

# Evaluation of the efficacy of *Ekal Dravya Jyotishmati (Celastrus paniculatus)* in the management of Generalized Anxiety Disorder (*Chittodvega*) - A single-arm study

## Research Article

Reeya Gamne<sup>1\*</sup>, Sadhana Misar Wajpeyi<sup>2</sup>

1. PG Scholar, 2. Professor and HOD, Department of Kayachikitsa, Mahatma Gandhi Ayurved College, Hospital & Research Centre, Salod (H), Wardha, Datta Meghe Institute of Higher Education & Research (Deemed to Be University), Maharashtra. India.

## Abstract

**Background:** Generalized Anxiety Disorder (GAD) is a mental disorder characterized by an anxious state of mind that presents with symptoms like restlessness, irritability, sleep disturbances, tension, palpitations, dry mouth, and sweating. It predominantly affects women, especially in midlife, with a prevalence of 10% among women over 35. In modern treatment, selective serotonin reuptake inhibitors (SSRIs) such as sertraline are commonly prescribed as first-line therapy. GAD is referred to as *Chittodvega* in Ayurveda. *Jyotishmati (Celastrus paniculatus* Wild), is mentioned as a *Medhya* drug in the Ayurvedic texts that enhances cognitive function and emotional well-being potentially offering benefits for managing GAD. **Aim and Objectives-** To evaluate the efficacy of *Jyotishmati* in the management of GAD (*Chittodvega*). **Materials and Method:** In this trial, a total of 35 patients were enrolled for the study. Patients between 20–50 years of age of either gender having symptoms of GAD (*Chittodvega*) and a Hamilton anxiety rating (HAM-A) scale score less than 24 (i.e., mild to moderate) were selected for the study. In the trial intervention, *Jyotishmati* Capsules 500 mg were given twice a day after food with water for 60 days. **Observations and Result:** Data of 35 patients were used for statistical analysis and significant improvements were noticed in the HAM-A Score, Serum cortisol levels and the WHOQOL Score from baseline to the subsequent follow-ups on the 30<sup>th</sup>, 60<sup>th</sup>, and 90<sup>th</sup> day. **Conclusion:** *Jyotishmati* Capsule is effective in significantly reducing anxiety symptoms, HAM-A Score, and Serum Cortisol levels and improves the quality of life of patients.

**Keywords:** *Chittodvega*, *Celastrus paniculatus*, GAD, HAM-A Scale, *Jyotishmati*, *Medhya*.

## Introduction

Generalized Anxiety Disorder (GAD) is a chronic mental health condition characterized by excessive, uncontrollable worry about various aspects of life, as well as symptoms including muscle tension, poor focus, autonomic arousal, restlessness or feeling "on edge" (1). It is associated with significant psychological distress and functional impairment, affecting daily activities and overall quality of life. The global prevalence of anxiety disorders, including GAD, is estimated to affect 4.05% of the population, translating to approximately 301 million people (2). This number has seen an increase post-pandemic, with anxiety disorders rising by 13.8% to 25.6%. In India, anxiety disorders are also widespread, impacting around 3.3% of the population, or 44.9 million people (3). GAD itself has been reported

in several Indian studies with a prevalence rate of 5.8%, making it one of the most common subtypes of anxiety disorders (4). The global burden of GAD is substantial, with high prevalence rates and recurring episodes, often requiring long-term treatment. Selective Serotonin Reuptake Inhibitors (SSRIs) and Cognitive Behavioral Therapy (CBT) are often first-line treatments for many mental health conditions due to their effectiveness and safety profiles. Selective Norepinephrine Reuptake Inhibitors (SNRIs) can also be used, providing additional options for those who might not respond as well to SSRIs or CBT (5). Prolonged use of these medicines is associated with several kinds of side effects. GAD is correlated with *Chittodvega* in Ayurveda due to the similarity of symptoms (6). Ayurveda offers a range of *Medhya Rasayana* herbs, which are renowned for their capacity to enhance mental health, cognitive function, and overall well-being (7). These herbs are traditionally believed to improve memory, intellect, and vitality, and promote balance in the body's systems. Among these, *Jyotishmati (Celastrus paniculatus* Wild) stands out for its anxiolytic properties and calming influence (8). Although preclinical studies in animals have demonstrated its efficacy in reducing anxiety, clinical research on its effectiveness as a standalone treatment for GAD (*Chittodvega*) in humans remains limited.

