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A CLINICAL VALIDATION OF SAFETY AND EFFECTIVENESS OF DE-STRESS & FOCUS TABLET

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ABSTRACT

Background: Neuropsychiatric conditions like Attention Deficit Hyperactivity Disorder (ADHD) and stress disorders significantly impact global population functioning. With worldwide ADHD prevalence ranging from 5.29% to 7.1%, there is a critical need for alternative therapeutic interventions. This clinical trial investigated the safety and efficacy of a novel nutraceutical formulation in managing stress and improving cognitive performance. **Materials and Methods:** A 30-day open-label, non-randomized clinical trial was conducted with 30 participants (10 males, 20 females). Participants received one De-Stress & Focus tablet daily. Efficacy assessments included haematological parameters, vital signs, and self-reported measures of alertness, memory, and energy levels using a 4-point Likert scale. Safety was evaluated through adverse event monitoring and biochemical investigations. **Results:** Significant improvements were observed in participants' cognitive functions. At baseline, 27 subjects reported worsened alertness and memory, which improved to 100% satisfactory levels post-intervention. Statistically significant reductions were noted in systolic blood pressure ($p=0.035$) and body temperature ($p<0.001$). Haematological parameters remained stable, with a notable increase in haematocrit levels (37.10% to 39.79%, $p=0.008$). Only 3 participants (10%) experienced mild adverse events unrelated to the investigational

product. **Conclusion:** The De-Stress & Focus tablet demonstrated excellent tolerability and potential efficacy in improving cognitive performance and managing stress. The comprehensive nutraceutical formulation shows promise as a safe alternative approach to supporting mental well-being and cognitive function.

KEYWORDS: De-stress, Focus, Alpinia galanga, Ashwagandha, Cognitive function, Stress reduction.

INTRODUCTION

The neuropsychiatric illnesses Attention Deficit Hyperactivity Disorder (ADHD) and stress disorders are common and significantly impede day-to-day functioning. Stress disorders impact a significant proportion of people globally and are typified by excessive concern, tension, and physiological arousal. ADHD, which is characterized by impulsivity, hyperactivity, and inattention, frequently first appears in infancy and frequently lasts into adulthood.[1] Worldwide, the estimated prevalence of ADHD varies from 5.29% to 7.1%. The range of 2% to 17% is the prevalence of ADHD in the Indian context.[2,3]

Pharmacotherapy, which uses drugs that target neurotransmitter systems including dopamine and norepinephrine, is a common part of the current allopathic therapies for these illnesses. As a first-line medication for attention-deficit/hyperactivity disorder (ADHD), long-acting stimulant formulations are advised. Extended-release (ER) amphetamine (AMP) and methylphenidate (MPH) formulations have been available for the last 20 years.[4,5] Methylphenidate hydrochloride has been reported to have the potential to cause behavioral alterations in several research investigations. These changes include being easily agitated, more prone to sobbing, staring fits, feeling anxious, depressed, biting one's nails, feeling euphoric, and speaking less. In particular, tiredness and anxiousness were the most commonly reported symptoms among adult participants.[6]

The discovery of methylphenidate hydrochloride side effects highlights the need to investigate other ADHD therapies, such as herbal remedies like *Alpinia galanga*. *Alpinia galanga* has drawn interest due to its possible efficacy in treating symptoms of ADHD, leading to analogies with traditional medication.[7] The purpose of research on the medicinal effects of *Alpinia galanga* is to compare the herb's effectiveness in reducing symptoms of ADHD and stress disorders to those of approved pharmaceutical therapies. The purpose of this study is to see whether *Alpinia galanga* provides results that are on par with or better

than standard drugs in terms of managing symptoms, maybe with fewer side effects. This kind of research is essential to improving patient-centered care using evidence-based techniques and increasing the range of ADHD and stress-related illness treatment choices.[8]

Growing interest has been shown in the use of natural substances like ashwagandha and Alpinia galanga in nutraceutical treatments for the treatment of attention difficulties and stress alleviation in recent years. In traditional Ayurvedic medicine, ashwagandha is a well-known adaptogenic herb that has attracted attention for its capacity to lower stress levels and enhance cognitive function.[9,10]

The purpose of this clinical trial study is to investigate the safety concerns and effectiveness profiles of these nutraceuticals, as well as their therapeutic potential whether used singly or in combination. This study aims to provide insight into their functions in stress reduction and focus improvement, which will help develop new strategies for treating these illnesses.

