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Effectiveness of homoeopathic therapeutics in the management of childhood autism disorder

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ABSTRACT

Background and Objectives: Childhood autism is severe and a serious disorder. A study was conducted by Spandan holistic institute of applied Homoeopathy, Mumbai, with the objective of demonstrating the usefulness of homeopathic management in autism.

Materials and Methods: Sixty autistic children of both sexes, ≤12 years were selected for this study. It was nonrandomized, self-controlled, pre and post-intervention study, wherein the initial 6 months of observation period was used as the control period and the same patients were thereafter treated for 1 year and compared with post-intervention findings.

Results: The study demonstrated significant improvement of autistic features with mean change in ATEC score ($ATEC_1$-pre-treatment with $ATEC_5$-post-treatment) was 15.12 and ATEC mean percent change was 19.03. Statistically significant changes in ATEC scores were observed in all the quarters analyzed through repeated measures ANOVA, with *F*-value 135.952, *P* = 0.0001. An impact was observed on all core autistic features, which included communication, 12.61%, socialization, 17%, sensory awareness, 18.82%, and health and behavior, 29% (*P* = 0.0001). Significant improvement was observed in behavior by Autistic Hyperactivity Scale, AHS_1 36 to AHS_5 14.30 with F-value 210.599 (*P* = 0.0001). Outcome assessment was carried out using MANOVA, which showed statistically significant changes in post-treatment scores, $P < 0.005$. Total 88.34% cases showed improvement, 8.33% showed status quo, and 3.33% cases worsened. Nine out of 60 cases showed a reversal of CARS putting them into non-autistic zone, *P* = 0.0001. A sharp decrease (34%) in ATEC scores, in the first quarter implied positive effect of homoeopathic medicines, prescribed, as per the homoeopathic principles.

Conclusion: The study has demonstrated usefulness of homoeopathic treatment in management of neuropsychological dysfunction in childhood autism disorder, which is reflected in significant reduction of hyperactivity, behavioral dysfunction, sensory impairment as well as communication difficulty. This was demonstrated well in psychosocial adaptation of autistic children.

Keywords: Autism treatment evaluation checklist, Autism, Childhood autism rating scale, Regression, Symptomatology

INTRODUCTION

Autism is a neuropsychiatric childhood disorder characterized by severe and pervasive impairment in several areas of development such as social interaction skills, communication skills and/or presence of stereotype behavior, interest and activities. The onset is usually within the first three years of life.[1]

Developmental regression among children with autism is a common phenomenon of unknown origin. Regression in language, social skills and play is usually observed between the first and third years of life.[2]

There has been an exponential rise in the prevalence of autism over the last 10 years.[3] Data released from the CDC (Centers for Disease Control and Prevention-national public health institute of the United States of America) in April 2012 placed the prevalence of autism in the U.S. at approximately 1 in 88 children. No data is available from India to provide an India-specific estimate of the prevalence.[4]

A review of homoeopathic literature identifies clinical experience of physicians in treatment of developmental and behavioral problems such as hyperactivity, impulsivity and delayed milestones.

A pilot study provides details about the treatment of seven autistic children with the remedies; *Arnica montana, Carcinosin, Stramonium, Natrum muriaticum, Thebaicum* and *Arsenic album* in 200CH along with compound of organo-therapeutics in 6CH potency.[5] Partial analysis of data of seven children out of 30 showed the positive interference of homoeopathic treatment in the cognitive, motor and behavioral performance in autistic patients. These results also suggest that the longer the use of the medication, the more remarkable the improvement in PEP-R (Psychoeducational Profile - Revised) scores.

Since 1998, Spandan has worked with children having developmental disability, including autism. Our co-ordination with multidisciplinary team gave us quite objective evaluation. Pilot study was carried out on autism, which gave us good insight about the nature of the disease. This study comprised a case series of 54 children registered, studied and managed at Spandan, during July 1998 to June 2003, suffering from autism spectrum disorder. The findings were as follows:

- 72% of cases who continued treatment for more than six months showed significant improvement in following order
  - Hyperactive behavior like restlessness and tantrums
  - Impaired sensory defenses
  - Eye contact
  - Speech.
- 60% of cases with mild autism regained speech
- 50% of cases (without significant retardation), which continued for more than two years got rehabilitated in mainstream school or slow learners' setup while others were enrolled in Special School
- Obsessive acts and self-stimulations showed insignificant change in first six months and took longer to respond
- All patients received indicated homoeopathic medications in which *Stramonium, Tarentula hispanica, Calcarea carbonica*, *Natrum muriaticum* and *Carcinosinum* came more often.

(The study was presented at a seminar organized by Asian Homoeopathic League in August 2003 at New Delhi, India).

This study demonstrated modifications in the behavior of autistic children as well as improvement in sensory impairment thus reducing autistic features. The findings were encouraging to undertake a systematic study.

A specific study was undertaken with following objectives.

OBJECTIVES

- To evaluate the usefulness of homoeopathic therapeutics in managing the neuro-psychological dysfunctions in childhood autism disorder
- To demonstrate the role of homoeopathic medicines in managing behavioral dysfunctions like hyperactivity, impulsiveness etc., in autism.

Study hypothesis

Administration of the homoeopathic medicines selected on the basis of similarity as elaborated in the Organon of Medicine in appropriate potency and repetition can reduce intensity of autistic features as reflected in significant reduction in the scores measured by study scales.

MATERIALS AND METHODS

Study design and setting

From October 2006 to September 2009, the institute conducted a study of 60 cases of autism.

The proposal was submitted to the institutional ethics committee along with comprehensive safety measures. Their approval was received and the committee was updated from time to time during the study.

This study was a non-randomized, self-controlled, pre and post-intervention study wherein six months was a self-control period and one year was the treatment period. Children were initially kept on observation for six months without homoeopathic treatment and their scores were recorded. This was followed by intervention with an observation period of one year and at the end of one year, the children were evaluated. The initial six months of observation was used as the control period (self-controlled) and the same patients were treated and compared with the one-year treatment period post-intervention. They did not receive any other pharmacological treatment during the entire period of study.

