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EFFECTIVENESS OF SARASWATARISTA IN MANAGEMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER: RANDOMISED, DOUBLE BLIND PLACEBO-CONTROL CLINICAL STUDY

Mahapatra Arun Kumar*[1] and K B Mahapatra[2]

[1]All India Institute of Ayurveda, Gautampuri, Mathura road, New Delhi -110076, India.
[2]PG Department of Prasutitantra and Stree Roga, Gopabandhu Ayurveda Mahavidyalaya, Puri, Odisha-752001, India.

ABSTRACT

Attention deficit/hyperactivity disorder (ADHD) is the commonest neurodevelopmental disorder of children. The present study was conducted to evaluate the effectiveness of traditional Ayurvedic formulation 'Saraswatarista' in the management of pediatric attention deficit hyperactivity disorder. Children aged 07-13 years suffering from ADHD were screened out from OPD of PG Department of Gopabandhu Ayurveda Mahavidyalaya, Puri and from various schools situated in Puri by survey method. Patients were randomized into two groups. Group A (15 patients) received Traditional Ayurvedic formulation 'Saraswatarista' (01ml/kg/body weight in divided dose) and group B received placebo syrup (01ml/kg/body weight in divided dose) for a period of 12 weeks. All the patients were subjected to thorough baseline screening and followed by assessment through NICHQ Vanderbilt assessment scale – parent's informant and NICHQ Vanderbilt assessment scale – teacher's informant. Group A patients showed highly significant (P<.001) improvement in overall scholastic performance, Participation in Organized Activities, Writing Skills, Mathematical Aptitude, Relationship with Parents, Relationship with Siblings, Relationship with Peers and Reading Ability while in group B the change from baseline was statistically not significant with $p > 0.05$. No adverse event was evident during the study period. Thus, Saraswatarista is found to be effective in managing Attention deficit/hyperactivity disorder (ADHD) by reducing the severity of core symptoms as evident by improvement in various assessment parameters.

Key words: *Ayurveda*, *Saraswatarista*, ADHD.

INTRODUCTION

Attention deficit hyperactivity disorder (ADHD) is the most common neurodevelopmental disorder in childhood, and it is found to be occurring in about 5.29% of children worldwide. [1] The core symptoms of ADHD include inattention, impulsivity and hyperactivity. ADHD has three subtypes defined as - the predominantly inattentive type, the predominantly hyperactive-impulsive type and the combined type. ADHD is associated with impairment in all aspects of a child's life, i.e. family, social, and academic. [2] American academy of child and adolescent psychiatry recommends stimulant medication as a first-line modality for treating ADHD. [3] The two main classes of stimulants are methylphenidate and its derivatives and amphetamine and its derivatives. Studies show that methylphenidate is quite effective in improving the core symptoms of ADHD[4] However no improvement is noted in academic achievement or social skills after administration of these stimulant drugs. Moreover these drugs are associated with various side effects including abdominal discomfort, loss of appetite and initial weight loss. [5] Apart from this, these drugs require continuous monitoring. Thus, need of hour is to search for therapeutic agents from natural sources which is effective and devoid of any adverse side effects. The present study was undertaken to evaluate the efficacy of traditional *Ayurvedic* formulation "*Saraswatarista*" in the management of ADHD.

Corresponding Author :- **Mahapatra Arun Kumar** Email:- ayuarun@gmail.com

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MATERIALS AND METHODS

A randomized double blind placebo control study was conducted in children with Attention Deficit hyperactivity disorder.

Selection of cases

- **Source-** Patients for the present study were screened out from OPD of P.G. Department of Gopabandhu Ayurveda Mahavidyalaya, Puri and from various schools situated in Puri, Odisha by survey method.
- **Age group -** Patients between 07 to 13 years of age were considered for the study.
- **Number of cases** - 35 children were registered out of which 05 children discontinued the treatment.
- **Grouping of patients** - Selected patients were randomly divided into two groups.

Group A: This group of 15 patients was treated with *Ayurvedic* formulation '*Saraswatarista'*

Group B: This group of 15 patients was given only placebo syrup.

