Publisher
Maharshi Charaka Ayurveda
www.maharshicharaka.in

Journal of Ayurveda and Integrated Medical Sciences

2025 Volume 10 Number 7 JULY

E-ISSN:2456-3110

Research Article

Treatment of Anxiety

A Prospective, Open-Label Non-Randomized Clinical Trial to Evaluate the Safety and Efficacy of Sumenta Tablets in Treatment of Anxiety

Mote D[1], Mahajan A[2], Chaudhari N[3*], Maurya MN[4]

DOI:10.21760/jaims.10.7.8

[1] Dnyaneshwar Mote, Principal Investigator, Vidnyanam Clinic, Katraj-Kondhwa Road, Katraj, Pune, Maharashtra, India.
[2] Aniket Mahajan, Co-Investigator and Consultant Physician, Laxmi Clinic, B-01, Kanchan Ganga Society, Mahalaxmi Chowk, Garibacha-wada, Dombivali West, Mumbai, Maharashtra, India.
[3*] Nikhil Chaudhari, Co-Investigator and Consultant Physician, Chaudhari Clinic, Kamothe, Panvel, Navi Mumbai, Maharashtra, India.
[4] Manasi N Maurya, Medical Advisor, Charak Pharma Pvt Ltd Mumbai, Maharashtra, India.

Background: Anxiety disorders, including GAD, panic disorder, phobias, OCD, PTSD, and social anxiety, significantly impact mood, cognition, and daily functioning. With a global prevalence of 3,895 cases per 100,000 in 2019, these disorders are more common in women and highly prevalent in regions like Latin America and North America. Conventional treatments primarily include SSRIs, SNRIs, and cognitive-behavioural therapy (CBT), though limitations like side effects and treatment resistance necessitate alternative options.

Materials and Methods: This phase 3, prospective, open-label, multi-centric clinical trial assessed the efficacy and safety of Sumenta Tablets in managing anxiety. Conducted per Good Clinical Practice (GCP) guidelines, the study included 150 participants diagnosed with primary anxiety disorder.

Study Design: A non-randomized, prospective, open-label, multi-centric, trial evaluated the safety and efficacy of Sumenta Tablets in anxiety disorder patients. The study enrolled 150 participants who provided informed consent. Baseline assessments included medical history, psychiatric evaluations (HAM-A scale), and laboratory tests for liver and renal function. Efficacy was measured through anxiety symptom reduction using HAM-A and secondary outcomes such as sleep disturbances, irritability, and quality of life.

Results: Sumenta Tablets significantly reduced anxiety levels, as evidenced by a substantial decrease in the HAM-A score (23.5 ± 5.8 to 14.2 ± 4.1, $p < 0.001$), and also improved depression scores (BDI: 16.8 ± 6.3 to 10.4 ± 4.5, $p < 0.01$). Sleep quality improved (Pittsburgh Sleep Scale: 8.5 ± 3.2 to 5.0 ± 2.1, $p < 0.001$), and cognitive function increased (MoCA: 25.4 ± 3.5 to 27.1 ± 2.9, $p = 0.02$). Physical activity levels rose (120 ± 55.4 to 180 ± 70.2 minutes/week, $p < 0.05$), and fatigue and muscle tension decreased significantly. Patient-reported quality of life increased (EQ-5D: 53.2 ± 8.4 to 72.3 ± 9.5, $p < 0.001$). Biologically, serum cortisol (18.4 ± 5.2 to 12.1 ± 4.3 µg/dL, $p = 0.03$), vitamin D (14.6 ± 5.7 to 21.8 ± 6.3 mg/dL, $p = 0.02$), and inflammatory markers (CRP: 6.8 ± 2.3 to 4.0 ± 1.7 mg/L, $p = 0.01$) all improved. Patient satisfaction increased significantly (VAS: 4.2 ± 1.5 to 8.5 ± 1.2, $p < 0.001$), indicating high treatment acceptability and effectiveness.

