

Evaluation of the Efficacy of Mentat in Children with Learning Disability: A Placebo-Controlled Double-Blind Clinical Trial

(Ms.) Upadhyay, S.K., *Reader in Child Psychology,*
Abhijeet Saha, *Senior. Resident**

Bhatia, B.D., *MD, DCH, MNAMS, FICN, FIAP*

Department of Pediatrics, Institute of Medical Sciences, Banaras Hindu University, Varanasi, India.
and

Kala Suhas Kulkarni, *M.D.*

Medical Advisor, R&D Center, The Himalaya Drug Company, Bangalore, India

[*Now at SGPGI, Lucknow]

ABSTRACT

A double blind placebo controlled clinical trial was conducted to evaluate the efficacy of Mentat in children with learning disability. The study was carried out in 100 students with learning disability belonging to class VI to XI students aged between 11-16 years who had secured $\leq 45\%$ marks in the annual examination, had potential for performing academically better and had $IQ \geq 90$ and also who did not have any visual or auditory problem. Children with space occupying lesion, genetic disorder, renal failure preceding for the last 6 months, with recent cerebrovascular episodes and those suffering from non-concomitant severe illness necessitating other treatment and children who are not co-operative. These children were further divided into four groups: Group N (Placebo), Group P (Drug), Group S/F (Placebo) and Group R/G (Drug). The assessment of cognitive functions was done with Malin's intelligence scale of Indian children and Bender visual motor Gestalt test. Mentat was administered orally for 6 months, and results evaluated after 6 months. Children receiving Mentat performed significantly better on full scale and performance. An improvement in the attention and concentration as well as increase in their attention span was seen. They had better sequential ability. No child showed any behavior and speech abnormality during the trial. On the basis of the above observations it may be concluded that Mentat improved attention and concentration in learning disability in school children.

Key words: Mentat, learning disability, attention impairment, impairment in concentration, speech defects, decreased memory, cognitive functions

INTRODUCTION

A deep rooted concern among educationists and planners has been the significantly high failure and dropout rate in schools. It is estimated that between 3-7% children in the world have learning disability, the incidence of which is likely to be higher in India due to recurrent infections and early malnutrition. Agarwal *et al.* have reported that 16.3% children from rural schools were learning disabled¹.

In a survey conducted in 1994, the dropout rate was 4.8% among boys and 7.6% in girls². The students in the age group 6-14 years had not attended school for a period of more than seven months.

The wastage of human talent, and its significance in terms of national waste during the primary years is alarming. A number of factors in the environment influence this phenomenon, thus, not all children who are eligible for admission in school perform uniformly well. There are pupils who do exceptionally well, those who do average work, few who do not master the required curriculum targeted for their expected age and educational standards.

With an increasing number of children being identified and diagnosed as suffering from learning disability, scholastic underachievement, minimal cerebral dysfunction and the like, an increasing interest has been shown by educationists and others in this field to diagnose and identify them at the earliest, and plan rehabilitation programs for such children according to their deficient areas of cognitive functioning.

The development of self-image and self-esteem is based on the success in schools. Feedback from school concerning academic performance and social interaction, influences parents' image of their children. Thus, if something interferes with the success of a child in school, it also impacts the emotional, social and family functioning. Academic performance requires the integrated interaction of the cognitive, motor and language functions of the brain. This disability affects every aspect of the individual's life during each stage of psychosocial development.

Children with learning disabilities present a wide variety of problems, which include impairment of attention and concentration, impulsiveness, poor memory, speech defects, poor visual-motor co-ordination, low score in mathematics and writing disability^{1,3-8}. In view of the above, a detailed examination is necessary to identify the cause of the deficit and plan a rehabilitation programme for such children according to their deficient areas of cognitive functioning.

