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ORIGINAL ARTICLE

Effect of *Kalyanaka Avaleha Choorna* along with *ghrita* (ghee) in Language Impairment of Children with Autism aged 3 - 6 years

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Abstract

Autism is a neurodevelopmental disorder characterized by impairments in social interaction and communication and restricted or repetitive patterns of interests, behaviours, or activities. In Ayurveda, Autism may be correlated to the condition "*Unmada*".[1] Considering the language impairment in Autism, where *Prana* and *Udana vayu dushti* plays the major role in the *samprapthi*, *'Kalyanaka Avaleha Choorna'* mentioned in the *'Swarabhanga adhikara'* of Bhaishajya Ratnavali' was selected as the trial drug.

The present study, which is an interventional pre and post-test was aimed at evaluating the effect of "*Kalyanaka Avaleha Choorna*" along with *ghrita* in language impairment of children with Autism aged 3-6 years, twice daily, after food, for a period of 60 days. 13 subjects satisfying the inclusion criteria were enrolled for the study and were assessed before and after the intervention and also after 1 month of follow-up period using the Childhood Autism Rating Scale (CARS) and the Receptive-Expressive Emergent Language Scale (REELS-Extended version) for the language age evaluation. The receptive and expressive language age were measured in ordinal scale and were statistically analysed using Wilcoxon Signed Rank Test.

The study results showed statistically significant outcomes ($p < 0.01$) which proved that the intervention *"Kalyanaka Avaleha Choorna"* along with *ghrita* was effective in improving the language impairments of children with Autism with remarkable outcomes in both receptive and expressive language.

Introduction

Neurodevelopmental disorders (NDDs) are characterized by impairments in one or more developmental domains, such as cognition, communication, social, and motor functioning, as a result of atypical brain development. Autism is a childhood onset neuro-developmental disorder characterized by persistent deficits in social communication and interaction, as well as restricted, repetitive behaviour and interests.[2]

According to the Centres for Disease Control and Prevention (CDC), approximately, 1 in 36 children are diagnosed with Autism worldwide.[3] In India, it is estimated that more than 2 million people are affected by Autism.[4]

Both genetics, especially de novo mutations and environmental factors early in developmental period play a vital role in the aetiology of Autism. One of the earliest signs of Autism is a delay in language development which is often accompanied by lack of social interest or social interactions, odd play pattern and unusual communication patterns. Many people with Autism exhibit language deficits ranging from language delays, poor comprehension, echoing of speech, and extremely literal language to even complete lack of speech. Even when formal language skills (e.g., vocabulary, grammar) are intact, the use of language for reciprocal social communication is impaired in Autism. Since receptive language may lag behind expressive language development in Autism, both skills should be considered separately.[5]

Ayurveda has included all *manasika vikaras* under the umbrella term *"Unmada".* Hence, on comparing the clinical features of Autism, it can be well correlated with *Unmada*. At present, no approved pharmacological treatments that target the core deficits of Autism are available.

The currently available pharmacological treatments are able to only minimise the comorbidities like hyper activity, aggression, self - injurious behaviour, depression, anxiety etc. But none are clinically proven in altering the pathophysiology of the condition and improve the language function and Autistic traits. Apart from the non - promising results, these anti - psychotic drugs impart serious side effects too like disturbed sleep, lethargy etc. In addition to these medications, other treatment modalities usually advised are Applied Behavioural Analysis and Occupational therapy which mainly focus on behavioural modifications and improving social skills.[6]