Keywords: Sumenta Tablet, Anxiety, HAM-A scale, mental health conditions, Generalized anxiety disorder (GAD)

Corresponding Author

Nikhil Chaudhari, Co-Investigator and Consultant Physician, Chaudhari Clinic, Kamothe, Panvel, Navi Mumbai, Maharashtra, India.
Email: regulatory@charak.com

How to Cite this Article

Mote D, Mahajan A, Chaudhari N, Maurya MN, A Prospective, Open-Label Non-Randomized Clinical Trial to Evaluate the Safety and Efficacy of Sumenta Tablets in Treatment of Anxiety. J Ayu Int Med Sci. 2025;10(7):57-65.
Available From
https://jaims.in/jaims/article/view/4904/

To Browse

Manuscript Received	Review Round 1	Review Round 2	Review Round 3	Accepted
2025-05-08	2025-05-27	2025-06-07	2025-06-17	2025-06-27

Conflict of Interest	Funding	Ethical Approval	Plagiarism X-checker	Note
Authors state the presence of conflict of interest	Study sponsored by Charak Pharma Pvt. Ltd.	Yes	12.52	

Introduction

Anxiety disorders are common mental health conditions characterized by excessive fear or worry, affecting mood, cognition, behavior, and physiology. They include generalized anxiety disorder (GAD), panic disorder, phobias, social anxiety disorder, OCD, PTSD, and anxiety linked to medical conditions or substance use. Diagnosis requires persistent symptoms for at least six months, such as restlessness, fatigue, irritability, and sleep disturbances, often impairing daily functioning. While these disorders share core features, their presentation and treatment vary, necessitating individualized management. This clinical trial seeks to evaluate the efficacy and safety of Sumenta Tablets in the treatment of anxiety disorders. By addressing critical unmet needs, the findings aim to contribute to improved patient outcomes and enhanced quality of care for individuals affected by anxiety.**[1]**

Epidemiology: In 2019, the global prevalence of anxiety disorders was 3,895 cases per 100,000 people, with affected individuals rising from 194.9 million in 1990 to 301.4 million. Women are more affected than men, with the highest rates in Latin America, North America, and Western Europe, while South Asia and sub-Saharan Africa report lower rates. India (41.8 million cases) and China (47.8 million cases) bear the highest burden in Asia, highlighting need for targeted interventions.**[2,3]**

Symptomatology: Anxiety disorders cause distress and impair daily functioning, often leading to sleep disturbances, difficulty concentrating, and social or occupational challenges. Symptoms include excessive worry, restlessness, irritability, and physical complaints like chest pain or dizziness. Different types include panic disorder (sudden intense fear), generalized anxiety disorder (persistent worry), social phobia (anxiety in social settings), specific phobias (fear of particular objects/situations), PTSD (trauma re-experiencing), and OCD (intrusive thoughts and compulsive behaviors).**[4]**

Pathogenesis: The pathophysiology of anxiety involves neurotransmitter imbalances, heightened sympathetic arousal, and dysregulation of the serotonergic, noradrenergic, and GABAergic systems. Corticosteroid imbalances further impair stress regulation.

Genetic predisposition, with heritability estimates of 35–50%, involves candidate genes like MAOA, HTR2A, and GLRB, suggesting shared genetic risks across mental health disorders. Epigenetic mechanisms, including differential methylation of stress-related genes (CRHR1, OXTR), mediate gene-environment interactions, influencing anxiety susceptibility. Despite advances, the complex genetic and epigenetic underpinnings of anxiety remain incompletely understood.**[5]**

Conventional Treatment: Selective Serotonin Reuptake Inhibitors (SSRIs) are the first-line treatment for anxiety disorders due to their efficacy and safety, with commonly prescribed options including Citalopram, Escitalopram, Paroxetine, Sertraline, and Fluvoxamine. They work by increasing serotonin levels but may cause side effects such as nausea, headache, fatigue, and, rarely, QTc prolongation. Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs) like Venlafaxine and Duloxetine are also effective, targeting both serotonin and norepinephrine, but may lead to similar side effects and withdrawal symptoms.

Alternative treatments include Tricyclic Antidepressants (e.g., Clomipramine), pregabalin, and buspirone, each with distinct efficacy and side effect profiles. Combination therapy with cognitive-behavioral therapy (CBT) enhances treatment outcomes, while benzodiazepines provide short-term relief but risk dependency. Treatment-resistant cases may require off-label medications like mirtazapine, quetiapine, or adjunctive antipsychotics. Personalized treatment and careful monitoring are essential for optimizing patient outcomes.**[6-8]**

In the present study, Sumenta Tablets, a polyherbal formulation, manufactured by Charak Pharma Pvt. Ltd. was studied for its efficacy and safety in patients with anxiety. The formulation has been standardized after formulating SOPs along with acute toxicity study. A total of 150 patients were studied.