Diagnostic criteria

Diagnostic screening of children for ADHD was done according to DSM-IV Criteria (American psychiatiric association, 2000) [6]

Inclusion criteria

1. Subjects aged 07-13 years of age of either sex satisfying DSM-IV criteria
2. Children with normal IQ level
3. Parent or Legal guardian of each patient willing to give consent to participate in the clinical trial.
4. Unwilling to take any other therapy of psychiatric intervention during the study period.

Exclusion criteria

1. Subjects below 07 and above 13 years of age
2. Subjects with mental retardation
3. Presence of any genetic or chromosomal abnormality
4. Presence of space occupying lesion, convulsive disorder etc
5. Association with any metabolic disorder
6. Subjects with visual and/or auditory problems
7. Patients who have used any other investigational drug one month prior to start of the study treatment
8. Non- concomitant severe illness necessitating other therapeutic intervention

Subject withdrawal criteria

1. Patient/parent/legal guardian who wished to discontinue the treatment during trial period
2. Patients loosing follow-up visits

Post screening Assessment methodology

The selected patients were interviewed along with their parents and teachers to obtain detail history and to collect data for the demographic and clinical profile of patients with attention deficit hyperactivity disorder (ADHD). *Sharirika* and *Manasika prakriti pariksha* was done as the part of evaluation.

Parameters of assessment

All the patients were subjected to baseline screening followed by assessment tests like:-

1. NICHQ Vanderbilt assessment scale – parent informant
2. NICHQ Vanderbilt assessment scale – teacher informant

Side effect evaluation criteria

To rule out possible side effects of the study drug, clinical criteria were adopted. It included the documentation of information, related to change in appetite, sleep, abdominal discomfort, drowsiness, irritability etc.

Trial drug

Saraswatarista (without gold) was selected as trial drug for the present study. The drug was prepared in the pharmacy of Gopabandhu Ayurveda Mahavidyalaya Puri, Odisha

Classical reference

Bhaisajya Ratnawali Rasayan Prakaran 73/182-196

Dose

01 ml/kg/day in two divided doses with equal amount of water after principal meals

Duration of drug administration

Trial drug and placebo was administered for a total period of 12 weeks.

Placebo

The placebo for the study was also in the same form as study drug. The doses were similar to that of study drug

Statistical tests

Data obtained from these parameters before treatment (BT), after 06 weeks of treatment (AT1) and after 12 weeks of treatment (AT2) were subjected to statistical analysis. Paired t-test was used for the purpose of test of significance. Group comparison was made through unpaired t-test. The effectiveness of therapy was assessed through p-value.

Overall efficacy assessment

Overall effect of treatment was assessed according to the following classification

1. Completely remission Improvement more than 80%
2. Markedly cured Improvement between 60-79%
3. Moderately cured Improvement between 40-59%

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4. Slightly cured Improvement between 11-39%
5. Unchanged Improvement less than 10%

Observation and results

A total of 35 patients were included for the study; 05 patients discontinued treatment. Thus, the study was conducted on 30 patients. Of the total patients, 73.33% were in the age-group of 07-09 years, 16.67% in the age-group of 09-11 years, and 10.00% in the age-group of 11-13 years. The majority of the children (83.33%) were males; the male: female ratio was found to be 5:1. Majority of patients included under the study i.e. 27 (90%) were Hindus, whereas 02 (6.67%) patients were Muslims and only 01 (3.33%) patient was found to be Christian by religion. Of the total 30 patients, 70.00% (21 nos.) of patients were found to be belonging to lower middle socioeconomic class followed 16.67% (05 nos.) patients from upper middle class. Maximum patients i.e. 43.33% showed positive family history of ADHD in siblings whereas 23.33% of the patient's father had positive history and in 10% case positive maternal side family history of ADHD was evident.

Poor father-child relationship was found in 24 (80%) cases. Relationship was rated as average in 05 (16.67%) cases while it was satisfactory in only 01 (03.33%) case. Similarly poor mother-child relationship was found in 26 (86.67%) cases while only 04 (13.33%) cases reported average relationship with mother in the family. Majority of patients i.e. 25 (83.33%) cases showed abnormal classroom behavior while only 05 (16.67%) patients showed normal behavior in classroom as reported by teachers. Teacher student relationship was found to be poor in 26 (86.67%) patients while it was found to be average in only 04 (13.33%) cases. Maximum number of patients i.e. 23 (76.67%) were poor academic performers. Average academic performance was reported in 04 (13.33%) whereas only 03 (10%) patients showed satisfactory academic performance.

