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# "PROSPECTIVE, COMPARATIVE, PHASE II CLINICAL STUDY TO EVALUATE THE EFFICACY OF COMPLETE REGIMEN SHIRODHARA, NASYA, JATAMANSI GHANA, SHAVASANA IN CHITTODVEGA WITH SPECIAL REFERENCE TO GENERALIZED ANXIETY DISORDER"

**Dr. Sanjivani Rathod[1], Dr. Abhay Kulkarni[2], Dr. Jayant Dhake[3]**

1. Associate Professor & HOD. Dept. of Kayachikitsa,
2. Professor & HOD, Dept. of Swasthvrutta,
3. Psychologist,

**Ayurved seva sangh Ayurved Mahavidyalaya, Nashik**

## ABSTRACT:

Chittodvega, classified as a ManasRoga in Ayurveda, correlates closely with generalised anxiety disorder (GAD) in modern psychiatric terms, both characterised by states of heightened anxiety and mental unrest. This prospective, comparative, phase II clinical study aims to evaluate the efficacy of a comprehensive Ayurvedic regimen consisting of Shirodhara, Nasya, Jatamansighana, and Shavasana in managing Chittodvega with a specific focus on GAD.

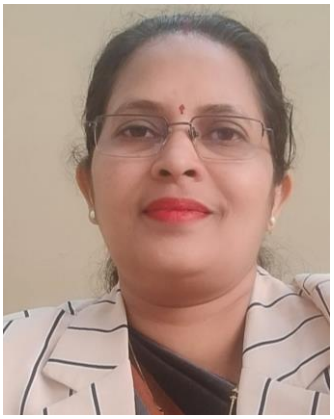
The study will be conducted over a duration of 3 months at OPD No. 14, Arogyashala Rugnalaya, Panchvati, Nashik, involving 6 adult patients diagnosed with GAD.



**KEY WORDS:-** Chittodvega, Manasroga, Generalized Anxiety Disirder (GAD), Mental unrest

**Corresponding Details:**

**Dr. Sanjivani Rathod**
Kayachikitsa Dept.
Ayurved Seva Sangh Ayurved Mahavidyalaya Nashik.
Mobile No. 8007229141
E-Mail: sanjivanirathod431@gmail.com



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## INTRODUCTION

Chittodvega, a type of ManasRoga, develops due to the vitiation of Raja and Tama and can be correlated with generalised anxiety disorder (GAD) based on its etymology indicating an anxious state of mind. The present study aims to explore the effectiveness of Shirodhara, Nasya, Jatamansighana, and Shavasana in patients with GAD. Data suggests that approximately 5.8% of individuals suffer from GAD in anxiety disorder clinics. (1) Modern medical treatments for GAD often involve long-term use of sedatives, hypnotics, and anxiolytic drugs, which can lead to side effects. (2) Therefore, it is imperative to seek treatments that effectively cure the disease without causing additional health issues.

## AIM AND OBJECTIVE

### Aims:

1. To evaluate the impact of Shirodhara on Chittodvega.
2. To assess the effectiveness of Nasya in managing Chittodvega.
3. To examine the efficacy of Jatamansighana in alleviating symptoms of Chittodvega.
4. To investigate the effects of Shavasana in the treatment of Chittodvega.
5. To evaluate the combined effectiveness of Shirodhara, Nasya, Jatamansighana, and Shavasana in providing symptomatic relief for Generalized Anxiety Disorder (GAD).
6. To measure improvement in HAM-A (Hamilton Anxiety Rating Scale) scores post-treatment.[3]

### Objectives:

- Assess changes in corticosteroid levels from baseline.
- Evaluate the conceptual understanding of Chittodvega and its management using Bruhatrayee and relevant ancient methodologies.
- Measure improvements in clinical symptoms including anxious mood (Unmattchittatvam), tension (Dhayana), fears (Sammoha), insomnia, intellectual clarity (ShirashShoonyata), depressed mood, muscular (Swanokarnayo) and sensory (Chakshushorakulta) somatic symptoms, cardiovascular symptoms (Hridgraha), respiratory symptoms (Ucchaswasasyadhikyam), gastrointestinal symptoms (Anannabhilasa, Avipaka), genitourinary symptoms, autonomic symptoms, and behavior during interviews (Udvega).[4]
- Assess drug safety by monitoring adverse drug reactions and clinically significant laboratory abnormalities.

