

## Pre and post test clinical study to assess the combined effect of Brahmi Gritha-Nasya, Ksheerabala Taila-Abhyanga and Saraswatha-Churna in reducing the symptoms of Generalized Anxiety Disorder on Hamilton Anxiety Rating Scale

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Generalized Anxiety Disorder (GAD) is the most frequently occurring anxiety disorder. It is characterized by tension, persistent worry about a variety of everyday problems and other anxiety symptoms for at least 6 months. Although there have been significant improvements over the years in its treatment, GAD remains the least successfully treated among anxiety disorders. This paper aims to explore the efficacy of Ayurvedic treatment protocol in providing a remedy for GAD. A clinical trial was conducted with 20 patients in the proposed age group of 20 years to 60 years, diagnosed with GAD according to ICD 10 F 41.1 Criteria, and having a score between 17-24 (mild to moderate) on Hamilton Anxiety Rating Scale. The patients were administered 7 days of Sarvanga-Abhyanga (full body massage) with Ksheerabalataila and Brahmigritha-Nasya, followed by internal intake of Saraswatha-Churna for 21 days. The assessment was done using Hamilton Anxiety Rating Scale at baseline and after treatment. Patients' age ranged from 27 to 60 years. Maximum incidence of the disease was seen in the age-wise classification group 20-29 years. There were 8 male subjects and 12 female subjects. After 28 days of treatment, the mean scores of Hamilton Anxiety Rating Scale, which was 21 before treatment, reduced to 9.8 with a mean difference of 11.2 and a statistically significant p-value of 0.01. Thus the present protocol was effective in reducing the symptoms of GAD within a short time-span and without producing any side effects.

**Keywords:** Abhyanga, Brahmi-Gritha, Generalized Anxiety Disorder, Nasya, Saraswatha-Churna

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Anxiety is a type of response to threat or stressful events. Due to the growing influence of stress and strain, consequent loss of balancing temperament of the mind, more and more people are falling prey to mental instabilities, amongst which anxiety disorders are the most common. Among anxiety disorders, Generalized Anxiety Disorder (GAD) has the most frequent occurrence and in India, its prevalence (weighted) is 5.8%<sup>1</sup>. It is a prevalent and disabling disorder characterized by tension, persistent worry about a variety of everyday problems and other anxiety symptoms for at least 6 months<sup>2</sup>. Due to its increased occurrence GAD has become a burning problem faced by the society at large and it is indirectly reducing the quality of life as well as the working capacity of citizens.

Despite several development milestones in its treatment, GAD remains one of the least successfully

treated anxiety disorders, owing to non-availability of a drug of choice. The present standard of care involves anxiolytics, prolonged usage of which may lead to over-dependence and associated conditions like nausea, blurred vision, headache, confusion, tiredness and recurring nightmares<sup>3</sup>.

While enumerating the various disorders affecting the mind, Acharya Charaka, in the text Charaka Samhita, has mentioned Cittodvega as one among them<sup>4</sup>. It refers to the Udvega Avastha of Manas (excited state of mind) which is caused by vitiated Rajas and having the predominance of Vata-Dosha and Pitta-Dosha. The state of Cittodvega can be compared to the state of GAD due to its close resemblance in symptoms. Cittodvega can exist as a separate disease or can be an etiological factor for other psychosomatic disease.

In Ayurveda, treatment for disease having predominance of Vata-Dosha and Pitta-Dosha involve

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Snehana and Bruhmanachikitsa (nourishing therapies). Considering this principle, a treatment protocol with Abhyanga (full body massage), Nasya (Nasal administration), followed by internal medicine was planned. Abhyanga is one among the Bahya-Snehana (external nourishing therapy) which is Śramahara (helps mitigate fatigue), Swapna janaka (improves sleep)<sup>5</sup> and is beneficial in reducing somatic symptoms of anxiety like tremors. The large number of researches being carried out in this disease have already compared various clinical intervention including Snehapana, Dhara, Pranayama and various Shamanaushadis. Nasya, which is considered as the best treatment for diseases pertaining to the regions of the human body above the shoulder including head, is less explored but is more effective<sup>6</sup>. Considering this, Nasya was taken for the present study. Saraswata-Churna, selected as internal medicine, is indicated in people with Durmedha (faulty retention), Viceta (absence of mind) and for disorders resulting from impaired thought process. It increases Budhi (intellect) Medha (retention), dhṛti (control of mind) and smṛti (memory)<sup>7</sup>. This may be beneficial in a mental health condition like GAD. The drug used for Nasya was Brahmi Gritha mentioned in Astangahridaya Uttarasthana<sup>8</sup>, in which all the four ingredients have proven anxiolytic effect and Ksheerabala Taila was selected for Abhyanga as it is Vatahara (mitigate Vata) and is Indriyaprasadana (good for senses)<sup>9</sup>.