Table 1. Statistical analysis showing the effectiveness of treatment in Group A in different Performance parameters of NICHQ-Vanderbilt Assessment Scale (Parent Informant)

Performance Parameters	Duration	Mean ± S.D.	Mean diff. ± S.D.	d.f.	t-value	p-value
Overall School Performance	B.T.	4.6 ± 0.91	-	14		
	A.T.1	3.2 ± 0.56	1.4 ± 1.06		5.14	< 0.001***
	A.T.2	1.8 ± 0.41	2.8 ± 1.08		10.02	< 0.001***
Reading Ability	B.T.	4.47 ± 0.92	-	14		
	A.T.1	3.2 ± 0.68	1.27 ± 1.16		4.22	< 0.001***
	A.T.2	1.93 ± 0.46	2.53 ± 1.13		8.72	< 0.001***
Writing Skills	B.T.	4.53 ± 0.92	-	14		
	A.T.1	3.13 ± 0.74	1.4 ± 1.24		4.37	< 0.001***
	A.T.2	1.87 ± 0.52	2.67 ± 1.18		8.79	< 0.001***
Mathematical Aptitude	B.T.	4.67 ± 0.72	-	14		
	A.T.1	3.0 ± 0.76	1.67 ± 1.11		5.80	< 0.001***
	A.T.2	1.73 ± 0.46	2.93 ± 0.88		12.86	< 0.001***
Relationship with Parents	B.T.	4.6 ± 0.91	-	14		
	A.T.1	3.13 ± 0.64	1.47 ± 1.06		5.36	< 0.001***
	A.T.2	1.8 ± 0.56	2.8 ± 1.01		10.69	< 0.001***
Relationship with Siblings	B.T.	4.27 ± 0.88	-	14		
	A.T.1	3.0 ± 0.53	1.27 ± 1.03		4.75	< 0.001***
	A.T.2	1.67 ± 0.49	2.6 ± 1.06		9.54	< 0.001***
Relationship with Peers	B.T.	4.53 ±0.74	-	14		
	A.T.1	3.13 ± 0.64	1.4 ± 1.06		5.14	< 0.001***
	A.T.2	1.67 ± 0.49	2.87 ± 0.92		12.13	< 0.001***
Participation in Organized Activities	B.T.	4.07 ± 1.03	-	14		
	A.T.1	3.13 ± 0.64	0.93 ± 1.22		2.96	< 0.05*
	A.T.2	1.4 ± 0.51	2.67 ± 1.11		9.28	< 0.001***

Table 2. Statistical analysis showing the effectiveness of treatment in Group B in different Performance parameters of NICHQ-Vanderbilt Assessment Scale (Parent Informant)

Performance Parameters	Duration	Mean ± S.D.	Mean diff. ± S.D.	d.f.	t-value	p-value
Overall School Performance	B.T.	4.47 ± 0.92	-	14	-	
	A.T.1	4.33 ± 0.9	0.13 ± 0.35		1.47	> 0.05#
	A.T.2	4.27 ± 0.88	0.2 ± 0.41		1.87	> 0.05#

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Reading Ability	B.T.	4.53 ± 0.92	-	14	-	
	A.T.1	4.47 ± 0.92	0.067 ± 0.46		0.56	> 0.05#
	A.T.2	4.4 ± 1.06	0.13 ± 0.52		1.0	> 0.05#
Writing Skills	B.T.	4.6 ± 0.91	-	14	-	
	A.T.1	4.53 ± 0.92	0.067 ± 0.26		1.0	> 0.05#
	A.T.2	4.47 ± 0.92	0.13 ± 0.35		1.47	> 0.05#
Mathematics	B.T.	4.6 ± 0.74	-	14	-	
	A.T.1	4.6 ± 0.74	0 ± 0		0.0	No effect
	A.T.2	4.4 ± 0.83	0.2 ± 0.414		1.87	> 0.05#
Relationship with Parents	B.T.	4.53 ± 0.92	-	14	-	
	A.T.1	4.47 ± 0.92	0.067 ± 0.26		1.0	> 0.05#
	A.T.2	4.4 ± 0.91	0.13 ± 0.35		1.47	> 0.05#
Relationship with Siblings	B.T.	4.27 ± 0.88	-	14	-	
	A.T.1	4.2 ± 0.94	0.067 ± 0.26		1.0	> 0.05#
	A.T.2	4.13 ± 1.06	0.13 ± 0.35		1.47	> 0.05#
Relationship with Peers	B.T.	4.47 ± 0.92	-	14	-	
	A.T.1	4.47 ± 0.92	0 ± 0		0.0	No effect
	A.T.2	4.27 ± 0.96	0.13 ± 0.35		1.47	> 0.05#
Participation in Organized Activities	B.T.	4.47 ± 0.74	-	14	-	
	A.T.1	4.47 ± 0.74	0 ± 0		0.0	No effect
	A.T.2	4.4 ± 0.74	0.067 ± 0.26		1.0	> 0.05#