Rationale of the study

Since this condition does not have an effective treatment protocol despite many recent research studies and giving a placebo to the control group is not ethically feasible, a single group design was opted. It has been reported that approximately 63 percent of the children diagnosed with Autism exhibit language impairment. Language skills have been demonstrated to be the most stable determinants of social and educational well-being and achievement. Failure to meet language development milestone is one of the earliest red flags of Autism. While some of the patients show delay in language development, others show regression of language. Thus, an emphasis on addressing language requirements is integral in formulating intervention goals for children with Autism. The widely used intervention to deal with the language impairments in Autism is Speech and Language Therapy. As far as Autistic children are concerned especially in severe cases, there are many practical difficulties associated with speech therapy which are as follows. Each child demands individualized therapy modes as communication of each child is affected differently. As age-appropriate receptive language is not developed, the speech and language pathologists find it difficult to properly convey the instructions and educate them. At the same time, these children fail to perceive the instructions and commands in the right way. Lack of joint attention, eye contact, poor sitting tolerance, adaptive difficulties, auditory sensory issues etc. makes the speech therapy a challenging one. Continuous hours of sessions may irritate the child and non-cooperation from the side of the patient also hinders the therapy sessions. The lack of availability of regular sessions of speech therapy in government institutions and the expensive fees charged for each session in private sector are also another reason for decreased accessibility to speech therapy by Autistic children.

Due to the above-mentioned reasons, speech therapy was not given as an add on therapy in this study. Moreover, Autism is not a condition with merely problems with expressive language like articulation problems. It is a neurodevelopmental condition with severely impaired receptive language and pragmatics, in addition to the problems with the expressive language. Hence, there is no point in giving these sessions, as the core deficits in cognition at receptive level needs to be addressed first.

In consideration of the above-mentioned practical difficulties, in order to address the language impairment in Autism, a *yoga* from the context of *swarabheda chikitsa* from *"Swarabhanga Adhikara"* of *Bhaishajya Ratnavali* named *"Kalyanaka Avaleha Choorna"* along with *ghrita* as *anupana* was selected.[7] Most of the drugs in this formulation are *katu -thikta rasa pradhana*[8] [9] which is mainly responsible for the *kapha-hara* and *srothosodhana* property of the formulation, thereby removing the *avarana* from *manovaha srotas* and imparting clarity to the sense organs.

Apart from this, majority of the drugs like *Vacha (Acorus calamus)* and *Yastimadhu* (*Glycyrrhiza glabra),* have *medhya prabhava* (nootropic action*)* and *rasayana karma,* which has proven action on higher mental functions and cognition which might be due to the activation of many areas of brain. *Ghrita* [10] is the best drug of choice to be selected as the *anupana* in this study, as it is able to cross the blood brain barrier because of its lipophilic property, and transport the bio active principles of the herbal drugs directly to the brain. [11] Overall, the formulation can be expected to improve the language, cognitive function and intelligence of the Autistic individuals. Considering the above action, the study was designed with an aim to evaluate the "Effect of *Kalyanaka Avaleha Choorna* along with *ghrita (*ghee*)* in language impairment of children with Autism aged 3-6 years" as assessed by the improvement in the receptive and expressive language age using REELS.

Materials and Methods

Kalyanaka Avaleha Choorna mentioned in the context of *Swarabheda chikitsa* in *"Swarabhanga Adhikara"* of Bhaishajya Ratnavali was selected as the trial drug for internal administration.

Method of preparation

The genuinity of the collected raw drugs and ghee with Agmark standards were checked and confirmed by the Department of *Dravyaguna,* Government Ayurveda College, Thiruvananthapuram. The medicine was prepared as per the classical reference in Bhaishajya Ratnavali following the guidelines prescribed for *Choorna Kalpana.* Equal quantities of the drugs - *haridra, vacha, kushta, pippali, shunti, ajaji, ajamoda*, *yastimadhu* and *saindhava* were taken. The herbal drugs were cleaned, and dried well. All the ingredients were powdered separately until they become very fine powder and then sieved through a mesh size of 85. The final product '*Kalyanaka Avaleha Choorna'* is obtained by blending the powdered drugs. The *sookshma choorna* thus obtained, was then packed in plastic sachets with 3 g quantity each for easy administration in correct dose.

Methods

Research Question

Is *Kalyanaka Avaleha Choorna* along with *ghrita* (ghee) given internally for a period of 60 days effective in the language impairment of children with Autism aged 3-6 years attending the OPD of Kaumarabhritya, Govt. Ayurveda college Hospital for Women and Children, Poojappura?

Aim and Objective

To evaluate the effect of *"Kalyanaka Avaleha Choorna* along with *ghrita* in the language impairment of children with Autism aged 3-6 years as assessed by the improvement in the receptive and expressive language age using REELS-Extended Version.