### \* Corresponding Author:

#### Reeya Gamne

PG Scholar, Dept. of Kayachikitsa, Mahatma Gandhi Ayurved College, Hospital & Research Centre, Salod (H), Wardha, Datta Meghe Institute of Higher Education & Research (Deemed to Be University), Maharashtra. India.

Email Id: [reeya.gamne@gmail.com](mailto:reeya.gamne@gmail.com)

This single-arm study aims to evaluate the therapeutic efficacy of *Jyotishmati* (*Celastrus paniculatus* Wild) in the management of GAD.

**Aim and Objectives:** To evaluate the efficacy of the *Jyotishmati* Capsule on the HAM-A Scale Serum Cortisol levels and the Quality of Life of patients through the WHO Quality of Life questionnaire.

## Materials & Methods

### Study design: A case series

**Study setting:** This study was conducted at MGACH AND RC, Wardha. Before the commencement of the study, ethical clearance was obtained from the Institutional Ethical Committee (Ref no. MGACHRC/IEC/June-2023/708) on 27/06/2023. Before screening, each participant received a patient information sheet outlining the study details. Written informed consent was obtained in the local language. Additionally, a detailed medical history was recorded for each participant before the study commenced.

**Study participants:** 35 participants with Generalized Anxiety Disorder (GAD), meeting the study's inclusion criteria, were enrolled from both the outpatient and inpatient departments at MGACH & RC, Wardha. All the baseline parameters were recorded at the start of the study. The patients underwent treatment for 60 days. All the parameters were recorded on the 0<sup>th</sup>, 30<sup>th</sup>, 60<sup>th</sup>, and 90<sup>th</sup> day of the study duration.

### Inclusion criteria

Patients willing to participate in the study were ready to give written informed consent. Patients who met the criteria for anxiety disorders listed in DSM-V criteria. A HAM-A scale score of less than 24 (Mild to moderate cases). Age group of 20 to 50 years of either sex.

### Exclusion Criteria

Patients who were currently receiving CBT with a psychologist. GAD (*Chittodvega*) brought on by medical conditions such as hyperthyroidism, drug addiction, or prescription drugs. Pregnant and lactating women.

**DSM-V:** A diagnostic manual used to classify mental disorders based on standardized criteria, aiding clinicians in accurate diagnosis (9).

**HAM-A Scale:** A scale to measure anxiety severity, consisting of 14 items scored from 0 to 4. Total scores range from 0–56, with higher scores indicating greater anxiety levels (10).

Interpretation: 0–17: Mild; 18–24: Mild to moderate; 25–30: Moderate to severe.

**WHOQOL-BREF (26 items):** A questionnaire developed by WHO to assess quality of life across physical health, psychological well-being, social relationships, and environment. Higher scores indicate a better quality of life (11).

## Withdrawal Criteria

In instances where a patient's symptoms worsened during the trial, appropriate medical care was provided. Patients who declined the prescribed treatment were respected in their decision and were offered alternative options. Additionally, patients experiencing drug intolerance or developing other illnesses during the trial received free therapy, ensuring their health was prioritised. The trial protocol was designed to maintain patient safety and comfort throughout the study.

## Study Intervention

The intervention involved administering *Jyotishmati* Capsules at 500 mg twice daily after food, for 60 days (12). Assessments were conducted on days 0, 30, and 60, with a follow-up assessment performed on day 90. Drug dose and posology is depicted in Table 1.