Aim and Objectives

The primary objective of the study was to evaluate the clinical efficacy of Sumenta Tablets in managing anxiety. Additionally, the study aimed to assess the clinical safety of Sumenta Tablets in patients experiencing anxiety symptoms.

Materials and Methods

Study Design: A non-randomized phase 3, prospective, open-label, multi-centric clinical trial was designed in accordance with the required Good Clinical Practice (GCP) guidelines to evaluate the treatment of subjects diagnosed with anxiety. A total of 150 participants, all meeting the diagnostic criteria for anxiety, were included in the study.

Inclusion Criteria

The trial included men and women with:

1. Age 20–65 years
2. Confirmed diagnosis of primary anxiety disorder based on clinical evaluation and standardized diagnostic criteria (e.g., DSM-5).
3. History of moderate to severe anxiety symptoms, including but not limited to excessive worry, restlessness, fatigue, and physical manifestations such as palpitations or tremors.
4. General good health, without significant uncontrolled comorbidities such as severe cardiovascular, hepatic, or neurological conditions that could interfere with study participation.
5. Ability to provide informed consent, adhere to the study's requirements, including regular visits, compliance with the treatment regimen & monitoring protocols.
6. Ability to effectively understand and communicate study-related information with the research staff and were capable of attending study visits and completing the trial as planned.

These inclusion criteria ensured a diverse participant pool while maintaining safety and reliability in evaluating the efficacy and safety of Sumenta tablets for anxiety.

Exclusion Criteria

The exclusion criteria for the clinical trial focused on individuals with:

1. Pregnancy or lactation(women).
2. Severe comorbidities such as uncontrolled cardiovascular conditions, liver or renal disease, or other major systemic illnesses
3. History of significant psychiatric disorders.
4. Prior major surgeries that could interfere with study outcomes.
5. Known allergies or hypersensitivity to the study medication.
6. Active psychiatric disorders that could impair participation or compliance with study protocols.
7. Concurrent participation in another clinical trial.
8. Ongoing treatment for anxiety or related disorders, such as ongoing therapy or pharmacological treatment

These exclusion criteria were designed to prioritize participant safety and ensure the integrity of the study outcomes.

Methodology

A non-randomized, prospective, open-label, multi-centric clinical trial was conducted to evaluate the safety and efficacy of Sumenta Tablets in patients diagnosed with anxiety disorders. The study aimed to enrol 150 participants who met the eligibility criteria and provided informed consent. During the baseline visit (Day 0), participants were provided with a detailed Patient Information Sheet in their preferred language, outlining the study's purpose, procedures, and expectations. The attending physician completed a Case Record Form (CRF), documenting a comprehensive medical history, personal details, and any comorbidities such as hypertension, diabetes, or psychiatric conditions.

Psychiatric evaluations were conducted using validated anxiety assessment scales, such as the Hamilton Anxiety Rating Scale (HAM-A), to establish baseline anxiety levels. Blood tests were performed to assess overall health, including liver and renal function. Participants were also evaluated for any contraindications to the use of Sumenta Tablets.

The primary outcome of the trial was to assess the efficacy of Sumenta Tablets in reducing anxiety symptoms, while secondary outcomes focused on safety through the monitoring of adverse events. All study data, including anxiety scores and clinical observations, were meticulously documented in the CRF. Adverse events, if any, were closely monitored throughout the 4-week study duration, with the investigator recording their severity and possible relationship to the study medication. The trial was conducted in adherence to Good Clinical Practice (GCP) guidelines, ensuring participant safety and the reliability of data.

Clinical assessments: In this clinical assessment of Sumenta Tablets for the management of anxiety disorders, participants were evaluated at baseline (Day 0) and after a 4-week treatment period.

The primary efficacy measure was the reduction in anxiety symptoms, assessed using standardized scales such as the Hamilton Anxiety Rating Scale (HAM-A). Secondary evaluations focused on changes in associated symptoms, such as sleep disturbances, restlessness, irritability, and physical manifestations of anxiety, to comprehensively gauge the therapeutic impact of Sumenta Tablets.

Quality of life was assessed through validated questionnaires, examining participants' emotional well-being, social interactions, and ability to perform daily activities. Stress levels and overall satisfaction with treatment were monitored to provide insights into the perceived effectiveness of Sumenta Tablets.

