



Research Article

A CLINICAL ASSESSMENT AND EVALUATION OF *MANTHA SANN* (AUTISM SPECTRUM DISORDER) WITH SIDDHA THERAPEUTIC MANAGEMENT IN CHILDREN

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ABSTRACT

Autism is most common mental disabilities in childhood with unknown aetiology nowadays. In our Siddha paediatric text, the symptoms of *Mantha sann* are nearly correlated with Autism Spectrum Disorder (ASD). **Objectives:** The Main objectives of the study is to evaluate the Siddha therapeutic management and to analyse the clinical assessment of *Mantha sann* (Autism Spectrum Disorder) with Experimental formulations and procedures and the secondary objectives are to calibrate the resemblance and the equivalence of *Mantha Sanni* with Autism Spectrum Disorder and to explore the Siddha therapeutic management in Autism children. **Methods:** In preclinical studies of Physicochemical, Phytochemical activities and Pharmacological activities were done. In clinical studies, among 30 children were included in inclusion criteria and received *Kuruver kudineer* as internal twice a day and *Sambrani thivalai* and *Mysatchi pugai* as external once in a day. The Experimental period was 90 days and the activities of ASD children were recorded 0th day followed by every 30th day. **Results and Discussion:** In this clinical study indicating that both internal and external medicine had superior action as far as improvement in ASD is considered. Since *Kuruver Kudineer* use is to enhance cognitive skills, enhance nerve impulse transmission, research has been focused on the mechanism behind this activity. *Thivalai* with *Sambrani ennai* use to enhance the Sitting tolerance, invigorating feeling and can give comfort. Fumigation with *Mysatchi pugai* is one of the methods of treatment in ancient period. It has to enhancing the mind calming activity, reduced hyperactivity, induced sound sleep, reduced screaming and irritable cry. In Statistical analysis, there is significant difference between before and after treatment on clinical assessment parameter score i.e. 86% improvement in this score after treatment. Based on the results of this clinical study, it can be conclude that *Kuruver kudineer* as internal and *Sambrani thivalai* and *Mysatchi pugai* as external. It has a definite action as well as clinical efficacy on symptoms in ASD children seen in regular OPD and IPD. The effects of Internal and external therapies may be due individual drugs multipronged action. Further study is required for scientific validation to prove its clinical efficacy in multicentre clinical study.

KEYWORDS: *Mantha Sanni*, Autism Spectrum disorder, *Kuruver Kudineer*, *Sambrani thivalai* and *Mysatchi pugai*.

INTRODUCTION

Autism in this era is the most common developmental disorder seen in paediatric population. It is associated with Impairment in Social and communication Skills, Emotional skills, Behavioural problems sensory issues and lack of cognitive development. The Word Autism comes from the Greek word "Autos" which means self. It describes condition in which a person removed from social interaction. In other words, he becomes an "isolated self". Eugen Bleuler, a swiss psychiatrist was the first person to use this term^[1].

The latest analysis from the centres for Disease control and prevention estimate that 1 in 68 has ASD. The Early signs of ASD can be seen by above 18 months after birth. In all over the world, it is believed that 1 in 42 boys and 1 in 189 girls are suffering from it. This surveillance study identified 1 in 68 children. That represents a tenfold rise in the past 40 years. It was found about 1 to 1.5 % autistic children between ages 2-9 years says Dr.N.K.Arora, Executive director of the international clinical epidemiology network trust which led the study. That

means the prevalence rate is 23 children of every 10,000 in India. In Tamil Nadu, the prevalence rate is 1:116 and in Chennai, that is 1:100.^[2]

In India, Siddha is one of the oldest systems of medicine practiced. The word 'Siddha' comes from 'Siddhi' which means an object to be attained or perfection of heavenly bliss. The basis of treatment is the three element theory or 'Trithodam' (three humours). The three humours are *Vatha* (air), *Pitta* (bile) and *Kapha* (phlegm). It is believed that without these humours an individual cannot exist and imbalance of these may cause diseases. The main aim of Siddha is to assure a healthy life to mankind. In our Siddha paediatric text, the symptoms of *Mantha sann* are nearly correlated with Autism Spectrum Disorder (ASD) ^[3]. Thus the aim and objectives of the present study were to test the efficacy of the Siddha medicines/methodologies in ASD children.

