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Ayurveda Section

Assessment of Add-on Effect of Satvavajaya Chikitsa (Counselling), Bhramari Pranayama versus Brahmi Ghrita in Vishada (Depression): A Three-arm Randomised Control Trial Protocol

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ABSTRACT

Introduction: Depression (Vishada) has emerged as a significant mental health concern worldwide, affecting over 300 million individuals globally, with a particular rise in young people in India. Traditional Ayurvedic approaches offer alternative and holistic treatments, emphasising the balance of mind (Mana) and body (Sharira). Vishada, as described in classical texts like Charaka Samhita and Sushruta Samhita, represents a state of persistent sadness, loss of self-confidence, and mental incapacity, often leading to disturbances in daily functioning. Traditional Ayurvedic treatments such as Satvavajaya Chikitsa (Counselling), Bhramari Pranayama, and Brahmi Ghrita have been suggested for managing Vishada. The current study aims to evaluate the efficacy of these interventions in comparison.

Need of the study: Over 300 million people globally suffer from depression, projected to be the leading cause of disability by 2030. In India, 31-57% of youth are affected, yet 75% in low and middle-income countries lack access to treatment. Conventional antidepressants often have side effects, highlighting the need for affordable, holistic alternatives. This study evaluates the effectiveness of three Ayurvedic therapies - Satvavajaya Chikitsa (counselling), *Bhramari Pranayama* (breathing exercise), and Brahmi Ghrita (herbal formulation)-in managing depression.

Aim: To assess the add-on effect of *Satvavajaya Chikitsa* (Counselling), *Bhramari Pranayama* versus *Brahmi Ghrita* in *Vishada* (Depression).

Materials and Methods: The present study will adopt a randomised controlled trial design. The study will start from June 2025 and be conducted over 21 days for all groups, with measurements recorded on the 0th, 7th, 14th, and 21st days. Patients will be enrolled for treatment at the Mahatma Gandhi Ayurved College, Hospital, and Research Centre in Wardha Maharashtra, India, covering both Outpatient Department (OPD) and Inpatient Department (IPD) services under the Kayachikitsa Department. The sample consists of 123 patients diagnosed with depression, aged 16-40 years, both male and female, with a Beck Depression Inventory (BDI) score between 21-30 and a Hamilton Depression Rating Scale (HDRS) score between 17-23. Participants are randomly assigned to three groups: Satvavajaya Chikitsa (Counselling) and Brahmi Ghrita, Bhramari Pranayama, Brahmi Ghrita, and Brahmi Ghrita alone. Each group undergoes a 24 day treatment period. The primary outcome was the reduction in depression symptoms measured by the BDI and HDRS scales. Secondary outcomes include improved psychological well-being, reduced anxiety and stress, and overall patient satisfaction.

Keywords: Charaka samhita, Mansik vikar, Mental health

INTRODUCTION

Ayurveda follows a holistic approach to healthy and long life. The disturbance of *Doshas* in *Sharira* (Body) and *Mana* (Mind) leads to disease [1]. According to *Ayurveda*, Mental and physical health are necessary. In today's era, the number of *Mansik Vikar's* incidents is rising daily, affecting all age groups and genders. In the classical text, a wide range of *MansikVikars* has been mentioned.

In Charak Samhita, Sushruta Samhita, and Vagbhatta Samhita, etc., the term Vishada (Depression) [2], has been mentioned in various contexts as the cause as well as a symptom of the diseases and a disease itself. Vishada is described as having a persistent sad mood and a feeling of incompetence due to the perturbation resulting in proper Mana (Mind) and Sharira (Body). Depression (Vishada) is a condition that originates from the fear of failure in our lives, which results in an inability of the mind and body to function do things properly. Depression is a feeling of self-incapability to act upon any desired work or loss of self-confidence [3]. The sense of constant sadness [4], unsuitable guilt, and sadness are the symptoms of Depression [5].

Depression includes anxiety (Avasada), which is characterised by lassitude of the body, intellect, and speech. This suggests that one is feeling unresponsive or that one's mental and physical actions are being delayed [6].

Depression has existed for thousands of years; it is not a recent illness. Arjun's Depression (Vishada) marked the beginning of the *Bhagwat Geeta* itself. As Arjuna told Krishna, the Geeta must be spoken to rescue *Arjuna* from these objects of Depression (*Vishada*). As a result, *Arjuna Vishada Yoga* is the name given to the first chapter of the *Geeta* [7].