### Objective:

Study the comprehensive efficacy of the complete regimen of Shirodhara, Nasya, Jatamansighana, and Shavasana in managing Chittodvega, with specific focus on Generalized Anxiety Disorder (GAD).[5]

## MATERIAL AND METHODS

### Study Design

**Study Type:** Pilot study

**Duration:** 3 months

**Setting:** OPD No. 14, Arogyashala Rugnalaya, Panchvati, Nashik

**Participants:** 6 patients

- **Inclusion Criteria:**
  - Diagnosed with Generalized Anxiety Disorder (GAD)
  - Age range between 20 to 50 years
  - Willing to participate in the study
- **Exclusion Criteria:**
  - Severe psychiatric disorders other than GAD
  - Concurrent serious medical conditions that could interfere with the study or treatment protocols

### Interventions

- **Shirodhara:**
  - **Procedure:** Administered using warm bramhi oil
  - **Duration:** 30 minutes per session
  - **Frequency:**For 1 weak daily
- **Nasya:**
  - **Administration:**Panchendriyavardhan tail administered nasally
  - **Frequency:** Daily 8 -8 drops
  - **Duration:** Each session lasts for 15 minutes
- **Jatamansi Ghana:**
  - **Form:** Powder extract of Jatamansi (Nardostachysjatamansi)
  - **Dosage:** 500 mg twice daily
  - **Duration:** Taken daily for 3 months
- **Shavasana:**
  - **Practice:** Supine relaxation posture emphasizing conscious relaxation
  - **Duration:** Daily practice 20 minutes for 3 months

### Outcome Measures

- **Primary Outcome:** Improvement in HAM-A scores pre- and post-treatment
- **Secondary Outcomes:**
  - Changes in corticosteroid levels from baseline

- Assessment of clinical symptoms using a checklist (e.g., anxious mood, tension, insomnia)[6]
- Evaluation of adverse drug reactions and laboratory abnormalities

**Data Collection**

- **Baseline Assessment:** Conducted before starting interventions, includes HAM-A scores, corticosteroid levels, and clinical symptom assessment.[7]
- **Follow-up Assessments:** Weekly assessments of HAM-A scores and clinical symptoms throughout the 3 month period.
- **Data Analysis:** Descriptive statistics for HAM-A scores and clinical symptoms, paired t-tests for pre- and post-treatment comparisons.

**Ethical Considerations**

- **Informed Consent:** Obtain informed consent from all participants before enrollment.
- **Ethical Approval:** Ensure the study protocol is approved by the ethics committee or institutional review board (IRB) of ArogyashalaRugnalaya.

**Limitations**

- Small sample size (6 patients)
- Short duration of study (3 months)
- Limited generalizability due to specific setting and sample characteristics

**Method of Selection of Study Subjects**



**A) Inclusion Criteria:**

1. Age between 20 - 50 years.
2. Both sexes.
3. Patients who score at least 14 on the Hamilton Anxiety Rating Scale (HAM-A) at baseline visit.
4. Patients experiencing symptoms including:
    - Anxious mood (Unmattchittatvam)
    - Tension (Dhayana)
    - Fears (Sammoha)
    - Insomnia
    - Intellectual clarity issues (ShirashShoonyata)
    - Depressed mood
    - Muscular somatic symptoms (Swanokarnayo)
    - Sensory somatic symptoms (Chakshushorakulta)
    - Cardiovascular symptoms (Hridgraha)
    - Respiratory symptoms (Ucchaswasasyadhikyam)
    - Gastrointestinal symptoms (Anannabhilasa, Avipaka)

- Genitourinary symptoms
- Autonomic symptoms
- Behavioral issues during interview (Udvega)[8]

5. Subjects willing to follow the procedures as per the study protocol.

**B) Exclusion Criteria:**

1. Pregnant women and lactating mothers.
2. Presence of major co-existing illnesses such as malignancy, renal or hepatic disease, stroke, or autoimmune diseases.
3. Alcohol abuse.
4. Known allergy to any component of the formulation being tested.
5. Refusal to give informed consent.
6. Subjects with known chronic, contagious infectious diseases such as active tuberculosis, Hepatitis B or C, or HIV.
7. Subjects using any other investigational drug within 3 months prior to recruitment.
8. Subjects currently participating in any other clinical study.
9. Any other medical or surgical condition considered unsuitable for subject participation as per Investigator judgment.

