Research Article

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A RANDOMIZED CONTROLLED TRIAL TO ASSESS THE EFFICACY OF ASHTAMANGALA GRITHA IN THE MANAGEMENT OF MENTAL RETARDATION

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ABSTRACT

Mental Retardation is a state of developmental deficit, beginning in childhood, resulting insignificant limitation of intellect or cognition and poor adaptation to the demands of everyday life. It is not always a disease but the consequence of some pathogenic process, resulting in a lifelong disability. Abundant research works are going on around the globe and a multidisciplinary approach incorporating different level of management strategies including the parent and the society is the primary option nowadays. Ayurvedic parlance is really a treasure of several therapeutic combinations advisable in conditions like Mental Retardation. Many drugs are being handled in clinical practise with positive claims. Behaviour modification therapy is a proven method capable of improving the overall performance of children with mental sub normalities, if performed with professional excellence. Ashtamangala gritha mentioned in baalaroga chikitsa in Bhaishajya ratnavali had been selected as study drug for this Randomised Controlled Trial (RCT). Behaviour modification therapy had been tried against its efficacy with the selected gritha as it is a proven therapy. The study was conducted with 40 subjects. The study group with Ashtamangala gritha along with Behaviour modification therapy was tried against the control with only Behaviour modification therapy. Assessment was done before treatment, after 30 days of treatment and after 30 days of follow up. The assessment was done using the Malin's IQ Scale and Madras Development Programming System (MDPS) scoring. It was observed that Ashtamangala gritha has significant effect in the improving the IQ of children with Mental Retardation.

Keywords: Ashtamangala gritha, Mental Retardation, Behaviour modification therapy

INTRODUCTION

Mental retardation is a condition of incomplete development of mind, characterized by impairment of skills manifested during the developmental period, marked by subnormal intelligence¹. The child is having significant limitation in intellectual functioning and in adaptive behaviour. The IQ levels of children with 70 or below are being considered for the diagnosis as mental retardation (MR).

Biological factors as well as the socio cultural factors are being discussed under the aetiological factor. According to Diagnostic and Statistical Manual (DSM), Sub average intellectual functioning (IQ<70), deficit in adaptive behaviour (communication, self care etc.) and the onset before 18 years makes the diagnosis of MR².

In the management aspect, Nootrophic medicines are having limited use, as per reported controlled studies in conditions like MR. It affects the social and occupational life very badly. The current scenario point towards the services such as early intervention, education, vocational training and social rehabilitation. Medical world is in search for the evolution of new as well as effective drugs to be proven clinically in this regard. The aim is to enable affected child to lead a normal life.

In Ayurvedic literature, there are ample references regarding the mind and intellect and also the physiology of cognition. But the condition like MR as such cannot be traced as a separate condition or disease. The terms like 'jadata' alpabudhi, 'abudha' has been described in the classics³. The ancient science emphasizes the importance

of the mental status of the couple, preconception strategy and right into the care of the newborn as a preventive aspect. Acharya Charaka explains the Satwa vaiseshakara bhavas as the factors influencing the formation of satva of the individual⁴. The word 'Ajnaanatwa' has been explained as the people who are having direct knowledge but fail to think and understand from hidden knowledge⁵. The reasons for a vikrita progeny has been narrated by Charaka as beeja (gamates), Aatmakarma(sinfual acts), aasaya (uterine conditions), kaala (time and age regarding conception) and maaturaahara vihara (diet and regimen of mother) by which the doshas get deranged leading to alterations in progeny⁶. In conditions like MR, the dominant dosha involved is Kapha along with Vatha, eventhough there is evidence of tridosha kopa. The altered functioning of these doshas and a higher concentration of Taamasa guna leads to the impairment of budhi in the individual⁷.

The management includes two aspects - preventive measures and specific treatment assessing the doshas of manas as well as the sareera. To improve the mental faculties and intelligence, several drugs like medhya rasayanas and grithas have been recommended. For stabilizing the mano doshas, the techniques such as jnaana, vijnana, dhairya, smriti and samaadhi has been advocated⁷. Behaviour modification therapy can be explained in such conditions with efficacy.

