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OPEN CLINICAL TRIAL TO ASSES THE EFFECT OF *BACOPA MONNIERA* ON STRESS RELATED PROBLEM IN HUMAN VOLUNTEERS

Tirath Kumar^{1*}, Ranjit Singh¹, A.K. Wahi², H.K. Singh³

Affiliated to:

1. School of Pharmaceutical Sciences, Shobhit University, Meerut, Uttar Pradesh.
2. Former Deputy Director CDRI Lucknow, Uttar Pradesh.
3. Former Professor, Department of Pharmaceutics IT., BHU, Uttar Pradesh.



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ABSTRACT

The effect of bacoside enriched standardized extract of *Bacopa monniera* (BESEB-CDRI-008) on stress related problem was studied in human volunteers. The volunteers were randomly selected; both male and female of age between 25 to 70 years, ambulatory and cooperative were employed in study. The parameter like effect on Blood Pressure, TLC, Pulse, Ache of muscle, appetite, sleep abnormality, well being, anxiety, dizziness, stress, were studied, on area under curve (AUC) of responses. A clinical assessment of each eligible volunteer was carried out at a base line (0 month) and scheduled clinical visits at 1, 2, and 3....up to 12 months. The progress of trial and compliance of instruction were weekly monitored by personal visit or telephonically. The effect of drug was compare between the first six month response and the second six month response. Statistical analysis was done by student t test. The data indicate that BESEB has shown the improvement in all the parameter ($p>0.01$), and confirms the anti stress property.

Keywords: - *Bacopa monniera* (BESEB-CDRI-08), Stress, Area under curve (AUC)

INTRODUCTION

Brahmi, *Bacopa monniera* (Linn.) Wettst, (schophulariaceae) is reported to a nerve tonic, cardiogenic and diuretic in Indian traditional medicine.¹

It is a small, creeping herb with numerous branches, small oblong leaves, and light purple flowers. In India and the tropics it grows naturally in wet soil, shallow water, and marshes. It is also found in Nepal, Srilanka, China, Taiwan, Vietnam, Florida and Southern states of USA.^{2,3}

Brahmi is frequently mentioned in the religious, social and medical treatises of India since the period of Vedic civilization antiquity and can be traced to the time of *Ather ved* (800 BC) where *Brahmi* finds a mention in the very first *richa* of the third chapter.

Although, it has been frequently mentioned in the religious, social and medical treatises of India since the time of *Athar-Ved* (C.800 BC), The first clear reference to its memory augmenting property is to be found in *Charak Samhita* (C.100BC), where *Brahmi* is prescribed as a cure for mental disorder (retardation) leading to insanity (10:62). The etiology of the mental disorder according to *Charak* is a combination of anxiety, weak intellect and lack of concentration. Another authentic *Ayurveda treatise*, i.e., *Susruta Samhita* has described *Brahmi* as efficacious in loss of intellect and memory.

Brahmi has been used by Ayurvedic medical practitioners in India for almost 3000 years and is classified as a *Medhya rasayana*, a drug used to improve memory and intellect (medhya). It has been used to treat conditions such as bronchitis, coughs, asthma, hoarseness, arthritis, allergies, rheumatism, inflammatory conditions, constipation, boils, ulcers, fever,

digestive problems, epileptic fits, depression including post natal depression, diarrhoea, irritable bowel syndrome, frigidity, irregular menstruation, mental and physical fatigue, exhaustion, restlessness, insomnia and over active mind, mental deterioration of the elderly, forgetfulness, confused and cloudy thoughts, anxiety, stress, nervous breakdown, insanity and to improve circulation, strengthen capillaries and stimulate hair, skin and nail growth.⁴

Although, *Brahmi* is used as a potent antioxidant and broncho-vasodilator. It decreases the rate of forgetting of newly acquired information and improves cognitive function in healthy human, no work on Rasayana effect of *Brahmi* has been reported so far. The Rasayana therapy (Rejuvenating therapy) aims specially at the promotion of strength and vitality. The other benefits of *Rasayana* therapy are promotion of memory and intelligence, immunity against diseases and decay, preservation of youthfulness, luster, complexion and voice.

Therefore, the present study, a clinical evaluation of efficacy of *Brahmi* (*Bacopa monniera*) in reducing stress and promotion of health in adult human volunteers was undertaken.

Now a day's stress is a common world wide problem. The word **stress** is derived from the Latin word "stringi", which means, "to be drawn tight".⁵ Stress can be defined as "a physical or psychological stimulus that can produce mental tension or physiological reactions that may lead to illness."

World Health Organization has stated that stress has become a "World Wide Epidemic." Stress, anxiety, worry, aggression have all increased significantly in recent years. Individuals throughout the world are reacting

physically and mentally to constant stress, tension, and anxiety.

Exposure to stressful situations is one of the most common human experiences. According to a Gallup poll, 80% of workers feel stress on the job, and according to the National Institute of Occupational Safety and Health (OSHA), job-related stress is fast becoming the most prevalent reason for worker disability.

Stress reduces the performance level down, ultimately leading to exhaustion, ill-health and, finally breakdown.⁶

The main causes of stress are headache, lack of energy, sadness, angerness, memory problem, trouble in sleeping, mental health problem such as anxiety and depression. Also due to muscle ache and tension, faster hearts beat and rise in blood pressure, increased risk of cholesterol and heart attack, stomach pain, heartburn, and weight gain. Due to diabetes, diarrheal constipation, and other digestive problem, problems in reproductive system and reduction in immune response are the main causes of stress.

