

## **To Study The Efficacy Of Passiflora Incarnata Mother Tincture In Cases of Insomnia, A Placebo Controlled Cross Over Trial**

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### **Abstract**

**Background and Aim:** Insomnia is a common sleep disorder that can make it hard to fall asleep, hard to stay asleep, or cause one to wake up too early and not be able to get back to sleep. One may still feel tired when they wake up. Insomnia can sap not only your energy level and mood but also your health, work performance and quality of life. How much sleep is enough varies from person to person, but most adults need seven to eight hours a night. At some point, many adults experience short-term (acute) insomnia, which lasts for days or weeks. It's usually the result of stress or a traumatic event. But some people have long-term (chronic) insomnia that lasts for a month or more. Insomnia may be the primary problem, or it may be associated with other medical conditions or medications. Even though adults need at least seven hours of sleep per night, about 35% of people get less than that. Age appears to be linked to lack of sleep, with 37% of people age 20–39 reporting low sleep duration and 40% of people age 40–59 getting too little sleep. Homoeopathy while treating insomnia evaluates a person's unique, presenting symptoms, since no two individuals with sleep problems display the same symptoms. It also addresses one's sleep problems effectively, by way of a customised, tailor-made approach to treatment. Homoeopathy aims to induce natural sleep, gently. Homeopathic medicines for insomnia [sleeplessness], or sleep loss, are safe, non-habit-forming and effective. They endeavour to treat the individual's temperament and nature, not just sleeplessness alone — although this is a significant part of the entire treatment process. This cross over study aimed to see how efficiently *Passiflora incarnata* Q works in managing the cases of Insomnia.

**Methodology:** An attempt was made to understand the role of *Passiflora incarnata* Q in Insomnia on the basis of Pittsburg Sleep Quality Index. In this study 30 patients were enrolled, having symptoms of Insomnia. The mental state and age factor was also considered to understand the precipitating, exciting or maintaining factors for Insomnia. The PSQI scoring was calculated before and after treatment for assessment of the result.

**Result:** After the study of 30 cases, it was found that *Passiflora incarnata* Q was significantly superior to placebo in relieving the symptoms of insomnia patients, but showed no significant improvement in cases which were chronic in nature.

**Conclusion:** The findings are encouraging with some points to be taken into consideration and can open avenues for further studies to draw evidence on Insomnia and mental states and age factor of individuals.

**Keywords:** Insomnia, *Passiflora incarnata* Q, Cross over study, Pittsburg Sleep Quality Index.

### **Introduction:**

Sleep plays an integral role in health. A good night's sleep empowers the body to recover and lets you wake up refreshed and ready to take on the day.

Unfortunately, many people have sleep problems and don't get the rest that they need. Insufficient sleep and poor quality sleep can be due to diverse factors including sleep disorders, medical conditions, and mental health. Sleep issues affect people of all ages, and its impacts can be far-reaching.<sup>1</sup>

According to the American Academy of Sleep Medicine's ICSD-3 manual, insomnia is defined as "persistent difficulty with sleep initiation, duration, consolidation or quality." Insomnia has many potential contributing factors and symptoms, but its diagnosis hinges on two essential components: sleep difficulties that occur despite adequate opportunities for normal sleep, and daytime impairment that directly results from poor sleep quality or duration.

**Acute insomnia** lasts from 1 night to a few weeks.

**Chronic insomnia** is characterized by symptoms that occur at least three times per week for at least three months. Insomnia that lasts or less than three months is known as short-term insomnia. In rare cases, patients may exhibit insomnia symptoms without meeting the criteria for short-term insomnia and may warrant some form of treatment. This is known as other insomnia.

While insomnia can manifest in different ways, most diagnoses fall into one of two categories:

- Sleep-onset insomnia refers to difficulty falling asleep. This type of insomnia may occur with people who have a hard time relaxing in bed, as well as people whose circadian rhythm is not in sync due to factors like jet lag or irregular work schedules.
- Sleep maintenance insomnia refers to difficulty staying asleep after initially nodding off. This type of insomnia is common in elderly sleepers, as well as people who consume alcohol, caffeine, or tobacco before bed. Certain disorders like sleep apnea and periodic limb movement disorder can also cause sleep maintenance insomnia.

