



Research Article

EFFICACY OF *DRAKSADI PHANTAM* IN GENERALIZED ANXIETY DISORDER- AN UNCONTROLLED CLINICAL TRIAL

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ABSTRACT

Anxiety disorders are one of the most prevalent class of mental disorders in the general population. Generalized anxiety disorder (GAD) is a common anxiety disorder that comprises continuous and long-lasting worrying, tension, which making normal life problematic and relaxation impossible

The prevalence rate of GAD disorder is increasing constantly in modern era. Though many different types of modern medications used currently to treat anxiety disorders provide temporary relief, they come with various side effects, Drug dependence and safety concerns. In Ayurveda the symptoms of this disease show resemblance with the condition. *Cittodvega* (excited state of mind) which is one among the *Manovikara* in *Ayurveda* caused by dysfunction of increased *Vata* and *Pitta dosha*.

The present study was conducted as an Uncontrolled clinical trial to study the Efficacy of *Drakshadi Phantam* in 38 diagnosed participants of Generalized Anxiety Disorder with the age group 20–50 were administered with 100ml of *Drakshadi Phantam* twice daily before food continuously for a period of 45 days.

Five assessments were done starting from 0th day of treatment to 60 the day of the study with a gap of 15 days, using Hamilton anxiety rating scale and *Rajas Tams* rating scale. The assessment scores of different intervals were statistically analysed using RM ANOVA. Effect of the therapy were statistically analysed in each domain of HAM – A rating scale in different intervals of the study. The therapy was found statistically significant in reducing the symptoms of GAD in all the 14 domains of the HAM- A Rating scale.

Based on results it has been concluded that *Drakshadi Phantam* has statistically significant effect in reducing the symptoms of all the 14 domains of Hamilton anxiety rating scale and reducing the *Rajasika* and *Tamasika* qualities of the study participants.

INTRODUCTION

Mental disorder is a psychological issue reflected in the behaviour, which disturbs the standard growth of a person's culture. These conditions can alter one's ability to relate to other people, work, and can prevent from living a normal life.^[1]

The most common types of mental illness are anxiety disorders, mood disorders, and schizophrenia disorders^[2]. Anxiety disorders are consistently found to be the most prevalent class of mental disorders in the general population

The prevalence of anxiety disorders across the world varies from 2.5 to 7 percent by country. Globally an estimated 284 million people experienced an anxiety disorder in 2017^[3], making it the most prevalent mental health or neuro developmental disorder. Around 63 percent (179 million) were female, relative to 105 million males^[4]. Anxiety disorders arise in a number of forms including phobic, social, Obsessive Compulsive Disorders (OCD), post-

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traumatic disorder (PTSD), or generalized anxiety disorders^[5].

Generalized anxiety disorder (GAD) is a common anxiety disorder that comprises continuous and long-lasting worrying, tension, and nervousness, trembling, muscular tensions, sweating, light-headedness, palpitations, dizziness, and epigastric discomfort^[6]. The worrying involved in GAD is, excessive, intrusive, persistent, disruptive^[7].

ICD-10 classification of mental and behavioural disorders by WHO includes the Generalized anxiety disorders in the category of neurotic, stress-related and somatoform disorders under the classification other anxiety disorder F41.1^[8]. The Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (also known as the DSM-5) published by the American Psychiatric Association include GAD under the category 300.02^[9].

The treatment of anxiety disorder includes psychological therapy, pharmacotherapy, or a combination of both. First-line drugs are the selective serotonin reuptake inhibitors (SSRI), serotonin-norepinephrine reuptake inhibitors (SNRI)^[10] and Benzodiazepines etc

However, many patients do not respond to SSRIs. Both the SSRIs and benzodiazepine has adverse effects such as sexual dysfunction, Trembling, impaired coordination, vision problems, increased risk of dementia and physical dependence^[11] and a delayed onset of action have reduced the acceptability of SSRIs in clinical practice.