Hypothesis

Null Hypothesis

Kalyanaka Avaleha Choorna along with *ghrita* is not effective in improving the language impairment of children with Autism in the age group 3-6 years.

Alternate Hypothesis

Kalyanaka Avaleha Choorna along with *ghrita* is effective in improving the language impairment of children with Autism in the age group 3-6 years.

Methodology

Study design - Single group assignment, Interventional, Pre and post Test.

Study setting - OPD of Department of Kaumarabhritya, Government Ayurveda College Hospital for Women and Children, Poojappura, Thiruvananthapuram.

Study duration - 60 days

Follow up - 1 month

Dose - 3 gm, twice daily (morning and evening)

Study Population:

Children of both sex of age group 3-6 years, affected with Autism having impairment in language development attending the Out - patient wing of Department of Kaumarabhritya, Govt. Ayurveda College Hospital for Women and Children, Poojappura, Thiruvananthapuram.

Inclusion Criteria

- Children of the age group 3- 6yrs.
- Autistic children with language impairment diagnosed by Childhood Autism Rating Scale (CARS) (score above 30) and Receptive - Expressive Emergent Language Scale - Extended Version (REELS) respectively.

Exclusion Criteria

- Asperger Syndrome & Pervasive Developmental Disorders - Not Otherwise Specified (PDD -NOS).
- Rett Syndrome
- Childhood Disintegrative Disorder
- Children with other neuro - developmental disorders, neurocutaneous syndrome, metabolic disorders, genetic, congenital disorders and neurological disorders.
- Children having a major hearing impairment.

Sample Size

Sample size, n = 13, was decided by the formula,

$$\mathbf{n} = \frac{(Z\alpha + Z\beta)^2\sigma^2}{d^2}$$

σ = Average SD of pre and post study = 1

d= Mean difference = 1.2

Zα= 2.58 (at α = 1 %) - p value 0.01

Zβ = 1.28 (at β = 10 %) - power 90 %

$$n = \frac{(2.58 + 1.28)^2 (1)^2}{(1.2)^2}$$

$$= \frac{14.8996}{1.44}$$

= 10.34 + 20 % dropouts.

= 10.34 + 1.9072

= 12.247

» 13

Sampling Technique : Consecutive

Data Collection

Data was collected by direct interview with the parents and observation of the subjects using semi structured case proforma, Childhood Autism Rating Scale (CARS) and Receptive - Expressive Emergent Language Scale.

Study Tools

- Childhood Autism Rating Scale - CARS
- Receptive - Expressive Emergent Language Scale - REELS - Extended Version

Procedure

Subjects of the age group 3 - 6 years having qualitative impairment in the area of language development or communication skills, social interactions and reciprocity, and imaginative play or diagnosed cases of Autism satisfying the DSM - 5 criteria attending the OPD of Kaumarabhritya, Government Ayurveda Hospital for Women and Children, Poojappura were selected for the study. 13 subjects who satisfied the inclusion criteria were recruited for the study. Data were collected by detailed case taking using semi - structured case proforma, CARS for Autism assessment and the extended version of the tool REELS (Receptive-Expressive Emergent Language Test) for language age evaluation by a Speech and language pathologist. The participants were given the trial drug *Kalyanaka Avaleha Choorna* in a dose of 3 gm mixed with sufficient quantity of *ghrita* twice daily - one dose in the morning and the second dose in the evening after food for a period of 60 days with proper dietary advices considering the age, weight and digestive capacity of the medicine. An assessment session was conducted after 60 days of intervention. After 1 month of the study period**,** a follow up assessment was also done. Statistical analysis was done with the obtained data.

Outcome Variable

- Changes noted in the language age as assessed by REELS - Extended version (Receptive - Expressive Emergent Language Scale).

Statistical Analysis

The data were collected and statistically analysed using appropriate statistical methods. The receptive and expressive language age were measured in ordinal scale as per the literature (REELS - Authors: Kenneth R. Bzoch and Richard League, 1971). Changes observed after trial and after follow up were statistically analysed using cross tables, frequency tables, median levels and Wilcoxon Sign Rank Test.

