

# Double Blind Placebo Controlled Randomized Study to Assess the Efficacy & Safety of a Brahmi Based Unani Formula in Children with Autism

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**Abstract**—Modern medicine is trying to introduce a number of experimental therapies for reversal of neuronal based damage or enhancement of neuronal functions. One of these is a Unani therapy for cognitive management based on *Centella asiatica*. The objective of this study is to evaluate the status of biochemical and chemical properties in children with autism, and then try to improve their developmental standards and quality of life. In this study each selected subjects was given a balanced diet, standard rehabilitation therapies and Brahmi semisolid paste provided by Ministry of Ayush for the research. This was compared with a placebo or matching group given the test formulation of Unani herbal Neuro –restorative health supplement, for three months. This is a standardized safe herbal Neuro-Restorative general health supplement based on classical Unani literature, available with the Central Council of Research in Unani Medicine (CCRUM) New Delhi, which has been found to be suitable for children. It contains brahmi, badaam, khazoor, amla, kalimirch and jadwar. Assessments were done at 2-month intervals for 6 months using outcome measures such as ATEC and VSMS to assess the improvement in quality of life, cognitive and communication skills. Pre assessment data (before therapy and post assessment data after the completion of therapy) were collected for the purpose of data analysis. The statistical analysis using SPSS results shows that the group “A” has 3-4%-much more improvement in VSMS and ATEC scores as compared to group “B” within 2 to 4 months. This encourages us to continue with the study.

## 1. INTRODUCTION

Named after one of the highest states of consciousness (Brahman or God of consciousness), Brahmi (*Centella asiatica* or Gotu Kola) is one of the most powerful brain tonics in the Ayurvedic apothecary. Brahmi supports restful sleep, calms emotional turbulence, and simultaneously improves concentration and alertness.

*Brahmi* is obtained from *Centella asiatica* (Linn.) Urban. It is valued in Indian systems of medicine for improving memory

and for the treatment of nerve disorders and skin diseases. It has been used extensively as memory enhancer.

It has been envisaged that in this century, disorders of the central nervous system will have a significant bearing on the healthcare concerns of the human population worldwide. Such neurological and psychiatric disorders are generally associated with loss of memory, cognitive deficits, impaired mental function etc. Due to the multi-factorial nature of these diseases, modern medicine based psychoactive drugs have met with limited success. Therefore, there is a growing demand for novel products that could target multiple pathways and improve the mental capabilities either independently or in combination with conventional drugs. In the recent times, herbal products based on traditional knowledge have been increasingly used both in developed and developing countries.

Pervasive Developmental Disorder or PDD is a behavioral disorder of speech, communication, social interaction, and repetitive type compulsive behavior. Autism is a form of PDD or PDD-NOS.

The common clinical features of Autism

are:-

- 1) Autism manifests as impairment in reciprocal social and interpersonal interaction
- 2) There is marked impairment in language and non-verbal communication.
- 3) Abnormal behavioral characteristics
- 4) There is often normal development, followed by regression that occurs by 1 to 3 years of age.

The diagnosis of childhood autism must meet the specific DSM IV or V criteria and will therefore present with poor eye

contact, pervasive ignoring, language delay, and other features.

## 2. MATERIAL AND METHOD

This study was carried out in the OPD of UDAAN (a Govt approved NGO), C-27-28, Dayanand Colony, Lajpat Nagar IV, New Delhi 110024, where a pool of Autism affected children are available.

The duration of study is 2 years. The study is a randomized placebo controlled double blind clinical trial.

Twenty autistic children aged 2-10 years were registered and, all the patients fulfilled the criteria of selection and followed the protocol of study and follow-up.

The clinical trial is being carried out to evaluate the efficacy of Unani Formulation in the following cognitive parameters:-

- Relating to People
- Speech
- Imitation
- Emotional Response
- Socialization
- Adaptation to Change
- Command Following
- Understanding of things
- Eye Contact

The Formulation was given at a dose based on body weight.

Adequate stock of medicines for 1 month at a time was given to the parents, as per randomization, to the children on regular basis to be given at an empty stomach.

The case record form for each patient was documented and maintained regularly during follow up. The assessment of the patients was made on day 1 before starting of drug, after 2<sup>nd</sup> months of starting of drug, then on 4<sup>th</sup> month and the last assessment was done on 6<sup>th</sup> month as given in case record form .

## 3. INCLUSION & EXCLUSION CRITERIA

### Inclusion Criteria:

- Children diagnosed as Autism using the DSM IV Autism Criteria.
- Certified to be in adequate healthy state by panel Pediatrician or Physician.
- Age 2 to 10 years and of either sex.
- Well-educated parents who can understand the experimental nature of the study, and can give informed

voluntary written permission for inclusion of their autistic child for this study.