In order to the drugs chosen for the project included *Kuruver Kudineer* as internal medicine, *Sambrani Thuvalai* for *Thuvalai* and *Mysatchi Pugai* for fumigation therapy as external, all of which have been used in the Siddha system of medicine for many centuries. All the ingredients in both Internal and External medicines are herbal. This Study is conducted on ASD to see the improvement in the quality of life by employing the Siddha therapeutic formulations and procedures.

Materials and Methods

Preparation of experimental formulations

Kuruver kudineer as internal and *Sambrani thuvalai*, *Mysatchi pugai* as external were identified for this study. Raw drugs to prepare the products were purchased from the well reputed country shop in Tambaram. The raw materials have got authentication from the department of Medicinal Botany, National institute of Siddha, Chennai. After process the medicine was proper purification and prepared in Gunapadam lab of NIS. The Prepared medicine was stored in glass container authenticated by the concerned guide for its completeness.

Kuruver Kudineer

Kuruver kudineer^[4] was prepared as described as in the Sasthric Siddha literature in *Bala vagadam* such as *Vettiver* (*Vettiver zaizanoids*), *Vilamichu* (*Plectranthus vettiveroids*), *Parpadagam* (*Hedyotis corymbosa*), *Siruthaeku* (*Clerodendrum serratum*) roots are used in above plants and *Chukku* (*Zingiber officinalae*) has dried rhizome. All the drugs are taken in ¼ palam as equal quantity.

Preparation method

Ingredients mentioned above are made as a coarse powder and then soaked it in a vessel

containing of water 1 *Padi* (1 lit.) and heat till it comes to 1/8th of its volume. Twice a day.

Duration: 90 days

Dispensing: Prepared medicine will be given as decoction.

External medicine I-Sambrani thuvalai

Sambrani thuvalai^[5] was prepared as described as in the Siddha literature of *Dhanvanthri thylam* such as all parts of *Vellerukan samoolam* (*Calotropis giganteae*) and gum resins of *Sambrani* (*Styrax benzoin*) in 1kg. The oil of *Neem* (*Azadiracta indica*) in 2 litres.

Method: Take all the above ingredients in equal quantity except neem oil and make it as a decoction then boiled with neem oil. After the oil is apply over whole body like a *thuvalai* once in a day^[6].

Duration: 90 days

External Medicine- II Mysatchi pugai

Mysatchi Pugai^[3] was prepared as described as in the sasthric Siddha literature in *Bala vagadam* such as Gums of *Mysatchi* (*Shorea robusta*), gum resins of *Sambrani* (*Styrax benzoin*), Woods of *Agirkattai* (*Aquillaris agalocha*), Seeds of *Sanninayagam* (*Nigella sativum*) and roots of *Velai ver* (*Cleome viscosa*) and *Sathisaranai ver* (*Trianthema decandra*). All the above plants are taken in ½ Kg.

Method

Take 1- 4 ingredients mentioned above in equal quantity make as a powder and then 5-6 ingredients make it as a flamed substances. After that fumigate once in a day^[7].

Duration: 90 days

Preclinical studies

Physicochemical and Phytochemical Studies

The physicochemical and phytochemical studies were done in The Tamil nadu, Dr. MGR University, Guindy, Chennai. The physicochemical testing employed for *Kuruver kudineer* profiling which is depend on the specific characteristics of formulation as per method given in PLIM guidelines and Siddha Pharmacopoeia of India contains various parameters for testing such as 1. Loss on drying, 2.Total ash value, 3.Acid insoluble ash, 4.Water soluble ash, 5.Water soluble extraction, 6.Alcohol soluble extraction. The Phytochemical studies were employed for *Kuruver Kudineer* profiling contains various parameters such as 1. Alkaloids 2.Carbohydrates 3.Glycoside 4.Saponin 5.Phytosterol 6.Phenols 7.Tannins 8.Flavonoids 9.Proteins and amino acids 10.Diterpene 11.Gum & Mucilage 12.Fat & Fixed Oil 13.Quinones.