Ethical Consideration

- Ethical clearance for the study was obtained from the Institutional Ethics Committee.
- IEC No: 523/05/08/2021
- The children were allowed to discontinue the study if their parents want to.
- The information obtained from the participants was kept confidential and informed consent was taken.

Observation and Analysis

The present study was an interventional single group pre - and post - test. 13 subjects satisfying the inclusion criteria were recruited and there were no drop outs in the study. Demographic details of the participants were recorded in the case proforma. Out of the 13 participants, 69.2 % belonged to the age group 3 - 4 years. 76.9 % were male participants, 61.5 % of them were severely autistic, 77 % showed regression of the language milestone, 84.6 % were first born children and 46.2 % of the mothers had maternal stress during pregnancy.

Effect of Intervention on REELS Score

Effect on Receptive Language

The table 1 shows the change in the receptive language levels from before treatment (BT) to after treatment (AT) and follow up (AF). It can be observed that in all cases, the language increased from 1 to 6 levels.

As per Table: 2, 4 subjects advanced to 1 level, 3 subjects to 2 levels, 3 subjects to 3 levels, 2 subjects to 4 levels, no subjects showed a 5-level advancement and 1 subject showed a 6-level advancement in the language age. Hence, it can be inferred that in all cases, the language age showed an advancement of minimum of 1 level to maximum of 6 levels. At the same time, no change could be observed from AT during the follow up.

As per table 3, there is no change in any of the observations from After Treatment to After Followup (so there is no need of comparison among AT and AF). Wilcoxon signed rank test is used to test the significance of difference in between BT and AT. The minimum level before treatment was 7-8 months, maximum 33-36 months and median 18-20 months. The minimum level after treatment was 10-11months, maximum 3-3.5 years and median 24-27 months. On an average 3 levels increased from BT to AT and which is significant at 1% level of significance. There is no change in receptive language levels at AF from AT (Table: 3) which shows the consistency of the intervention even after the study period.

Table. 1: Distribution of the changes of levels of Receptive Language Age after Treatment

AT*(AF)**									
10 -11 months	**11 - 12 months**	**18 - 20 months**	**22 - 24 months**	**24 - 27 months**	**27 - 30 months**	**30 - 33 months**	**33 - 36 months**	**3 - 3.5 years**	**Total**
1(1)									1
	1(1)								1
	1(1)								1
		1(1)							1
			1(1)						1
			1(1)				**1(1)**		2
					1(1)	**1(1)**			2
				1(1)	**1(1)**				2
					1(1)				1
								1(1)	1
1	2	1	2	1	3	1	1	1	13

Note:

*AT - After Treatment ** AF -After Follow up

Table. No: 2: Frequency distribution of the number of steps advanced after treatment in the case of Receptive Language Age

No. of steps advanced from BT* to AT**	Frequency (%)
1	4 (30.7)
2	3 (23.1)
3	3 (23.1)
4	2 (15.4)
5	0
6	1 (7.7)
Total	**13 (100)**

Note:

*BT - Before Treatment **AT - After Treatment

Table. 3 - Wilcoxon Signed Rank Test to test the changes in levels in between before and after trial in the case of Receptive Language Age

	N	Minimum	Maximum	Median	Mean	SD	SE
BT	13	8 (7 - 8 months)	22 (33 - 36 months)	16 (18 - 20 months)	15.31	3.945	1.09
AT	13	11 (10 - 11 months)	23 (3 - 3.5 years)	19 (24 - 27 months)	17.85	3.955	1.10
AF	13	11 (10 - 11 months)	23 (3 - 3.5 years)	19 (24 - 27 months)	17.85	3.955	1.10

Effect on Expressive Language

The table 4 shows the change in the expressive language levels from before treatment (BT) to after treatment (AT) and follow up (AF). It can be observed that in all cases the language increased from 0 to 3 levels.

As per Table. 5, 2 subjects did not show any advancement in language age, 6 subjects advanced to 1 level, 3 subjects to 2 levels and 2 subjects advanced to 3 levels of language age. During the follow up, no change could be observed from AT.

