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Efficacy of Tagaradi Ghana Vati in Generalised Anxiety Disorders, Chittodvega in Adolescent's of Age 14-16 Years – A Double Blind Randomized Controlled Trial

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ABSTRACT

Introduction : Anxiety disorders are highly prevalent among children and adolescents, causing significant impairment in social, academic, and family functioning. Generalised Anxiety Disorder (GAD), characterised by excessive and persistent worry, affects 3–5% of adolescents and often continues into adulthood if untreated. Although selective serotonin reuptake inhibitors are commonly used, concerns regarding adverse effects and long-term safety in paediatric populations necessitate safer alternatives. In Ayurveda, anxiety-related conditions are described under *Manasika Rogas*, with *Chittodvega* closely resembling GAD and attributed to *Vata* vitiation with imbalance of *Rajas* and *Tamas*. *Tagaradi Kwatha*, described in *Pralapaka Chikitsa Prakarana*, contains herbs with anxiolytic, sedative, adaptogenic, and *Medhya Rasayana* properties.

Materials and Methods: This prospective, interventional, double-blind randomized controlled clinical trial will be conducted on 30 adolescents aged 14–16 years. Participants will be screened using the SCARED scale, diagnosed according to DSM-5-TR criteria, and assessed using the Hamilton Anxiety Rating Scale (HAM-A). Eligible subjects will be randomized into two groups after obtaining parental informed consent.

Results: Group A will receive *Tagaradi Ghana Vati* 500 mg twice daily, while Group B will receive Tablet *Brahmi* extract 250 mg twice daily. Both interventions will be administered orally before food with *sukhoshna jala* for a duration of 30 days**.** Data will be collected using a specially designed Case Report Form (CRF) incorporating standardised assessment scales and will be analysed using MS Excel and SPSS version 26. data will be maintained with strict confidentiality, and the findings will be disseminated through peer-reviewed scientific publications.

Discussion: The study aims to evaluate the efficacy of *Tagaradi Ghana Vati* in reducing core symptoms of GAD in adolescents and to compare its therapeutic effects with *Brahmi* extract. The findings are expected to provide scientific evidence supporting *Tagaradi Ghana Vati* as a safe and effective Ayurvedic intervention for integrative management of adolescent GAD.

Keywords: Ayurveda, Generalised Anxiety disorders, *Tagaradi Ghana Vati*, Tablet *Brahmi* Extract, Hamilton Anxiety Rating Scale (HAM-A).

Dissemination Policy:

The trial results will be disseminated through appropriate channels to relevant stakeholders. Study findings will be communicated to participants and their parents/guardians using a brief, plain-language summary after trial completion. Results will be shared with healthcare professionals through presentations at scientific conferences and publication in peer-reviewed journals. The findings will be reported in the applicable clinical trial registry and communicated to institutional authorities and ethics committees as required. Public dissemination may occur through educational forums to promote awareness of integrative approaches to child and adolescent mental health. Participant confidentiality will be maintained, and both positive and negative results will be reported.

Background and rationale:

Anxiety disorders are the most common mental health conditions affecting children and adolescents, often impacting social, academic, and family functioning.[1] Typically beginning in late childhood or early adolescence a critical developmental stage these disorders, if left untreated, can persist into adulthood as chronic conditions.[2] Anxiety disorders affect a significant portion of youth, with studies estimating a diagnosis rate of 15–20% and long-term data showing a prevalence of 31.9% among adolescents aged 13–18 years.[1] Females are nearly twice as likely as males to be affected, with a gender ratio of approximately 2:1.[3]

Anxiety disorders are marked by pathological anxiety that disrupts social interactions, development, and goal achievement, often leading to low self-esteem, social withdrawal, and poor academic performance. In adolescents, this can significantly impair academics, relationships, and future employment, placing a substantial socio-economic burden on families and society.[4]

Generalised Anxiety Disorder (GAD) in children and adolescents is marked by persistent, excessive worry about everyday situations, occurring most days for at least six months and significantly impairing daily functioning. The lifetime prevalence among adolescents is around 3%, rising to 5% when considering shorter three-month duration.[5]