**Table 1. Showing drug dosage and posology**

|                           |                               |
|---------------------------|-------------------------------|
| <b>Sample size</b>        | 35                            |
| <b>Intervention</b>       | <i>Jyotishmati</i> Capsule    |
| <b>Dose And Frequency</b> | 500 mg twice a day after food |
| <b>Anupana</b>            | With water                    |
| <b>Duration</b>           | 60 days                       |
| <b>Assessment</b>         | Day 0, 30, 60, 90             |

**Procurement of drugs:** The study drug *Jyotishmati* (*Celastrus paniculatus*) was purchased from the market from a recognized shop. *Jyotishmati* (*Celastrus paniculatus*) seeds were pulverized into a powdered form, which then was sieved and three *bhavanas* (trituration) of *Jyotishmati phanta* were given to it according to the *Churnakriya* method mentioned in *Sharangadhara Samhita* in Dattatreya Ayurved Rasashala, Salod (H), Wardha (13). Subsequently, it was dried in a dryer to reduce stickiness. This cycle of bhavana and drying was repeated three times. After completing this process, the final powdered *Jyotishmati* material was prepared and successfully filled into capsules and packed in air-tight containers.

**Diagnostic and Assessment criteria:** Patients were recruited based on DSM-V Diagnostic criteria for Generalized Anxiety Disorder and assessed using the Hamilton Anxiety Rating Scale, Serum cortisol levels and the WHO Quality of Life questionnaire. All the baseline parameters were recorded at the start of the study. All the parameters were recorded on the 0<sup>th</sup>, 30<sup>th</sup>, 60<sup>th</sup>, and 90<sup>th</sup> day of the study duration.

**Outcome measures:** The outcome of the study was measured using the Hamilton Anxiety Rating Scale (HAM-A), and the Quality of life (QOL) of patients through the WHOQOL questionnaire, which was assessed at baseline (day 0), day 30, day 60, and day 90. Additionally, serum cortisol levels were evaluated at baseline and on day 60.

**Statistical Analysis:** Statistical analysis was conducted using descriptive and inferential statistics, including the

student's paired t-test. The software used was SPSS 27.0 and GraphPad Prism 7.0, with a level of significance of  $p < 0.05$ .

## Observations and Results

A total of 35 GAD patients were recruited for this. *Jyotishmati* Capsule of 500 mg twice daily after meals was administered to the patients for 60 days. Patients were assessed on days 0, 30, 60 and 90 using parameters such as the Hamilton anxiety rating scale, and the WHO quality of life questionnaire and serum cortisol levels were assessed at baseline and after completion of the treatment. Data from 35 patients were used for statistical analysis.

### Demographic profile of the study participants

The trial group comprised 35 participants, with 57.14% being female and 42.86% male. Generalised Anxiety Disorder (GAD) is commonly observed in the 20–50 age group, and in this study, the majority of participants were also from this age range, highlighting its prevalence within this demographic. Most participants (62.86%) were aged 20–30 years, with a mean age of 31.22 years. Occupations were predominantly students (40%) and job holders (34.29%), followed by housewives (14.29%) and business professionals (11.43%). The majority (65.71%) of patients followed a mixed diet, while 68.57% belonged to the middle socio-economic class. Regarding *Prakriti* (body constitution), *Vata Pittaj* was the most common type (40%). This demographic and constitutional data offers insight into the participants' varied backgrounds and potential influences on GAD treatment outcomes. [Table 2]

### Prevalence of GAD symptoms based on DSM-V Criteria

The high prevalence of symptoms like restlessness (68.57%) and irritability (68.57%) highlights the significant impact of GAD on patients' lives. Physical symptoms such as muscle tension (65.71%) and sleep disturbances (60%) show the somatic burden of the disorder. Cognitive impairments, including fatigue (45.71%) and difficulty concentrating (42.86%), further illustrate the disorder's extensive reach. These findings support the need for treatments that address both mental and physical aspects of GAD, with *Jyotishmati* showing promising results for holistic management. [Table 3]

### Effect of trial drug on HAM-A Score

The study results indicate a significant reduction of HAM-A mean scores over 90 days, reflecting improvement in participant's conditions. Starting at  $22.02 \pm 1.82$  on Day 0, the score decreased to  $7 \pm 1.08$  by Day 90. Mean differences were notable at each interval  $7.94 \pm 1.41$  (Day 30),  $12.71 \pm 1.63$  (Day 60), and  $15.02 \pm 2.06$  (Day 90), all statistically significant with  $p$ -values of 0.0001.