Study population and recruitment

The cases were enrolled from general OPD of M.B. Barvalia Foundation's Spandan Holistic Institute of Applied Homoeopathy and from the institute's mobile clinic. Regular awareness and screening camp were conducted in the community to screen and spot the cases. A series of workshops were held for parents to educate them. The seminars were conducted for teachers of mainstream school of urban areas to sensitize them about role of homoeopathy in autism. Similar seminars were held for teachers from Anganwadis and Balwadis conducted by Central Government in the urban slum areas of M and N wards of BMC (Greater Mumbai Municipal Corporation).

Potential cases identified from the above sources were screened by the attending physicians for prominent symptoms of autism. Voluntary informed written consent was taken from their parents/guardians prior to their enrollment into the study, *i.e.* before the observation period.

Eligibility criteria

Inclusion criteria

- Children from both sexes up to the age of 12 years
- Children diagnosed as suffering from childhood autism as per DSM-IV (Diagnostic and Statistical Manual).

Exclusion criteria

- Children suffering simultaneously from other chronic infections like tuberculosis or HIV disease. Children presenting with very severe autism as diagnosed by CARS with history of severe and frequent violent exacerbations, which required continuous allopathic medications and/or hospitalization
- Children undertaking pharmacological treatment or any recent history of such treatment to treat autism within 30 days of participation into the study.

Sample size

A total of 60 children fulfilling above criteria were selected for the study.

A sample size of 60 was selected on the following considerations:

1. Type I error α was taken as 0.05 giving us 95% confidence interval
2. Power of the study was taken as 80%. As there was not much data with similar studies available, this study is a first of its kind and also considering a minimal required sample size based on the availability of such patients in the population, considering the confidence interval of 95% and alpha as 0.05, Power was conservatively taken as 80%
3. 10% change in ATEC score was considered as clinically significant. Autism research institute has provided ATEC range from mild to severe with percentile and corresponding ATEC percentage change in scale and subscale. When we study this range, we get some idea about changes in score range 10% change from previous level before intervention has been seen and clinically verified as significant.

Clinical diagnosis of childhood autism disorder

The diagnosis of childhood autism disorder was made conjointly by homoeopathic physicians (PMB, PO), clinical psychologist, neurologist and psychiatrist.

Diagnostic parameters were essentially DSM-IV; an autistic child presents with varying degree of cognitive ability. This was assessed by SQ (Social Quotient) through Vineland Social Maturity Scale.

Additionally, EEG, BERA (Brainstem-Evoked Response Audiometry), audiometry, serum serotonin, and genetic karyotyping were carried out at the time of enrollment. Serum serotonin was repeated at the end of the study. According to previous reports, serum serotonin levels were often but not always elevated in autistic children. Therefore, we examined any possible linkage.[6]

Treatment

Children were given homoeopathic medicine based on the totality of symptoms. All patients were given medicine in centesimal scale based on their individual susceptibility.

Outcome measures

Treatment response is evaluated through change in areas such as communication skills, socialization, cognitive and sensory awareness and general behavior. These were measured through ATEC[7] and CARS[8] where lower scores show improvement while higher scores signify deterioration/regression of skills.

ATEC score was taken six months prior to intervention (ATECprev). Just before intervention, ATEC (Autism Treatment Evaluation Checklist score) was repeated. ATEC score was evaluated every three months during the entire period of study, which provided five readings during one year of intervention ($ATEC_1$ to $ATEC_5$).

CARS was evaluated at the beginning and at the end of intervention.

The AHS (Autistic Hyperactivity Scale) was evaluated at every three months during the entire period of study, which provided five readings during one year of intervention.

The SQ was evaluated at the beginning and at the end of intervention.

A detailed homoeopathic case was taken on a specially designed case record for autism and each case was processed through standardized protocol (Case analysis, Evaluation, Totality formation, Repertorization, Drug differentiation and arriving at Similimum). Each case was examined by a neurologist and child psychiatrist who evaluated the response to intervention. The scales were applied by a clinical psychologist.

The children who were from special school and OPD were receiving occupational therapy while those children who were identified through camps were either not receiving any therapy or were receiving therapy irregularly. This mode of adjuvant therapeutic inputs received by the children regularly or irregularly, during self-control phase of six months was not disturbed during intervention phase.

Safety measures described during the treatment period was also followed during the observation period.

A quantitative study was carried out with respect to change in various scores. But, in addition to this, a qualitative observation was also made regarding changes in child's behavior, social interaction, activities, interests and academic performance.

Data analysis

The following scores were utilized for analysis: ATEC (with its various components like communication, socialization, cognitive, sensory awareness, and health and behavior), CARS, AHS and SQ. In addition to the above, impact of intervention on autistic features in relation to different variables like degree of autism, cognitive level, time dimension etc., were also studied.

ATEC score was primarily taken for outcome assessment. Subsequently CARS and other parameters were also analyzed for outcome assessment. Treatment outcome assessment was accordingly classified as Mild, Moderate and Marked Improvement.

Comprehensive analysis of ATEC scores taken at quarterly intervals was carried out at 95% confidence interval using Repeated measures ANOVA.

To check whether the difference is statistically significant after treatment between independent variable (Improvement grades - worsening, Status Quo, Mild Improvement, Moderate improvement, and Marked Improvement) and among all the dependent variables CARS, ATEC, AHS, and SQ, a multivariate analysis of variance (MANOVA) was performed using SPSS software ver. 20. General linear model (GLM) was used in which $CARS_1$ $CARS_2$, $ATEC_1$ $ATEC_5$, AHS_1 AHS_5, and SQ_1 SQ_2 are kept as dependent variables and independent variable (Improvement grades - worsening, Status Quo, Mild Improvement, Moderate improvement and Marked Improvement) are kept as fixed effects at 5% alpha level of significance. Change in ATEC scores six months prior to intervention *i.e.* ATECprev- $ATEC_1$ was tested and found statistically significant.

RESULTS

A summary of baseline distribution of children is provided in Table 1. The following observations were made out of the study data with respect to the following variables.