Selective serotonin re-uptake inhibitors (SSRIs) are the preferred treatment for anxiety disorders in children and adolescents due to their effectiveness and safety. Benzodiazepines, though effective, are not routinely used in this age group due to limited evidence and risks of dependency and side effects like constipation and dry mouth.[6]

Imbalance of *Vata* and the *Manas* (Mind) plays a key role in the development of *Manasika Rogas* (Psychiatric disorders), including conditions resembling Generalised Anxiety Disorder (GAD).[7] *Vata,* as the controller of mental functions (*"Niyanta Praneta Cha Manasa"*),[8] when aggravated, disturbs the *Manodoshas Rajas* and *Tamas* leading to mental unrest.[9] Disruption of *Sattva Guna*, especially when over-powered by *Rajas* or *Tamas,* results in psychosomatic imbalances manifesting as anxiety and stress. *Vata*, being *Rajo guna*-dominant, when vitiated, further destabilizes the mind.[10]

Although GAD lacks a direct Ayurvedic equivalent, classical terms like *Chittodvega,*[11] *Vishada*,[12] *Atattvabhinivesha,*[13]*Anavasthita Chitta,*[13] reflect its symptomatology. *Chittodvega* marked by mental agitation (*Udvega*) and heightened *Rajas* with aggravated *Vata* and *Pitta* most closely aligns with GAD.

Ayurveda offers promising interventions through individualized therapies, including herbal formulations (e.g., *Manasamitra Vati,*[14] *Kushmanda Ghrita*[15] *etc*) and *Panchakarma* treatments like *Takradhara,*[16] *Nasya*[17] *etc* . While studies support their efficacy in adults, there is a lack of focused research in paediatric and adolescent populations-despite adolescence being a critical phase for early intervention. This gap highlights the need for well-designed clinical trials to validate Ayurvedic approaches in managing anxiety among youth.

Tagaradi Kwatha is a traditional Ayurvedic formulation described in *Pralapaka Chikitsa Prakarana*, comprising key ingredients such as *Tagara, Jatamamsi, Brahmi, Shankhapushpi, Ashwagandha* etc. This combination holds promise in managing Generalised Anxiety Disorder (GAD) in adolescents.[18]

Brahmi (Bacopa monnieri) extract is a well-established nootropic and adaptogenic herb with proven efficacy in reducing stress and anxiety while enhancing cognitive functions such as memory, attention, and learning. Its neuroprotective and neurotransmitter-modulating actions support mental resilience, making it an effective and safe intervention for stress-related cognitive and emotional disturbances in adolescent age group.[19]

Research on *Tagara* indicates its sedative effects through central nervous system relaxation and enhanced GABA (Gamma-aminobutyric acid) activity, which contributes to improved sleep and reduced anxiety.[20] Similarly, *Ashwagandha,*[21] *Jatamamsi,*[22] *Shankapushpi,*[23] and *Brahmi*[24] recognized as potent *Medhya Rasayanas* support cognitive function and help alleviate various psychosomatic conditions, making *Tagaradi Kwatha* a potentially effective holistic remedy for anxiety-related disorders in younger populations.

With this aim, the present study evaluates the efficacy of *Tagaradi ghana vati*, a modified form of *Tagaradi Kwatha*, in managing Generalised Anxiety Disorder (GAD), conceptualized in *Ayurveda* as *Chittodvega*, in children. If effective, it could offer a pioneering, evidence-based Ayurvedic approach to childhood anxiety, contributing significantly to paediatric mental health care.

