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A RANDOMIZED CONTROLLED TRIAL TO ASSESS THE EFFECT OF ASHTAMANGALA GHRITA IN DEVELOPMENTAL LEARNING DISORDER IN CHILDREN

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ABSTRACT

Introduction: Learning disorder is a group of neuro-developmental disorders and Developmental Learning Disorder (DLD) refers to ongoing problems in one of the three areas, reading, writing and mathematics. Learning disability can be understood as a defective processing of knowledge, i.e. *Tamoavarana* in *Manobuddhivahasiras*, leading to impairment in the process of *jnyanotpatti*(at the level of *Manas* and *Buddhi*) and improper execution of *Karma* by *Vak* and *Hastendriya*, i.e. impaired *Vaktrubuddhi* (impairment in reading) and *Kartrubuddhi* (impairment in writing & doing calculations) are together considered as DLD in Ayurveda.In such a condition *Medhya* drugs mentioned in our classics can be used. *Ashtamangalaghrita* is one such preparation which is known to render *Dridhasmriti*, *Kshipramedha* (instant intelligence) and makes the child *Buddhiman*(intelligent). **Objectives:** Objective of the study is to evaluate the efficacy of *Ashtamangalaghrita* in children with Developmental learning disorder. **Material and methods**: A total of 60 subjects of DLD of both genders

were registered. These patients were divided into 2 groups by random sampling method in Group A and Group B. In Group A subjects were given with *Ashtamangala ghrita* and group B were given with *Saraswata Churna*. To assess its effectiveness, assessment was done before treatment (0^{th} day), after treatment (60^{th} day) and after follow up (90^{th} day) using NIMHANS index for DLD. **Results:** Statistical analysis was done after the intervention. The assessment was done based on the NIMHANS index for DLD. Group A showed more statistical significant compared to Group B. **Conclusion***: Ashtamangala ghrita* is effective in DLD.

KEYWORDS: *Ashtamangala ghrita; Buddhi;* Developmental Learning Disorder(DLD), *Manobuddhivaha siras.*

INTRODUCTION

The neurodevelopmental disorders are a group of conditions characterized by developmental deficits that produce impairments of personal, social, academic, or occupational functioning in the developmental period and often before the child enters to grade school. The developmental deficit varies from very specific limitations to global impairments of social skills or intelligence.[1] Developmental learning disorder is a group of neurodevelopmental disorders, which manifest in childhood as persistent difficulties in learning efficiently to read (dyslexia), write (dysgraphia)/ do mathematical calculations (dyscalculia) despite normal intelligence, conventional schooling, intact hearing and vision, adequate motivations and socio- cultural opportunities.[2]

Skills like reading, writing, doing calculations is a complex phenomenon resulting from coordinated activities of *Jnyanendriyas* (sensory faculty), *Manas* (mind), *Buddhi*(knowledge) and *Karmendriyas* (motor organs). There are various factors influencing the development of these skills in children. Learning disability can be understood as a defective processing of *Jnyanotpatti*; involving *Dhee* (power of acquisition), *Dhriti* (retention), *Smriti* (memory), *Manas* (mind) and *Buddhi* (knowledge).[3]

Tamoavarana in *Manobuddhivaha siras* lead to impairment in the process of *jnyanotpatti*(at the level of *Manas* and *Buddhi*), leading to improper execution of *Karma* by *Vak* and *Hastendriya*, i.e. impaired *Vaktrubuddhi* (impairment in reading) and *Kartrubuddhi* (impairment in writing and doing calculations) are together considered as DLD.

Here, *Chikitsa* should be aimed at removing the *Avarna* and enhancing the *Buddhi*. So in this study *Ashtamangala ghrita* was selected, which is known to render *Dridhasmriti, Kshipramedha* (instant intelligence) and makes the child *Buddhiman*(intelligent).[4]

Objectives of the study

1. To evaluate the efficacy of *Ashtamangala ghrita* in children with Developmental Learning Disorder.
2. To compare the efficacy of *Ashtamangala ghrita* and *Saraswata churna* in children with Developmental learning disorder.