There are a few studies which were done previously in this disease and shows promising results. A study conducted by Chawla Deep N with the drugs Vacha,

Haridra, Hingu and Rudraksha showed response over psychological factors like cognition and mood in children with mental retardation⁸. Another study conducted by Hrishikesh D in this institute with Kalyanaka Choorna in Mental Deficiency found significant effect in improving the Intelligent Quotient and Social Quotient of the children⁹. This study was proposed to evaluate the efficacy of the selected Ayurvedic drug when compared with the Behavior Modification Therapy.

Aims and objectives

- To assess the efficacy of Ashtamangala gritha in the management of Mental retardation when administered internally.
- To compare the efficacy of Ashtamangala gritha with behaviour modification therapy in the management of Mental Retardation.

MATERIALS AND METHODS

Study was carried out as per the Ethical clearance number IEC/CL/010/09 dated 07/04/11 from VPSV Ayurveda College, Kottakkal, India.

- Concerned Modern and Ayurvedic literature
- Participants 40 in number
- Ashtamangala gritha
- Patient Consent Form
- Case Record Form

Drug Study

Table 1: The ingredients of Ashtamangala gritha¹¹

Drug	Rasa	Guna	Veerya	Vipaaka	Prabhava	Karma
<i>Acorus calamus</i>	Tikta Katu	Laghu, Teekshna Sara	Ushna	Katu	Medhya	KV samana samjna sthapana
<i>Saussarea lappa</i>	Katu Tikta, Madhura	Laghu, Teekshna Rooksha	Ushna	Katu	-	KV samana Rasayana
<i>Bacopa monneiri</i>	Tikta Kashaya Madhura	Laghu Sara	Seeta	Madhura	Medhya	VPK samana Dhee- smritikara
<i>Brassica juncea</i>	Katu Tikta	Snigdha	Ushna	Katu	-	KV samana Srothosodhaka
<i>Hemidesmus indicus</i>	Madhura Tikta	Guru snigdha	Seeta	Mahura	-	VPK samana raktaprasadana Rasayana
Saindhava	Lavana	Laghu sookshma	Seeta	Madhura	-	VPK samana
<i>Piper longum</i>	Katu	Laghu Teekshna Snigdha	Anushna seeta	Madhura	-	KV samana balya Rasayana, Medhya
Goghrita	Madhura	Guru Snigdha Mridu	Seeta	Madhura	Medhya	VP samana Rasayana

36.4% of the drugs are Kapha Vatha hara in property and 63.6% of the drugs are Tridosha samana in nature when analysed.

The drug was prepared as per the sneha kalpana mentioned, from the Arya Vaidya Sala Kottakkal, India.

Mode of administration

5 ml twice daily at 7 am and 9 pm followed by half a glass of hot water

Duration of treatment- 2 months

Data Collection

The data was collected as per Case Record Form.

Clinical Study

Study Design

Randomized Controlled Trial

Settings

Child Psychiatry OPD & IPD-VPSV Ayurveda College Hospital, Kottakkal

Duration of Treatment

2 months intervention and 1 month follow up

Sample size: 20 in each group

Diagnostic criteria

Satisfying the DSM IV criteria for Mental Retardation¹⁰.

Inclusion criteria

- Children with IQ below 70
- No discrimination of sex or religion
- Age group : 5 - 12 yrs

Exclusion Criteria

- Children with severe sensory impairments
- Autism, ADHD etc.
- Hypothyroidism, on anti epileptics

Assessment Criteria

- Malin's IQ scale
- Madras Development Programming System
- The Rajas and Tamas Scale

The assessments were done before treatment, after two months treatment and after one month follow up in both the groups.

Severity of symptoms was rated with the help of Malin's IQ Scale and Madras Developmental Programming system and Manasa bhava questionnaire¹².

Rating was done before treatment, after 60 days of internal medication and after 1 month of follow up.