MATERIALS AND METHODS

Study Design

The current study was designed as an open-label, single-arm clinical trial conducted at Lokmanya Medical Research Centre & Hospital in Pune, India. The research protocol received comprehensive approval from the Institutional Ethics Committee and was officially registered with the Clinical Trial Registry of India (registration number CTRI/2024/03/064117).

Investigational Product Details

The investigational product was a carefully formulated botanical blend designed to address stress and sleep-related concerns. The active ingredients comprised Enxtra Extract (*Alpinia galanga* 300 mg), Saffron Extract (*Crocus sativus* 30 mg), Vitamin B-3 (Nicotinamide 14 mg), Vitamin B-6 (Pyridoxine hydrochloride 1.90 mg), Vitamin B-12 (Cyanocobalamin 2.20 mcg), Ashwagandha KSM 66 Full Spectrum Extract (*Withania somnifera* 250 mg), Blueberry Extract (*Vaccinium corymbosum* 500 mg) and the product was stored under controlled environmental conditions.

Inclusion Criteria

Participant selection followed stringent inclusion criteria. The study recruited healthy volunteers aged 18 to 60 years, with specific focus on individuals experiencing mild to

moderate stress and insomnia symptoms, experiencing a perceived impact on alertness, memory, and energy levels; Subjects able to provide written informed consentapproved by the ethics committee, and willing to complete the study intervention and follow-up were enrolled in the study. Eligible participants demonstrated Perceived Stress Scale (PSS) scores between 7-26 and had abstained from sedatives, anti-depressants, and mood-altering medications for at least one year.

Exclusion Criteria

Exclusion criteria were comprehensive, precluding participation of individuals with specific health conditions, including pregnant or lactating women, those with histories of substance abuse, recent surgeries, neurological conditions, or significant comorbidities.

METHODOLOGY

This was an open-label, non-randomized study, wherein each subject received 1 bottle containing 30 De-Stress & Focus Tablets for 30 days. A total of 30 male and female subjects were enrolled in the study, and there were no subject dropouts as depicted in Fig. 1. During the screening visit, the subjects'; demographic details, including sex, age, body weight (kg), height (cm), and habits, were recorded. Medical history and concomitant diseases & medication assessment were also conducted. Efficacy assessments were performed at baseline and on day 30 to evaluate clinical improvement, vital signs, symptoms, and rescue medication use. Hematological parameters (CBC), liver function tests (LFT), and renal function tests (RFT) were also assessed at screening and on day 30. The study included participants with mild to moderate perceived stress. The subjects'; self-reported alertness, memory, and perceived energy throughout the day were assessed using a Likert scale (0-worsened, 1- not improved, 2- improved, 3-improved satisfactory) at screening and on day 30. Treatment compliance, safety, and tolerability of the study intervention were evaluated in terms of adverse events (AEs) and serious adverse events (SAEs) from baseline to the end of the study.

