

Mentat in Hyperactivity and Attention Deficiency Disorders – A double-blind, placebo-controlled study

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ABSTRACT

Behaviour disorders present a very important problem in paediatric practice. They may be associated with normal physical development and intelligence or may be associated with some degree of disturbance of cerebral functions. Various therapies have been tried with varying results. In ancient Indian medical literature, many drugs have been advocated for mental disorders. A double-blind, placebo-controlled study was carried out to confirm the efficacy of Mentat in 60 children with behavioural problems. Thirty patients in each group received either placebo or Mentat syrup in a random manner at a dose of 1-2 tsp. for 12 weeks. Evaluation was carried out by using Yale's Behaviour Inventory Scale at week 0, 6 and 12. Significant improvement was noted in the parameters following Mentat treatment as compared to placebo and the pre-treatment period. Improvement was evident in hyperactivity, social behaviour and attention.

INTRODUCTION

Behavioural disorders which present a very important problem in paediatric practice, may be associated with normal physical development and intelligence or with disturbance of the cerebral function. Learning and behavioural disabilities may be of various degrees and associated with deviation in the functioning of the central nervous system.

The Hyperkinetic Syndrome involves an increase in norepinephrine neurotransmission¹. Treatment with amphetamine and other therapies have given varying results and side effects². Hence more emphasis is laid on the search for a herbal preparation which would be helpful in the management of psychiatric disorders. Ancient Indian medical literature advocates the use of various drugs for mental disorders. Mentat is a complex herbal formulation of ingredients quoted in the books on Ayurveda as useful in improving memory and having a tranquillising action in mental disorders³⁻⁶. In an earlier pilot open study with Mentat in 25 cases of behavioural problems, marked improvement in behaviour was observed following administration of Mentat for 6-12 weeks⁷. A double-blind, placebo-controlled study was therefore planned to objectively evaluate the efficacy of Mentat by using Yale's Behavioural Inventory.

MATERIAL AND METHODS

Sixty children in the age group of 3-16 years with a history of behavioural disorders for 3-15 years were enrolled in the study. There were 49 boys and 11 girls (4.45:1), which compared well to the known sex ratio of hyperactivity (4:1). These children were first evaluated on Yale's Behavioural Inventory Scale. After noting the pre-treatment score, patients were randomly allocated to two groups to receive either the active drug (A) or placebo (B) in a double-blind, placebo-controlled study. The dose of Mentat syrup or placebo syrup was 1 tsp. t.d.s. initially which was increased gradually over a period of 12 weeks to 2 tsp. t.d.s. diluted with an equal amount of water. Children

were followed up regularly in the OPD and evaluation on an objective scale was performed at 6 and 12 weeks.

The Yale Scale is an objective scale with 8 main parameters comprising attention, hyperactivity, impulsivity, tractability, habituation, conduct disorders (socialised and aggressive), negative effects and academics. In each parameter, there were appropriate symptoms and each point was rated as severe (3), moderate (2), mild (1) or nil (0) and the scores were then added up. Statistical evaluation was done to check the significance at 95% confidence limits between the scores of each subgroup, before and after treatment, in both the placebo and active treatment groups and also between the groups. The total scores for each parameter were also checked between the groups and before and after treatment. Paired 't' test was applied to check the level of significance between pre and post treatment scores in each treatment group and unpaired 't' test to check the significance between the groups.

RESULTS

The data in Table 1 show that there was significant reduction in scores of hyperactivity, tractability, adaptation to new situations, social and aggressive conduct disorders, impulsivity and negative effects after 6 weeks of treatment with Mentat. There was further significant reduction in scores after treatment for 12 weeks. In the case of placebo treatment, there was reduction in scores in all the above items but the difference was not statistically significant after treatment for 6 weeks. There was no further reduction in the scores after treatment for 12 weeks. In attention span (Fig. 1), there was significant reduction in scores after 6 weeks of treatment with Mentat as well as placebo. However, treatment with Mentat caused significant further reduction in scores at the end of 12 weeks but no change occurred on further treatment with placebo.