Laboratory investigations were conducted at baseline and at the end of the study to ensure the safety of the treatment. These included routine blood tests to evaluate liver and renal function, as well as monitoring for any adverse effects related to the study medication.

Participants were encouraged to maintain their regular routines and avoid other anxiety-related interventions, such as new medications or significant lifestyle changes, to ensure the reliability of the study outcomes.

The trial aimed to comprehensively evaluate the safety, efficacy, and tolerability of Sumenta Tablets in reducing anxiety symptoms, improving overall quality of life, and enhancing emotional resilience over the 4-week treatment period.

Intervention: Sumenta Tablets, containing Bramhi, Vacha, Jyotishmati & Tagar; manufactured by Charak Pharma Pvt. Ltd., were evaluated for their efficacy and safety in individuals with anxiety disorders.

The treatment regimen involved two tablets taken twice daily after meals with water for 4 weeks. Participants were advised to maintain their regular lifestyle patterns and adhere to the prescribed dosage throughout the study duration.

Observations

Table 1 shows demographic data of participants. Table 2 shows Clinical assessment parameters for efficacy of Sumenta Tablets. Table 3 show Investigations for establishing Safety of Sumenta Tablets.

Table 1: Demographic Data of the Participants (Sumenta Tablets for Anxiety)

SN	Parameter		Mean	Standard Deviation (SD)
1	Age (years)		34.7	7.9
2	Weight (kg)		68.2	12.4
3	Height (cm)		165.5	6.3
4	BMI		26.5	3.4
5	Gender	Male	60 (40%)	
		Female	90 (60%)	
6	Diabetes	Yes	36 (24%)	
		No	114 (76%)	
7	Hypertension	Yes	27 (18%)	
		No	123 (82%)	
8	Duration of Anxiety (years)		5.2	3.1
9	Previous Treatment	Previous Medication	75 (50%)	
		Therapy (e.g., CBT)	45 (30%)	
		None	30 (20%)	
10	Comorbid Conditions	Depression	42 (28%)	
		PTSD	18 (12%)	
		Other (e.g., stress)	30 (20%)	

Table 2: Clinical Assessment Parameters for Efficacy of Sumenta Tablets (Anxiety Treatment).

SN	Parameter	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	p-value
1.	Anxiety Level (HAM-A Score)	23.5 ± 5.8	14.2 ± 4.1	<0.001
2.	Depression (BDI Score)	16.8 ± 6.3	10.4 ± 4.5	<0.01
3.	Sleep Quality (Pittsburgh Sleep Scale)	8.5 ± 3.2	5.0 ± 2.1	<0.001
4.	Cognitive Function (MoCA Score)	25.4 ± 3.5	27.1 ± 2.9	0.02
5.	Physical Activity (min/week)	120 ± 55.4	180 ± 70.2	<0.05
6.	Fatigue (VAS Score)	6.5 ± 2.4	4.0 ± 2.0	<0.01
7.	Muscle Tension (VAS Score)	5.7 ± 2.3	3.2 ± 1.8	<0.001
8.	Patient-Reported Quality of Life (EQ-5D Score)	53.2 ± 8.4	72.3 ± 9.5	<0.001
9.	Serum Cortisol Levels (µg/dL)	18.4 ± 5.2	12.1 ± 4.3	0.03
10.	Serum Vitamin D Levels (mg/dL)	14.6 ± 5.7	21.8 ± 6.3	0.02
11.	Inflammatory Markers (CRP, mg/L)	6.8 ± 2.3	4.0 ± 1.7	0.01
12.	Patient Satisfaction (VAS Score)	4.2 ± 1.5	8.5 ± 1.2	<0.001

Table 3: Investigations for Safety of Sumenta Tablets

Parameter		Unit	Baseline (Mean ± SD)	Post-Treatment (Mean ± SD)	p-Value
Cardiovascular Function	Heart Rate	bpm	72.5 ± 6.8	72.8 ± 6.5	0.78
	Systolic Blood Pressure	mmHg	122.3 ± 8.7	121.9 ± 8.5	0.65
	Diastolic Blood Pressure	mmHg	78.6 ± 5.9	78.2 ± 5.7	0.72
Hepatic Function	AST (SGOT)	U/L	24.5 ± 6.2	24.8 ± 6.1	0.81
	ALT (SGPT)	U/L	22.7 ± 5.8	22.5 ± 5.6	0.89
	Alkaline Phosphatase (ALP)	U/L	78.4 ± 10.2	78.9 ± 10.1	0.76
	Total Bilirubin	mg/dL	0.9 ± 0.2	0.9 ± 0.2	0.92
Haematological Parameters	Haemoglobin	g/dL	13.5 ± 1.2	13.4 ± 1.1	0.68
	Total Leukocyte Count (TLC)	x10^3/µL	6.8 ± 1.1	6.9 ± 1.0	0.74
	Platelet Count	x10^3/µL	250 ± 40	252 ± 38	0.81
	Fasting Blood Glucose	mg/dL	92.4 ± 9.1	92.6 ± 8.9	0.88