The table 6 gives the minimum, maximum and median levels at BT, AT and AF. The minimum level before treatment was 7-8 months, maximum 3-3.5 years and median 16-18 months. The minimum level after treatment was 8-9 months, maximum 3.5-4 and median 18-20 months. On an average 1 level increased from BT to AT, which is significant at 1% level of significance. There is no change in expressive language levels at AF from AT which shows the consistency of the intervention even after the study period.

The Wilcoxon signed rank test was used to test the significance in between BT and AT which is given below.

Hence, it is proved that the intervention was able to improve the speech and vocabulary in Autistic subjects.

Table. No: 5: Frequency distribution of the number of steps advanced after treatment in the case of Expressive Language Age

No. of steps advanced from BT* to AT**	Frequency (%)
0	2 (15.4)
1	6 (46.1)
2	3 (23.1)
3	2 (15.4)
Total	**13 (100)**

Note: *BT - Before Treatment **AT - After Treatment

Table. 4: Distribution of the changes of levels of Expressive Language Age after Treatment

BT \ AT	8 - 9 months	10 - 11 months	11 - 12 months	14 - 16 months	16 - 18 months	18 - 20 months	22 - 24 months	24 - 27 months	27 - 30 months	3.5 - 4 years	
7 - 8 months		**1(1)**									**1**
8 - 9 months	**1(1)**										**1**
9 - 10 months			**2(2)**								**2**
11 - 12 months				**1(1)**							**1**
14 - 16 months					**1(1)**						**1**
16 - 18 months						**2(2)**					**2**
18 - 20 months						**1(1)**					**1**
20 - 22 months							**1(1)**		**1(1)**		**2**
22 - 24 months								**1(1)**			**1**
3 - 3.5 years										**1(1)**	**1**
Total	**1**	**1**	**2**	**1**	**1**	**3**	**1**	**1**	**1**	**1**	**13**

Note: *AT - After Treatment **AF - After Follow up

Table. 6 - Wilcoxon Signed Rank Test to test the changes in levels in between before and after trial in the case of Expressive Language Age

	N	Minimum	Maximum	Median	Mean	SD	SE
BT	13	8 (7 - 8 months)	23 (3 - 3.5 years)	15 (16 - 18 months)	14.15	4.26	1.18
AT	13	9 (8 - 9 months)	24 (3.5 - 4 years)	16 (18 – 20 months)	15.54	4.10	1.14
AF	13	9 (8 - 9 months)	24 (3.5 - 4 years)	16 (18 – 20 months)	15.54	4.10	1.14

Difference	Mean difference	SE of mean difference	No. of negative ranks (Mean rank)	No. of positive ranks (Mean rank)	No. of Ties	Wilcoxon signed rank test Z-value (p-value)
AT-BT	-2.54	0.418	0(0)	13(7.0)	0	-3.2 (<.01)

* Negative rank = AT < BT * Positive rank = AT > BT * Ties=AT=BT

Difference	Mean difference	SE of mean difference	No. of negative ranks (Mean rank)	No. of positive ranks (Mean rank)	No. of Ties	Wilcoxon signed rank test Z-value (p-value)
AT-BT	-1.39	0.266	0(0)	11(6.0)	2	-2.99 (<.01)

* Negative rank = AT < BT * Positive rank = AT>BT * Ties = AT = BT

Results

It is statistically proven by Wilcoxon Signed Rank test that the intervention *'Kalyanaka Avaleha Choorna'* could bring about significant improvement in both the receptive language and expressive language of children with Autism aged 3 - 6 years which remained consistent even after the follow up period. With 2 months of intervention, parents reported significant changes in their children which are as follows: A considerable improvement in the receptive language and other domains of Autism too. They were able to comprehend things faster and give better response without much delay either verbally or non - verbally. The name - call response improved in many subjects along with eye contact. They could attentively complete the tasks given in the behavioral therapy sessions with much attention and calmness. Those children who previously indicated their wants by bringing the hands of the parents to the desired objects, now started pointing to the object of concern. Joint attention showed significant improvement which enabled both the parents and therapists to make the learning process and therapy sessions effective and easier.

