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Utility of individualised homoeopathic medicines in improving social interaction in childhood autism: A prospective, open-label, single arm study

Sreeja Kudukayil Radhakrishnan Nair
National Homoeopathy Research Institute in Mental Health, Kottayam, Kerala, India, jaisankarsreeja@gmail.com
Deepthi Gilla
National Homoeopathy Research Institute in Mental Health, Kottayam, Kerala, India, drdeepthigilla@gmail.com
Mohan Narvelil Devasia
National Homoeopathy Research Institute in Mental Health, Kottayam, Kerala, India, drndmohanktm@gmail.com
Author(s) ORCID Identifier:
https://orcid.org/0000-0003-0411-7022

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Background: Childhood autism is a pervasive developmental disorder. There has been an upsurge in its prevalence in past few decades. The social deficit is the most disabling symptom of autism. There is an immediate need to explore new interventions to effectively address childhood autism. **Objective:** The objective of the study was to assess the usefulness of individualised homoeopathic medicine in improving social interaction in childhood autism. **Materials and Methods:** This one-year duration study was conducted in the outpatient department of the National Homoeopathy Research Institute in Mental Health, Kottayam, Kerala. Thirty-five children fulfilling the diagnostic criteria of childhood autism (as per ICD 10-F84.0) were enrolled. Individualised homoeopathic medicines were prescribed in centesimal potencies following homoeopathic principles. Subjects were assessed by using Indian scale for Assessment of Autism (ISAA) and Vineland Social Maturity Scale (VSMS) at baseline and every month up to one year. The outcome was analysed using Friedman test. **Results:** Median scores of ISAA and VSMS at baseline were 132 and 39 which were improved to 35.5 and 56, respectively, at the end of the study. There was a marked reduction in the total ISAA score of 34 patients (statistically significant with $p < 0.001$). The change of median scores from baseline of social relationship and reciprocity domain of ISAA, Social quotient improved from 41.5 to 10 and 32.8 to 82.7, respectively ($p < 0.001$). **Conclusion:** Individualised homoeopathic medicines are useful in improving social interaction in the cases of childhood autism. A controlled clinical trial is suggested as the arena of future research.

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Original Article

Utility of individualised homoeopathic medicines in improving social interaction in childhood autism: A prospective, open-label, single arm study

Sreeja Kudukayil Radhakrishnan Nair*, **Deepthi Gilla, Mohan Narvelil Devasia**

Central Council for Research in Homoeopathy-National Homoeopathy Research Institute in Mental Health, Kottayam, Kerala, India

Abstract

Background: Childhood autism is a pervasive developmental disorder. There has been an upsurge in its prevalence in past few decades. The social deficit is the most disabling symptom of autism. There is an immediate need to explore new interventions to effectively address childhood autism. **Objective**: The objective of the study was to assess the usefulness of individualised homoeopathic medicine in improving social interaction in childhood autism. **Materials and Methods:** This one-year duration study was conducted in the outpatient department of the National Homoeopathy Research Institute in Mental Health, Kottayam, Kerala. Thirty-five children fulfilling the diagnostic criteria of childhood autism (as per ICD 10-F84.0) were enrolled. Individualised homoeopathic medicines were prescribed in centesimal potencies following homoeopathic principles. Subjects were assessed by using Indian scale for Assessment of Autism (ISAA) and Vineland Social Maturity Scale (VSMS) at baseline and every month up to one year. The outcome was analysed using Friedman test. **Results:** Median scores of ISAA and VSMS at baseline were 132 and 39 which were improved to 35.5 and 56, respectively, at the end of the study. There was a marked reduction in the total ISAA score of 34 patients (statistically significant with $p < 0.001$). The change of median scores from baseline of social relationship and reciprocity domain of ISAA, Social quotient improved from 41.5 to 10 and 32.8 to 82.7, respectively ($p < 0.001$). **Conclusion:** Individualised homoeopathic medicines are useful in improving social interaction in the cases of childhood autism. A controlled clinical trial is suggested as the arena of future research.

Keywords: Autism, Homoeopathy, Individualised medicine, ISAA, Social interaction, VSMS

Introduction

Childhood autism is a pervasive developmental disorder manifested before the age of 3 years, showing abnormal social interaction, communication and restricted, repetitive behaviour.[1] In DSM V, the condition is described by the name autism spectrum disorder (ASD).[2] Approximately one in 100 children is diagnosed with ASD around the world, and the incidence has been on the rise over the past 10 years.[3] The definite cause of autism is still unknown.[4] A large body of genetic and genomic studies has identified a wide spectrum of genetic variants that contribute to the pathogenesis of ASD, such as single nucleotide polymorphisms, epigenetic alterations, copy number variations and chromosomal abnormalities.[5] The high rates of mental retardation and seizure disorders in ASD suggest the possibility of various medical and genetic aetiologies.[4] Children with autism have reduced concentrations of immunoglobulins, which are correlated with severe behavioural symptoms. This suggests possible immune causes.[6] The pathogenesis of ASD is not completely understood. A very small molecular protein referred to as brain-derived neurotrophic factor involved in brain development, which is closely associated with the improvement of learning and memory abilities in young children, is in low expression in ASD patients.[7] The hyperdopaminergic functioning of the brain explains the overactivity and stereotyped movements seen in autism.[8] As per the 'broken mirror neuron theory' for autism, frontal and parietal regions with mirror neurons

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***Address for correspondence:** Sreeja Kudukayil Radhakrishnan Nair, National Homoeopathy Research Institute in Mental Health, Kottayam, Kerala, India. E-mail: jaisankarsreeja@gmail.com

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are abnormally activated in individuals with ASD. Broken frontoparietal mirror neurons might be responsible for impaired imitation.[9] The limbic system, especially the amygdala, is part of a neural system that supports social and emotional functioning. Studies could reveal amygdala enlargement in autism and a decrease in total neuron number.[4]