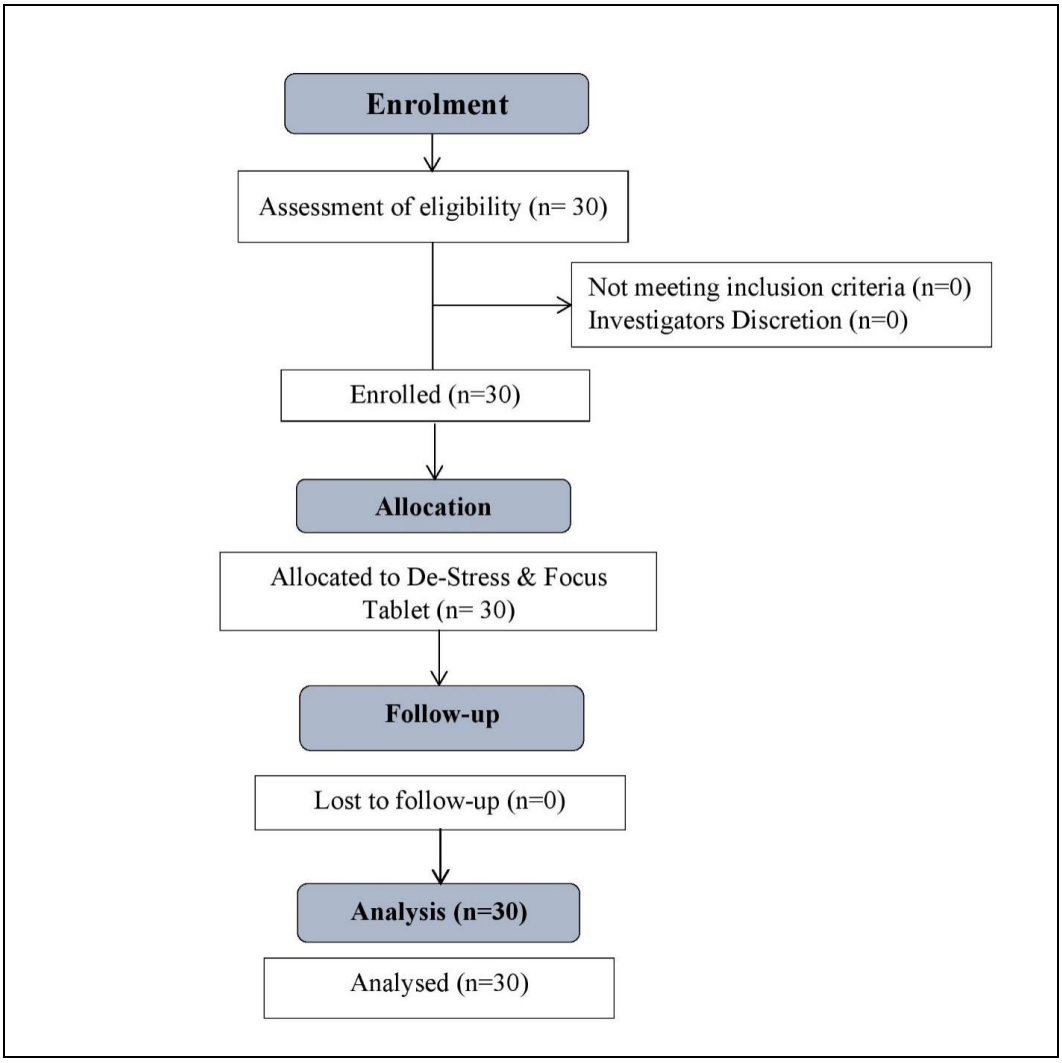

Figure 1: CONSORT Diagram.

Statistical Analysis

Data normality was assessed using the Kolmogorov-Smirnov Test. Demographic details were analysed via Independent student t-test. Hematological and biochemical investigations were evaluated using dependent student t-test and Wilcoxon signed rank test. Self-reported alertness, memory, and energy levels were analysed through Wilcoxon Signed-Rank Test.

RESULTS

Demographic Characteristics

All 30 participants (10 males and 20 females) successfully completed the study. The average age of the subjects was 47.13±10.27 years. Male participants had an average weight of 68.00 kg, a height of 166.40 cm, and a BMI of 24.72 kg/m². Female participants had an average weight of 65.20 kg, a height of 155.65 cm, and a BMI of 26.90 kg/m². These demographic details are summarized in **Table 1**.

Table 1: Demographic Details.