Discussion

Analysis of the Classical *Yoga*

In Ayurveda, Autism may be correlated with *Unmada* which is a *vata - pitta pradhana sannipataja vyadhi*. *Vak pravrutti* happens due to the combined efforts of *prana* and *udana vayu* along with the co - ordination of *manas.* The *sanchara sthana* of *Udana vayu* is *uras* and *uras* is one of the *kapha sthanas.* Whenever there is *kapha avaranatwam* resulting from *apathya nidana seva* or *beeja dusti,* it disrupts the proper functioning of *prana* and *udana vayu,* which may eventually lead to impairment in *vak pravrutti* (speech and language). It is this *kapha avaranatwa,* which is also responsible for the impaired cognition and behavioural abnormalities in Autism by hindering the *jnanotpattikrama.* Taking this into consideration, *Kalynaka Avaleha Choorna* from the context of '*swarabheda chikitsa'* in *"Swarabhanga Adhikara"* of Bhaishajya Ratnavali, was administered as the trial drug along with *ghrita* as *anupana* with an aim to find out whether it has any action in the language (both receptive and expressive language) of the subjects.

This formulation consists of 8 drugs which are as follows: *haridra, vacha, kushta, pippali, nagara, ajaji, ajamoda, yastimadhu* and *saindhava.* In the *phalasruthi* of the *yoga*, it is said that if it is consumed for a period of 21 nights, the person becomes *sruthadhara* (easily grasps everything). This statement is a proof that, it can improve the receptive language very effectively. Similarly, the speech and voice become so clear like the *megha dundubhi nirghosha* (thunder) and voice of *Kokila* (Cuckoo). It also pacifies speech disorders like *jada, gadgada* (stuttering) and *mookatwam* (mutism) which substantiates its effect on expressive language of the individual including the articulation problems. Over all, this formulation can be considered as the best drug of choice in language impairment (both expressive and receptive).

Mode of action of the formulation

On analysing the *rasa panchaka* of the overall formulation, majority of the drugs in *Kalyanaka Avaleha Choorna* are predominantly *katu - thikta rasa pradhana, ushna veerya* and *katu vipaka.* All these attributes aid in removing the *kapha avaranatwam* from *rasa vaha* and *mano vaha srotas.* The *thikta rasa* by virtue of its *laghu, rooksha* property is *deepana - pachana* and *lekhana* in action. It has got *kanta vishodhana* and *aruchighna* property also. Since *thikta rasa* is the most *laghu rasa,* it performs the *medhya karma* effectively. It is also responsible for the *rasa shudhi.* Hence, *thikta rasa* helps in improving the *medha* and cognition. *Katu rasa* by virtue of its *laghu, ushna* and *rooksha* property, helps in the disintegration of obstruction *(chinatti bandhan)* and performs *sroto vivaranam* (opening of channels), thereby facilitating the *kaphashamanatwam.* It also has *deepana - pachana* action. The *indriya sphuteekarana* property of *katu rasa* makes the sense organs perceive the information accurately. *Yastimadhu* is the only *madhura rasa pradhana dravya* in this formulation. Madhura rasa has *shat indriya prasadhana* property and helps in the clarity of sense organs which is a vital part of

cognition. It is *ajanma satmya,* gives *dhatu bala* and is good for *indriya, ojus* and *kanta.* It also gives *prahladana* (soothing effect) to *ghrana, mukha, kanta, osta and jihwa* which facilitates the proper articulation of speech. *Saindhava lavana* which is *agni deepana* in action has *tridosa shamana* property and act as a catalyst in this combination.

Deepana, pachana, medhya and *rasayana* properties are the common attributes of most of the drugs in this formulation which helps in correcting the *agni* and to act at *manasika* level. Since *hridaya* is the *sthana* of both *rasa dhatu* and *manas*, *mana shudhi* is indirectly attained through *rasa suddhi.* The *katu - thikta rasa pradhanyatva* and *agni deepana property* removes the *kapha avaranatvam* of *srotas* and *manas,* leading to the *rasa shuddhi* which finally gives clarity to the *indriyas* and *manas.* This helps in cognition and may stimulate the language areas of brain and thereby aids in *vak pravrutti.*