Indian Scale for Assessment of Autism (ISAA) is an assessment measure developed to diagnose children based on 40 different items that reflects various problem behaviours seen in ASD. This scale was developed based on the childhood autism rating scale (CARS) while considering the Indian sociocultural context.[10]

Autism is a lifelong disability, and currently, no specific treatment is available for it other than training for behavioural modification, which is time-consuming and costly.[11] Allopathic medicines Risperidone and Aripiprazole are found to be used in the treatment of symptoms associated with ASD. However, significant side effects are seen associated with their use, such as increased appetite, increased weight gain, drowsiness, vomiting, somnolence and tremors, which lead to the discontinuation of treatment.[12] The existing treatments commonly used for mood, anxiety and stereotyped behaviours in ASD are usually anti-depressants, including selective serotonin reuptake inhibitors. Patients may have an increased risk for adverse events, most prominently behavioural activation, which may worsen their irritability and aggression.[13] Due to the adverse effects associated with conventional treatment, many people are opting for complementary and alternative systems for the treatment of ASD.[14] Dietary therapies like gluten-free casein-free diets have been found successful in improving the symptoms of autism in some studies, whereas others have reported that such diets have no effect.[15] Melatonin therapy,[16] hyperbaric oxygen therapy,[17] occupation therapy,[18] sensory integration therapy, speech therapy, chiropractic therapy,[19] music therapy[20] and art therapy[21] are other available treatment options. But they all have certain limitations.

Homoeopathic medicines have shown their scope in different child psychiatric conditions like attention deficit hyperactive disorder (ADHD),[22] intellectual disability,[23] learning disability[24,25] conduct disorder[26,27] and oppositional defiant disorder.[28] Adverse effects were not detected in any of these studies and literature shows there is a scope of Homoeopathy in ASD too. The social deficit is the most disabling of all the symptoms of autism because the functional impairment in social interaction skills causes a deficit in emotion recognition in autism, extending beyond the recognition of facial expressions.[29,30] Robinson did a pilot study on 12 adults with autism using homoeopathic medicine *Secretin*. However, there occurred some worsening of symptoms and the improvements observed were not recordable.[31] Improvement was found in other different types of studies.[32-34] Gupta *et al* conducted a study where a comparison was done between classical and non-classical homoeopathic treatment and observed a 60% improvement in mild-to-moderate autism cases and a 38% improvement in severe autism cases. However, comparative groups were non-identical in this study.[35] A single-arm study by Barvalia on 123 cases showed statistically significant improvement with homoeopathic treatment.[36] Significant improvements were detected in different studies.[37-40] However, there is no special reference to the most troublesome domain of social interaction in them. Hence, a study was conducted to find the usefulness of individualised homoeopathic medicine in improving the social interaction domain in children affected with autism.

Materials and Methods

Study design and setting

This prospective, single-arm clinical study was carried out for one year at Child Psychiatry outpatient department (OPD) of the National Homoeopathy Research Institute in Mental Health (NHRIMH), Kottayam, Kerala, India.

The objectives of the study were to assess the usefulness of individualised homoeopathic medicines in improving social interaction in childhood autism and to find out any frequently indicated remedy for this condition.

A total of 176 cases from the Child psychiatry OPD and peripheral OPD were screened with a screening form based on ICD 10 diagnostic criteria. Thirty-five cases fulfilling the inclusion criteria were enrolled. Diagnoses were confirmed and certified by the consultant psychiatrist of the institution. A baseline assessment was done to assess the severity of symptoms by using ISAA. The Social Quotient (SQ) was assessed by the Vineland Social Maturity Scale (VSMS) every month. The study was conducted from 11 November 2019 to 31st January 2020.

After obtaining approval from the Institutional Ethical Committee held at NHRIMH on July 24, 2019 (Ref no: 4-59/2019–20/NHRIMH/IEC/1552) and University, the study was registered under the Clinical Trial Registry-India (CTRI/2019/11/021860). This study was conducted according to the declaration of Helsinki and good clinical practice. Informed consent was obtained from guardians of children following inclusion criteria. The study flow chart is shown in Figure 1. All details were recorded in the case record for child psychiatry cases. Special attention was given to the pregnancy history of the mother and also the mental condition of the mother and father at the time of conception. The totality of symptoms was erected according to Kent's method. Cases were repertorised using Synthesis repertory with the help of RADAR software (Version 10). Repertorial totality was analysed and the individualised homoeopathic constitutional medicine was finally selected by referring to materia medica.

The general restrictions of diet pertaining to homoeopathic medicines such as avoidance of tea and coffee immediately after medicine were advised. Three cases, that were following the casein-restricted diet previously, were allowed to follow the same.

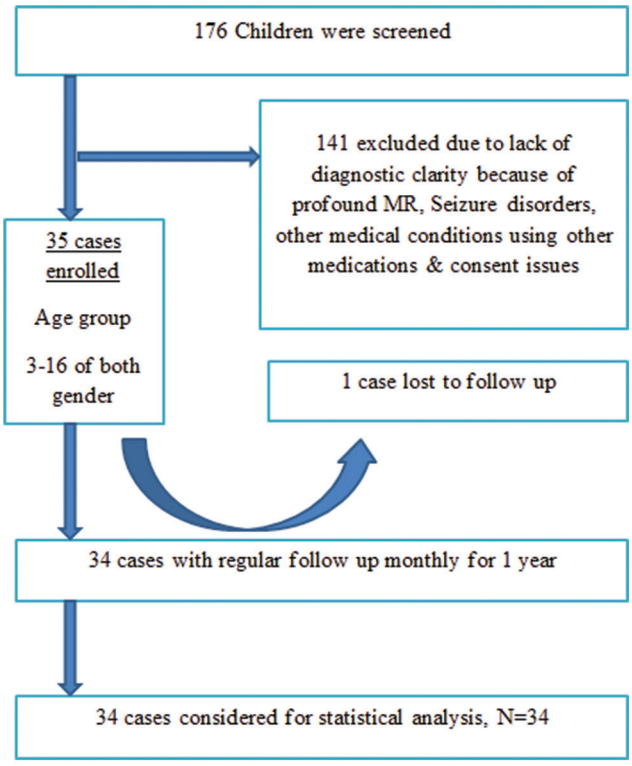

Figure 1: Study flow chart

Participants

Inclusion criteria

Cases diagnosed as childhood autism (F84.0) as per ICD 10 diagnostic criteria in the age group of 3–16 years of any gender were included in the study.