OBJECTIVES:

Primary objective:

1. To study the efficacy of *Tagaradi ghana vati* in the management of Generalised Anxiety Disorders, *Chittodvega* in adolescent children of age 14-16 Years, Based upon- Hamilton anxiety rating scale scores (HAM-A).[25]
2. To study the changes in the *Mano Bhava's* of Generalised Anxiety Disorders, *Chittodvega* in adolescent children of age 14-16 Years, Based upon- *Manasa Pariksha Bhava's* scale.[15]

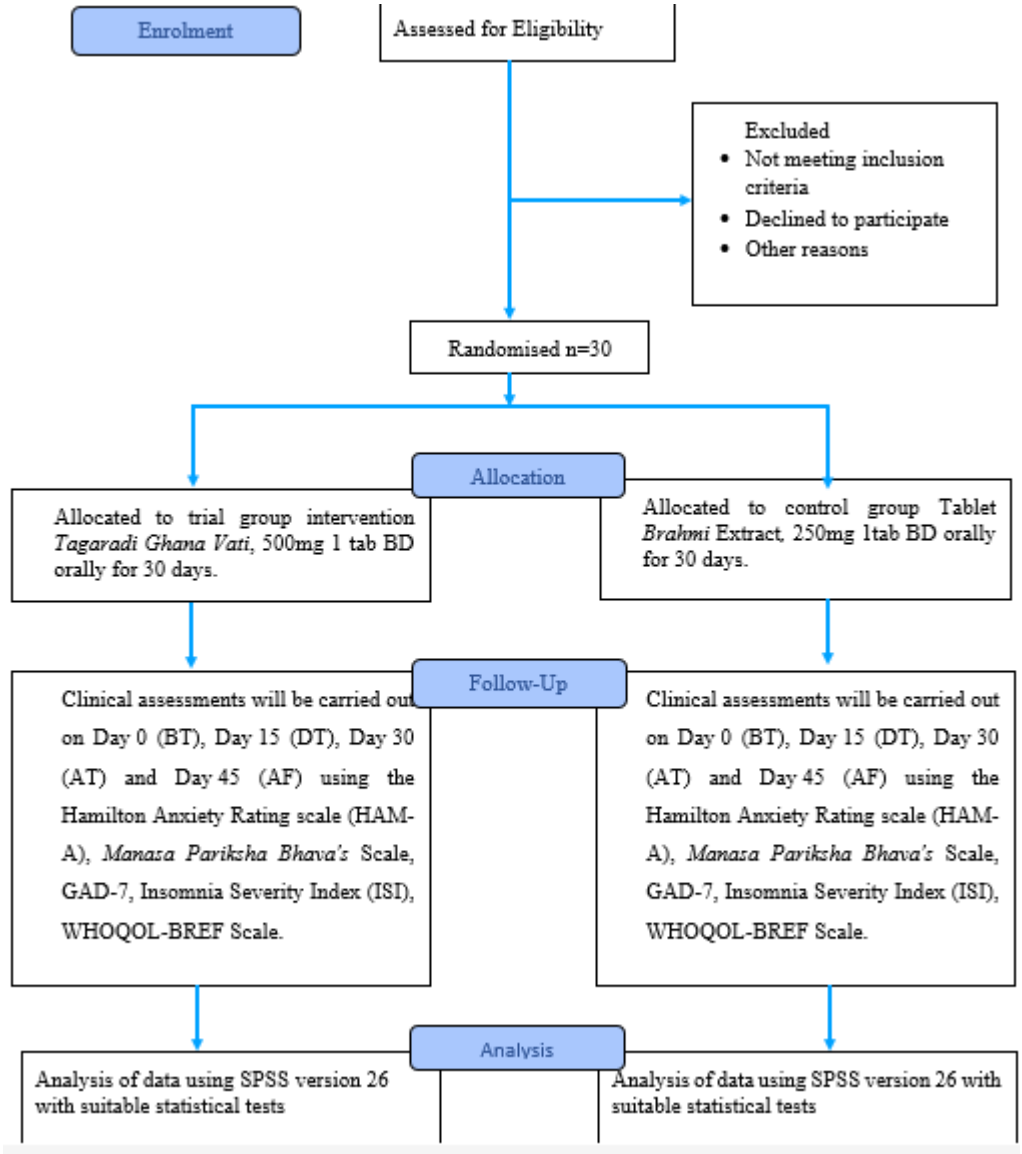
Secondary objective:

1. To assess the efficacy of *Tagaradi ghana vati* in reducing the severity of Generalised Anxiety Disorder in adolescent's aged 14–16 years diagnosed with Generalised Anxiety Disorder, based on -GAD-7 scale.[26]
2. To assess the efficacy of *Tagaradi ghana vati* in enhancing sleep quality in adolescent's aged 14–16 years diagnosed with Generalised Anxiety Disorder (GAD), using the Insomnia Severity Index (ISI).[27]
3. To evaluate the efficacy of *Tagaradi ghana vati* in improving quality of life among adolescent's aged 14–16 years diagnosed with Generalised Anxiety Disorder, based on - WHOQOL-BREF scale.[28]

TRIAL DESIGN:

A double-blind, randomised controlled clinical study will be conducted on a minimum of 30 children attending the Outpatient Department of Kaumarabhritya at Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital, Bengaluru. Participants will be recruited over a 45-day period following comprehensive screening using the SCARED scale.[29] Diagnosis of Generalised Anxiety Disorder will be confirmed in accordance with DSM-5-TR criteria.[30] Eligible participants will be randomly allocated into two groups. The intervention period will be 30 days, during which participants will receive their respective treatments as per group allocation. Both the participants and the researcher will remain blinded to the treatment allocation throughout the study.

Figure 1: CONSORT 2025 Flow Diagram



STUDY DURATION:

The total duration of clinical study is 45 days.

ELIGIBILITY CRITERIA:

ICD 11 CODE - 6B00 [GENERALISED ANXIETY DISORDER- GAD]
NAMC CODE - EM [*MANOVAHA SROTO VIKARA*]

7.3.1. INCLUSION CRITERIA

Children of either sex, aged between 14 and 16 years, who meet the DSM-5 TR diagnostic criteria for Generalised Anxiety Disorder (GAD) will be included in the study.

7.3.2 EXCLUSION CRITERIA

- Children below 14 years or above 16 years of age.
- Children currently undergoing psychological or psychiatric treatment.
- Subjects presenting with anxiety symptoms secondary to trauma, surgery, or underlying organic lesions.
- Children diagnosed with Neuro-behavioural disorders such as ADHD, Autism, Intellectual Disability, congenital disorders, developmental delays, or any autoimmune or genetic conditions.
- Children with chronic illnesses or systemic disorders currently under treatment that may interfere with the outcome or continuity of the study.

INTERVENTIONS:

Group	Drug	Dose	Age	Anupana	Duration	Clinical Assessment
TRIAL GROUP	*Tagaradi Ghana Vati*	500 mg BD	14-16 years	With *Sukhoshna Jala* before food	45 Days (30 Days - Intervention period, 15 Days Follow-up)	0th Day (BT) 15th Day Monitoring Day(DT) 30th Day (AT) 45th Day(AF)
CONTROL GROUP	Tablet *Brahmi* Extract	250mg BD				

METHODOLOGY :

Trial Group: Group-A Tagaradi ghana vati orally in a dose of 1 tablet (500mg) twice daily before food with sukhoshna jala for a period of 30 days

Control Group: Group-B Tablet *Brahmi* extract orally in a dose of 1 tablet (250mg) twice daily before food with sukhoshna jala for a period of 30 days

CONCOMITANT MEDICATION

Details of concurrent illness/medications consumed by participants registered under the trial will be recorded in the case report form. Registered patients will be instructed to avoid the use of any other drugs on their own for any ailment and will be clearly instructed to consult the treating Investigating physician for any symptom or complaint, or if they feel anything unusual. The Investigating physician will record any medication(s) he/she may prescribe to alleviate their concurrent ailments.