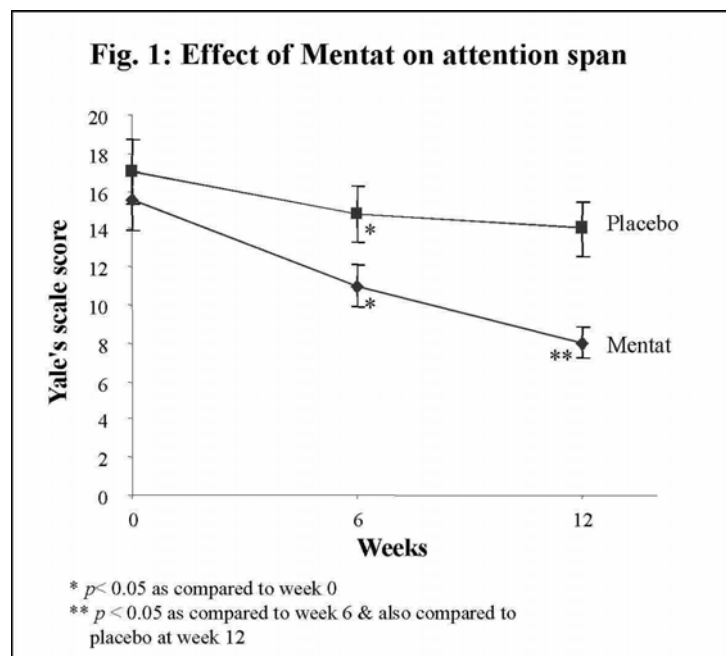


Table 1: Mean Yale Inventory Scores for each symptom before and after 6 and 12 weeks of treatment with Mentat and Placebo

Symptom	Mentat Week			Placebo Week		
	0	6	12	0	6	12
Hyperactivity	11.94±0.61	7.34*±0.77	5.00**±0.67	13.18±0.42	10.75±0.96	10.50±0.98
Tractability	11.25±0.92	6.72*±0.87	4.53**±0.70	12.29±0.69	10.25±1.07	9.57±1.07
Habituation	6.97±0.83	4.28*±0.69	2.56**±0.52	7.11±0.77	6.18±0.90	6.38±0.90
Conduct Disorders Socialised	4.25±0.58	2.47*±0.52	1.50**±0.42	4.71±0.51	3.64±0.54	3.68±0.58
Conduct Disorders Aggressive	5.28±6.69	2.13*±0.36	1.75±0.35	6.00±0.71	4.64±0.69	4.89±0.69
Negative Effects	6.25±0.93	3.44*±0.67	2.06**±0.42	6.11±0.83	5.32±0.85	5.21±0.81
Academics	12.44±1.04	8.53±1.16	5.75**±1.06	12.93±1.23	10.29±1.43	10.14±1.41
Impulsivity	10.47±0.72	6.69*±0.74	4.66**±0.69	10.96±0.69	9.14±1.00	9.07±1.01

* $p < 0.05$ as compared to respective week 0.

** $p < 0.05$ as compared to week 6 and also compared to placebo at week 12.

The total scores also show significant reduction at the end of 6 weeks with both Mentat and placebo. However, Mentat caused further significant reduction in total score, whereas there was no further change with placebo treatment at the end of 12 weeks (Fig. 2).