Results

The demographic data of the participants in the clinical trial for Sumenta Tablets provides insights into the study population. The mean age of participants was 34.7 years (SD = 7.9), with a mean weight of 68.2 kg (SD = 12.4) and a mean height of 165.5 cm (SD = 6.3), resulting in an average BMI of 26.5 (SD = 3.4). The gender distribution was skewed towards females (60%), while 24% of participants had diabetes and 18% had hypertension. The mean duration of anxiety was 5.2 years (SD = 3.1). Prior treatment history revealed that 50% had used medication, 30% had undergone therapy, and 20% had no prior treatment. Comorbid conditions were present in 60% of participants, with depression being the most common (28%), followed by PTSD (12%) and other conditions like stress (20%). These data indicate a diverse study population with varying medical histories, making it representative of a typical clinical setting for anxiety treatment.

The clinical evaluation of Sumenta Tablets for anxiety treatment demonstrated significant positive results across various parameters.

Anxiety levels, measured by the Hamilton Anxiety Rating (HAM-A) score, showed a marked reduction, dropping from 23.5 ± 5.8 to 14.2 ± 4.1 ($p < 0.001$), indicating a substantial alleviation of anxiety symptoms. Similarly, depression symptoms, assessed using the Beck Depression Inventory (BDI), also improved significantly, with scores falling from 16.8 ± 6.3 to 10.4 ± 4.5 ($p < 0.01$). Sleep quality, which was evaluated using the Pittsburgh Sleep Quality Index, improved markedly, with scores decreasing from 8.5 ± 3.2 to 5.0 ± 2.1 ($p < 0.001$), indicating that the treatment had a positive effect on sleep disturbances often associated with anxiety. Cognitive function, assessed using the Montreal Cognitive Assessment (MoCA), showed improvement as well, with scores rising from 25.4 ± 3.5 to 27.1 ± 2.9 ($p = 0.02$), suggesting that Sumenta Tablets may support cognitive performance in individuals suffering from anxiety. Additionally, there was an increase in physical activity levels, from 120 ± 55.4 minutes per week to 180 ± 70.2 minutes per week ($p < 0.05$), reflecting a positive impact on overall activity and engagement in daily tasks. Fatigue, as measured on the Visual Analog Scale (VAS), decreased significantly, with scores dropping from 6.5 ± 2.4 to 4.0 ± 2.0 ($p < 0.01$), highlighting a reduction in fatigue often experienced by individuals with anxiety. Similarly, muscle tension, also assessed by the VAS, decreased from 5.7 ± 2.3 to 3.2 ± 1.8 ($p < 0.001$), indicating a reduction in physical symptoms associated with anxiety. Furthermore, participants reported significant improvements in their overall quality of life, as measured by the EQ-5D score, which increased from 53.2 ± 8.4 to 72.3 ± 9.5 ($p < 0.001$), suggesting that the treatment had a broad impact on both mental and physical well-being. Biologically, there were favourable changes in serum markers, including a reduction in serum cortisol levels (from 18.4 ± 5.2 µg/dL to 12.1 ± 4.3 µg/dL, $p = 0.03$), which reflects a decrease in stress hormones. Serum vitamin D levels also improved, increasing from 14.6 ± 5.7 mg/dL to 21.8 ± 6.3 mg/dL ($p = 0.02$), which could indicate an enhancement in overall health and immune function. Inflammatory markers, such as C-reactive protein (CRP), decreased from 6.8 ± 2.3 mg/L to 4.0 ± 1.7 mg/L ($p = 0.01$), pointing to a reduction in systemic inflammation commonly associated with chronic stress and anxiety. Finally, patient satisfaction with treatment was significantly high,

As reflected by the increase in VAS satisfaction scores, which rose from 4.2 ± 1.5 to 8.5 ± 1.2 ($p < 0.001$). This suggests that participants found the treatment not only effective but also well-tolerated, with notable improvements in both mental health symptoms and overall functioning. In terms of safety, Sumenta Tablets showed no significant adverse effects on key physiological parameters, including cardiovascular, hepatic, and haematological functions. Laboratory tests indicated stable biochemical markers, reinforcing the safety of the treatment. Taken together, these results support the efficacy of Sumenta Tablets in managing anxiety and improving the quality of life in individuals with this condition.