OUTCOMES:

Primary outcome measures:

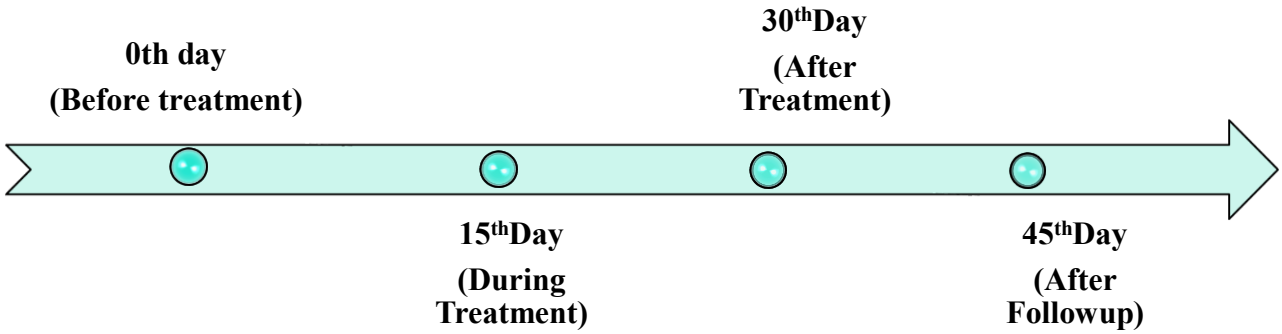
- Changes in symptoms of Generalised Anxiety Disorder (*Chittodvega*) among adolescents aged 14–16 years, using the Hamilton Anxiety Rating Scale (HAM-A).

- Changes in the *Mano Bhava's* among adolescents aged 14–16 years with Generalised Anxiety Disorder, assessed through *Manasa Pariksha Bhava's* scale.

Secondary outcome measures:

- Improvement in quality of life among adolescents aged 14–16 years with Generalised Anxiety Disorder, as measured by the WHOQOL-BREF scale.
- Reduction in severity of anxiety in adolescents aged 14–16 years with Generalised Anxiety Disorder, assessed using the GAD-7 scale.
- Enhancement in sleep quality among adolescents aged 14–16 years with Generalised Anxiety Disorder, evaluated through the Insomnia Severity Index (ISI).

PARTICIPANT TIMELINE:



SAMPLE SIZE:

The sample size is determined using a standard formula.

Sample size has been calculated based upon the Standard deviation of Previous Clinical study.

n (sample size) = $2(SD)^2 \times [Z(1-\alpha) + Z\beta]^2 / d^2$ this generates the minimum sample of 16children in each arm, considering 10% drop out, 30 sample size with 15 in each group will be taken.

RECRUITMENT:

Study group:

A total of fifteen school-going children aged 14-16 years attending the Outpatient Department of Kaumarabhritya at Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital, Bengaluru, will be initially screened for Generalised Anxiety Disorder (GAD) using the SCARED – Children's Anxiety Rating Scale. Diagnosis will be confirmed based on DSM-5 TR criteria for GAD, followed by detailed assessment using the Hamilton Anxiety Rating Scale (HAM-A). Subjects meeting the eligibility criteria will be enrolled in the study after obtaining informed consent from their parents.

Control group

A total of fifteen fifteen school-going children aged 14-16 years attending the Outpatient Department of Kaumarabhritya at Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital, Bengaluru, will be initially screened for Generalised Anxiety Disorder (GAD) using the SCARED – Children's Anxiety Rating Scale. Diagnosis will be confirmed based on DSM-5 TR criteria for GAD, followed by detailed assessment using the Hamilton Anxiety Rating Scale (HAM-A). Subjects meeting the eligibility criteria will be enrolled in the study after obtaining informed consent from their parents.

ALLOCATION AND CONCEALMENT:
Random allocation using computer generated random tickets which will be kept labelled in a sealed cover, to be opened in front of guide while starting the intervention.

METHODS:
The present study will be conducted as a double-blind, prospective, interventional, randomized controlled clinical trial**,** in which both the participants and the investigators will remain blinded to group allocation, while the study guide will be aware of the assigned groups.

DATA COLLECTION METHOD:
Data will be collected using a specially designed case report form (CRF) and assessment tools used would be Hamilton Anxiety Rating scale (HAM-A). *Manasa Pariksha Bhava's* Scale. GAD-7, Insomnia Severity Index (ISI), WHOQOL-BREF Scale.

