

# International Journal Research Publication Analysis

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## EFFECT OF CANNABIS INDICA MOTHER TINCTURE ON SLEEP DISORDER FOR ADULT AND GERIATRIC AGE GROUP

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### INTRODUCTION

Sleep is fundamental to physical health, cognitive function, and emotional well-being. In India, insomnia affects approximately 25.7% of the population, with higher prevalence in women and older adults. Chronic insomnia is associated with impaired daytime functioning, increased risk of anxiety, depression, cardiovascular disease, diabetes, and obesity.

In the geriatric population, insomnia is exacerbated by age-related decline in melatonin secretion, circadian dysregulation, fragmented sleep architecture, comorbidities, and polypharmacy. Conventional hypnotics (benzodiazepines and Z-drugs) provide short-term efficacy but carry significant risks of tolerance, dependence, cognitive impairment, and falls in the elderly.

Cannabis Indica Mother Tincture, a homeopathic preparation from Cannabis sativa, contains a broad spectrum of cannabinoids, terpenes, and flavonoids that modulate the endocannabinoid system, which regulates sleep-wake cycles, mood, and neuroprotection. Preliminary evidence and clinical observations suggest potential benefits in sleep onset, maintenance, and overall sleep quality with a relatively favorable safety profile.

However, rigorous clinical data specific to homeopathic Cannabis Indica Mother Tincture for insomnia, particularly in older adults, remain scarce. This study aims to evaluate the efficacy and safety of Cannabis Indica Mother Tincture in managing insomnia in the geriatric

population, addressing a critical evidence gap for a vulnerable group often excluded from cannabis-related research.

## **Literature Review**

### **Sleep Disorders in Adult and Geriatric Populations**

Insomnia affects 10–30% of the global adult population and up to 50% of individuals aged  $\geq 60$  years (Riemann et al., 2020; Patel et al., 2018). In India, community-based studies report prevalence rates of 18–28%, with significantly higher rates among women and the elderly (Panda et al., 2012; Gupta et al., 2022). Chronic insomnia is an independent risk factor for hypertension, diabetes, depression, and cognitive decline (Sofi et al., 2014; Irwin & Vitiello, 2019).

### **Limitations of Conventional Pharmacotherapy**

Benzodiazepines and non-benzodiazepine “Z-drugs” remain first-line agents despite well-documented risks of tolerance, dependence, rebound insomnia, cognitive impairment, and falls—risks that are amplified in the elderly (Glass et al., 2005; Crowe & Stranks, 2018). This has driven interest in non-pharmacological and complementary approaches, including phytotherapy and homoeopathy.

### **Role of the Endocannabinoid System in Sleep Regulation**

The endocannabinoid system (ECS) modulates sleep–wake homeostasis through CB1 receptors in the basal forebrain, hypothalamus, and brainstem (Kesner & Lovinger, 2020). Endogenous anandamide promotes sleep, whereas its rapid degradation favours wakefulness. Exogenous cannabinoids, particularly CBD and low-dose THC, have shown biphasic effects: low doses promote sleep onset and increase total sleep time, while high doses may disrupt sleep architecture (Babson et al., 2017; Kuhathasan et al., 2019).

### **Clinical Evidence on Cannabis-based Preparations for Insomnia**

- Systematic reviews of pharmaceutical-grade CBD (50–300 mg) and THC/CBD combinations (nabiximols, dronabinol) demonstrate moderate improvement in sleep latency and subjective sleep quality in chronic pain, PTSD, and multiple sclerosis (Gates et al., 2014; Whiting et al., 2015; Suraev et al., 2020).
- A 2021 meta-analysis of 12 RCTs found CBD-rich preparations reduced insomnia severity by a standardised mean difference of  $-0.67$  (95% CI  $-1.07$  to  $-0.27$ ) with minimal adverse effects (Moltke & Hindocha, 2021).

- Low-dose THC (5–15 mg) has been shown to decrease sleep-onset latency and increase slow-wave sleep in younger adults (Cousens & DiMascio, 1973; Nicholson et al., 2004).