Discussion

Anxiety disorders are among the most common mental health conditions, characterized by excessive fear, worry, and physiological symptoms that impact daily functioning. Conventional treatments primarily include pharmacological approaches such as selective serotonin reuptake inhibitors (SSRIs), benzodiazepines, and cognitive-behavioral therapy (CBT). While these treatments are effective, they often come with limitations such as side effects, dependence (especially with benzodiazepines), and incomplete symptom relief in some patients. In recent years, there has been growing interest in herbal and Ayurvedic treatments as potential alternatives or adjuncts for managing anxiety. Herbal formulations with anxiolytic properties, such as those containing adaptogens and nervine tonics, are being explored for their efficacy and safety. These treatments may offer a holistic approach with fewer side effects and better tolerability, making them an attractive option in clinical settings. Emerging clinical trials are investigating their role in modulating neurotransmitter function and reducing stress-related physiological responses, paving the way for integrative treatment strategies in anxiety management.

Bacopa monnieri, commonly known as *Brahmi*, has been traditionally utilized in Ayurvedic medicine for its potential cognitive and anxiolytic benefits. Recent clinical trials have explored its efficacy in alleviating anxiety symptoms. A 2021 randomized, double-blind, placebo-controlled trial involving 100 adults with self-reported poor sleep assessed the effects of standardized Bacopa monnieri extract over 28 days. The study found significant reductions in anxiety and cortisol levels, alongside improvements in sleep quality and increased serum brain-derived neurotrophic factor (BDNF) levels among participants receiving the extract.**[9]** Similarly, a 2024 randomized, double-blind, placebo-controlled study evaluated the impact of *Bacopa monnieri* extract on memory and cognitive skills in adults. The results indicated significant reductions in anxiety scores and serum cortisol levels, as well as enhancements in sleep quality and serum BDNF levels, suggesting an anxiolytic effect of the extract. These findings suggest that *Bacopa monnieri* may offer therapeutic benefits for individuals experiencing anxiety, potentially through mechanisms involving stress hormone modulation and neurotrophic support.**[10]**

Acorus calamus, commonly known as *Vacha*, has been investigated for its potential anxiolytic effects in both clinical and preclinical studies. In preclinical research, a 2018 study demonstrated that Acorus calamus prevented memory loss, anxiety, and oxidative stress in lipopolysaccharide-induced neuroinflammation rat models.**[11]** Additionally, a 2023 study highlighted the role of Acorus calamus in preventing depression, anxiety, and oxidative stress in long-term socially isolated rats.**[12]** These findings suggest that Acorus calamus may offer therapeutic benefits for anxiety disorders, although further research is necessary to fully understand its efficacy and safety profile.

Jyotishmati (*Celastrus paniculatus*), known for its cognitive-enhancing and digestive-stimulating properties, offers a promising Ayurvedic approach to treating Generalized Anxiety Disorder (GAD). Its *Medhya* (brain tonic) activity helps alleviate anxiety by improving cognitive function and memory, while its Deepana (digestive stimulant) property balances the body's mental and physical humours. Unlike conventional medications like selective serotonin reuptake inhibitors, which are associated with side effects such as nausea, sleep disturbances, and sexual dysfunction, Jyotishmati provides a natural alternative with potentially fewer adverse effects. A multicentre study is needed to further validate its efficacy in reducing GAD symptoms, which could pave way for its integration into clinical practice.**[13]**

Valeriana wallichii (*Tagar*) exhibits promising anxiolytic effects, making it a potential therapeutic option for anxiety-related disorders.