Table 3. Statistical analysis showing the effectiveness of treatment in Group A in different Academic Performance parameters of NICHQ-Vanderbilt Assessment Scale (Teacher Informant)

Academic Performance Parameters	Duration	Mean ± S.D.	Mean diff. ± S.D.	d.f.	t-value	p-value
Reading ability	B.T.	4.53 ± 0.92	-	14	-	
	A.T.1	3.27 ± 0.59	1.27 ± 1.03		4.75	< 0.001***
	A.T.2	2.0 ± 0.38	2.53 ± 0.99		9.91	< 0.001***
Mathematical Aptitude	B.T.	4.67 ± 0.62	-	14	-	
	A.T.1	3.13 ± 0.64	1.53 ± 0.83		7.12	< 0.001***
	A.T.2	1.87 ± 0.52	2.8 ± 0.86		12.58	< 0.001***
Written expression	B.T.	4.4 ± 0.63	-	14	-	
	A.T.1	2.93 ± 0.59	1.47 ± 0.83		6.81	< 0.001***
	A.T.2	1.73 ± 0.59	2.67 ± 0.98		10.58	< 0.001***

Table 4. Statistical analysis showing the effectiveness of treatment in Group B in different Academic Performance parameters of NICHQ-Vanderbilt Assessment Scale (Teacher Informant)

Academic Performance Parameters	Duration	Mean ± S.D.	Mean diff. ± S.D.	d.f.	t-value	p-value
Reading ability	B.T.	4.6 ± 0.91	-	14	-	
	A.T.1	4.47 ± 0.92	0.13 ± 0.35		1.47	> 0.05#
	A.T.2	4.4 ± 1.06	0.2 ± 0.414		1.87	> 0.05#
Mathematical Aptitude	B.T.	4.53 ± 0.64	-	14		
	A.T.1	4.47 ± 0.74	0.067 ± 0.26		1.0	> 0.05#
	A.T.2	4.33 ± 0.82	0.2 ± 0.414		1.87	> 0.05#
Written expression	B.T.	4.67 ± 0.62	-	14		
	A.T.1	4.67 ± 0.62	0 ± 0		0.0	No effect
	A.T.2	4.53 ± 0.64	0.13 ± 0.35		1.47	> 0.05#

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Table 5. Statistical analysis showing the effectiveness of treatment in Group A in different Classroom Behavioral Performance parameters of NICHQ-Vanderbilt assessment Scale (Teacher Informant)

Parameters	Duration	Mean ± S.D.	Mean diff. ± S.D.	d.f.	t-value	p-value
Relationship with Peers	B.T.	4.6 ± 0.91	-	14	-	
	A.T.1	3.13 ± 0.64	1.47 ± 1.07		5.36	< 0.001***
	A.T.2	1.8 ± 0.56	2.8 ± 1.01		10.69	< 0.001***
Following Direction	B.T.	4.53 ± 0.92	-	14	-	
	A.T.1	3.27 ± 0.59	1.27 ± 1.03		4.75	< 0.001***
	A.T.2	2.0 ± 0.38	2.53 ± 0.99		9.91	< 0.001***
Class Disruption	B.T.	4.67 ± 0.82	-	14	-	
	A.T.1	3.33 ± 0.62	1.33 ± 1.18		4.394	< 0.001***
	A.T.2	1.87 ± 0.52	2.8 ± 0.68		16.04	< 0.001***
Assignment Completion	B.T.	4.2 ± 1.01	-	14	-	
	A.T.1	3.2 ± 0.56	1.0 ± 1.07		3.62	< 0.01**
	A.T.2	1.6 ± 0.51	2.6 ± 1.06		9.54	< 0.001***
Organizational Skills	B.T.	4.27 ± 1.03	-	14	-	
	A.T.1	3.13 ± 0.64	1.13 ± 1.19		3.697	< 0.01**
	A.T.2	1.53 ± 0.52	2.73 ± 1.09		9.63	< 0.001***

