of 6.47 points per individual.

Table 1. Age group distribution in study	
Age group	Percentage
18-25	23.3%
26-35	50%
36-45	6.7%
46-55	20%

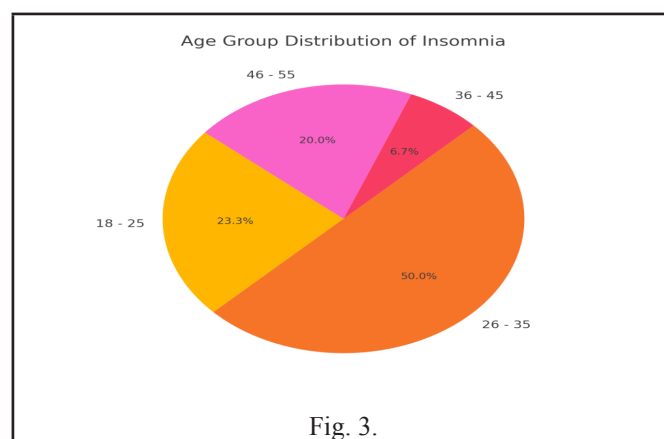
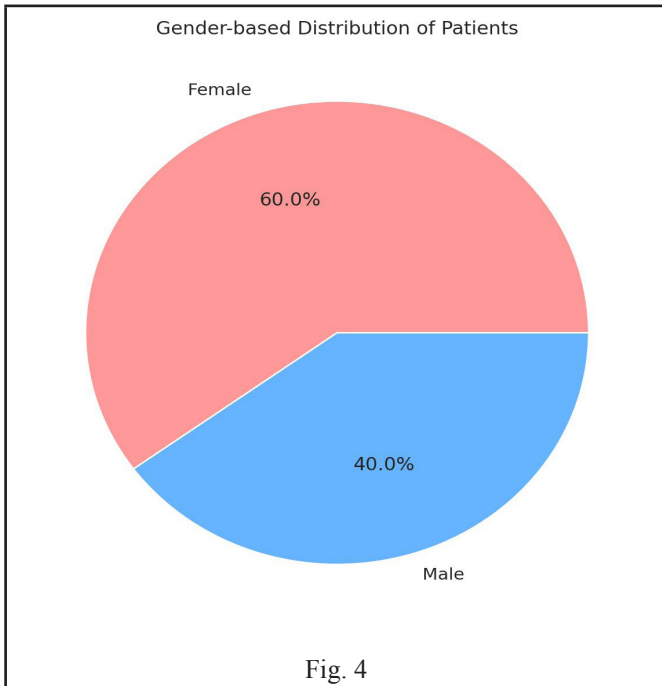


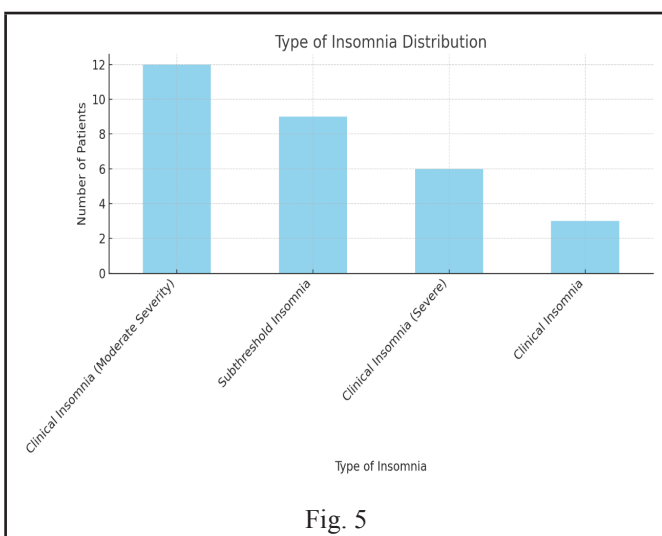
Fig. 3.

Table 2. Gender based distribution of Patients

Gender	Percent
Male	40%
Female	60%

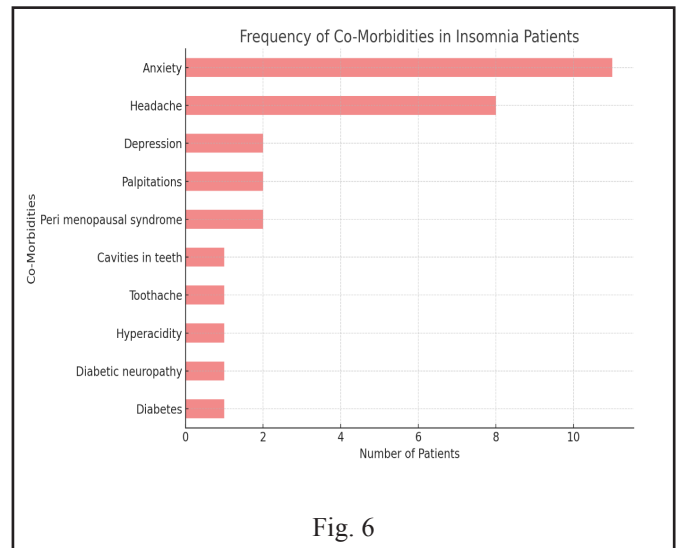
**Table 3.** Type of Insomnia Distribution