### Exclusion Criteria:

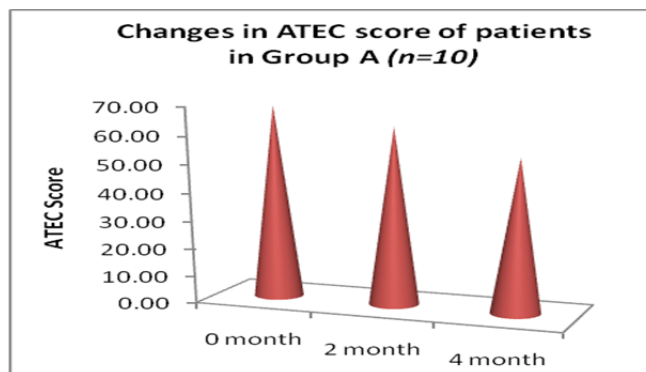
- Children having other genetic disabilities or cerebral palsy.
- Insufficiency of liver / kidney / marrow functions as per appropriate biochemical tests.
- Chronic uncontrolled illness that may need medical therapy which could interfere with diagnosis, treatment and assessment of the Autism symptoms.

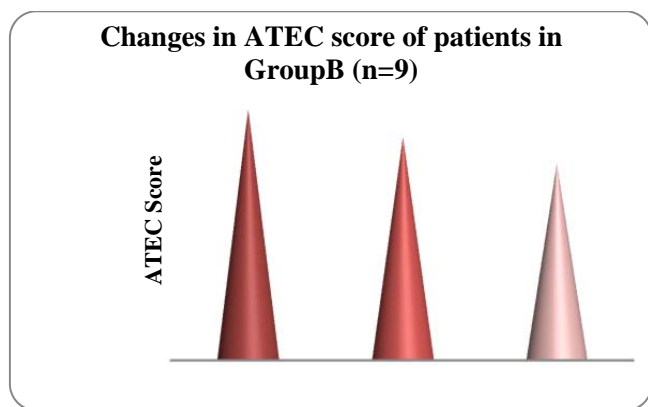
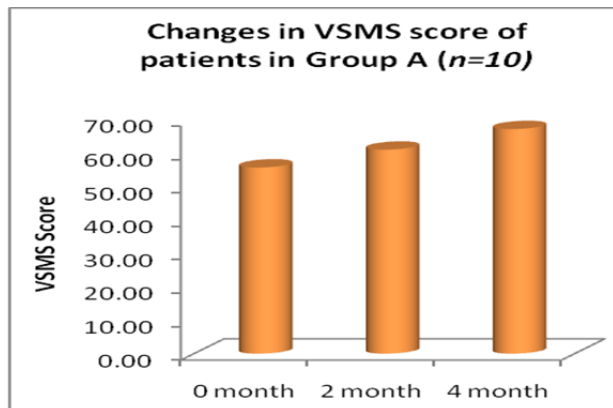
## 4. OUT COME MEASURES

**The Autism Treatment Evaluation Checklist (ATEC)** is a one-page form designed to be completed by parents, teachers, or caretakers. ATEC is not a diagnostic checklist. It basically provides several subscale scores as well as a total score to be used for comparison at a later date. Basically, the lower the score, the fewer the problems. Many parents and teachers use the ATEC to monitor how well the child is doing over time. In addition, researchers have used the ATEC to document improvement following an intervention by comparing the baseline ATEC scores with the post-treatment ATEC scores.

**Vineland Social Maturity Scale** is a uniquely useful instrument in measuring social maturity of children and young adults. Thorndike was the first psychologist to have thought of three types of intelligence i.e. abstract intelligence, social intelligence and mechanical intelligence. It is true that individual vary in the amount of intelligence they possess. Some may have better social intelligence than the other two. However it is recognized by one and all that social intelligence or social maturity matters in a big way in life. This quality may be more easily identified as the social adaptability of the individual.

## 5. RESULT





The statistical analysis using SPSS results shows that the group “A” has 3-4%-much more improvement in VSMS and ATEC scores as compared to group “B” within 2 to 4 months. This encourages us to continue with the study.

## 6. ACKNOWLEDGEMENTS

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## REFERENCES

- [1] [https://www.autism.com/ind\\_atec](https://www.autism.com/ind_atec) last accessed on 20 Feb. 2017
- [2] Vineland social maturity scale Indian adaptation, Ed. Dr J. Bharath Raj
- [3] Diagnostic and Statistical Manual of Mental Disorder –IV edition text revision
- [4] <http://lifespa.com/ayurvedic-supplement-facts/brahmi/> last accessed on 20 Feb. 2017
- [5] CENTELLA ASIATICA (L.): A PLANT WITH IMMENSE MEDICINAL POTENTIAL BUT THREATENED Sakshi Singh\*, Asmita Gautam, Abhimanyu Sharma and Amla Batra Lab no. 5, Department of Botany, University of Rajasthan, Jaipur, India. Volume 4, Issue 2, September – October 2010; Article 003
- [6] [www.udaan.org](http://www.udaan.org) last accessed on 20 Feb. 2017