Table 1: Baseline distribution of children

Variables	Sub-groups	Number of children	Percentage
Age	≤6 years	24	40
	>6 years	36	60
Sex	Male	44	73
	Female	16	27
Degree of Autism	Mild	24	40
	Mod	27	45
	Severe	9	15
Cognitive ability	Dull normal (high functioning)	13	22
	Mild	30	50
	Mod	11	18
	Severe	6	10
	Total	60	100
Number of children with abnormal EEG		6	10
Karyotype distribution of cases	Fragile X	2	3.33
	Y chromosome inversion	1	1.6
	Translocation of X chromosome	1	1.6
	Total	4	6.6
Serotonin levels	Normal	56	93.33
	High	4	6.6
	Low	0	0
BERA	Abnormal	0	0
Audiometry	Abnormal	0	0

BERA: Brainstem-evoked response audiometry; EEG: Electroencephalogram

A consort flow chart showing the number of participants at each stage of the study is provided in Figure 1.

Autistic Savant cases

Autistic Savant is an autistic child who possesses brilliantly exceptional qualities. Such three cases with age 9, 9 and 8 years, respectively, presented with possessing qualities like brilliant flair of languages, ability to read and write nine languages. One child presented with a remarkable memory of recalling any passage from epic or novel, superlative skills for swimming, skating and calculations and unusual ability to read mother's mind. Another child had amazing ability to draw sketches just from his memory.

Serum serotonin level

According to previous reports, serum serotonin levels were often but not always elevated in autistic children. Therefore, we examined any possible linkage.[6]

Four children had elevated serum serotonin levels before treatment. All of the four showed decrease in levels after the homoeopathic treatment. There was corresponding clinical improvement in these cases.

Four other cases had normal serum serotonin levels before treatment, which increased above normal after homoeopathic treatment. These cases also showed significant clinical improvement.

In severe autism cases, out of nine cases, only one showed high serotonin level before treatment.

ATEC scores

The mean ATEC score obtained six months prior to the treatment (ATECprev) was 72.70. The children were observed for six months without any treatment. An ATEC was recorded at the time of commencement of treatment; pre-treatment ($ATEC_1$) and post-treatment ($ATEC_5$) were 79.45 and 64.33, respectively.

Comparison of ATEC scores with six months prior to the start of treatment

When we examined the profile of cases in six months prior to homoeopathic treatment, where some children were receiving regular traditional therapies but none of them received homoeopathic medicines, we could see that there were a number of children who were not doing well. When we analyzed these data, the following pattern emerged. Ascending pattern of ATEC scores during the self-control period indicated deterioration of autism and post-intervention descending pattern of ATEC scores indicated improvement.

$ATEC_1$ score of 79.45 suggest worsening of autism when compared to ATECprev score of 72.70 at six months prior to treatment (self-control period). After starting the homoeopathic treatment, there was reversal in the post-treatment $ATEC_3$ score to 70.42. The difference of the mean ATEC scores six months prior to homoeopathic treatment and at the start of the homoeopathic treatment (ATECprev-$ATEC_1$) was – 6.75 (minus 6.75). The difference in pre-treatment and post-treatment mean ATEC scores ($ATEC_1$ – $ATEC_3$) were 9.03 *i.e.* mean percent change of 11.36. Thus, we can see that there is a significant change after the introduction of Homoeopathy.

Subsequently, ATEC scores repeated every three months *i.e.* $ATEC_4$ (67.35) and $ATEC_5$ (64.33) showed reduction. Post-intervention, difference in ATEC scores *i.e.* $ATEC_1$-$ATEC_5$ was 15.12 [Figure 2]. This

