WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 14, Issue 7, 936-948. Research Article ISSN 2277–7105

CLINICAL STUDY TO EVALUATE THE EFFICACY OF HERBAL NEUTRACEUTICAL (ADAPTOGEN) WLTH CALM EASE IN STRESS MANAGEMENT

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Article Received on
09 Feb. 2025,

Revised on 02 March 2025,
Accepted on 23 March 2025

DOI: 10.20959/wjpr20257-36032

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ABSTARCT

Stress is a common experience all around throughout all human lifetime. It may be both external with environmental reason, and caused by internal discernments of the person. One of the most helpful techniques for dealing with stress is to consume stress-reducing nutrients. Considering these facts, neutraceuticals is one of the important measure to handle the crisis stress. In this background, neutraceuticals efficacy was measured in mitigating the stress. It was a randomized participant blinded placebo controlled trial to study the efficacy of herbal neutraceutical in stress management. The trial formulation in powder form in a dose of 3.5 gm was given with luke warm water, once a day. This was compared with Placebo group. The time points were before treatment, after treatment(14th day); and a follow up measurement done on on 28th day. Blood cortisole level and Hamilton Anxiety Rating scale were analyzed, and the study reported betterment in these parameters after the study.

INTRODUCTION

Stress is a global health epidemic, affecting millions worldwide. Studies have shown a strong link between chronic stress and a range of health problems, including heart disease, anxiety disorders, and even weakened immune systems. In today's fast-paced world, stress has become an unwelcome constant. From demanding jobs and strained relationships to financial worries and global anxieties, the pressures on modern life are immense. Everyone will experience it throughout their witness. Stress is one the exceptional characteristics of life and its incidence has been much tinted in all aspects of life. The motive of the extend existence and extensiveness of stress in human communities is the intricacy of human communal, individual, and environmental surroundings, numerous and at the same time interactions of human with adjacent issues, and range in stress expression. The current study was registered in the CTRI (ICMR REF/2022/08/057650) and was done after getting the ethical clearance from the concerned authority. **WLTH Calm Ease** contains herbal extracts sourced from various parts of the globe. The ingredients are Brahmi Extract (Bacopa Monnieri), Hops Powder (Humulus Lupulus L), Mulberry Fruit Extract, Passionflower Extract (Passiflora Foetida), Sage Extract (Salvia Officinalis), Silk Tree Extract (Albizia Lebbeck L.) and Valerian Extract (Valeriana Wallichii).

METHODOLOGY

It was an Interventional study in the field of Ayurveda and Nutraceutical with Randomized, Parallel Group, Placebo Controlled participant blinded design. The health condition studied was stress. WLTH calm ease (Herbal Neutraceutical); 3.5 gram sachet containing powdered herbal adaptogen blend mixed with 150 ml of luke warm water, given once a day for 14 days in trial group. And in comparator group, 3.5 gram sachet containing powdered Rawa with added natural flavors mixed with 150 ml of Luke warm water, given once a day for 14 days. Participants who favour the diagnostic criteria of stress were included in the study from 18 to 60 year of age. Individuals with Hypertension, Cardiac disorders, IBD, Herb sensitivity, endocrine disorders, pregnancy and lactation etc were excluded for study. Method of Generating Random Sequence was lottery method. Pre-numbered or coded identical Containers were used for Method of Concealment. Primary outcome was measured with blood cortisole and Secondary Outcome evaluated with Hamilton Anxiety Rating scale. Time points were before treatment, after 14 days; and follow-up on 28th day.

RESULTS AND DISCUSSION

The average age of populace was 45 year, 80% 0f populace were married, 15 % were single and 5% were divorced in total populace. 60% were female and rest belongs to male population. The parameters recorded are as follows.

Table 1: Hamilton rating scale for anxiety result on anxious parameter in trial group.

Anxious Trial group	BT	AT
Mean	0.91	0.65
SD	1.08	0.78
SEM	0.23	0.16
N	23	23
t	2.7865	
p	0.0108 (statistically significant)	

Table 2: Hamilton rating scale for anxiety result on anxious parameter in control group.

