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Effect of *Draksha Samangadi Kashaya Ghan Vati* in Adolescents with Psychological Distress - A Double Blind Randomized, Placebo Controlled Trial

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ABSTRACT

Aim of study: A double blind randomized, placebo-controlled trial was planned to evaluate the Clinical efficacy of *Draksha Samangadi Kashaya Ghan Vati* an Ayurveda multi-dimensional herb preparation in Adolescents suffering with Psychological Distress. The trial drug contains *Draksha, Samanga, Gavakshi, Trayamana, Yashtimadhu, Chandana, Maricha, Pippali, Shunthi*. All ingredients of the study drug possess anti-stress, anti-depression, anti-anxiety, nootropic and anti-oxidant properties. **Materials and Methods:** A total of 40 patients complected the trial, including male and female patients, were studied for suffering of Psychological Distress and were registered and divided into 2 groups (Group A, B,). In group A, patients were administered *Draksha Samangadi Kashaya Ghan Vati,* dose 500 mg/day twice a day for 2 months in children suffering from Psychological Distress. In group B, Placebo - Chocolate Coated Starch Tablets were administered to 20 patients at a dose of 500 mg/day. All the treated cases were assessed at each follow-up on the 14th day, 28th day, 42nd day, and 56th day, and post-follow-up was done after 1 month. The efficacy of drugs was assessed clinically and also based on Depression, anxiety and stress scale (DASS 42). **Result:** Group A consistently shows significant improvements across all three psychological conditions (Depression, Anxiety, and Stress) compared to Group B. **Conclusion:** *Draksha Smangadi Kashaya Ghan Vati* (Chocolate Coated) is effective in the management of Psychological Distress in Adolescents.

Key words: *Draksha Samangadi Kashaya Ghan Vati, Trayamana, Yashtimadhu, Chandana, Maricha, Pippali, Shunthi.*

INTRODUCTION

The word adolescent comes from the Latin verb adolescent meaning “To grow up. According to WHO adolescents lies in between 10-19 years of age.[1] Because of the physical, psychological, and sexual changes that occur during adolescence, the psychiatric complaints like depression, anxiety, and stress occurs during this phase of life is a cause for alarm. The world’s highest population of adolescents live in India that is 253 million and every 5th individual is in the middle of 10 to 19 years.[2] In adolescent the term psychiatric morbidity is defined as abnormality in relationship, emotions, general behavior and activity which is developmentally inapt and responsible for persistent suffering or handicap the adolescents and/or distress to the households or society. Adolescents experience psychosocial issues at some point during their growth. The majority of these issues are temporary and generally go unrecognized. It's worth noting that adolescents can have these issues in one situation but not in another (e.g., family, school and friend’s circle). Consequently, these psychiatric morbidities are often misinterpreted. They may be measured intentional or purposefully, their self-

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esteem may be diminished as a result of social exclusion, sanctions, and criticism. Children and teenagers may be denied the help they require due to a faulty and improper understanding of these mental illness.

"Adolescence is a critical period characterized by vulnerability to psychological distress, and is therefore an important time for promotion of psychological well-being and early mental health intervention, in order to safeguard against the development of mental health issues".[3] Adolescence is frequently marked by fresh stress, behavioural changes, and relationship issues, which have an impact on psycho-social development. Adolescent children who have their parents taking part in their life are better able to deal with challenges and maintain their physical and emotional wellbeing. High levels of parental participation and the formation of a close relationship between children and parents have been linked to lower rates of depression and loneliness among young people in high-income countries.[4,5,6]

The prevalence of mental problems among teenagers attending primary health care institutions in underdeveloped nations ranges from 12 to 29 percent.[7] India accounts for 21% of the world's adolescent population. One out of six children affected with psychiatric morbidities. Early Indian community-based studies reported the prevalence rate of psychiatric disorders among children ranging from 2.6% to 35.6%.[8] Untreated mental health problems among adolescents may lead to poor school performance, school dropout, strained family relationships, substance abuse, and engaging in risky sexual behaviors.[9]

Modern psychiatry still has limitations to access the diversity of mind and its functional aspects. Etiopathogenesis of several psychiatric morbidities are still mysterious, and contemporary management is often only partially effective along with lots of adverse effects.