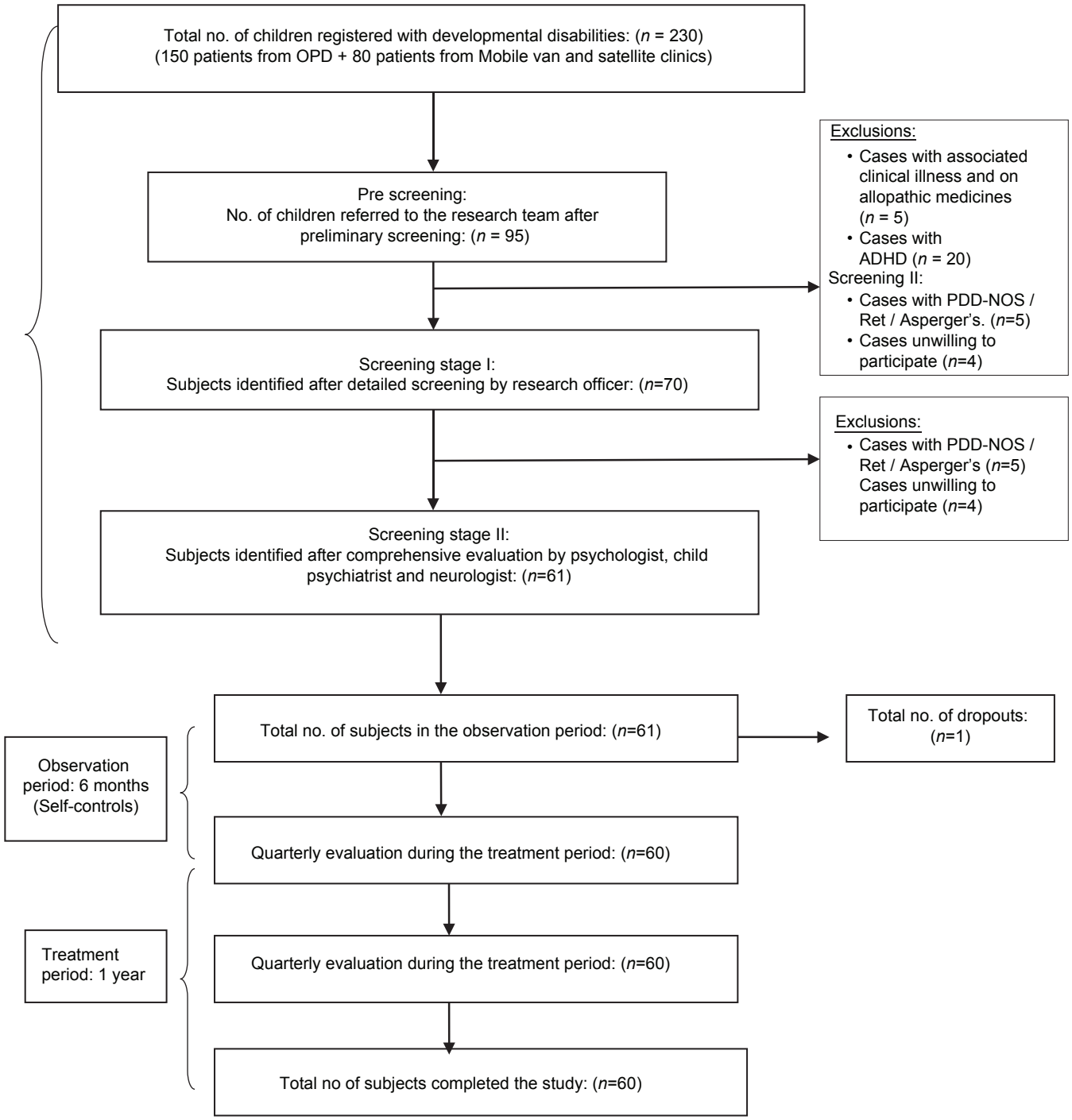

Figure 1: Consort flow chart

implies ATEC mean percent change was 19.03. Post-intervention highest change observed was 44% and there were 16 cases where ≥30% change was noted.

At the end of the observation period of six months before homoeopathic treatment, out of 60 cases, 52 cases showed deterioration in ATEC scores, five cases showed status quo and three cases improved.

A statistically significant difference ($P = 0.0001$) was observed in ATEC score at one year ($ATEC_5$) compared with baseline ($ATEC_1$), which also justifies clinically significant improvement in autistic features of the children. Also, a statistically significant difference was observed in all the ATEC scores ($ATEC_2$, $ATEC_3$, and $ATEC_4$) recorded at different quarters compared with baseline ($ATEC_1$) [Tables 2 and 3].

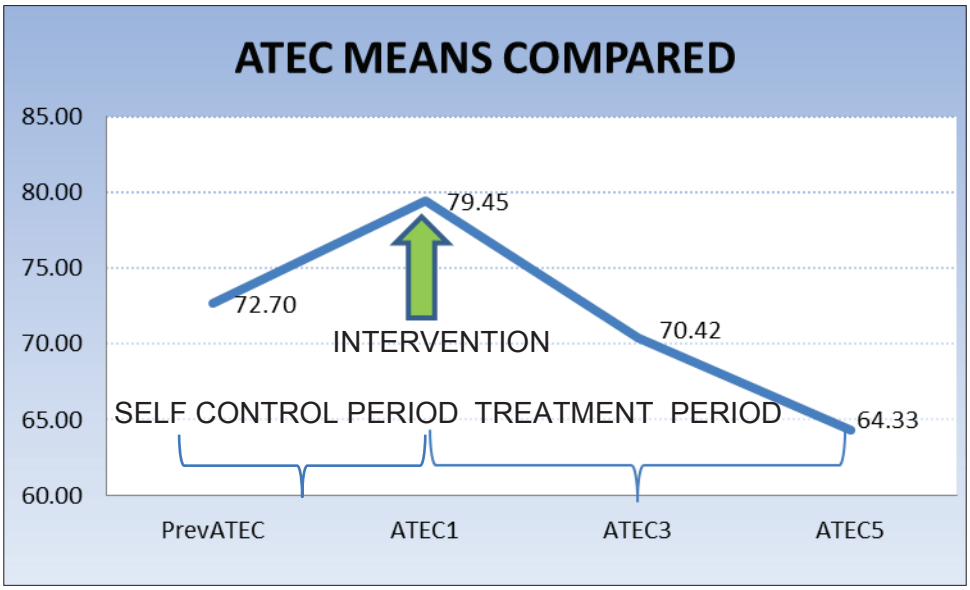

Figure 2: ATEC Means comparison

Table 2: Repeated measures ANOVA for ATEC and AHS

	Mean	SD	*N*	95% confidence interval		*F*	*P*
				Lower bound	Upper bound		
ATEC1	79.45	20.929	60	74.044	84.856	135.952	0.0001
ATEC2	74.28	20.348	60	69.027	79.540		
ATEC3	70.42	20.138	60	65.214	75.619		
ATEC4	67.35	20.224	60	62.126	72.574		
ATEC5	64.33	20.130	60	59.133	69.533		
AHS1	36.60	11.537	60	33.620	39.580	210.599	0.0001
AHS2	28.53	9.661	60	26.038	31.029		
AHS3	22.47	7.901	60	20.426	24.508		
AHS4	17.93	7.201	60	16.073	19.794		
AHS5	14.30	6.667	60	12.578	16.022		

SD: Standard deviation; ANOVA: Analysis of variance; ATEC: Autism treatment evaluation checklist; AHS: Autistic hyperactivity scale

ATEC sub-scores reflecting on changes in autistic features

ATEC assesses change in impairment in specific aspects of autistic features like communication, socialization, sensory awareness, and health and behavior. A statistically significant difference was observed in all the autistic features recorded at different quarters compared with baseline, which also justifies clinical improvement in all the autistic features of the children [Table 4].

Maximum improvement observed is in behavioral component followed by sensory aspects [Figure 4].