**Study Assessments**

**Assessment of Efficacy Parameters**

1. **Assessment of Chittodvega:**
   - Study the efficacy of the complete regimen (Shirodhara, Nasya, Jatamansighana, Shavasana) in managing Chittodvega.
2. **Improvement in HAM-A - Hamilton Anxiety Rating Scale:**
   - Measure changes in HAM-A scores from baseline to endpoint and at monthly intervals during the study. Conduct follow-up assessments at 2 months after the end of the study.
3. **Symptoms and Physical Examination:**
   - Evaluate symptoms and perform physical examinations before the start of the study, at the end of the study, and at monthly intervals during the study period.

**Assessment of Corticosteroid Levels**

- **Assessment of Change in Corticosteroid Levels from Baseline:**
  - Measure corticosteroid levels at baseline and compare with levels at the end of the study period to assess changes. By following these structured methods and assessments, you can effectively evaluate the efficacy of Ayurvedic interventions in managing Chittodvega (GAD) while ensuring participant safety and ethical standards are maintained throughout the study.

**Assessment of Clinical Symptoms**

| Category | Patient 1 Before | Patient 1 After | Patient 2 Before | Patient 2 After | Patient 3 Before | Patient 3 After |
|---|---|---|---|---|---|---|
| Anxious mood (Unmattchittatvam) | +++ | + | ++ | + | + | - |
| Tension (Dhayana) | ++ | + | + | - | + | - |
| Fears (Sammoha) | ++ | - | ++ | + | ++ | - |
| Insomnia | ++ | - | - | - | ++ | + |
| Intellectual (ShirashShoonyata) | + | + | + | + | - | + |
| Depressed mood | ++ | - | ++ | - | + | - |
| Somatic (muscular) (Swanokarnayo) | + | - | - | - | - | + |
| Somatic (sensory) (Chakshushorakulta) | ++ | + | + | + | - | - |
| Cardiovascular symptoms (Hridgraha) | ++ | + | ++ | + | + | - |
| Respiratory symptoms (Ucchaswasasyadhikyam) | ++ | - | ++ | - | - | + |
| Gastrointestinal symptoms (Anannabhilasa, Avipaka) | +++ | + | + | + | - | - |
| Genitourinary symptoms | + | + | - | - | + | - |
| Autonomic symptoms | + | - | - | + | + | - |
| Behavior at interview (Udvega) | ++ | + | ++ | - | + | + |



**Assessment of objective criteria**:- Cortisol Level Chart

| Patient | BT | AT |
|---|---|---|
| **Patient 1** | 10.60 | 9.71 |
| **Patient 2** | 12.30 | 11.73 |
| **Patient 3** | 16.0 | 14.67 |
| **Patient 4** | 4.9 | 4.4 |
| **Patient 5** | 5.0 | 4.7 |
| **Patient 6** | 5.5 | 4.9 |

**Interpretation:**

- **Before Treatment:** Patients generally exhibited higher severity in symptoms such as anxious mood, tension, fears, insomnia, and somatic sensations.
- **After Treatment:** There is a noticeable reduction in severity for many symptoms across all three patients, with improvements in anxious mood, tension, fears, and various somatic and psychological symptoms.