Anxious control group	BT	AT
Mean	1.04	0.71
SD	1	0.86
SEM	0.20	0.18
N	24	24
t	1.2396	
p	0.2214 (not statistically significant)	

Table 3: Hamilton rating scale for anxiety result on tension parameter in trial group.

Tension trial group	BT	AT
Mean	1.53	1.11
SD	1.07	0.99
SEM	0.25	0.23
N	24	24
t	3.0237	
Standard error of difference	0.139	
p	0.0073 (very statistically significant)	

Table 4: Hamilton rating scale for anxiety result on tension parameter in control group.

Tension control group	BT	AT
Mean	1.43	1.26
SD	0.99	1.01
SEM	0.21	0.21
N	23	23
t	0.5892	
Standard error of difference	0.295	
p	0.5587	

Table 5: Hamilton rating scale for anxiety result on fears parameter in trial group.

Fears Trial group	BT	AT
Mean	0.43	0.30
SD	0.73	0.47
SEM	0.15	0.10
N	23	23
t	0.7218	
Standard error of difference	0.181	
p	0.4742	

Table 6: Hamilton rating scale for anxiety result on fears parameter in control group.

Fears Control group	BT	AT
Mean	0.42	0.16
SD	0.78	0.50
SEM	0.16	0.12
N	24	24
t	1.2593	
Standard error of difference	0.205	
p	0.2150	

Table 7: Hamilton rating scale for anxiety result on Insomnia parameter in trial group.

Insomnia trial group	BT	AT
Mean	0.75	0.41
SD	0.94	0.80
SEM	0.19	0.17
N	24	24
t	2.6137	
Standard error of difference	0.157	
p	0.0162 (Statistically significant)	

Table 8: Hamilton rating scale for anxiety result on Insomnia parameter in control group.

Insomnia control group	BT	AT
Mean	0.52	0.35
SD	0.79	0.65
SEM	0.16	0.13
N	23	23
t	0.8165	
Standard error of difference	0.213	
p	0.4186	

Table 9: Hamilton rating scale for anxiety result on Cognitive parameter in trial group.

Cognitive trial group	BT	AT
Mean	0.84	0.58
SD	0.76	0.69
SEM	0.18	0.16
N	24	24
t	2.5355	
Standard error of difference	0.104	
p	0.0207(Statistically significant)	

Table 10: Hamilton rating scale for anxiety result on Cognitive parameter in control group.

Cognitive control group	BT	AT
Mean	0.61	0.30
SD	0.84	0.63
SEM	0.17	0.13
N	23	23
t	1.7754	
Standard error of difference	0.171	
p	0.0797 (not quite statistically significant)	

Table 11: Hamilton rating scale for anxiety result on mood parameter in trial group.

Depressed mood Trial group	BT	AT
Mean	0.57	0.22
SD	0.95	0.52
SEM	0.20	0.11
N	23	23
t	2.5771	
Standard error of difference	0.135	
p	0.0172 (Statistically significant)	

Table 12: Hamilton rating scale for anxiety result on depressed mood parameter in control group.

Depressed mood Control group	BT	AT
Mean	0.58	0.32
SD	0.77	0.67
SEM	0.18	0.15
N	24	24
t	1.4237	
Standard error of difference	0.185	
p	0.1716 (not statistically significant)	

Table 13: Hamilton rating scale for anxiety result on Somatic (muscular) parameter in trial group.

Somatic (muscular) Trial group	BT	AT
Mean	1.13	0.83
SD	1.06	0.89
SEM	0.22	0.18
N	23	23
t	2.0765	
Standard error of difference	0.147	
p	0.0497 (Statistically significant)	

Table 14: Hamilton rating scale for anxiety result on Somatic (muscular) parameter in control group.

