

Original Research Article

A Randomized Controlled Trial to Assess the Effect of Ayurveda Dominated Multidisciplinary Intervention Compared to Individualised Education Plan in Children Suffering from Learning Disability with Hyperactivity

Dinesh K.S.¹Santhi Krishna A S² Reshmi Pramod³

¹Professor and Head, Department of Kaumarabhritya, Vaidyaratnam P S Varier Ayurveda College, Kottakkal, Kerala, India.

²Junior Research Fellow, AYUSH Extra Mural Research, Department of Kaumarabhritya, Vaidyaratnam P S Varier Ayurveda College, Kottakkal, Kerala, India.

³Chief Consultant, Jeevaneeyam Ayurveda Hospital and Research Centre, Ernakulam, Kerala, India.

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ABSTRACT

Background: The academic dysfunction and learning disability hold pluralistic definitions but possess similar effects so far, the parents and teachers of affected students are concerned. The ambiguous apprehension of parents regarding the remedial training and interventions has enforced them to receive direction from Complementary and Alternative Medical Systems (CAM). Since Ayurveda significantly outstands among CAM system in Kerala, it proves better management in children with Learning Disability. **Aim:** To test the effect of a proposed Ayurveda dominated multidisciplinary intervention in addition to the Individualized Education Plan (IEP), in LD children with hyperactivity and suspected organic background, selected from Kerala who are under Sarva Shiksha Abhiyaan [SSA] program. **Materials and Methods:** A randomized controlled trial of 46 children diagnosed with Learning Disability having hyperactivity and suspected organic background were subjected to Ayurveda dominated multidisciplinary interventions alongside IEP in test group and only IEP in control group. Either groups were then subjected to two formal interim analysis in an interval of 3 months, in addition to the baseline and end line analysis. Visual analogue scale, IQ analysis and digit span were measured for the assessment of therapies. **Results:** Excluding 3 dropouts, 43 children has completed the trial and as per the global satisfaction index, multidisciplinary group shows highly significant results [$p < 0.001$] in comparison with IEP group both from parental and teachers' side. Comparatively better outcome is measured in multidisciplinary group [$p = 0.009$] in IQ assessment and digit span test. **Conclusion:** Learning disability with suspected organic background if associated with hyperactivity, is treated with a multidisciplinary approach including yoga, music therapy and Ayurveda Treatments, in addition to usual IEP, showed significant outcomes in terms of IQ and global satisfaction index.

INTRODUCTION

Learning disability [LD] is the significant discrepancy between the predicted and obtained achievement of IQ [1]. It has been technically defined as a heterogeneous group of disorders manifested by significant difficulties in the acquisition and use of academic skills presumed to have a root cause at the level of central nervous system [2]. Whereas academic dysfunction [AD] is defined as the extent to which a student, teacher or institution has not achieved their educational goals, that has been validated through examinations or continuous assessment criteria's [3]. A wide range of variability in the prevalence of learning disability among Indian students was reported to be 3-13 per cent by different studies [4] [5] and this in turn correlates sensitive variabilities like their inhabitation as well as the precision in the terminologies to diagnose the child as learning disability and academic dysfunction. On evaluating the common trends existing in Kerala, a state of India it was noticed that the choice of interventions is strictly based on the knowledge base of parents [6]. The ambiguous apprehension of parents regarding the remedial training and interventions like special education offered by various streams has enforced them for a second opinion from the Complementary and Alternative Medical Systems (CAM) prior approaching mainstream chemical-based medications for LD.

In addition, the factors like economical overburden [7] [8], chemo phobia [9] and in conditions requiring long term interventions [7] the first choice of intervention would be an Alternative method. Since Ayurveda significantly outstands among Complementary and Alternative Medical system in Kerala and many Ayurveda Practitioners generally claims to have excellent tools [10] [11] in the form of Medicines, Yoga and Lifestyle Guidelines. Thus, the existing health paraphernalia present under the Department of AYUSH (Ayurveda, Yoga, Unani, Siddha and Homeopathy) has received wide public acceptance in the management of LD in India. However, from the literature reviews, it has been evident that there were no prospective longitudinal studies to assess the efficacy of the clinical practices of AYUSH system in LD. The aforementioned circumstances evolved a proposal of a randomized controlled trial, aimed at testing the claims of Alternative Medicines and other related packages in the

management of Learning Disability. The trial was jointly initiated by the Centre for disability studies, Government of Kerala and Department of Kaumarabhritya (Ayurveda Pediatrics), Vaidyaratnam PS Varier Ayurveda College in collaboration with Jeevaneeyam Ayurveda Hospital and Research Centre, Kerala.

AIM

To test the effect of a proposed Ayurveda and Yoga intervention in addition to the individualized education plan, in LD children with hyperactivity and suspected organic background, selected from Kerala who are under Sarva Shiksha Abhiyaan [SSA] program which is the government primary education program of India.