Table 3: Post-hoc test for repeated measure ANOVA

Pair-wise comparisons Measure: ATEC						
(I) factor 1	(J) factor 1	Mean difference (I-J)	Std. error	*P* value[b]	95% confidence interval for difference[b]	
					Lower bound	Upper bound
ATEC1	ATEC2	5.167*	0.654	0.0001	3.858	6.475
	ATEC3	9.033*	0.867	0.0001	7.298	10.769
	ATEC4	12.100*	1.082	0.0001	9.935	14.265
	ATEC5	15.117*	1.074	0.0001	12.968	17.265
ATEC2	ATEC1	−5.167*	0.654	0.0001	−6.475	−3.858
	ATEC3	3.867*	0.433	0.0001	2.999	4.734
	ATEC4	6.933*	0.686	0.0001	5.561	8.306
	ATEC5	9.950*	0.738	0.0001	8.473	11.427
ATEC3	ATEC1	−9.033*	0.867	0.0001	−10.769	−7.298
	ATEC2	−3.867*	0.433	0.0001	−4.734	−2.999
	ATEC4	3.067*	0.367	0.0001	2.333	3.800
	ATEC5	6.083*	0.467	0.0001	5.149	7.018
ATEC4	ATEC1	−12.100*	1.082	0.0001	−14.265	−9.935
	ATEC2	−6.933*	0.686	0.0001	−8.306	−5.561
	ATEC3	−3.067*	0.367	0.0001	−3.800	−2.333
	ATEC5	3.017*	0.308	0.0001	2.401	3.632
ATEC5	ATEC1	−15.117*	1.074	0.0001	−17.265	−12.968
	ATEC2	−9.950*	0.738	0.0001	−11.427	−8.473
	ATEC3	−6.083*	0.467	0.0001	−7.018	−5.149
	ATEC4	−3.017*	0.308	0.0001	−3.632	−2.401

Based on estimated marginal means. *The mean difference is significant at the 0.05 level. b. Adjustment for multiple comparisons: Least significant difference (equivalent to no adjustments). ATEC: Autism treatment evaluation checklist; ANOVA: Analysis of variance

Table 4: Repeated measures ANOVA for ATEC components

	Mean	SD	95% confidence interval		*F*	*P*	% difference in means
			Lower bound	Upper bound			
Communication							Comm1-Comm5
Comm1	18.5	5.137	17.173	19.827	20.167	0.0001	12.61
Comm2	17.43	5.16	16.1	18.766			
Comm3	17.03	5.165	15.699	18.368			
Comm4	16.53	5.173	15.197	17.87			
Comm5	16.17	5.192	14.825	17.508			
Socialization							Soc1-Soc5
Soc1	20.33	7.104	18.498	22.168	18.435	0.0001	17.00
Soc2	19.15	6.859	17.378	20.922			
Soc3	18.22	6.747	16.474	19.96			
Soc4	17.62	6.623	15.906	19.328			
Soc5	16.88	6.421	15.225	18.542			
Sensory aspects							Sens1-Sens5
Sens1	23.67	5.827	22.161	25.172	37.578	0.0001	18.82
Sens2	22.47	5.744	20.983	23.951			
Sens3	21.22	5.752	19.731	22.703			
Sens4	20.25	5.786	18.755	21.745			
Sens5	19.22	5.883	17.697	20.736			
Health and behavior							H and B1-H and B5
H and B1	16.78	8.253	14.651	18.915	27.63	0.0001	29.00
H and B2	15.07	8.107	12.972	17.161			
H and B3	13.6	7.76	11.596	15.604			
H and B4	12.78	7.632	10.812	14.755			
H and B5	11.92	7.312	10.028	13.806			

ATEC: Autism treatment evaluation checklist; ANOVA: Analysis of variance

Improvement in autistic features with respect to time dimensions (quarter-wise)

ATEC scores were evaluated every three months. Hence, we could compare changes in autistic features at the end of each quarter and quantify in percentage form. There was a reduction in the ATEC score after starting the homoeopathic treatment *i.e.* 34% improvement in the first quarter [Figure 3].

Degree of behavioral dysfunction (AHS)

AHS allows us to perceive degree of behavioral dysfunction. The mean pre-treatment score (AHS_1 36.6) and post-treatment score (AHS_5 14.3) showed statistically significant change of 22.30, which is 59.08% change ($P = 0.0001$), which clinically indicates improvement in behavioral dysfunction by reduction in hyperactivity, impulsivity, tantrums, self-injurious behavior, *etc.*, Also, a statistically significant difference was observed in all the AHS scores (AHS_2, AHS_3, and AHS_4) recorded at different quarters compared with baseline (AHS_1) [Table 2].

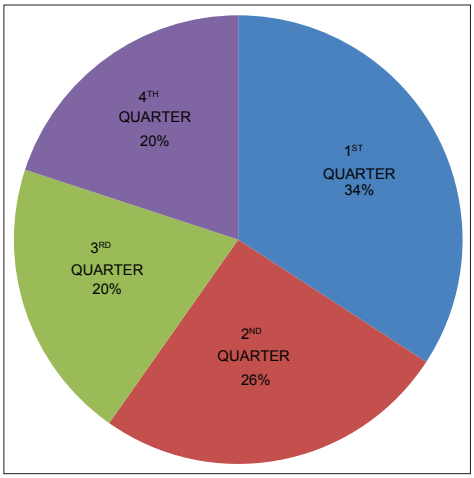

Figure 3: Quarter-Wise Change in ATEC

CARS scores

A mean value of CARS score before treatment ($CARS_1$) was 33.93 while the mean CARS score after treatment ($CARS_2$) was 31.44. A paired *t*-test showed a *T*-value of 9.496 and *P* value of 0.0001, which indicates statistically significant difference at one year ($CARS_2$) compared with baseline ($CARS_1$) [Table 5].

Of 60 children, a total of 9 children, who had mild autism, had CARS score as <30 at post treatment which indicates becoming non-autistic after intervention (*P* value 0.0001), while 10 cases with moderate autism became mild [Table 9].

Improvement in autistic features with respect to degree of autism

A statistically significant difference in the mean scores was observed in children belonging to all the categories based on degree of autism, *i.e.* mild, moderate, and severe (14.45, 16.81 and 11.78 respectively with $P < 0.005$) [Table 6].

Improvement in autistic children belonging to different categories of cognitive ability

A statistically significant difference in the mean scores was also observed in autistic children belonging to different categories of cognitive ability, *i.e.* dull normal, mild MR, moderate MR, and severe MR (17.46, 15.23, 14.64, and 10.33, respectively with $P < 0.05$) [Table 6].