Parameter	Male Mean ± SD (n=10)	Female Mean ± SD (n=20)	P value
Average Age (Years)	**43.40±15.07**	49.00±16.52	0.163
	47.13±10.27		
Anthropometric Parameters			
Weight (kg)	**68.00±9.57**	65.20± 12.85	0.548
Height (cm)	**166.40±5.15**	155.65 ± 7.51	<0.001
BMI (kg/m^2)	**24.72±4.61**	26.90± 4.69	0.234

All parameter data was analyzed using the independent student t-test at p-value < 0.05.

Assessment of haematological and biochemical investigations

The analysis of the hematological and biochemical parameters showed no statistically as well as clinically significant changes between the screening and day 30-time points, except for a statistically significant increase observed in the hematocrit (PCV) levels from screening (37.10 ± 5.62%) to day 30 (39.79 ± 5.70%) (p = 0.008).). All other blood parameters, including white and red blood cell counts, hemoglobin, liver function tests, and kidney function tests, remained stable and within the respective reference ranges throughout the study period. These findings indicate the study intervention did not have any clinically relevant impact on the participants' overall blood profile during the 30-day evaluation (**Table 2**).

Table 2: Assessment of hematological and biochemical investigations.

Blood Parameters				
Parameters	**Screening**	**Day 30**	**P Value**	**Reference range**
Hematological Parameters				
White Blood Cell Count (WBC)	7240.00±1904.01	7140.33±1765.74	0.539	(4000 - 11000 cell/cu.mm)
Red Blood Cell Count (RBC)	4.50±0.65	4.70±0.59	0.271	(4.7 - 6.0 mil/cu.mm)
Hemoglobin (Hb)	12.13±1.62	12.35±1.39	0.176	(Female: 11.6 - 15 gm/dL & Male: 13.2-16.6 gm/dL)
Haematocrit (PCV)	37.10±5.62	39.79±5.70	0.008	(42 - 52 %)
Mean Corpuscular Volume (MCV)	83.23±11.91	81.57±9.56	0.364	(78 - 100 fL)
Mean Corpuscular Haemoglobin (MCH)	26.97±4.60	26.53±3.81	0.622	(27 - 31 pg)
Mean Corpuscular Haemoglobin Concentration (MCH)	32.32±1.12	32.00±1.13	0.184	(32-36 gm/dL)
Platelet Count	278.60±74.37	280.90±73.47	0.790	(150 - 450 10^3/ul)
Neutrophils	55.13±6.45	56.53±7.11	0.124	(40 - 75 %)

Lymphocytes	35.90±6.80	34.50±4.94	0.097	(20 - 40 %)
Monocytes	5.17±1.66	5.13±1.50	0.786	(2-10 %)
Eosinophils	3.47±1.07	3.43±0.97	0.712	(1-6 %)
Basophils	0.00±0.00	0.00±0.00	1	(0-1 %)
Liver Function Test				
Protein Total	6.96±0.58	6.96±0.77	0.974	(6.0 - 8.3 g/dL)
Albumin	4.25±0.35	4.27±0.52	0.754	(3.2 - 5.5 g/dL)
Globulin	2.71±0.58	2.68±0.72	0.553	(1.8 - 3.6 g/dL)
A/G Ratio	1.63±0.39	1.71 ±0.55	0.136	(1.2 - 2.2)
Bilirubin Total	0.51±0.20	0.52±0.19	0.575	(0.1-1.2 mg/dL)
Bilirubin Direct	0.17±0.11	0.18±0.11	0.539	(0-0.4 mg/dL)
Bilirubin Indirect	0.34±0.15	0.33±0.15	0.864	(0.1-0.8 mg/dL)
Aspartate Transaminase (AST/SGOT)	26.33±9.91	25.96±9.48	0.694	(49 U/ L)
Alanine Transaminase (ALT/SGPT)	22.81±8.34	24.01±8.81	0.231	(49 U/ L)
Alkaline Phosphatase	108.18±42.48	110.48±41.33	0.177	(80 - 306 U/ L)
Kidney Function Test				
Urea	24.03±7.03	24.26±6.75	0.799	(7-40 mg/dL)
Creatinine	0.82±0.19	0.79±0.21	0.231	(0.5-1.5 mg/dL)
Uric Acid	4.70±1.06	4.66±0.98	0.430	(3.0 to 7.2 mg/dL)