MATERIALS AND METHODS

Current study is a randomized controlled open clinical trial conducted in an Ayurveda hospital having multidisciplinary interventions facility situated at Kerala, India. The Students of either gender, aged between 5-12 years, studying in various normal schools following same syllabus and curriculum named, Sarva Shiksha Abhiyan (SSA), the government primary education program of India and who were regularly attending the classes with poor academic performance and hyperactivity assessed by the parental and teachers report were included under the study. Diagnosis was made on the basis of academic performance using school progress records followed by assessment of Intelligence by using Mallins Intelligence Scale. Scholastic backwardness was accounted with an organic background featured by a problem in developmental pattern or by any neurological features. DSM criteria for ADHD were applied to children for the diagnosis of hyperactive disorders.

The Students with severe global developmental disorders, chronic systemic illness, psychiatric illness such as depression and anxiety were excluded. They were randomly assigned (1:1) with a computer-generated randomization code without any allocation concealment and were allocated to two groups by Graph Pad Software and no changes in the trial design were made.

The primary outcome measures are the Global satisfaction index by visual analogue scale from the parents and teachers. The secondary outcomes

measured were Mallin's intelligence scale, Digit span test and Conner's Rating scale.

A total of 865 participants were screened for the study using the formula $n = (z)^2pq/d^2$ and allowing a 95% confidence interval, 46 children with learning disability were recruited for the study and 23 children were placed into the intervention arm and 23 children into the non-intervention arm. The project administrator, who is a non-medical personal, generated the allocation sequence and the project manager enrolled the participants to the study.

Intervention: The principal investigator of the study assigned participants to specific intervention groups comprising of Group A and Group B. The following interventions were made in both the group for duration of one year (Table 1).

Age appropriate participants were enrolled to the Multidisciplinary and IEP groups of the study with having Individualized Education Plan [IEP] as the common element of this multidisciplinary intervention. The Multidisciplinary and IEP groups were subjected to two formal interim analysis with an interval of 3 months, in addition to the baseline and end line analysis. The triggering factors influencing the intervention and outcome in any means were subjected to the stopping guidelines. The enrollments of participants to respective groups were initiated on August 2017 and the same was completed after reaching the accrual target on July 2019.

The data were entered in excel and analyzed using the statistical software SPSS version 20. The descriptive statistics were calculated and presented as frequencies and percentages. Comparisons were found using one-way ANOVA and independent sample t test. $p < 0.05$ was taken as the statistical significance. The trial was registered with the Clinical Trials Registry of India, CTRI NO: CTRI/2018/ 10/ 016114 after getting Institutional ethical approval.

RESULTS

For each group, the numbers of participants who were randomly assigned, received intended interventions, and were analyzed for the primary outcome. The number of participants included in analysis of Multidisciplinary and IEP groups is 23 each and there were no harms or unintended effects

happened in both the groups during the period of study.

The number of post-randomization exclusions together with the reason for exclusion is displayed in Table 3. Overall, three patients were excluded from the study from the Multidisciplinary group.

DISCUSSION

The process of learning such as cognition, perception and memory are a highly complex mechanism [12]. The areas of brain circuits performing these Motor coordination [13], cognition [14], perception [15] and memory [16] are intimately interrelated, displaying marked parallels and multiple points of connection. Arithmetic reading and writing problems indicate an altered and impaired mechanism by which all these complex physiological functions are pathologically affected by any of the intrinsic or extrinsic causes [17]. Music, [18] Yoga [19] and complex, nonlinear dynamic attribute of Ayurveda Medication [20] in addition to educational and psychological reasons, may work through these organic areas of brain. The underlying Organic background of the population seems to have equally distributed in the current intervened population which marks the suitability of these interventions in LD. The extrinsic factors adding to the etiological background of LD like syllabus curriculum cognition mismatch [21] has not affected the current study population since the students followed a uniform syllabus and curriculum delivery with a fairly regular attendance. Unlike general Indian population, the geographical density of Kerala bearing a maximum of middle-class socio-economic status has been reflected in the current study population and its impact on the school performance [22] [23] of children excludes the heterogeneity that may found in terms of nutritional and educational resource impartation. Antenatal, perinatal and post-natal period of study population beholds a not so negligible complication accounting 20%, 30% and 20% respectively. This might be because of the organic background emphasizing to the embryogenetic and CNS maturation period insults, possibility during the antenatal perinatal and postnatal periods [24]. All these factors might have account to the organic reasons affecting the related areas of learning, cognition, reasoning, and comprehension factors of children in their

developmental phase. Learning impairment and hyperactivity are the clinical evidence substantiating this organic background and delay in the developmental milestones accounting to 6% also contributes to this fact.