Some people may have mixed insomnia that involves both sleep-onset and sleep maintenance difficulties, and people with chronic insomnia may find that these symptoms shift over time.<sup>2</sup>

### **Risk factors**

Nearly everyone has an occasional sleepless night. But your risk of insomnia is greater if:

- You're a woman. Hormonal shifts during the menstrual cycle and in menopause may play a role. During menopause, night sweats and hot flashes often disrupt sleep. Insomnia is also common with pregnancy.
- You're over age 60. Because of changes in sleep patterns and health, insomnia increases with age.
- You have a mental health disorder or physical health condition. Many issues that impact your mental or physical health can disrupt sleep.
- You're under a lot of stress. Stressful times and events can cause temporary insomnia. And major or long-lasting stress can lead to chronic insomnia.
- You don't have a regular schedule. For example, changing shifts at work or traveling can disrupt your sleep-wake cycle.

### **Symptoms**

Insomnia symptoms may include:

- Difficulty falling asleep at night
- Waking up during the night

- Waking up too early
- Not feeling well-rested after a night's sleep
- Daytime tiredness or sleepiness
- Irritability, depression or anxiety
- Difficulty paying attention, focusing on tasks or remembering
- Increased errors or accidents
- Ongoing worries about sleep<sup>3</sup>

**Worldwide statistics**

According to the data, not one country, out of the 48 that participated, manages an average of 8 hours of sleep a night. In fact, in Japan, the national average is 5 hours and 59 minutes, representing a drastically low sleep average for the country. The 5 worst countries for average hours of sleep, in order of worst sleepers, include:

- Japan = 5 hours and 59 minutes
- Saudi Arabia = 6 hours and 8 minutes
- Sweden = 6 hours and 10 minutes
- India = 6 hours and 20 minutes
- The Philippines = 6 hours and 22 minutes

When the minimum amount of 7 hours of sleep a night is taken into consideration, it's evident that these countries have an inordinately high sleep debt, falling well below their sleep needs. For comparative purposes, the 5 best countries for average sleeping time, in order of most hours achieved, includes:

- New Zealand = 7 hours and 30 minutes
- The Netherlands = 7 hours and 28 minutes
- Finland = 7 hours and 26 minutes
- Great Britain = 7 hours and 24 minutes
- Ireland = 7 hours and 22 minutes<sup>4</sup>

**A study conducted by Philips Health Survey says that,**

72% of Indians are waking up one to three times per night and 87% of them say lack of sleep is affecting health. On the impact on productivity, the study reveals that more than 58% of Indians believe their work suffers due to lack of adequate sleep whereas 38% have witnessed a colleague falling asleep at work.

“Food habits, lack of exercise, irregular sleep and varying working styles are basic reasons of sleep disorders. Interestingly, patients don't take sleep disorders seriously which is a cause behind many other ailments including obesity, hypertension and diabetes.”<sup>5</sup>

Sleep is as important to your health as a healthy diet and regular physical activity. Whatever your reason for sleep loss, insomnia can affect you both mentally and physically. People with insomnia report a lower quality of life compared with people who are sleeping well.

Complications of insomnia may include: Lower performance on the job or at school, Slowed reaction time while driving and a higher risk of accidents, Mental health disorders, such as depression, an anxiety disorder or substance abuse, Increased risk and severity of long-term diseases or conditions, such as high blood pressure and heart disease.

Some Epidemiological data relating to the Indian Population in regards to the consequences/effects of Insomnia:

- 93% of Indians are sleep deprived, getting less than 8 hours per night.
- 58% believe their work suffers due to lack of adequate sleep
- 11% take leave from work because of lack of sleep.
- 11 % have fallen asleep at work due to a poor night's sleep and 38% witnessed a colleague falling asleep at work.
- Lack of sleep also affects family relationships according to 19% of people who participated in survey.
- 87% of Indians say lack of sleep affects health.
- 72% of Indians are waking up 1 to 3 times per night.
- 15% wake up over stress at work.
- 33% Indians snore.
- Up to 14% snore as loud as or louder than talking.<sup>6</sup>

#### Bridging existing gaps using Homeopathy: Safe and Effective Treatment for Sleeplessness

Homoeopathy is ideally geared to help you — because, it evaluates your unique, presenting symptoms, since no two individuals with sleep problems display the same symptoms. It also addresses one's sleep problems effectively, by way of a customised, tailor-made approach to treatment.