The  $t$ -values (33.25, 45.94, 43.05 for Days 30, 60, and 90) confirm the robustness of these findings.

The consistent decline in scores suggests the intervention effectively manages symptoms, indicating long-term therapeutic benefits. [Table 4]

**Table 2: Showing the Demographic Profile of Participants**

| Gender            | Trial Group | (n%)     |
|-------------------|-------------|----------|
| Male              | 15          | (42.86%) |
| Female            | 20          | (57.14%) |
| Total             | 35          | (100%)   |
| Age in years      |             |          |
| 20-30 yrs         | 22          | (62.86%) |
| 31-40 yrs         | 4           | (11.43%) |
| 41-50 yrs         | 9           | (25.71%) |
| Total             | 35          | (100%)   |
| Range             | 20-50 yrs   |          |
| Occupation        |             |          |
| Business          | 4           | (11.43%) |
| Job               | 12          | (34.29%) |
| Student           | 14          | (40%)    |
| Housewife         | 5           | (14.29%) |
| Total             | 35          | (100%)   |
| Type of diet      |             |          |
| Veg               | 12          | (34.29%) |
| Mixed             | 23          | (65.71%) |
| Total             | 35          | (100%)   |
| Socio-economic    |             |          |
| Poor              | 11          | (31.43%) |
| Middle            | 24          | (68.57%) |
| Total             | 35          | (100%)   |
| Prakriti          |             |          |
| Kapha Pitta       | 4           | (11.43%) |
| Kapha Vataj       | 4           | (11.43%) |
| Pitta Kaphaj      | 4           | (11.43%) |
| Pitta Vataj       | 2           | (5.71%)  |
| Vata Kaphaj       | 3           | (8.57%)  |
| Vata Pittaj       | 14          | (40%)    |
| Vata Pitta Kaphaj | 4           | (11.43%) |
| Total             | 35          | (100%)   |

**Table 3: Showing the Prevalence of GAD symptoms based on DSM-V Criteria**

| Symptoms                    | Trial Group (n=35) | (n%)     |
|-----------------------------|--------------------|----------|
| Restlessness                | 24                 | (68.57%) |
| Fatigue                     | 16                 | (45.71%) |
| Difficulty in concentration | 15                 | (42.86%) |
| Irritability                | 24                 | (68.57%) |
| Muscle Tension              | 23                 | (65.71%) |
| Sleep Disturbance           | 21                 | (60%)    |

**Table 4: Showing the effect of the trial drug on HAM-A Score**

|                    | Day 0            | Day 30           | Day 60           | Day 90           |
|--------------------|------------------|------------------|------------------|------------------|
| <b>Trial Group</b> |                  |                  |                  |                  |
| Mean $\pm$ SD      | 22.02 $\pm$ 1.82 | 14.08 $\pm$ 2.13 | 9.31 $\pm$ 1.60  | 7 $\pm$ 1.08     |
| Mean Difference    | -                | 7.94 $\pm$ 1.41  | 12.71 $\pm$ 1.63 | 15.02 $\pm$ 2.06 |
| t-value            | -                | 33.25            | 45.94            | 43.05            |
| p-value            | -                | 0.0001, S        | 0.0001, S        | 0.0001, S        |

### Effect of trial drug on WHOQOL Score

The WHO Quality of Life scores demonstrate a marked improvement in participants' quality of life over the 90-day study period. The initial mean score of 58.45 increased significantly to 99.34 by Day 90. Notably, the mean differences between assessment points reveal progressive improvements an increase of 19.31 from Day 0 to Day 30, followed by 29.85 from Day 30 to Day 60, and a substantial jump of 40.88 from Day 60 to Day 90. The statistical analysis further supports these findings, with t-values showing robust significance, especially at Day 90 ( $t = 44.70$ ,  $p < 0.0001$ ). This evidence strongly suggests that the intervention implemented in the trial effectively contributed to improved quality of life for participants experiencing generalized anxiety disorder, highlighting the importance of the treatment strategy used in the study. [Table 5]