Here comes the role of complementary and alternative medicine in the management of GAD. The symptoms of this disease show resemblance with the *Cittodvēga* (excited state of mind) which is one among the *Manōvikāra* (disease of mind) explained by *Ācārya Caraka*^[12]. *Cittodvēga* is more applicable term to illustrate whole anxious state of mind. So, in this study *Cittodvēga* is compared with generalized anxiety disorder. *Cittodvēga* is a *Manōvikāra* characterized by *Udvēga avastha* of *Manas* (excited state of mind) which denotes increased *Rajas* (quality of mind) and the increased state of *Vāta* and *Pitta doṣa*. As *Vāta* and *Pitta* is vitiated and main symptoms is *Aticinta* and *Bhaya*^[13].

Among different Ayurvedic formulations effectively using for treating GAD (*Cittodvēga*), *Drākṣādi Phāṇṭam* the formulation, which is mentioned by *Ācārya vagbhata* in the treatment of *Vāta pitta jvara* were found to be giving promising result in GAD on administration. The formulation is exclusively indicated for conditions like, *Jvara*, *Madātyaya* (alcohol intoxication), *Cardi* (vomiting), *Mūrca* (giddiness), *Dāha* (burning sensation), *Śrama* (tiredness), *Brama* (delirium), *Raktapitta*, (bleeding disorders), *Pipāsa* (increased thirst) and *Kāmala* (hepato-biliary disease)

in Ayurvedic texts^[14]. *Drākṣādi phāṇṭam* is the formulation which is conventionally being practiced among the Ayurvedic practitioners of Kerala in Generalized anxiety disorder. Though it is used conventionally, scientifically documented data in support of its efficacy is not available till date.

Ethics Committee Clearance

The study synopsis with case record form of the research proposal was submitted to institutional ethical committee of VPSV Ayurveda college, Kottakkal, after considering the expert opinions suggestions on the topic and after undergoing different levels of scrutiny. The approval was obtained from research committee and final ethical clearance was gained from institutional ethical committee, Approval No. IEC /doc/10/17: on 21-4-17.

AIM AND OBJECTIVE

To evaluate the action of *Drākṣādi phāṇṭam* in Generalized Anxiety Disorder and to study the efficacy of the same in Generalized anxiety disorder.

MATERIALS AND METHODS

Study was conducted in 34 diagnosed patients of Generalized Anxiety Disorder selected from Manassanthi OPD, VPSV Ayurveda College, Kottakkal with a Study design Uncontrolled Clinical Trial for a study period of 18 months during 2016-2019

Diagnostic Criteria

Diagnostic criteria used was, ICD-10 diagnostic criteria of GAD

Inclusion Criteria

- ❖ Those who fulfilled the criteria for the diagnosis of Generalized anxiety disorder
- ❖ Age group 20-50 years
- ❖ Subjects with informed consent

Exclusion criteria

- ❖ Major systemic disorders like CAD, HTN.
- ❖ Metabolic disorders- DM, Thyroid dysfunction.
- ❖ Subjects on psychiatric medication
- ❖ Other psychiatric disorders

Method of Intervention

Method of preparation of *Drākṣādi phāṇṭam*

Coarse powder of *Drākṣādi* yoga was purchased from GMP certified company and *Phanta* is prepared according to *Phāṇṭa kalpana* in *Śarghandhara Samhita*^[15], (*Madyama* 3rd chap) i.e., 50g coarse powder of *Drākṣādi* yoga was added to 200ml boiled water (1:4 ratio) for the *Phāṇṭa* preparation.

The formulation of medicine was administration orally with an *Anupana* of *Sita* in a Dose 100ml twice daily before food (morning 6 and evening 6 pm) for a duration of 45 days.

Assessment Criteria

The effect of *Drākṣādi Phāṅṭam* in various signs and symptoms of generalized anxiety disorder is done using Hamilton anxiety rating scale. 14 domains of Hamilton anxiety rating scale were assessed for changes with administration of medicine, which includes anxious mood, tension, fear, insomnia, intellectual symptoms, depressed mood, somatic (muscular symptoms), somatic (sensory) symptoms, cardio vascular symptoms, respiratory symptoms, gastro intestinal symptoms, genitourinary symptoms, autonomic symptoms, behaviour at interview and Total Hamilton anxiety scale score

Data Collection

Five assessments

1. 0th day- 1st assessment
2. 15th day- 2nd assessment
3. 30th day- 3rd assessment
4. 45th day- 4th assessment
5. Follow up 60th day

Drug Review

Drākṣādi Phāṅṭam is a polyherbal efficacious Ayurvedic formulation recommended to deal with a broad range of health issues. It is mentioned in *Jvara cikitsa* in Ayurvedic classics especially of *Vāta Pitta* origin. Though it is specially told in *Jvara* it is indicated in many other ailments of *Vāta Pitta* origin also. Clinically it is found to be effective in anxiety disorders which is understood as mainly of *Vāta Pitta* origin, but there are no clinical studies were reported in this observation till now to substantiate its efficacy.