DATA MANAGEMENT:
The collected data will be recorded in a specially designed case report form (CRF) by the researcher and later transferred to MS Excel and IBM SPSS Version 26 for analysis.

STATISTICAL METHODS:
For statistical analysis the data obtained from case report form (CRF) designed encompassing all aspects for the study and will be compiled on toa MS office excel sheet. Data will be tabulated and analysis will be done using SPSS (Statistical package for social sciences) version 26 for the following statistical tests.

DESCRIPTIVE STATISTICS:
Demographic data and other relevant information will be analyzed with descriptive statistics, Continuous data will be expressed by mean, standard deviation, Nominal and ordinal data will be expressed in percentage, Nominal and ordinal data will be analyzed with Wilcoxon-signed rank test and chi square test, Chi-square test will be analyzed for before and after intervention of numerical data.

INFERENTIAL STATISTICS:
To infer the clinical study and to draw conclusions Parametric and Non-Parametric tests will be applied accordingly.
LEVEL OF SIGNIFICANCE: $P<0.05$

NON-PARAMETRIC TEST:
For subjective data, Wilcoxon-signed rank test will be employed to assess before and after treatment differences within group. Mann Whitney U test will be done between the trial and control group. For multiple comparison more than 2 sets within same group Freidman test for non-parametric data would be used.

PARAMETRIC TEST:
For objective data, Unpaired t-test will be assessed between the group and Paired t-test will be assessed within group before and after treatment. Categorical data would be assessed with Chi square test. Effect

size is calculated by Cohen's D Formula.

DATA MONITORING:
The researcher and guide will oversee data monitoring, ensuring adherence to the intervention protocol, tracking adverse effects, and managing participant enrolment.

AUDITING: since it is a small trial external audit is not applicable. Self-funded.

ETHICAL ISSUES AND INFORMED CONSENT:
On August 16, 2025, the Institutional Ethics committee of Sri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital (SDMIAH) granted the trial ethical approval (**SDMIAH/IEC/17/2025**). The researcher will adhere to the Helsinki statement to maintain ethical principles.
The trial participants will sign a written informed consent before enrolment. The respondent's participation will be voluntary, and they will have the ability to leave at any point during the trial. Withdrawal from the trial will not have any effect on their treatment process. The completed trial dataset will be made available to the primary investigator, data auditors, and authors when the procedure has been made anonymous. The investigators are independent individuals who evaluate the patients and record their findings in hard copies; they are under contract not to disclose or have access to the final data. If there are any unfavourable consequences, there will be post-trial treatment.

STUDY STATUS: Open for Recruitment.

DISCUSSION:
Anxiety disorders are the most common mental health conditions affecting children and adolescents, significantly impairing academic performance, social relationships, and family functioning. Adolescence represents a critical developmental phase, during which untreated anxiety often persists into adulthood, resulting in long-term psychological and socio-economic consequences.
From an Ayurvedic perspective, anxiety disorders fall under *Manasika Rogas*, primarily involving vitiation of *Vata Dosha*and imbalance of *Manodoshas* (*Rajas* and *Tamas*), with disturbance of *Sattva Guna*, *Chittodvega* - characterised by mental agitation due to aggravated *Vata* and *Rajas*—provides the most appropriate Ayurvedic correlation.
Ayurveda offers promising interventions through *Medhya Rasayana* formulations; however, most existing studies focus on adults, with limited evidence in paediatric and adolescent populations. *Tagaradi Kwatha*, described in *Pralapaka Chikitsa Prakarana*, contains drugs such as *Tagara*, *Brahmi*, *Jatamamsi*, *Shankhapushpi*, and *Ashwagandha*, which possess anxiolytic, adaptogenic, sedative, and cognitive-enhancing properties.
To improve palatability and compliance in children, *Tagaradi Ghana Vati* was selected for evaluation. The present study was undertaken to scientifically assess its efficacy in managing GAD, conceptualised as *Chittodvega*, with the aim of establishing a safe, effective, and evidence-based Ayurvedic approach for adolescent anxiety.

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