Intervention studies in such children include counseling the parents, teachers and the child. In children associated with behavioral problems, behavior modification and many drugs have been tried. Mentat (manufactured by The Himalaya Drug Company, Bangalore, India), a herbal formulation, has been proven by many physicians to be effective in improving the scholastic performance. Mentat contains herbs like *Bacopa monnieri* (Brahmi), *Centella asiatica* (Mandukaparni), *Withania somnifera* (Ashwagandha), *Nardostachys jatamansi* (Jatamansi), *Acorus calamus* (Vacha), *Tinospora cordifolia* (Guduchi), *Emblica officinalis* (Amalaki), *Terminalia arjuna* (Arjuna) and others, which act as nervine tonics, correct impaired mental function, prevent loss of memory and help in improving intelligence and memory.

MATERIAL AND METHODS

A placebo controlled double-blind clinical trial was undertaken to evaluate the efficacy and safety of Mentat, in children with learning disability. The study was carried out in an urban school, Gopi Radha Balika Inter College, Ravindrapuri, Varanasi, Uttar Pradesh, India. Students of classes VI to XI, aged 11-16 years, participated in the study. Initially each child was subjected to clinical examination – both general and systemic, to rule out any chronic ailment that might interfere with the learning abilities of the child, including antenatal and perinatal history. A semistructured interview was conducted with the parents to obtain information on various parameters such as parental education and occupation, caste, per capita monthly income, size and family and psychosocial stimulation available to the child at home for learning.

Social status was calculated using Prasad's classification of socioeconomic status (1961), modified in October 2000. For modification (Kumar, 1993), values of the All India Consumer Price Index (AICPI), i.e., 449 were used (Oct., 2000) (Table 1).

Table 1: Social classification		
Social class	Per capita monthly income limits (RS.)	
	1961	October 2000
I	100 and above	2200 & above
II	50 - 99	1100 – 2199
III	30 – 49	660 – 1099
IV	15 – 29	330 – 659
V	Below 15	<330

Study group:

One thousand one hundred and fifty eight students were registered in the age group of 11-16 years. Analysis of marks obtained in the annual examination in different subjects during the previous academic session (1999-2000) was done. Out of the total, 532 children were selected who achieved $\leq 45\%$ marks in their annual examination. In these, children having learning disabilities were identified using following tools:

1. *Mathematics marks*: Students who secured $\leq 45\%$ marks in the annual examination during the previous academic session (1999-2000).
2. *Teachers' Assessment*: Each student was interrogated by a panel of three teachers and students found to have potential for performing academically better inspite of poor marks in the annual examination were carried further in the study. Teachers were also asked regarding classroom behavior of the child and those having behavioral difficulties were excluded.
3. *IQ Testing*: Malin's intelligence scale for Indian children was administered and students having $IQ \geq 90$ were taken for the study.

The criteria for labeling a child as learning disabled was:

1. A child who does not manifest mental subnormality or whose $IQ \geq 90$.
2. Who does not have any visual or auditory problems.
3. Who achieved poor marks in arithmetics and performed poorly on teacher's assessment.

Criteria for exclusion:

1. Space occupying lesion.
2. Genetic disorder.
3. Renal failure preceeding 6 months.
4. Recent cerebrovascular episodes.
5. Non-concomitant severe illness necessitating other treatment.
6. Non co-operation.

On the basis of the above criterias, 100 students were identified as having learning disability. These children were further divided into four groups:

Group – N (Placebo)

Group – P (Drug)

Group – S/F (Placebo)

Group – R/G (Drug).

Assessment of cognitive functions

The following tests were administered individually on each child in the study and control groups:

1. Malin's intelligence scale for Indian children⁹.
2. Bender Gestalt visual motor scale¹⁰.

Mental status examination

At the time of testing, the appearance and behavior, speech and memory functions of each child were observed for his or her appearance and behavior. The following observations were done for the above three parameters.

- A. Appearance and behavior
 - i. Tidy
 - ii. Responding easily
 - iii. Easy to make contact with
 - iv. Cheerful
 - v. Anxious
 - vi. Overactive
 - vii. Impulsive/agitated
 - viii. Hyperactive
 - ix. Appropriate behaviour
 - x. Makes eye contact
 - xi. Co-operative with examiner
 - xii. Talks very fast.
- B. Speech
 - i. Clear
 - ii. High-pitched
 - iii. Speech content relevant
 - iv. Slurred speech/mumbling
 - v. Quick reaction time
 - vi. Intelligibility meaningful.
- C. Memory
 - i. Remote memory
 - ii. Recent memory
 - iii. Immediate retention/recall
 - iv. Concentration.