Table 6. Statistical analysis showing the effectiveness of treatment in Group B in different Classroom Behavioral Performance parameters of NICHQ-Vanderbilt assessment Scale (Teacher Informant)

Parameters	Duration	Mean ± S.D.	Mean diff. ± S.D.	d.f.	t-value	p-value
Relationship with Peers	B.T.	4.47 ± 0.92	-	14	-	-
	A.T.1	4.4 ± 0.91	0.067 ± 0.26		1.0	> 0.05#
	A.T.2	4.33 ± 0.9	0.13 ± 0.35		1.47	> 0.05#
Following Direction	B.T.	4.6 ± 0.91	-	14	-	-
	A.T.1	4.47 ± 0.92	0.13 ± 0.35		1.47	> 0.05#
	A.T.2	4.4 ± 1.06	0.2 ± 0.414		1.87	> 0.05#
Class Disruption	B.T.	4.67 ± 0.82	-	14	-	-
	A.T.1	4.67 ± 0.82	0 ± 0		0.0	No effect
	A.T.2	4.6 ± 0.83	0.067 ± 0.26		1.0	> 0.05#
Assignment Completion	B.T.	4.33 ± 1.05	-	14	-	-
	A.T.1	4.27 ± 1.03	0.067 ± 0.2		1.0	> 0.05#
	A.T.2	4.2 ± 1.01	0.13 ± 0.35		1.47	> 0.05#
Organizational Skills	B.T.	4.6 ± 0.74	-	14	-	-
	A.T.1	4.6 ± 0.74	0± 0		0.0	No effect
	A.T.2	4.53 ± 0.74	0.067 ± 0.26		1.0	> 0.05#

Table 7. Showing the overall Clinical Assessment of Results

Clinical Assessment	AT1		n=15		AT2		n=15	
	Group A		Group B		Group A		Group B	
	f	%	f	%	f	%	f	%
Complete remission	00	00.00%	00	00.00%	00	00.00%	00	00.00%
Markedly Improved	03	20.00%	00	00.00%	12	80.00%	00	00.00%
Moderately Improved	04	26.67%	00	00.00%	02	13.33%	01	06.67%
Slightly Improved	08	53.33 %	01	06.67%	01	06.67%	01	06.67%
Unchanged	00	00.00%	14	93.33%	00	00.00%	13	86.67%

DISCUSSION

Direct description about pediatric Attention Deficit hyperactivity disorders in not available in Ayurvedic texts. However, certain condition like *Anavasthitachitata*, *Manovibhrama* simulates the aforesaid disease.In t he present study, the age range of selected children for the study was 07-13 years, which is in accordance with DSM-IV criteria. Maximum numbers of ADHD children (73.33%) were between 07-09 years followed by 16.67% in age group 09-11 years. This shows higher prevalence of Attention deficit Hyperactivity Disorder in elementary school years. Study included maximum number of male children (83.33%). After analyzing both the groups, it was observed that all groups had male predominance and the male to female ratio ranged from 4:1 to 6.5:1. The overall incidence of Male:

Female ratio was 5:1. The finding is in accordance with previous research studies in India [7, 8] which report male predominance nature of Attention Deficit Hyperactivity Disorder. Study showed maximum children from middle socioeconomic strata (70.00%) followed by middle economic strata (16.67%). The findings are consistent with study of Biederman *et al*., (1995) [9] and Chawla PL *et al*., (1981) [10], which enlisted the low socioeconomic class as one of the etiological factors of the disease.