Ayurveda *Medhya Rasayana* are specifically indicated for maintenance of mental/psychological well-being. Several studies also certify that these drugs have nootropic as well as psychotropic effect and work variously to improve the psychological functioning of an individual. Therefore, it is supposed that these drugs can be beneficial in this area also.

Aim and Objective

To evaluate the effect of *Draksha Samangadi Kashaya Ghan Vati* in management of Psychological distress.

Materials and Methods

Study Type: Clinical Study

A Double blind, randomized, placebo-controlled trial was conducted under a strict protocol to prevent bias and to reduce the sources of error.

Selection of Cases

Source: In present clinical study total 42 patients were registered under the clinical trial from O.P.D./I.P.D., National Institute of Ayurveda, Deemed to be University, Jaipur. and 42 patients were randomly divided into 2 groups. 20 patients in Group A and 22 patients in Group B. Total 40 patients completed the trial 2 Subjects discontinued the trial from group B.

Inclusion Criteria

1. Adolescents of age between 13-19 years of either sex.
2. Adolescents having signs and symptoms Psychological distress (DAS).
3. Overtly healthy adolescents.
4. Adolescents whose parents were willing to give consent for clinical trial.

Exclusion Criteria

1. Any past history of diagnosed mental illness.
2. Any severe mental illness requiring hospitalization.
3. Adolescents suffering from major systemic illness necessitating long term treatment like, Known Case of Anaemia, Hypothyroidism and Juvenile Diabetes mellitus.
4. H/o hypersensitivity to any drug.
5. Adolescents whom parents were not willing to give consent for clinical trial.

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Withdrawal Criteria

The participant may be withdrawn from the trial if there was:

1. Any major ailment necessitating the institution of new modalities of treatment.
2. Non-compliance of the treatment regimen (minimum 70% compliance was essential to continue in the study).
3. Participant not willing to continue trial.

The decision to withdraw a participant from the trial was taken only by the Principal Investigator, who then have to set out a detailed justification and also indicate the line of further management if was needed. The same needs to the Sponsor and the Ethics Committee within two working days.

Laboratory Investigation (Required to exclude)

Complete Blood Count (CBC), Thyroid Stimulating Hormone (TSH) and Random Blood Sugar (RBS) for exclusion of patients suffering from Chronic Anaemia, Hypothyroidism and Diabetes Mellitus.

Trial Drug - *Draksha Samangadi Kashaya Ghan Vati*

Table 1: Showing ingredients of *Draksha Samangadi Kashaya Ghan Vati*

Drug	Scientific Name	Family	Part used	Drug Ratio
Draksha	*Vitis Vinifera*	Vitaceae	Fruit	1 Part
Samanga	*Rubia cordifolia*	Rubiaceae	Root	1 Part
Gavakshi	*Cirullus colocynthis*	Cucurbitaceae	Fruit	1 Part
Trayamana	*Gentina kurroo*	Gentiananacea	Root	1 Part
Yashtimadhu	*Glycyrrihza glabra*	Leguminosiae	Stolon	1 Part
Chandana	*Santalum album*	Santaliaceae	Stem	1 Part
Maricha	*Piper nigrum*	Piparaceae	Fruit	1/3 Part
Pippali	*Piper longum*	Piparaceae	Fruit	1/3 Part
Shunthi	*Zingiber officinale*	Zingibaraceae	Rhizome	1/3 Part

Table 2: Showing Grouping and Intervention

	Group A	Group B
Drug	*Draksha Smangadi Kashaya Ghan Vati* (Chocolate Coated)	Placebo - Chocolate Coated Starch Tablets
No. of Cases	20	20
Dosage form	Tablets (250 mg)	Tablets (250mg)
Route of administration	Oral	Oral
Vehicle	Water	Water
Time of administration	12 hourly (500 mg/day)	12 hourly (500mg/day)
Duration of therapy	8 weeks	8 weeks
Dose	500 mg/day	500 mg/day

Follow ups: Every 2 weeks (Day 14th, 28th, 42th and 56th)

Duration of drug administration/ trial: 8 weeks

End Point: Safety and Efficacy

Assessment Criteria

- Depression, anxiety and stress scale (DASS 42)
- AyuSoftware Tool for *Prakriti* assessment

Methods of Assessment

1. **Prior to selection - (screening)**
   - Informed consent/assent
   - Eligibility evaluation based on survey
2. **During selection - (baseline)**
   - General information (personal identification and demographic profile).