Exclusion criteria

Childhood autism cases with seizure disorders, profound magnetic resonance and other chronic medical illnesses requiring conventional medicine were excluded from the study.

Sample size

The cases were selected by purposive sampling, a non-probability sampling technique where the researcher selects only those subjects that satisfy the objectives of the study based on the researcher's conviction. The sample selection was strictly based on the inclusion/exclusion criteria.

As this study is apparently a first of its kind in Homoeopathy for studying social interaction in autism-affected children, it was decided to keep a minimum sample of 30. Considering the possibility of dropouts, 35 diagnosed cases of Childhood Autism, who attended the OPD from November 2019 to January 2020, were enrolled after screening 176 cases.

Assessment tools

ISAA

This scale covers six domains - social relationships and reciprocity (SRR); emotional responsiveness; speech, language and communication; behaviour patterns; sensory aspects and cognitive component. All the 40 items are rated on a Likert scale from 1 to 5 based on history and interviewer observation, and the increasing score indicates the increasing severity of the problem. The minimal score that can be obtained is 40 and the maximum score that can be obtained is 200. A score of <70 indicates no autism, 70–106 (mild autism), 107–153 (moderate autism) and >153 (severe autism). It takes about 20–30 min for administration of ISAA.

VSMS

The social maturity was assessed by calculating social quotient through this scale.

Intervention

The medicines were supplied from the pharmacy of NHRIMH which were procured from Kerala State Homoeopathic Co-operative Pharmacy. The homoeopathic principles of single remedy and minimum dose were strictly followed. A single dose of the indicated remedy was administered following administration of sugar of milk, blank tablets and globules. The medicine was repeated only when there was no perceptible improvement of symptoms in the preceding month. In the first prescription, all children were provided with the indicated remedy in 30C potency as per the protocol. If improvement stopped at a period, the potency was raised to 200C. For acute complaints that occurred in between, current acute totality was taken and the most suitable remedy was provided. Potencies ranging from 30 to 1M potencies were used for the study during follow-up visits. The intervention continued all through the study period of one year.

Remedy response, posology and indicated remedies observed during the study

Centesimal scale potencies starting from 30th potency were utilised whenever required and were repeated weekly, biweekly and monthly. When no further improvement was observed the potency was raised from 200C to 1M. Switching of potency to 200C was required in 20 cases and in three cases switched from 200C to 1M. The remedies prescribed in this study are presented in Figure 2.

Follow-ups

The assessment was done every month by the principal investigator under the supervision of the consultant psychiatrist with ISAA and VSMS. Monthly follow-ups were taken for one year as per the protocol.

During the lockdown period due to COVID-19, those patients who could not visit the hospital were provided with the prescribed medicine from their nearby Government Homoeopathic Dispensaries by communicating with the corresponding Medical Officer and medicines were provided as per the investigator's instructions. During that time, telephonic assessment was done to communicate with the parents or caregivers. All scheduled and unscheduled follow-up visits

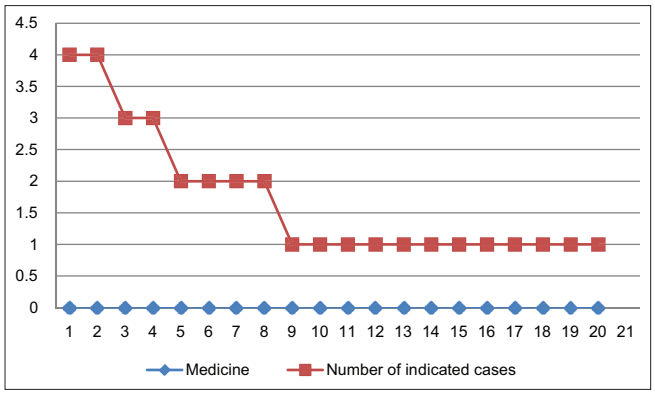

Figure 2: Medicines indicated in this study based on Individualisation. Medicines 1–20 are *Carc*., *Ign*., *Sulph*., *Tarent.hisp*., *Anac*., *Calc.carb*., *Calc.phos*., *Stram*., *Acon*., *Aur. mur. nat*., *Aur. sulph*., *Caust*., *Coloc*., *Lyco*., *Op*., *Phos*., *Podo*., *Puls*., *Sep*., *and Verat. alb*. respectively

were recorded in the case record format. The outcome of treatment was measured by analysing the ISAA score, the score under the domain of SRR, individual domain scores, VSMS score and SQ score at baseline, and then at the 3rd, 6th, 9th and 12th months.

Statistical analysis

Data obtained through this study were checked for normality using the Shapiro–Wilk test. As the data did not follow the criteria for normalcy, a non-parametric test of significance, the Friedman test, is used. Spearman's correlation coefficient is used for testing the correlation of change in SQ with the age of children before and after treatment as the data was not following a normal distribution. IBM SPSS 20 Subscription version was used for the data analysis.