The herbal drugs administered in the study [table 2] are proven for its nootropic, anxiolytic, and anti-stress activity [25]. Some of the active herbal ingredients like *Nardostachys jadamansi* is supposedly a calming drug from Ayurveda adding to its desired therapeutic efficacy [26]. The whole school performance is multifactorial in its output; however, the IQ and other common objective parameters are not sufficient to assess it completely. The complimentary scales like visual analogue scale is warranted for its global assessment [27] and in this trial significant results were obtained in global scales. Many a time interventions like yoga [28] and music [29] paves a good substratum [30] to cognition, learning and memory and in amalgamation with nootropic effect of herbs obviously multidisciplinary interventions provides better outcome when compared with IEP group. Hence combined effects of these multidisciplinary interventions would have produced positive organic changes to the whole system related to cognition, learning and memory when coupled with IEP and this might have been the basis of better output in multidisciplinary intervention group. Thus, in grant, the academic interventions should always be coupled with other interesting activities for nurturing significant output.

LIMITATIONS

Blinding which is crucial to ensure the unbiased ascertainment of outcomes using novel creative techniques must have been adopted in current clinical trial. Similarly, if the assessment of any biological parameters has been included, better interpretations on its organic background be derived from the study.

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3. Jeevaneeyam Ayurveda Hospital and Research Centre, Thammanam, Ernakulam, Kerala, India

AUTHORS' CONTRIBUTIONS

Dinesh K. S– Conceptualization and Design, Project Administration, Analysis and interpretation of data, Validation and Drafting Manuscript
Santhi Krishna A S - Analysis and interpretation of data, Review and Editing, Drafting Manuscript
Reshmi Pramod- Acquisition of data, Supervision and Validation. All authors read and approved the final manuscript

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Table 1: Interventional Plans

Multidisciplinary Group [Individualized Education Plan (IEP) +Ayurveda + Music therapy + Yoga]	IEP Group
<ol style="list-style-type: none"> 1. Ayurveda herbal medicine powders administration for 1 year (Herbal Medicine Details Table 2) 2. 12 sessions of Yoga with home practice instructions 3. Music therapy sessions with home practice instructions by CD ROM. 4. 12 sessions of IEP each with 45 minutes of duration 5. Home work for parents on IEP basis 6. Six monthly follow up 	<ol style="list-style-type: none"> 1. 12 sessions of IEP each with 45 minutes of duration 2. Home work for parents 3. Monthly follow up.

Table 2: Herbal Medicines powders Administered

Sr. No.	Medicinal Herbs	Latin Name	Dose/day	Part Used
1	Aswaganda	Withaniasomnifera	125 mg	Roots / leaves
2	Jatamansi	Nardostachys jatamansi	125 mg	Rhizome
3	Brahmi	Bacopa monnieri	500 mg	Leaves
4	Shunti	Zingiber officinale	500 mg	Rhizome

Table 3: Post Randomization Exclusions

Post randomization exclusion reasons	Multidisciplinary group	IEP group
Palatability	1	NA
Compliance	1	0
Epilepsy	1	0

Table 4: Distribution of children as per their demographic and clinical characteristics

Sr. No	Demographic data & clinical characteristics		Multidisciplinary group		IEP group			
			% of Students	CI and range	% of Students	CI and range	P value	
1	Academic Dysfunction	Reading	95%	85.45% - 100%	100%		0.278	
		Writing	100%		100%		1	
		Arithmetic	75%	56.02% - 93.98%	47%	27.38% - 68.22%	0.069	
2	Regularity in Class	Regular	100%		100%		1	
		Irregular	0%		0%			
3	Socio Economic Status	Below Poverty Line	5%		8.6%		0.635	
		Middle Class	95%		91.3%			
		Upper Class	0%		0%			
4	Natal Complications	Antenatal	Yes	20%	2.47% - 37.43%	21.7%	4.85% - 38.55%	0.889
			No	80%		78.2%		
		Perinatal	Yes	15%	0.64% - 30.64%	43.4%	23.16% - 63.64%	0.054
			No	85%		56.5%		
		Postnatal	Yes	25%	6.02% - 43.98%	17.3%	1.93% - 32.67%	0.714
			No	75%		78.2%		
5	Delay in Developmental Milestones	Yes	5%	0% - 14.55%	8.6%	2.92% - 21.1%	1	
		No	95%		86.9%			

Table 5: Global satisfaction index of Multidisciplinary Group by visual analogue scale from the parent and teacher

	Visual analogue scale	N	Mean	Sd.	p-value
Parent	1 st visit	20	1.30	0.470	<0.001
	2 nd visit	20	2.05	0.605	
	3 rd visit	20	2.30	0.470	
Teacher	1 st visit	20	1.15	0.366	<0.001
	2 nd visit	20	1.75	0.639	
	3 rd visit	20	2.35	0.489	