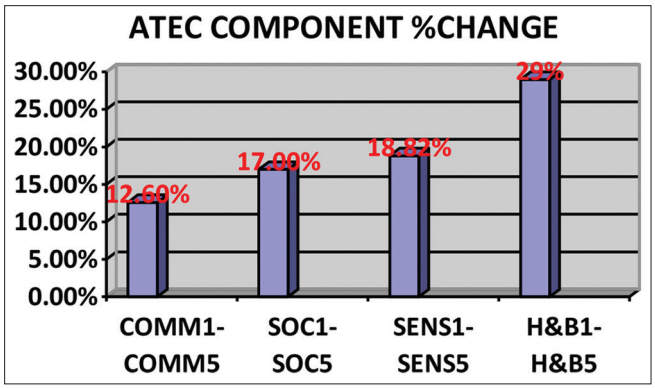

Figure 4: Percentage change in ATEC sub-scores pre and post-treatment

Table 5: Mean values comparison for CARS scores and SQ scores pre and post-treatment with paired *T*-test

	Mean	*N*	SD	*T*	*P*
$CARS_1$	33.925	60	3.6311	9.496	0.0001
$CARS_2$	31.433	60	3.1856		
SQ_2	61.083	60	18.1316	3.864	0.0001
SQ_1	57.917	60	16.0231		

P value is calculated for the comparison of CARS and comparison of SQ using paired *t*-test. SQ: Social quotient

Changes in cognitive ability (mental retardation)

A statistically significant difference was observed in SQ score at one year (SQ_2) compared with baseline (SQ_1) [Table 5]. It was observed that 43 children belonging to dull normal and mild MR category have shown significant change in cognitive ability; however, very less significant change in SQ was observed in children with moderate and severe retardation.

Parents, teachers and therapist reported positive improvement in behavior and activities of daily living. High-functioning children reported improvement in scholastic performance.

Overall outcome assessment

Autism research institute has provided ATEC range from mild to severe with percentile and corresponding ATEC scores. Based on changes in category, outcome measures in ATEC were defined. CARS gives range of mild, moderate and severe Autism, based on that % of improvement was taken up.

At one year post-treatment, a mild (16), moderate (21), and marked (16) improvement was observed in majority of the children. However, a total of seven children were observed with either worsening or status quo scores [Table 7 and Figure 5].

A multivariate analysis of variance performed on CARS, ATEC, AHS, and SQ scores showed significant results. A statistically significant difference in almost all the

Table 6: Improvement in autistic features with respect to degree of autism and with respect to different categories of cognitive ability

	No of cases	Mean ATEC1	Mean ATEC5	Difference of means	*T*	*P*
Autism degree						
Mild	24	64.33	49.88	14.45	11.08	0.0001
Moderate	27	85.74	68.93	16.81	8.69	0.0001
Severe	9	100.89	89.11	11.78	5.56	0.001
Cognitive ability						
Dull normal (high functioning)	13	61.69	44.23	17.46	7.968	0.0001
Mild MR	30	78.07	62.83	15.23	8.995	0.0001
Mod MR	11	91.64	77	14.64	6.715	0.0001
Severe MR	6	102.5	92.17	10.33	5.622	0.002

ATEC: Autism treatment evaluation checklist; MR: Mental retardation

scores at one year post-treatment compared with baseline indicates the significant change in all the dependent variables of improvement grade [Table 8].

A trend in improvement of degree of autism and different categories of cognitive ability was observed with regards to number of cases assessed pre-treatment and post-treatment. It was noted that a total of nine children became non-autistic after the treatment [Table 9].

List of remedies that came during management of cases [Table 10]

First prescription means, first remedy which was prescribed at the time of commencement of treatment. In 22 cases, symptomatology changed, which demanded second prescription. Similarly four cases demanded further change leading to a third prescription. At a given time, only one indicated remedy was prescribed irrespective of the severity of the autism.

From above Table 10, *Carcinosinum* has come up in maximum number of cases (18 + 1 + 1) and it has also come maximum times as first prescription (18). *Hyoscyamus* came up in maximum cases as the second prescription.

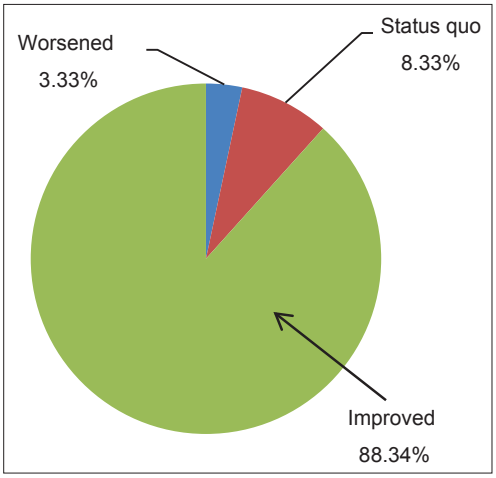

Figure 5: Study outcome

Remedy response and posology observed during the study

Centesimal scale potencies were utilized commencing with 200C potency. Symptomatology was reviewed periodically. When there was no further improvement, potency was raised to 1 M and later 10 M. Changes in symptomatology necessitated second prescription.

A total of 23 cases demanded infrequent doses (where remedy is repeated at an interval of two or greater than two weeks), while 28 cases demanded moderately frequent repetition (where remedy is repeated one in a week or for three consecutive days of the week), while nine cases required very frequent repetition (where remedy is repeated once every day of more than once in a day) to the extent of being repeated even twice or thrice in a day.

Acute exacerbations of intense autistic features during the course of treatment

Eight cases presented with acute exacerbations of symptoms like intense agitation, restlessness, unmanageable aggression, oversensitivity especially to sound and sometimes marked self-injurious behavior and incontinence of urine and stool. *Stramonium* and *Hyoscyamus* came up to control these episodes and required to be repeated very frequently, even every four hours. Acuteness reduced in 4-5 days while the indicated medicine was required to be continued for two weeks. None of the cases required to be hospitalized or transferred to other experts. But of course it needed close supervision.

DISCUSSION

The study demonstrated a significant reduction in autistic features ($P = 0.0001$). Homoeopathic intervention brought about modification in the behavior followed by significant changes in other aspects viz., sensory impairment, socialization and communication.