Medhya drugs improve memory and intellect with their *prabhava.* The drugs recommended under "nootropic drugs" may therefore be helpful in enhancing the cognition, learning, language, speech and memory. *Medhya rasayanas* works on *dhi* (power of grasping), *dhriti* (power of retention) and *smriti* (power of recollection) and act by enhancing the level of neurotransmitters and blood flow to the brain, thereby improving the oxygen supply and nutritional availability towards the brain. Besides producing anti- stress, adaptogenic and memory enhancing effects, they retard brain aging and help in regeneration of neural tissues. They also enhance cognition, memory, intelligence, creativity, learning skills and executive functions. *Medhya rasayanas* improves brain circulation, regulates neurotransmitter concentrations, prevents brain inflammation, stimulates the formation of new brain cells and protects the brain from free radical damage. As a result, nootropic drugs can be very helpful in the management of these conditions.

Madhura vipaka of majority of the drugs in this formulation provide nourishment to the brain by helping in the formation of *ojas*. *Ushna veerya* drugs stimulate *saadhaka pitta* that aids in promoting *medhya* action. Therefore, these drugs have beneficial effect on the body as well as on mind. *Prana* and *udana vayu, sadhaka pitta, tarpaka* and *avalambaka kapha* have been considered to contribute in the *medhya* action.

One such drug mentioned as *medhya rasayana* by Acharya Kasyapa is *Vacha* (*Acorus calamus*) which is one if the ingredients of the trial drug *'Kalyanaka Avaleha Choorna.'* A. calamus is an excellent stimulant of higher cognitive function. It has been attributed with various properties like *medhya* (nootropic) and *vak-suddhikara* (improves speech) *karmas.*

Prabhava of *Yastimadhu* brings about its *medhya* action. *Madhura rasa, snigdha guna* and *madhura vipaka* of *yastimadhu* regulates the *chala guna* of *vata* and thereby influence the functions of *manas* and *buddhi.* They not only enhance the *dhi* (power of acquisition), *dhriti* (power of retention) and *smriti* (power of recollection), but also rejuvenate the whole system and their pathways. Glycyrrhizin is generally regarded as the active principle of *G. glabra* and is responsible for its sweetness, which is 50 times that of sucrose. It thereby increases the bioavailability of glucose at brain level and thus enhances the activity of brain.

Ghrita is considered to be the best among the 4 *sneha dravyas* and has the property of destroying inauspiciousness and giving protection. It is one of the *nitya rasayanas* (can be consumed daily) mentioned in Ayurveda which possess multi-systemic benefits. *Ghrita* has *agni deepana* property and enhances *dhee, dhriti, smriti, medha, bala, ayus* and eyesight. It is known best for treating *mada, unmada, apasmara, murcha,* etc. The most highlighted property of *ghrita* is the *samskaravahi* property by which it assimilates the property of the drug added to it providing a synergetic action in combination.

Alpa satva individuals who lacks physical and mental strength, are more easily prone to *unmada*. Due to *agni mandya,* the digestion and assimilation are impaired, which in turn affect their overall health and *ojus* and it is the primary cause for *shareerika* and *manasika vyadhis.* This *agni mandya* can be compensated by the judicial use of *ghrita*. *Vata* is the controller of the manas and *medha* (intellect) is the property of *pitta.* So, bringing proper channelisation to *vata* and normalcy to *pitta* are the major concerns in the treatment of psychiatric illnesses like *unmada* which can be achieved by the *vatapitta hara* property of *ghrita.* It improves the functions of *sadhaka pitta* and *prana vata* in general causing the person to reduce stress produced by the psychological causes of fear, depression and stress.