Over 300 million people worldwide suffer from depression, which the World Health Organisation (WHO) estimates will be the major cause of disability by 2030 [8]. According to recent studies, the prevalence of depression among young people in India is rising, with rates ranging from 31% to 57% [9]. Additionally, according to United Nations International Children Education Fund (UNICEF), one in seven Indian youth aged 15 to 24 experience constant depression or lack of interest in activities [10]. This implies that mental health issues are quite common in this group, which may have detrimental long-term effects on their general well-being and standard of living.

A poor mood or a prolonged loss of enjoyment or interest in any activity is hallmarks of depression, a common mental health illness. Because depression impacts many aspects of life, including relationships with family, friends, and the community, it differs from other mood swings and sentiments about day-to-day living [11].

Now, the depression is widely spreading because the new generation does not know how to deal with their problems. They do not know that excitement cannot remain constant; it is contrary to the rhythm of life. If we want to avoid sadness, the child should be taught during upbringing that life is not a highway but a path to a mountain.

In Ayurveda, one of the three broad-based therapeutic philosophies is called Sattvavajaya Chikitsa, or counseling therapy. It is especially recommended for the management of mental health conditions. Charaka says it involves keeping the mind away from unwholesome things (Arthas). According to Ayurvedic literature, Sattvavajaya is essentially psychotherapy. The term "Sattvavajaya" was first used by the scholar Charaka. His definition leaves a lot of room for interpretation and practical application. "Sattvavajaya Punah Ahitebhyo Arthebhyo Manognigrah" [12].

Therefore, the method is therapeutic for emotional or mental stressors and disruptions, according to Sattvavajaya. This is best achieved by cultivating Gyana, Vigyana, Dhairya, Smrti, and Samadhi and controlling the mind's attraction to unwholesome things and guiding it toward wholesome ones. Every one of these actions aids in developing control on top of the mind, or *Manas*, which is inherently unstable.

Acharya Charaka has detailed several psychologically uplifting methods that fall under the general category of Ayurvedic counseling therapy, or *Sattvavajaya Chikitsa*. *Santwana* (rehabilitation and reassurance), *Tadana* (physical shock), *Trasana* (mental shock), *Istavinasana* (verbal shock: milieu therapy), *Adbhuta darshana* (showing extraordinary things), *Suhritvakya* (guidance and suggestion), *Dharmarthavakya* (education for individuals and families), and *Aswasana* (reassurance and clarification) are psychological interventions that he advocates for [13].

Pranayama is a method for regulating health and managing medications. This practice enables individuals to achieve a profound state of relaxation while maintaining mental alertness [14]. Pranayama is associated with numerous anti-aging benefits, extending beyond physical health to include emotional, spiritual, and social improvements. Additionally, it alleviates stress and depression (Vishada) and is notably accessible, as it can be performed anywhere and at any time without the need for specialised equipment or attire [15].

The word "Bhramari" comes from the Sanskrit word "Bhramar," which means wasp. Because of the buzzing sound made during expiration, which resembles the flying wasp, it is known as Bhramari pranayama. The exploration of the advantages of this Pranayama reveals that the self-generated humming sound produced during the practice resembles the technique of mantra repetition. Bhramari pranayama modifies the typical breathing pattern by extending the exhalation and shortening the inhalation, leading to notable effects on the physiological system [16].

Bhramari Pranayama can induce a meditative state; thus, it can be considered as a form of meditation [17,18]. Bhramari Pranayam assists in clearing the mind of anger and other mental agitation, annoyance, or anxiety. Among older adults, it enhances memory and focus and helps with many sleep-related issues [19].

Brahmi Ghrita is a classical Ayurvedic Ghrita-based herbal formulation, like Brahmi, Vacha, Kushtha, Shankhapushpi, and Purana Ghrita [20]. The main content of Brahmi ghrit is Brahmi (Bacopa monneri). Brahmi is a Medhya drug (nootropic drug) and is used in the management of various psychiatric and psychosomatic disorders. It is used as a medicine as well as in preparatory procedures for Panchakarma, like snehakarma. Brahmi Ghrita

balances all three *doshas-Vata*, *Pitta*, and *Kapha*. It is used in the management of *Unmada* (insanity), *Apasmara* (epilepsy), and *Graharogas* (diseases afflicted by evil spirits). It helps to improve intelligence, speech, and learning skills [21].