DISCUSSION

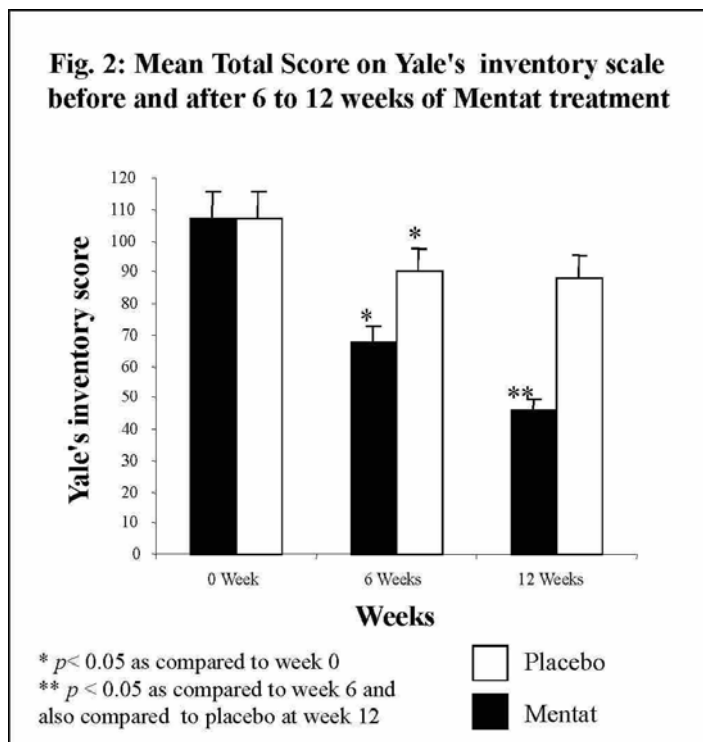
The results show striking characteristics. Statistically significant difference was observed from pre-treatment score at weeks 6 and 12 after Mentat treatment and also in comparison with placebo in improving attention, hyperactivity, impulsivity, tractability, habituation, socialised and aggressive conduct disorders, negative effects and academics. There was some improvement in almost all the parameters from week 0 to week 6 in the placebo group. However there was no further change in this group from week 6 to 12. This is a characteristic placebo response. Since children entering the trial get more attention, a change in the behaviour is expected in the initial phase.

With Mentat statistically significant improvement was observed from week 0 to week 6 and further significant improvement between weeks 6 and 12. The improvement at weeks 6 and 12 was significantly more as compared to placebo. This is the characteristic of a gradual onset of drug effect.

The differences at 12 weeks in respect of language and fine motor functions do not seem to differ from placebo at week 12, but in both these groups the initial scores were different and the change from week 6 to 12 was evident with active treatment and not with the placebo.

The evaluation of cognitive functions and the affect have been subjective. Several steps were taken to reduce bias and bring objectivity in the evaluation. We used Yale's Behavioural Inventory, adhering to all the details involved in it. We also used placebo in a double-blind study. Since there is no definite effective treatment available at present, the use of a placebo did not involve any ethical problem and the trial was reviewed and approved by the institutional committee.

The biochemical basis of the hyperkinetic syndrome is not entirely clear. It is probable that several interdependent transmitter systems may be involved. There are not many single agents which can cause such global improvement in the hyperkinetic syndrome and single drug agents affecting only one transmitter process have not proved satisfactory. Mentat is a complex formulation of herbal remedies. It is possible that this formulation has several chemical agents influencing the various transmitter systems in a useful manner to produce global improvement. Though it is not possible to identify these chemicals and their individual actions, it is remarkable that the method of processing has been able to get these chemicals into the final formulation in effective concentration and in a balanced way from commonly known herbs so as to produce global improvement.



CONCLUSION

Thus it was observed that children on the active drug Mentat responded significantly well in all the parameters of the Yale Scale.

They did better on the parameters of attention, hyperactivity, impulsivity, tractability, academics, language development and fine motor functioning as compared to conduct habituation and negative effects, which also did show some changes. Most of the effects were observed within the first 6 weeks of treatment and progressed further up to 12 weeks.

Children on the inactive drug showed some improvement at the end of 6 weeks of trial, but did not show further improvement in behaviour by the end of the 3 month trial. This could be explained by the 'placebo effect'.

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