Results

Sociodemographic data and baseline severity

Of 35 enrolled cases, 28 were boys and seven were girls. The mean age of children in the study was 8.17 years and the mean duration of illness was 6.05 years. About 9% of cases were of mild autism, while 77% cases belonged to moderate and 14% to severe autism, as per ISAA scoring. Sociodemographic data of all the enrolled cases (n = 35) are represented (Table 1). Out of 35, one patient lost to follow-up and the remaining 34 patients were regularly followed up for one year and were included in the data analysis.

Comorbidities, family history and prenatal stress observed in cases

Comorbid conditions identified included mental retardation (n = 5), involuntary urination (n = 2), recurrent urinary tract infections (n = 1), bowel issues (n = 3), sleep disturbances (n = 2) and myopia (n = 1). Family histories commonly showed cancer, myocardial infarction and hypothyroidism (11, 9 and 8 cases, respectively). In addition, family members also had a history of mental retardation, alcoholism, autism, schizophrenia, depression and seizure disorders.

Change in scale scores

Friedman test showed a statistically significant reduction in the social reciprocity score over 12 months. Improvement was seen in all items under the domain of SRR of ISAA. Individualised homoeopathic medicines were found effective in improving social interaction. The statistical analysis of this domain is represented in Table 2.

Median scores of ISAA and VSMS at baseline were 132 and 39 and turned to 35.5 and 56, respectively, at the end of the study. There was a marked reduction in the total ISAA score of 34 patients (one child lost to follow-up) after treatment, showing a statistical significance of $p < 0.001$. The score of SRR domain in ISAA changed to 10 from the baseline median score of 41.5 ($p < 0.001$). SQ also changed from the baseline median of 32.8 to 82.7 ($p < 0.001$).

Statistical analysis is represented in Table 3. Change in VSMS total score and SQ throughout the year is shown in Figures 3 and 4, respectively. Change detected in all the domains of ISAA is shown in Table 3.

Table 1: Sociodemographic profile of the participants (N=35)

Sociodemographic profile	Total number of participants
Age (in years)	
2-6	13
7-11	14
12-16	8
Birth weight	
Underweight (<2.5Kg)	7
Overweight (>4kg)	2
Normal weight	26
Gender	
Male	28
Female	7
Place	
Urban	32
Rural	3
Schooling	
Normal	22
special	13
Socioeconomic status	
High class	11
Middle class	14
Low class	10
Birth order	
1st born	26
Last born	9
Religion	
Hindu Community	16
Christian Community	13
Muslim Community	6
Type of birth	
Vaginal	18
LSCS	16
Vaccum	1

Table 2: Statistical analysis of symptoms in social relationships and reciprocity

Variable	Baseline median (IQR)	3rd month median (IQR)	6th month median (IQR)	9th month median (IQR)	End median (IQR)	X2*	*P*-value
Q1	4.5 (4.0, 5.0)	2.0 (1.0, 3.0)	1.0 (1.0, 2.0)	1.0 (0.0, 1.0)	0.0 (0.0, 1.0)	110.498	<0.001
Q2	5.0 (4.0, 5.0)	3.0 (2.0, 4.0)	2.0 (1.0, 3.0)	1.0 (0.0, 2.00)	0.0 (0.0, 1.25)	108.581	<0.001
Q3	5.0 (5.0, 5.0)	3.0 (2.0, 4.0)	3.0 (2.0, 4.0)	2.0 (1.0, 2.25)	1.0 (0.0, 2.0)	107.265	<0.001
Q4	5.0 (4.0, 5.0)	3.0 (2.0, 4.0)	2.0 (1.0, 2.25)	1.0 (0.0, 2.0)	0.0 (0.0, 1.0)	98.982	<0.001
Q5	5.0 (4.0, 5.0)	3.0 (2.0, 4.25)	2.0 (1.0, 4.0)	1.0 (0.0, 3.0)	0.5 (0.0, 3.0)	88.080	<0.001
Q6	5.0 (4.75, 5.0)	4.0 (3.0, 5.0)	3.5 (2.0, 4.0)	3.0 (1.0, 4.0)	2.0 (0.75, 3.0)	93.311	<0.001
Q7	5.0 (4.75, 5.0)	4.0 (3.0, 5.0)	3.0 (2.0, 4.0)	2.0 (1.0, 2.25)	1.0 (0.0, 2.0)	93.837	<0.001
Q8	5.0 (5.0, 5.0)	4.0 (3.75, 5.0)	3.0 (3.0, 4.0)	2.0 (1.0, 3.0)	2.0 (0.75, 3.0)	106.589	<0.001
Q9	5.0 (5.0, 5.0)	4.0 (3.0, 4.0)	3.0 (2.75, 4.0)	2.0 (1.0, 3.0)	1.5 (0.0, 3.0)	115.993	<0.001

Q1: Has poor eye contact, Q2: Lack of social smile, Q3: Remains aloof, Q4: Does not reach out to others, Q5: Unable to relate to people, Q6: Unable to respond to social or environmental cues, Q7: Engages in solitary and repetitive play activity, Q8: Unable to take turn in social interaction, Q9: Does not maintain peer relationships. IQR: Interquartile range

