

A DOUBLE BLIND RANDOMISED CONTROLLED CLINICAL STUDY TO EVALUATE
THE EFFECT OF GUDUCHI IN CHITTODVEGA W.S.R TO EXAM STRESSDr. Gadde Chetan^{1*}, Dr. Shrilatha Kamath T.² and Dr. Dhaneshwari H. A.³P. G. Scholar¹, Hod & Professor², Assistant Professor³Department of Kayachikitsa and Manasa Roga, Sri Dharmasthala Manjuntheshwara College of Ayurveda and Hospital,
Kuthpady, Udupi, 574118, Karnataka, India.***Corresponding Author: Dr. Gadde Chetan**P. G. Scholar, Department of Kayachikitsa and Manasa Roga, Sri Dharmasthala Manjuntheshwara College of Ayurveda and Hospital,
Kuthpady, Udupi, 574118, Karnataka, India.

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ABSTRACT

Background: *Raja* and *tama* are two important *dosha* of *manas*. If any imbalance happens it leads to many *manasika roga* and *chittodvega* is one among them. Exam stress can create lots of complications. Thus it has become a need of the hour to help students to tackle their stress during the examination days and to achieve their goal comfortably. *Guduchi* is one among the *medhya rasayana*. This might help in managing exam stress without causing adverse/side-effect. **Objective:** To evaluate the therapeutic effect of *Guduchi* in *chittodvega*/exam stress. **Design:** A double blind randomised controlled clinical study with pre-test and post design. **Setting:** Opd of Shri Dharmasthala Manjuatheshwara Ayurveda College and hospital, Kuthpady, Udupi. **Methodology:** - 30 patients diagnosed with *chittodvega*/ exam stress. Interventions: Patients were allocated in to 2 groups using permuted block randomisation where in 15patients (Group A) were treated with Cap.Placebo 500mg 5 BD and 15 patients (Group B) administered with Cap.Guduchi 500 mg 5 BD for 30days with warm water. **Outcome Measures:** Assessment parameters like Hamilton anxiety rating scale, Hamilton depression rating scale, positive symptoms and negative symptoms were considered in this study. **Results** Both Group A and Group B had remission in the parameters comparing the percentage of relief of the parameters and overall effect showed that Group B had better improvement in the ailment.

KEYWORDS: *Raja*, *Tamas*, *Manasika Roga*, *Chittodvega*. *Examstress*.**INTRODUCTION**

Ayurveda is a science which believes that body is made up of *dhosha*, *dathu*, *mala*.^[1] If there is any derangement in these will lead to diseases. *Dosha* are again classified into two; *shareerika* and *manasika*. In *Ayurveda* both *shareera* and *manas* are given equal importance.

As *Raja* and *Tama* are two important *dosha* of *mana*, If any imbalance happens, it leads to *manasika roga*.^[2] *Chittodvega* is one among them and it is also caused by the derangement of *shareerika vata dosha*.^[3] It is explained as *poorva roopa* of *unmada*.^[4] Today's youth is tomorrow's nation and today's youth are our students. In the current era, students do play a vital role in the society and how a society is shaped, generation after generations. The formative period of an individual is during the student phase and hence it is known to be the crucial time of life. What is being sown today is what shall be reaped later. Among them competition is the trademark. Struggle to Survive and to get success has become the ultimate goal in every field. To achieve that goal almost all category of people get afflicted with psychological stressors irrespective of their strength and weakness. There are two types of stress -eustress and

distress.^[5] Eustress is positive stress. This is good for achieving certain goals in life and this stress will have positive impact on life. Distress is another type of stressor which is having negative impact on life causing ill effect on health. Any stressor which is more than the normal will be causing distress. Such as excessive thinking on social, economic matters and repetitive thought patterns during exams will cause ill effects on health. These things have impact on endocrine system which will lead to several regulatory changes in the hormones. This distress can be seen in few members of student's community during the examination.