**Table 5: Showing the effect of the trial drug on the WHOQOL Score**

|                    | Day 0            | Day 30           | Day 60           | Day 90           |
|--------------------|------------------|------------------|------------------|------------------|
| <b>Trial Group</b> |                  |                  |                  |                  |
| Mean $\pm$ SD      | 58.45 $\pm$ 4.50 | 77.77 $\pm$ 5.40 | 88.31 $\pm$ 4.25 | 99.34 $\pm$ 2.84 |
| Mean Difference    | -                | 19.31 $\pm$ 6.61 | 29.85 $\pm$ 6.95 | 40.88 $\pm$ 5.41 |
| t-value            | -                | 17.28            | 25.40            | 44.70            |
| p-value            | -                | 0.0001, S        | 0.0001, S        | 0.0001, S        |

### Effect of trial drug on Serum Cortisol Levels

The assessment of serum cortisol levels reveals a significant reduction. The mean cortisol level decreased from 7.83 $\pm$ 2.11 before treatment to 7.29 $\pm$ 1.77 after treatment, resulting in a mean difference of 0.53 $\pm$ 1.02. This change was statistically significant, as indicated by a t-value of 3.09 and a p-value of 0.004, suggesting that the treatment effectively lowered cortisol levels. Elevated cortisol is often associated with stress and various health issues so this reduction may indicate improved physiological well-being and potential therapeutic benefits. The findings highlight the efficacy of treatment modulating stress hormone levels, demanding further investigation into its long-term impacts on health. [Table 6]

**Table 6: Showing the effect of the trial drug on Serum Cortisol Levels**

|                 | Before treatment | After treatment |
|-----------------|------------------|-----------------|
| <b>Group A</b>  |                  |                 |
| Mean $\pm$ SD   | 7.83 $\pm$ 2.11  | 7.29 $\pm$ 1.77 |
| Mean Difference | -                | 0.53 $\pm$ 1.02 |
| t-value         | -                | 3.09            |
| p-value         | -                | 0.004, S        |

## Discussion

*Chittodvega*, described in Ayurvedic texts, shares many symptomatic similarities with Generalized Anxiety Disorder (GAD), including persistent worry, restlessness, and mental instability. From an Ayurvedic standpoint, *Chittodvega* is primarily caused by the imbalance of *Vata* and *Pitta Doshas*, along with

disturbances in the *Manas Doshas* (*Rajas* and *Tamas*), which influence emotional and cognitive faculties (13). In this clinical study, the efficacy of *Jyotishmati* capsules was evaluated over 60 days. Clinical parameters such as the Hamilton Anxiety Rating Scale (HAM-A), serum cortisol levels, and the WHOQOL-BREF scores were assessed at baseline and at the 30th, 60th, and 90th days to provide a multidimensional perspective on the psychological and physiological response to treatment.

The results indicated a higher prevalence of *Chittodvega* among individuals in the age group of 20–30 years, consistent with observations made by researchers like S.G. Khot et al. and Vishal et al. (14,15). A greater number of female participants were affected, although gender distribution did not significantly differ between groups, aligning with the epidemiological data presented by Gupta et al. (16). Occupational stress was a contributing factor, as the majority of participants were jobholders or students, which is corroborated by the findings of Vishal et al. Furthermore, most participants belonged to the middle socio-economic class, a trend observed in the studies by S.G. Khot et al. and Gupta et al. A significant proportion (65.71%) had mixed dietary habits, and 40% exhibited *Vata-Pittaja Prakriti*, indicating a strong constitutional link to the manifestation of *Chittodvega*, in alignment with traditional Ayurvedic principles and prior literature (17).

### Probable mode of action of *Jyotishmati* Capsule

The mode of action of *Jyotishmati* (*Celastrus paniculatus*) in the management of *Chittodvega* is rooted in its multifaceted therapeutic attributes, as described in classical Ayurvedic texts and supported by modern research. According to Ayurveda, the vitiation of *Prana*, *Udana*, and *Vyana Vata*, along with deranged *Sadhaka Pitta* and *Tarpaka Kapha*, plays a key role in mental disorders. These factors contribute to the derangement of *Ojas*, leading to emotional and cognitive dysfunctions that manifest as anxiety and related symptoms (18,19).

