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"A RANDOMISED CONTROLLED CLINICAL TRIAL OF ADD ON EFFECT OF JATAMANSI (Nardostachys jatamansi DC) FANT WITH CONVENTIONAL POST COVID PROTOCOL IN POST COVID ANXIETY"

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ABSTRACT:

Anxiety is such a biggest problem for society can be simply explained in terms of *chittodweg*[1] which means hyper activated state of mind. In management of such manas vikruti various '*Medhya'* dravya are mentioned in Ayurved like *Bramhi, Shankhapushpi, Kushmand, Jyotishmati, Jatamansi*, etc. The corona virus disease 2019 (covid 19) pandemic has affected people globally by causing psychological, social and economic status. However, many people after getting corona positive and even after completion of standard covid treatment are getting anxious and this post covid anxiety is becoming a severe problem. In Ayurveda covid 19 can be explained as '*Anukta Vyadhi*' since it is newly found viral disease. The drug

'Jatamansi'5 is traditionally being used by many Vaidya's in treating various psychological conditions such as stress, anxiety, insomnia, etc. due to its cognitive *(medhya)* effect.

INTRODUCTION:

While explaining the definition of 'Swastha'[2] Acharya Sushrut says that,

समदोषः समाग्निश्च समधातुमलक्रियः ।

प्रसन्नात्मेन्द्रियमनाः स्वस्थ इत्यभिधीयते ॥

In this definition, along with dosh, dhatu and other factors he gives equal importance to 'manas' factor also. Nowadays, manas health of people has been globally affected and its causes are variable.

Generally, anxiety[3] can be defined as a feeling of fear, dread and uneasiness. It might cause someone to sweat, feel restless, tense and have rapid heartbeats. There are several types of anxiety such as generalized anxiety disorder, panic disorder and phobia, etc. In case of post covid anxiety, corona virus could induce psychopathological sequence through direct viral infection of the central nervous system or indirectly via immune response and lead to anxiety disorder which will stay even after completion of standard treatment of covid 19.

In Ayurveda covid 19 can be explained as 'Anukta Vyadhi'[4] since it is newly found viral disease. As WHO declared novel coronavirus disease (covid 19) outbreak as pandemic and by taking in consideration the prevalence of 'Post Covid Anxiety' its due need of society to do clinical research work on it.

MATERIAL AND METHODS :

CLINICAL STUDY :

Sample size:

Study group - Two independent study groups

Primary endpoints – continuous (means)

Statistical parameters – Mean, group 1 = 60; Mean, group 2 = 50; Alpha = 0.05; Beta = 0.1; Power = 90% Sample Size n = 21.

However, by considering dropout rate of 10 % it will become n = 24.

Thus, Group A = 24 and Group B = 24. So total no. of patients will be 48.

Study design: Randomized, controlled clinical trial, Prospective.

Study setting:

A randomized control trial study.

⬇

No objection certificate from the institution ethics committee was obtained.

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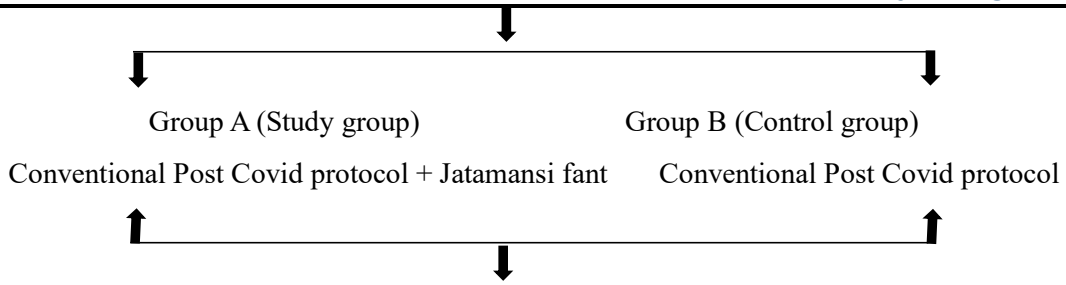
Baseline screening and patient enrollment as per inclusion and exclusion criteria.

⬇

Written informed consent of patients was taken.

⬇

Random allocation of two groups was done (lottery method)



SOP of *Jatamansi fant* preparation was taught to patients

Daily monitoring the patients was done via telephone

Follow-up of the patients after 7 days

Collection of data

Statistical Analysis

Discussion

Conclusion

Ethical clearance:

1. No objection certificate was obtained from the Institutional Ethics Committee (IEC) prior to initiation of the project.
2. Bilingual patient information sheets were prepared.
3. Informed consent was taken from all patients before initiation of the trials.

Inclusion Criteria:

1. Post covid patients of Mild and Moderate anxiety of age group 18-80 yrs. was selected irrespective of their gender and religion.
2. As per clinical examination and specific anxiety disorder scale post covid patients fulfilling the criteria of Mild and Moderate anxiety was selected.
3. Patients willing to give consent to participate in the trial.