Studies previously conducted in discrete ingredients of this formulation shows various level of action on central nervous system like enhancement of the antioxidant status in the central nervous system, significant beneficial effect on brain function. the ingredients like *Madhuca longifolia* has Anticonvulsant effect^[16] and *Glycyrrhiza glabra* has shown promising effect as a memory-enhancing agent on learning and memory animal models^[17]. The root extract of *Glycyrrhiza glabra* proved to have an antidepressant and anti-stress activity in rodents.^[18] Ethanolic extract of *Cyperus rotundas* has proven for its anxiolytic, antidepressant and hypnotic effect in mice.^[19] *Embelica officinalis* is known for neuroprotective and memory enhancing activities.^[20] *Nilumbo nucifera* flowers extract at all doses used in a study showed the enhanced neuron density in hippocampus together with the improved spatial memory in stress induced rodents.^[21]

More than 70% of the drugs of this formulation are *Madhura tikta* in *Rasa*, 65% possesses *Laghu guna* and *Madhura vipaka* 95% of the drugs are of *Sīta virya*. So mainly the formulation act as *Pitta vāta śamaka*

OBSERVATION AND ANALYSIS

The effect of *Drākṣādi Phāṅṭam* in various signs and symptoms of generalized anxiety disorder using Hamilton anxiety rating scale were statistically analysed by using software SPSS version 25. Repeated measure ANOVA were used for analysing the result within various level of assessment. All symptoms Hamilton anxiety rating scale including psychological, somatic and other were statistically analysed.

Descriptive Statistics Total HAM-A scale score		
Day	Mean	Std. Deviation
D0	31.52	6.09
D15	26.14	5.32
D30	20.14	5.21
D45	16.20	5.79
D60	15.20	5.21

Pair wise Comparisons of Total HAM-A scale score

HAM TOTAL	HAM TOTAL	Mean Difference	Std. Error	P Value
BT	AT1	5.38	0.53	<0.001
	AT2	11.38	0.96	<0.001
	AT3	15.32	0.99	<0.001
	AF	16.32	1.06	<0.001
AT1(D15)	AT2	6.00	0.82	<0.001
	AT3	9.94	0.97	<0.001
	AF	10.94	0.90	<0.001

AT2 (D30)	AT3	3.94	0.74	<0.001
	AF	4.94	0.68	<0.001
AT3 (D45)	AF (D60)	1.00	0.72	>0.05

Percentage of relief in various domains of Hamilton anxiety rating scale

S. No.	Domains	% of relief after treatment	% of relief after follow up
1	Anxious mood	44.36	45.10
2	Tension	38.72	43.38
3	Fear	37.25	24.26
4	Insomnia	39.95	47.80
5	Intellectual symptoms	42.40	47.55
6	Depressed mood	58.57	66.91
7	Somatic (muscular symptoms)	48.04	37.00
8	Somatic (sensory) symptoms	50.98	36.76
9	Cardio vascular symptoms	49.50	58.33
10	Respiratory symptoms	46.56	57.84
11	Gastro intestinal symptoms	41.42	44.36
12	Genitourinary symptoms	38.23	46.56
13	Autonomic symptoms	34.31	34.80
14	Behaviour at interview	62.74	68.62
15	Total Hamilton anxiety scale score	48.8	51.2

Discussion on the Effect of therapy

Analysis was done for both psychological and physiological symptoms of anxiety as different domains. Scales used for assessments was Hamilton anxiety rating scale.^[22] To assess the effect of the therapy at different intervals, Repeated measures ANOVA was used. In the present study internal administration of *Drākṣādi Phāṅtam* for a period 45 days were found to be effective in reducing the symptoms present in different domains of generalized anxiety disorder.