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- Medical history, general physical and systemic examination.
- Assessment of psychological distress (DAS).
- Issue of drugs.
- Instructions to come after 2 weeks

3. During treatment i.e., on 14th, 28th, 42nd

Assessing drug compliance.

- Issue of drugs.
- Instructions to come at each follow up after 2 weeks
- ADR Assessment

4. At the end of the treatment i.e. at the end of 8 weeks (56th Day)

- Medical history, general physical and systemic examination.
- Assessment of Psychological Distress by DASS Score.
- ADR Assessment

Assessment Tool

Depression, anxiety and stress scale (DASS 42)

Outcome Measures

1. Primary outcome measures

- Change in depression, anxiety and stress scale (DASS 42) Score.

2. Secondary outcome measures

- Improvement in total well being.

Adverse Drug Reaction (ADR)

No ADR (Adverse Drug Reaction) was reported during the course of trial. This is confirmed by the ADR certificate with reference number F.NO.-IPvC /NIA/0055/23.

Institutional Ethics Committee Clearance

The ethical approval of the present trial has been taken by the Institutional ethics committee, National Institute of Ayurveda, Jaipur, Order No. IEC/ACA/2021/02-36, dated 01-09-2021.

Clinical Trial Registry of India Registration

Prior to the start of trial, the study was applied for registration in CTRI with reference number REF/2022/03/052596 and in march 2022 trial was registered to CTRI with registration No. CTRI/2022/03/041548.

Data Documentation and Analysis

All information regarding clinical trial were properly documented, carefully handled and meticulously stored in order to ensure its accurate interpretation and verification. Observation documented during the study were analysed and findings were evaluated by using statistical methods.

For Objective parameters: Students - Paired t-Test.

For Subjective parameters: - Ordered chi-square test.

Observation and Results

Table 3: Basic details of two groups

	Variables	Frequency	Percent
Group	A	20	50
	B	20	50
	Total	**40**	**100**
Gender	Male	10	25
	Female	30	75
	Total	**40**	**100**
Religion	Hindu	36	90
	Muslim	4	10
	Total	**40**	**100**
Economic status	High	1	2.5
	Middle	38	95
	Low	1	2.5
	Total	**40**	**100**
Immunization Status	Complete	32	80
	Incomplete	1	2.5

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	Unknown	7	17.5
	Total	40	100
Habitat	Rural	8	20.0
	Urban	32	80.0
	Total	**40**	**100.0**
Family Type	Nuclear	26	65
	Joint	14	35
	Total	**40**	**100**
Total no. of family member	4	10	25
	5	16	40
	6	1	2.5
	7	8	20
	9	4	10
	11	1	2.5
	Total	**40**	**100.0**
Diet Habit	Regular	23	57.5
	Irregular	17	42.5
	Total	**40**	**100.0**
Type of diet	Veg	34	85.0
	Mixed	6	15.0
	Total	**40**	**100.0**
Frequency of fast food (time/weeks)	1	2	5.0
	2	22	55.0
	3	10	25.0
	4	4	10.0
	5 or more	2	5.0
	Total	**40**	**100.0**

Frequency of carbonated drink (time/week)	No	2	5.0
	1	7	17.5
	2	17	42.5
	3	8	20.0
	4 or more	6	15.0
	Total	**40**	**100.0**
Frequency of tea/coffee (time/days)	No	7	17.5
	1	7	17.5
	2 or more	26	65.0
	Total	**40**	**100.0**
Use of Tobacco, Alcohol, Cigarette	No	40	100.0
Appetite	Normal	23	57.5
	Increased	1	2.5
	Decreased	16	40.0
	Total	**40**	**100.0**
Micturition	Normal	39	97.5
	Reduced	1	2.5
	Total	**40**	**100.0**
Bowel Habit	Regular	30	75.0
	Irregular	10	25.0
	Total	**40**	**100.0**
Bowel frequency	Normal	30	75.0
	Constipated	10	25.0
	Total	**40**	**100.0**
Pattern of Menstruation Cycle	0 (Male)	10	25.0
	Regular	21	52.5
	Irregular	9	22.5