In this study, initially internal medicine to improve digestion (Pachana and Deepana) for better absorption of medicine was given followed by Nasya and Abhyanga for 7 days and Saraswata Churna as Shamanaushadhi (discharge medicine) for next 21 days.

## Methodology

### A. Source of data

The patients who attended the OPD and IPD of the Amrita Ayurveda Hospital, Vallikkavu, Karunagapally, Kerala between 1/7/2018 and 31/6/2019 with signs and symptoms of GAD were screened. Among them, 20 patients who fulfilled the inclusion criteria were included in the study. Each subject was required to execute written informed consent to participate in the trial, which was approved by the Institutional Ethics Committee of Amrita Institute of Medical Sciences, Kochi. CTIR registration was obtained for the trial with number CTIR/2018/06/014626. A pre-structured proforma

containing the details of socio-demographic data, chief complaints, personal history, family history and mental status examination was used for documentation.

### B. Diagnosis

Diagnosis was made based on ICD 10 F41.1 criteria.

### C. Inclusion criteria

- 1 Patients fulfilling the diagnostic criteria for GAD as per ICD 10 F 41.1.
- 2 Patients with score between 17– 24 on Hamilton's Anxiety Rating Scale.
- 3 Age between 20-60 years.
- 4 Patients fit for Nasya and Abhyanga Karmas.

### D. Exclusion criteria

- 1 Patients with psychotic features and other psychiatric illness.
- 2 Patients with other systemic illness like diabetes, hypertension and thyroid disorders.

### E. Study design

It was a single group clinical study with pre and post –test study design.

### F. Source of medicine

Brahmi gritha, Ksheerabalataila and Saraswatha Churna were prepared at GMP certified pharmacy of AV Oushadhashala, Thattarkonam, Kollam, Kerala state. Pincode: 691 005.

### G. Treatment schedule

*Phase 1 (OP treatment)* Pachana and Deepana (digestants) therapy to improve digestion and enzyme activity for better absorption of medicine.

#### *Phase 2 (IP treatment)*

1. Sarvanga Abhyanga (Full body massage)
2. Nasya Karma (Nasal instillation)

#### *Phase 3 (OP treatment)*

1. Saraswatha Churna

Details are provided in Table 1 below:

### H. Assessment

Assessment was done using Hamilton Anxiety Rating Scale on baseline and after completion of the treatment. Statistical significance of the data was analysed with Paired t test using SPSS software.

## Results

Out of the 20 subjects of GAD studied in the research, maximum number of patients were in the age group 20 - 29 years. Sixty percent of the subjects were females which showed more incidence of this

Table 1 — Table showing details of therapeutic intervention

Treatment	Drug	Dose	Duration
1 Deepana-Pachana Chikitsa	Trikatuchurna	5 g twice daily Before food	3-5 days
2 Sarvanga Abhyanga and Mrudu Sweda in the form of Ushnambu Snana	Ksheerabala Taila	120 mL (40 min)	7 days
3 Nasya	Brahmi Gritha	4 mL in each nostril	7days
4 Oral medication	Saraswatha Churna	4 g thrice daily with ghee and honey	21 days