Data is represented as Mean ± S.D. Analysis was done using the dependent student t-test (within the group) and Wilcoxon signed rank test (within the group). Significant at p< 0.05.

Assessment of vital signs

The study results showed a statistically significant decrease in systolic blood pressure (p = 0.035) and body temperature (p < 0.001) from screening to day 30. However, the changes observed in diastolic blood pressure, heart rate, and respiratory rate were not statistically significant as demonstrated in **Table 3**.

Table 3: Assessment of vital signs.

Parameters	Duration	Test(n=30)	P value
Systolic Blood Pressure (mmHg)	**Screening**	121.87±7.27	0.035
	Day 30	118.33±7.00	
Diastolic Blood Pressure (mmHg)	**Screening**	75.83±7.22	0.425
	Day 30	76.93±6.01	
Heart Rate (beats per minute)	**Screening**	74.77±7.93	0.810
	Day-30	75.27±9.76	
Body Temperature (°F)	**Screening**	97.90±0.71	<0.001
	Day-30	97.06±0.75	
Respiratory Rate (breaths per minute)	**Screening**	16.97±0.85	0.094
	Day-30	17.47±1.22	

Data is represented as Mean ± S.D. Analysis was done using the dependent student t-test (within the group) and Wilcoxon signed rank test (within the group). Significant at p< 0.05.

Assessment of adverse events

The adverse events observed during the study are presented in **Table 4**. Out of the 30 participants, a total of 3 subjects (10%) experienced at least one adverse event. The most commonly reported adverse events were fever and headache. For each adverse event, the number of subjects affected and the corresponding rescue medication used are shown. AE's observed were not related to the investigational product.

Table 4: Adverse Events Observed in the Study.

Adverse Events	Number of subjects with AE (N=30)	Rescue Medication
Headache	2	Paracetamol, Aspirin
Fever	1	Paracetamol
Total No. of Events	**2**	**-**
Total No. of subjects (%)	**3 (10%)**	**-**

Assessment of alertness, memory, and perceived energy by 4-point Linkert Scale

The subjects' self-reported assessments of alertness, memory, and perceived energy were evaluated using a 4-point Likert scale (0-worsened, 1-not improved, 2-improved, 3-improved satisfactory) at screening and on day 30. The results showed statistically significant improvements in all three parameters from screening to the end of the study period.

At the screening, 27 subjects reported worsened alertness and memory. After 30 days of treatment, all participants (100%) reported increased alertness and memory, transitioning to the improved-satisfactory category. Likewise, 28 subjects reported worsened energy levels at the screening; however, after 30 days of treatment, all participants (100%) exhibited improvement in their perceived energy levels.

These findings suggest that the administration of De-Stress & Focus Tablets for 30 days resulted in clinically meaningful improvements in the subjects' self-reported alertness, memory, and perceived energy levels compared to the baseline assessments as shown in **Table 5**.

Table 5: Assessment of alertness, memory, and perceived energy by 4-point Linkert Scale.

Assessment of alertness, memory, and perceived energy (Number of subjects)			
Parameter	**Score**	**Screening (n=30)**	**Day 30 (n=30)**
Alertness	0	27	00
	1	03	00
	2	00	23
	3	00	07
Memory	0	27	00
	1	03	00
	2	00	24
	3	00	06
Perceived Energy	0	28	00
	1	02	00
	2	00	23
	3	00	07

Data is represented as Mean ± S.D. Within group analysis was done by using the dependent student t-test and Wilcoxon signed rank test. Significant at p< 0.05.