Present study showed maximum patients (43.33%) to have positive history of Attention deficit hyperactivity Disorder in Siblings. 23.33% fathers and 10.00% mothers reported to have ADHD. This indicates that attention deficit hyperactivity Disorder has a genetic involvement. These findings are well correlated with previous research studies involving genetic basis of ADHD. [11, 12, 13, 14] Poor father-child relationship was found in 24 (80%) cases. Relationship was rated as average in 05 (16.67%) cases while it was satisfactory in only 01 (03.33%) case. This shows that father-child relationship is deviant from normal in maximum number of cases. Various researchers [15, 16, 17] have reported negative father-child relationship in attention deficit hyperactivity disorder which is consistent with the present study. Similarly poor mother-child relationship was evident in 26 (86.67%) cases while only 04 (13.33%) cases reported average relationship with mother in the family. This finding converges with prior studies documenting poor mother-child relationship in children. [18-21] As children with ADHD are more talkative, defiant, less compliant; are less likely to remain in task; mothers often display more directive and commanding behavior, more disapproval and more overall negative behavior than the parent of normal do [22].

Tallmadge and Barkley (1983) [23] reported that ADHD children appear to be more disruptive with their mothers than their father. This pattern was also seen in the present study as evident by poor mother child relationship in 86.67% cases vs. Poor father child relationship in 80.00% cases. Majority of patients i.e. 25 (83.33%) cases showed abnormal classroom behavior while only 05 (16.67%) patients showed normal behavior in classroom as reported by teachers. This finding is consistent by previous researches involving classroom behavior and student-teacher relationship. More specifically, children with ADHD have difficulty in completing independent seatwork, poor test performance, deficient study skills, disorganized notebooks, desks, and written reports, as well as trouble attending to lectures and group discussions.[24] Moreover, given these academic difficulties and problematic behaviors, it is not surprising that children with ADHD also often experience difficulties in their relationship with teachers and peers. [25, 26] Teacher student relationship was found to be poor in 26 (86.67%) patients while it was found to be average in only 04 (13.33%) cases. Maximum number of patients i.e. 23 (76.67%) were poor academic performers. Average academic performance was reported in 04 (13.33%) whereas only 03 (10%) patients showed satisfactory academic performance. This suggests that children with ADHD perform poorly in schools. This finding is consistent with previous research publications [27-31]. Which reported that children with Attention deficit hyperactivity disorder show significant academic underachievement, poor academic performance and educational problems.

The trail drug '*Saraswatarista'* is well recognized in *Ayurveda* for its *Rasayan* properties and its role in management of *Manasik vikar* (Psychosomatic and Neurobehavioral disorders). The main ingredient of *Saraswatarista* is *Brahmi* (*Bacopa monnieri*). *Brahmi* is widely acclaimed for its *Medhya* property in *Ayurveda* [32]. Dammarane-type triterpenoid saponins classified as Pseudojujubegenin and jujobegienin glycosides are reported to be responsible for cognition enhancing activity of this plant. Bacoside A and Bacoside B are the most important glycosides involved in improving cognitive function and attention in human subjects**.** [33, 34, 35, 36] Bacosides aids in repair of damaged neurons by enhancing kinase activity, neuronal synthesis and restoration of synaptic activity [37]. Moreover, Bacosides appear to have antioxidants activity in the hippocampus, frontal cortex and striatum [38]. In vitro research has shown that Bacopa exerts a protective effect against DNA damage in astrocytes [39]. Researchers have shown the cognitive enhancing, antioxidant, anxiolytic, and anticonvulsant effect. These properties make this herb ideal for the use in Attention Deficit hyperactivity disorder. All other ingredients of *Saraswatarista* act synergistically to enhance cognitive function, Attention, learning acquisition, and intelligence. Systemic review of research literature reveals that this traditional Indian medicinal plant Bacopa monniera (brahmi) possess therapeutic potential in attention deficits and hyperkinetic disorders [40]. Administration of Saraswatarista leads to reduction in core symptoms of ADHD which ultimately leads to improvement in performance parameters like, reading skills, writing skill, mathematical aptitude etc as evident in the present study.

CONCLUSION

The present study shows that Pediatric Attention Deficit Hyperactivity Disorder can be managed by *Rasayana* drugs like *Saraswatarishta*. Neurobehavioral disorder like ADHD affects the lives of pediatric patients in form of poor academic performance, difficult peer relationship, difficult parental relationship and proneness to accidents and trauma. Medications prescribed for managing ADHD like stimulants are effective in reducing symptoms of ADHD, but these are not devoid of adverse reactions. In this context, Traditional Ayurveda *Medhya* Drug like *Saraswatarista* shows promise in managing Pediatric ADHD effectively and safely.

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