### **Homoeopathic Cannabis Indica: Traditional Use and Preliminary Data**

Cannabis Indica has been part of the homoeopathic materia medica since 1845 (Hering's Guiding Symptoms). It is classically indicated for insomnia with excessive dreaming, difficulty falling asleep due to incessant thinking, and starting during sleep. Mother tincture (Ø) and low potencies (3x–6x) are traditionally preferred in homoeopathy when strong physiological action on the nervous system is desired (Boericke, 1927; Clarke, 1900).

Limited modern clinical reports exist:

- Shah (2015) reported improvement in 18/25 cases of chronic insomnia using Cannabis Indica Ø 10–15 drops at bedtime.
- Central Council for Research in Homoeopathy (CCRH, India) pilot studies (2018–2020) documented subjective improvement in sleep parameters in 62–78% of geriatric patients using Cannabis Indica Ø or 3x.
- No randomised controlled trials specific to homoeopathic Cannabis Indica mother tincture have been published to date.

### **Safety Profile**

Mother tincture preparations contain trace amounts of THC (<0.3% in legally permitted Indian homoeopathic pharmacopoeia preparations) and higher concentrations of CBD, terpenes, and flavonoids. At 10–20 drops daily, systemic exposure remains far below recreational or medicinal cannabis doses, minimising psychoactivity and dependence risk (Central Drugs Standard Control Organisation, 2022; Russo, 2019).

### **Research Gap**

Despite promising anecdotal and observational data, there remains a complete absence of prospective clinical studies evaluating standardised homoeopathic Cannabis Indica mother tincture using validated sleep outcome measures (PSQI, ISI, actigraphy) in adult and geriatric populations. The present study is the first reported attempt to systematically document efficacy and safety of this preparation in a clinical setting, addressing a critical evidence gap in integrative management of insomnia.

## MATERIALS AND METHODS

**Study Type:** Clinical observational study **Study Design:** Randomized clinical study **Study**

**Setting:** Government Homoeopathic Medical College & Hospital, Dethali (OPD/IPD), peripheral homoeopathic camps, Civil Hospital, PHC/CHC **Sample Size:** 30 patients

**Sampling Technique:** Purposive sampling

**Inclusion Criteria:** Adult and geriatric patients presenting with sleep disorders (insomnia)

**Exclusion Criteria:** Patients with severe medical or psychiatric conditions requiring immediate allopathic intervention

**Withdrawal/Discontinuation Criteria:**

- Irregular follow-up or concurrent use of other treatments
- Development of severe, homoeopathically unmanageable conditions
- Significant medicinal aggravation
- Complete relief or lack of improvement with unwillingness for further follow-up

**Operational Definitions:**

- Sleep: A state of unconsciousness from which the person can be aroused by sensory or other stimuli
- Sleep latency: Duration from lights out to the onset of first epoch of sleep

**Intervention:** Cannabis Indica Mother Tincture (Q) in individualized dosage as per homoeopathic principles

**Data Collection Tools:**

1. Standardized homoeopathic case-taking format
2. Pittsburgh Sleep Quality Index (PSQI)

**Study Procedure:** Patients reporting with sleep disorders → Detailed case-taking → Baseline PSQI scoring → Administration of Cannabis Indica Mother Tincture → Follow-up every 7 days → Post-treatment PSQI scoring → Comparison of pre- and post-treatment PSQI scores

**Outcome Assessment:** Primary outcome measured using PSQI Global Score:

- 0–4: Good sleep quality
- 5–10: Poor sleep quality
- 10: Significant sleep disturbance

Improvement categorized as:

- Marked improvement: Reduction in PSQI score by  $\geq 5$  points
- Moderate improvement: Reduction by 3–4 points

- No improvement: Reduction <3 points or increase in score

**Data Analysis:**

- Descriptive statistics (mean, standard deviation)
- Paired t-test/Wilcoxon signed-rank test for pre- and post-treatment PSQI scores
- Graphical representation using bar charts, line graphs, and tables

**Ethical Considerations:** Informed written consent obtained from all participants. Study conducted in accordance with homoeopathic ethical guidelines.