All thirty subjects were compliant and showed excellent tolerability to the investigational product.

DISCUSSION

The current clinical study investigated the safety and efficacy of De-Stress & Focus tablets, a nutraceutical formulation designed to address stress and cognitive challenges. The study's comprehensive evaluation encompassed multiple parameters, offering insights into the potential benefits of this novel supplement. The carefully formulated tablet contains a blend of active ingredients, including Alpinia galanga (Enxtra Extract), Ashwagandha KSM 66, Saffron Extract, Blueberry Extract, and essential B vitamins (Vitamins B-3, B-6, and B-12).[11,12] The 30-day open-label trial involving 30 participants (10 males, 20 females) with an average age of 47.13 years provided valuable data on the intervention's physiological and cognitive impacts.

The hematological and biochemical analysis revealed minimal significant changes, with the notable exception of a statistically significant increase in hematocrit (PCV) levels from 37.10 ± 5.62% at screening to 39.79 ± 5.70% at day 30 (p = 0.008) (13). This increase in PCV could potentially indicate enhanced blood oxygen-carrying capacity or improved red blood cell formation. The stability of other blood parameters, including white and red blood cell

counts, hemoglobin, liver function tests, and kidney function tests, underscores the intervention's safety profile and minimal systemic disruption.

Notably, the study observed statistically significant reductions in systolic blood pressure and body temperature, which may indicate potential stress management benefits.[14,15] The decrease in systolic blood pressure correlates positively with improved vascular health and reduced cardiovascular stress, while the lower body temperature might suggest a reduction in physiological stress and metabolic activity. These findings align with previous research highlighting Alpinia galanga's potential in modulating stress-related physiological markers.[16]

The adverse event profile was remarkably favorable, with only 3 out of 30 participants (10%) experiencing mild events such as headache and fever, which were not attributed to the investigational product.[17] This low incidence of adverse events further supports the supplement's safety and tolerability.

Perhaps most compelling were the subjective improvements reported by participants. Using a 4-point Likert scale, the study demonstrated significant enhancements in self-reported alertness, memory, and perceived energy levels.[18] At the screening, a substantial majority of participants reported worsened cognitive function, but by the study's conclusion, 100% of participants reported improvements in these domains.[19,20] Participants transitioned from reporting worsened conditions to experiencing satisfactory improvements in cognitive performance and energy levels.

The combination of ingredients, particularly Alpinia galanga and Ashwagandha, appears to synergistically contribute to these cognitive and energetic improvements. Ashwagandha, a well-known adaptogenic herb in Ayurvedic medicine, has previously been associated with stress reduction and cognitive enhancement. Similarly, Alpinia galanga has shown promise in addressing attention-related challenges and supporting overall cognitive function.

These findings are significant in the context of neuropsychiatric conditions like stress disorders and Attention Deficit Hyperactivity Disorder (ADHD), which continue to pose substantial challenges in day-to-day functioning. With global ADHD prevalence estimates ranging from 5.29% to 7.1%, and the Indian context showing a range of 2% to 17%, there is a critical need for alternative and complementary therapeutic approaches.[1,2,3]

While the current study provides promising initial results, the authors acknowledge the need for further research. Future investigations should focus on elucidating the underlying mechanisms of these cognitive and physiological improvements, exploring long-term efficacy, and potentially comparing the nutraceutical intervention with conventional pharmacological treatments.

CONCLUSION

This study presents compelling evidence for the safety and potential efficacy of De-Stress & Focus Tablets in improving cognitive performance, managing stress, and enhancing overall well-being. The low adverse event profile, coupled with significant self-reported improvements, suggests that this nutraceutical formulation could offer a valuable alternative or complementary approach to managing stress and cognitive challenges.

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CONFLICT OF INTEREST

Dr. Kriti Soni and Dr. Sachin Mulik are part of Herbolab India Pvt. Ltd. Other author declare no conflict of interest.

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