Table 3: Statistical result of Friedman's test

Variable	Baseline median (IQR)	3rd month median (IQR)	6th month median (IQR)	9th month median (IQR)	At end median (IQR)	X^{2*}	*P*-value
D1	41.5 (38.0, 44.0)	28.5 (22.0, 36.0)	23.0 (18.0, 28.25)	15.0 (8.0, 21.0)	10.0 (3.75, 16.25)	127.621	<0.001
D2	19.0 (14.0, 22.5)	12.0 (9.75, 18.0)	10.0 (5.0, 13.5)	6.0 (3.0, 9.25)	4.0 (1.0, 6.0)	113.700	<0.001
D3	25.0 (20.0, 30.0)	16.0 (13.0, 20.5)	14.0 (9.0, 20.0)	8.0 (4.0, 15.0)	6.0 (2.0, 11.0)	113.827	<0.001
D4	24.0 (18.75, 28.25)	13.50 (10.5, 18.25)	11.0 (8.0, 1.5)	8.0 (3.75, 13.0)	5.0 (2.0, 11.25)	96.855	<0.001
D5	10.0 (6.0, 15.0)	5.5 (4.0, 8.5)	6.0 (3.0, 8.25)	3.0 (1.0, 5.25)	2.0 (0.0, 4.0)	84.646	<0.001
D6	10.0 (10.0, 15.0)	9.0 (6.75, 13.0)	8.0 (4.0, 10.0)	7.5 (3.0, 9.0)	5.0 (3.0, 8.0)	104.723	<0.001
IT	132.0 (114.0, 144.0)	90.5 (73.0, 101.25)	77.0 (57.0, 99.25)	48.5 (30.75, 66.75)	35.5 (15.0, 51.5)	127.032	<0.001
VT	39.0 (32.75, 42.0)	48.0 (41.55, 55.25)	52.5 (45.0, 59.0)	55.0 (48.0, 64.0)	56.0 (51.25, 65.25)	124.679	<0.001
SQ	32.8 (22.3, 61.0)	56.1 (28.4, 90.63)	73.8 (34.5, 96.0)	82.7 (40.5, 98.05)	82.7 (44.57, 100.0)	100.079	<0.001

Domains D1: Social relationships and reciprocity, D2: Emotional responsiveness, D3: Speech- language and communication, D4: Behaviour patterns, D5: Sensory aspects, D6: Cognitive component, IT-ISAA Total Score, VT-VSMS Total Score, SQ: Social quotient. (*Friedman test is used. *P*<0.05, considered as statistically significant.) IQR: Interquartile range

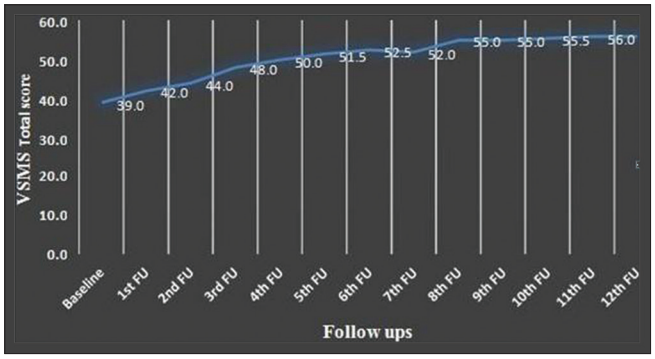

Figure 3: Change in Vineland Social Maturity Scale score during follow ups (*FU-follow up)

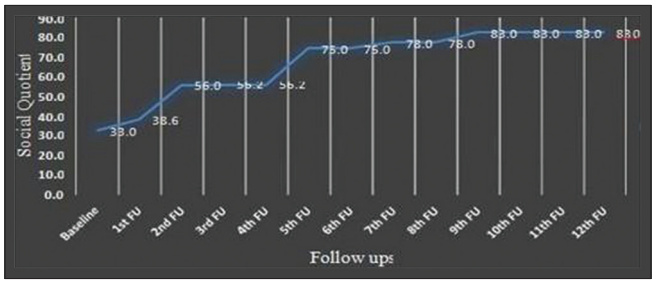

Figure 4: Change in Social Quotient during follow-ups (*FU-follow up)

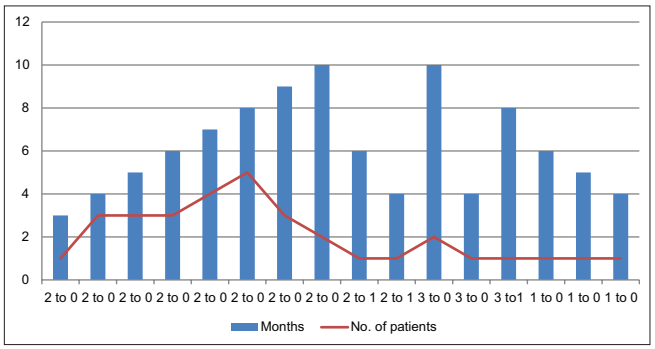

Figure 5: Change in severity and month at which noticed after intervention. 3: Severe autism, 2: Moderate autism, 1: Mild autism, 0: Non autistic

Change in severity after intervention

Thirty cases in this study turned non-autistic as per ISAA scoring and the mean duration of time taken to become non-autistic was 6.2 months [Figure 5].

Acute management

Acute ailments during the study period were managed with medicines prescribed on the basis of sector totality. Acute remedies were provided in four cases, namely *Aconite*, *Arsenicum album*, *Belladonna* and *Pyrogenium*. In one case,

where there were episodes of violence on emotional excitement in the early months of treatment, *Belladonna,* the acute remedy of the constitutional medicine *Calc. carb*., was prescribed in high potency, considering the susceptibility of the patient.

Discussion

A significant improvement in social interaction was found in childhood autism after homoeopathic intervention in the study, which correlates with the literature where 92% improvement was noticed in the domain of social interaction.[35] No adverse reactions were reported during the current study. The current study also revealed the fact that social deficits are more severe in children with childhood autism compared to other domains.[30] The current study shows male preponderance which correlates with the literature.[4] The available literature describes that the first and last born are more vulnerable to ASD.[41] In this study, 26 patients were 1st and nine were 2nd children in birth order.