Objectives

Primary objectives: To evaluate the add-on effect of *Satvavajaya Chikitsa* (Counselling) and Brahmi Ghrita *Vishada* (Depression). To evaluate the add-on effect of *Bhramari Pranayama and Brahmi Ghrita in Vishada* (Depression).

Secondary objective: To compare the efficacy of *Satvavjaya Chikitsa* (Counselling), *Bhramari Pranayam*, and *Brahmi Ghrita Vishada* (Depression).

REVIEW OF LITERATURE

Depression (Vishada) is described as swift in mood, marked by a tone of sadness that can range from a sliding sense of bloom to the deepest despair [22]. The shift in mood that occurs during Depression is comparatively permanent and can last for days, weeks, months, or even years.

In addition to depression (Vishada) descriptions by Acharya Charak, Sushrut, and Vagbhatt, commentators Chakrapani Dutt and Dalhanhave expanded on it and provided precise definitions that align with contemporary scientific perspectives. Acharya Charak mentioned that Vishada is a VatikaNanatmaja Vyadhi (disease) [23]. It is what broadens the spectrum of all illnesses. The Charak Samhita mentions Anumanjanyabhava like "BhayamVishaden" which refers to comprehending the anxiety that a person feels when they witness a depressed mood or behavior [24].

According to *Manovikaras*, *Aacharya Sushrut* referred to it. Some of the terminologies employed in Ayurvedic classics are only comparable to 'Avsad'. Examining the phenomena of *Nidra*, *Buddhi*, *Krodh*, *Medha*, *Abhimana*, *Shok*, *Manodainya*, *Glani*, etc., might help one better understand the idea of depression [25].

Regarding Nidra (Sleep), Aacharya Dalhan stated that Sadhak Pitta cleared the Tama and Kapha that surrounded the heart (Hriday), allowing the Mana (mind) to see clearly [26]. According to Sushrut [27], depression is widespread in Tamasika prakriti individuals and is caused by the dominance of Tamoguna, which Vagbhatt mentioned [28]. Vishadacan be associated with Depression, i.e., state of emotion (MansikBhav) and a medical ailment (MansikVyadhi), as its symptoms are comparable to those of Depression in severalreferences [29].

MATERIALS AND METHODS

An interventional study will be conducted for 21 days from June 2025, on patients diagnosed with moderate Depression (*Vishada*) using the BDI and Hamilton scale (BDI scale 21 to 30 and Hamilton score 17 to 23) at the Mahatma Gandhi Ayurved College Hospital and Research Centre and ABVRH DMIHER Wardha, India. The institutional ethics committee of MGAC DMIHER has approved the study under reference number MGAC/HRC/IEC/June 2024/86.

Before beginning the study, each participant will be asked for their informed consent. Additionally, on November 1, 2024, the study was registered with the Clinical Trial Registry of India (CTRI) under registration number 2024/11/076152.

Inclusion criteria: Patients are willing to give written informed consent to participate in the study; Patients between the age group of 16 to 40 years of either gender; Patients with a BDI score between 21 to 30 and a Hamilton scale of 17-23; Patients having symptoms of Depression (*Vishada*).

Exclusion criteria: Severe patients of Depression have BDI scores more than 30 and Hamilton; Patients below the age of 16 and over 40; History of psychosis, bipolar disorders other severe psychiatric

illnesses; Any patient using psychotropic medications; Pregnant and lactating women; Known cases of CKD (chronic kidney disease), CLD (Chronic Liver Disease), CAD (coronary artery disease), and Cancer.

Sample size calculation: Using the formula, the estimated sample size for the study was determined [30].

- Alpha (α): 0.05 (Significance level) =1.96
- Beta (β): 0.2 (Power = 1 β = 0.8) =0.80
- Proportion in Group-1 (P1): improvement in *Mandacheshta* (45.99%) = 0.4599 (As per reference article)
- Proportion in Group-2 (P2): improvement in Mandacheshta (75.99%) = 0.7599
- Ratio of group sizes (Group-2/Group-1): 1:1 (r) =1

The formula for calculating the sample size for comparing two proportions is: n \geq [(Z_{1-\alpha/2} \(\sqrt{(r+1} \cdot p(1-p) \)) + Z_{1-\beta} \(\sqrt{(r} \ p_1(1-p_1) + p_2(1-p_2) \)]^2 / [r \((p_2 - p_1)^2 \)]

Where,

- $-p = (p_1 + r \cdot p_2)/(1 + r)$
- r is the ratio of the group sizes.
- Z_{1- α /2} is the Z-score that corresponds to the significance level with two sides.