This chart provides a snapshot of symptom changes before and after treatment, illustrating the potential effectiveness of the Ayurvedic interventions in managing the clinical symptoms associated with Chittodvega (GAD).[9]

## DISCUSSION

The connection between the body and mind is fundamental in Ayurveda, as emphasised by Acharya Charaka, who identified stress (Chinta) and overthinking (Atichintan) as key factors in the disruption of Rasavaha Srotas, leading to various diseases. Stress exacerbates Vata, the dosha associated with movement and air, which adversely impacts the heart and destabilises buddhi (intellect) and smriti (memory). Ayurvedic physiology describes Tridosha (Vata, Pitta, and Kapha) as the functional units that maintain or disturb bodily equilibrium. [10]

**Shirodhara**: This treatment involves the steady dripping of warm oil, typically sesame or medicated herbal oil, on the forehead for 30 to 42 minutes. Shirodhara helps control aggravated Vata, thereby reducing its negative effects on Buddhi and smriti. Studies have shown that Shirodhara significantly decreases anxiety levels and reduces plasma noradrenaline, a stress hormone, contributing to a calming effect on the nervous system. [11]

**Nasya Karma**: The administration of medication through the nose, Nasya Karma targets the central nervous system and upper body by delivering herbal oils or powders directly into the nasal passages. This method eliminates morbid doshas from the head, improving cognitive functions and relieving conditions like sinusitis, migraines, and stress. The drugs administered through Nasya reach the ShringatakaMarma, a critical area formed by the union of vessels supplying the nose, ears, eyes, and throat, thus purifying these channels.[12]

**Shavasana**: Shavasana, a supine relaxation posture, is practiced for physical and mental relaxation. Unlike simple rest, it involves conscious relaxation of the mind and body, aiming to release tensions at a deep level. Yoga practices, including asanas and pranayama, help regulate the autonomic nervous system. They stimulate the vagus nerve, which enhances parasympathetic nervous system (PNS) activity, reducing stress and anxiety. These practices lower cortisol levels, decrease sympathetic nervous system activity, and increase vagal tone, thus promoting relaxation and reducing symptoms of stress. [13]

**Jatamansi (Nardostachysjatamansi)**: This herb has been studied for its significant anti-stress, anxiolytic, and antidepressant properties. Jatamansi acts as a nervine tonic, reducing mental exhaustion and lowering cortisol levels. It enhances GABA (gamma-aminobutyric acid) levels, promoting relaxation and reducing anxiety. It also improves cognitive functions, enhances memory, and protects against stress-induced memory impairments. Additionally, Jatamansi improves sleep quality by calming the nervous system and regulating sleep patterns. [14]

Combined, these Ayurvedic and yoga-based techniques promote physical and mental relaxation, balance physiological responses to stress, and improve overall health and well-being. They are particularly effective in reducing anxiety, enhancing cognitive functions, and improving sleep quality, making them comprehensive strategies for managing stress and anxiety.

## CONCLUSION

In conclusion, Ayurvedic practices and yoga-based techniques offer holistic approaches to managing stress and promoting overall well-being. Through methods like Shirodhara, Nasya Karma, and Shavasana, Ayurveda targets the root causes of stress by balancing the Tridosha system and calming the nervous system. These therapies not only alleviate symptoms of anxiety but also enhance cognitive functions and improve sleep quality. Moreover, herbs like Jatamansi further support these benefits by reducing cortisol levels and promoting relaxation. By integrating these ancient wisdoms into modern lifestyles, individuals can cultivate resilience against stress, foster mental clarity, and achieve enduring harmony between body and mind. Thus, Ayurveda and yoga represent powerful tools for navigating the complexities of contemporary life while nurturing enduring states of tranquillity and vitality. As the serum cortisol level of the 6 individuals in this study is in a normal range (i.e., 5–23 at 8am, 3–16 at 4pm, and less than 50% of 8am at 8pm),. 8 a.m. is an ideal time for the rise of sr. cortisol level in human blood; there is not much significant difference in serum cortisol level in the individuals during use of this regimen. [15]

By structuring this pilot study with a rigorous methodology and ethical considerations, you aim to evaluate the initial efficacy and safety of Ayurvedic interventions for managing generalised anxiety disorder (GAD). This study will provide preliminary insights and lay the groundwork for larger-scale studies to further explore these traditional treatments in integrative medicine.

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