Drug: Mentat Syrup or Tablets

Route of Administration: Oral

Duration of treatment: 6 months.

RESULTS

The present study was conducted in 1158 girls studying in classes VI to XI in the age group of 11-16 years. Out of these, those who obtained $\leq 45\%$ marks in their annual examination were identified (n=532). This group of 532 girls were further subjected to IQ testing and teacher's assessment. A few more criteria like having an IQ ≥ 90 , securing $\leq 45\%$ marks in mathematics in their annual examination and learning potential according to the teachers' rating scale, narrowed the groups to 100 students who were finally selected for the study.

It is evident that the two groups (i.e. drug and placebo) did not show any difference in their scores at the time of initial testing. However, after 6 months, those receiving Mentat performed significantly better on full scale and performance IQ ($p<0.05$, Tables 2 and 3).

Table 2: Mean $\pm$ SD full scale, Verbal and performance IQ in the two groups at the time of initial and final testing

Measures	Group N (24)			Group P (23)		
	Initial testing	Final testing	<i>t</i> -values	Initial testing	Final testing	<i>t</i> -values
Full Scale IQ	98.5 ± 8.92	105.41 ± 6.99	1.15	99.69 ± 7.74	106.95 ± 7.60	2.18*
Verbal IQ	101.87 ± 11.58	109.25 ± 7.22	0.48	102.78 ± 8.02	110.13 ± 8.21	1.72
Performance IQ	95.29 ± 8.06	101.70 ± 8.99	0.91	97.00 ± 8.93	103.56 ± 8.50	1.35

Figures in parentheses indicate number of subjects, * $p<0.05$

Table 3: Mean $\pm$ SD full scale, Verbal and performance IQ in the two groups at the time of initial and final testing

Measures	Group S/F (23)			Group R/G (25)		
	Initial testing	Final testing	<i>t</i> -values	Initial testing	Final testing	<i>t</i> -values
Full Scale IQ	95.34 ± 5.12	102.43 ± 6.55	1.26	99.04 ± 6.55	110.70 ± 6.38	2.26*
Verbal IQ	100.56 ± 6.65	106.91 ± 7.22	1.06	101.92 ± 9.73	115.39 ± 6.99	1.69
Performance IQ	90.13 ± 8.89	98.08 ± 8.31	0.95	96.20 ± 6.59	105.43 ± 7.63	2.11*

Figures in parentheses indicate number of subjects, * $p<0.05$

The scores on various verbal and performance subtests for the study and control groups indicated that children in the study groups (both P and R/G) scored significantly better on arithmetic, digit span and coding subtests ($p<0.01$). This shows an improvement in their attention and concentration as well as an increase in their attention span (Tables 4-7).

Table 4: Mean IQ's for various verbal subtests in the two groups at the time of initial and final testing

Measures	Group N (24)			Group P (23)		
	Initial testing	Final testing	<i>t</i> -values	Initial testing	Final testing	<i>t</i> -values
Information	96.20 ± 14.21	100.58 ± 8.62	0.43	93.73 ± 10.46	99.82 ± 10.56	0.67
Comprehension	123.75 ± 18.07	127.66 ± 12.24	0.42	122.04 ± 13.33	126.04 ± 14.41	0.21
Arithmetic	87.83 ± 10.13	94.33 ± 8.72	0.89	90.91 ± 10.18	105.30 ± 9.38	3.01**
Similarities	98.62 ± 18.77	110.58 ± 13.96	0.35	105.04 ± 17.04	120.65 ± 20.30	1.06
Vocabulary	116.41 ± 18.03	131.25 ± 11.82	0.80	114.39 ± 11.75	123.39 ± 8.31	0.86
Digit span	87.70 ± 9.73	93.33 ± 10.47	0.76	90.95 ± 14.37	107.3 ± 13.16	3.49**