In spite of preparedness for the exam, because of the excessive pressure created by parents, institutions and society, students are struggling and facing severe distress while appearing for the exam. Survey reveals that incidence of exam stress has risen from 2009 to 2010⁵. Exam stress presents with several symptoms like anxiety, worry, muscle tension, fatigue, restlessness, and sleep disturbance etc.^[6] Exam stress can create lot of complications in student's life like Suicidal tendencies, Personality disorder, Insomnia and other chronic diseases Every hour one student commits suicide in India, with

about 28 such suicides reported every day, there may be several causes but the main among them is academic stress. Among those the highest rates are in the young age. Fear of failure is a leading cause for suicide among students. When students pass through an unsuccessful phase, everything seems pessimistic to them. They feel their future is bleak and this may result in committing suicide.^[7]

Personality disorders lead to a disturbance in functioning as great as that in most major mental disorders. They are associated with high rates of separation and divorce; unemployment and inefficiency; and poor quality of life for the individual and his/her family. Students with personality disorders have an increased risk of mortality through suicide, homicide, and accidents. Moreover, when a personality disorder is present, the treatment of other coexisting psychiatric or medical conditions is frequently more complicated, lengthier, or less successful; a pattern that may at times be due to lack of recognition of the personality disorder.

Normal sleep pattern is the key factor to maintain healthy behaviour and physiology. This is lacking in the young students, because of their academic stress students are prone to sleep disturbances.

For combating these situations and to prevent complications students need several kinds of help and support from everyone, parents, society, and social media. More over the student should have great mental strength to tackle these stressors. Thus, it has become a need of the hour to help students to tackle their stress during the examination days and to achieve their goal comfortably. By practicing various preventive protocols mentioned in Ayurveda and following certain *medhya rasayana* will improve the mental strength⁷. *Guduchi* is one among the *medya rasayana*.^[8]

MATERIALS AND METHODS

Objective: To evaluate the therapeutic effect of *Guduchi* in *chittodvega*/exam stress.

Study design

- Study type: Interventional
- Interventional Model: Double group
- Allocation: Randomization Method (Permuted block randomization)
- End point classification: Efficacy study
- Primary purpose: Treatment

Participants

Subjects were screened for exam stress through a questionnaire and 30 subjects were selected for the study and randomly allocated into 2 groups using permuted block randomisation. A special Performa was prepared with details of history taking, including signs and symptoms as mentioned in Ayurveda classics and allied science.

Intervention

GROUP A (Control group) -15 Subjects

Treatment: Placebo (starch caps) 500mg

Dosage: 5 Caps BD

Duration: 30 days (treatment was started 30days prior to the exam)

Anupana: Lukewarm Water

Time of administration: 1/2 an hour before food

GROUP B (Study group) – 15 Subjects

Treatment: Cap Guduchi (Aqueous extract) 500mg

Dosage: 5 Caps BD

Duration: 30 DAYS (treatment was started 30days prior to the exam)

Anupana: Lukewarm Water (1/2 an hour before food)

Time of administration: 1/2 an hour before food

Duration of clinical study

- Intervention: 30days
- Follow up: 30 days after completion of the study.
- Total duration of the study: 60 days

Diagnostic criteria

Diagnostic criteria for generalized anxiety disorder as per DSM-5.^[9]

The anxiety and worry are associated with three (or more) of the following symptoms (with at least some symptoms having been present for more days than not for the past 6 months).

1. Restlessness or feeling keyed up or on edge.
2. Being easily fatigued.
3. Difficulty concentrating or mind going blank
4. Irritability
5. Muscle tension.
6. Sleep disturbance (difficulty falling or staying asleep, or restless, satisfying sleep).

Inclusion criteria

- Subjects who presented with exam stress and fit into the diagnostic criteria
- Subjects who have signed consent form for taking treatment
- Subjects of age group between 18 – 30 years.

Exclusion criteria

- Subjects suffering from any other Psychiatric Diseases.
- Subjects with any systemic disorders interfering with the illness and treatment.

Assessment Criteria

Assessment was done by scoring the parameters and assessing them before the treatment on 0th day i.e. just before the first internals and treatment was started 30 days prior to the exams and on 30th day (after treatment) & 60th day (follow up).

Statistical analysis: - Obtained data was analysed statistically using Wilcoxon signed rank test and Man Whitney u test.

Blinding technique adopted in the study.

Blinding technique was done based on the random method. The prepared capsules were packed in a box which contained 300 capsules and it was given a serial no. 1,2,3 etc . Randomly these bottles were filled with a control group (Cap.Placebo) and study group (Cap.Guduchi) and were noted in a blinding sheet (which was not revealed to investigators till 30thday) by the coordinator.

The patients of the study were given a serial no.1, 2, 3 etc. By the investigator on the 0th day the assessment was done and the serial no. 1 patient was administered with bottle which was labelled as no.1 and so on.