Homoeopathy aims to induce natural sleep, gently. Homeopathic medicines for insomnia [sleeplessness], or sleep loss, are safe, non-habit-forming and effective. They endeavour to treat the individual's temperament and nature, not just sleeplessness alone — although this is a significant part of the entire treatment process.<sup>7</sup>

#### **PASSIFLORA INCARNATA**

- COMMON NAME: Maypop; purple passionflower; wild passion vine.
- PARTS USED: Leaves and stem
- CHEMICAL CONTENT: Three main groups of active principles: 1. Alkaloids 2. Glycosides 3. Flavonoids

Passiflora incarnata is a homoeopathic medicine prepared from the leaves of the plant Passion Flower. This medicine is mainly used for nervous symptoms and especially for lack of sleep (insomnia) in infants and old people. The different pharmacological properties of Passiflora are anti-anxiety, analgesic, anti-diabetic, anticonvulsant, aphrodisiac, anti-withdrawal, anti-asthmatic, anti-cough, and anti-Helicobacter pylori in nature.<sup>8</sup>

Dr. William Boericke in his Materia medica describes the drug as follows:

An efficient anti-spasmodic. Whooping-cough. Morphine habit. Delirium tremens. Convulsions in children; neuralgia. Has a quieting effect on the nervous system. Insomnia, produces normal sleep, no disturbance of cerebral functions, neuroses of children, worm-fever, teething, spasms. Tetanus. Hysteria; puerperal convulsions. Painful diarrhoea. Acute mania. Atonic condition generally present. Asthma, 10-30 gtt every ten minutes for a few doses. Locally, in erysipelas.

**Head:** Violent ache as if top of head would come off-eyes felt as if pushed out.  
Stomach: Leaden, dead feeling after or between meals; flatulence and sour eructations.

**Sleep:** Restless and wakeful, resulting from exhaustion. Especially in the feeble, infants and the aged. Insomnia of infants and the aged, and the mentally worried, and overworked, with tendency to convulsions. Nocturnal cough.

**Dose:** Large doses of mother tincture are required-thirty to sixty drops, repeated several times.<sup>9</sup>

### **Materials And Methods**

#### **Study Setting:**

The patients for study were selected from the OPD/IPD of college, health camps, private practice, online survey.

#### **Selection Of Samples:**

Simple random sampling method was adopted for sample selection.

#### **Sample Size:**

Sample size was 30.

#### **Inclusion Criteria:**

1. Patient above the age of 30years.
2. Patients below the age of 60years.
3. Patients fulfilling the operational definition of insomnia.
4. Patients of both the sexes

#### **Exclusion Criteria:**

1. Patients below the age of 30years.
2. Patients above the age of 60years.
3. Patients who are lactation or are pregnant.
4. Patients undergoing treatment for life threatening illnesses.
5. Patients suffering from terminal illnesses.

#### **Study Design:**

Placebo controlled cross over trial.

#### **Study Duration:**

Total duration is of 18months.

DOES THE STUDY REQUIRE ANY INVESTIGATION OR INTERVENTION TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY:

- Yes, the study requires intervention with homoeopathic medicine, Passiflora incarnata mother tincture.
- Life style modification, diet and regimen is to be taken care of.

#### **Selection Of Tool:**

History of patient, Pittsburg sleep quality index score (PSQI Score).

#### **Brief Of Procedures:**

- *n* number of people screened/ known patients of insomnia identified through online and offline surveys.