MATERIAL AND METHODS

The study was a randomized controlled clinical study. 30 patients fulfilling the diagnostic criteria were selected irrespective of their sex and religion and grouped into 2 randomly. Informed consent was taken from all parents before inclusion into the trail. The study was approved by Institutional Ethics Committee (SSIEC NO- SSIEC/135/2020) and the same was registered in CTERI (Registration number – CTRI/2021/04/033238).

Ashtamangala ghrita and *Sarawatha churna* were administered orally in group A and group B respectively along with breakfast and dinner (*Sabhakta*) twice a day for continuous 60 days and follow up was done on 90th day. *Sarawatha churna* was selected as the control drug, which is known to render *Dhee*, *Dhriti* and *Smriti*[10] and has been proven to be effective in case of Dyslexia.

Dose of *Ashtamangalaghrita* & *Saraswathachurna***(Table1)**[5,6]

Dose of *Ashtamangalaghrita* was calculated according to the reference from dosage calculation in of *Yogaratnakara*.[5] Dose of *Saraswathachurna* was calculated according to Young's formula.[6]

Ingredients of *Ashtamangalaghrita*[4] and *Saraswathachurna*[10]: (Table2, 3)

Preparation of *Ghrita*

Ashtamangala ghrita was prepared in the teaching pharmacy of Department of Rasashastra and Bhaishajyakalpana of the institute as per the Ghritapakavidhi mentioned in Sharangadharasamhita.[9]

Preparation of *Saraswathachurna*

*Saraswathachurna*was prepared in the teaching pharmacy of Department of Rasashastra and Bhaishajyakalpana of the institute as per the classics mentioned in BhaishajyaRatnavali.[10]

Inclusion Criteria

a) Children in the age group of 8 to 12 years with Developmental learning disorder, irrespective of gender, religion and socio-economic status.

b) Children of those parents who were willing to sign the written consent form were included.

Exclusion criteria

a) Children in the age group below 8 years and above 12 years were excluded.

b) Children with sensory impairment were excluded.

c) Children clinically diagnosed with seizures, psychiatric disorders and other neurodevelopment disorders like ADHD, ASD were excluded.

d) Children with Congenital and Genetic disorder were excluded.

e) Children with chronic systemic illness, requiring regular medications were excluded.

Diagnostic and assesment criteria

Diagnostic criteria

Diagnostic Criteria of Developmental learning disorder mentioned in ICD 11 (The International Classification of Diseases).[11]

Assessment Criteria

1. NIMHANS index for SLD/DLD level 2 was used to assess the children with Developmental learning disorder in both the groups before (on 0^{th} day), after the study (on 60^{th} day) and during follow up (on 90^{th} day).
2. *Vaktrubuddhi* and *Kartrubuddhi* was assessed based on NIMHANS index for DLD-level 2.[12]

CRITERIA FOR WITHDRAWAL

a) Subjects in whom parents were not willing to continue their participation in the study.

b) Subjects in whom any emergency interventions were needed.

Research Proforma

A specialized case proforma was prepared, which includes the details of patient and the disease. It consists of demographic data, presenting complaints, personal history, and family

history, details of academic activities, *Aturabala pareekshya* and related *Sroto pareeksha.* NIMHANS index for DLD level-2 was used for the assessment of DLD along with *Vakrtubuddhi* and *Kartrubuddhi*in children.

Satatistical Analysis

a) The collected data was represented in mean ± standard deviation, mean ± standard error mean. The data was analysed by using paired and unpaired t – test.[13]

b) p value ≤ 0.05 was considered as statistically significant.[14]

c) IBM SPSS software version 20 was used for analysis.

OBSERVATION AND RESULTS

The present study was conducted to assess the efficacy of *Ashtamangala ghrita* in developmental learning disorder in children. Study was carried out with a specifically designed case proforma & assessment was done by NIMHANS index for SLD. Based on the obtained data the below conclusions or observations were drawn.

Maximum number of subjects, i.e., 69.9 % belonged to age group of 10.1-12 years. 73.3 % of subjects were male and 26.6 % were female gender and the ratio was almost 3:1, 53.3 % subjects belonged to upper middle class, 30 % of subjects with DLD were from 7th standard, 23.3 % from 6th standard, 16.6 % from 4th standard, 16.6 % from 5th standard and 13.3% from 3rd standard. 29 subjects had the complaints of Dyslexia, all the 30 subjects had complaints of Dysgraphia and 28 subjects had complaints of Dyscalculia. All the 30 subjects had the incidence of excess use of electronic gadgets. 13 subjects belonged to *Vata-pittala*, 12 belonged to *Pitta-kaphala* and 5 belonged to *Vatakaphala prakruti* and 18 subjects belonged to *Rajasika prakruti* and 12 subjects belonged to *Tamasika prakruti*. 100 % of subjects belonged to *Madhyama Satva*.