On the 30th day the patients were assessed unblinding was done based on the blinding sheet by the investigator and the patients were divided into two Groups; Group A (control group- placebo) and Group B (cap. Guduchi). Based on the grading given statistical analysis was done.

Subjective parameters

- Restlessness or feeling keyed up or on edge.
- Being easily fatigued.
- Difficulty concentrating or mind going blank.
- Irritability.
- Muscle tension.
- Sleep disturbance (difficulty falling or staying asleep, or restless, satisfying sleep)
- Hamilton scale of anxiety.^[10]
- Hamilton scale of depression.^[11]
- Manas bhava rating scale.

RESULTS

In Group A there was 36.19% reduction in symptoms in Hamilton anxiety rating scale. There was 37.9% reduction in symptoms in Hamilton depression rating scale. The study proved that there was 50% improvement in *bhaya*, 19.94% on *krodha*, 25% on *Shoka*, 25.44% on *dwesha*, 28.57% *rajaha*, 35.56% *maasaa arthesu avyabicharena*, 50% *chinta*. On positive symptomsthe study proved that there was 40% improvement in *dhairyam*, 37.5 % on *dhriti*, 6.2%.On *harsha*, 47.03% on *preethi*, 47 % *veeryam*,47.03% on *shraddha*, 50% on *medha*, 28.88% on *avasthana*, 13.326% on *upadhi*, 33.3% on *vignana*, 29.44% on *sheela*, 35.6% on *samjna*., 27.23 % on *smriti*. Group B there was 63.67 % reduction in symptoms in Hamilton anxiety rating scale, 59.31 % reduction in symptoms in Hamilton depression rating scale. On negative symptoms study proved that there was 78.9% improvement on *bhaya*, 61.08% on *krodha*, 75.00 % on *shoka*,90.00 % on *dwesha*, 75.00% on *rajaha*, 85.744 % on *manaha*, 93.82% on *chintha*.On positive symptoms study proved that there was 94.11% improvement on *dhairyam*, 64.30% on *dhriti*, 73.3% on *harsha*,81.79% on *preethi*, 93.22% on *veeryam*,88.8% on *shraddha* , 100% on *medha*, 100% on *avasthana*, 90.99% on *upadhi*, 69.20% on *vignana*, 46.13% on *sheela*,76.93% on *samjna*, 64.30% on *smriti*.

In Group A (Placebo) analysing the overall effect 6.6% of the patient had mild remission, 73.3 % patients had moderate remission, 6.6% patients had good improvement, ,6.6% patients had marked improvement and 6.6% patients had no improvement.

In GROUP B (Guduchi) analysing the overall effect 26.6% of the patient had moderate remission, 60 % patients had marked remission, and 13.3% excellent improvement was seen in patients. No improvement was not seen.

Comparison between the groups shows that Group B (Guduchi) showed more improvement than Group A (Placebo).

EFFECT OF TREATMENT ON HAMILTON ANXIETY SCALE

Effect on Group A Shows initial mean score on HAS which was 13.125 was reduced to 8.375 after the treatment. Thus recording a remission by 36.19 By adopting the Wilcoxon signed rank test.it is found that the improvement occurred with the treatment is greater than would be expected by chance; there is a statistically significant difference ($p = <0.001$).Effect on Group B initial mean score on HAS which was 15.600 was reduced to 5.667after the treatment. Thus, a recording remission by 63.67%.By adopting the Wilcoxon signed rank test the change that occurred with the treatment is greater than would be expected by chance there is a statistically significant difference ($p <0.001$). Details are shown in table no. 1 and figure no. 1.

Effect of comparison between the groups: The average improvement in Group A is 36.19 % and the Group B is 63.67%. This indicates that better response was in Group B and) the difference in the median values between the two groups is greater than would be expected by chance; there is a statistically significant difference. The details are shown in the table no.2.