Cases with sensitivity to touch, sound, smell and vision fall under the sensory pattern of presentation. Those present in a hyperactive state are in a kinetic state. In the kinetic state, there are two subtypes. Those with a self-injuring nature are aggressive, while others are without aggression. Children presenting with involuntary stool and urine, lasciviousness, lustful behaviour, masturbation, eating faeces and dust come into a regressive state.[36] In this study, according to the symptom presentations, 16 cases were in the kinetic state, 12 cases showed sensory patterns and seven cases were in the regressive state. Among the kinetic states, four were aggressive and 12 were non-aggressive. Mood and affective disturbances are also seen as associated features in children with autism.[4] One child showed affective symptoms such as sudden weeping and anger outbursts in this study.

Reduction in the total score of ISAA shows the overall improvement in childhood autism. Change in VSMS total score and SQ shows the improvement in social maturity in children with autism. Hence, it is found that individualised homoeopathic medicines have a significant effect in improving social interaction in childhood autism. Global improvement in the symptoms of autism was also found in the study. However, this study could not find any frequently indicated remedy which was a secondary objective.

The literature shows an association between prenatal maternal stress and ASD in children.[42] The current study also found maternal mental stress in most of the cases during the first trimester. Obstetric factors such as advanced maternal age, use of medications, meconium staining, prematurity, post-maturity and early or mid-trimester bleeding are found to have a causative association with ASD in children.[43] Maternal age at the time of conception >35 years is found only in two cases, and paternal age of more than 40 years is found among four cases in the current study. Oligohydramnios is detected in one case. Frequent uterine contractions, leading to total bed rest, were found in one case. Reduced foetal movements were found in two cases. In eight cases, the birth cry was absent. Seven cases showed low birth weight (ranging from 1.8 kg to 2.4 kg). Two cases were born overweight (4 kg and 4.5 kg).

Features like outstanding abilities inconsistent with their general functioning are described as Savant syndrome, usually seen in areas of music, art, calendar, calculating, mathematics or visual-spatial skills and outstanding memory.[44] In this study, savant syndrome was seen in six cases in the form of musical skills (two cases), linguistic skills (two cases), creative skills (two cases—logo designing and clay work), time assessment skills (one case) and shloka recital skills (one case).

Animal remedies are described as having more action in psychiatric conditions. *Tarentula hispanica* was suggested in the literature for ASD.[34] Only *Tarentula hispanica* and *Sepia* are the remedies indicated in the animal group remedies. Plant remedies were indicated in 16 cases, mineral remedies in seven cases and nosode remedies in four cases. Literature suggests that it is better to deal with a polychrest remedy, which is found to be the exact similimum rather than using a rare remedy.[45] The current study also supports this information. A higher potency was found to have more effectiveness in treating autism.[38] However, in this study, nine cases showed responses to 30th potency alone throughout the study. Cases were demonstrated to show the evidence of the action of homoeopathic remedies such as *Carcinosinum*, *Syphylinum*, *Nux vomica*, *Stramonium* and *China*.[36,46-48] The current study could not find any frequently indicated remedy or group of remedies. Hence, one of the secondary objectives of the study, to find out the frequently indicated homoeopathic remedies for childhood autism, is not achieved. This shows the importance of individualisation in treating children with childhood autism.

From the current study, it is evidenced that the prognosis of a case cannot be predicted based on the severity at the baseline but on the response of each child to the indicated remedy. Common comorbid physical conditions seen with ASD are sleep problems, epilepsy, sensory impairments, autoimmune disorders and obesity[49]. Literature finds evidence for the association of ADHD with ASD[50] In the current study, 16 cases had hyperactive features but did not fulfil all the criteria for a separate diagnosis of ADHD.

ISAA is an indigenous scale based on the CARS. A comparison of ISAA with CARS showed its high validity and reliability.[50-52] Dawson and Fernald in their study found the VSMS useful to assess the social development of Autistic children.[53] Although the ISAA score has come to the non-autistic range (<70) in many of the cases, still, it is not possible to say that those children have become normal in behaviour. There are still certain elements of mild autistic features persisting in the children but they were not suggestive of calling them as children with autism. This observation stresses the fact that it is a developmental disorder; children with autism need long-term treatment.[54]

The study also observed that children who received treatment in the very early years of the onset of illness had better results compared to those who started treatment in late childhood. This stresses the importance of early detection and early

intervention.[32,55] Social interaction in the form of speech and language was difficult to obtain in a few cases, though they were showing nonverbal communication and emotional reciprocity. Speech therapy as an adjunctive to Homoeopathy is highly recommendable in such cases. Further studies using randomisation techniques utilising other interventional methods such as speech therapy and sensory therapy can show whether homoeopathy can provide better results in the domain of speech and language than other methods. The use of an indigenous scale ISAA appropriate for the sociocultural forms of the Indian population is one of the strengths of this study. The diagnosis of all cases was confirmed by the psychiatrist. Stringent measures were taken to prevent dropouts and to maintain regular follow-ups despite the COVID-19 context.

As the IQ test of children was not assessed during the study, it is not possible to classify the level of intelligence in cases apart from the clinical observation. Due to the lack of a control group, the degree of improvement of the children due to homoeopathic medicines apart from the normal course of development of a child cannot be comprehended exactly. Thirty children out of 34 in the study were turned non-autistic by the end of the study, but, as most of the (77%) children in this study fall under moderate severity as per the ISAA score, the effectiveness of homoeopathic medicines in improving the social interaction of severe cases of autism is not understood clearly.

A study with a larger sample size and control group assessing investigative markers such as neurotransmitters and the use of EEG, which can further validate the outcome, is an arena of future research.

Conclusion

The study concludes that homoeopathic medicines prescribed on the basis of strict individualisation are useful in the management of childhood autism by improving social interaction along with global improvement. The remedies found effective were *Carcinosinum*, *Ignatia*, *Sulphur*, *Tarentula hispanica*, *Anacardium*, *Calc-c*, *Calc-phos and Stramonium*. No specific remedies were prescribed in this study, which reaffirms the concept of individualisation, a cardinal principle of homoeopathy, thus suggesting 'treat the child, not the disease.' Future research studies with control groups and specific assessment parameters are suggestive.