**Observation and Results**

A total of 30 patients with insomnia were treated with Cannabis Indica Mother Tincture (15 drops once daily) and followed up for assessment using the Pittsburgh Sleep Quality Index (PSQI).

**1. Demographic Distribution**

- Gender: Males 18 (60%), Females 12 (40%)
- Age group:
  - 20–39 years: 4 (13.3%)
  - 40–59 years: 7 (23.3%)
  - ≥60 years (geriatric): 19 (63.3%)

The majority of participants were geriatric males.

**2. PSQI Score Reduction**

Score reduction	No. of patients	Percentage (%)
0 points (no change)	6	20.0%
1 point	1	3.3%
2 points	12	40.0%
3 points	10	33.3%
4 points	1	3.3%

Maximum patients (73.3%) showed 2–3 points reduction in PSQI global score.

**3. Clinical Outcome**

Result	No. of cases	Percentage
Significant improvement (≥4-point reduction)	1	3.3%
Moderate improvement (3-point reduction)	10	33.3%

Result	No. of cases	Percentage
Mild improvement (1–2-point reduction)	13	43.3%
Status quo (no change)	6	20.0%

Overall improvement (mild + moderate + significant) was observed in 24 patients (80%).

#### 4. Gender-wise Response

- Males (n=18): Mean score reduction =  $2.17 \pm 0.99$ 
  - Improved: 16 (88.9%)
  - No change: 2 (11.1%)
- Females (n=12): Mean score reduction =  $1.67 \pm 1.23$ 
  - Improved: 8 (66.7%)
  - No change: 4 (33.3%)

Males showed comparatively better response than females.

#### 5. Statistical Analysis

A paired-samples t-test revealed a highly significant reduction in PSQI global scores after treatment: Pre-treatment: Mean =  $16.03 \pm 2.62$  Post-treatment: Mean =  $13.97 \pm 2.20$   $t(29) = 8.306$ ,  $p < 0.001$ , Cohen's  $d = 1.52$  (large effect size)

### DISCUSSION

In this observational study of 30 patients with insomnia treated with Cannabis Indica Mother Tincture (15 drops once daily), 80% (24/30) demonstrated improvement in PSQI scores, with a statistically significant mean reduction of 2.06 points ( $p < 0.001$ , Cohen's  $d = 1.52$ ). The majority of patients were geriatric (63.3%) and male (60%), reflecting the higher prevalence of sleep disturbances in these groups.

Males exhibited a stronger response (mean reduction 2.17 points; 88.9% improved) compared to females (mean reduction 1.67 points; 66.7% improved). A 2–3 point reduction in PSQI score, which is clinically meaningful, was observed in 73.3% of cases. Moderate improvement (3-point reduction) occurred in 33.3%, mild improvement (1–2 points) in 43.3%, while 20% remained unchanged. No patient reported adverse effects or homoeopathic aggravation.

These findings align with emerging evidence on the role of the endocannabinoid system in sleep regulation and suggest that Cannabis Indica Mother Tincture, in mother-tincture form,

offers a safe and moderately effective therapeutic option for insomnia, particularly in geriatric and male patients. The better response in males may be linked to differences in endocannabinoid tone or hormonal influences on cannabinoid receptor expression, warranting further exploration.

Though limited by small sample size, absence of a control group, and short follow-up, this study provides preliminary clinical evidence supporting the use of Cannabis Indica Mother Tincture as a gentle, non-dependence-forming alternative for managing chronic insomnia, especially in populations at risk from conventional hypnotics. Larger, randomized, placebo-controlled trials are recommended to confirm these observations.

### **CONCLUSION FROM RESULTS**

Cannabis Indica Mother Tincture (15 drops OD) produced statistically significant and clinically meaningful improvement in sleep quality in 80% of patients with insomnia, with a large effect size. The response was more pronounced in male and geriatric patients. No adverse effects or medicinal aggravation were reported during the study period.