Type of Insomnia	Number of Patients
Clinical Insomnia (moderate severity)	12
Clinical Insomnia (severe)	6
Subthreshold Insomnia	9
Clinical Insomnia	3

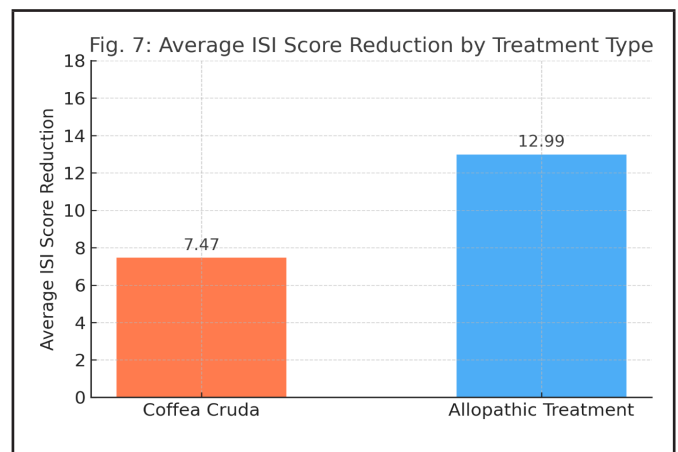
**Table 4.** Frequency of Co-morbidities in patients

Co-Morbidities	No. of patients
Anxiety	11

Headache	8
Depression	2
Palpitations	2
Peri-menopausal syndrome	2
Cavities in teeth	1
Toothache	1
Hyperacidity	1
Diabetic Neuropathy	1
Diabetes	1

**Table 5.** Average ISI score reduction with medicine

Treatment Type	Average Score Reduction
Coffea Cruda	7.47
Allopathic Treatment	12.99



DISCUSSION

The study aimed to assess the benefits of Coffea Cruda in treating insomnia among 30 patients. Insomnia, a pervasive disorder, causes disrupted sleep and often manifests alongside anxiety, hyperactivity, and poor daytime performance. The study utilized the Insomnia Severity Index (ISI) to measure symptom changes before and after treatment.

The analysis of age distribution in this study shows that half of

the participants (50%) were within the 26–35 years age group, making it the most represented category. This was followed by the 18–25 years group, which comprised 23.3% of the total. Participants aged 46–55 years accounted for 20%, while only 6.7% were between 36–45 years. These results indicate that a significant proportion of the study population consisted of young adults, with over 70% being under the age of 35. This trend might reflect the demographic characteristics or risk profiles specific to this age group.

Regarding gender distribution, a larger share of the participants were female, making up 60% of the total, while males represented the remaining 40%. This difference may point to either a higher occurrence of the health condition being studied in females or a greater inclination among women to seek medical care and participate in research.

The study's findings regarding the types of insomnia revealed that Clinical Insomnia with moderate severity was the most commonly diagnosed, affecting 12 patients. Subthreshold Insomnia followed closely, occurring in 9 individuals. Meanwhile, 6 patients were identified as suffering from Clinical Insomnia with severe symptoms. This distribution suggests that moderate insomnia was the most frequently encountered condition among the study participants, with fewer individuals experiencing either severe or subthreshold forms of insomnia.

Looking at the presence of co-existing health conditions, Anxiety was the most frequently reported, present in 11 patients. Headaches were also common, affecting 8 participants. Other co-morbidities included Depression, Palpitations, and Peri-menopausal Syndrome, each reported by 2 patients. Less common conditions, each affecting a single patient, were Cavities in teeth, Toothache, Hyperacidity, Diabetic Neuropathy, and Diabetes. These findings indicate that insomnia often occurs alongside psychological and neurological complaints, with anxiety and headaches being particularly prevalent in this patient group.

All participants displayed clinical improvements. Initial ISI scores ranged from 13 to 25, indicating moderate to severe insomnia. Following Coffea Cruda treatment in potencies from 100C to 1M, ISI scores dropped to between 7 and 17, suggesting significant improvement, often reducing insomnia to minimal or subclinical levels.

Patients with anxiety-driven insomnia, racing thoughts, mental overactivity, and heightened sensitivity showed notable benefits, aligning well with Coffea's traditional symptom profile. Even participants with additional conditions like diabetes, menopausal symptoms, or headaches experienced relief, suggesting homeopathy's value in complex cases.

Despite limitations such as a small sample, the study results align with existing research advocating homeopathy as a useful tool for managing chronic insomnia. Positive outcomes across varied cases highlight homeopathy's potential role in integrative sleep care.

CONCLUSION

This clinical trial evaluated the impact of Coffea Cruda, used as an individualized homeopathic remedy, in managing insomnia. A total of 30 participants were treated and monitored using ISI scores before and after intervention. Most showed moderate

to severe insomnia paired with emotional, psychological, or lifestyle stressors.

After homeopathic treatment, all patients improved to varying degrees, with many transitioning from moderate/severe insomnia to mild or subclinical categories. These improvements underline the possible advantages of homeopathy as a safe, non-invasive, and holistic option for insomnia management.

While the findings are encouraging, future studies with larger, more diverse samples are recommended to verify these results.

Conflict of Interest:None

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