It is because of the lipophilic molecular structure of the blood brain barrier (BBB) that the lipids and lipid soluble drugs can easily pass through BBB.[11] As a result, the drugs that are administered in the form of ghee, which are lipids, are rapidly absorbed in the Central Nervous System's target areas. DHA, an omega 3 long chain poly unsaturated fatty acid, is found in traditionally prepared ghee *(ghrita).* This is seen in high concentration in brain cells too. Moreover, studies have shown that DHA have positive outcomes in cognitive decline. Ghee is known to have antioxidant property which acts upon the degenerative brain cells and repair them. By balancing the neurotransmitters, it also contributes to restoring the brain's chemical balance.[12] Hence, in this condition, *ghrita* is the best *anupana.*

Effect of Intervention on Receptive and Expressive Language

Receptive language refers to the ability to understand and comprehend spoken language or other forms of communication. Autistic subjects have difficulty in understanding language within a specific context, difficulty grasping figurative language, idioms, sarcasm or jokes. Analysis of the effect of intervention on the 'receptive language age' of the subjects using REELS proved the action of the intervention in language areas of the brain, thereby improving the receptive language of the subjects. During the follow up, no change was observed which reports a sustained action of the drug.

Expressive language refers to the ability to communicate thoughts, ideas, feelings and needs using spoken words, gestures, writing or other forms of communication which encompasses both verbal and non - verbal forms of communication. Analysis of the effect of intervention on the expressive language age of the subjects using REELS proved that the intervention was able to improve the speech and vocabulary in Autistic subjects. Much improvement in the expressive language (verbal communication) while comparing the receptive language could not be observed within this short period of intervention. Another justification for this can be attributed to the extent of severity of Autism in the recruited participants. The language impairment of participants who were diagnosed with mild Autism was not much severe. They already had some vocabulary. The intervention yielded faster results in those with mild Autism with more vocabulary and 2-to-3-word sentences. Those diagnosed with severe Autism with no spoken language, except jargon speech and echolalia, showed only mild improvements in vocabulary (5 to 6 words were added to vocabulary).

As language is a higher mental function, it takes time to cause changes in the brain pathophysiology. But with continuous medications, it is possible to generate tremendous changes in the language function of the brain and thereby improve the cognition in Autistic children.

Limitations of the study

- Small sample size.
- Palatability issues.

Conclusion

The study "Effect of *Kalyanaka Avaleha Choorna* along with *ghrita* (ghee) in language impairment of children with Autism aged 3 - 6 years", was carried out with the objective to determine the effect of '*Kalyanaka Avaleha Choorna'* in improving both the receptive and expressive language age of Autistic subjects. A failure to develop language is one of the most frequent reasons for referral among children who are later diagnosed with Autism. Impairment in language in turn leads to the impaired social interaction, both of which run hand in hand. In the current scenario of increasing prevalence of Autism, wherein speech therapy and medications do not yield much promising results, it is the high time to clinically prove the effect of the classic formulation which has been practiced in Ayurveda for so long.

The extensive research evidences available on the individual ingredients of *Kalyanaka Avaleha Choorna* suggests that it is a promising formulation for the management of various neurodegenerative and psychiatric disorders. The drugs with *medhya* action may stimulate the various areas of brain related to cognition including the language areas and brings about significant changes in the language age as well as the Autistic traits. Since, the blood brain barrier is highly permeable to lipids, the most suitable *anupana* to get the desired effect on brain is *ghrita*. Mixing the *choorna* formulation along with *ghrita* also make it into a lickable consistency, which helps in the easy administration to this paediatric age group.

The effect of *"Kalyanaka Avaleha Choorna* along with *ghrita* in language impairment of children with Autism aged 3 - 6 years" was statistically proved with internationally accepted assessment criteria. The language ages (Receptive and Expressive) of the subjects were determined using the tool 'REELS - extended version'. The study has proved significant improvements in the receptive and expressive language age of the subjects after the trial, which was sustained without regression even after the follow up period. Even though, both were statistically significant, a highly significant clinical response was seen in terms of the receptive language. This has indirectly, influenced other domains of Autism with improvement in social interaction, eye contact, non - verbal communication etc. This was one of the main highlights of the research.

Hence the alternative hypothesis was proved and the study concluded that the trial drug *"Kalyanaka Avaleha Choorna* along with *ghrita"* is effective in improving the language impairment of children with Autism and also in improving the core features of ASD. From the above positive results, it can be inferred that the formulation may have the capability to act at the higher centre and may stimulate the language areas of the brain within a short duration along with influence over other areas of brain which might be considered as a possible reason for such a significant improvement in the cognitive, behavioral and social domains of development.

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Conflicts of Interest

Nil

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