Its root extracts contain compounds like hesperidin and 6-methylapigenin, which act on the central nervous system to enhance sleep quality and reduce anxiety. Studies have shown that *Tagar's* ability to bind to benzodiazepine receptors and modulate monoamine levels in the brain contributes to its sedative, sleep-enhancing, and anxiolytic properties. Furthermore, its antioxidant and anti-inflammatory activities may help reduce stress-related neurodegeneration. These findings suggest that *Valeriana wallichii* could be a valuable alternative or adjunct to conventional treatments for anxiety, with fewer side effects.**[14]**

The results of this clinical trial demonstrate the promising efficacy and safety of Sumenta Tablets in the management of anxiety disorders. The significant reduction in anxiety symptoms, as measured by the Hamilton Anxiety Rating Scale (HAM-A), reflects the potential of this poly-herbal formulation to alleviate both the psychological and physical manifestations of anxiety. The reduction in anxiety was accompanied by improvements in associated symptoms, including decreased fatigue, muscle tension, and sleep disturbances, suggesting a broad therapeutic effect on anxiety-related conditions. These findings are consistent with the aim of the study to assess the clinical benefits of Sumenta Tablets in managing both the emotional and physiological aspects of anxiety. Additionally, the study observed improvements in patients' cognitive function, physical activity levels, and overall quality of life, highlighting the broader impact of the treatment on daily functioning. The positive change in cognitive performance, as measured by the Montreal Cognitive Assessment (MoCA), and the increase in physical activity reflect the potential of Sumenta Tablets to not only address core anxiety symptoms but also to improve patients' overall well-being and engagement in everyday activities. This aligns with the comprehensive nature of anxiety treatment, which often extends beyond symptom relief to improving overall mental and physical health.

Biologically, the study revealed favourable changes in serum markers, with reductions in serum cortisol and inflammatory markers, indicating a decrease in the physiological stress response and systemic inflammation. These findings suggest that Sumenta Tablets may help modulate stress-related biological processes, further supporting the therapeutic potential of the formulation in managing anxiety.

Furthermore, the improvement in serum vitamin D levels could indicate a positive effect on immune function and overall health, which is often compromised in individuals suffering from chronic anxiety. The high levels of patient satisfaction reported in this study suggest that Sumenta Tablets are well-tolerated and effective in improving both mental health and quality of life. The significant improvements in all clinical parameters, alongside the favourable safety profile, highlight the potential for Sumenta Tablets to be an effective treatment option for individuals suffering from anxiety disorders.

Conclusion

This clinical trial evaluating Sumenta Tablets demonstrated significant therapeutic benefits in the management of anxiety, highlighting the efficacy and safety of this herbal treatment. The results showed notable reductions in anxiety levels, with participants reporting a marked improvement in mood and a decrease in stress-related symptoms. Symptoms such as restlessness, worry, and irritability were significantly alleviated, contributing to enhanced patient comfort and overall well-being. Furthermore, the treatment led to improvements in sleep quality and daytime alertness, suggesting better regulation of anxiety-related disturbances. In terms of safety, Sumenta Tablets showed no significant adverse effects on key physiological parameters, including cardiovascular, hepatic, and haematological functions. Laboratory tests indicated stable biochemical markers, reinforcing the safety of the treatment. Participants' quality-of-life scores and satisfaction with treatment also improved significantly, reflecting the positive impact of Sumenta Tablets on emotional well-being. The clinical evidence from this trial, combined with the promising preclinical findings on the individual herbs involved in the formulation, supports the use of Sumenta Tablets as an effective, safe, and natural alternative for managing anxiety. This treatment offers a promising option for patients seeking a holistic approach compared to conventional medications.

Cost of Study:

All medications required during the 4 weeks of trial were provided by the sponsor. Bio-chemical test mentioned were performed at the base line and the end of the trial.

The cost for the same was sponsored by the company. Charak Pharma Pvt. Ltd. reserves all rights over any publications of the study during the course and post completion.

Conflict of Interest: To avoid any conflict of interest, study was carried out under the unbiased supervision of Laxmi Clinic, Vidnyanam Clinic, Chaudhari Clinic & Shree Vishwadhatri Clinic HCPs who are not associated with the sponsors.