EFFECT OF TREATMENT ON DEPRESSION SCALE

Effect on group A initial mean score on HDS which was 11.6 was reduced to 7.2 after the treatment. Thus recording a remission by 38.1 %.By adopting the Wilcoxon signed rank test.it is found that the improvement is statistically significant $p = <0.001$.Effect on Group B initial mean score on HDS which was 9.66 was reduced to 3.933 after the treatment. Thus recording a remission by 59.31%.By adopting the Wilcoxon signed rank test change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant difference ($p <0.001$). The details are shown in the table no.3 & figure no.2

Effect of comparison between the groups: The average improvement in Group A is 38.1 % and the Group B is 59.1%. This indicates that better response was in Group B and the difference in the median values between the two groups is greater than would be expected by chance;

there is a statistically significant difference ($p = 0.312$). The details are shown in table no. 4.

moderate remission, 6.6% patients had good improvement, 6.6% patients had marked remission and 6.6% patients had no improvement. In GROUP B (Guduchi) analysing the overall effect 26.6% of the patient had moderate remission, 60% patients had marked remission, and 13.3% excellent improvement was seen in patients. No improvement was not there. The details are shown in table no.5.

OVERALL EFFECT OF THE THERAPY

In Group A (Placebo) analysing the overall effect 6.6% of the patient had mild remission, 73.3% patients had

Group N= 15	Table no.1 Effect of treatment on Hamilton anxiety rating scale within groups								
	Bt Mean	At Mean	Diff of bt-at	% of relief	Wilcoxon signed rank test				
					Sd	Sem	Median	Z value	P value
Group A	13.125	8.375	4.75	36.19	4.272	1.068	14.000	-3.494	P = <0.001
					2.604	0.651	8.500		
Group B	15.600	5.667	9.933	63.67	5.054	1.305	15.000	-3.423	P(exact)= <0.001
					2.526	0.652	5.000		

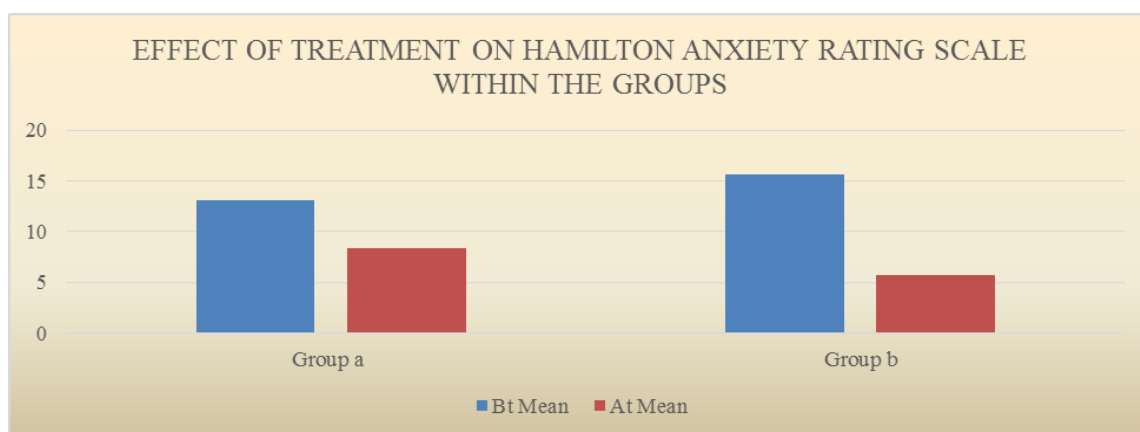


Figure no.1 Effect of treatment on Hamilton anxiety rating scale within groups.

Group N= 15	Table no.2 Effect of treatment of Hamilton anxiety rating scale						
	Mean	Sd	Sem	Median	Man Whitney u test		
Group A	5.133	2.264	0.584	4.000	T value	U value	P value
Group B	9.933	4.096	1.058	9.000	T= 150.0	195.000	P = <0.001