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	Total	**40**	**100.0**
Dysmenorrhoea	0 (Male)	10	25.0
	Yes	15	37.5
	No	15	37.5
	Total	**40**	**100.0**
Prakriti	*KP*	9	22.5
	KV	13	32.5
	PK	1	2.5
	VK	17	42.5
	Total	**40**	**100.0**
Vikriti	*Prakriti Sam Samvaya*	40	100.0
Saara	*Asthi*	5	12.5
	Mansa	3	7.5
	Meda	1	2.5
	Rakta	6	15.0
	Twak	25	62.5
	Total	**40**	**100.0**
Samhanana	*Madhyama*	40	100.0
Satmya	*Madhyama*	40	100.0
Satva	*Madhyama*	9	22.5
	Avara	31	77.5
	Total	**40**	**100.0**
Ahara Shakti	*Madhyama*	14	35.0
	Avara	26	65.0
	Total	**40**	**100.0**
Vyayama Shakti	*Madhyama*	19	47.5
	Avara	21	52.5
	Total	**40**	**100.0**
***Drishti* (Vision)**	Normal	29	72.5
	Abnormal	11	27.5
	Total	**40**	**100.0**
Sleep	Normal	35	87.5
	Disturbed	5	12.5
	Total	**40**	**100.0**

Table 4: Comparative Distribution of Anthropometric Measures between Group A and Group B

	Group A			**Group B**		
	Min.	**Max.**	**Mean ± SD**	**Min.**	**Max.**	**Mean ± SD**
Age (years)	13	17	15.25±1.118	13	18	15.20±1.281
Weight (kg)	36.4	74.0	47.125±9.850	29.9	54.3	42.505±6.572
Height (CM)	140.0	177.0	159.240±8.740	143.0	174.0	156.200±7.466
BMI	13.5	24.4	18.485±3.176	13.8	21.3	17.360±1.837

Table 5: Comparative Distribution of Treatment Effects on Depression, Anxiety, and Stress Levels in Group A and Group B

	Grade	**Group A**			**Group B**		
		Before Treatment	**After Treatment**	**p value**	**Before Treatment**	**After Treatment**	**p value**
Depression	1 (Normal)	5	9	0.002	5	11	0.162
	2 (Mild)	2	10		7	7	

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	3 (Moderate)	8	1		5	2	
	4 (Severe)	4	0		1	0	
	5 (Extremely severe)	1	0		2	0	
Anxiety	1 (Normal)	3	8	0.00005	2	6	0.1211
	2 (Mild)	1	6		6	8	
	3 (Moderate)	3	6		5	5	
	4 (Severe)	5	0		3	1	
	5 (Extremely severe)	8	0		4	0	
Stress	1 (Normal)	2	14	0.00007	5	9	0.058
	2 (Mild)	6	3		4	8	
	3 (Moderate)	6	3		9	3	
	4 (Severe)	6	0		2	0	
	5 (Extremely severe)	0	0		0	0	

Ordered chi-square test of independence

There are varying degrees of improvement across the different psychological conditions and groups. In terms of Depression, participants in Group A demonstrated a statistically significant improvement (p = 0.002). Conversely, the change in Group B, though positive, was not statistically significant (p = 0.162). Similarly, when considering Anxiety levels, participants in both Group A and Group B showed noteworthy improvements post-treatment. Group A exhibited a highly significant reduction (p = 0.0005). In contrast, Group B experienced though the effect did not reach statistical significance (p = 0.121).

For Stress levels, participants in both groups displayed improvements, but the changes were more pronounced in Group A. Group A experienced a highly significant reduction in stress levels (p = 0.0007). Group B, on the other hand, which was not statistically significant (p = 0.058). Group A consistently shows significant improvements across all three psychological conditions (Depression, Anxiety, and Stress) compared to Group B. Specifically, Group A experiences statistically significant reductions in scores for Depression (p = 0.002), Anxiety (p = 0.0005), and Stress (p = 0.0007) after treatment. In contrast, while Group B also shows positive changes, these improvements do not reach statistical significance for any of the three conditions. Overall, the data suggests that Group A responds more favourably to the treatment in comparison to Group B.