Table 2 — Table Showing effect of treatment on Hamilton Anxiety Rating Scale

Sl No	PARAMETERS	BT MEAN	AT MEAN	BT-AT MEAN	SD	t-value	p-value
1	Anxious mood	2.8	0.7	2.100	.718	13.077	.0001
2	Tension	2.95	1.05	1.900	.718	11.831	.0001
3	Fear	1.75	0.7	1.050	.999	4.702	.0001
4	Insomnia	2.65	1	1.650	.933	7.906	.0001
5	Intellectual symptoms	0.8	0.65	.150	.366	1.831	.083
6	Depressed mood	1.5	0.95	.550	.686	3.584	.002
7	Somatic (muscular )	1.45	0.85	.600	.754	3.559	.002
8	Somatic (sensory)	0.5	0.15	0.35	.587	2.664	.05
9	Cardiovascular symptoms	1.55	1.05	.500	.607	3.684	.002
10	Respiratory symptoms	1.35	0.8	.550	.605	4.067	.001
11	Gastrointestinal symptoms	0.8	0.6	.200	.410	2.179	.042
12	Genitourinary symptoms	0.2	0.15	.050	.224	1.000	.330
13	Autonomic symptoms	0.6	0.25	.35	.744	2.100	.05
14	Behaviour at interview	2.1	0.4	1.700	.657	11.573	.0001

disease in females. Fifty five percent of subjects were married, 30% unmarried, 10% divorced and 5% widowed. Among 20 subjects, 10 subjects had a positive family history of anxiety disorder. Ninety percent of the subjects reported to have disturbed sleep.

Subjects were re-assessed on the 29<sup>th</sup> day for change in symptoms. There were significant statistical and clinical effects for patients after the complete therapeutic intervention. The quality of sleep markedly increased in patients and overall condition improved. Effect of the treatment on individual parameters on Hamilton Anxiety Rating Scale is given in Table 2 below.

#### Effect on total score of Hamilton Anxiety Rating Scale

The mean score of Hamilton Anxiety Rating Scale was 21 before treatment and reduced to 9.3 after treatment with a mean difference of 11.7 and was statistically significant with p-value 0.01. Effect of overall treatment is shown in Fig. 1.

#### Discussion

Cittodvega is a clinical condition characterised by Udvega Avastha of Manas, having predominance of Vata- Pitta Doshas, producing both physical and psychological symptoms. The major symptoms of GAD like anxiety (*Udvega*), fear (*Bhaya*), loss of sleep (*Nidranasa*), depression (*Shoka*), anger

Total Mean score of Hamilton Anxiety Rating Scale

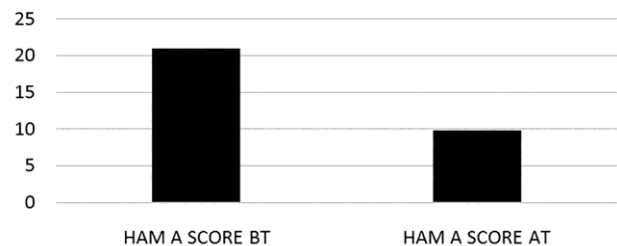


Fig. 1 — Showing the effect of therapy on total score of Hamilton Anxiety Rating Scale

(*Krodha*) can be seen as a clinical condition described in Ayurveda as resulting from vitiated Vata and Pitta dosha along with Manasika Dosha Rajas.

Since the Doshas to be pacified are Vata and Pitta, Bruhmana Chikitsa (nourishing treatment) in the form of Sneha Nasya and Abhyanga was adopted. Bruhmana Nasya was given with ghee, processed with drugs having anxiolytic effect while Abhyanga was given with oil having Vata-Pitta reducing property. The protocol aimed at reducing both physical and psychological symptoms of anxiety.

In the present study, the pre-morbid personality of all subjects revealed their predominant nature was prone for anxiety. Most subjects used avoidance as strategy

when faced with problems. Majority of the subjects belonged Vāta- Pitta Prakriti (body constitution), whom by nature are Akleshasaha (intolerant to stress). The family history of 50% of the subjects were positive for generalized anxiety disorder. All these were the predisposing factors in subjects.