Table 7: Outcome assessment of improved cases

	ATEC and/or	CARS	Improvement grades	No. of cases (*n*)	Percentage of cases
Worsening	<0% change (increase in score from baseline)	<0% change	1	2	3.33
Status quo	0% (no change in baseline scores)	0% (no change in baseline scores)	2	5	8.33
Mild improvement	<15% - ≥10% change	<7% change	3	16	26.67
Moderate improvement	≥15% - <30% change	≥7% - <10% change	4	21	35.00
Marked improvement	≥30% change	≥10% change or CARS score<30 (non-autistic range)	5	16	26.67

ATEC: Autism treatment evaluation checklist

Challenges in the treatment of autism have been phenomenal. Allopathic medications like Risperidone therapy addresses hyperactivity and aggressive behaviors and is more suited to conditions like ADHD as it does not help in addressing to the core features of autism *viz.* repetitive and stereotyped patterns of behavior, interests, and activities as well as social and communicative impairment of autism.[9] Homoeopathic medicinal treatment of autism by Gupta *et al.*[10] found 60% (n = 6) improvement in autistic symptoms by classical method of homeopathic treatment, whereas non-classical showed 38% (n = 3) improvement. This showed positive role of Homoeopathy in the management of autism. Patient compliance and small sample size were the limitations of this study.

Table 8: Multivariate analysis

Source	Dependent variable	*F* value	*P* value
Improvement grade	$CARS_1$	6.898	0.0001
	$CARS_2$		
	$ATEC_1$	8.802	0.0001
	$ATEC_5$		
	AHS_1	4.208	0.005
	AHS_5		
	SQ_1	10.616	0.0001
	SQ_2		

P value is calculated for the comparison of all dependent variable using multivariate analysis of variance

Table 9: Distribution of cases pre and post-treatment with respect to degree of autism and different categories of cognitive ability

	No. of cases	
	Pre-treatment	Post-treatment
Degree of autism		
Non-autistic	0	9
Mild	24	34
Moderate	27	13
Severe	9	4
Total	60	60
Cognitive ability		
Dull normal	13	21
Mild MR	30	23
Moderate MR	11	10
Severe MR	6	6
Total	60	60

MR: Mental retardation

Current study was extensive enough to cover up children from both the sexes as well as evenly distributed in age groups. It covered up the entire range of autism; mild, moderate and severe, while from the standpoint of cognitive ability, children were from high functioning to mild, moderate, and severe mental retardation.

Children who were gradually regressing and showing trend toward deterioration showed improvement in the autistic features. Across this range, changes achieved in the scores were statistically significant and intervention helped to bring down the autistic load. When we study the pattern of response in behavioral disturbances as well as core autistic features, following points emerge.

A statistically significant difference (P = 0.0001) was observed in ATEC score at one year ($ATEC_5$) compared with baseline ($ATEC_1$), also a statistically significant difference was observed in all the ATEC scores ($ATEC_2$, $ATEC_3$, and $ATEC_4$) recorded at different quarters compared with baseline ($ATEC_1$), which justifies the clinically significant improvement in autistic features of the children reflected not only in behavior like hyperactivity and impulsivity, but also in all the core autistic features, such as sensory impairment, socialization, communication etc.

Table 10: Remedies list and their frequencies of prescriptions

First prescription (*n*=60)		Second prescription (*n*=22)	Third prescription (*n*=4)
Carcinosinum (18)	*Borax* (1)	*Carcinosinum* (1)	*Carcinosinum* (1)
Stramonium (7)	*Medorrhinum* (1)	*Stramonium* (4)	*Nux vomica* (1)
Nux vomica (5)	*Lyssin* (1)	*Nux vomica* (1)	*Lachesis* (1)
Hyoscyamus (1)	*Zincum metallicum* (1)	*Hyoscyamus* (5)	*Veratrum album* (1)
Tuberculinum bovinum (4)	*Cina* (1)	*Tuberculinum bovinum* (2)	
Tarentula hispanica (5)	*Baryta carbonica* (1)	*Natrum muriaticum* (1)	
Phosphorus (5)	*Calcarea carbonica* (1)	*Silicea* (1)	
Natrum muriaticum (2)	*Veratrum album* (1)	*Calcarea silicata* (2)	
Opium (2)		*Lycopodium clavatum* (2)	
Silicea (1)		*Causticum* (1)	
Natrum phosphoricum (2)		*Plumbum metallicum* (1)	
		Calcarea carbonica (1)	

This is further validated by statistically significant difference ($P = 0.0001$) in ATEC components mean, *viz*. communication, socialization, cognitive and sensory awareness, and health and behavior. Analysis of the components also indicates that Homoeopathy brought about improvement in the area of behavior and sensory impairment quite early during the course of treatment. These changes facilitated psychosocial adaptation of autistic children.

Pace of improvement after homoeopathic intervention is worth studying. There was reduction in the ATEC score within the first quarter after intervention. This implies the positive role of intervention. This is consistent with what Dr Rimland has written about ATEC. If improvement occurs due to maturation, then gradual improvement is seen over a period of time. However, if there is a perceivable improvement after the intervention is started then treatment is helping (Autism Research Institute).[11]

Rate of change as well as quantum of change in the autistic features is not directly proportional to degree of autism but partially dependent on it.

There is a statistically significant difference ($P \leq 0.005$) in the mean scores of all the types of autism, *i.e.* mild, moderate, and severe. This implies that Homoeopathy can bring about significant improvement in all the types of cases of autism. However, mild and moderate autism indicate superior change in comparison to severe autism.

Treatment had impact on all the categories of autistic children classified from the standpoint of cognitive ability ($P = 0.0001$). However, children with dull normal intelligence showed the highest improvement followed by children with mild retardation. This implies that cognitive ability is an imoportant variable, which has an impact on the outcome of treatment.

Overall mean SQ has shown improvement post treatment. Study demonstrated significant change in SQ in children with dull normal and mild retardation while those with moderate and severe retardation have not shown significant change in SQ, while their autistic features have improved.