Biochemical analysis

The Chemical analysis of *Kuruver Kudineer* was done at the Biochemistry lab at National Institute of Siddha, Chennai by the method of Kolkate. The Biochemical studies were employed for *Kuruver Kudineer* profiling contains various parameters such as Acid radicals test, Basic radical test and Miscellaneous test.

Pharmacological Activity (Anxiolytic study-Elevated plus maze method)

The pharmacological study protocol has got an approval from Institutional ethical committee of National Institute of Siddha, Chennai (NIS/IAEC/-IV/04105012017).

The Swiss albino Mice age and weight are 6 – 8 weeks/20-35g and the gender was Male and female were selected this study. The drug was administrated by oral route. The room temperature and humidity was 22±40-65%. Same sex of 3 animals was housed in propylene cages with husk bedding. Each animal has marked in picric acid on the fur for identification (Head, Neck, Body and Base of tail) and it was indicated in cage card along with the number. CPCSEA guidelines would be strictly adhered. Animals would be monitored for health, food with adequate nutrition (Rodent pellets) and water atlibidum etc. for 24 x7 days per week. Animal husbandry would be 12-hour light and 12-hour dark cycle. Monitoring room temperature at 22°C (±3°) and relative humidity are 30–70%. Polypropylene cages would be used with proper husk bedding.

Animal excreta would be disposed properly and monitored hygienic condition. All animals would be observed for signs of illness, injury or abnormal behaviour treated with veterinary surgeon. If any animal die immediately post-mortem would done for observation of autopsy changes. Diseased animals would be monitored, treated and quarantined in the separate cages.

After the experimental period, animals would be reutilized for another study followed by acclimation period or else would be leave independently.

Clinical Studies

The Present study was a interventional, preclinical and open clinical, out-patient and In-patient based, Single Arm trail conducted in the department of *Kuzhandai Maruthvam* (Paediatric), National Institute of Siddha, Chennai. It was conducted during 2015 to Oct 2018 after obtains approval from Institutional Ethics Committee NIS/IEC/2016/11-19/ 14.10.2016. After getting the approval from committee, registration done in CTRI

and number is CTRI/2017/05/008698. The first 60 children with ASD were screened during this period. Children of either sex between the age group of 3-12 years who were diagnosed with ASD were identified and included in the study. Other type of ASD along with epilepsy, cerebral palsy and heart disease were excluded from the study. 30 children satisfied the inclusion criteria and were willing to participate in the study, signed the informed consent. The parents of children who were enrolled was informed about the study, trail drug, possible outcomes and the objectives of the study in the language and terms understandable for them.

All the 30 children, under OPD and ipd treatment received *Kuruver kudineer* as Internal (3-6 years – 30ml, 7-9 years – 40 ml, 10-12 years – 50ml) twice a day and *Sambrani thuvalai, Mysatchi pugai* as external once in a day. Experimental period was 90 days and the improvement was recorded 0th day and followed by every 90th day. Experimental formulations were assigned to each subject and regular study drug reconciliation was performed to document the drug assigned, consumed and remaining are logged on the drug reconciliation form with sign and date.

Clinical assessment parameters

1.Social relationship and reciprocity such as Eye contact, Social smile, Solitary and repetitive activities, Social interaction and Peer relationship.

2. Emotional responsiveness such as Inappropriate emotional response, Exaggerated emotions, Self-stimulating emotions, Fear for danger, Excited for no apparent reasons.

3.Speech: language and communication such as Non-verbal language to communicate the others, Stereotyped and repetitive use of language, Unusual noises, Meaningless words, Understand the meaning of communication.