- Patients qualifying the inclusion criteria were added to the study and patients fitting in the exclusion criteria were discarded.
- 30 patients were randomised into Group 'A' (Study group) and Group 'B' (Control group).
- Group 'A' received Passiflora incarnata Q and group 'B' received Placebo in the first half of the study period.
- The observations were noted down for almost a period of 90days after which the cross over was done.
- In the second half of the study period the group 'B' received Passiflora incarnata Q and group 'A' received Placebo and the observations were noted down.
- During the whole study period the outcomes were assessed on the basis of the Pittsburg sleep quality index score which was measured- before the study and after the study (with Passiflora incarnata Q and with Placebo, before crossover and after crossover).

**Outcome Assessment:**

Cases were assessed on the basis of improvement seen as per the Pittsburg sleep quality index (PSQI) score and also improvement associated with the symptoms and quality of patient's life. The result criteria is-

**Improved:** Decrease in signs and symptoms or mild relief of complaints with general well being of patient and a reduction in PSQI score than before.

**Not improved:** No relief of complaints with no reduction in the PSQI score after sufficient period of treatment.

**Data Collection:**

Data is collected from 30 patients, diagnosed of having Insomnia, in Case Recording Format. Inclusive of, preliminary data, chief complaints, associated complaints if any, patient as a person at the level of mind and body, past history, family history, physical examination and investigations.

**Statistical Techniques:**

The data generated is quantitative type. Hence proportion is used for data analysis. No statistical testing Was Done.

**Data Analysis:**

Data is grouped on the basis of intensity of symptoms and score obtained through PSQI scoring. The total score of Pittsburg sleep quality index (PSQI) is 21. After treatment with Passiflora incarnata Q any reduction in the before treatment score will be considered as improvement.

**Ethical Issues, If Any:**

Ethical clearance has been obtained from the institute's ethical committee.

**Observations And Results**

**OBSERVATION NO. 1: AGE WISE DISTRIBUTION: (Table no. 1)**

Sr no.	Age groups	Number of patients
1	30-40years	7
2	40-50years	8
3	50-60 years	15
	<b>Total</b>	<b>30</b>

**OBSERVATION NO. 2: SEX WISE DISTRIBUTION: (Table no. 2)**

Sr no.	Sex	Number of patients
1	Male	13
2	Female	17
	<b>Total</b>	<b>30</b>

**OBSERVATION NO. 3: DISTRIBUTION OF CASES AS PER PSQI SCORE BEFORE AND AFTER TREATMENT: (Table no. 3)**

Sr no.	PSQI Score	Number of patients before treatment	Number of patients after treatment	
			(With Passiflora Incarnata Q)	(With Placebo)
1	0-7	0	0	0
2	8-14	3	17	7
3	15-21	27	13	23
	<b>Total</b>	<b>30</b>	<b>30</b>	<b>30</b>

**OBSERVATION NO. 4: STATUS OF RESPONSE OF PATIENTS: (Table no. 4)**

Sr no.	Response of patients after treatment	Number of patients
1	Improved - with Passiflora incarnata Q	18
2	Not improved- with Passiflora incarnata Q	12
	<b>Total</b>	<b>30</b>
1	Improved- with Placebo	7

Sr no.	Response of patients after treatment	Number of patients
2	Not improved- with placebo	23
	<b>Total</b>	<b>30</b>

**OBSERVATION NO.5: CAUSE WISE DISTRIBUTION (Table no. 5)**

Sr no.	Cause	Number of patients
1	Stress	6
2	Stress+ pain	6
3	Pain	4
4	Anxiety	4
5	Bereavement	4
6	Poor sleeping habits	3
7	Shift work	2
8	Electronic device	1
	<b>Total</b>	<b>30</b>

**OBSERVATION NO. 6: STATUS OF RESPONSE OF PASSIFLORA INCARNATA Q IN ACUTE AND CHRONIC CASES (Table no. 6)**

SR NO.	STATUS OF RESPONSE	ACUTE CASES	CHRONIC CASES
1	Improved	15	3
2	Not improved	3	9
	<b>Total</b>	<b>18</b>	<b>12</b>