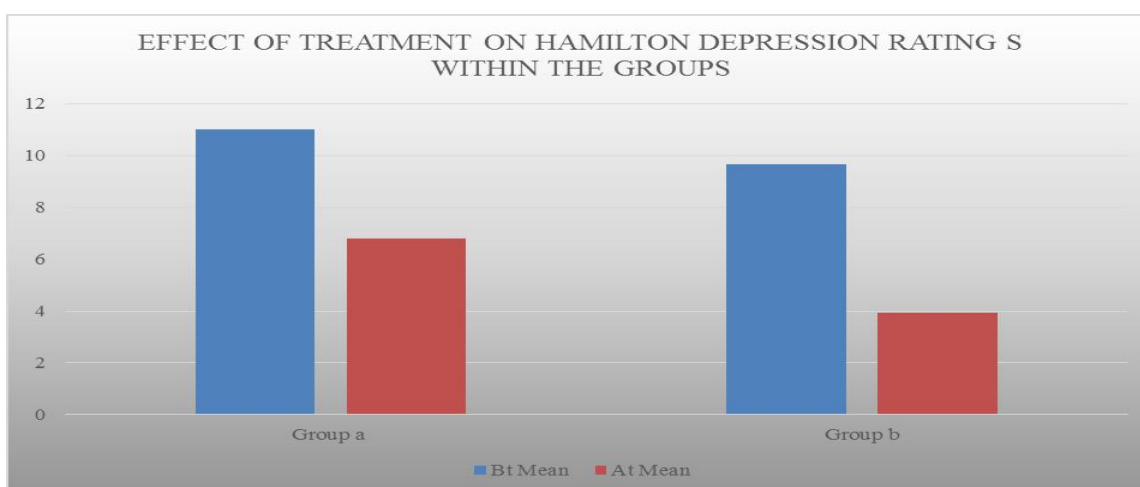


Figure no.2: Effect of treatment on Hamilton depression within groups.

Group N= 15	Table no.3 Effect of treatment of Hamilton depression rating scale within groups				
	Bt	At	Diff of	% of	Wilcoxon signed rank test

	Mean	Mean	bt-at	relief	Sd	Sem	Median	Z value	P value
Group A	11.6	7.2	4.4	37.9	3.460	0.893	13.000	-3.450	P = <0.001
					3.688	0.952	6.000		
Group B	9.667	3.933	5.734	59.31	4.435	1.145	8.000	-3.331	P = <0.001
					1.751	0.452	3.000		

Group N= 15	Table no.4 Effect of treatment of Hamilton depression rating scale						
	Mean	Sd	Sem	Median	Man Whitney u test		
Group A	4.400	2.293	0.592	4.000	T value	U value	P value
Group B	5.533	3.681	0.951	5.000	208.000	137.000	p = 0.312

Table no.5: overall effect of the therapy						
S.NO	IMPROVEMENT	SCALE	Group A		Group B	
			PATIENTS		PATIENTS	
			No.	%	No.	%
1	No	0	1	6.6	0	0
2	Mild	1-25	1	6.6	0	0
3	Moderate	26-50	11	73.3	4	26.6
4	Marked	51-75	1	6.6	9	60.0
5.	Excellent	76-100	1	6.6	2	13.3
			Total	Total	Total	Total
			15	100	15	100

DISCUSSION

Exam stress is having so much impact on student especially the young age to combat such situations and to help students during exam days 30 patients fulfilling the diagnostic criteria of exam stress were selected for the study and subjected to a randomized comparative clinical trial with pre-test and post-test design. Group A was administered with Cap.Placebo, and Group B was administered with Cap.Guduchi. Both drugs were administered for a time period of 30 days. Both groups showed statistically significant improvement in the outcome measures. This shows that both the treatment modalities are effective in *chittodvega*/exam stress. On comparison between the groups it was evident that the effectiveness of Cap Guduchi is more than that of Cap placebo with statistically significant results on analysis. Cap guduchi being a *tridoshashamaka* acts on *vata* which is causing disturbance in *mana* function. It will normalise *vata*, it will normalise the *sadhaka pitta* and *tarpaka kapha*. *Medhya rasyana* is chiefly indicated for specific conditions related to *manas* and its *medhya* property has contributed in obtaining the positive result. Guduchi acts on neurotransmitters and reduces the stress. Due to this antistress activity there will be normalisation of biochemical changes in norepinephrine, dopamine and 5-hydroxytryptamine. It was proved in experimental rats. In depressive patients the monoamine levels in brain reduces. Guduchi reduces the mono amine oxidase and increases the mono amine levels, with this there will be increase in the dopamine and thus acts as antidepressant. Berberine is an alkaloid present in Guduchi will be acting as anti-depressant. It contains alkaloids, diterpenoid, lactones, glycosides, sesquiterpenes, arabinogalactan. Its anti-stress and anti-depression property has been established. Thus similar results were shown in this study helping the students to

cop up with exam stress. The students who were having symptoms like anxiety, worry, restlessness, sleep disturbance, muscle tension.

CONCLUSION

- Both Formulations Cap.placebo and Cap.Guduchi are effective in the remission of the symptoms of *chittodvega* as evidenced statistically significant reduction in the symptoms score of various subjective parameters
- The effectiveness of Cap.Guduchi is tremendous comparing to that Cap.placebo as evidenced by the various outcome measures which was proved by statistical analysis.

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