4. Behavioural patterns such as Hyperactivity and restlessness, Aggressive behaviour Attachment to inanimate objects, Self-injurious behaviour, Temper tantrums.

5. Sensory aspects such as unusual visions, Stares into space for long periods of time, Insensitive to pain, Responds to object, Tracking objects.

Children were assessed for improvement on 0th, 30th, 60th, 90th day of treatment and the results were entered in the assessment forms. The results were analysed by computing the scores as 0 score – Never (5), 1 score – Sometimes (10), 2 score – Often (15), 3 score – Mostly (20), 4 score – Always (25) exhibits the skills in Autism Clinical Assessment Parameters.

Autistic child	Severe	Moderate to severe	Mild to Moderate	Mild	Normal to Mild
Score Range	(125-249)	(250-374)	(375-499)	(500-624)	(≥ 625)

DATA COLLECTION FORMS

FORM 1 Screening and Selection Proforma

FORM 2 Consent Form

FORM 3 Case Report Profoma

FORM 4 Patient's Information Sheet

FORM 5 Drug Compliance

FORM 6 Withdrawal Form

FORM 7 adverse Reaction Form

FORM 8 Pharmacovigilance Form

FORM 9 Dietary Advice Form

RESULTS AND DISCUSSION**Physicochemical Analysis of *Kuruver Kudineer***

The physicochemical testing employed for *Kuruver kudineer* profiling which is depend on the specific characteristics of formulation as per method given in PLIM guidelines and Siddha Pharmacopoeia of India contains various parameters for testing such as 1. Loss on drying – 5.54%, 2.Total ash value- 6.82%, 3.Acid insoluble ash-1.81%, 4.Water soluble ash- 2.40%, 5.Water soluble extraction – 33.23%, 6.Alcohol soluble extraction – 10.76%.

Phytochemicals Result

The Phytochemical studies were employed for *Kuruver Kudineer* profiling contains various parameters indicates positive results such as 1. Alkaloids in Mayer's test, 2.Carbohydrates in Molish's and Benidicts test 3.Saponin in Froth's test, 4.Flavonoids in Alkaline Reagent and Lead acetate Test, 5.Proteins and amino acids, 6.Diterpene in Copper Acetate Test, 7.Gum & Mucilage, 8.Fat & Fixed Oil, 9.Quinones in NAOH + Extract.

Biochemical analysis of *Kuruver kudineer***Results of Acid radicals studies****Interpretation**

The acidic radicals test shows the presence of Sulphate, Chloride.

Results of basic radicals studies**Interpretation**

The basic radical test shows the presence of **Iron**, and absence of heavy metals such as lead, arsenic and mercury.

Results of Miscellaneous test**Interpretation**

The Miscellaneous test shows the presence of Alkaloid, Tannic acid, Type of Compounds.

Table 1: Anxiolytic activity of *Kuruver Kudineer*

Average Calculation (n=6)				
Control group	Open arm		Closed arm	
	Number of entry	5	Number of entry	12
Spent time	34sec	Spent time	1min56sec	
Standard group (Alprazolam IP)	Open arm		Closed arm	
	Number of entry	8	Number of entry	11
Spent time	1min7sec	Spent time	2min4sec	
Low Dose (<i>Kuruver kudineer</i>)	Open arm		Closed arm	
	Number of entry	13	Number of entry	12
Spent time	1min8sec	Spent time	2min5sec	
High Dose (<i>Kuruver kudineer</i>)	Open arm		Closed arm	
	Number of entry	9	Number of entry	10
Spent time	1min2sec	Spent time	2min9sec	

It shows low dose and high dose of *Kuruver kudineer* action were good when compared to control and standard group (I.p. Alprazolam). The results were satisfactorily good.