Somatic (muscular) Control group	BT	AT
Mean	0.94	0.83
SD	1.00	0.79
SEM	0.24	0.19
N	24	24
t	0.3344	
Standard error of difference	0.332	
p	0.7421 (not statistically significant)	

Table 15: Hamilton rating scale for anxiety result on Somatic (sensory) parameter in trial group.

Somatic (sensory) Trial group	BT	AT
Mean	0.68	0.32
SD	0.72	0.57
SEM	0.15	0.12
N	23	23
t	2.1602	
Standard error of difference	0.168	
p	0.0425 (Statistically significant)	

Table 16: Hamilton rating scale for anxiety result on Somatic (sensory) parameter in control group.

Somatic (sensory) Control group	BT	AT
Mean	0.32	0.42
SD	0.58	0.51
SEM	0.13	0.12
N	24	24
t	1.000	
Standard error of difference	0.105	
p	0.3306 (not statistically significant)	

Table 17: Hamilton rating scale for anxiety result on CVS parameter in trial group.

CVS Trial group	BT	AT
Mean	0.74	0.39
SD	0.75	0.58
SEM	0.16	0.12
N	23	23
t	2.9124	
Standard error of difference	0.119	
p	0.0081(Statistically significant)	

Table 18: Hamilton rating scale for anxiety result on CVS parameter in control group.

CVS Control group	BT	AT
Mean	0.32	0.26
SD	0.58	0.56
SEM	0.13	0.13
N	23	23
t	0.5669	
Standard error of difference	0.093	
p	0.5778(not statistically significant)	

Table 19: Hamilton rating scale for anxiety result on Respiratory symptoms parameter in trial group.

Respiratory symptoms Trial group	BT	AT
Mean	0.48	0.17
SD	0.67	0.39
SEM	0.14	0.08
N	23	23
t	3.1024	
Standard error of difference	0.098	
p	0.0052 (very statistically significant)	

Table 20: Hamilton rating scale for anxiety result on Respiratory symptoms parameter in control group.

Respiratory symptoms Control group	BT	AT
Mean	0.32	0.21
SD	0.67	0.54
SEM	0.15	0.12
N	24	24
t	1.000	
Standard error of difference	0.105	
p	0.3306 (not statistically significant)	

Table 21: Hamilton rating scale for anxiety result on Gastrointestinal symptoms parameter in trial group.

Gastrointestinal symptoms Trial group	BT	AT
Mean	0.39	0.13
SD	0.72	0.46
SEM	0.15	0.10
N	23	23
t	2.7865	
Standard error of difference	0.094	
p	0.0108 (Statistically significant)	

Table 22: Hamilton rating scale for anxiety result on Gastrointestinal symptoms parameter in control group.

Gastrointestinal symptoms Control group	BT	AT
Mean	0.42	0.21
SD	0.69	0.54
SEM	0.16	0.12
N	24	24
t	1.7143	
Standard error of difference	0.123	
p	0.1036 (not statistically significant)	

Table 23: Hamilton rating scale for anxiety result on Genitourinary symptoms parameter in trial group.

Genitourinary symptoms Trial group	BT	AT
Mean	0.19	0.14
SD	0.51	0.48
SEM	0.11	0.10
N	23	23
t	0.5680	
Standard error of difference	0.084	
p	0.5764 (not statistically significant)	

Table 24: Hamilton rating scale for anxiety result on Genitourinary symptoms anxious parameter in control group.

Genitourinary symptoms Control group	BT	AT
Mean	0.28	0.28
SD	0.57	0.57
SEM	0.14	0.14
N	24	24
t	0.000	
Standard error of difference	0.081	
p	1.0 (not statistically significant)	

Table 25: Hamilton rating scale for anxiety result on Autonomic symptoms parameter in trial group.

Autonomic symptoms Trial group	BT	AT
Mean	0.91	0.64
SD	0.87	0.49
SEM	0.19	0.10
N	23	23
t	2.3238	
Standard error of difference	0.117	
p	0.0303(Statistically significant)	

Table 26: Hamilton rating scale for anxiety result on Autonomic symptoms parameter in control group.