Effect of Therapy on Anxious Mood

In this study all the participants were presented with anxious mood and *Drākṣādi Phāṅtam* administration was found to have statistically significant effect over symptom anxious mood at $p < 0.001$ during treatment period. The probable mode of action of *Drākṣādi Phāṅtam* over the *Udwēga* may be understood as the symptom *Udwēga* probably caused by dysfunction of *Doṣas rajas, Vāta* and *Pitta*. The properties of *Drākṣādi Phāṅtam*, like *Sita, Tarpana, Mṛidu* and *Vāta Pitta śamaka* are helps to subside the increased *Rajas* and correct the both *Vāta* and *Pitta* and brings the calmness to the mind.

Effect of Therapy on Tension

The domain tension of Hamilton anxiety rating scale includes fatigability, startle response, moves to tears easily, trembling, feeling of restlessness, and

inability to relax.^[223] the symptoms are more related with that of *Ōjo kṣaya*^[24] and *Rasa dhatu kṣaya lakṣānās*.^[25] Here the *Drākṣādi Phāṅtam* due to its *Saumya guna* does the *Rasa dhatu prīnana, Nirvāpana* and further helps to normalize the *Rasa dhatu* and *Ōjas* in its quantity and functions. In the current study *Drākṣādi Phāṅtam*, statistically it has got significant effect in reducing the symptom tension at $p < 0.001$.

Effect of Therapy on Fear

In the present study, the effect of *Drākṣādi Phāṅtam* found to be statistically significant in reducing the symptom fear at $p < 0.001$. In the present study, irrational fear is the cardinal feature of anxiety disorder. In Ayurveda classics According to *Ācārya Caraka* the *Bhaya* is caused by improper misplaced *Sādhaka Pitta* by *Prakupita Vāta*^[26] (Ca.S/u 12/8 and cakra), *Drākṣādi Phāṅtam* here acts over *Sādhaka Pitta* which is sited in *Hṛdaya* through its *Sita vīrya mridu guna, Kaṣaya madhuara rasa*.

Effect of Therapy on Insomnia

In this study *Drākṣādi Phāṅtam* found to have a statistically significant result in reducing the symptom insomnia ($p < 0.001$). The percentage of relief in the symptom insomnia was observed as 40% after the treatment and 48 % after follow up. In the Ayurvedic perspective, insomnia is considered as *Nidra nāsa or*

Nidra bramśa which are mainly by the dysfunction of *Vāta* and *Pitta dośas*.^[27]

Effect of Therapy on Depressive mood

The current study administration of *Drākṣādi Phāṅṭam* is shown statistically significant result in reducing the symptoms of depressive mood at $p < 0.001$. Comparing with all other psychological domains of Hamilton anxiety rating scale, highest percentage of relief was found in the domain of depressive mood. The percentage of relief after treatment was 58.5% and after treatment the percentage relief improved to 68%.

Effect of Therapy on Intellectual symptoms

The effect of *Drākṣādi Phāṅṭam* on intellectual symptoms were statistically assessed by RM ANOVA and was found to be significant in reducing the fear at $p < 0.001$. *Drākṣādi Phāṅṭam* provided 42.40% relief in intellectual symptoms after treatment and the percentage of relief increased to 47.55% after the follow up, which showed moderate relief in intellectual symptoms.

Action of *Drākṣādi Phāṅṭam* in this domain can be understood by its *Rasa dhatu tarpana*, *Prīnana* (nourishes) properties due to *Saumya sītha guna*. On long term use probably, it can act as *Rasāyana* and have an action over intellectual symptom.

Effect of Therapy on Somatic symptoms

Reductions in somatic symptoms of anxiety on administration of *Drākṣādi Phāṅṭam* were noted. Statistically the result was significant at $p < 0.001$ after treatment. The percentage of relief on somatic symptoms after treatment was 48.04%. After follow-up some of the symptoms reappeared and the percentage of relief was reduced to 37 %.