The changes in relation to dyslexia, dysgraphia and dyscalculia were assessed with various criteria and results obtained.

Effect of treatment on Dyslexia

Effect of treatment on Dyslexia was assessed with respect 2 domains namely comprehension and reading errors. Both groups showed highly significant (H.S) improvement in comprehension (p-value 0.000) and highly reduction in reading errors(p-value 0.000), while gropu A was more effective than group B in improving comprehension (p-value). **(Table4, 5)**

Effect of treatment on Dysgraphia

Effect of treatment on Dysgraphia was assessed with respect to 3 domins namely spelling, writing errors and time taken for writing. Both groups showed HS improvement in spelling and HS reduction of writing errors while group A was more effective in improving the spelling (p-value). Group A showed HS reduction in time taken for writing while group B was not significant (p-value). **(Table7, 8, 9, 10)**

Effect of treatment on Dyscalculia

Both groups showed HS improvement with respect to Dyscalculia (p-value). **(Table 11)**

DISCUSSION

Ayurveda emphasizes that the quality of life depends equally on Shareerika and Manasikaprakriti of an individual. It is said the Manas is the controller of both Gnyanendriya and karmendriya – "IndriyanamManonatha". When Manas is enriched in its SatvikaAmsha, it is reflected by its Guna and Karma. It enables the superior state of co-ordinated activities of Gnyanendriya and Karmendriyas. Thus the functional excellence of Gnyanendriyas and Karmendriyas are dependent on the healthy status of one's own Satva.

It was observed in the present study that 21(70%) children belonged to the age group of 10-12 years probably because the condition was left unrecognized by parents in the earlier years of schooling was more apparent when entered the middle school age. 22 of them (73.3%) were males which was consistent with the observation in the previous studies though the exact reason is unknown.[15]

29(97%, 30 (100%) and 28 (93%) children had dyslexia, dysgraphia and dyscalculia respectively. The observation shows that dyslexia and dysgraphia are closely associated i.e., language disabilities in relation to spoken and written co-exists in children.

Some of the important *Nidanas* observed in the current study which may be considered contributing are maternal mental status during pregnancy, family history and use of electronic gadgets by children. 43.2% of mothers were stressed, anxious or depressed during pregnancy. This probably led to the *Rasa dushti* that did the *Poshana* of *Manas* and *Buddhi* in the developing foetus. In relation to family history 20% of children had H/O DLD, 3.3% had H/O language delay, 16.6 % had H/O drug addiction or alcoholism in their families showing that genetic factors play an important role in occurrence of DLD. All children had excess use of

electronic gadgets which could be considered as *Prakopakahetu.* Excess exposure to electronic gadgets interferes with attention, leading to scattered brain condition, thus reducing the problem solving ability of the brain.

The prenatal and postnatal causes as mentioned by *Charakacharya*[16] combinedly lead to the *Prakopa* of *Shareerika* and *Manasikadosha* which cause *Avarana* of *Manobuddhivahasiras*. This results in impairment in the process of*Gnyanotpatti* and its interpretation at the level of *Buddhi*. Improper *Gnyana* leads to imprope execution of *Karma* by *Vak*and *Hasta*i.e impairment in *Vaktru* and *Kartrubuddhi* resulting in DLD.

Both *Ashtamangalaghrita* & *Saraswatachurna* had *Ushna, Teekshna* drugs with *Medhya* properties. *Ashtamangalaghrita* had better efficacy in dyslexia & dysgraphia while both groups should same efficacy with regards to dyslexia.

*Ashtamangalaghrita*porbably was able to reach the distant & minute*srotas* of *Mamas* & *Buddhi* by *Ushma- teekshnaguna* of drug which were administered in *ghrita* form, an additional advantage. This probably removed the *Tamoavarana* enhancing the *Satvaguna*(drugs were *Akasha + Vayumahabhutapradana*) of *Manas* promoting its *Chintya, vicharya*ete functions. Thus facilitated the processing of *Gnyana*in a better way, analyse the complex forms of knowledge in a simpler way establishing a better memory.