Figures in parentheses indicate number of subjects, ** $p<0.01$

Table 5: Mean IQ's for various verbal subtests in the two groups at the time of initial and final testing

Measures	Group S/F (23)			Group R/G (25)		
	Initial testing	Final testing	<i>t</i> -values	Initial testing	Final testing	<i>t</i> -values
Information	89.00 ± 8.85	96.13 ± 9.01	1.01	94.04 ± 8.95	101.06 ± 8.35	0.862
Comprehension	121.47 ± 13.52	126.82 ± 13.17	0.26	118.84 ± 16.23	129.52 ± 14.00	0.62
Arithmetic	88.13 ± 6.04	95.00 ± 4.96	0.98	90.72 ± 8.46	110.92 ± 7.94	3.35**
Similarities	105.08 ± 15.84	111.43 ± 20.01	0.34	98.96 ± 13.26	110.24 ± 12.87	0.63
Vocabulary	108.60 ± 24.95	113.95 ± 23.62	0.33	115.44 ± 21.42	130.64 ± 15.47	0.81
Digit span	86.91 ± 9.51	94.21 ± 8.61	0.60	94.12 ± 10.67	110.38 ± 10.03	3.58**

Figures in parentheses indicate number of subjects, ** $p<0.01$

Table 6: Mean IQ for various verbal subtests in the two groups at the time of initial and final testing						
Measures	Group N (24)			Group P (23)		
	Initial testing	Final testing	<i>t</i> -values	Initial testing	Final testing	<i>t</i> -values
Picture completion	92.41 ± 14.34	103.58 ± 14.00	0.52	97.04 ± 7.35	101.21 ± 13.25	0.40
Block design	98.54 ± 9.65	103.33 ± 13.20	0.36	102.73 ± 16.41	107.47 ± 13.88	0.48
Object assembly	83.12 ± 12.73	97.29 ± 14.83	0.97	89.91 ± 17.54	105.52 ± 14.83	0.70
Coding	102.29 ± 14.09	107.58 ± 16.89	0.32	98.39 ± 11.32	115.13 ± 10.17	3.03**
Mazes	99.87 ± 10.44	98.91 ± 14.28	0.06	95.26 ± 15.36	99.82 ± 14.42	0.23
Figures in parentheses indicate number of subjects, ** <i>p</i> <0.01						

Table 7: Mean IQ for various verbal subtests in the two groups at the time of initial and final testing						
Measures	Group S/F (23)			Group R/G (25)		
	Initial testing	Final testing	<i>t</i> -values	Initial testing	Final testing	<i>t</i> -values
Picture completion	93.65 ± 13.43	100.43 ± 12.81	0.52	94.40 ± 12.74	102.28 ± 11.93	0.60
Block design	94.60 ± 15.77	102.00 ± 11.08	0.58	102.64 ± 10.78	106.72 ± 11.76	0.62
Object assembly	82.00 ± 14.46	98.21 ± 17.23	0.73	84.64 ± 15.46	96.52 ± 17.23	0.92
Coding	91.21 ± 13.07	97.69 ± 12.54	0.44	102.44 ± 11.39	124.68 ± 11.15	3.91**
Mazes	89.30 ± 14.95	92.91 ± 13.75	0.21	96.64 ± 10.68	98.36 ± 13.38	0.09
Figures in parentheses indicate number of subjects, ** <i>p</i> <0.01						

Table 8: Mean IQ in various Bannatyne categories						
Bannatyne categories	Group N (24)			Group P (23)		
	Initial testing	Final testing	<i>t</i> -values	Initial testing	Final testing	<i>t</i> -values
Verbal conceptualization	109.44 ± 14.23	117.58 ± 8.66	0.70	109.76 ± 9.49	118.53 ± 11.47	0.69
Spatial	93.58 ± 8.53	100.53 ± 9.35	0.84	96.45 ± 9.32	103.51 ± 9.22	1.06
Sequential	92.68 ± 9.05	98.42 ± 9.02	1.04	94.06 ± 8.90	109.78 ± 8.45	7.17***
Acquired knowledge	101.27 ± 10.68	109.64 ± 8.67	1.06	99.72 ± 8.63	110.24 ± 6.20	1.48
Figures in parentheses indicate number of subjects, *** <i>p</i> <0.001						