Effect of Therapy in Sensory symptoms

Drākṣādi Phāṅṭam provided 50.98% of relief after treatment on sensory symptoms of GAD but the percentage of relief reduced to 36.76% after the follow up. The results showed that the relief obtained by the administration of medicine was diminished after stopping the medicine. On statistical analysis on comparison with BT, the effect of the therapy was statistically significant after treatment at $p < 0.001$. As per Ayurveda the sensory symptoms must be understood as *Indriyadaurbalya*, which is one among the major feature of *Pitta vruddhi* (Su. Su.15/13)^[28] and *Ōjas kṣaya* (Cha.su.17/60^[29], Cha. chi 16/5)

Effect of Therapy Cardio in Vascular Symptoms

Among physiological domains, highest percentage of relief was noted in cardiovascular symptoms. The reduction found by the treatment was statistically significant at $p < 0.001$ and the percentage of relief after treatment was 49.5 and which was increased to 58.3 after follow-up. From Ayurvedic purview cardiovascular symptoms of GAD can be

compared with symptoms of *Rasa dhatu kṣaya* and *Vyāna Vāta vaigunaya*^[30]. Both *Rasa dhatu* and *Vyāna Vāta* are situated in *Hṛdaya* and whenever the *Hṛdaya* is afflicted by increased *Vāta dośa* that further leads to *Rasa kṣaya* and *Vaigunya* in *Vyāna Vāta karma*. Here the *Hṛudpīda/ Hrudrava*, *Kampa*, *Hrud sūlam*, *Sirāspandana* are the equivalent symptoms explained in Ayurveda with that of cardiovascular symptoms^[31]. It can be inferred from the study that, the main site of action of the *Drākṣādi Phāṅṭam* is probably in *Hṛdaya*. Properties of *Drākṣādi Phāṅṭam* like *Brahmana*, *Tarpana*, etc helps to regulate the increased *Vāta* in *Hṛdaya* which further leads to nourishment of *Rasa dhatu* and reducing the cardio vascular symptoms.

Effect of Therapy in Respiratory Symptoms

The effect of *Drākṣādi Phāṅṭam* was found to be statistically significant in reducing the respiratory symptoms of GAD on analysis at $p < 0.001$. There were 46.56% of relief was noted after treatment and the percentage of relief was improved to 57.84 after follow up. The respiratory symptoms are primarily caused by difficulties with ventilation in anxiety or phobia. *Drākṣādi Phāṅṭam* helps in correcting the function of both *Prāna* and *Udāna Vāta* and gradual reduction in symptoms takes place.

Effect of Therapy in Gastro Intestinal Symptoms

On statistical analysis of the assessment scores in different intervals were found to have, the medicine *Drākṣādi Phāṅṭam* has got significant effect in reducing the GI symptoms at $p < 0.001$. There were marked percentage of relief of 41.42% noted after the administration of medicine and on follow up the percentage of relief was improved to 44.5%.

Effect of therapy in Genito urinary symptoms

Drākṣādi Phāṅṭam was found to have an action in reducing the Genito urinary symptoms. The result was noted at p value < 0.001 . The percentage of relief in Genito urinary symptoms noted was 38.23 after treatment and which was increased to 46.56 after follow up.

Vāta anulomana action of *Drākṣādi Phāṅṭam* brings normalcy in dysfunctional *Apāna Vāta* and *Vāta* present in *Koṣṭha* and *Pakvāsaya* thus results in reducing the Genito urinary symptoms.

Effect of Therapy in Autonomic Symptoms

Statistically significant reduction ($p < 0.001$) was noted in the autonomic symptoms of GAD on pair wise comparison of all assessment scores. The percentage of relief noted in autonomic symptoms after treatment was 31.38 and the relief continued after follow up as well.

Ayurveda consider the autonomic symptoms are of mainly due to *Pitta dośa*. Which include *Pipāsa*, *Pāndutva*, *Ati sveda*, *Śirasoola*, *mūrca*. Here the formulation *Drākṣādi Phāṅṭam* is typically advised in

similar kind of presentation as per Ācārya in Ayurvedic classics^[32], which are *Mūrca*, *Brama*, *Pipāsa*, *Kāmala* etc. From this it can be inferred that *Drākṣādi Phāṇṭam* is a formulation which have specific action on reducing the autonomic symptoms.

Effect of Therapy on Behaviour at Interview

Marked improvement with highest percentage of relief was noted in this domain on comparing with all other domains of Hamilton anxiety rating scale. The percentage of relief noted after the treatment was 62.74% and on follow up the percentage of relief was improved to 68.62%.

The improvement in behaviour at interview can be considered as due to the overall effect of the therapy. Reduction in anxiety, fear, tension, motor symptoms, etc, helps the person to built-up self-confidence which will further help the person face the situations with self-esteem.