Autonomic symptoms Control group	BT	AT
Mean	0.47	0.58
SD	0.70	0.69
SEM	0.16	0.16
N	24	24
t	1.000	
Standard error of difference	0.105	
p	0.3306 (not statistically significant)	

Table 27: Hamilton rating scale for anxiety result on Behavior at interview parameter in trial group.

Behavior at interview Trial group	BT	AT
Mean	0.17	0.00
SD	0.39	0.00
SEM	0.08	0.00
N	23	23
t	2.1521	
Standard error of difference	0.081	
p	0.0426 (Statistically significant)	

Table 28: Hamilton rating scale for anxiety result on Behavior at interview parameter in control group.

Behavior at interview Control group	BT	AT
Mean	0.17	0.17
SD	0.38	0.38
SEM	0.09	0.09
N	24	24
t	0.000	
Standard error of difference	0.081	
p	1.000(not statistically significant)	

Table 29: Hamilton rating scale for anxiety result on total in trial group.

Total Trial group	BT	AT
Mean	14.10	12.29
SD	4.43	4.78
SEM	0.97	1.04
N	23	23
t	3.0356	
Standard error of difference	0.596	
p	0.0065(Statistically highly significant)	

Table 30: Hamilton rating scale for anxiety result on total parameter in control group.

Total Control group	BT	AT
Mean	14.13	13.96
SD	5.46	5.47
SEM	1.11	1.12
N	24	24
t	1.8593	
Standard error of difference	0.627	
p	0.0758 (not statistically significant)	

Table 31: Cortisole parameter in trial group.

Cortisole Trial group	BT	AT
Mean	7.338	6.438
SD	1.524	2.356
SEM	0.332	0.514
N	23	23
t	2.3624	
Standard error of difference	0.381	
p	0.0284(Statistically highly significant)	

Table 32: Cortisole parameter in control group.

Cortisole control group	BT	AT
Mean	6.660	6.247
SD	2.067	2.291
SEM	0.534	0.593
N	24	24
t	0.8056	
Standard error of difference	0.513	
p	0.4339(not statistically significant)	

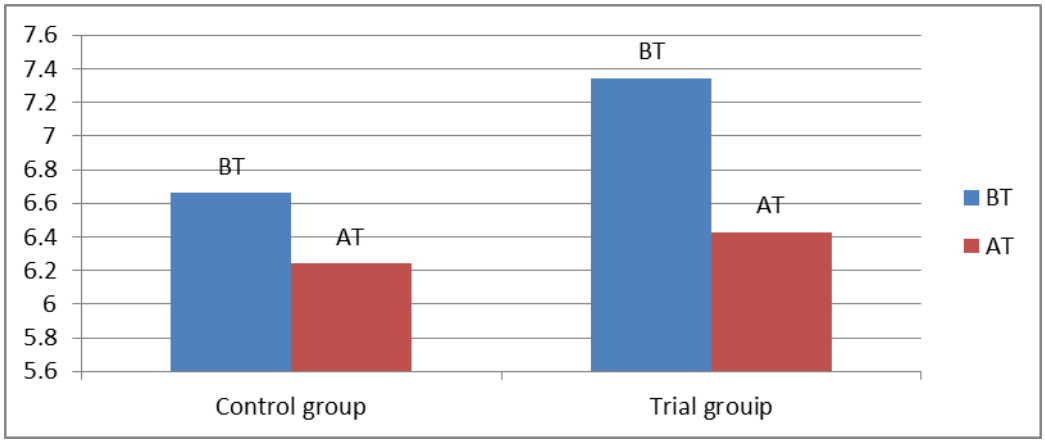

Figure 1: Cortisole changes in control and trial group, before treatment and after treatment.