*Jyotishmati* is known for its unique combination of *Rasa Kashaya* (astringent), *Tikta* (bitter), and *Katu* (pungent), along with *Tikshna* (sharp), *Snigdha* (unctuous), and *Sara* (mobile) *Gunas*. It possesses *Ushna Virya* (hot potency) and *Madhura Vipaka* (sweet post-digestive effect), which make it a potent *Vatahara*, *Medhya* (intellect-promoting), *Nadibalya* (nervine tonic), and *Mastishka Shamaka* (brain soother) (20). These properties collectively contribute to the stabilization of mental functions, improvement in cognitive abilities, and reduction of psychological disturbances.

Its *Deepana* (digestive stimulant) and *Pachana* (digestive) properties assist in correcting *Mandagni* (low digestive fire), which, from an Ayurvedic viewpoint, is responsible for the improper formation of neurotransmitters. The *Tikshna* and *Ushna Gunas* help to eliminate *Kapha-Tama Avarana* (covering of intellect by inertia and dullness), restoring clarity of intellect (*Buddhi*), memory (*Smriti*), and comprehension

(*Medha*) (21). Furthermore, *Jyotishmati* oil, due to its *Sukshma* (subtle), *Vyavayi* (spreading), and *Tikshna* properties, is believed to penetrate deeply into the brain tissues, enhancing the nourishment of *Medha Dhatu* and activating the *Sadhaka Agni*, which is associated with emotional processing and decision-making (22).

Modern pharmacological research supports the ancient claims regarding *Jyotishmati*'s effects. It is rich in active constituents such as alkaloids, flavonoids, terpenoids, phytosterols, and saponins.

These phytochemicals are known to exhibit a wide range of effects, including antidepressant, nootropic, anxiolytic, tranquilizing, and neuroprotective actions (23,24). The presence of antioxidants like flavonoids and terpenoids combats oxidative stress, which is a significant contributing factor in anxiety disorders. These antioxidants neutralize free radicals, thereby protecting neural tissues from degeneration (25).

Additionally, phytosterols and saponins reduce neuroinflammation, preventing the chronic progression of stress-induced neurological conditions. One of the significant mechanisms is the inhibition of monoamine oxidase-A (MAO-A), which helps preserve neurotransmitters such as serotonin and dopamine, key regulators of mood and emotional balance (26). *Jyotishmati* thus plays a role in modulating brain chemistry and preserving neuronal structure and function. Sesquiterpenes present in the plant further protect neurons from oxidative damage, enhancing mental clarity and reducing anxiety manifestations.

Various animal and clinical studies have demonstrated the anxiolytic and cognitive-enhancing activities of *Jyotishmati*. Rajkumar R. et al. conducted an animal study that validated its anxiolytic potential, supporting the present findings (27). The observed reductions in HAM-A scores, along with improvements in WHOQOL-BREF scores, substantiate the clinical relevance of *Jyotishmati* in anxiety management. Its holistic and integrative action positions it as a promising natural alternative for the treatment of *Chittodvega* (GAD), providing both symptomatic relief and long-term mental wellness.

## Conclusion

The study shows that *Jyotishmati* was effective in treating Generalized Anxiety Disorder (GAD), leading to a significant reduction in anxiety symptoms and an improvement in patients' quality of life. Its anxiolytic, tranquillizing, antioxidant, and anti-inflammatory properties make it a promising natural alternative to conventional treatments like sertraline. Further research is needed to explore its long-term benefits.

## Limitations of the study

The limitations of the study include the absence of a control arm and a small sample size. Without a control group, it's challenging to assess the effectiveness of the intervention accurately. Additionally, the small sample size may lead to

variability in results, reducing the statistical power of the study. To enhance the robustness of future research, conducting a larger study with an appropriate control arm is recommended.

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## Conflict of interest

There are no conflicts of interest

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