Discussion

In the present study, for internal use, *Draksha Smangadi Kashaya Ghan Vati* was selected for oral route of administration. The effect attained by the study drug can be explained by multiple mechanism. The ingredients of *Draksha Smangadi Kashaya Ghan Vati* have predominantly *Laghu, Tikshna, Ruksha, Snigdha* and *Sara Guna. Laghu Guna* is explained to be similar in property with *Satva Guna* which improves the persons stress tolerance levels. *Tikshna* and *Ruksha Guna* by virtue of their characteristics removes the obstruction in *Manovaha Srotas* caused vitiated *Kapha Dosha*. *Snigdha Guna* nourishes the *Tarpaka Kapha* which help the proper functioning *Indriyas* (Sense organs). *Sara Guna* improves the emotional and thought aspects and improves the insight of the recipients.

Analysis of *Rasa* of the drugs depicts that majority of the drugs possesses *Katu* and *Tikata Rasa* which helps

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in *Pachana* of *Ama dosha* and at the same time pacified vitiated *Kapha Dosha.* Also, some drugs possess *Madhrua Rasa* which does *Shadindriye Prasadana* and also acts a *Medhya.*

Considering the *Vipaka* of all ingredients of study drug, 50% drugs have *Madhura Vipaka* and 50% have *Katu Vipka*. *Madhura Vipaka* is said to increase all the *Sharira Dhatus*, including the brain tissue, nourishes the *Mana* and *Indriyas*. Thus, it can be assumed that it has nourishing effect on the brain. *Katu Vipaka* on the other hand increases the overall metabolism in the body including the brain, helps in absorption of nutrients, thereby reducing nutrients deficiency and stimulates all sense organs to perceive their functions normally.

Vishada and *Chittodvega* is described as the state of elevated *Vata* and *Kapha dosha*. The vitiated *Kapha dosha* does the *Avarana* of *Vata Dosha* which in turn leads to improper functioning of *Vata*. The study drug is mainly *Kapha-Vata Shamaka* property and removes the vitiated *Kapha Dosha Avarana* and clears the channels for proper functioning of *Vata Dosha*. Also vitiated *Kapha Dosha* impairs the functioning of *Sadhaka Pitta*. Once this *Vata Dosha* gets normal, it helps in normal perception of environmental inputs which leads to proper acquisition of knowledge. As the knowledge is acquired accordingly the level of anxiety and stress is decreased and the confidence levels are improved.

Drugs like *Pippali* and *Yasthimadhu* in the study drug are proven *Medhya* drugs. These drugs through their properties improves the cognition and perception in the brain tissues and acts as nootropic drugs. These drugs improve the analysis aspect of the brain and improve the tolerance state of the brain.

Majority of constituents of study drug possess *Rasayana* property. By virtue of this property the study drug nourishes all the Dhatu in the body including the brain tissues. As the brain tissues are nourished their potency improves and the cognition is improved.

Trikatu is a known drug which possess *Deepana* and *Pachana* property. This property results in the improvement of *Jatharagni* (metabolism) which does the proper assimilation of food. As the food is properly digested the forming *Dhatu* will be of optimum quality. Also, *Trikatu* (*Pippali*, *Shunthi* and *Maricha*) improves the bioavailability of the drugs and helps in proper assimilation and absorption of the drug towards the site of action.

Various clinical and experimental study proved that all ingredients of the study drug possess anti-stress, anti-depression, anti-anxiety, nootropic and anti-oxidant properties. By virtue of these properties the study drugs act on the brain tissues and improves the cognition and perception state of the brain. These drugs at the same time improves the learning and memory state of the child which improves their academic performance. As the academic performance is improved the level of associated stress is reduced.

CONCLUSION

In this study, Group A (Trial drug intervention) consistently showed significant improvements across all three psychological conditions (Depression, Anxiety, and Stress) compared to Group B. Specifically, Group A experiences statistically significant reductions in scores for Depression ($p = 0.002$), Anxiety ($p = 0.0005$), and Stress ($p = 0.0007$) after treatment. In contrast, while Group B (placebo group) also showed positive changes, these improvements do not reach statistical significance for any of the three conditions. Therefore, it can be concluded that *Draksha Smangadi Kashaya Ghan Vati* (Chocolate Coated) is effective in the management of Psychological Distress in Adolescents.

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