(BT: Before treatment, AT: After treatment)

DISCUSSION

The results of current study are showing positive remarks in mitigating the stress. The different facets of Hamilton rating scale (HRS) shows the efficacy of WLTH cam ease in reducing symptoms of anxiety. The Anxious domain of HRS shows significant reduction in trial group, but it was not significant in control group. This shows that WLTH calm ease is very effective in reducing the symptoms of anxiety, which is an important indicator of stress. This may be attributed to the unique combination of WLTH calm ease. Some research suggests that Bacopa monnieri may have anxiolytic properties, helping to reduce anxiety and improve mood.[1] *Bacopa* has been reported to protect against oxidative damage via decreased protein carbonyl levels in both cytosol and mitochondria in all brain regions.[2] Hops contain compounds that may interact with neurotransmitters in the brain, such as GABA, which plays a role in relaxation and anxiety reduction. Acetylcholinesterase (AChE) activity significantly decreased in mice treated with the extract of sage. Tension parameter of HRS also shown very significant improvement in WLTH calm treated individual against control group, in which the results were insignificant. At the same time, the fear parameter showed not much significance in both the groups. Insomnia is an another indicator of mental stress. This domain showed satisfying reports in trial group as per HRS. WLTH calm ease ingredients in total helps in getting good sleep. Cognition is yet another parameter in analyzing the stress level. P value of 0.0207 in trial group which was statistically significant and it makes WLTH calm ease as a better option in accelerating the cognitive domain. Depressed mood is the one of the feature of psychological stress. The judicial administration of WLTH calm ease in

treated population showed significant reduction in depressed mood. In previous researches, the passion flower extract investigated and study appears to be effectual in improving resilience and QoL in patients suffering from nervous restlessness and is well tolerated. The currently studied neutraceutical herbal agent contains the extract of passion flower.[3] The statistically significant results were observed in different parameters like somatic motor, somatic sensory, CVS(cardio vascular symptoms), GIT(Gastrointestinal symptoms) and Autonomic symptoms in individuals administered with WLTH calm ease. In addition to this, Respiratory symptoms got relief in very highly significant in these strata of population. At the same time, in control group all these parameters result wereinsignificant against the trial group. Genitourinary symptoms showed insignificant results in both the groups. This was doesn't projected in total results, as total score showed significant changes in trial group, however total scores were insignificant in control strata of population.

It is recommended that cortisol appears to be an adequate index for mental stress.[4] The level of this parameter will rise under stress. The data and results of current study are also in line with this theory and it is observed that the WLTH calm ease has the efficacy in bringing down the stress level, which was reflected in the attenuation of cortisole level. The range was not crossed the average level, still the change observed was statistically significant in trial group. But this change observed in control group was insignificant. All these results suggests the upper hand of WLTH calm ease in reducing the stress level.

All the results are may be attributed to net efficacy of the ingredients of WLTH calm ease. The effect of saponin containing n-butanolic fraction extracted from dried leaves of Albizzia lebbeck was studied on cognitive behavior and anxiety in albino mice. The studies showed that Albizia lebbe has got anxiolytic and nootropic activity.[5] Valeriana wallichii, an Indian medicinal plant, has been on trial for its function in stress disorders in hospital based clinical set-up. The observations exhibited that, V. wallichii not only significantly ($p<0.001$) attenuated stress and anxiety, but also significantly ($p<0.001$) enhanced depression and enhanced the compliance to adjustment.[6] Indian ancient medicinal system, Ayurveda credentials several plants, including V. wallichii, passion flower, baccopa monnerie and other ingredients of WLTH calm ease which are, sort out as rasayanas. The assets ascribed to rasayanas in Ayurveda are extremely akin to those of adaptogens, to bring back the mental stress.

CONCLUSION

Stress is a ordinary experience all around all over all human life. WLTH calm ease is best option to minimize the effect of stress. The results of current clinical trial acknowledges the use of this product in attenuating the effect of stress as it showed best improvements in Hamilton rating scale for anxiety and cortisole level.

ACKNOWLEDGEMENT: All the population studied, CTRI and Funding agency.

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