The required power's Z-score is represented by $Z_{1-\beta}$.

- p₁ and p₂ are the proportions for the two groups.
- Minimum sample size needed is 41 per Group

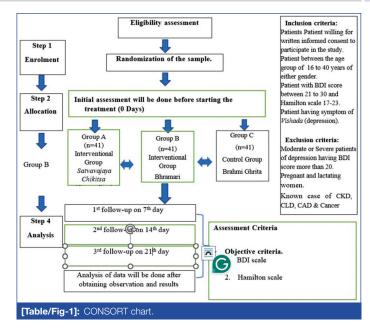
Study Procedure

Patients will be randomly chosen and assigned to three distinct groups based on the Beck Depression Inventory (BDI) [31] and the Hamilton scale scoring method [32]. Following the established inclusion and exclusion criteria, a comprehensive physical examination and clinical history will be collected. Participants will be selected if they have BDI scores ranging from 21 to 30 and Hamilton scores between 17 and 23. These individuals will be recruited from ABVRH and the Mahatma Gandhi Ayurveda College Hospital and Research Center in Sawangi (Meghe), Wardha, Maharashtra India. Total 123 patients will be allocated into three groups, each consisting of 41 participants, designated as Group-A, Group-B, and Group-C. Group-A will receive Satvavajaya Chikitsa (counseling) weekly, along with 6 mL of Brahmi Ghrita administered twice daily, one hour before meals with lukewarm water. Group-B will undergo Bhramari Pranayam for 5-10 minutes daily, in addition to the same dosage of Brahmi Ghrita as Group-A. Group-C will be treated solely with 6 mL of Brahmi Ghrita twice daily, one hour before meals with lukewarm water. Follow-up assessments will occur every seven days to evaluate depression symptoms using the BDI and Hamilton scale. The study will span a total of 21 days, as mentioned in [Table/ Fig-1]. Informed consent will be obtained from all participants, and patient data will be kept confidential during and after the study. The study will adhere to ethical guidelines and applicable regulatory standards.

The Gantt chart outlines the phased timeline of the study over six quarters, starting with IEC approval and literature review, followed by drug preparation, patient enrollment and data collection. The final phases include statistical analysis, thesis writing, and submission, ensuring systematic completion of the researchas mentioned in [Table/Fig-2].

Primary outcome: Change in the intensity of depression as determined by the Hamilton Depression Rating Scale (HARS) on the BDI. A popular and validated clinician-rated scale that offers a thorough evaluation of depressed symptoms is the BDI and Hamilton Rating Scale for Depression (HAM-D).

Secondary outcome: Shift in the BDI depression severity scale. A validated depression-specific quality-of-life questionnaire can be



Scholar/Investigator	Dr. Vikas Chaurasiya					
Title	"Assessment of add-on effect of Satvavajaya Chikitsa (Counselling), <i>Bhramari Pranayama</i> versus Brahmi Ghrita in Vishada (Depression)- A three-arm Randomised Control Trial"					
Steps	Q1	Q2	Q3	Q4	Q5	Q6
Approval from IEC						
Review of literature						
Drug preparation						
Enrollment of the patients						
Data collection						
Statistical analysis						
Thesis writing						
Submission						
[Table/Fig-2]: Showing a Gantt Chart.						

used to measure improvements in quality of life. A standardised sleep questionnaire can be used to measure changes in the quality of sleep. Anxiety scales, such as the generalised anxiety disorder scale, can be used to measure changes in anxiety levels.

STATISTICAL ANALYSIS

For statistical analysis, we will use Statistical Package for Social Sciences (SPSS) version 27.0, a statistical software for social sciences. Continuous variables will be presented as mean ± SD, median, and standard deviation (Interquartile Range (IQR), and group differences will be presented as frequency (%). The Kolmogorov-Smirnov test will be used to determine whether the data are normal. Continuous differences between depressed patients (Vishada) and healthy controls will be compared with the Wilcoxon rank sum test, the rank sum test, or student t-test (for data with normal distribution). Kruskal-Wallis test (for data with abnormal distribution) or analysis of variance (ANOVA) was used when more than two groups were compared. The Chi-square test can be used to examine and measure the relationship and dependency between different categorical variables, and the Pearson test (for normally distributed data) or the Spearman test (for randomly distributed data) can be used to test the correlation between different variables. Categorical variables (movement) will be used to associate with a continuous variable. A p value of less than 0.05 will be considered significant.

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