Effect of therapy in Total Hamilton anxiety rating scale score

The mean score of total Hamilton anxiety scale score on initial assessment were 31.53±6.09 which was reduced to 15.2±5.2 after follow up. On analysis total score in each assessment were statistically significant in comparison with subsequent assessments, and the effects of the therapy were found significant at total Hamilton anxiety score at p value < 0.001. The marked decrease in Total Hamilton anxiety rating score indicates the overall symptomatic reduction in generalized anxiety disorder. The percentage of relief in total score noted after the study was 48.8 and after the follow up the percentage of relief was increased to 52.2

Probable Mode of Action *Drākṣādi Phāṇṭam*

Observing from an Ayurvedic perspective, the signs, symptoms, stages and complications pathology of GAD happens at different levels. In the *Doṣa* level *Vāta Pitta* along with *Manō doṣa raja tamas* are vitiated. Among sub types of *Vāta* mainly *Udāna*, *Vyāna*, *Samana* and *Apāna* are affected functionally. Among sub types of *Pitta Pachaka* and *Sadaka Pitta* are affected, and the pathology mainly happens in *Hrudaya* which is the *Sthāna* of *Manas*, *Rasadhātu*, *Ōjas*, *Sādaka Pitta* and *Vyāna Vāta*. Due to vitiated *Doṣa* affecting *Hrudaya*, *Rasa dhatu kṣaya lakṣana* and *Ōjo kṣaya lakṣanas* are also evident in GAD.

Drākṣādi Phāṇṭam is one of the perfect formulations which can do break the *Samprāpti* of the condition. *Drākṣādi Phāṇṭam* is known for its soothing and nourishing action. By its *Snigda*, *Saumya*, *Madhura* properties once the *Vāta* in *Koṣṭha* get normalized will helps in correction of *Agni*. The *Viṣamāgni* of the person get normalised along with *Samāna*, *Udāna vāta*. Probably once the *Pācakāgni* is got corrected the *Rasa dhatu* also start to produce normally. Then specific

action of the formulation mainly takes place in *Hrudaya*. Dysfunction of *Sādaka agni/Pitta* is considered as the cause for increased irrational fear and lack of self-confidence as per Ayurveda. Being *Sādaka agni*^[33] is the one leads to the proper production of *Ōjas* as per Ayurvedic texts, *Sādaka agni* in its normalcy helps in standard production of *Ōjas* and further leads to *Ōjo vṛuddhi*. *Ōjas* is the one of the key factors which controls the normal function of all *Jñānendriya* as well as *Manas*. Once the *Ōjas* gets in to its sufficient quantity then by the virtue of that the *Mana* starts to perform its function normally

Even though psychological action of the formulation is not explained directly in classical Ayurvedic texts, clinically the formulation seems to potent enough to bring marked changes in psychological domain, along with this modern pharmacological perspective many of the ingredients of the formulation are proven for their sleep-inducing anti-depressant, anti-stress, anxiolytic, neuro protective and memory enhancing actions through different animal studies and clinical trials.

Action of Therapy Over *Satva*, *Rajas*, and *Tamas*

All creatures of the world consist of various combinations of *Satva*, *rajas*, and *Tamas*. They are the energies through which mind and its deeper consciousness functions. Among these three *rajas* and *Tamas* are considered as *Doṣas* of *Manas*. *Rajas* and *Tamas* when overpowers *Satva* (the purest aspect of the mind) it will lead to dysfunction at psychological level.

In the present study on administration of *Drākṣādi Phāṇṭam* marked reliefs were noted in *rajas* and *Tamas* score. Here the reduction in *Rajasika* and *Tamasika bhavas* indicates the change in mental wellbeing. After treatment participants of the study were reported with the calmness of mind, happiness, enthusiasm, confidence and more tolerability. From the above change it can be inferred the *Rajasika* and *Tamasika* qualities reduced and *Satwika* qualities increased.

CONCLUSION

The study concluded that administration of *Drākṣādi Phāṇṭam* 100ml twice daily for a period of 45 days has statistically significant effect on reducing the symptoms of Generalized anxiety disorder in all the domains of Hamilton anxiety rating scale and total score of Hamilton anxiety rating score, also marked reduction were noted in *Rajas* and *Tamas* qualities of the study participants.

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