Assessments of IQ, Adaptive Behaviour as well as Manasa bhavas were done.

Data Analysis

The Outcome data was measured and statistically analysed by the 'student paired t test'.¹³

The comparison in between groups was done by student's unpaired t- test for equal sample size.

RESULTS**Data related to clinical picture**

15 % of the parents were having consanguinity between parents in this study. 35% of the cases were having a family history of mental retardation, learning dysfunction in 15% and other psychiatric illness in other 15% of the cases. Antenatal events such as leaking per vagina were observed in 35% of the mothers, Eclampsia in 25% and infection during pregnancy in the other 15%. On analyzing the perinatal events, foetal distress was observed in 30% of the cases, birth asphyxia in 35% of the cases, delayed first cry and cyanosis in 35% of the cases.

Regarding birth weight, 35% belong to the low birth weight group (<2.5 kg) and the rest being of normal birth

weight. 20% were of having enuresis and another 20% were having ADHD as co-morbidity. Regarding the presence of abnormal behaviour, 30% showed unusual smiling/ talking, tantrums in 35%, hyperactivity in 25%, irritability in 55%, social withdrawal in 40% and destructiveness in 15% of the children. Delayed milestones were noticed in 75% of the study cases.

85% of the cases were having mild MR, 10% were of moderate and 5% were severely retarded. 60% were of Vatha Kapha prakrithi, 20% each were of Kapha pitta prakrithi and Vatha Pitha prakrithi. On the analysis of manodoshas, in 54%, tamas was predominant and rajas was 46% in the subjects.

Data related to clinical study**Table 2: Effect of therapy on Malin's IQ scale**

Group	BT	AT	MD	% increase	SD	T value	P value
Trial	55.45	59.34	-3.89	7	11.5	6.6	<0.001
Control	56.34	57.9	-1.6	2.8	14.2	4.3	<0.01

BT – before treatment; AT – after treatment; MD – mean deviation; SD – standard deviation

On comparing the effect of therapy, the test was significant at 1% level.

Table 3: Effect of Therapy on Individual symptoms in control group

Symptoms	BT	AT	% of relief	SD	t value	P
Gross Motor functions	1.1	0.9	18.2 %	0.56	1.49	>0.05
Fine Motor Movements	6.5	4.5	30.8%	2.72	4.2	<0.01
Meal time activities	2.80	1.60	42.9%	2.28	2.4	<0.05
Deficits in dressing	6.9	4.5	34.8%	3.44	3.27	<0.01
Deficits in grooming	5.7	3.3	42.1%	2.76	5.62	<0.001
Deficits in toileting	1.9	1.1	42.1%	2.06	1.71	>0.05
Deficits in receptive language	3.2	2.2	31.25%	1.53	3.87	<0.01
Deficits in expressive language	6	4.5	25 %	1.51	4.39	<0.01
Deficits in social interaction	5.8	4.1	29.3 %	3.32	3.79	<0.01
Deficits in reading	14.9	13.8	7.38 %	2.81	2.54	<0.05
Deficits in writing	11.3	10.2	9.7 %	3.59	2.54	<0.05
Deficits in number	12.2	11	9.8 %	3.05	3.67	<0.01
Deficits in time	16.2	13.6	16.04%	2.73	4.28	<0.01
Deficits in money	16.4	15.4	6.09 %	3.02	3.87	<0.01
Deficits in domestic activities	12.9	8.4	34.9 %	4.79	4.39	<0.01
Deficits in community orientation	10.2	7.3	28.4%	2.55	4.95	<0.001
Deficits in recreation	12.6	9.5	24.6%	3.02	4.39	<0.01