Academic stress like exam fear, fear of lagging behind in assignments, occupational stress like target achievement, frequent transfer to different places, familial stress like not being able to balance professional/academic commitments and family responsibilities were reported by subjects of young and middle aged group. While the age group between 50-60 years were more affected by social withdrawal, anxiety of being left alone and fear of being ill. They displayed more physical symptoms of anxiety. Even though not a major cause, increased intake of food items such as coffee pickle, and irregular eating habits seem to have contributed to GAD. Acid producing foods like pickles reduce magnesium levels in the body which is necessary for production of neurotransmitter GABA, in the absence of which anxiety is exacerbated<sup>3</sup>. Moreover, caffeine in coffee is also proved to be anxiogenic<sup>4</sup>. These were the perpetuating factors in different groups of subjects. The precipitating factors were not evident in all subjects but some subjects reported change in work environment and being away from home as immediate factors for aggravation of symptoms.

#### **Probable mode of action of therapy and drugs**

Nasya is considered as a direct pathway from nose to brain. Drug administered through nasal route, besides stimulating higher centers of brain will also be available for systemic circulation. Brahmi gritha, being lipophilic will be easily absorbed through this route.

Brahmigritha has four ingredients namely Brahmi, Vaca, Kuṣṭha and Shankhapuṣpi with all having properties to reduce anxiety. The nootropic effect of Brahmi is attributed to the presence of two major saponins, bacoside A and B<sup>10</sup>. Research works have established the presence of these in Brahmi Gritha. In anxiety, dysregulation of HPA axis result in increased expression of emotions like anxious mood, tension and depressed mood<sup>11</sup>. Brahmi has action over the HPA axis causing reduced levels of cortisol<sup>12</sup>. Also it is known to cause an increase in serotonin and gamma aminobutyric acid<sup>13</sup>. It also helps to improve cognitive functions like memory and concentration which is generally impaired in GAD<sup>14</sup>. The drug Vaca has neuroprotective action and Kuṣṭha is known to possess anxiolytic properties. Shankhapuṣpi is one of

the most important Medhya Rasayana (intellect promoting drug) and helps regulating the production of the stress hormones cortisol and adrenaline.

Abhyāṅga is beneficial in reducing subjective stress. It also reduces cortisol level (which is main culprit in stress response) and increase amount of dopamine and serotonin, reducing stress and anxiety<sup>13</sup>.

Ksheerabala taila used for Abhyāṅga had Bala and Ksheera as its main ingredients. Both are Madhura Rasa, Snigdha Guṇa and Vāta Hara. Balamūla is known to possess anti-stress and adaptogenic property<sup>15</sup>. Moreover, Ksheerabala taila is said to be Indriyaprasadana (good for the senses).

Sarawatha Churna was selected as internal medicine. Among its ingredients, Aśwagandha, Kuṣṭha, Shaṅkhapuspi, Ajamōḍa, Śuṅṭhi, Jīraka are having proven anxiolytic property. Ingredients like Ajamōḍa, Jīraka, Śuṅṭhi, Marica and Pippali are carminatives that helps regulate the Agni and control gastrointestinal symptoms of the disease. Fear results from failure of coping strategies which is resultant of reduced adaptogenic behaviour. Adaptogenic activity of drugs like Aśwagandha and Brahmi help adopt better coping strategies there by reducing fear<sup>16</sup>. Aśwagandha having the active ingredient triethylene glycol (TEG), helps in initiation of sleep by increasing the number of frequency of NREM<sup>17</sup> and Jīraka, a rich source of magnesium, helps increase the production of GABA which encourages sleep. The ingredients are subjected to Bhāvana (trituration) with Brahmi Swarasa for 9 h which act as a potentiator increasing the therapeutic efficacy of the drug. The Churna was beneficial in regulating the uncontrolled thoughts in subjects and significantly improved the quality of sleep.

#### **Conclusion**

The present study showed significant improvement in symptoms after the therapeutic intervention with combination of Nasya, Abhyāṅga and Saraswatha churna, within a short span of time without producing any undesired side-effects. Some subjects reported recurrence of sleep disturbance after one month of trial. This indicates the Shamanaushadi can be continued for a longer duration to have more sustained effects.

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### Conflict of Interest

The authors declare that no conflict of interest exists.

### Author's Contributions

CCP contributed in conception and design, acquisition of data, analysis and interpretation of data and drafting the manuscript. MCG contributed in conception and design. MCG, JC and DS contributed in critical revision and final approval of the manuscript.

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