Exclusion Criteria:

1. Patients with known case of serious illness such as cancer, kidney disease, heart disease.
2. Patients with known case of Mental retardation or having any other psychological disorder.

(c) **Duration of study**- 28 days (Reference from the previous work done).

(d) **Route of Administration** - Oral administration of Jatamansi fant

(e) **Dosage** – 1/2 Pal134 (20 ml)[5]

(f) **Time** – Nisha kaal (at bedtime).

Intervention of drug:

	Group A.	Group B
Route of administration	Oral	Oral/councelling
Time	*Nisha kaal*	BD
Duration	28 days	28 days

Follow up chart:

Visit Day	0th day	7th day	14th day	21st day	28th day
Date					
Written consent	+				
Complete medical history	+				
Clinical examination	+				
Demographic record	+				
Vitals	+	+	+	+	+
Ayurvedic examinations	+	+	+	+	+
Efficacy parameters	+	+	+	+	+

Criteria for assessment of efficacy of drug:

Criteria of assessment for efficacy of drug was as follows:

Modern parameter:

Hamilton's Anxiety Rating Scale (HAM-A)[6]

Ayurvedic Assesement Criteria:

Grading of Chittodweg according to Ayurveda

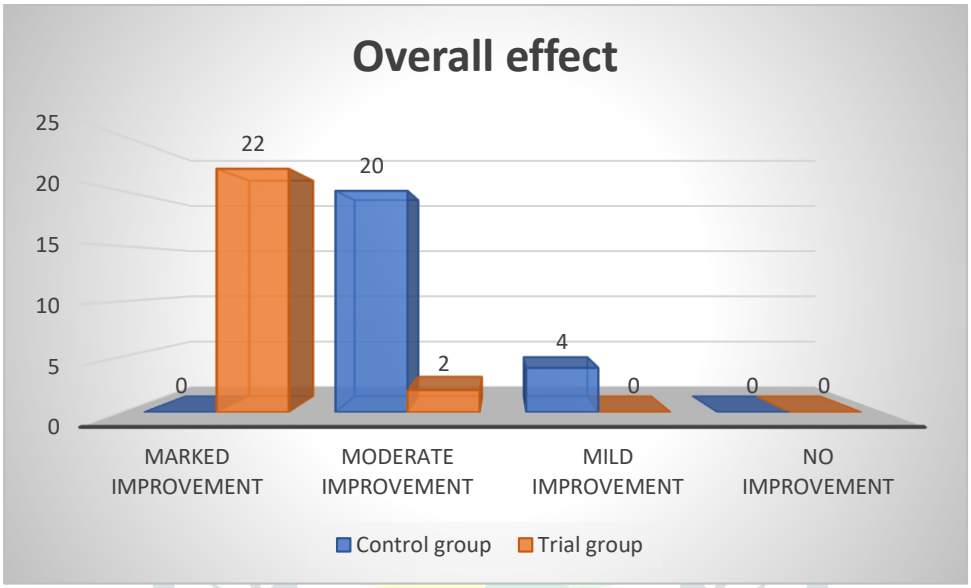
OBSERVATIONS AND RESULTS:

Overall conclusion:

As per above result of comparison between both groups, trial group shows more effective result in 8 parameters out of 13 parameters. In remaining 4 parameters both groups are equally effective and in 1 parameter control group is more effective. So, by overall result trial group is more effective than control group.

Overall Effect

Overall effect	Control group	Trial group
Marked improvement	0	22
Moderate improvement	20	2
Mild improvement	4	0
No improvement	0	0



Interpretation: Above table and graph reveal that, 83% patients in control group showed moderate improvement, 17% showed mild improvement. In trial group, 92% patients showed marked improvement, 8% showed moderate improvement and no patient with mild improvement. No patient in both groups with no improvement.

DISCUSSION:

In control and trial group sample size is 24. On each sample 13 parameters are measured in 5 follow ups. Out of 13 parameters 12 are qualitative (ordinal) in nature and 1 parameter is quantitative in nature.

According to type of parameter the appropriate statistical

tests are as follows:

Type of variable	What is going to check	Appropriate test
Quantitative	Follow up wise treatment results	Repeated Measures ANOVA
	Before and after treatment results	Paired t test
Ordinal	Follow up wise treatment results	Friedman test
	Before and after treatment results	Wilcoxon signed rank test

Data of each Parameter metioned earlier has been displayed graphically. As per result, on an average 'Hamiltons Anxierty Rating Scale' is decreased from 19.71 to 13.29. As p value < 0.05, there is significant difference in 'Hamiltons Anxierty Rating Scale' after treatment. So, treatment is effective to decrease 'Hamiltons Anxierty Rating Scale'. On the other hand result of comparison between both groups, trial group shows more effective result in 8 parameters out of 13 parameters. In remaining 4 parameters both groups are equally effective and in 1 parameter control group is more effective. So, by overall result trial group is more effective than control group.

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