Children who were diagnosed to have mental retardation demonstrate significant adaptive living skills deficits. Measured intellect deficit could be reflection of current behavioral, communicative, and social difficulties in autistic children.[12] Overall improvement in core autistic features can bring about significant change in child's adaptive skills. To that extent, we can see improvement occurring in retardation as reflected in SQ as well as in special educator's observation about child's improved ability.

By effectively reducing core autistic features consistently over a one-year period, the study demonstrated a good improvement in these children's psychosocial adaptation, activities of daily living, and even scholastic performance.

Carcinosinum came up in maximum number of instances as first prescription ($n = 18$), which was followed by *Stramonium*. What is significant is to observe second prescription coming up in the management. Changes in the set of characteristic indications demanded the second prescription. We observed this phenomenon in 22 instances. Thus, out of 60 cases, in 22 cases, 2 remedies were required in sequence, for *e.g. Opium* followed by *Causticum, Stramonium* followed by *Hyoscyamus*. While in four cases, three remedies were required in sequence. For *e.g. Nux Vomica – Stramonium – Carcinosin* and *Medorrhinum-Lycopodium-Lachesis*, while in 34 cases, only one remedy was required. The study allowed us to obtain the profile of characteristic symptoms of prescribed medicines and has also given us a number of clinical indications. These aspects have not been discussed here.

Autism is a serious chronic disorder hence homoeopathic treatment will demand careful observation and analysis of the changes in symptomatology, which will be reflected in identification of second prescription.

The number of children suffering from mild, moderate, and severe autism is not uniform, nor large enough to study comprehensively differential impact on different types of autism. Multi-centric, double-blind, placebo-controlled, randomized study will be further helpful.

Change in cognitive ability with regards to mental retardation is a complex phenomenon and would take into account number of variables. To analyze all these is beyond the scope of the current study.

CONCLUSION

The study has demonstrated the usefulness of homoeopathic treatment in the management of neuropsychological dysfunction in childhood autism

disorder, which is reflected in the significant reduction of hyperactivity, behavioral dysfunction, sensory impairment as well as communication difficulty. This was demonstrated well in psychosocial adaptation of autistic children. Autism is a serious developmental disorder and demands administration of homoeopathic medicines through holistic perspective. However, more extensive multicenter double-blind study with diverse population will be extremely helpful.

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बाल्यावस्था स्वलीनता (ओटिज्म) व्याधि के प्रबन्धन में होम्योपैथिक औषधियों की प्रभावशीलता

सारः

पृष्ठभूमि एवं उद्देश्यः बाल्यावस्था स्वलीनता एक कष्टमय व गंभीर व्याधि है। बाल्यावस्था स्वलीनता व्याधि के प्रबंधन में होम्योपैथिक औषधियों की प्रभावकारिता को प्रदर्शित करने के उद्देश्य से स्पन्दन व्यावाहारिक होम्योपैथी संस्थान, मुम्बई (स्पन्दन इस्टीट्यूट फॉर एप्लाइड होम्योपैथी) द्वारा एक अध्ययन संचालित किया गया।

विधियाँः दोनो लिंगो के 12 साल एवं उससे कम उम्र के 60 स्वलीनता ग्रसित बच्चो को अध्ययन के लिए चयन किया गया। यह एक अयादृच्छिक, स्वनियन्त्रित, पूर्वपश्च हस्तक्षेपण अध्ययन था, जिसमें कि शुरू के 6 महीने के अवलोकन समय को नियन्त्रित/मानक के रूप में प्रयोग किया गया व उसके बाद वही रोगी 1 साल के लिये उपचारित किये गये व पश्च हस्तक्षेप परिणामों के साथ तुलना की गई।

परिणामः अध्ययन ने स्वलीनता कारको में महत्वपूर्ण सुधार एटीईसी स्कोर के माध्य परिवर्तन 15.12 एवं एटीईसी प्रतिशत माध्य परिवर्तन 19.03 के साथ दिखाया। सभी विश्लेषित तिमाही में सांख्यिकीय रूप से दुहराये कारक एनोवा के द्वारा एटीईसी स्कोर में एफ मूल्य 135.952, पी मूल्य 0.0001 के साथ महत्वपूर्ण परिवर्तन देखे गये। सभी महत्वपूर्ण स्वलीनीय कारकों में एक प्रभाव देखा गया जिसमें कि संचार 12.61%, सामाजिकीकरण 17 प्रतिशत, संवेदी जागरूकता 18.82 प्रतिशत एवं स्वास्थ्य एवं व्यावहारिक 29 प्रतिशत (पी मूल्य 0.0001) व्यवहार में ओटिस्टिव हाइपर एक्टिविटी स्केल एफ मूल्य 210.599 के साथ एएचएस में 36 से 14.30 महत्वपूर्ण परिवर्तन देखे गये। परिणाम मूल्यांकन एनोवा के द्वारा किया गया जिसने कि सांख्यकीय रूप से पश्च उपचार परिणामों में पी मूल्य <0.005 स्कोर के साथ महत्वपूर्ण परिवर्तन दर्शाये। 88.34 प्रतिशत मामलो ने सुधार दर्शाया, 8.33 प्रतिशत यथा स्थिति दर्शायी और 3.33 प्रतिशत मामलो ने बदतर स्थिति दर्शायी। 60 में से 6 मामलो ने सीएआरएस में उत्क्रमण दर्शाया, उनको अस्वलीनता क्षेत्र में रखा गया। पी मूल्य 0.0001 प्रथम तिमाही में एटीईसी स्कोर में तेजी से कमी (34 प्रतिशत) के साथ होम्योपैथिक सिद्धान्त के अनुसार सुझायी गई दवाओ ने सकारात्मक प्रभाव गर्भित किया।

निष्कर्षः सभी प्रकार के मामलों में स्वलीनता व्याधि के कारको में प्रभावी कमी पाई गई यह अध्ययन होम्योपैथी की प्रभावशीलता न केवल तंत्रिका मनोवैज्ञानिक प्रतिगमन बल्कि इन बच्चों में मनोवैज्ञानिक सामाजिक अनुकूलित, दैनिक क्रियाकलापों एवं शैक्षिक प्रदर्शन में सकारात्मक सुधार दिखाया गया।