Bacosides of *Brahmi*, Acetylcholine esterase in Sariva enhance nerve impulse transmission[17], learning & memory. Nitric acid, Mg, & B-complex of *Siddartaka*[18] act on prefrontal cortex enhancing executive functions & complex cognitive processes. It also helped in improving orthrohraphic skills, phonological ability & comprehension.

Swawathachurna also consisted of *Brahmi, Siddarthaka, Sariva*etc drugs which probably had similar action on various areas of Brain.

Both *Ashtamangala ghrita* and *Saraswata churna* were equally effective in dyscalculia whereas *Ashtamangalaghrita* was more effective than *Saraswata churna* in dyslexia and dysgraphia. *Ashtamangala ghrita* showed better results because of its *ghrita* base probably. *Ghrita*could probably had better absorption and could breach the target site by probably crossing the blood brain barrier thus accomplishing *Medha* & *Dridhasmriti*.[19]

CONCLUSION

Clinically and statistically *Ashtamangala ghrita* was found to be more effective than *Saraswata churna* especially in dyslexia and dysgraphia. Both the groups helped in improving comprehension and reducing spelling errors which had an overall impact on reading & writing skills. They also helped in reducing dyscalculia by improving comprehension i.e. understanding the Steps of mathematical problems and resolving them.

LIMITATIONS OF THE STUDY

Small sample size.

SCOPEF OR FURTHER STUDY

1. This study can be carried out in larger sample size.
2. There are ample of *Medhya* drugs mentioned in Ayurveda, whose effect can be studied on DLD in comparison to *Ashtamangala ghrita.* Conclusion Randomized controlled clinical study to evaluate the efficacy of *Ashtamangala ghrita* in Developmental learning disorder in children.
3. Effect of *Ashtamangala ghrita* on healthy children with DLD was studied.
4. Further study of *Ashtamangala ghrita*in conditions like ADHD, ASD, Mental retardation, Developmental disorders etc. can throw more light on its effectiveness on wider spectrum of conditions.
5. Efficacy of *Ashtamangala ghrita* in DLD through other route of administration like *Nasya* & *Basti* in children can be studied.

LIST OF TABLES

Table 1: Dose of medicine.

Age (Years)	*Ashtamangalaghrita*	*Saraswatachurna*
8 to 9	08 *Masha* (08g)	05g
9.1 to 10	09 *Masha* (09g)	05g
10.1 to 11	10 *Masha* (10g)	06g
11.1 to 12	11 *Masha* (11g)	06g

Table 2: Ingredients of *Ashtamangalaghrita.*

Drugs	Latin name
1) *Vacha*	*Acoruscalamus* Linn
2) *Kushta*	*Saussurialappa* .C.B.Clark
3) *Brahmi*	*Bacopamonneri* Linn
4) *Sidhartaka*	*Brassica nigra* Linn
5) *Sariva*	*Hemidesmus indicus*.R.Br

6) *SaindhavaLavana*	Rock salt
7) *Pippali*	*Piper longum* Linn
8) *Go ghrita*	Cow's ghee

Table 3: Ingredients of *Saraswatha churna.*

Drugs	Latin name
1) *Vacha*	*Acoruscalamus* Linn
2) *Kushta*	*Saussurialappa* .C.B.Clark
3) *Brahmi*	*Bacopamonneri* Linn
4) *Shunti*	*Zingiberofficianale*Roscoe
5) *Maricha*	*Piper nigrum*Linn
6) *SaindhavaLavana*	Rock salt
7) *Pippali*	*Piper longum* Linn
8) *Ashwagandha*	*Withaniasomnifera*Linn
9) *Ajamoda*	*Apiumleptophyllum*(pers.) F.v.m.exbenth.
10) *Jeeraka*	*Cuminumcyminum*linn.
11) *Krishna jeeraka*	*Carumcarvi*linn.
12) *Patha*	*Cissampelospariera*Linn
13) *Shankapushpi*	*Convolvulus pluricaulis*Choicy

Table 4: Showing the effect of treatment on comprehension in relation to Dyslexia (*Vaktrubuddhi*) on 60th day.