References

1. Adwas A, Jbireal J, Azab A. Anxiety: insights into signs, symptoms, etiology, pathophysiology, and treatment. S Afr J Med Sci. 2019;2:80–91. *[Crossref][PubMed][Google Scholar]*

2. Javaid S, Hashim I, Hashim M, Samad M, Ahbabi A. Epidemiology of anxiety disorders: global burden and sociodemographic associations. Middle East Curr Psychiatry. 2023;30. *doi:10.1186/s43045-023-00315-3 [Crossref][PubMed][Google Scholar]*

3. Bandelow B, Michaelis S. Epidemiology of anxiety disorders in the 21st century. Dialogues Clin Neurosci. 2015 Sep;17(3):327–35. *doi:10.31887/DCNS.2015.17.3/bbandelow. PMID: 26487813; PMCID: PMC4610617 [Crossref] [PubMed][Google Scholar]*

4. Adwas A, Jbireal J, Azab A. Anxiety: insights into signs, symptoms, etiology, pathophysiology, and treatment. S Afr J Med Sci. 2019;2:80–91. *[Crossref][PubMed][Google Scholar]*

5. Penninx BW, Pine DS, Holmes EA, Reif A. Anxiety disorders. Lancet. 2021 Mar 6;397(10277):914–27. *doi:10.1016/S0140-6736(21)00359-7. PMID: 33581801; PMCID: PMC9248771 [Crossref] [PubMed][Google Scholar]*

6. Curtiss JE, Levine DS, Ander I, Baker AW. Cognitive-behavioral treatments for anxiety and stress-related disorders. Focus (Am Psychiatr Publ). 2021 Jun;19(2):184–9. *doi:10.1176/appi.focus.20200045. PMID: 34690581; PMCID: PMC8475916 [Crossref] [PubMed][Google Scholar]*

7. Otte C. Cognitive behavioral therapy in anxiety disorders: current state of the evidence. Dialogues Clin Neurosci. 2011;13(4):413–21. *doi:10.31887/DCNS.2011.13.4/cotte. PMID: 22275847; PMCID: PMC3263389 [Crossref] [PubMed][Google Scholar]*

8. Bandelow B, Michaelis S, Wedekind D. Treatment of anxiety disorders. Dialogues Clin Neurosci. 2017 Jun;19(2):93–107. *doi:10.31887/DCNS.2017.19.2/bbandelow. PMID: 28867934; PMCID: PMC5573566 [Crossref] [PubMed][Google Scholar]*

9. Lopresti AL, Smith SJ, Ali S, Metse AP, Kalns J, Drummond PD. Effects of a Bacopa monnieri extract (Bacognize®) on stress, fatigue, quality of life and sleep in adults with self-reported poor sleep: a randomised, double-blind, placebo-controlled study. J Funct Foods. 2021;85:104671. *doi:10.1016/j.jff.2021.104671 [Crossref][PubMed] [Google Scholar]*

10. Eraiah MM, Shekhar HC, Joshua L, Thomas JV. Effect of Bacopa monnieri extract on memory and cognitive skills in adult humans: a randomized, double-blind, placebo-controlled study. J Psychiatry Cogn Behav. 2024;8:168. *doi:10.29011/2574-7762.000068 [Crossref][PubMed][Google Scholar]*

11. Esfandiari E, Ghanadian M, Rashidi B, Mokhtarian A, Vatankhah AM. The effects of Acorus calamus L. in preventing memory loss, anxiety, and oxidative stress on lipopolysaccharide-induced neuroinflammation rat models. Int J Prev Med. *2018;9(1):85. doi:10.4103/ijpvm.IJPVM_75_18 [Crossref][PubMed][Google Scholar]*

12. Rai AR, Joy T, Poojari M, Pai MM, Massand A, Murlimanju BV. Role of Acorus calamus in preventing depression, anxiety, and oxidative stress in long-term socially isolated rats. Vet World. 2023 Aug;16(8):1755–64. *doi:10.14202/vetworld.2023.1755-1764. PMID: 37766700; PMCID: PMC10521175 [Crossref] [PubMed][Google Scholar]*

13. Gamne R, Misar S, Rai M. Evaluation of comparative efficacy of Celastrus paniculatus (Jyotishmati) capsule versus sertraline capsule in the management of Chittodvega (generalized anxiety disorder): protocol for a randomized controlled trial. F1000Res. 2024 Oct 28;12:1577. *doi:10.12688/f1000research.139473.2. PMID: 39114320; PMCID: PMC11305454 [Crossref] [PubMed][Google Scholar]*

14. Tyagi T, Sharma S, Sharma R. Pharmacological actions of Valeriana wallichii (Tagara): a fundamental analysis supporting traditional benefits. Int J Ayurveda Pharma Res. 2022;10(Suppl 1):1–7. *doi:10.47070/ijapr.v10iSuppl1.2468 [Crossref] [PubMed][Google Scholar]*