Ethical considerations

The study was conducted after obtaining the Institutional Ethical Committee approval and CTRI registration (CTRI/2019/11/021860).

Written informed consent was obtained from the parents of these children with the assurance that the identity of their child will not be disclosed.

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Conflicts of interest

None declared.

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Utilité des médicaments homéopathiques individualisés pour améliorer l'interaction sociale dans l'autisme infantile : une étude prospective, ouverte, à un seul bras

Contexte: L'autisme infantile est un trouble envahissant du développement. Sa prévalence a augmenté au cours des dernières décennies. Le déficit social est le symptôme le plus invalidant de l'autisme. Il existe un besoin immédiat d'explorer de nouvelles interventions pour traiter efficacement l'autisme infantile. **Objectif:** L'étude visait à évaluer l'utilité des médicaments homéopathiques individualisés pour améliorer l'interaction sociale dans l'autisme infantile. **Matériel et méthodes:** Cette étude d'une durée d'un an a été menée dans le service ambulatoire de l'Institut national de recherche homéopathique en santé mentale, à Kottayam, au Kerala. Trente-cinq enfants répondant aux critères diagnostiques de l'autisme infantile (conformément à la CIM 10 - F84.0) ont été recrutés. Des médicaments homéopathiques individualisés ont été prescrits en concentrations centésimales selon les principes homéopathiques. FrançaisLes sujets ont été évalués à l'aide de l'échelle indienne d'évaluation de l'autisme (ISAA) et de l'échelle de maturité sociale de Vineland (VSMS) au départ et tous les mois jusqu'à un an. Les résultats ont été analysés à l'aide du test de Friedman. **Résultats:** Les scores médians de l'ISAA et de la VSMS au départ étaient de 132 et 39, qui ont été améliorés à 35,5 et 56, respectivement, à la fin de l'étude. Il y a eu une réduction marquée du score total de l'ISAA chez 34 patients (statistiquement significatif avec $p < 0.001$). Le changement des scores médians par rapport à la ligne de base du domaine des relations sociales et de la réciprocité de l'ISAA, le quotient social s'est amélioré de 41,5 à 10 et de 32,8 à 82,7, respectivement ($p < 0.001$). **Conclusion:** Les médicaments homéopathiques individualisés sont utiles pour améliorer l'interaction sociale dans les cas d'autisme infantile. Un essai clinique contrôlé est suggéré comme domaine de recherche future.

Nutzen individualisierter homöopathischer Arzneimittel zur Verbesserung der sozialen Interaktion bei Autismus im Kindesalter: Eine prospektive, offene, einarmige Studie

Hintergrund: Autismus im Kindesalter ist eine tiefgreifende Entwicklungsstörung. In den letzten Jahrzehnten hat die Prävalenz dieser Störung stark zugenommen. Das soziale Defizit ist das am meisten beeinträchtigende Symptom von Autismus. Es besteht ein dringender Bedarf an der Erforschung neuer Interventionen zur effektiven Behandlung von Autismus im Kindesalter. **Ziel:** Ziel der Studie war es, den Nutzen individualisierter homöopathischer Arzneimittel zur Verbesserung der sozialen Interaktion bei Autismus im Kindesalter zu untersuchen. **Materialien und Methoden:** Diese einjährige Studie wurde in der Ambulanz des National Homoeopathy Research Institute in Mental Health in Kottayam, Kerala, durchgeführt. 35 Kinder, die die Diagnosekriterien für Autismus im Kindesalter (gemäß ICD 10 – F84.0) erfüllten, wurden in die Studie aufgenommen. Individualisierte homöopathische Arzneimittel wurden in Centesimalpotenzen nach homöopathischen Prinzipien verschrieben. Die Probanden wurden zu Studienbeginn und monatlich über einen Zeitraum von bis zu einem Jahr mithilfe der Indian Scale for Assessment of Autism (ISAA) und der Vineland Social Maturity Scale (VSMS) beurteilt. Die Ergebnisse wurden mithilfe des Friedman-Tests analysiert. **Ergebnisse:** Die Medianwerte von ISAA und VSMS lagen zu Studienbeginn bei 132 bzw. 39 und verbesserten sich bis zum Ende der Studie auf 35.5 bzw. 56. Bei 34 Patienten war eine deutliche Verringerung des Gesamt-ISAA-Scores zu verzeichnen (statistisch signifikant mit $p < 0.001$). Die Veränderung der Medianwerte vom Studienbeginn im Bereich soziale Beziehungen und Reziprozität von ISAA, Sozialer Quotient, verbesserte sich von 41.5 auf 10 bzw. von 32.8 auf 82.7 ($p < 0.001$). **Schlussfolgerung:** Individualisierte homöopathische Arzneimittel sind hilfreich bei der Verbesserung der sozialen Interaktion bei Autismus im Kindesalter. Als Bereich für künftige Forschung wird eine kontrollierte klinische Studie vorgeschlagen.