Groups	Mean		Mean diff.	% of improvement	S.D	S.E.M	t-value	p-value	Inference
	BT	AT							
Group A	1.705	4.00	2.294	134.48	0.771	0.187	12.257	0.000	HS
Group B	1.375	3.06	1.687	122.36	0.478	0.119	14.100	0.000	HS

Table 5: Showing the effect of treatment on reading errors in relation to Dyslexia (*Vaktrubuddhi*) on 60th day.

Groups	Mean		Mean diff.	% of improvement	S.D	S.E.M	t-value	p-value	Inference
	BT	AT							
Group A	7.82	5.06	2.765	35.2	2.251	0.546	5.064	0.000	HS
Group B	7.81	5.75	2.063	26.4	1.482	0.370	5.567	0.000	HS

Table 6: Showing the effect of treatment on total time take for reading in relation to Dyslexia (*Vaktrubuddhi)* on 60th day.

Groups	Mean		Mean diff.	% of improvement	S.D	S.E.M	t-value	p-value	Inference
	BT	AT							
Group A	6.53	5.12	1.41	21.5	1.906	0.462	3.054	0.008	HS
Group B	6.50	4.49	1.563	24	1.861	0.465	3.357	0.004	HS

Table 7: Showing the effect of treatment on comprehension in relation to Dysgraphia (*Kartrubuddhi)* on 60th day.

Groups	Mean		Mean diff.	% of improvement	S.D	S.E.M	t-value	p-value	Inference
	BT	AT							
Group A	1.476	3.823	2.352	159.99	0.606	0.147	16.000	0.000	HS
Group B	1.375	3.125	1.750	127.27	0.447	0.111	15.652	0.000	HS

Table 8: Showing the effect of treatment on spelling in relation to Dysgraphia (*Kartrubuddhi*) on 60th day.

Groups	Mean		Mean diff.	% of improvement	S.D	S.E.M	t-value	p-value	Inference
	BT	AT							
Group A	1.476	3.823	2.352	159.99	0.606	0.147	16.000	0.000	HS
Group B	1.375	3.125	1.750	127.27	0.447	0.111	15.652	0.000	HS

Table 9: Showing the effect of treatment on writing errors (copying and answers to questions) in relation to Dysgraphia (*Kartrubuddhi*) on 60th day.

Groups	Mean		Mean diff.	% of improvement	S.D	S.E.M	t-value	p-value	Inference
	BT	AT							
Group A	6.29	4.41	1.882	29.9	1.409	0.342	5.508	0.000	HS
Group B	6.56	4.56	2.000	30.48	2.309	0.577	3.464	0.003	HS

Table 10: Showing the effect of treatment on total time take for writing / copying in relation to Dysgraphia (*Kartrubuddhi*) on 60th day.

Groups	Mean		Mean diff.	% of improvement	S.D	S.E.M	t-value	p-value	Inference
	BT	AT							
Group A	7.88	6.18	1.70	21.57	1.160	0.281	6.063	0.000	HS
Group B	7.19	6.00	1.18	15.2	2.536	0.634	1.873	0.081	NS

Table 11: Showing the effect of treatment on Dyscalculia (*Kartrubuddhi)* on 60th day.

Groups	Mean		Mean diff.	% of improvement	S.D	S.E.M	t-value	p-value	Inference
	BT	AT							
Group A	1.352	2.529	1.176	86.96	0.635	0.154	7.628	0.000	HS
Group B	1.187	2.500	1.312	111.08	0.478	0.119	10.967	0.000	HS

Table 12.Showing the age wise Incidence.

Age	Group A	Percentage (%)	Group B	Percentage (%)	Total	Total %
8.1-9 years	1	6.6	0	0	1	3.33
9.1-10 years	3	20	5	33.3	8	26.6
10.1-11 years	4	26.6	7	46.6	11	36.6
11.1-12 years	7	46.6	3	20	10	33.3

Table 13: Showing the gender wise Incidence.

Gender	Group A	%	Group B	%	Total	Total %
Male	11	73.3	11	73.3	22	73.3
Female	4	26.6	4	26.6	8	26.6

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