The symptoms of stress are Acid reflux, Anger, Back pain, Chest pain, Constipation or diarrhea, Depression, Dizziness, Headaches (tension or migraine), Heartburn, High blood pressure, Insomnia, Irritable bowel syndrome (IBS), Ligament and tendon problems, Rapid heartbeat or heart palpitations, Relationship problems, Shortness of breath, Stiff neck, Sweaty palms, Weight gain or loss, Hypertension, Addiction (drinking too much, smoking, overeating, or doing drugs), Anxiety or panic attacks, Memory problems, Obesity, sleeping problems, Sadness or depression.

Methodology –

Dose schedule

The volunteers received standardized *Brahmi* extract at a dose of 300 mg per day for 180 days

and than the same dose for next 180 days.

Study design-

The Clearance of institution ethics committee was taken from the college of Pharmacy IFTM, Moradabad. The 15 volunteers were randomly selected after following, inclusion criteria and exclusion criteria, the subjects were healthy, age between 25-70 years, Ambulatory and cooperative, included in the study. Subjects were not included in the study who were suffering from Cancer, AIDS, kidney related disorder and liver dysfunction, undergoing treatment for serious chronic illness, with any other medical condition that, in the judgment of the investigator, confounded the objectives of the study, which was undergone major hospitalization or any surgery during past 3 years.

Assessment of each selected volunteer was carried out at a base line (0 month) and scheduled clinical visits at 1, 2, and 3....up to 12 months. At each study visit including the initial visit all volunteers went for same determination. As per plan, before administration of drug to volunteers, the sample of blood was taken for analysis and the data recorded in a file of each volunteer. All the volunteers were given monthly schedule for coming for blood analysis and other tests. The progress of trial and compliance of instruction were weekly monitored by personal visit or telephonically.

Methods-The parameter like effect on Blood Pressure by korotkoff method.⁷ TLC by, Pulse by pulse oxymeter, Ache of muscle, appetite, sleep abnormality, well being, anxiety, dizziness, stress, were studied by visual analogue scale, the visual analogue scale was based on 10 point scale from 0 to 10 point. 0= no improvement to 10 improvement.⁸

Withdrawal and termination criteria: During the course of the trial treatment serious condition, if developed, which requires urgent treatment such subjects, were withdrawn from the trial.

Statistical analysis- was done by employing student t test.

Table 1: Table showing effect of *Bacopa monniera* analyze on 12 Months AUC

	DIASTOLIC B.P.	SYSTOLIC B.P.	PULSE	Ache of muscles in General	sleep abnormality
N	15.000	15.000	15.000	15.000	15.000
Mean 1-6	478.467	720.100	456.967	12.433	7.400
SD 1-6	27.804	52.919	33.271	13.783	10.516
SE 1-6	7.179	13.664	8.591	3.558	2.715
Var 1-6	773.052	2800.400	1106.981	189.960	110.579
N	15.000	15.000	15.000	15.000	15.000
Mean 6-12	413.367	620.467	383.933	28.000	21.100
SD 6-12	19.949	35.655	19.185	6.819	5.292
SE 6-12	5.151	9.206	4.954	1.760	1.366
Var 6-12	397.981	1271.267	368.067	46.500	28.007
SE-Pooled Mean12-Mean6	8.836	16.476	9.916	3.970	3.040
t-Value	-65.100	-99.633	-73.033	15.567	13.700
Significance	**	**	**	**	**

Table 2: Table showing effect of *Bacopa monniera* analyze on 12 Months AUC.

	Anxiety	Dizzeness	TLC	Assessment of General Well-being	STRESS
N	15.000	15.000	15.000	15.000	15.000
Mean 1-6	11.700	3.033	41328.000	13.800	11.367
SD 1-6	8.462	8.247	4008.215	5.095	10.192
SE 1-6	2.18	2.14	1034.917	1.31	2.631
Var 1-6	71.600	68.017	16065785.	25.957	103.874
N	15.000	15.000	15.000	15.000	15.000
Mean 6-12	22.933	18.967	49813.333	40.267	22.900
SD 6-12	4.153	3.351	4743.886	6.079	6.345
SE 6-12	1.072	0.86	1224.866	1.56	1.63
Var 6-12	17.245	11.231	22504452.381	36.960	40.257
SE-Pooled Mean12-Mean6	2.434	2.299	1603.543	2.048	3.100
t-Value	11.233	15.933	8485.333	26.467	11.533
Significance	4.616	6.932	5.292	12.923	3.721
	**	**	**	**	**

TLC levels were increased by 13.07 % ($p < 0.01$), 17 % ($p < 0.01$) respectively. The level of systolic and diastolic **blood pressure** was reduced by 13.5% and 13.8% ($p < 0.01$) respectively. **Pulse rate** was reduced by 15% ($p < 0.01$). **Muscle Ache improvement** was 87.6% ($p < 0.01$), **sleep abnormality**, 38% ($p < 0.01$), respectively. Improvement in the **stress** level was observed by 100% ($p < 0.01$), **Assessment of general well being** observed by 191% ($p < 0.01$). A decrease in dizziness was 52.5 % ($p < 0.01$) in the second half of the study than the first half.

Discussion- Increased in TLC shows the BESEB increase the immunity. The blood pressures both systolic and diastolic were found to be reduced. Over all it can be said that BESEB reduce the stress. It is also supported by decrease in the pulse rate; further the drug has shown the improvement in depth of sleep. The general wellbeing is improved and the volunteer feels good in health. Dizziness was also reduced which shows further improvement in health to reduced the stress related problem.

Conclusion- BESEB has shown improvement on both chemical and physical level, it has shown improvement in stress related symptoms, as well as effective in causes of stress. So it is effective in reduction of stress. Volunteers were able to work more as they were feeling fresh and more energetic.

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