Clinical studies

In this study we tested the influence of adding *Thuvalai* and fumigation to *Kuruver kudineer* on the level of improvement in ASD children. Based on the results of study, both internal and external medicine had superior action as far as improvement in ASD children has concerned. Since *Kuruver Kudineer* use is to enhance cognitive skills, enhance nerve impulse transmission, research has been focused on the mechanism behind this activity. *Thuvalai* with *Sambrani ennai* use to enhance the Sitting tolerance, invigorating feeling and can give comfort. Fumigation with *Mysatchi pugai* is one of the methods of treatment in ancient period. It has to enhancing the mind calming activity, reduced hyperactivity, induced sound sleep, reduced screaming and irritable cry.

Table 2: Summary values of Clinical assessment parameters for Autism spectrum disorder in Children

Treatment	No. of Patients	Mean	Std Dev	Min	Max
0 score (Before)	30	248.33	102.53	125	600
0 Score (After)	30	503.33	125.55	250	625
4 Score (Before)	30	49.66	20.50	25	120
4 Score (After)	30	100.66	25.11	50	125
Social skills (Before)	30	49.83	21.06	25	120
Social Skills (After)	30	102.83	25.85	50	150
Emotional skills (Before)	30	47.16	22.19	25	120
Emotional skills (After)	30	98.66	26.12	50	125
Communication Skills (Before)	30	50.66	20.16	25	120
Communication Skills (After)	30	98	25.37	50	125
Behaviour Skills (Before)	30	52.66	22.88	25	120
Behaviour Skills (After)	30	104.5	27.92	50	125
Sensory Skills (Before)	30	46.83	19.54	25	120
Sensory skills (After)	30	99.66	25.01	50	125

Table 3: Statistical significance of treatment on ASD

Treatment	t value	P value
0 score (Before & After)	11.46	>1.0000
4 Score (Before & After)	11.46	>1.0000
Social skills (Before & After)	10.53	>1.0000
Emotional skills (Before & After)	11.00	>1.0000
Communication Skills (Before & After)	10.36	>1.0000
Behaviour Skills (Before & After)	10.75	>1.0000
Sensory Skills (Before & After)	11.73	>1.0000

The mean and standard deviation of clinical assessment parameters, before and after treatment of 0 score, 4 Score, Social skills, Emotional skills, Communication Skills, Behaviour Skills, Sensory Skills were 283.33±102.53, 503.33±125.55, 49.66±20.50, 100.66±25.11, 49.83±21.06, 102.83±25.85, 47.16±22.19, 98.66±26.12, 50.66±20.16, 98±25.37, 52.66±22.88, 104.5±27.92, 46.83±19.54, 99.66±25.01 respectively which is statistically highly significant (Score 0:t- value - 11.46, P>1.0000, Score 4: t- value - 11.46, P>1.0000, Social skills: t- value - 10.53,

P>1.0000, Emotional skills: t- value - 11.00, P>1.0000, Communication skills: t- value - 10.36, P>1.0000, Behavioural Skills: t- value - 10.75, P>1.0000, Sensory skills: t- value - 11.73, P>1.0000).

There is significant difference between before and after treatment on clinical assessment parameter score i.e., 86% improvement in this score after treatment.

CONCLUSION

In general, based on the results of this study, were found to be improvement in all the cases. No adverse effects were noticed during the treatment. Further follow up of these patients showed good recovery and fine improvement. The preparation of the medicine is simple as well as economical. The trial drug has anxiolytic actions. The Global burden of *Mantha sann* (Autism spectrum disorder), increasing prevalence and its impact in reducing the quality of life in children has prompted the author to choose an efficient and nutritive drug which is believed to good in central nervous system. The treatment of *Mantha sann* with *Kuruver Kudineer* has showed good response with no adverse effect, very effective and simple to administer. This has, in turn, provided a golden opportunity for new drug established in the management of *Mantha sann* It can be conclude that *Kuruver kudineer* as internal and *Sambrani thivalai* and *Mysatchi pugai* as external and it has a definite action as well as clinical efficacy on symptoms in ASD children seen in regular OPD and IPD. The effects of Internal and external therapies may be due individual drugs multipronged action. Further study

is required for scientific validation to prove its clinical efficacy in multicentre clinical study.

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