**OBSERVATION NO. 7: PSQI SCORE BEFORE AND AFTER TREATMENT (Table no. 7)**

CASE NO.	PSQI SCORE BEFORE TREATMENT	PSQI SCORE AFTER TREATMENT- WITH P. INCARNATA	PSQI SCORE AFTER TREATMENT- WITH PLACEBO
1	19	16	19
2	17	17	17
3	16	12	16
4	14	9	9
5	16	12	16
6	17	17	17
7	17	17	17
8	15	10	10
9	16	16	16
10	17	17	17
11	15	11	15
12	17	17	17
13	16	12	16
14	16	16	16
15	15	9	9
16	16	16	16
17	17	17	17
18	15	10	15
19	14	8	8
20	16	11	16
21	18	12	18
22	17	11	17
23	15	10	10
24	16	16	16
25	16	12	16
26	18	13	18
27	14	9	9

CASE NO.	PSQI SCORE BEFORE TREATMENT	PSQI SCORE AFTER TREATMENT- WITH P. INCARNATA	PSQI SCORE AFTER TREATMENT- WITH PLACEBO
28	18	18	18
29	16	10	10
30	16	16	16

## Discussion

A prospective study of 30 cases was done to evaluate the effect of Passiflora incarnata Q in cases of Insomnia through the PSQI scoring. After the study of 30 cases, analysis and observations were obtained, from which the following points were observed:

### 6. Age Wise Distribution Of Insomnia:

Most of the patients of Insomnia fall in the age group of 50-60years (15cases, 50%); 26.6% (8cases) fall in 40-50years of age and 23.4% (7cases) fall in the age group of 30-40years of age in this study. It is revealed from different studies that prevalence of insomnia increases as the age advances. The present data clearly justifies by the above mentioned studies.

### 2. Sex Wise Distribution:

It was found that the number of female sufferers were more than that of males, in this study. Amongst 30 cases, 57% i.e. 17 patients were female and 43% i.e. 14 patients were males. In literature, it has been found that, the incidence of Insomnia is higher in females than males.

The reasons for the higher prevalence of insomnia in females are multifactorial. Females are more vulnerable to negative socioeconomic factors, such as lower income or education level. In addition, females are more likely to experience certain physical problems compared to males, such as osteoporosis, fractures, and back problems. Furthermore, females have higher risk of developing certain psychiatric problems, such as depression and anxiety, all of which could increase the risk of insomnia in females.<sup>34</sup>

### 3. Distribution Of Cases As Per Psqi Score Before And After Treatment:

In the study it was found that, before treatment there were 0 patients in the score range 0-7, 3 patients in the score range 8-14 and 27 patients in the score range of 15-21. After the treatment with Passiflora incarnata Q and dietary regimen for over a period of almost 3months, out of 30 patients, 0 patients were in the score range of 0-7, 17 patients were in the score range of 8-14 and 13 patients were in the score range of 15-21; with placebo 0 patients were in the score range of 0-7, 7 patients were in the score range of 8-14 and 23 patients were in the score range of 15-21

### 4. Status Of Response Of Patients:

In the study of 30 cases, after treatment, with administration of Passiflora incarnata Q 18 patients were improved and 12 were not improved; with administration of Placebo 7 patients were improved and 23 patients were not improved.

### 5. Cause Wise Distribution:

In the study of 30 patients it was found the most common cause for insomnia was stress (6cases, 20%) and stress along with physical pain (6 cases, 20%) then pain (4cases, 13.3%), Anxiety (4cases, 13.3%), Bereavement (4cases, 13.3%), Poor sleeping habits (3cases, 10%), Shift work (2 cases, 6.6%), Electronic

device (1 case, 3.3). In literature they say, common causes of insomnia include stress, an irregular sleep schedule, poor sleeping habits, mental health disorders like anxiety and depression, physical illnesses and pain, medications, neurological problems, and specific sleep disorders. For many people, a combination of these factors can initiate and exacerbate insomnia.

#### **6. Status Of Response Of Passiflora Incarnata Q In Acute And Chronic Cases:**

In the study of 30 cases it was found that after treatment with Passiflora incarnata Q, out of 18 acute cases 15 cases were improved and 3 showed no significant improvement and out of 12 chronic cases 3 were improved and 9 were not improved. This tells us that Passiflora incarnata Q is more efficacious in acute type of insomnia i.e, insomnia of few months through its quieting effect on the nerves.