बाल्यावस्था में ऑटिज्म में सामाजिक संपर्क को बेहतर बनाने में व्यक्तिगत होम्योपैथिक दवाओं की उपयोगिता: एक संभावित, ओपन लेबल, एकल हाथ अध्ययन

पृष्ठभूमि: बाल्यावस्था में ऑटिज्म एक व्यापक विकासात्मक विकार है। पिछले कुछ दशकों में इसके प्रचलन में वृद्धि हुई है। सामाजिक कमी ऑटिज्म का सबसे अक्षम करने वाला लक्षण है। बाल्यावस्था में ऑटिज्म को प्रभावी ढंग से संबोधित करने के लिए नए इलाजों की खोज करने की तत्काल आवश्यकता है। **उद्देश्य:** अध्ययन का उद्देश्य बाल्यावस्था में ऑटिज्म में सामाजिक संपर्क को बेहतर बनाने में व्यक्तिगत होम्योपैथिक दवा की उपयोगिता का आकलन करना था। **सामग्री और विधियाँ:** यह एक वर्ष की अवधि का अध्ययन राष्ट्रीय होम्योपैथी अनुसंधान संस्थान मानसिक स्वास्थ्य, कोट्टायम, केरल के बाह्य रोगी विभाग में किया गया। बाल्यावस्था में ऑटिज्म के नैदानिक मानदंडों (ICD 10 - F84.0 के अनुसार) को पूरा करने वाले पैंतीस बच्चों को नामांकित किया गया था। होम्योपैथिक सिद्धांतों का पालन करते हुए सेंटीसीमल पोटन्सी में व्यक्तिगत होम्योपैथिक दवाएँ निर्धारित की गईं। विषयों का मूल्यांकन भारतीय ऑटिज्म आकलन पैमाने (आईएसएए) और विनलैंड सामाजिक परिपक्वता पैमाने (वीएसएमएस) का उपयोग करके आधार रेखा पर और एक वर्ष तक हर महीने पर किया गया। परिणाम का विश्लेषण फ्राइडमैन परीक्षण का उपयोग करके किया गया। **परिणाम:** आधार रेखा पर आईएसएए और वीएसएमएस के औसत अंक 132 और 39 थे, जिसका अध्ययन के अंत में क्रमशः 35.5 और 56 तक सुधार हुआ। 34 रोगियों के कुल आईएसएए स्कोर में उल्लेखनीय कमी आई (सांख्यिकीय रूप से महत्वपूर्ण पी < 0.001 के साथ)। आईएसएए के सामाजिक संबंध और पारस्परिकता डोमेन में आधार रेखा से औसत अंकों में परिवर्तन देखा गया जिसमे सामाजिक भागफल क्रमशः 41.5 से 10 और 32.8 से 82.7 तक सुधरा (पी < 0.001)। **निष्कर्ष:** व्यक्तिगत होम्योपैथिक दवाएं बचपन में ऑटिज्म के मामलों में सामाजिक संपर्क में सुधार करने में उपयोगी हैं |

Utilidad de los medicamentos homeopáticos individualizados para mejorar la interacción social en el autismo infantil: un estudio prospectivo, abierto y de un solo brazo

Antecedentes: el autismo infantil es un trastorno generalizado del desarrollo. Su prevalencia ha aumentado en las últimas décadas. El déficit social es el síntoma más incapacitante del autismo. Existe una necesidad inmediata de explorar nuevas intervenciones para abordar eficazmente el autismo infantil. **Objetivo:** el estudio tuvo como objetivo evaluar la utilidad de los medicamentos homeopáticos individualizados para mejorar la interacción social en el autismo infantil. **Materiales y métodos:** este estudio de un año de duración se llevó a cabo en el departamento ambulatorio del Instituto Nacional de Investigación en Homeopatía en Salud Mental, Kottayam, Kerala. Se inscribieron treinta y cinco niños que cumplían los criterios de diagnóstico del autismo infantil (según la CIE 10 - F84.0). Se prescribieron medicamentos homeopáticos individualizados en potencias centesimales siguiendo los principios homeopáticos. Los sujetos fueron evaluados utilizando la escala india para la evaluación del autismo (ISAA) y la escala de madurez social de Vineland (VSMS) al inicio y cada mes hasta un año. El resultado se analizó utilizando la prueba de Friedman. **Resultados:** Las puntuaciones medias de ISAA y VSMS al inicio fueron 132 y 39, que mejoraron a 35,5 y 56, respectivamente, al final del estudio. Hubo una marcada reducción en la puntuación total de ISAA de 34 pacientes (estadísticamente significativa con $p < 0.001$). El cambio de las puntuaciones medias desde el inicio del dominio de relación social y reciprocidad de ISAA, el cociente social mejoró de 41.5 a 10 y de 32.8 a 82.7, respectivamente ($p < 0.001$). **Conclusión:** Los medicamentos homeopáticos individualizados son útiles para mejorar la interacción social en los casos de autismo infantil. Se sugiere un ensayo clínico controlado como el ámbito de la futura investigación.

个性化　势　法　物在改善儿童自　症社交互动中的效用：一　前瞻性、　放　　、单臂研究

背景：儿童自　症是一种广泛性　育障碍。在过去的几十年里，其患病率不断上升。社交障碍是自　症最　重的症状。迫切需要探索新的干　措施来有效治　儿童自　症。**目的：**本研究旨在　估个性化　势　法　物在改善儿童自　症社交互动中的效用。**材料和方法：**这　　期一年的研究是在喀拉拉邦科塔　姆国家　势　法精神健康研究所的　部　行的。有 35 名符合儿童自　症　断　准的儿童（根据 ICD 10 - F84.0）参加了研究。根据　势　法原　，以百倍效力　具个性化　势　法　物。在基　和　达一年的每个月，使用印度自　症　估量表 (ISAA) 和 Vineland 社会成熟度量表 (VSMS) 对受　者　行　估。使用 Friedman　　分析　果。　**果：**基　时 ISAA 和 VSMS 的中位分数分别　132 和 39，在研究　束时分别提高到 35.5 和 56。34 名患者的 ISAA　分　着降低（　　学意义，$p < 0.001$）。ISAA 的社会　系和互惠　域的中位分数从基　的　化，社交商分别从 41.5 提高到 10 和从 32.8 提高到 82.7（$p < 0.001$）。　　：个性化　势　法　物有助于改善儿童自　症患者的社交互动。建　将对照　床　作　未来研究的　域。