Table 4: Effect of Therapy on Individual symptoms in trial group

Symptoms	BT	AT	% of relief	SD	t value	P
Gross Motor functions	1.5	1.2	20%	1.87	1	>0.05
Fine Motor Movements	6.5	4.5	30.8%	2.72	4.2	<0.01
Meal time activities	2.80	1.60	42.9%	2.28	2.4	<0.05
Deficits in dressing	6.9	4.5	34.8%	3.44	3.27	<0.01
Deficits in grooming	5.7	3.3	42.1%	2.76	5.62	<0.001
Deficits in toileting	1.9	1.1	42.1%	2.06	1.71	>0.05
Deficits in receptive language	3.2	2.2	31.25%	1.53	3.87	<0.01
Deficits in expressive language	6	4.5	25 %	1.51	4.39	<0.01
Deficits in social interaction	5.8	4.1	29.3 %	3.32	3.79	<0.01
Deficits in reading	14.6	12	17.8 %	2.64	5.46	<0.001
Deficits in writing	10.9	8.3	23.85 %	3.72	5.46	<0.001
Deficits in number	12.4	9.1	26.6 %	4.24	4.83	<0.001
Deficits in time	15.6	11.9	23.7 %	3.39	4.69	<0.01
Deficits in money	16.5	14.2	13.9 %	2.68	4.64	<0.01
Deficits in domestic activities	12	6.2	48.3 %	4.96	4.91	<0.001
Deficits in community orientation	10.6	6.9	34.9 %	3.16	4.69	<0.01
Deficits in recreation	12.2	7.9	35.2 %	3.62	4.74	<0.01

Table 5: Effect of therapy on total score of MDPS scale after treatment

Group	B T	A T	M D	% of relief	S D	't' value	'P' value
Trial	154.6	107.9	46.7	30.2	38.53	5.49	< 0.001
Control	146.6	116.5	30.1	20.5	27.22	6.22	< 0.001

The comparison between the two groups after the follow-up showed insignificance. (P> 0.05)

DISCUSSION

Mental retardation is now being viewed from a different angle and in the present study, an attempt was made to approach the condition from physical, psychological and social angles¹⁴. In this study the cognitive counterpart was assessed by Malin's IQ scale and the behavioural counterpart by the MDPS scale. The reason of vikritha garbha by Acharya Charaka gives a composite description of the aetiological factors resulting in a developmental disability.¹⁵

The sahaja nidanas can be viewed as the genetic factors contributing to the aetiology of 8-12 % of the mental retardation. The samprapthi is to be explained at three levels. The pre-conceptional level explains the genetic component of MR¹⁶. The intrauterine level explains the cause of vitiation of doshas in the condition. The post natal samprapthi defines the representation of the disability at cognitive, physical as well as the behavioural levels. The post natal samprapthi can be visualised in the light of description of 'Phakka' roga explained by Acharya Kashyapa¹⁷. Based on the level of impairment of dhatus as well as the defect at the mind and budhi, does the presentation varies from case to case.

Analysis of deha prakrithi shows that in this study, 60% were of kapha vatha prakrithi, 20 % each of vatha pitta and kapha pitta prakrithi. As far as manodoshas are considered, a predominance of tamodosh was found in 54 % and rajas in 46 % of the subjects.

The trial showed significant improvement on comparing the effects at the end of the therapy pointing that the trial drug has advantage over the control group in improving the IQ.

The trial drug Ashtamangala gritha is having a good proportion of teekshna, sookshma and Ushna veerya drugs, which seems to remove the Tamo guna, thereby bringing clarity of mind and intellect¹⁸. The trial drug showed significance in several areas of MDPS scale such as expressive language, reading and writing, fine motor movements, toileting and receptive language¹⁹ but it seems insignificant in dressing, grooming, social interaction, domestic activities and recreation. The trial and control group showed significant improvement in the total scores of MDPS scale after the treatment. The comparisons between the two groups showed insignificant at the final assessment. This propose that the trial and control is having individual limitations, suggesting the role of combined method of intervention in improving conditions like MR.

CONCLUSION

From this study, we can conclude that Ashtamangala gritha is effective in the management of mental retardation when compared with behaviour modification therapy. The drug improves the IQ level in the children, when assessed with

Malin's IQ scale and is significant as well. It is also effective in several domains of MDPS when compared with the behaviour therapy. But it is not effective significantly when compared with the control group in MDPS.

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