#### **Conclusion**

The study explored the usefulness of Passiflora incarnata Q in cases of Insomnia with the help of the Pittsburg Sleep Quality Index. The findings are encouraging with some points to be taken into consideration and can open avenues for further studies to draw evidence on Insomnia and mental states and age factor of individuals.

Analysis concludes that most of the patients of Insomnia fall in the age group of 50-60years, the prevalence of insomnia increases as the age advances.

It was found that the number of female sufferers were more than that of males. The reasons for the higher prevalence of insomnia in females are multifactorial. Females are more vulnerable to negative socioeconomic factors, such as lower income or education level. In addition, females are more likely to experience certain physical problems compared to males, such as osteoporosis, fractures, and back problems. Furthermore, females have higher risk of developing certain psychiatric problems, such as depression and anxiety, all of which could increase the risk of insomnia in females.

The study also concludes that the most common cause for insomnia is stress and stress along with physical pain. The other causes were Anxiety, Bereavement, Poor sleeping habits, Shift work, Electronic device. For many people, a combination of these factors can initiate and exacerbate insomnia.

It was also seen that patients were relieved of their symptoms as long as they were taking the medication (Passiflora incarnata Q) and when the medication was discontinued the symptoms reappeared as they were before. Passiflora incarnata Q also created some kind of dependency on its prolong usage, therefore cannot be administered for long period of time. Passiflora incarnata Q was also seen to be acting efficiently when the nature of insomnia was acute rather than in chronic cases.

In this study of 30 cases, Passiflora incarnata Q showed improvement in 18 cases, amongst which 15 were acute and 3 were chronic in nature.

Thus, the above conclusion states that the Passiflora incarnata Q is superiorly effective than placebo in temporarily allaying the symptoms of Insomnia, but it is not advisable to administer it for long duration or in chronic cases.

#### **Summary**

Insomnia is a common sleep disorder that can make it hard to fall asleep, hard to stay asleep, or cause you to wake up too early and not be able to get back to sleep. You may still feel tired when you wake up.

Insomnia can sap not only your energy level and mood but also your health, work performance and quality of life.

Homeopathic treatment for sleeplessness aims at treating the disease at the root level as the underlying cause of sleeplessness is taken into consideration while selecting the medicine. During the case study or case taking a homoeopath tries to evaluate the presentation of the symptoms, history of the present complaints, the lifestyle of the person, emotional make-up of the person, current mental state, the stress which person is going through, the past medical history, family history, etc. In such a way, the cause of sleeplessness (such as anxiety, stress, depression, faulty lifestyle, hormonal imbalance, or any other medical condition, etc.) is identified during the case taking and the treatment is aimed towards treating that cause to treat the disease at a deeper level. It has got no adverse effects like sleeping pills.

In order to understand the role of *Passiflora incarnata Q* in management of Insomnia a detailed study of 30 patients suffering from Insomnia was done. It was also attempted to understand the psyche involvement as a precipitating, exciting or maintaining factors for Insomnia, by applying certain tools. Mental factors were found to be involved as precipitating, exciting and maintaining factors for Insomnia and they were stress and anxiety in most of the cases.

In this study it is concluded that, *Passiflora incarnata Q* is effective in acute type of Insomnia rather than chronic cases of Insomnia. It gives relief as long as you are taking the medication as soon as the medicine is stopped the symptoms return, it was also found that it creates dependency on long usage, therefore in order to get a permanent and safe cure constitutional homoeopathic medicines which are best suited for any given case should be sorted out.

**Limitations:**

- Less sample size.
- Patients in the age group of 30-60 years of age were only taken into consideration, whereas Insomnia is a problem of every age group.
- Patients taking medication for other conditions and with mental disorders were not included in the study and the literature shows high incidence of Insomnia in such cases.
- Pregnant and lactating females were not included in the study in whom insomnia is commonest.
- Patients suffering from life threatening illnesses in whom insomnia rates are much high were not included in the study.

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