Table 9: Mean IQ in various Bannatyne categories						
Bannatyne categories	Group S/F (23)			Group R/G (25)		
	Initial testing	Final testing	<i>t</i> -values	Initial testing	Final testing	<i>t</i> -values
Verbal conceptualization	105.33 ± 12.62	113.39 ± 9.28	0.84	107.75 ± 13.58	118.00 ± 8.27	0.86
Spatial	89.86 ± 10.35	98.41 ± 8.94	0.89	94.58 ± 7.35	100.92 ± 8.85	1.13
Sequential	88.76 ± 6.15	95.54 ± 6.24	1.29	95.79 ± 7.94	115.21 ± 7.22	7.79***
Acquired knowledge	96.84 ± 6.79	103.22 ± 5.86	1.01	99.82 ± 9.70	114.30 ± 6.83	1.77
Figures in parentheses indicate number of subjects, *** <i>p</i> <0.001						

Scores were also determined for each child on the four Bannatyne categories³ by computing their mean IQ scores in four groups of miscellaneous subjects in following categories: verbal conceptualization (similarities, vocabulary, comprehension), spatial (picture completion, object assembly, block design), sequencing (arithmetic, digit span, coding) and acquired knowledge

(information, arithmetic, vocabulary). The analyses of the profiles according to the Bannatyne categories are presented in Tables 8 and 9. It shows that children having Mentat Tablets (Group P) scored significantly better on sequential ability ($p < 0.001$). Further, those having syrup (Group R/G) also showed significantly higher scores on sequencing tasks ($p < 0.001$), indicating improvement in their attention and concentration. On the Bender Gestalt test, no difference was observed between the study (drug) and control groups (placebo). On mental status examination at the time of testing, no child showed any behavior and speech abnormality. Eleven children out of the 100 learning disabled children had poor memory scores.

On the basis of the above observations, it may be concluded that Mentat improved attention and concentration in learning disabled children.

DISCUSSION AND CONCLUSION

Mentat improved memory and intellect. Charaka samhitha describes the effect of *Bacopa monnieri* (Brahmi) on intellect and memory, where it is prescribed for mental retardation of various degrees. The other effects on loss of intellect and memory are also described precisely in the traditional Ayurvedic treatise, Sushruta Samhitha. The active ingredients of *Bacopa monnieri* are saponins and bacosides. It is also used to control anxiety, restlessness and stress-induced forgetfulness. The entire plant can also be used for memory enhancement and as an anti-stress agent.

Apart from memory enhancement properties, *Acorus calamus* is also useful in anxiety-related disorders, as an anticonvulsant, in patients with aggressive behavior and in elderly people.

Stress related disorders are controlled by *Withania somnifera* (Ashwagandha), *Embllica officinalis* (Amalaki) and *Bacopa monnieri*. The alkaloids of *Withania somnifera*, withanine and somniferine, are responsible for the control of stressful conditions. *Withania somnifera* is a premier adaptogen¹¹, is used as a medharasaayan (anti-stress tonic), which promotes learning acquisition and memory retrieval. They are also useful in general debility and fatigue. Fatigue is also controlled with *Embllica officinalis*, *Acorus calamus* (Vacha) and *Withania somnifera*.

Centella asiatica (Mandukaparni) contains brahmic acid, isobrahmic acid, brahmoside and brahminoside. It has psychotropic, sedative and anti-convulsant properties. It is also useful in dementia, mental disorders, epilepsy and anxiety.

Thus, it can be concluded that Mentat, a polyherbal formulation where all the herbs act in synergistic manner, produces improvement of memory, attention and concentration in children with learning disability.

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