Table 6: Global satisfaction index of IEP Group by visual analogue scale from the parent and teacher

	Visual analogue scale	N	Mean	Sd.	p-value
Parent	1 st visit	23	1.00	0.00	<0.001
	2 nd visit	23	2.09	0.60	
	3 rd visit	23	2.22	0.42	
Teacher	1 st visit	23	1.04	0.21	<0.001
	2 nd visit	23	2.26	0.54	
	3 rd visit	23	2.43	0.51	

Table 7: Effect of therapies in Malin’s intelligence scale

Group	Malins intelligence scale	n	Mean	SD	p-value
Multidisciplinary group	1 st visit	20	84.95	8.538	0.009
	2 nd visit	20	86.10	8.226	
	3 rd visit	20	87.30	7.161	
IEP group	1 st visit	23	83.04	5.740	0.065
	2 nd visit	23	84.48	4.337	
	3 rd visit	23	84.83	4.811	

Table 8: Effect of therapies in the Digit Span test

Group	Digit Span test	n	Mean	SD	p-value
Multidisciplinary group	1 st visit	20	3.60	1.50	<0.005
	2 nd visit	20	4.80	1.32	
	3 rd visit	20	5.75	1.16	
IEP group	1 st visit	23	5.22	2.19	<0.005
	2 nd visit	23	6.22	2.35	
	3 rd visit	23	6.78	1.57	

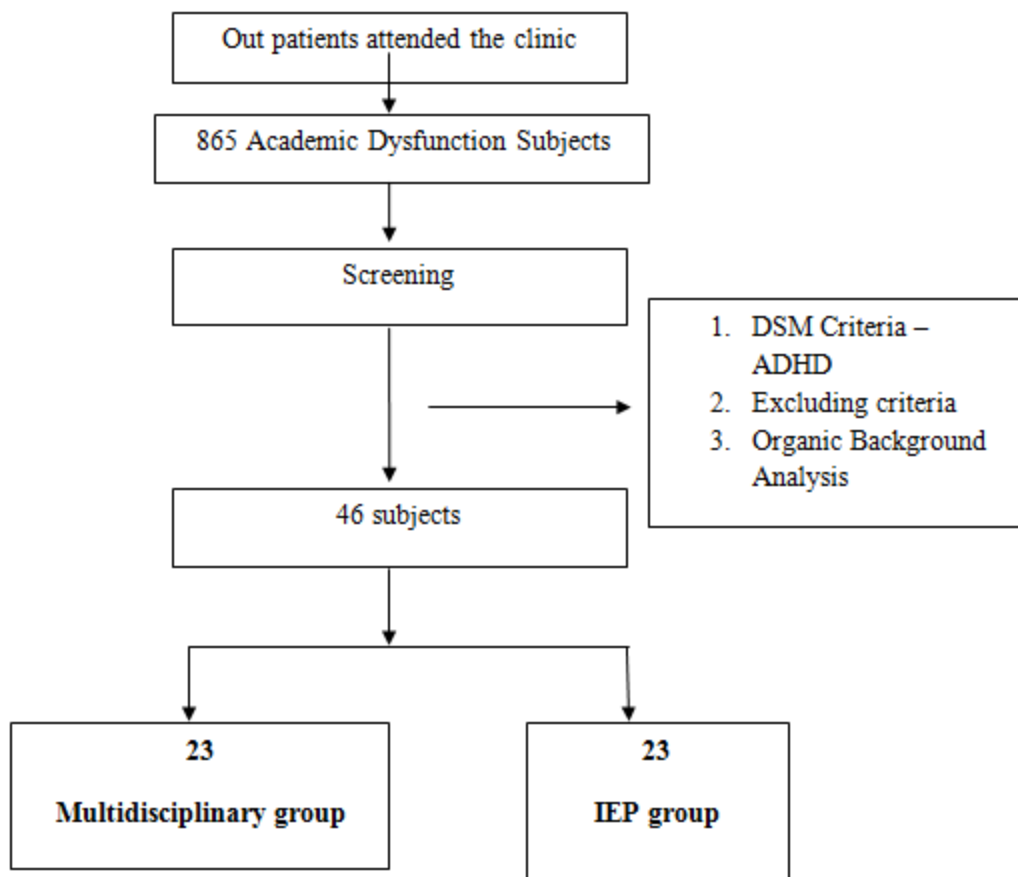


Fig.1: Participant Flow

Corresponding Author: Dr. Dinesh K.S.

Professor and Head, Department of Kaumarabhritya,
Vaidyaratnam P S Varier Ayurveda College, Kottakkal, Kerala,
India.

E-mail: drayurksd@gmail.com

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